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Conflicts of Interest

All authors declare that they have no relevant conflict of interest in relation to this project.

Author Statement

LI, JD and SA wrote the first draft of the manuscript and developed the registry protocol. JS has led the development of the Australian and New Zealand Thyroid Cancer Registry (ANZTCR) and is the chair of the ANZTCR Steering Committee. The remaining authors had input into the protocol development and reviewed and approved the final manuscript.

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Abstract

Background

The occurrence of thyroid cancer is increasing throughout the developed world, including Australia and New Zealand, and since the 1990s has become the fastest increasing malignancy. In 2014, 2,693 Australians and 302 New Zealanders were diagnosed with thyroid cancer, with this number projected to rise to 3,650 in 2018. Following the success of a number of institutional databases that monitor outcomes after thyroid surgery, the Australian and New Zealand Endocrine Surgeons (ANZES) agreed to auspice the development of a national thyroid cancer registry.

Objectives

To establish a bi-national population-based clinical quality registry with the aim of monitoring and improving the quality of care provided to patients diagnosed with thyroid cancer in Australia and New Zealand.

Patients & Methods

The Australian and New Zealand Thyroid Cancer Registry (ANZTCR) aims to capture clinical data for all patients over the age of 18 years with thyroid cancer, confirmed by histopathology report, that have been diagnosed, assessed or treated at a contributing hospital. Data is collected by endocrine surgeons using a web-based interface, REDCap, primarily via direct data entry.

Results

A multi-disciplinary Steering Committee was formed which, with operational support from Monash University, established the ANZTCR in early 2017. The pilot phase of the registry is currently operating in Victoria, New South Wales and South Australia, with over 20 sites expected to come on board across Australia and New Zealand in 2018. A modified-Delphi process was undertaken to determine the clinical quality indicators to be reported by the registry, and a minimum dataset was developed comprising information regarding thyroid cancer diagnosis, pathology, surgery and 30-day follow up.

Conclusion

There are very few established thyroid cancer registries internationally, yet clinical quality registries have shown valuable outcomes and patient benefits in other cancers. The establishment of the ANZTCR provides the opportunity for Australia and New Zealand to further understand current practice in the treatment of thyroid cancer and reasons for variation in outcomes. The engagement of endocrine surgeons in supporting this initiative is crucial. While the pilot registry has a focus on early clinical outcomes, it is anticipated that future collection of longer term outcome data particularly for patients with poor prognostic disease will add significant further value to the registry.

Keywords: thyroid cancer, clinical registry, population health, quality improvement

Article Summary

Strengths & Limitations of this Study

- We outline the establishment of a b-national clinical quality registry (CQR) for thyroid cancer, including the establishment of governance, recruitment framework, clinical quality indicators, minimum data set, data access policy and reporting structure. This CQR was developed as per the Australian Operating Principles for Clinical Quality Registries.
- There are very few established thyroid cancer registries internationally. This a surgeon-driven opt-out CQR for thyroid cancer, with endocrine surgeons contributing data directly to the registry. This can be used a model for researchers developing CQRs.

- Not all thyroid cancer surgery is performed by endocrine surgeons. Currently site participation, although desirable, does not require all surgeons performing surgery for thyroid cancer at a site to participate. This will be an important future activity for the registry.
- The time consuming and labour-intensive site governance approval process in Australia and New Zealand is a major impediment for roll-out of the registry.

Introduction

Thyroid cancer is the 4th most common cancer in Australian males and 3rd most common cancer in Australian females aged 15 to 39 (1). The occurrence of thyroid cancer is increasing throughout the developed world, including Australia and New Zealand, and since the 1990s, it has become the fastest increasing malignancy. Between 1991 and 2009, the number of thyroid cancer cases increased by 250% in Australia (2). In 2018, it is expected there will be approximately 3,300 new cases of thyroid cancer in Australia (3), and approximately 350 new cases in New Zealand (4). From 2007 to 2020 thyroid cancer rates are projected to increase at a slightly lower rate, by 33% in males and 62% in females (3, 5).

The most common types of thyroid cancer have very good long-term prognoses, and of all non-cutaneous cancers, thyroid cancer has the highest five-year survival rate at 98% (6). Patients with thyroid cancer typically undergo surgery with total- or hemi-thyroidectomy. After total thyroidectomy, higher risk patients may undergo thyroid bed ablation with radioactive iodine (RAI), followed by suppressive thyroxine therapy. The removal of the whole thyroid gland and RAI ablation results in a lifelong dependence on pharmacotherapy with thyroid hormone (levothyroxine) (7).

Treatment Complications

Despite highly effective treatments and good long-term outcomes, a number of significant surgical and postoperative complications may occur and be associated with long-term physical and psychological morbidity (8). Specifically, complications of thyroidectomy, such as temporary voice change, may occur in up to 80% of patients, and permanent vocal cord palsy due to injury to the recurrent laryngeal nerve resulting in hoarseness, both potentially affect employment and quality of life (9-11). Postoperative hypocalcemia, due to damage leading to inadequate functioning of remaining parathyroid glands (hypoparathyroidism) may cause symptoms such as severe cramps requiring prolonged inpatient stays on a temporary (in up to 15%) or permanent (in 0.7-3%) basis following surgery (12) and require permanent therapy with calcitriol therapy and calcium supplementation. Haemorrhage; and wound infection is not uncommon (13), and there may be side effects from radioactive iodine (RAI) treatment, such as xerostomia. Depending on cancer pathology and stage of disease, cancer recurrence may occur, requiring additional treatments. Distant metastases may occur in up to 6-20% of cases at follow up and markedly increases the risk of cancer-specific mortality (14).

Variation in Management, Treatment & Outcome

There are significant variations in the management, treatment and outcomes of thyroid cancer, particularly in the role of: diagnostic investigation and pre-treatment scanning; optimal extent of surgery (total or hemi-thyroidectomy); use of active surveillance for small low-risk cancers; central lymph node dissections (therapeutic and/or prophylactic); outcomes following surgery (e.g. recurrent laryngeal nerve palsy, hypoparathyroidism); post-surgical hormone treatment, calcium and vitamin D therapy; and radioactive iodine treatment (provision and dosage) (15). Extent of surgery may be influenced by surgeon case volume (a measure of surgeon experience) and geographical location (16). Experienced surgeons are more likely to perform central neck dissections, arrange administration of RAI where appropriate, and have lower rates of surgical complications.

Thyroidectomies performed by high volume thyroid surgeons have less than a 2% risk of hypoparathyroidism, recurrent laryngeal nerve injury and permanent paralysis (depending on the size of the primary tumour). In contrast, higher rates of complications occur when the procedure is performed by less-experienced surgeons (17, 18). It has therefore been recommended that surgeons operating on patients with thyroid cancer should perform a minimum of 20 thyroidectomies per year (19).

Clinical Quality Registries

A proven strategy to reduce variation in outcomes is to measure and compare high quality disease-specific data using clinical quality registries (CQRs). This strategy has been successfully tested in a range of surgical disciplines including trauma (20), cardiac surgery (21), transplantation (22), breast surgery (23), bariatric surgery (24), joint surgery (25) and cancer care (26). CQRs provide the most effective means of collecting high quality data and are a tool for quality improvement. Where they have been introduced at a state or national level, CQRs have become one of the most clinically valued tools for quality improvement (27). The Australian Commission on Safety and Quality in Health Care (ACSQHC) has advocated development of CQRs, particularly in key high burden areas including cardiac disease, musculoskeletal disease and cancers (28).

Measuring Quality of Care in Thyroid Cancer

To date there are very few thyroid cancer registries internationally. Some of the more notable thyroid cancer registries include a prospective national clinical thyroid cancer database (DATHYRCA) implemented in 1996 by the Danish Head and Neck Cancer Group that collects data from the five Danish centres treating patients with thyroid carcinoma in Denmark; and the Thyroid Cancer Care Collaborative (TCCC) a multi-institution thyroid cancer registry established in the US in 1986 which includes 14 major academic medical centres and follows patients up annually to an average of five years (29). In the US, the American Thyroid Association (ATA) is collaborating with the Medullary Thyroid Carcinoma (MTC) Registry Consortium to establish a database of all patients newly diagnosed with MTC over the next 10-15 years. While single-institution databases have been well published and provided extremely valuable data with regard to understanding thyroid cancer, little data has been published from multi-institution databases and/or registries regarding quality of thyroid cancer care (30).

Rationale

Thyroid cancer management is informed by well-regarded international guidelines (31). However, given the lack of population-level data regarding patient outcomes from thyroid cancer in Australia and New Zealand, it is likely that there is clinician variation in adherence to best practice and therefore, individual patient outcomes of thyroid cancer. Furthermore, while detailed guidelines exist, there remain questions regarding optimal management of patient subpopulations. The Australian and New Zealand Thyroid Cancer Registry (ANZTCR) is a clinical quality registry being developed to provide a comprehensive evidence base regarding the care and outcomes of patients diagnosed with thyroid cancer in Australia and New Zealand. The registry will identify differences in quality of care and outcomes, with the aim to reduce variation and improve patient outcomes and survival. This paper describes the establishment and initial implementation of the ANZTCR.

Methods

Establishment of ANZTCR

In Australia, the majority of thyroid surgery is undertaken by specialist endocrine surgeons, represented by the Australian and New Zealand Endocrine Surgeons (ANZES). Long-standing and significant data regarding thyroid surgery has been collected at a number of academic and

healthcare institutions across Australia. In 2016, ANZES agreed to lead the evolution of thyroid cancer quality improvement via the establishment of a multi-centre, bi-national CQR for thyroid cancer which would include clinical indicators against which to monitor and benchmark clinical care. Across Australia and New Zealand it is likely that over fifty sites undertake surgery on patients with thyroid cancer including metropolitan, regional and private centres. Although confined to short-term follow-up at the outset, the importance of obtaining patient follow-up information to provide further evidence regarding long-term outcomes following treatment for thyroid cancer has also been identified, and will be implemented in a subsequent phase of the registry.

Funding

The ANZTCR is funded from industry, philanthropic foundations, and ANZES members.

Ethics

This project has received ethics approval from Alfred Health HREC under the National Mutual Acceptance (NMA) scheme (HREC/16/Alfred/61).

Governance Structure

Coordinating Centre

The ANZTCR Coordinating Centre is located in the Department of Epidemiology and Preventive Medicine (DEPM) at Monash University which manages the registry's core activities under the direction of the ANZTCR Steering Committee. Monash University has custodianship of the data which includes accountability for the privacy, security and integrity of patient information held within the registry.

Site Investigators

The ANZTCR registry is a multi-centred, investigator-driven endeavour. The Primary Investigator (PI) at each site is responsible for ensuring that research activities undertaken at their site are conducted in accordance with Ethics committee approval, the research protocol, site registry agreements and related policy documentation. Site research activities include identification of patients for recruitment and data collection, overseen by the PI at each site.

Steering Committee

The ANZTCR Steering Committee is multi-disciplinary, chaired by the ANZTCR Clinical Lead, and comprises representation of: endocrine surgeons (from each jurisdiction); endocrinologists; ANZES; consumers; the Australian Thyroid Foundation; and Monash University. It meets quarterly and has a significant role in guiding registry strategy and policy, monitoring data collection and quality assurance, reviewing data requests, and producing data reports and publications, as per the Australian Operating Principles for Clinical Quality Registries (32).

Management Committee

A Management Committee meets fortnightly and oversees the day to day running of the registry. Further subcommittees including a data access subcommittee will be established as required.

Registry Population

All patients with a confirmed diagnosis of primary thyroid cancer ≥18 years of age that have been diagnosed, assessed or treated at a participating site are eligible to participate in the registry.

Opt-Out Process

Recruitment to the registry utilises an opt-out process which has been used successfully in over 75% of CQRs in Australia (33). The rationale for this approach is based on minimising selection bias by achieving near 100% coverage of a population. By limiting the possibility of 'cherry picking'

participants or omitting specific groups of patients otherwise not able to be captured by standard consenting processes, clinical validity increases, enabling meaningful analysis and comparison of variation in health outcomes across sites and other geographical areas. The opt-out process enables the full spectrum of public health information to be reported and analysed, increasing capacity to influence and inform clinical guidelines, policy development and funding decisions (34-36).

Data Collection

Patient demographic and clinical data is submitted by sites primarily via direct data entry using REDCap, a secure web based database. Clinicians (or their data managers) are responsible for entering their patient data directly into the REDCap database. Opportunities to import data into the REDCap database from existing institutional databases are also being developed. Site staff are trained to use the database and are provided with a data entry manual to assist with good quality data collection. Data to be collected includes demographic and clinical data up to 90 days follow-up. ANZTCR staff will check case ascertainment periodically via each site's Health Information Services unit. The use of agreed definitions of the data elements ensures that the information collected is consistent and uniform, providing reliable and comparable data for analysis. A detailed data dictionary containing the data elements, formats, ranges and validation rules and definitions has been developed and will be maintained under document management with version control.

Reporting

As per the 2008 ACSQHC Operating Principles, the ANZTCR will undergo a period of establishment and on-boarding of participating sites before the commencement of regular reporting. At the conclusion of approximately two years, the ANZTCR will be reviewed regarding its achievement against its aims and suitability for further rollout. Beyond two years and when sufficiently mature data is available, the ANZTCR is anticipated to produce a range of regular reports including: annual reports and benchmarked de-identified reports of clinical quality indicators (with identified data made available confidentially to participating sites).

Data Access Policy

Clinicians can access their own data through the registry database. Researchers may access registry data following approval by the ANZTCR Steering Committee and Ethics Committee as per the ANZTCR Data Access Policy (Supplementary Material). Monash's ANZTCR Coordinating Centre is the point of contact for matters relating to access to registry data.

Results

The ANZTCR is an observational study of patients with newly diagnosed thyroid cancer receiving surgical treatment. It collects identifiable patient key diagnostic, clinical, treatment, and complication data from diagnosis to 90-days post-thyroid cancer surgery. The registry is multi-centred operating across participating sites in Victoria, New South Wales, Queensland, Western Australia and South Australia, as well as New Zealand. Since the establishment of the registry we have received interest from almost 30 endocrine surgeons from over 35 sites throughout Australia and New Zealand.

Clinician Recruitment

Endocrine surgeons are informed about the registry through ANZES. Quarterly ANZTCR newsletters are distributed to all ANZES members to inform them of the activities and progress of the registry. Registry staff visit clinicians at their participating hospitals to introduce the registry. The primary (PI) and associate investigators (AI) for the registry at each site also act as ambassadors for the registry

and promote participation within their site. Clinician participation forms are sent to all endocrine surgeons, outlining the project and inviting clinicians to participate in the registry.

The Monash University ANZTCR coordination centre is responsible for distributing the clinician participation forms to surgeons and collating signed forms prior to the recruitment of patients and data collection. This is a once-only process for clinicians and provides agreement by the surgeon to participate in the registry and enter data on all patients for whom they are listed as the diagnosing or treating clinician in participating hospitals and private practice.

Participant Recruitment

Patient recruitment at a participating site commences following the appointment of a PI to take responsibility for the registry at the site, and authorisation by the participating site's research governance office. An outline of the recruitment framework is provided in Figure 1.

*** Figure 1 here ***

Phase 1

All patients diagnosed with thyroid cancer, based on histological confirmation (provided approximately 1-2 weeks post-surgery) at a hospital with ANZTCR research governance approval are eligible to participate. The treating endocrine surgeon (or designated staff member) at the surgical endocrine unit will enter minimal patient details into the ANZTCR REDCap Database, in addition to confirming thyroid cancer diagnosis and patient disclosure, at sites where a waiver of consent has been approved for the clinician to provide this information to the registry.

Phase 2

The Monash University ANZTCR coordinating centre will identify patients in the registry and invite them to participate in the study via a mail-out. The mail-out will include an introductory letter explaining the study, including information about the purpose, and possible outcomes of the research (including publication of research results) and a copy of the ANZTCR Participant Explanatory Statement. Using the opt-out process the patient will contact Monash University if they choose to not participate in the study. If the patient does not contact the study coordinator within two weeks participation is assumed.

Phase 3

If the participant has not opted-out of the registry the endocrine surgeon will enter participant diagnosis, surgical, pathology and treatment data into the registry database 90 days post-surgery.

Minimum Data Set & Quality Indicators

To benchmark clinical care, clinical quality registries require systematic measurement at predefined intervals and the capacity to report back information to participating clinical units. A modified-Delphi approach, informed by international Thyroid Cancer Guidelines and relevant literature, was used to develop a set of thyroid cancer clinical indicators, the parameters of which are shown in Table 1. A detailed methodology of the modified-Delphi process will be published separately. Following the development of the clinical indicators, a minimum data set was developed that included variables relating to the indicators, variables required for patient identification and contact, and other variables of particular relevance to early thyroid cancer management. The selection of data fields and their definitions were derived from national data specifications such as Metadata Online Registry (METeOR) where they exist and from international thyroid cancer registry data dictionaries where terms are not defined within the Australian context. Once a final list was generated it was

then endorsed by the ANZTCR Steering Committee. Data items collected by the ANZTCR are outlined in Table 2.

Table 1. Framework of consensus set of clinical quality indicators

Ref. No.	Clinical Quality Indicator	
Preoperative		
CQI 1	Ultrasound (US)	Process
CQI 2	Fine Needle Aspiration (FNA)	Process
CQI 3	Voice Assessment	Process
Surgery		
CQI 4	Total (Near-Total) Thyroidectomy	Process
CQI 5	Lymph Node Dissection	Process
Surgical Complications		
CQI 6	Recurrent Laryngeal Nerve (RLN) Palsy	Outcome
CQI 7	Hypoparathyroidism (Hypocalcaemia)	Outcome
CQI 8	Haemorrhage Requiring Return to Theatre	Outcome
Staging & Treatment Planning		
CQI 9	Postoperative TNM Staging	Process
CQI 10	Multi-disciplinary Team Meeting (MDM)	Process
Post-Surgical Treatment		
CQI 11	Completion Thyroidectomy	Process
CQI 12	Radioactive Iodine (RAI)	Process

Table 2. Data Items collected by the ANZTCR.

Recruitment	Patient Details	Preoperative	Procedure(s)	Postoperative	Treatment
• Patient ID • Given Name(s) • Surname • Date of Birth • Sex • Country • Street Address • Suburb • State/City • Postcode • Medical Record Number • Surgeon Name • Date of Diagnosis • Basis of Diagnosis • Disclosure of Diagnosis to Patient • Vital Status • Date of Death • Cause of Death	• Contact Number • Email Address • Country of Birth • Preferred Language • Interpreter Required • Aboriginal, Torres Strait Islander Status • Maori Status • Biobank Sample	• Presence of Comorbidities • Medication at Diagnosis • Thyroid Function at First Presentation • Neck Examination • Palpable Lymph Nodes • Family History of Thyroid Disease • Previous Exposure to Radiation • Previous Thyroid Surgery • Preoperative Imaging • Presence of Suspicious Lymph Nodes • Largest Thyroid Nodule Diameter • Fine-Needle Aspiration • Clinical Voice Abnormality • Preoperative Laryngeal Exam	• Date of procedure • Procedure Type • Indication for Procedure • Residual Tumour • Lymph Node Dissection • Lymph Node Dissection Intent • Lymph Node Dissection Levels • Recurrent Laryngeal Nerve • Nerve Integrity Monitor • Primary & Secondary TC Pathology • PTC, FTC, HCC Variants • Incidental Finding of Cancer • Thyroid Benign Pathology • Largest Tumour Diameter • Margin Status • Multifocal Cancer • Lymphovascular Invasion • Extrathyroidal Extension • Lymph Node Metastases • Distant Metastases • Distant Metastases Sites	• Surgical Complications • TNM Staging • Vitamin Supplementation • Genetic Testing	• Maximum Stimulated Tg (ug/L) • Maximum TgAb (U/ml) • Method of TSH Stimulation • Maximum Stimulated TSH (mU/L) • RAI Remnant Ablation (RRA) • Other Adjuvant Therapy

Discussion

Following its national establishment, the ANZTCR will monitor diagnosis, treatment and outcomes allowing for the identification of patterns of care and practices associated with better outcomes through improved compliance with best practice-based guidelines for the management of thyroid cancer. The registry will also be able to identify risk factors that predict favourable and unfavourable treatment outcomes, postoperative complications, and prognosis, leading to the stratification of treatments and follow up. The ANZTCR will highlight risks and benefits of specific approaches to thyroid cancer as well as establish international benchmarks in the routine management of thyroid cancer surgical care. Further, the ANZTCR provides a basis as a platform for longer-term clinical follow-up, sub-studies exploring treatment outcomes, and clinical trials. We believe that the ANZTCR through its accumulation of a significant thyroid cancer cohort will assist in identifying best practice management specifically in complex poor prognostic thyroid cancer cases of low incidence.

One of the key features of the ANZTCR is that it is a surgeon-based CQR, with surgeons entering their patient data directly into the ANZTCR-RCD. While there are a number of benefits to this structure, including reduced data collection costs related to hiring additional staff and subject specific training, there are also a number of potential challenges. One of the major challenges is surgeon engagement. However, due to the registry being funded by the Australian and New Zealand Endocrine Surgeons, a speciality society of endocrine surgeons, we have had high engagement during the establishment phase. In order to maintain this engagement we have circulated quarterly newsletters with updates on the registry and invited the surgeons to be involved in the development of the clinical quality indicators and minimum data set. Continual review and refinement of the dataset will ensure that the data collection burden is kept to a minimum. Additionally, the registry database allows surgeons to run site patient-level and aggregate data reports in real-time for use in clinical care. The registry will also provide surgeons with an 'ANZTCR Valued Contributor' logo for use on their email signature, letterhead and/or website, and has been approved as a clinical audit activity by the Royal Australian College of Surgeons (RACS) Continuing Professional Development (CPD) program.

Data from CQRs generally have strong external validity particularly with regard to generalisability and extrapolation of outcomes, however bias can exist (37), particularly due to the nature of the registry data being surgeon-derived. Initial quality assurance processes will include sample audits of participating surgeon records. In the future to ensure case ascertainment, the ANZTCR could potentially receive monthly data extracts from participating site Health Information Services (HIS) or the Victorian Cancer Registry (VCR), pending approval. As the registry expands it will also consider recruiting non specialist endocrine surgeons who undertake thyroid cancer surgery including head and neck surgeons.

In order to commence patient recruitment the registry needs to seek ethics approval and governance authorisation at the participating site. As CQRs are becoming more common, standard guidelines have been introduced to make the ethics process more manageable. In particular, the National Mutual Acceptance (NMA) scheme has streamlined ethics for all public hospitals in all states except Tasmania (and the Northern Territory). Private hospitals can still choose to participate through the NMA scheme. Nevertheless, the process of obtaining site governance approval remains both time consuming and labour intensive (38, 39). Finally, perhaps the most important challenge faced by CQRs include ongoing funding to ensure their sustainability. Currently the ANZTCR has enough funding to support the registry during the initial pilot phase, however in order to progress to national rollout and implement longer-term clinical follow-up and patient-reported outcomes

additional funding is required. This is particularly relevant as lengthy follow-up is required to ascertain outcomes relating to recurrence (30, 40). Nevertheless, given the benefits to patients, clinicians and wider stakeholders, and high level of clinician engagement, we are optimistic that in time these benefits will be realised.

References

1. Western Australian Cancer Registry. Cancer incidence and mortality in Western Australia. In: Data Integrity Directorate PaSPD, editor. Perth Western Australia,: Department of Health,; 2014.
2. Australian Government. Cancer in Australia: an overview, 2012. In: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries, editors. Canberra: AIHW; 2012.
3. Australian Government. Australian Cancer Database (ACD). In: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries, editors. Canberra: AIHW; 2011.
4. New Zealand Cancer Registry (NZCR). Cancer Data and Stats. In: Health Mo, editor. Wellington: New Zealand Government; 2017.
5. Australian Government. National Mortality Database (NMD). In: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries, editors. Canberra: AIHW; 2011.
6. Jemal A, Ward EM, Johnson CJ, Cronin KA, Ma J, Ryerson AB, et al. Annual report to the nation on the status of cancer, 1975–2014, featuring survival. JNCI: Journal of the National Cancer Institute. 2017;109(9).
7. Husson O, Haak HR, Mols F, Nieuwenhuijzen GA, Nieuwlaat WA, Reemst PH, et al. Development of a disease-specific health-related quality of life questionnaire (THYCA-QoL) for thyroid cancer survivors. Acta Oncologica. 2013;52:447–54.
8. Mendoza A, Shaffer B, Karakla D, Mason EM, Elkins D, Goffman TE. Quality of life with well-differentiated thyroid cancer: Treatment toxicities and their reduction. . Thyroid. 2004;14:133 – 40.
9. Lee JC, Breen D, Scott A, Grodski S, Yeung M, Johnson W, et al. Quantitative study of voice dysfunction after thyroidectomy. Surgery. 2016;160(6):1576-81.
10. Serpell JW, Lee JC, Yeung MJ, Grodski S, Johnson W, Bailey M. Differential recurrent laryngeal nerve palsy rates after thyroidectomy. . Surgery. 2014;156(5):1157-66.
11. Hayward NJ, Grodski S, Yeung M, Johnson WR, Serpell J. Recurrent laryngeal nerve injury in thyroid surgery: a review. ANZ journal of surgery. 2013;83(1-2):15-21.
12. Serpell JW. Preventing hypoparathyroidism after total thyroidectomy. ANZ journal of surgery. 2018;88(3):127-8.
13. Lee JC, Chang P, Grodski S, Yeung M, Johnson W, Serpell J. Temporal analysis of thyroid cancer management in a Melbourne tertiary centre. ANZ journal of surgery. 2016.
14. Nixon IJ, Whitcher MM, Palmer FL, Tuttle RM, Shaha AR, Shah JP, et al. The impact of distant metastases at presentation on prognosis in patients with differentiated carcinoma of the thyroid gland. Thyroid. 2012;22(9):884-9.
15. Hall SF, Irish JC, Groome PA, Urbach DR. Practice patterns in the management of patients with differentiated thyroid cancer in Ontario Canada 2000-2008. Journal of Otolaryngology-Head & Neck Surgery. 2014;43(1):29.
16. Tasevski R. Management Patterns and Outcomes of Differentiated Thyroid Cancer in Ontario: A Population-based Study. (Doctoral dissertation). 2013.
17. Cobin RH, Gharib H, Bergman DA, Clark OH, Cooper DS, Daniels GH, et al. AACE/AAES medical/surgical guidelines for clinical practice: management of thyroid carcinoma. American Association of Clinical Endocrinologists. American College of Endocrinology. Endocrine practice: official journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists. 2001;7(3):202.

18. Pacini F, Schlumberger M, Dralle H, Elisei R, Smit JW, Wiersinga W. European consensus for the management of patients with differentiated thyroid carcinoma of the follicular epithelium. . European journal of endocrinology. 2006;154(6):787-803.
19. Perros P, Colley S, Boelaert K, Evans C, Evans RM, Gerrard GE, et al. British Thyroid Association Guidelines for the Management of Thyroid Cancer. Third Edition. Clinical Endocrinology. 2014;81(Suppl. 1):1-122.
20. Cameron PA, Gabbe BJ, McNeil JJ, Finch CF, Smith KL, Cooper DJ, et al. The trauma registry as a statewide quality improvement tool. Journal of Trauma and Acute Care Surgery. 2005;59(6):1469-76.
21. Australasian Society of Cardiac and Thoracic Surgeons Database Project Steering Committee. Victorian Cardiac Surgery Database Project.
22. Australia and New Zealand Dialysis and Transplant Association (ANZDATA). Australia and New Zealand Dialysis and Transplant Registry [Web Page] [Available from: http://www.anzdata.org.au/.
23. Malycha P, Tyson S. National breast surgery audit. Australian and New Zealand Journal of Surgery. 2000;70(12):834-6.
24. Poelemeijer YQ, Liem RS, Nienhuijs SW. A Dutch Nationwide Bariatric Quality Registry: DATO. Obesity surgery. 2017:1-9.
25. Graves SE, Davidson D, Ingerson L, Ryan P, Griffith EC, McDermott BF, et al. The Australian orthopaedic association national joint replacement registry. Medical Journal of Australia. 2004;180(5):S31.
26. Cancer Institute NSW. NSW Clinical Cancer Registry [Web Page] [Available from: http://www.cancerinstitute.org.au/cancer_inst/programs/registryccr.html.
27. Sweden E. Handbook for Establishing Quality Registries. Karlskrona: Eyenet Sweden. 2005.
28. Australian Commission on Safety and Quality in Health Care. Information Strategy. Sydney: ACSQHC; 2007.
29. Londero SC, Mathiesen JS, Krogdahl A, Bastholt L, Overgaard J, Bentsen J, et al. Completeness and validity in a national clinical thyroid cancer database: DATHYRCA. Cancer epidemiology. 2014;38(5):633-7.
30. Mehra S, Tuttle RM, Milas M, Orloff L, Bergman D, Bernet V, et al. Database and registry research in thyroid cancer: striving for a new and improved national thyroid cancer database. Thyroid. 2015;25(2):157-68.
31. Haugen BR, Alexander EK, Bible KC, Doherty GM, Mandel SJ, Nikiforov YE, et al. 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid. 2016;26(1):1-133.
32. Australian Commission on Safety and Quality in Health Care. Operating Principles and Technical Standards for Australian Clinical Quality Registries [Web Page] [Available from: http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/EA520128CB313DE9CA2573AF007BC590/$File/OP_TS-Nov2008.pdf.
33. Tu JV, Willison DJ, Silver FL, Fang J, Richards JA, Laupacis A, et al. Impracticability of informed consent in the Registry of the Canadian Stroke Network. New England Journal of Medicine. 2004;350(14):1414-21.
34. Cancer Council of Victoria. Cancer Council of Victoria Registry & Statistics 2013 [Available from: http://www.cancervic.org.au/research/registry-statistics.
35. Junghans C, Jones M. Consent bias in research: how to avoid it. Heart. 2007;93(9):1024-5.
36. Buckley B, Murphy AW, Byrne M, Glynn L. Selection bias resulting from the requirement for prior consent in observational research: a community cohort of people with ischaemic heart disease. Heart. 2007;93(9):1116-20.
37. Stub D, Lefkovits J, Brennan AL, Dinh D, Brien R, Duffy SJ, et al. The Establishment of the Victorian Cardiac Outcomes Registry (VCOR): Monitoring and Optimising Outcomes for Cardiac Patients in Victoria. Heart, Lung and Circulation. 2018;27:451-63.

38. Clay-Williams R, Taylor N, Braithwaite J. Potential solutions to improve the governance of multi centre health service research. MJA. 2018;208(4):152-4.
39. Brown WA, Smith BR, Boglis M, Brown DL, Anderson M, O'Brien PE, et al. Streamlining ethics review for multisite quality and safety initiatives: national bariatric surgery registry experience. Med J Aust. 2016;205(200-1).
40. Pearce EN, Lee SL, Weiss R, Magner J, Garber JR, Campion FX, et al. Unique obstacles to establishing thyroid cancer registries. Journal of clinical & translational endocrinology. 2016;3:12-3.

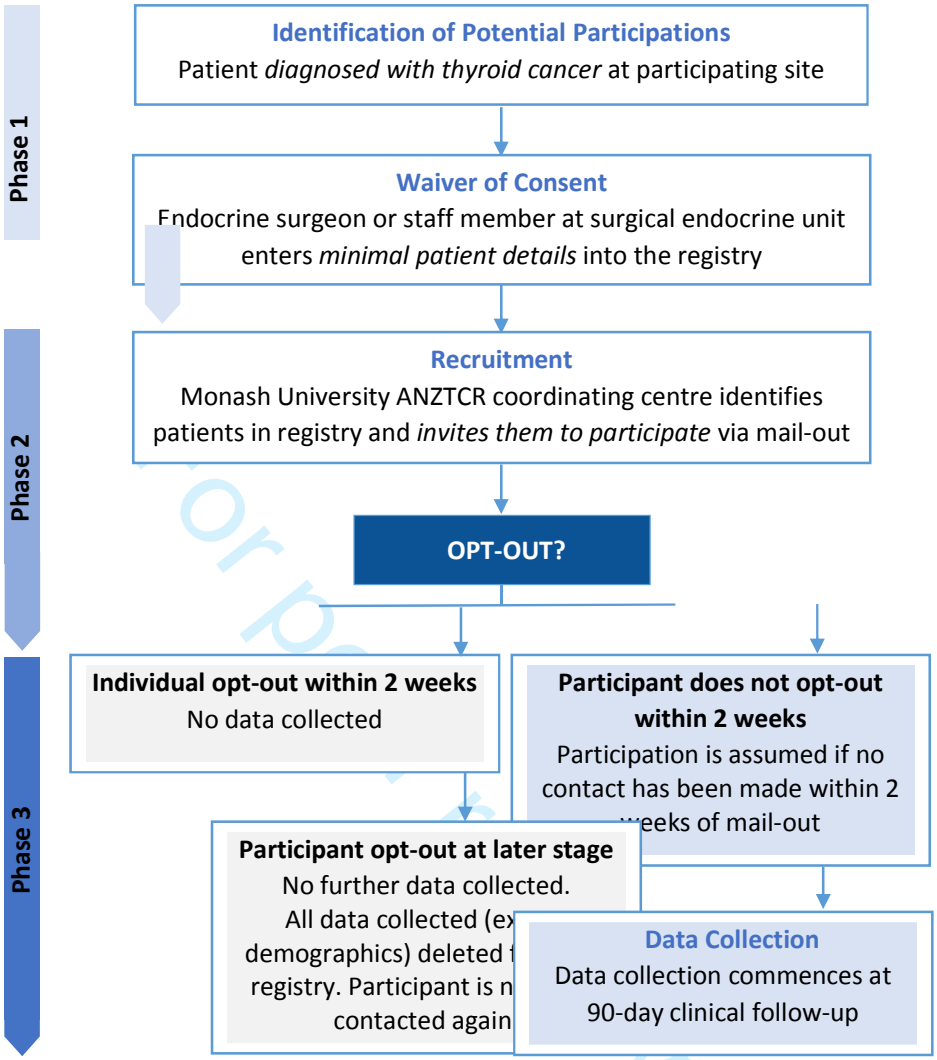

Figure 1. Patient Recruitment Framework

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

PROTOCOL

Data Custodian
Dr Susannah Ahern

Monash University
School of Public and Preventive Medicine
Faculty of Medicine, Nursing and Health Sciences

Statement of Compliance
This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007), Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ASCSQH Operating Principles and technical standards for Australian Clinical Quality Registries, University research policies and procedures and federal laws governing privacy and confidentiality.

Recommended citation:

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

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AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

1. CONTENTS

2. GLOSSARY OF ABBREVIATIONS & TERMS

Abbreviation	Description (using lay language)
ACSQHC	Australian Commission on Safety and Quality in Health Care
ANZES	Australian and New Zealand Endocrine Surgeons
ANZTCR	Australian & New Zealand Thyroid Cancer Registry
BES	Breast Endocrine Surgery
CQR	Clinical Quality Registry
DEPM	Department of Epidemiology & Preventive Medicine
HREC	Human Research Ethics Committee
ICD-10	International Classification of Disease 10
METeOR	Metadata Online Registry
PI	Principle Investigator
RAI	Radioactive Iodine
RLN	Recurrent Laryngeal Nerve

3. BACKGROUND INFORMATION

3.1 LAY SUMMARY

The Australian & New Zealand Thyroid Cancer Registry (ANZTCR) is a quality project which monitors treatment and outcomes for patients diagnosed with thyroid cancer at participating Australian and New Zealand sites. The project will collect patient information regarding their thyroid cancer diagnosis, treatment, and disease status. No other research project in Australia/New Zealand is collecting such a significant amount of data for thyroid cancer patients.

The ANZTCR will use the information collected to:

- Allow doctors to better understand changes in thyroid cancer incidence, treatment and post-operative outcomes across multiple sites
- Enable clinicians to measure their clinical performance against evidence-based guidelines and identify areas for improvement
- Provides data for research

The ANZTCR will collect information from patients using an opt-out approach, allowing patients the opportunity to opt-out of the registry if they wish. Information will be collected at the time of the patient's surgery for thyroid cancer and at a post-operative visit. This information will be stored

securely on a registry database managed by Monash University. Access to the information held by the registry for research and other study purposes will be in accordance with a Data Access Policy, and patient privacy will at all times be respected.

3.2 INTRODUCTION

The Monash University Breast Endocrine Surgery (BES) Unit has since 2009 collected data with HREC approval relating to thyroid cancer undertaken at the majority of its related hospitals. The data has led to academic publications, but has not been used for reporting back to participating health services. The Monash University BES Unit is now seeking to transition from the previous audit to become a national thyroid cancer registry for the following reasons:

- There is interest and support for this from interstate endocrine surgeons and from Australian and New Zealand Endocrine Surgeons (ANZES). It is likely that over fifty sites nationally manage thyroid cancer patients, including regional and private sites.
- There is interest in moving to a clinical quality registry (CQR) model and defining a suite of clinical indicators against which to assess and benchmark clinical care
- There is interest in obtaining patient follow-up information to provide further evidence regarding long-term sequelae and outcomes following treatment for thyroid cancer

The ANZTCR aims to determine the feasibility and usefulness of a national thyroid cancer CQR by implementing the model of a CQR, but on a smaller scale i.e. across a sample of eligible sites. It is expected that a national thyroid cancer registry may provide data to inform best-practice guidelines as well as benchmark performance in Australia and New Zealand with data from comparable international registries.

The short-term aims of the ANZTCR is to:

- Develop a broad-based registry governance structure
- Engage clinician support for the registry
- Refine a minimum data set
- Define a set of clinical indicators (outlined in section 6)
- Undertaken the ethics requirements to establish the registry, and establish the registry in a number of sites with existing thyroid cancer databases, and new sites across multiple jurisdictions
- Develop and use the REDCap software tool for data entry and storage
- Develop a statistical analysis plan for the registry evaluation report
- Produce an evaluation report at the conclusion of two years comprising initial data analysis and an assessment regarding the registry's potential for ongoing consolidation, expansion, and funding.

3.3 THYROID CANCER

Thyroid Cancer Characteristics

The incidence of thyroid cancer in Australia in 2012 was 2,297 new cases, with females comprising approximately 75%, and with an average age of diagnosis of approximately 52 years (1). However the incidence has been increasing steadily, particularly among females. In 2013, there were 133 deaths caused by thyroid cancer. 70-80% of thyroid cancers are papillary; with approximately 25% being follicular. Less common thyroid cancers include medullary thyroid cancer, anaplastic thyroid cancer and thyroid sarcoma or lymphoma.

Thyroid cancer may be treated surgically, and/or with thyroid hormone replacement therapy, radioactive iodine treatment, radiotherapy or chemotherapy depending on the type and stage of cancer. The most common types of thyroid cancer have very good long-term prognoses, and of all cancers, thyroid cancer has the highest five-year survival rate at 96%.

However, despite highly effective treatments and good long-term outcomes, there are a number of short and long-term complications that may occur including thyrotoxic storm, haemorrhage, wound infection, temporary or permanent hoarseness or loss of voice due to injury to the recurrent laryngeal nerve, damage to the parathyroid glands resulting in hypoparathyroidism and hypocalcaemia, effects of radioactive iodine (RAI) treatment, and cancer recurrence.

Burden of Disease

Thyroid cancer is the seventh commonest cancer amongst women in Australia. The occurrence of thyroid cancer is increasing throughout the developed world, including Australia, and since the 1990s, it has become the fastest increasing malignancy. Between 1991 and 2009, the number of thyroid cancer cases increased by 250% in Australia (1). In 2016 it is expected there will be approximately 2,700 new cases of thyroid cancer in Australia. From 2007 to 2020 thyroid cancer rates are projected to increase by 33% in males and 62% in females (2, 3).

Treatment for Thyroid Cancer

Patients with thyroid cancer typically undergo surgery with total thyroidectomy, followed by thyroid bed ablation with RAI and then subsequently high dose suppressive thyroxine therapy. Patients are monitored following this therapy with clinical assessment, specific blood tests, follow up RAI scanning and imaging of the neck with ultrasound. Best practice guidelines exist to help guide these treatment practices, however controversy continues in a number of areas.

Complications of thyroidectomy, such as voice change – occurring in up to 80% of patients, and permanent vocal cord palsy resulting in hoarseness (0.6%), both potentially affect employment and quality of life. Postoperative low calcium levels (due to under function of parathyroid glands), causing symptoms such as tingling and cramps, resulting in prolonged inpatient stays, may occur on a temporary (in up to 15%) or permanent (in 0.7-3%) basis following surgery. This results in poor quality of life and a huge economic burden.

Variation in treatment/outcome/practice

Close attention to quality measures and standardisation of treatment to align with international recommendations and guidelines will improve outcomes for patients with thyroid cancer. Currently

there are variations in multiple aspects of thyroid cancer management and treatment, including the role of:

- pre-treatment scanning (i.e. preoperative scanning of cervical lymph nodes);
- optimal extent of surgery (hemi- or total-thyroidectomy);
- central lymph node dissections; and
- radioactive iodine treatment.

Furthermore, there are variations in outcomes following thyroid surgery, with significantly greater risk of complications for total thyroidectomy and with surgeons who have less experience. Variations in outcomes include:

- hypoparathyroidism and hypocalcemia; and
- laryngeal nerve damage (i.e. RLN palsy).

3.4 THYROID CANCER REGISTRY

Previous Australian Thyroid Cancer Audit activity

The previous Thyroid Cancer Audit collected data relating to thyroid cancer from the majority of its related hospitals (Alfred Health, Monash Health, Peninsula Health, Cabrini Health, Dandenong Valley and Peninsula Private), comprising a dataset of more than 1,500 patients. Additionally, the Royal North Shore hospital in New South Wales and its related public and private hospitals have also collected similar (but not identical) data under ethics oversight. The data collected has comprised a number of mandatory and desirable data fields and has been collected at sites via a range of methods including paper-based, on-line direct entry, or via excel spreadsheets. The data from these databases has resulted in a number of peer-reviewed publications and led to the proposal of a national thyroid cancer registry.

National Thyroid Cancer Registry

The ANZTCR aims to extend data collection to all major hospitals providing treatment for thyroid cancer in Australia (and, eventually, New Zealand) to form a National Thyroid Cancer Registry.

3.5 CLINICAL QUALITY REGISTRIES

A proven strategy to reduce variations in outcome and to improve survival is to measure and compare it using high quality clinical registry data. This has been successfully tested in a range of clinical areas including in the management of surgery (e.g. trauma, (4) cardiac surgery, (5) transplantation, (6) and breast surgery (7)) and in the medical management of patients (e.g. stroke care, (8) cardiac care, (9) dialysis (6) and cancer care (10)). Clinical registries provide the most effective means of collecting high quality data and are a tool for quality improvement.

Where they have been introduced at a state or national level, registries have become one of the most clinically valued tools for quality improvement. (11) The Australian Commission on Safety and Quality in Health Care (ACSQHC) has advocated development of clinical registries (12). Registries can improve quality of care by:

- providing credible risk adjusted data;
- giving clinicians information about how their outcomes benchmark with others, both locally

and where appropriate internationally;

- identifying and investigating variations in clinical practice and outcomes; and
- providing an early warning if quality of care deteriorates.

In addition to being important tools in improving quality of care, clinical registries provide unparalleled ability to track how innovation in biomedical science translates into longer term outcomes in the 'real world' (13, 14). Biomedical science laboratories are involved in identifying new mechanisms of disease, new prognostic markers, new early diagnostics and measures of response to treatment. This work is often impeded by lack of access to human populations where outcomes are systematically and accurately collected and can be related to laboratory findings.

Clinical registries at Monash University

The Department of Epidemiology and Preventive Medicine (DEPM) at Monash University has a strong track record in the development and operation of clinical and clinical quality registries at a state and national level (15). It currently operates 24 clinical registries, including those monitoring the Victorian trauma system (16), cardiac surgery and interventional cardiology, burns, hyperbaric medicine and blood diseases (17). It fosters a thriving research environment supporting high quality research and researchers with extensive experience in registry methodology including recruitment, data collection, linkage and analysis underpinned by effective registry governance structures.

In 2008, Monash was requested by the ACSQHC to develop Operating Principles for Australian Clinical Registries (18). Principles outlined in this document will guide the development of all registries in Australia, including the Australian & New Zealand Thyroid Cancer Registry.

The ability to monitor care and benchmark performance requires the collection of high quality epidemiological data collected on all patients diagnosed with thyroid cancer. A registry allows the capacity to identify and benchmark against best practice, provide regular feedback to clinicians regarding their clinical outcomes, and, provide a platform for further research into thyroid cancer care. Investment in long-term registry data will allow better analysis of outcomes on spending and health, including through post-marketing assessment of new treatments (19)

4. STUDY OBJECTIVES

4.1 HYPOTHESIS

We hypothesize that a clinical quality registry established to monitor treatment and outcomes of thyroid cancer will reduce variation in treatment and outcome, and improve knowledge and management of the disease.

4.2 REGISTRY AIMS

The aim of this project is to develop a population-based thyroid cancer clinical quality registry to optimize quality of care provided to individuals diagnosed with thyroid cancer. This will be achieved by:

1. Assessing patterns of care and access to care;
2. Identifying variability in treatment/outcome amongst individuals with thyroid cancer and studying its causes and consequences;

3. Benchmarking of process and outcomes measures amongst providers of care;
4. Determining the degree of compliance (and reasons for non-compliance) with best practice-based guidelines for the treatment of thyroid cancer;
5. Identifying factors that predict favourable and unfavourable treatment outcomes.

In addition we hypothesise that a thyroid cancer registry will provide the opportunity to improve knowledge and advance treatment by:

6. Monitoring trends in incidence and survival over time,
7. Providing an infrastructure on which intervention or other studies can be established,
8. Determining the clinical effectiveness of treatments in a 'real world' setting
9. Provide information to assist in the credentialing of clinicians and identification of appropriate training resources
10. Provide information to patients about the risks and benefits of specific approaches to thyroid cancer care
11. Contribute to a biobank of specimens to enable research to be undertaken to better identify biological factors associated with thyroid cancer

4.3 REGISTRY OUTCOMES

Establishment of a thyroid cancer clinical quality registry offers the potential to make considerable inroads into our understanding of current practice in the treatment of thyroid cancer and reasons for variation in outcomes. Understanding reasons for and reducing variation in outcome is critical in driving improvements in the management of the disease.

The establishment of a thyroid cancer clinical quality registry will achieve the following outcomes of significance:

- Identify variation in care and explore reasons for it and impel change. Larger immediate improvements in outcomes for thyroid cancer treatment are likely to occur by reduction in variation and appropriate application of strategies already known to be effective, than by hoping for discovery of new drugs or techniques that: (a) have historically been not commonly discovered; (b) are marginal in their influence; (c) are often expensive; (d) are variable in their application; and (e) are commonly associated with long lead-times.
- Promote evidence-based practice by assessing compliance with established best practice. Registry staff will report findings to contributing sites and the Steering Committee. The knowledge gained will inform how to better engage with clinicians to enhance adoption of best practice models. Where practice variation exists, an escalation policy may be developed.
- Provide important information to inform public health policy and practice, including analysis of the cost benefit of new treatment, identification of areas of need and outcome of interventions.
- Provide confidence to clinicians and institutions that they are delivering a high quality service.

- Assure the public that thyroid cancer treatment is performed under the oversight of a robust quality assurance programme. This will instil patient confidence and confer a public relations advantage to hospitals contributing data.
- Provide patients with important information about treatment risks and benefits. This will empower patients to make informed decisions about care and treatment options. Benefits will be realised in the short term by producing risk adjusted comparative outcome data based on currently available treatment and in the longer term by assessing the impact of new technologies and discoveries on outcome.
- Provide the ability for consumers to inform the thyroid cancer research agenda. Consumer representation on the Steering Committee will help to ensure that the research addresses the needs of the patients suffering from thyroid cancer and their families.
- Provide a data spine from which other studies can be undertaken. As an observational tool, it will enable hypotheses for testing through subsequent studies.
- Provide an ability to track long term effects of innovations in thyroid cancer management.
- The registry will be capable of being linked to other databases containing information about histopathology, genetic markers, biochemical characteristics and other newly discovered laboratory markers. This will provide new opportunities to value add to discoveries in the basic science laboratories by providing high quality outcome information that has previously been lacking. The linkage to the biomedical data will allow new discoveries at a molecular level to be assessed in humans for their prognostic and/or early diagnostic value and may provide clues to the pathophysiological mechanisms underlying thyroid cancer.

4.4 REGISTRY OUTCOME MEASURES

To benchmark clinical care, clinical quality registries require systematic measurement of defined outcomes, at predefined intervals and capacity to report back information to participating clinical units. Clinical quality indicators will for the registry will be developed using a modified-Delphi approach.

5. RESEARCH PLAN

5.1 REGISTRY DESIGN

The Australian & New Zealand Thyroid Cancer Registry is an observational study of thyroid cancer patients assessed by an endocrine surgeon for surgical treatment collecting identifiable data obtained from patient medical records on key diagnostic, clinical, treatment, complications and outcomes from diagnosis to 90-days post-thyroid cancer surgery. The registry is multi-centred operating across participating sites in Victoria, New South Wales, Queensland, Western Australia and South Australia, as well as New Zealand. In Victoria the participating sites represent approximately 48% of sites providing this care in 2015.

The registry will conform to the national operating principles for CQR's as set out by the ACSQHC. The registry is expected to be ongoing and data will be retained indefinitely. Should for any reason, the registry close, data will be retained for a minimum of seven years. Figure 1 below provides a diagrammatic overview of the registries core set up and activities.

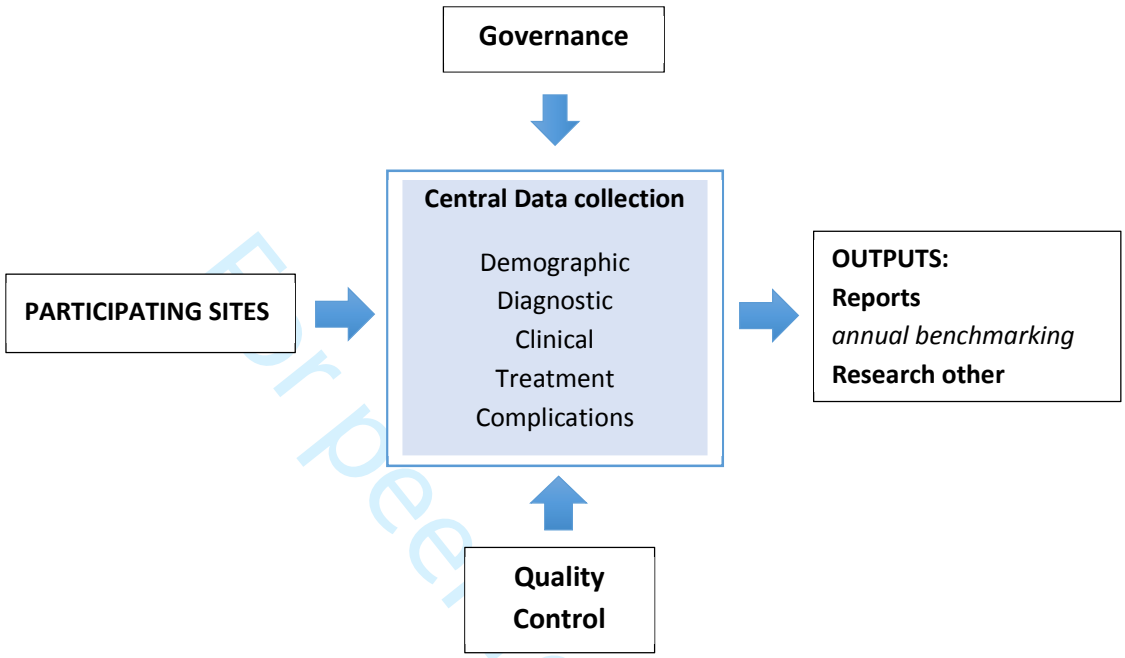

Figure 1: Operational overview of Thyroid Cancer clinical quality registry

6. STUDY POPULATION

All patients newly diagnosed with thyroid cancer >18 years of age that have been diagnosed, assessed or treated at a participating site will be eligible to participate in the registry.

Inclusion criteria

- All newly-diagnosed patients presenting to a participating hospital with a confirmed primary thyroid cancer.
- Patients with a diagnosis date which falls within the time frame specified for inclusion. This date will vary per institution.
- Patient is >/= 18 years of age.

Exclusion criteria

- Patients who were diagnosed more than one month before the registry commencement date at that site.

7. RECRUITMENT PROCEDURE

7.1 REGISTRY POPULATION

Following the appointment of a local investigator at a site, the receipt of ethics approval covering that site and hospital governance approval, patient recruitment will be initiated.

The following recruitment procedure will be used:

1. The patient is diagnosed with thyroid cancer, via histology (approximately 1-2 weeks) post-surgery, at the hospital participating in the ANZTCR project.
2. The endocrine surgeon or staff member at the surgical endocrine unit enters minimal patient details into the registry, in addition to confirming thyroid cancer diagnosis and patient disclosure, at sites where a waiver of consent has been approved for the clinician to provide this information to the registry.
3. Monash University ANZTCR coordinating centre identifies patients in the registry and invites them to participate in the study via a mail-out. The mail-out includes an introductory letter explaining the study, including information about the purpose, and possible outcomes of the research (including publication of research results) and a copy of the ANZTCR Participant Explanatory Statement.
4. Using the opt-out process the patient will contact Monash University if they do not want to participate in the study. If the patient does not contact the study coordinator within two weeks participation is assumed.
5. The surgeon enters participant data into the registry.
6. Participants may be contacted by the Monash University ANZTCR coordinating centre and invited to participate in patient-reported outcome measures (PROMs) questionnaires. If the participant consents to participate, PROMs questionnaires will be administered at pre-determined intervals. If the participant does not consent to participate, they will remain in the registry and no further contact will be made.

7.2 CLINICIAN RECRUITMENT

Treating endocrine surgeons will be informed about the registry through ANZES and a number of other sources. Quarterly ANZTCR newsletters will be distributed to all ANZES members. Education sessions will be provided within existing meetings at major hospitals to introduce the registry at sites with multiple clinicians involved in the management of patients. The primary and associate investigators for the registry at each site will also be ambassadors for the registry and promote participation at their site.

Due to the nature of the registry, with clinicians being responsible for their own data entry, and the large number of clinicians who work in both hospitals and private practices (where medical records are kept privately by clinicians), clinician participation forms will be sent to all endocrine surgeons at a participating institution. The participation forms will outline the project and invite the clinician to participate in the registry and to enter all relevant medical data from all eligible patients diagnosed or treated at the contributing hospital, following agreement by the patient to participate.

Monash University ANZTCR coordination centre will be responsible for distributing the clinician participation form to surgeons and collating signed forms prior to the recruitment of patients and

data collection. This is a once-only process for clinicians and provides approval for the surgeon to participate in the registry and enter data on all patients for whom they are listed as the diagnosing or treating clinician in participating hospitals and private practice.

8. OPT-OUT APPROACH

8.1 OPT-OUT PROCESS

Responsibility of recruitment to the registry rests with the Monash University ANZTCR Coordination centre. Patients will be recruited utilising an opt-out process. An opt-out approach was selected as the most appropriate due to the high volume of procedures and the generally non-chronic nature of disease resulting in low attendance for medical follow up.

The opt-out process has been used successfully in over 75% of clinical quality registries in Australia (20). The rationale for this approach is based on minimising selection bias by achieving near 100% coverage of a population. By limiting the possibility of 'cherry picking' participants or omitting specific groups of patients otherwise not able to be captured by standard consenting processes, clinical validity increases, enabling meaningful analysis and comparison of variation in health outcomes across sites and other geographical spaces. The opt-out process enables the full spectrum of public health information to be reported and analysed, increasing capacity to influence and inform clinical guidelines, policy development and funding decisions (21-23). The ANZTCR opt-out process is represented diagrammatically in Figure 2.

The participation status of patients will be stored in the database to assist in invitation oversight, auditing and case ascertainment purposes. This will include patients that have opted-out of the registry. For patients that have opted-out, date of procedure and reason for opting-out, if provided, will be stored.

Registry Opt-out Approach

Patients will be introduced to the registry via a mail-out by the coordinating centre following receipt of diagnosis from endocrine surgeon at their post-surgery follow-up appointment (approximately 1-2 weeks following surgery). The endocrine surgeon or staff member at the endocrine surgical unit will enter minimal patient details into the registry, in addition to confirming thyroid cancer diagnosis and patient disclosure at sites where a waiver of consent has been approved for surgeon direct entry into the registry database. Monash University ANZTCR Coordinating Centre will identify potential participants in the registry and post them an explanatory statement that highlights the voluntary nature of the registry and requirements of participation including how to opt-out of the registry via a free call number to the Monash University ANZTCR coordinating centre.

Patients will initially be registered for recruitment on the REDCap database however only minimal data will be entered into the registry at sites where a waiver of consent has been approved, sufficient to commence the recruitment process. Minimal data, related to date of procedure, demographics, histological diagnosis and patient disclosure of diagnosis, is required to be entered at the time of registration by the surgeon. This will provide Monash University with sufficient information to send the letter and explanatory statement to patients. Following the mail-out of the introductory letter

and explanatory statement, a two week opt-out window is provided, prior to the majority of the data being collected. Following two weeks, participation will be assumed if no contact is made by the participant to the Monash University ANZTCR coordinating centre.

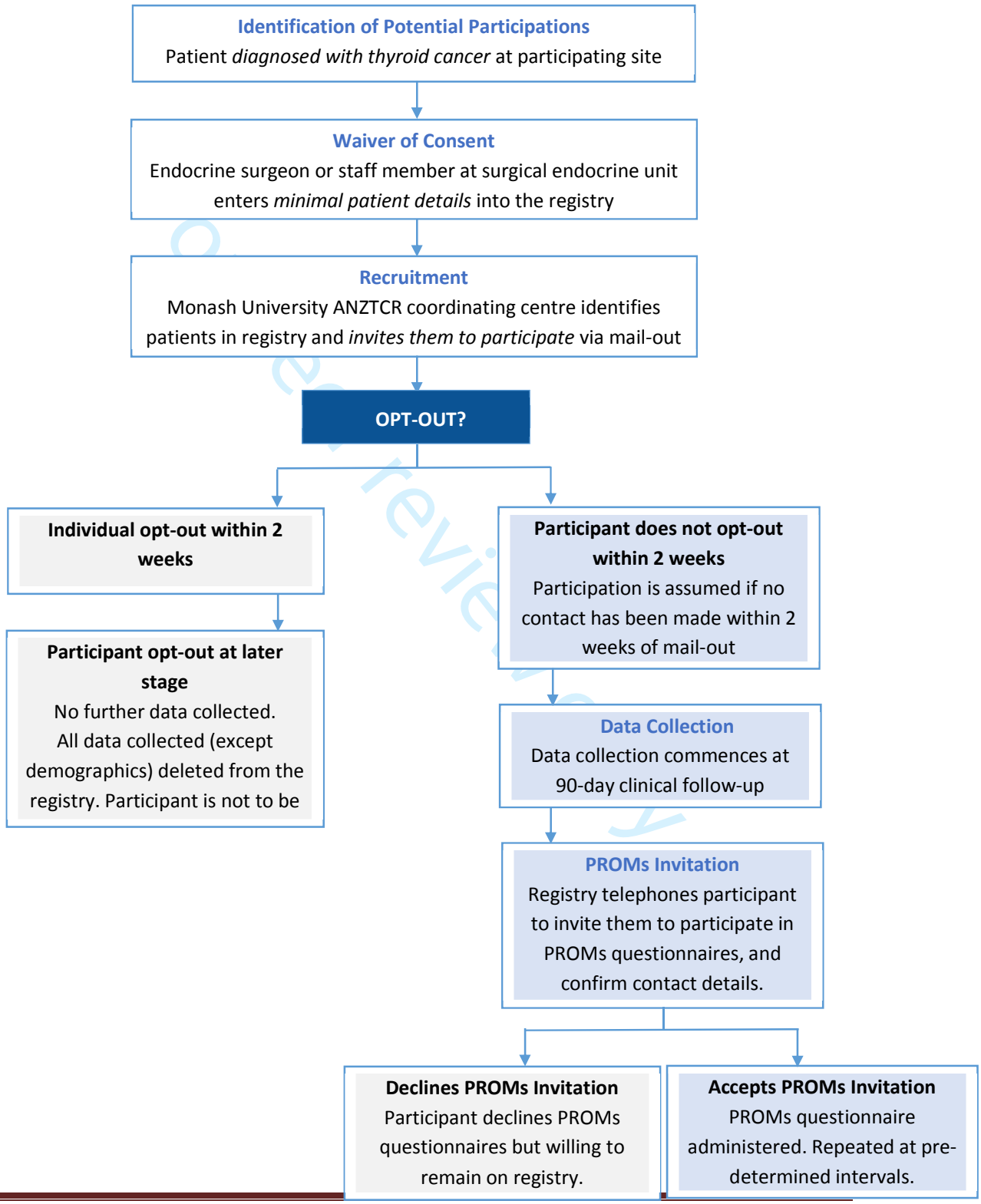

Figure 2: Registry recruitment and data collection schema

The date of the mail-out to the potential participant will be documented in the REDCap database.

Opt-out of the registry

Patients can opt-out of the registry at any time by calling a Monash University free call number.

The reason for opting-out from the registry will be noted if they are happy to share this information. All data will be removed from the database except for essential data items that will allow for case ascertainment audits. This will include: name of hospital/site, name of surgeon, date of diagnosis and date of surgery.

9. DATA

9.1 DATA COLLECTION

Clinicians will be responsible for entering their own data directly into the database portal (website), this will be the primary method of data collection, via a REDCap database. It is expected that all participating sites will use the REDCap database and portal to collect the registry data. Only prospective patient data is to be entered into the REDCap database. Data to be collected includes demographic and clinical data up to 90 day follow-up. Monash University will check case ascertainment through site's Health Information Services unit.

The data items collected from the patient's medical record are based on the standard care provided. The use of standardized definitions of data elements ensures data is consistent and uniform providing reliable and comparable data for analysis. A modified-Delphi approach will be used to develop a set of thyroid cancer clinical indicators which will provide a multidimensional report on quality. General data items required at particular time frames are listed in Table 3.

Patient-reported outcomes that measure quality of life and whether care is being well coordinated may be collected by administering questionnaires to participants who agree to this part of the registry. A questionnaire will be administered as close as practicable to the time of recruitment to the registry, and at pre-determined intervals thereafter, until the participant is in remission, opts-out or passes away.

Method of data collection

Data is submitted by sites via direct data entry using a web based interface, REDCap, which provides a secure online connection to the registry database.

The selection of data fields and their definitions will be derived from national data specifications such as Metadata Online Registry (METeOR) where they exist and from international thyroid cancer registry data dictionaries where terms are not defined within the Australian context. Site staff are trained to use the database and are provided with a data entry manual to assist with good quality data collection.

A detailed data dictionary containing the data elements, formats, ranges and validation rules and definitions will be maintained under document management with version control.

Table 3. Data Elements Collected

Data items collected	1-2 Weeks Post-Surgery (Recruitment)	3-Months Post-Surgery (90 days)
Demographics: Name, DOB, sex, address, date of diagnosis	X	
Eligibility confirmation and Participation	X	
Diagnosis Diagnostic test results, staging, method of diagnosis	X	
Treatment Surgery, procedure, treatment date and details.		X

9.2 DATA QUALITY

Data completeness and accuracy is optimized through in-built validation and completion checks in the registry database to minimize data entry error. These include:

- Data entry controlled by form logic and limited to feasible data
- The use of built in edit checks to ensure data meets required formats and ranges.
- Accuracy enhanced by the use of exhaustive drop down lists providing all possible answers to minimize free text entry where applicable.
- The use of hide and show mechanisms to guide data entry to required fields
- Use of explanatory texts to assist data entry
- Validation rules applied at the time of submission with alerts to assist with errors and missing data.
- The use of a participant management system to identify incomplete data and other actions required.

Additional quality checks post data entry includes checks for:

- duplicate data
- cross checking data obtained from multiple sources – medical notes vs self-report
- missing data

- data consistency

Quality checks will be undertaken by Monash University registry staff for case ascertainment and data accuracy and completion. An authorized registry staff member will liaise with a sample of sites to organise access to patient medical records.

Case ascertainment as well as both brief and comprehensive audit processes will be performed on site by Monash University registry staff. Completeness and accuracy of the eligible population captured by the registry will be assessed using hospital International Classification of Disease 10 (ICD-10) codes. Brief audits include the full review of key data fields associated with clinical quality indicators, against medical records. Other key fields will be selected based on results from data completeness and quality checks, discussion with relevant committees and stakeholders, and relevance to determining other important key registry outcomes. Comprehensive audit will include review of ALL data fields in a given calendar year from a specific, predetermined list of patient records.

It is only during times of audit and case ascertainment that registry staff will have access to patient medical records. Clinicians entering data are encouraged to conduct their own internal audits to ensure that all relevant cases are captured in the registry and for data completeness of existing records. Individual sites will receive the results of their audit.

Following audit and/or comprehensive review, an assessment of the data collection requirements in light of developed clinical indicators, annual and other reporting and research requirements will be undertaken to maximize the collection of near complete, high quality data.

9.3 DATA CONFIDENTIALITY

Data are collected by the registry in identifiable form.

All personnel at sites involved in treating patients and providing data to the registry will undertake training by Monash University to ensure that they understand their obligations in regard to data confidentiality and privacy relating to research activities. Each registry database user has their own username and password to access the database. Clinicians at recruiting centres only have access to their own patients at their site.

For the purpose of monitoring and/or audit to determine case ascertainment and level of accuracy and completion of the data, access to medical records will be in accordance with site requirements.

Monash University Registry staff are trained in confidentiality, privacy and good research practice through both the University's on-boarding program and through additional good research practice training.

Reporting for annual reports, benchmarking, other ad hoc reports and research will use aggregated data, ensuring patient confidentiality. Where an outlier occurs, patients may be identified for the purpose of investigation following steering committee approval. For benchmarking purposes, reporting of comparative data will be de-identified so that sites will only be aware of their own identity in any communal graphical or other display of information.

9.4 DATA SECURITY

All registry data are kept electronically. The database is physically hosted by Monash University in a secure environment. Monash Registry database security is maintained using encryption of data, a managed and audited protocol for access, training and accreditation of personnel, role-based access and authentication of data. Monash registry databases are housed and managed in an ISO 27001 certified environment. The ISO 27001 certification incorporates the Privacy Act 1988 (Cth) and Health Records Act 2001 (Vic) within its Applicability Statement. All communication between client (user's browser) and server (registry system) occurs on secure channel, commonly referred to as Secure Sockets Layer (SSL). SSL ensures that all data is encrypted by a private key on the server before it is sent on a wire to the client where it is decrypted by a public key. This ensures the data are not compromised in transit.

All users of the registry need to login to the system through a login screen with a pre-configured username and password controlled by administrators of the system.

10. PATIENT RISK MANAGEMENT & SAFETY

Participation in the registry involves the collection of pre-exiting data from medical records and is unlikely to result in any harm to patients. The collection of data to inform the registry's clinical quality indicators does not alter routine management of patients enrolled into the registry, nor does it alter the nature of the medical data documented. Inadvertent disclosure of information will be avoided by storing and handling data in line with applicable Privacy Principles and Good Research Practice. The privacy of individuals is of utmost importance to researchers in this project. Results will only be analysed in an aggregated form. Individuals will not be able to be identified in research presentations or reports.

11. INFORMATION OUTPUT

11.1 REPORTING

As per the 2008 ACSQHC Operating Principles, the ANZTCR will undergo a period of establishment. At the conclusion of 2 years an evaluation report will be developed. This report will be provided to the ANZTCR Steering Committee, funder and the Ethics Committee. Beyond 2 years and when sufficiently mature data is available, the ANZTCR will produce a range of regular reports including:

Annual Reports

Annual reports will be made available to the Registry Steering Committee and funder at the conclusion of each year.

Benchmarking reports

Benchmarked reports of clinical quality indicators will be available for participating sites.

Data Access for Research and Non-research purposes

Clinicians can access their own data through the registry database. Ad-hoc reports may be prepared following data requests approved in accordance with the ANZTCR Data Access Policy. This may include access for non-research use such as pharmaceutical company access to data for regulatory

or other activities. Researchers may access registry data for the purposes of undertaking their own external analysis following approval by the ANZTCR Steering Committee and Ethics Committee as per the ANZTCR Data Access Policy. Where a request for data for research purposes utilizes only de-identified existing registry data, ethics approval for the project may be sought from relevant ethics committee. Monash's ANZTCR Coordinating Centre is the point of contact for matters relating to access to registry data (see section 7 for contact details).

12. STATISTICAL METHODS

Statistical methods to be undertaken

Data quality and completeness is checked at a number of stages of the data management process and will only be included in analysis when strictly working within the agreed definition. Errors in data quality, when identified, may be referred back to contributing sites for review. All analyses on the ANZTCR will be undertaken with the support of the Biostatistics unit at Monash University. Specific analysis techniques will depend on the clinical indicators developed.

All eligible, participating patients in the registry will be included in analyses where appropriate to measure clinical quality indicators and outcomes. Samples size will be determined prior to analysis for specific research questions.

Descriptive statistics (e.g. mean, median, interquartile range and standard deviation) will be calculated for the variables in the dataset. Funnel plots will be used to compare key quality indicators across hospitals. The plots will be stratified by age-group, stage and histopathology.

The Cox regression model will be used to estimate hazard ratios. Both univariate and multivariate analysis will be undertaken. Data will be analysed in Stata V13.0 (Stata Corp, College Station, Tx, USA) and level of significance set at 5%.

Academic publications, in the short term, are expected to include a methods paper and interesting trends in processes of care.

13. ORGANISATION & GOVERNENCE

13.1 ANZTCR COORDINATION CENTRE

The ANZTCR Coordinating Centre is Monash University. Monash University Registry Staff working out of the DEPM will project manage the registry's core activities under direction of the ANZTCR Steering Committee. Registry activities include:

- Overall management of the registry
- Management of registry budget
- Ethical oversight and management on behalf of participating sites,
- Monitoring/audit visits to participating sites
- Training of participating sites/or in-house data collectors
- Data management and data querying
- Maintaining collected in a secure environment
- Data analysis

- Reporting
- Data access request management

13.2 REGISTRY RESPONSIBILITIES & GOVERNANCE

The ANZTCR registry is a multi-centred, investigator driven endeavour. The PI at each site will be responsible for ensuring that research activities undertaken at their site are conducted in accordance with the research protocol, site registry agreements and related policy documentation. Site research activities include identification of patients for recruitment, data collection and submission and will be conducted at participating hospitals by site staff, overseen by the PI at each site.

Day to day project management will be undertaken by DEPM, Monash University. While Monash registry staff will oversee all project related activities, participating hospitals will ultimately be responsible for ensuring timely and accurate data collection. This will be supervised by the Registry Coordinator who will report and provide feedback on data completion and quality to sites and the ANZTCR Steering Committee.

The ANZTCR Steering Committee will meet quarterly and have a significant role in guiding registry strategy and policy, ensuring deliverables are met, identify issues and review data requests, reports and publications.

A Management Committee will be established to oversee the day to day running of the registry that will involve Monash University Registry Staff, the registry coordinator and the clinical lead. Further subcommittees may be established as required.

Monash University has custodianship of the data. Custodianship responsibilities of Monash University entails accountability for the information held within the registry.

13.3 FUNDING

The ANZTCR will receive ongoing funding from the ANZES. The funding will be sufficient to maintain the registry for the next 2 years. Further funding will be required when the registry is rolled out to additional sites in Australia and New Zealand.

14. SIGNIFICANCE

We believe that the ANZTCR, under the custodianship of Monash University, will identify best practice which will result in change in treatment protocols and benefit patient outcomes. Specifically, the ANZTCR will monitor diagnosis, treatment and outcomes; assess patterns of care, and identify practices associated with better outcomes; reduce variation in diagnosis, treatment and outcome and hence improve quality-of-care; improve compliance with best practice-based guidelines for treatment of thyroid cancer; identify risk factors that predict favourable and unfavourable treatment outcomes, postoperative complications, and prognosis; and hence stratify treatments and follow up. The ANZTCR will highlight risks and benefits of specific approaches to thyroid cancer; establish a benchmark of survival, free of complications with minimal change in

quality of life; and evaluate relationships between outcome, case load and multidisciplinary management.

15. REFERENCES

1. Australian Government. Cancer in Australia: an overview, 2012. In: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries, editors. Canberra: AIHW; 2012.
2. Australian Government. Australian Cancer Database (ACD). In: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries, editors. Canberra: AIHW; 2011.
3. Australian Government. National Mortality Database (NMD). In: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries, editors. Canberra: AIHW; 2011.
4. Cameron PA, Gabbe BJ, McNeil JJ, Finch CF, Smith KL, Cooper DJ, et al. The trauma registry as a statewide quality improvement tool. Journal of Trauma and Acute Care Surgery. 2005;59(6):1469-76.
5. Australasian Society of Cardiac and Thoracic Surgeons Database Project Steering Committee. Victorian Cardiac Surgery Database Project.
6. Australia and New Zealand Dialysis and Transplant Association (ANZDATA). Australia and New Zealand Dialysis and Transplant Registry [Web Page] [Available from: http://www.anzdata.org.au/.
7. Malycha P, Tyson S. National breast surgery audit. Australian and New Zealand Journal of Surgery. 2000;70(12):834-6.
8. Asplund K, Hulter Åsberg K, Norrving B, Stegmayr B, Terént A. Riks-stroke–a Swedish national quality register for stroke care. Cerebrovascular diseases. 2003;15(Suppl. 1):5-7.
9. Eagle KA, Goodman SG, Avezum Á, Budaj A, Sullivan CM, López-Sendón J, et al. Practice variation and missed opportunities for reperfusion in ST-segment-elevation myocardial infarction: findings from the Global Registry of Acute Coronary Events (GRACE). The Lancet. 2002;359(9304):373-7.
10. Cancer Institute NSW. NSW Clinical Cancer Registry [Web Page] [Available from: http://www.cancerinstitute.org.au/cancer_inst/programs/registryccr.html.
11. Sweden E. Handbook for Establishing Quality Registries. Karlskrona: Eyenet Sweden. 2005.
12. Australian Commission on Safety and Quality in Health Care. Information Strategy. Sydney: ACSQHC; 2007.
13. Lee WR, Sharkey J, Cowan JE, DuChane J, Carroll PR, CaPSURE Investigators. Prostate brachytherapy: a descriptive analysis from capsure. Brachytherapy. 2007;6(2):123-8.
14. Köbel M, Kalloger SE, Boyd N, McKinney S, Mehl E, Palmer C, et al. Ovarian carcinoma subtypes are different diseases: implications for biomarker studies. PLoS Med. 2008;5(12):e232.
15. Monash University. Registry Science Handbook: Creating Knowledge for Improved Health. wwwmedmonashedu.
16. Cameron P, Gabbe B, Cooper D, Walker T, Judson R, McNeil J. A statewide system of trauma care in Victoria: effects on patient survival. Med J Aust. 2008;189(10):546-50.
17. Monash University. Monash Clinical Registries Portfolio. 2016.

18. Australian Commission on Safety and Quality in Health Care. Operating Principles and Technical Standards for Australian Clinical Quality Registries [Web Page] [Available from: http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/EA520128CB313DE9CA2573AF007BC590/$File/OP_TS-Nov2008.pdf.
19. Olver IA, Haines IA. What changes are needed to the current direction and interpretation of clinical cancer research to meet the needs of the 21st century? . Medical Journal of Austalia 2009;190(2):74-7.
20. Tu JV, Willison DJ, Silver FL, Fang J, Richards JA, Laupacis A, et al. Impracticability of informed consent in the Registry of the Canadian Stroke Network. New England Journal of Medicine. 2004;350(14):1414-21.
21. Cancer Council of Victoria. Cancer Council of Victoria Registry & Statistics 2013 [Available from: http://www.cancervic.org.au/research/registry-statistics.
22. Junghans C, Jones M. Consent bias in research: how to avoid it. Heart. 2007;93(9):1024-5.
23. Buckley B, Murphy AW, Byrne M, Glynn L. Selection bias resulting from the requirement for prior consent in observational research: a community cohort of people with ischaemic heart disease. Heart. 2007;93(9):1116-20.

16. SUPPORTING DOCUMENTS

List of supporting documents:

No.	Document Name
1	Master Participant Explanatory Statement
2	Master Participant Introductory Letter
3	Master Clinician Participation Form
4	Data Set
5	Data Access Policy

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN AND NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS POLICY

Version: 1
Date: 21 August 2017

Confidential

ANZTCR COORDINATING CENTRE CONTACT DETAILS

Address: Australian & New Zealand Thyroid Cancer Registry
Registry Sciences Unit
Monash University, Alfred Hospital Campus
533 St Kilda Road
Melbourne, Vic, 3004

Email: SPHPM.ATCRP@monash.edu

Monash University Registry Coordinator
Dr Liane Ioannou
Phone: (03) 9903 0046
Email: liane.ioannou@monash.edu

Clinical Lead
Professor Jonathan Serpell
Phone: (03) 9076 3290
Email: jonathan.serpell@alfred.org.au

Registry Custodian
Dr Susannah Ahern
Phone: (03) 9903 0139
Email: susannah.ahern@monash.edu

DOCUMENT VERSION CONTROL

Version	Date	Reason/Comments/Approvals
1.0	21.08.2017	Initial Version Release. Proposed to ANZTCR SC on 25.07.17

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

CONTENTS

This document describes the Australian & New Zealand Thyroid Cancer Registry (ANZTCR) guidelines and policies for governing the release of information for research purposes.

1. PREFACE

The Australian & New Zealand Thyroid Cancer Registry (ANZTCR) encourages the use of its data for a variety of purposes such as quality improvement, research, clinical planning and other activities that may lead to an improvement in care to patients with thyroid cancer. The ANZTCR will only facilitate access to its data for projects that meet appropriate standards of scientific merit and public health importance as determined by the Management Committee. This data access policy defines how data from the ANZTCR may be accessed. The policy includes the criteria and conditions for provision of de-identified individual level data, aggregate data, reports or analyses; and procedures for data request applications. It also outlines the cases in which fees for such access might be applicable, and any associated acknowledgement and publishing responsibilities.

Data collected and collated by ANZTCR is guided by strict protocols and procedures to ensure the security, privacy and confidentiality of all information collected and stored in the registry. All patient and stakeholder information will be handled in accordance with the Commonwealth Privacy Act (1988), the Privacy and Data Protection Act 2014 (Vic) and the Health Records Act 2001 (Vic), similar relevant interstate legislation, and any code of practice or guidelines made under these Acts.

All registry activities have been approved by a National Health Medical Research Council (NHMRC) approved Human Research Ethics Committee (HREC) and other participating site and Monash University Human Research Ethics Committees.

The University Privacy Compliance Framework is available at www.privacy.monash.edu.au.

2. PROJECT INFORMATION

2.1 PURPOSE OF ANZTCR

The Australian & New Zealand Thyroid Cancer Registry (ANZTCR) was developed by the Monash University Breast Endocrine Surgery (BES) Unit in collaboration with the Registry Sciences Unit (RSU). The ANZTCR is a clinical quality registry collecting data on patients diagnosed with thyroid cancer at participating health service sites in Australia to inform best-practice guidelines as well as benchmark performance in Australia with data from comparable international registries.

2.2 PROJECT OVERVIEW

The registry collects data relating to the patient's first presentation, preoperative investigations, cancer diagnosis and surgery, as well as adjuvant treatment and follow-up care up to 90 days post-surgery. Data is collected from patient medical records at diagnosis (1-2 weeks post-surgery) and 90 days post-surgery (follow-up data).

The registry allows comparison of high quality information, which can be used to develop criteria and procedures to evaluate and improve patient quality of care. Data is analysed to identify which

treatments are more successful than others and compare thyroid cancer services across Australia. This will lead to improvement in patient quality of care and thyroid cancer services in the future.

Information held by the registry is used by the ANZTCR Management Committee in two different ways. The data will be used to monitor:

- Performance of quality of thyroid cancer patient care in Australia;
- Performance of the Australian & New Zealand Thyroid Cancer Registry in collecting data about quality of thyroid cancer outcomes.

3. DEFINITIONS

Management Committee - The ANZTCR Management Committee is responsible for overseeing the daily operations of the registry. The Committee ensures data collection and data quality processes function effectively and complies with ethics committee regulations, legislation and registry policies.

Steering Committee - The ANZTCR Steering Committee is an independent entity which maintains governance and overall management of the ANZTCR. The Steering Committee develops and reviews policies and publications arising from the registry data.

Human Research Ethics Committee (HREC) - HRECs protect the welfare and rights of participants involved in research and they review proposals for research that involves humans. They monitor the conduct of research and deal with complaints that arise from research. Research projects requesting identifiable data and/or intending to contact patients must obtain approval from a National Health and Research Council (NHMRC) registered HREC.

Confidential Data - ANZTCR is responsible for protecting the data from unauthorised access and release by maintaining strict standards of confidentiality. Data that identifies or potentially identifies an individual patient, health care provider, institution or a caseload of a provider or reporting institution is considered propriety and confidential.

Identifiable Data – Data that contains individual identifiers making it possible to identify a specific individual.

Non-identifiable Data - Data that has never been labeled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data may be linked with other data so it can be known they are about the same data subject, although the individual's identity remains unknown.

Re-identifiable Data - Data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.

Disclose or Disclosure - The communication of any ANZTCR information to any individual or organisation other than to the researcher or the ANZTCR.

Research Project - A scientific investigation that has been reviewed by ANZTCR Management Committee.

Researcher - The principal investigator of a research project (as defined above) or the individual requesting data from the ANZTCR.

4. ACCESS TO DATA HELD BY ANZTCR

ANZTCR data is hosted on a REDCap server that is managed by Monash University. Access to data is subject to applicable privacy laws and principles, and ethics approvals. Specific measures have been put in place to maintain the confidentiality of personal identifying information at the patient and hospital level.

Data access is generally subject to the approval of the ANZTCR Steering Committee. When considering the approval of access to ANZTCR data, the ANZTCR Steering Committee will consider whether the project satisfies the principles of research merit and integrity.

Access to the data is subject to the Data Access Request Process outlined in section 5.

4.1 ELIGIBLE APPLICANTS

Researchers, medical professionals and pharmaceutical professionals working at research institutions, hospitals, private entities, government or other health services within Australia and industry are eligible to request access to data held within the registry. All requests for data are noted in the ANZTCR Steering Committee minutes and logged.

4.2 ACCESS TO ANZTCR DATA

1. Staff who report directly to the ANZTCR Data Custodian will have direct access to the database and for operational purposes Monash University IT staff, directly involved in supporting registry systems have access for upgrades and break fixes, and are bound by Monash University confidentiality agreements.

2. All uses of ANZTCR data, in whatever context, must receive prior approval from the ANZTCR Steering Committee unless a pre-existing funding agreement is in place and has been previously approved by the ANZTCR Steering Committee. Research related requests may require specific ethics committee approval. Use of data for any other purpose will require an additional request.

3. Data access may be subject to conditions in agreements and/or research ethics approvals.

4. Under no circumstances will individually identifiable data in respect to patients, contributing clinicians, or hospitals be made available to parties other than the ANZTCR Steering Committee, authorised ANZTCR personnel, and members of any working group directed by and reporting to the Steering Committee during the course of incident, complaint or outlier management. Requests for ANZTCR data which may potentially identify a cancer patient, their physicians, or institutions involved in the patient's diagnosis and/or treatment, and all research projects which require contact with cancer patients require ethics approval and full review from ANZTCR Management Committee.

5. The ANZTCR Management Committee will not release participant contact details or identifiable data that can be linked with other data. All contact with registered patients must be conducted by the ANZTCR office through the Management Committee. The cost of making such contact is to be borne by the researcher/s requesting the contact.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

6. If a third party research or student project requires individually identifiable data for linkage or further research, this cannot be provided by ANZTCR directly. Following ethics approval, sign off by involved Centre Directors or site Principal Investigators and ANZTCR steering committee approval, ANZTCR will provide the required data to the site/s involved to forward the data and patient identifying keys to the third party or student.

7. The ANZTCR Management Committee will only release data of a sufficiently high level of quality and will release the least sensitive level of data that is practicable in order to fulfil the uses identified in the research proposal submitted with the data request. Tabulated aggregate data with a cell count less than 5 will be suppressed to prevent re-identification of an individual patient, physician or organisation.

8. Where only basic summary data available through public reports is requested, this can be provided by ANZTCR staff without steering committee approval.

9. ANZTCR encourages the independent access of clinician data available through the ANZTCR web interface however, should a contributing clinician request access to their own patient data ANZTCR will provide this. All requests for this category of data should be made in writing to the ANZTCR Management Committee (**Appendix B**).

10. If a hospital executive makes a specific request for its own performance data, ANZTCR will provide this information. Identification of a clinician will not be provided without the written permission of the Centre Director/Principal Investigator. All requests for this category of data should be made in writing to the ANZTCR Director (**Appendix B**). Such data requests will require Steering Committee approval.

11. For requests from industry, comparative information i.e. market share will not be provided.

12. All requests for access to the ANZTCR data are undertaken in addition to routine ANZTCR workload. As a general rule, following submission of the request form, review by the ANZTCR steering committee will occur within 4 weeks. Requests involving reports or analysis will be provided with a quote and expected time frame for completion. Most data access requests will generally be provided within 2-6 weeks following Steering Committee approval.

13. Requests must be first made to the ANZTCR Management Committee at Monash University who will either table the request at the next ANZTCR Steering Committee meeting or, in some circumstances where the data is required earlier the ANZTCR Management Committee, may circulate the request for out of session approval. Data cannot be extracted until approval is given and relevant ethics approval from participating institutions are in place.

14. All data must only be used for the purposes outlined in the written request, and approved by the Steering Committee. The researcher may only use registry information for the specified research project. If the researcher wants to use registry information for another research project, he/she must first obtain the appropriate approval for the research project. The researcher, and any individual working on the research project, may not disclose registry information to others without the prior written consent of ANZTCR. Moreover, the cancer case information may not be reproduced in any form except for internal use or with prior written consent from the ANZTCR.

15. No data may be passed onto other researchers, clinicians or any other person/entity not explicitly mentioned in the written data request.

16. ANZTCR staff will perform record-linking tasks at the ANZTCR whenever feasibly possible. Researchers may provide identified data to the registry, and the ANZTCR will return medical information on records that were found to link. If the research project has the patient's informed consent, then linkage projects will be reviewed by the Management Committee.

17. Requests for access to data must comply with the National Statement on Ethical Conduct in Human Research (2007). Following ethics approval and data access sign off by the ANZTCR Steering Committee, de-identified data will be provided by secure file transfer. Following transfer, security and storage of the data provided will be the responsibility of the requester in accordance with good research practice guidelines.

18. Requests must be made in accordance with the data access policy and provide full disclosure in the request form for proposed access and usage of the data. Data access and usage must comply with all conditions in the approval given for data access.

19. Patient requests for data access to their information will be managed by the registry co-ordinator. Patients will need to provide identifying information prior to data release. (**Appendix C**)

20. If a research project continues beyond the original termination date stated in the proposal, the researcher must notify the ANZTCR in writing of the new termination date, submit corresponding approvals from an ethics committee, and obtain approval in accordance with Section 4.2 (Request for Patient Identifiable Data).

5. REQUESTING DATA

5.1 DATA ACCESS REQUEST PROCESS

1. All data requests must be formally lodged using the relevant Data Request Application Form (**Appendix A** or **Appendix B**) via email, post or fax to:

Email: SPHPM.ATRCP@monash.edu

Post: Dr Liane Ioannou
Australian & New Zealand Thyroid Cancer Registry
553 St Kilda Road
Melbourne, 3004

Upon receipt of the completed and signed form, the ANZTCR Management Committee will present the data request to the Steering Committee at the next scheduled meeting if required under Section 3.2. Meetings are held four times per year.

2. There are three possible outcomes of the data access request. The data access request may be approved; approved subject to amendment; or declined. If the application is declined, a major revision and subsequent resubmission will be required. Approval subject to minor revision will not require a full resubmission. An out of session review of the changes will be organised.

3. Upon approval, the ANZTCR Management Committee will provide a statement of the conditions of its use with a cost estimate if applicable.

    a. The researcher signs the Research Agreement (**Appendix D**).

    b. All project personnel who have access to the confidential data sign the Confidentiality Agreement (**Appendix E**).

    c. The Data Custodian releases the data to the researcher.

5.2 REQUEST FOR NON-IDENTIFIABLE DATA

Aggregate data such as incidence, mortality rates and frequencies may be released provided that such disclosure does not include sufficient information that would allow the researcher to identify an individual or organisation. This may include masking cell sizes less than 5 for tabulated data.

The ANZTCR may release non-identifiable tumour-level data, which can include details about the tumour and treatment information. Patient demographic information will not be released and the tumour data will not be identifiable.

The ANZTCR will not release patient contact details.

The researcher must indicate their request for *Non-Identifiable Data* on the Data Request Application Form (**Appendix A**) and submit the application to the ANZTCR Management Committee.

5.3 REQUEST FOR PATIENT RE-IDENTIFIABLE OR DE-IDENTIFIABLE DATA

The ANZTCR will generally not release patient identifiable data.

Hospitals and clinicians may request re-identifiable data for cases reported by their own institution or practice. All patient identifiers are removed and replaced with a code.

The researcher must discuss the approval process with a representative from the Management Committee, including the terms and conditions of the Research Agreement (**Appendix D**) to be signed by the researcher, provisions regarding maintenance of confidentiality, patient contact, and sanctions for violating these provisions.

The researcher must indicate their request for *Re-Identifiable or De-Identified Data* on the Data Request Application Form (**Appendix A**) and submit the application, in addition to their ethics application and letter of ethics approval, to the ANZTCR Management Committee.

It is a requirement of the ANZTCR Management Committee that applications for the release of data for research purposes are submitted and reviewed by a HREC. Section 95A of the Privacy Act 1988 allows the Management Committee to request researchers to submit a proposal to a HREC even if it has received written notification of ethics committee approval from the investigator's institution.

5.4 PATIENT REQUEST FOR DATA ACCESS

Patient requesting access to their data held on the ANZTCR will be required to complete a Data Request Application Form (**Appendix C**) which will be available from the ANZTCR Management Committee. Upon receipt of the completed form the, the ANZTCR coordinator will:

1. Telephone the patient to confirm that they have requested their details
2. Advise the patient that their information will be sent by registered post to the address recorded on their proof of identify documents.

6. DATA SECURITY FOR PATIENT IDENTIFIABLE INFORMATION

The following restrictions apply to the use of confidential information:

Maintenance and Storage of Data by Researcher - Patient identifiable data must be encrypted or kept separate from medical data stored by the researcher. This separation applies for data kept in paper format or on a computer. The medical data will not be identified except by an identifying number with no meaning in any data set other than the researcher's or ANZTCR. The patient identifiable cancer case information will not be attributed to a source that identifies the nature of the records. Identifiable data stored on a computer network must be secured from unauthorised network access by the most effective means that are technically available. If confidential information is lost, it will be reported to the ANZTCR Office and the approving Human Research Ethics Committee.

Penalties for Violations - In addition to terminating the agreement for a violation of this policy, the ANZTCR may impose sanctions on the researcher. Individuals who have witnessed inappropriate use of ANZTCR data or a breach in confidentiality may report violations to the ANZTCR. The ANZTCR recognises that violations may occur to various degrees, however, in all cases the Management Committee will be notified immediately and the research project will be suspended for a minimum of 30 days. During that time, the Management Committee will meet to discuss the magnitude of the violation and the steps needed to rectify the infraction(s). The Management Committee will also determine if the violation(s) should be reported to the proper authorities, including the HREC.

This document should be read in conjunction with the ANZTCR Data Security Policy which provides further information on this topic.

7. PUBLICATION

Any material or manuscript to be published using ANZTCR data must be submitted for review by the ANZTCR Steering Committee prior to release for publication. ANZTCR will have thirty (30) days after receipt of the draft publication to request in writing the removal of any portions of the publication deemed by ANZTCR to inappropriately disclose patient identifiable cancer case information. Upon receipt of such request from ANZTCR, the researcher and ANZTCR will attempt, in good faith, to agree upon the modifications or revisions to the draft publication, which are reasonably necessary to protect the privacy of the subjects of the cancer case information. In no event, however, will the researcher publish identifiable cancer case information.

It must contain appropriate acknowledgement of ANZTCR. Preferred wording for the acknowledgement will be provided with the data. If the data is the primary source for a report or publication, the source of the data must be acknowledged, along with a statement that the analysis and interpretation are those of the author, not the registry. Where a research collaborator has analysed data, ANZTCR, Monash

University should be acknowledged as a secondary institution. Where the author is a registry staff member, then the primary attribution should be ANZTCR, Monash University. ANZTCR reserves the right to dissociate itself from conclusions drawn if it deems necessary.

Authorship may be required when ANZTCR makes substantial contribution to the data.

Copies of all published abstracts, presentations, and papers that result from the study should be sent to the ANZTCR Management Committee.

8. DATA ITEMS

The ANZTCR Management Committee will provide a list of available data items upon request. It is the policy of ANZTCR that certain data elements are not released under any circumstances.

9. FORMS

The form(s) that must be completed for each data request will vary depending on whether the applicant is a researcher, non-researcher or patient. The forms may be obtained from the ANZTCR Management Committee.

The forms are as follows:

9.1 DATA REQUEST FORMS

1. Request Access to Data - Researcher Form (**Appendix A**). This form should be used for all research-related requests.

2. Request Access to Data – Non-Researcher Form (**Appendix B**). This form should be used for non-research purposes.

4. Request Access to Data – Patient Form (**Appendix C**). This form should be used for patients who would like access to information.

3. Research Agreement (**Appendix D**). This agreement must be signed by the researcher who has been approved to have identifiable information.

4. Confidentiality Agreement (**Appendix E**). Although the Principle Investigator is responsible for assuring that the data are kept confidential, all study staff with access to identifiable ANZTCR data are required to sign a confidentiality agreement. These signed agreements will be kept on file at the ANZTCR.

10. FEES

The ANZTCR does not receive any funding to perform non-routine adhoc data analysis. Therefore, provision of data may be subject to a fee-for-service on a cost recovery basis unless in line with existing funding agreements or MOUs between registry funders/supporters. Fees will be at the discretion of the

ANZTCR Steering Committee in consultation with the ANZTCR Management Committee and will be based on the complexity and estimated time taken to complete the request as well as current ANZTCR routine workload. Please see the Data Access Fee Schedule for an explanation of these.

APPENDIX A:
DATA ACCESS REQUEST – RESEARCHER FORM

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST - RESEARCHER

Please return your application via email or post using the details below:

Australian & New Zealand Thyroid Cancer Registry
533 St Kilda Rd
Melbourne, VIC 3004
Email: SPHPM.ANZTCR@monash.edu
Phone: (03) 9903 0046

PART A: RESEARCHER'S DETAILS

Date of Request: _____

Date required by: _____

Organisation	☐ Research/Academic Institution ☐ Government Department or Agency ☐ Hospital Industry: ☐ Pharmaceutical ☐ Private Health Insurance ☐ Device ☐ Other, *specify* …… ☐ Professional Medical Organisation ☐ Other *(please specify)*……		
Short title of data request:			
Principal Investigator :		**Title:**	
Position:			
Affiliation/Organisation:			
Address:			

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

Telephone:			
Email:			
Other Investigators: (add additional lines for each investigator)		**Title:**	
Are you a student?	☐ Yes ☐ No		
If YES, what degree are you working towards?			
Name and contact details of your supervisor			
Is this a funded research project?	☐ Yes ☐ No		
If YES, who has funded the project?			
Was the ANZTCR formally involved in the grant application?			
Does your project require Human Research Ethics committee (HREC) approval?	☐ Yes ☐ No	**If NO,** proceed to PART B	
If YES have you applied for HREC approval?	☐ Yes ☐ No		
If YES which organisation's HREC did you apply to?	_____		
Have you received HREC approval?	☐ Yes ☐ No	**If YES,** please attach a copy of your approval certificate/s, a full copy of your application and any other relevant documents	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART B: PROJECT DETAILS

Reason for data request. Please note that approval will only be given for the project described in this application. Use of data for any other purpose will require an **additional** request.

Type of data request	☐ De-identified patient level data ☐ Aggregated/summary data ☐ Report/Analysis ☐ Data linkage ☐ Other, specify ……..
Title of project	
Background and rationale for the project (500 word maximum plus key references)	
Hypothesis and specific research questions	
Possible outcomes and clinical significance of this research (250 word maximum)	
Methodology of project (500 word maximum)	
Inclusion and Exclusion criteria	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

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PART C: DATA FIELDS REQUIRED

An ANZTCR minimum dataset containing available data fields can be requested. ANZTCR is required to maintain patient privacy. No data will be released that could potentially identify patients, clinicians or hospitals.

Data item required	Justification

PART D: RESEARCHER'S SIGNATURE

I CERTIFY THAT I HAVE READ AND UNDERSTOOD THE ANZTCR DATA ACCESS POLICY. I AGREE TO COMPLY WITH THAT POLICY.
I AGREE TO UNDERTAKE ALL ACTIVITIES DESCRIBED IN THIS REQUEST IN ACCORDANCE WITH THE RESEARCH PROPOSAL, RESEARCH APPROVAL OF THE REVIEWING HUMAN RESEARCH ETHICS COMMITTEE (HREC) AND ALL RELEVANT STATE AND COMMONWEALTH PRIVACY LEGISLATION RELATING TO PATIENT INFORMATION AND HEALTH RECORDS.
I AGREE TO ADHERE TO ALL OF THE CONDITIONS PLACED ON USE AND STORAGE OF THE DATA AS OUTLINED IN ANY ANZTCR DATA ACCESS APPROVAL THAT WILL BE PROVIDED TO ME PRIOR TO COMMENCEMENT OF ANY RESEARCH ACTIVITY,DATA ANALYSIS OR REPORT.
I AGREE THAT THE INFORMATION PROVIDED BY ME TO ANZTCR IS TRUE, ACCURATE, COMPLETE AND WITHOUT MATERIAL OMISSION.
I AGREE THAT INFORMATON PROVIDED WILL NOT BE USED FOR ANY PURPOSE OTHER THAN DESCRIBED IN THE REQUEST FORM.
I AGREE THAT INFORMATION WILL NOT BE DISCLOSED TO ENTITIES OTHER THAT THOSE DESCRIBED IN THE REQUEST FORM.
I AGREE TO PROVIDE MONASH UNIVERSITY WITH A COPY OF ANY FINAL REPORT FOR REVIEW PRIOR TO PUBLISHING AND WILL ANZTCR AS THE DATA SOURCE AND WHERE APPLICABLE, MONASH UNIVERSTY AS HAVING UNDERGONE THE ANALYSIS OR COLLATED THE REPORT.
I ALSO AGREE THAT THE INFORMATION PROVIDED TO ME BY ANZTCR, WHETHER IN THE FORM OF DATA, REPORTS, MODELS, SAMPLES AND REGARDLESS OF HOW COMMUNICATED OR RECORDED, IS CONFIDENTIAL AND CONFIDENTIALITY OF ALL INFORMATION AND COMMUNICATIONS WILL BE MAINTAINED UNLESS OTHERWISE AGREED BY BOTH PARTIES.

Name: _____

Signature _____

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST - RESEARCHER

FOR OFFICE USE ONLY:

Short Title of Data Access Request: _____ _____	
ANZTCR Steering Committee decision (or delegate)	☐ Approved ☐ Approved – Subject to amendment ☐ Declined
If approved, subject to amendment, please list required changes	
Approved by ANZTCR Steering Committee Chairperson (or delegate): Signature: _____ Date of approval: _____	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

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APPENDIX B:
DATA ACCESS REQUEST – NON-RESEARCHER FORM

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST – NON-RESEARCHER

Please return your application via email or post using the details below:

Australian & New Zealand Thyroid Cancer Registry
533 St Kilda Rd
Melbourne, VIC 3004
Email: SPHPM.ANZTCR@monash.edu
Phone: (03) 9903 0046

PART A: APPLICANT'S DETAILS

Date of Request: _____

Date required by: _____

Organisation	☐ Research/Academic Institution ☐ Government Department or Agency ☐ Hospital Industry: ☐ Pharmaceutical ☐ Private Health Insurance ☐ Device ☐ Other, *specify* …… ☐ Professional Medical Organisation ☐ Other *(please specify)*……		
Authorised requester's name		**Title**	
Position			
Organisation:			
Address:			
Telephone:			
Email:			

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART B: PROJECT DETAILS

Please note that approval will only be given for the use described in this application. Use of data for any other purpose will require an **additional** request. This information will be reviewed by a committee and may incur a fee depending on the complexity of the request.

Request Title	
Type of data request	☐ Aggregated data/summary data ☐ Report/Analysis
Purpose of the request	
What question/s need to be answered by the information requested	
Description of the type of information required. (Please include the subpopulation, and cross tabulation of the variables of interest required)	
Reference period for the data of interest	
Possible outcomes and potential uses of this request	
Name all entities that the information requested will be disclosed to	☐ Internal use only ☐ Government department/agency, specify…… ☐ Other organisation, specify……
If this request is to be used to support an application for regulatory approval and are there potential implications for the registry? E.g. additional data items to be collected etc.	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART C: DATA FIELDS REQUIRED

An ANZTCR minimum dataset containing available data fields can be requested to ensure the information you require is utilised when requesting a summary report. ANZTCR is required to maintain patient privacy. No data will be released that could potentially identify patients, clinicians or hospitals.

Data item required	Justification

PART D: APPLICANT'S SIGNATURE

I CERTIFY THAT I HAVE READ AND UNDERSTOOD THE ANZTCR DATA ACCESS POLICY AND I AGREE TO COMPLY WITH THAT POLICY. I AGREE TO UNDERTAKE THE ACTIVITIES DESCRIBED IN THIS REQUEST IN ACCORDANCE WITH THE AGREED USE.
I AGREE THAT ANY INFORMATION PROVIDED WILL NOT BE USED FOR ANY PURPOSE OTHER THAN DESCRIBED IN THE REQUEST FORM
I AGREE THAT INFORMATION WILL NOT BE DISCLOSED TO ENTITIES OTHER THAT THOSE DESCRIBED IN THE REQUEST FORM.
I AGREE TO PROVIDE MONASH UNIVERSITY WITH A COPY OF ANY FINAL REPORT FOR REVIEW PRIOR TO PUBLISHING IF REQUESTED AND WILL ACKNOWLEDGE ANZTCR AS THE DATA SOURCE AND WHERE APPLICABLE, MONASH UNIVERSTY AS HAVING UNDERGONE THE ANALYSIS OR COLLATED THE REPORT.I AGREE THAT THE INFORMATION PROVIDED BY ME TO ANZTCR IS TRUE, ACCURATE, COMPLETE AND WITHOUT MATERIAL OMISSION.I ALSO AGREE THAT THE INFORMATION PROVIDED TO ME BY ANZTCR, REGARDLESS OF HOW COMMUNICATED OR RECORDED, IS CONFIDENTIAL AND CONFIDENTIALITY OF ALL INFORMATION AND COMMUNICATIONS WILL BE MAINTAINED UNLESS OTHERWISE AGREED BY BOTH PARTIES.

Name: _____

Signature _____

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST – NON-RESEARCHER

FOR OFFICE USE ONLY:

Short Title of Data Access Request: _____ _____	
ANZTCR Steering Committee (or delegate) decision	☐ Approved ☐ Approved – Subject to amendment ☐ Declined
If approved, subject to amendment, list required changes	
Approved by ANZTCR Steering Committee Chairperson (or delegate): Signature:_____ Date of approval: _____	

APPENDIX C:
DATA ACCESS REQUEST – PATIENT FORM

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST – PATIENT

Please return your application via email or post using the details below:

Australian & New Zealand Thyroid Cancer Registry
533 St Kilda Rd
Melbourne, VIC 3004
Email: SPHPM.ANZTCR@monash.edu
Phone: (03) 9903 0046

PART A: PATIENT DETAILS

Date of Request: _____

Date required by: _____

A certified copy of **proof of identity** is supplied as follows: (please tick x boxes) NEEDS TO DISPLAY NAME & ADDRESS AT TIME OF SURGERY	☐ Birth Certificate ☐ Passport ☐ Certificate of Australian Citizenship ☐ Medicare Card ☐ Drivers Licence ☐ Signed letter from General Practitioner verifying proof ☐ Other (utility bill, bank statement etc.)
First Name:	
Family Name :	
D.O.B:	
Address:	
Telephone:	
Email:	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART B: DETAILS REQUESTED

Data details that appear on the Data Capture Form (DCF) are shown in the table below. Please tick those you wish to access.

Surgeon Name	
Admission site	
Date of Surgery	
Right/Left /Bilateral	
Device Details	
Reason for Operation	

Operation Type	
Previous Radiotherapy	
Incision Site	
Intraoperative Technique	
Revision History	

I hereby apply for access to information relating to me held by the Australian Breast Device Registry.

Patient's signature: _____ Date: _____

Please send a copy of my information to above address: ☐

Please send a copy of my information to: _____

_____

PART C: THIRD PARTY RELEASE DETAILS

If your request relates to releasing this information to a third party/surgeon, please complete the following:

Name:	
Position:	
Address:	
Telephone Number:	

I hereby agree for information relating to me, held by the Australian Breast Device Registry, to be released to the above party.

Patient's signature: _____ Date: _____

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

APPENDIX D:
RESEARCH AGREEMENT

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

RESEARCH AGREEMENT

Name of Study: _____

BY THIS DECLARATION dated the _____ day of _____ 20__

I, _____ of _____

[Name of Investigator] [Institution]

recognise and accept as my responsibility regarding the use of information provided by the Australian & New Zealand Thyroid Cancer Registry (ANZTCR) for the above named study in accordance with the terms and conditions of this Agreement.

1. DEFINITIONS & ABBREVIATIONS

1.1. "Disclose" or "disclosure" shall mean the communication of information to any individual or organisation other than to the Researcher or the ANZTCR.

1.2. "Confidential information". Information accessed under the Public Health Act 2005 and/or information of a sensitive or confidential nature and any extract, derivation, or aggregation of this information that may enable identification of individuals, doctors, public or private facilities, or communities. This includes information derived from data linking or matching with information from other sources.

2. USE OF ANZTCR INFORMATION

The Researcher may use information provided by the ANZTCR only for the Research Project. If the Researcher wants to use such information for another research project, the Researcher must obtain the appropriate approval for the research project from an ethics committee and ANZTCR Management Committee. The Researcher, and any individual working on the Research Project, shall not disclose the ANZTCR information to others without the prior written consent of ANZTCR. Moreover, the ANZTCR information shall not be reproduced in any form except for internal use or with the prior written consent of ANZTCR.

3. PUBLICATION

In the event the Researcher wants to publish the results of the Research Project, the Researcher shall first provide to ANZTCR written notice of Researcher's intent to publish and a draft of the publication. ANZTCR shall have thirty (30) days after receipt of the draft publication to request in writing the removal of any portions of the publication deemed by ANZTCR to inappropriately disclose confidential information. Upon receipt of such a request from ANZTCR, the Researcher and ANZTCR shall attempt in good faith to agree upon the modifications or revisions to the draft publication which are reasonably necessary to protect the privacy of the subjects. In no event, however, shall the Researcher publish

confidential information without the written consent of ANZTCR.

4. CONTACTING PATIENTS

If the Researcher wants to contact patients, the Researcher shall submit a written request to ANZTCR identifying patients the Researcher wants to contact and the purpose of contacting the subjects. If ANZTCR approves such request, ANZTCR shall contact the patients (or the legal guardian of the subject if a guardian has been appointed by a court) and request the patient's written consent to be contacted by the Researcher. In no event shall Researcher contact a patient unless ANZTCR has first obtained such written consent.

5. CONFIDENTIALITY INFORMATION

All confidential data shall remain the property of ANZTCR and shall be destroyed, de-identified or promptly returned to ANZTCR at the end of the project, upon request of ANZTCR, or upon termination of this Agreement.

6. ANNUAL REPORTS

On or before the **[insert date]**, the Researcher shall submit to ANZTCR an annual report regarding the progress of the Research Project, all publications resulting from the Research Project, changes in the Research Project protocol, personnel or any incidents that may have resulted in the disclosure of confidential information, and any other information requested by the ANZTCR Management Committee.

7. REPRESENTATIONS OF THE RESEARCHER

The Researcher represents and warrants to ANZTCR, upon execution of this Agreement and throughout the term of this Agreement, that:

(a) The Researcher has obtained appropriate approval for the Research Project from (i) an ethics committee, (ii) the ANZTCR Management Research Committee.

(b) The Researcher, and any individual working on the Research Project, shall comply with the terms of this Agreement and the Australian & New Zealand Thyroid Cancer Registry's Policy: Requests for Data.

(c) The Researcher, and any individual working on the Research Project, shall conduct the Research Project in accordance with all applicable federal and state laws, rules, and regulations.

8. INDEMNIFICATION

The Researcher shall indemnify, defend and hold harmless ANZTCR against any claims, liabilities, damages, and expenses, including, without limitation, reasonable legal fees incurred by ANZTCR arising out of or related to the acts or omissions of the Researcher in connection with this Agreement.

9. TERM

The term of this Agreement shall commence on the date hereof and shall end on **[insert date]** or on the date the Research Project ends, whichever occurs first, unless sooner terminated as provided herein.

This Agreement may be renewed or extended for additional terms by mutual written agreement of the parties.

10. TERMINATION

(a) For Cause. ANZTCR may terminate this Agreement upon breach by the Researcher of any material provision of this Agreement, provided such breach continues for ten (10) working days after receipt by the Researcher of written notice of such breach from ANZTCR.

(b) Without Cause. Either party may terminate this Agreement without cause by giving the other party at least thirty (30) days' advance written notice thereof.

(c) Effect of Termination. In the event of such termination, the Researcher shall promptly return all ANZTCR information to ANZTCR, in any and all formats. The following provisions shall survive the termination of this Agreement: Paragraphs 3, 4, 5, and 9. Notices to the parties hereunder shall be deemed given if in writing when delivered in person, by registered or express post.

Notices shall be addressed as follows:

Researcher:

_____
_____
_____
_____
_____

Australian & New Zealand Thyroid Cancer Registry
School of Public Health & Preventive Medicine
Monash University
533 St Kilda Road, Melbourne, VIC 3004

(d) Entire Agreement. This Agreement contains the entire understanding of parties with respect to the subject matter hereof and supersedes all prior agreements, written or oral, and all other communications between the parties relating to such subject matter. This Agreement may not be amended or modified except by mutual written agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed and entered into by their authorised representatives as of the date first set forth above.

Australian & New Zealand Thyroid Cancer Registry	Researcher
_____	_____
Dr Susannah Ahern Registry Custodian	[Name] [Title] [Department]

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

APPENDIX E:
CONFIDENTIALITY AGREEMENT

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

CONFIDENTIALITY AGREEMENT

Name of Study: _____

BY THIS DECLARATION dated the _____ day of _____ 20__

I, _____ of _____

[Name of Appointee] [Address of Appointee]

recognise and accept as my responsibility the following obligations regarding the confidentiality of the information which has been provided to me by the Australian & New Zealand Thyroid Cancer Registry (ANZTCR).

1. DEFINITIONS & ABBREVIATIONS

1.1. "Confidential information". Information accessed under The Public Health Act 2005 and/or information of a sensitive or confidential nature and any extract, derivation, or aggregation of this information that may enable identification of individuals, doctors, public or private facilities, or communities. This includes information derived from data linking or matching with information from other sources.

1.2. "NHMRC". National Health and Medical Research Council

2. ETHICAL OBLIGATIONS

I certify that in my capacity as the holder of this information, I will comply with the guidelines and legislation detailed in the:

2.1. Commonwealth of Australia Privacy Act 1988, incorporating the Privacy Amendment (Private Sector) Act 2000.

2.2 Guidelines approved under Section 95A of the Privacy Act 1988 (National Health and Medical Research Council, December 2001).

2.3 Health Records and Information Privacy Act 2002 (NSW).

2.4 National Statement on Ethical Conduct in Research Involving Humans (National Health and Medical Research Council, 2007)

2.5 NHMRC's Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003).

3. CONFIDENTIALITY OBLIGATIONS

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

3.1. In the course of using confidential information for research purposes, I acknowledge that I will be exposed to information which if inappropriately used or disclosed may impact on individuals, public or private facilities or communities.

3.2. I will not disclose confidential information in any released output (eg in reports, publications).

3.3. I will not use this confidential information for purposes other than for performing the specific activities detailed in my application as approved by the Management Committee.

3.4. I will not use the confidential information except during the defined time period for which access to and use of this information was approved.

3.5. I agree to take all the reasonable steps necessary to ensure that the confidential information is kept confidential, including storing or disposing of all data, information, documents and associated correspondence in a secure manner.

3.6. I agree to re-apply for approval from the ANZTCR Management Committee if:

- I require additional confidential information;
- I want to extend the approved time period for access to or use of the confidential information;
- Additional individuals require access to this information as part of the approved research study.

3.7. I acknowledge that unauthorised use or disclosure of confidential information by me may subject me to prosecution under the laws of the relevant state or territory in Australia.

3.8. The declaration of my interests in Research Proposals and associated documents shall be held in strict confidence by the relevant Human Research Ethics Committee and ANZTCR Committee members or employees, and it shall not be used or disclosed to any other person without my prior consent or when it is legally required to be disclosed.

3.9. I agree to dispose of confidential data in a secure manner on completion of the project.

In signing this declaration, I declare that I will adhere to the obligations specified in this document.

_____

Signature

_____ _____

Name (Print) Position

_____ _____

Phone Email

BMJ Open

Development of a Bi-National Thyroid Cancer Clinical Quality Registry

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-023723.R1
Article Type:	Protocol
Date Submitted by the Author:	27-Jul-2018
Complete List of Authors:	Ioannou, Liane; Monash University, Department of Epidemiology and Preventive Medicine Serpell, Jonathan; Alfred Hospital, Endocrine Surgery Unit Dean, Joanne; Monash University, Department of Epidemiology and Preventive Medicine Bendinelli, Cino; John Hunter Hospital, Department of Surgery Gough, Jenny; The Wesley Hospital, Breast and Endocrine Surgery Lisewski, Dean; Fiona Stanley Hospital, Breast and Endocrine Surgery Miller, Julie; Royal Melbourne Hospital, Endocrine Surgery Unit; The University of Melbourne, Department of Surgery Meyer-Rochow, Win; Waikato Hospital, Department of Surgery Sidhu, Stan; Royal North Shore Hospital, Endocrine Surgery Unit, University of Sydney Topliss, Duncan; Alfred Health, Department of Endocrinology & Diabetes Walters, David; The Queen Elizabeth Hospital, Breast and Endocrine Surgical Unit Zalcberg, John; Monash University, Department of Epidemiology and Preventive Medicine Ahern, Susannah; Monash University, Department of Epidemiology and Preventive Medicine
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Surgery, Evidence based practice
Keywords:	Endocrine tumours < DIABETES & ENDOCRINOLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

Development of a Bi-National Thyroid Cancer Clinical Quality Registry

Submission to: BMJ Open

Word Count: 3,196

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Conflicts of Interest

All authors declare that they have no relevant conflict of interest in relation to this project.

Author Statement

LI, JD and SA wrote the first draft of the manuscript and developed the registry protocol. JS has led the development of the Australian and New Zealand Thyroid Cancer Registry (ANZTCR) and is the chair of the ANZTCR Steering Committee. The remaining authors, CB, JG, DL, JM, WMR, SS, DT, DW, JZ, are members of the steering committee; were involved in the protocol development; reviewed and provided feedback on various drafts of the manuscript; and approved the final manuscript.

Funding & Acknowledgements

The authors gratefully acknowledge the Australian and New Zealand Endocrine Surgeons (ANZES), their industry partners and the Alfred Foundation for their funding of the ANZTCR. We would also like to acknowledge the contribution of Ms Madeleine Allnutt, representative of the Australian Thyroid Foundation and member of the ANZTCR Steering Committee.

Abstract

Background

The occurrence of thyroid cancer is increasing throughout the developed world and since the 1990s has become the fastest increasing malignancy. In 2014, 2,693 Australians and 302 New Zealanders were diagnosed with thyroid cancer, with this number projected to rise to 3,650 in 2018.

Objectives

To establish a bi-national population-based clinical quality registry with the aim of monitoring and improving the quality of care provided to patients diagnosed with thyroid cancer in Australia and New Zealand.

Patients & Methods

The Australian and New Zealand Thyroid Cancer Registry (ANZTCR) aims to capture clinical data for all patients over the age of 18 years with thyroid cancer, confirmed by histopathology report, that have been diagnosed, assessed or treated at a contributing hospital.

Results

A multi-disciplinary Steering Committee was formed which, with operational support from Monash University, established the ANZTCR in early 2017. The pilot phase of the registry is currently operating in Victoria, New South Wales and South Australia, with over 20 sites expected to come on board across Australia and New Zealand in 2018. A modified-Delphi process was undertaken to determine the clinical quality indicators to be reported by the registry, and a minimum dataset was developed comprising information regarding thyroid cancer diagnosis, pathology, surgery and 30-day follow up.

Conclusion

The establishment of the ANZTCR provides the opportunity for Australia and New Zealand to further understand current practice in the treatment of thyroid cancer and reasons for variation in outcomes. The engagement of endocrine surgeons in supporting this initiative is crucial. While the pilot registry has a focus on early clinical outcomes, it is anticipated that future collection of longer term outcome data particularly for patients with poor prognostic disease will add significant further value to the registry.

Keywords: thyroid cancer, clinical registry, population health, quality improvement

Article Summary

Strengths & Limitations of this Study

- We outline the establishment of a b-national clinical quality registry (CQR) for thyroid cancer, including the establishment of governance, recruitment framework, clinical quality indicators, minimum data set, data access policy and reporting structure. This CQR was developed as per the Australian Operating Principles for Clinical Quality Registries.
- There are very few established thyroid cancer registries internationally. This a surgeon-driven opt-out CQR for thyroid cancer, with endocrine surgeons contributing data directly to the registry. This can be used a model for researchers developing CQRs.
- Not all thyroid cancer surgery is performed by endocrine surgeons. Currently site participation, although desirable, does not require all surgeons performing surgery for thyroid cancer at a site to participate. This will be an important future activity for the registry.
- The time consuming and labour-intensive site governance approval process in Australia and New Zealand is a major impediment for roll-out of the registry.

Introduction

Thyroid cancer is the 4th most common cancer in Australian males and 3rd most common cancer in Australian females aged 15 to 39 (1). The occurrence of thyroid cancer is increasing throughout the developed world, including Australia and New Zealand, and since the 1990s, it has become the fastest increasing malignancy. Between 1991 and 2009, the number of thyroid cancer cases increased by 250% in Australia (2). In 2018, it is expected there will be approximately 3,300 new cases of thyroid cancer in Australia (3), and approximately 350 new cases in New Zealand (4). From 2007 to 2020 thyroid cancer rates are projected to increase at a slightly lower rate, by 33% in males and 62% in females (3, 5).

The most common types of thyroid cancer have very good long-term prognoses, and of all non-cutaneous cancers, thyroid cancer has the highest five-year survival rate at 98% (6). Patients with thyroid cancer typically undergo surgery with total- or hemi-thyroidectomy. After total thyroidectomy, higher risk patients may undergo thyroid bed ablation with radioactive iodine (RAI), followed by suppressive thyroxine therapy. The removal of the whole thyroid gland and RAI ablation results in a lifelong dependence on pharmacotherapy with thyroid hormone (levothyroxine) (7).

Treatment Complications

Despite highly effective treatments and good long-term outcomes, a number of significant surgical and postoperative complications may occur and be associated with long-term physical and psychological morbidity (8). Specifically, complications of thyroidectomy, such as temporary voice change, may occur in up to 80% of patients, and permanent vocal cord palsy due to injury to the recurrent laryngeal nerve resulting in hoarseness, both potentially affect employment and quality of life (9-11). Postoperative hypocalcemia, due to damage leading to inadequate functioning of remaining parathyroid glands (hypoparathyroidism) may cause symptoms such as severe cramps requiring prolonged inpatient stays on a temporary (in up to 15%) or permanent (in 0.7-3%) basis following surgery (12) and require permanent therapy with calcitriol therapy and calcium supplementation. Haemorrhage; and wound infection is not uncommon (13), and there may be side effects from radioactive iodine (RAI) treatment, such as xerostomia. Depending on cancer pathology and stage of disease, cancer recurrence may occur, requiring additional treatments. Distant metastases may occur in up to 6-20% of cases at follow up and markedly increases the risk of cancer-specific mortality (14).

Variation in Management, Treatment & Outcome

There are significant variations in the management, treatment and outcomes of thyroid cancer, particularly in the role of: diagnostic investigation and pre-treatment scanning; optimal extent of surgery (total or hemi-thyroidectomy); use of active surveillance for small low-risk cancers; central lymph node dissections (therapeutic and/or prophylactic); outcomes following surgery (e.g. recurrent laryngeal nerve palsy, hypoparathyroidism); post-surgical hormone treatment, calcium and vitamin D therapy; and radioactive iodine treatment (provision and dosage) (15). Extent of surgery may be influenced by surgeon case volume (a measure of surgeon experience) and geographical location (16). Experienced surgeons are more likely to perform central neck dissections, arrange administration of RAI where appropriate, and have lower rates of surgical complications. Thyroidectomies performed by high volume thyroid surgeons have less than a 2% risk of hypoparathyroidism, recurrent laryngeal nerve injury and permanent paralysis (depending on the size of the primary tumour). In contrast, higher rates of complications occur when the procedure is performed by less-experienced surgeons (17, 18). It has therefore been recommended that surgeons

operating on patients with thyroid cancer should perform a minimum of 20 thyroidectomies per year (19).

Clinical Quality Registries

A proven strategy to reduce variation in outcomes is to measure and compare high quality disease-specific data using clinical quality registries (CQRs). This strategy has been successfully tested in a range of surgical disciplines including trauma (20), cardiac surgery (21), transplantation (22), breast surgery (23), bariatric surgery (24), joint surgery (25) and cancer care (26). CQRs provide the most effective means of collecting high quality data and are a tool for quality improvement. Where they have been introduced at a state or national level, CQRs have become one of the most clinically valued tools for quality improvement (27). The Australian Commission on Safety and Quality in Health Care (ACSQHC) has advocated development of CQRs, particularly in key high burden areas including cardiac disease, musculoskeletal disease and cancers (28).

Measuring Quality of Care in Thyroid Cancer

To date there are very few thyroid cancer registries internationally. Some of the more notable thyroid cancer registries include a prospective national clinical thyroid cancer database (DATHYRCA) implemented in 1996 by the Danish Head and Neck Cancer Group that collects data from the five Danish centres treating patients with thyroid carcinoma in Denmark; and the Thyroid Cancer Care Collaborative (TCCC) a multi-institution thyroid cancer registry established in the US in 1986 which includes 14 major academic medical centres and follows patients up annually to an average of five years (29). In the US, the American Thyroid Association (ATA) is collaborating with the Medullary Thyroid Carcinoma (MTC) Registry Consortium to establish a database of all patients newly diagnosed with MTC over the next 10-15 years. While single-institution databases have been well published and provided extremely valuable data with regard to understanding thyroid cancer, little data has been published from multi-institution databases and/or registries regarding quality of thyroid cancer care (30).

Rationale

Thyroid cancer management is informed by well-regarded international guidelines (31). However, given the lack of population-level data regarding patient outcomes from thyroid cancer in Australia and New Zealand, it is likely that there is clinician variation in adherence to best practice and therefore, individual patient outcomes of thyroid cancer. Furthermore, while detailed guidelines exist, there remain questions regarding optimal management of patient subpopulations. The Australian and New Zealand Thyroid Cancer Registry (ANZTCR) is a clinical quality registry being developed to provide a comprehensive evidence base regarding the care and outcomes of patients diagnosed with thyroid cancer in Australia and New Zealand. The registry will identify differences in quality of care and outcomes, with the aim to reduce variation and improve patient outcomes and survival. This paper describes the establishment and initial implementation of the ANZTCR.

Methods

Establishment of ANZTCR

In Australia, the majority of thyroid surgery is undertaken by specialist endocrine surgeons, represented by the Australian and New Zealand Endocrine Surgeons (ANZES). Long-standing and significant data regarding thyroid surgery has been collected at a number of academic and healthcare institutions across Australia. In 2016, ANZES agreed to lead the evolution of thyroid cancer quality improvement via the establishment of a multi-centre, bi-national CQR for thyroid cancer which would include clinical indicators against which to monitor and benchmark clinical care. Across Australia and New Zealand it is likely that over fifty sites undertake surgery on patients with

thyroid cancer including metropolitan, regional and private centres. Although confined to short-term follow-up at the outset, the importance of obtaining patient follow-up information to provide further evidence regarding long-term outcomes following treatment for thyroid cancer has also been identified, and will be implemented in a subsequent phase of the registry.

Patient and Public Involvement

A patient and representative of the Australian Thyroid Foundation (ATF) is a member of the ANZTCR steering committee and was involved in the design of the study. Results will be disseminated to study participants via the ANZTCR website which will have links to all our research output, reports and newsletters. The ATF will also play a role in dissemination of registry output to patients.

Funding

The ANZTCR is funded from industry, philanthropic foundations, and ANZES members.

Ethics

This project has received ethics approval from Alfred Health HREC under the National Mutual Acceptance (NMA) scheme (HREC/16/Alfred/61).

Governance Structure

Coordinating Centre

The ANZTCR Coordinating Centre is located in the Department of Epidemiology and Preventive Medicine (DEPM) at Monash University which manages the registry's core activities under the direction of the ANZTCR Steering Committee. Monash University has custodianship of the data which includes accountability for the privacy, security and integrity of patient information held within the registry.

Site Investigators

The ANZTCR registry is a multi-centred, investigator-driven endeavour. The Primary Investigator (PI) at each site is responsible for ensuring that research activities undertaken at their site are conducted in accordance with Ethics committee approval, the research protocol, site registry agreements and related policy documentation. Site research activities include identification of patients for recruitment and data collection, overseen by the PI at each site.

Steering Committee

The ANZTCR Steering Committee is multi-disciplinary, chaired by the ANZTCR Clinical Lead, and comprises representation of: endocrine surgeons (from each jurisdiction); endocrinologists; ANZES; consumers; the ATF; and Monash University. It meets quarterly and has a significant role in guiding registry strategy and policy, monitoring data collection and quality assurance, reviewing data requests, and producing data reports and publications, as per the Australian Operating Principles for Clinical Quality Registries (32).

Management Committee

A Management Committee meets fortnightly and oversees the day to day running of the registry. Further subcommittees including a data access subcommittee will be established as required.

Registry Population

All patients with a confirmed diagnosis of primary thyroid cancer ≥18 years of age that have been diagnosed, assessed or treated at a participating site are eligible to participate in the registry.

Opt-Out Process

Recruitment to the registry utilises an opt-out process which has been used successfully in over 75% of CQRs in Australia (33). The rationale for this approach is based on minimising selection bias by

achieving near 100% coverage of a population. By limiting the possibility of 'cherry picking' participants or omitting specific groups of patients otherwise not able to be captured by standard consenting processes, clinical validity increases, enabling meaningful analysis and comparison of variation in health outcomes across sites and other geographical areas. The opt-out process enables the full spectrum of public health information to be reported and analysed, increasing capacity to influence and inform clinical guidelines, policy development and funding decisions (34-36).

Data Collection

Patient demographic and clinical data is submitted by sites primarily via direct data entry using REDCap, a secure web based database. Clinicians (or their data managers) are responsible for entering their patient data directly into the REDCap database. Opportunities to import data into the REDCap database from existing institutional databases are also being developed. Site staff are trained to use the database and are provided with a data entry manual to assist with good quality data collection. Data to be collected includes demographic and clinical data up to 90 days follow-up. ANZTCR staff will check case ascertainment periodically via each site's Health Information Services unit. The use of agreed definitions of the data elements ensures that the information collected is consistent and uniform, providing reliable and comparable data for analysis. A detailed data dictionary containing the data elements, formats, ranges and validation rules and definitions has been developed and will be maintained under document management with version control.

Reporting

As per the 2008 ACSQHC Operating Principles, the ANZTCR will undergo a period of establishment and on-boarding of participating sites before the commencement of regular reporting. At the conclusion of approximately two years, the ANZTCR will be reviewed regarding its achievement against its aims and suitability for further rollout. Beyond two years and when sufficiently mature data is available, the ANZTCR is anticipated to produce a range of regular reports including: annual reports and benchmarked de-identified reports of clinical quality indicators (with identified data made available confidentially to participating sites).

Data Access Policy

Clinicians can access their own data through the registry database. Researchers may access registry data following approval by the ANZTCR Steering Committee and Ethics Committee as per the ANZTCR Data Access Policy (Supplementary Material). Monash's ANZTCR Coordinating Centre is the point of contact for matters relating to access to registry data.

Results

The ANZTCR is an observational study of patients with newly diagnosed thyroid cancer receiving surgical treatment. It collects identifiable patient key diagnostic, clinical, treatment, and complication data from diagnosis to 90-days post-thyroid cancer surgery. The registry is multi-centred operating across participating sites in Victoria, New South Wales, Queensland, Western Australia and South Australia, as well as New Zealand. Since the establishment of the registry we have received interest from almost 30 endocrine surgeons from over 35 sites throughout Australia and New Zealand.

Clinician Recruitment

Endocrine surgeons are informed about the registry through ANZES. Quarterly ANZTCR newsletters are distributed to all ANZES members to inform them of the activities and progress of the registry. Registry staff visit clinicians at their participating hospitals to introduce the registry. The primary (PI) and associate investigators (AI) for the registry at each site also act as ambassadors for the registry

and promote participation within their site. Clinician participation forms are sent to all endocrine surgeons, outlining the project and inviting clinicians to participate in the registry.

The Monash University ANZTCR coordination centre is responsible for distributing the clinician participation forms to surgeons and collating signed forms prior to the recruitment of patients and data collection. This is a once-only process for clinicians and provides agreement by the surgeon to participate in the registry and enter data on all patients for whom they are listed as the diagnosing or treating clinician in participating hospitals and private practice.

Participant Recruitment

Patient recruitment at a participating site commences following the appointment of a PI to take responsibility for the registry at the site, and authorisation by the participating site's research governance office. An outline of the recruitment framework is provided in Figure 1.

*** Figure 1 here ***

Phase 1

All patients diagnosed with thyroid cancer, based on histological confirmation (provided approximately 1-2 weeks post-surgery) at a hospital with ANZTCR research governance approval are eligible to participate. The treating endocrine surgeon (or designated staff member) at the surgical endocrine unit will enter minimal patient details into the ANZTCR REDCap Database, in addition to confirming thyroid cancer diagnosis and patient disclosure, at sites where a waiver of consent has been approved for the clinician to provide this information to the registry.

Phase 2

The Monash University ANZTCR coordinating centre will identify patients in the registry and invite them to participate in the study via a mail-out. The mail-out will include an introductory letter explaining the study, including information about the purpose, and possible outcomes of the research (including publication of research results) and a copy of the ANZTCR Participant Explanatory Statement. Using the opt-out process the patient will contact Monash University if they choose to not participate in the study. If the patient does not contact the study coordinator within two weeks participation is assumed.

Phase 3

If the participant has not opted-out of the registry the endocrine surgeon will enter participant diagnosis, surgical, pathology and treatment data into the registry database 90 days post-surgery.

Minimum Data Set & Quality Indicators

To benchmark clinical care, clinical quality registries require systematic measurement at predefined intervals and the capacity to report back information to participating clinical units. A modified-Delphi approach, informed by international Thyroid Cancer Guidelines and relevant literature, was used to develop a set of thyroid cancer clinical indicators, the parameters of which are shown in Table 1. A detailed methodology of the modified-Delphi process will be published separately. Following the development of the clinical indicators, a minimum data set was developed that included variables relating to the indicators, variables required for patient identification and contact, and other variables of particular relevance to early thyroid cancer management. The selection of data fields and their definitions were derived from national data specifications such as Metadata Online Registry (METeOR) where they exist and from international thyroid cancer registry data dictionaries where terms are not defined within the Australian context. Once a final list was generated it was

then endorsed by the ANZTCR Steering Committee. Data items collected by the ANZTCR are outlined in Table 2.

Table 1. Framework of consensus set of clinical quality indicators

Ref. No.	Clinical Quality Indicator	
Preoperative		
CQI 1	Ultrasound (US)	Process
CQI 2	Fine Needle Aspiration (FNA)	Process
CQI 3	Voice Assessment	Process
Surgery		
CQI 4	Extent of Surgery	Process
CQI 5	Lymph Node Dissection	Process
Surgical Complications		
CQI 6	Recurrent Laryngeal Nerve (RLN) Palsy	Outcome
CQI 7	Hypoparathyroidism (Hypocalcaemia)	Outcome
CQI 8	Haemorrhage Requiring Return to Theatre	Outcome
Staging & Treatment Planning		
CQI 9	Postoperative TNM Staging	Process
CQI 10	Multi-disciplinary Team Meeting (MDM)	Process
Post-Surgical Treatment		
CQI 11	Completion Thyroidectomy	Process
CQI 12	Radioactive Iodine (RAI)	Process

Table 2. Data Items collected by the ANZTCR.

Recruitment	Patient Details	Preoperative	Procedure(s)	Postoperative	Treatment
• Patient ID • Given Name(s) • Surname • Date of Birth • Sex • Country • Street Address • Suburb • State/City • Postcode • Medical Record Number • Surgeon Name • Date of Diagnosis • Basis of Diagnosis • Disclosure of Diagnosis to Patient • Vital Status • Date of Death • Cause of Death	• Contact Number • Email Address • Country of Birth • Preferred Language • Interpreter Required • Aboriginal, Torres Strait Islander Status • Maori Status • Biobank Sample	• Presence of Comorbidities • Medication at Diagnosis • Thyroid Function at First Presentation • Neck Examination • Palpable Lymph Nodes • Family History of Thyroid Disease • Previous Exposure to Radiation • Previous Thyroid Surgery • Preoperative Imaging • Presence of Suspicious Lymph Nodes • Largest Thyroid Nodule Diameter • Fine-Needle Aspiration • Clinical Voice Abnormality • Preoperative Laryngeal Exam	• Date of procedure • Procedure Type • Indication for Procedure • Residual Tumour • Lymph Node Dissection • Lymph Node Dissection Intent • Lymph Node Dissection Levels • Recurrent Laryngeal Nerve • Nerve Integrity Monitor • Primary & Secondary TC Pathology • PTC, FTC, HCC Variants • Incidental Finding of Cancer • Thyroid Benign Pathology • Largest Tumour Diameter • Margin Status • Multifocal Cancer • Lymphovascular Invasion • Extrathyroidal Extension • Lymph Node Metastases • Distant Metastases • Distant Metastases Sites	• Surgical Complications • TNM Staging • Vitamin Supplementation • Genetic Testing	• Maximum Stimulated Tg (ug/L) • Maximum TgAb (U/ml) • Method of TSH Stimulation • Maximum Stimulated TSH (mU/L) • RAI Remnant Ablation (RRA) • Other Adjuvant Therapy

Discussion

Following its national establishment, the ANZTCR will monitor diagnosis, treatment and outcomes allowing for the identification of patterns of care and practices associated with better outcomes through improved compliance with best practice-based guidelines for the management of thyroid cancer. The registry will also be able to identify risk factors that predict favourable and unfavourable treatment outcomes, postoperative complications, and prognosis, leading to the stratification of treatments and follow up. The ANZTCR will highlight risks and benefits of specific approaches to thyroid cancer as well as establish international benchmarks in the routine management of thyroid cancer surgical care. Further, the ANZTCR provides a basis as a platform for longer-term clinical follow-up, sub-studies exploring treatment outcomes, and clinical trials. We believe that the ANZTCR through its accumulation of a significant thyroid cancer cohort will assist in identifying best practice management specifically in complex poor prognostic thyroid cancer cases of low incidence.

One of the key features of the ANZTCR is that it is a surgeon-based CQR, with surgeons entering their patient data directly into the ANZTCR-RCD. While there are a number of benefits to this structure, including reduced data collection costs related to hiring additional staff and subject specific training, there are also a number of potential challenges. One of the major challenges is surgeon engagement. However, due to the registry being funded by the Australian and New Zealand Endocrine Surgeons, a speciality society of endocrine surgeons, we have had high engagement during the establishment phase. In order to maintain this engagement we have circulated quarterly newsletters with updates on the registry and invited the surgeons to be involved in the development of the clinical quality indicators and minimum data set. Continual review and refinement of the dataset will ensure that the data collection burden is kept to a minimum. Additionally, the registry database allows surgeons to run site patient-level and aggregate data reports in real-time for use in clinical care. The registry will also provide surgeons with an 'ANZTCR Valued Contributor' logo for use on their email signature, letterhead and/or website, and has been approved as a clinical audit activity by the Royal Australian College of Surgeons (RACS) Continuing Professional Development (CPD) program.

Data from CQRs generally have strong external validity particularly with regard to generalisability and extrapolation of outcomes, however bias can exist (37), particularly due to the nature of the registry data being surgeon-derived. Initial quality assurance processes will include sample audits of participating surgeon records. In the future to ensure case ascertainment, the ANZTCR could potentially receive monthly data extracts from participating site Health Information Services (HIS) or the Victorian Cancer Registry (VCR), pending approval. As the registry expands it will also consider recruiting non specialist endocrine surgeons who undertake thyroid cancer surgery including head and neck surgeons.

In order to commence patient recruitment the registry needs to seek ethics approval and governance authorisation at the participating site. As CQRs are becoming more common, standard guidelines have been introduced to make the ethics process more manageable. In particular, the National Mutual Acceptance (NMA) scheme has streamlined ethics for all public hospitals in all states except Tasmania (and the Northern Territory). Private hospitals can still choose to participate through the NMA scheme. Nevertheless, the process of obtaining site governance approval remains both time consuming and labour intensive (38, 39). Finally, perhaps the most important challenge faced by CQRs include ongoing funding to ensure their sustainability. Currently the ANZTCR has enough funding to support the registry during the initial pilot phase, however in order to progress to national rollout and implement longer-term clinical follow-up and patient-reported outcomes

additional funding is required. This is particularly relevant as lengthy follow-up is required to ascertain outcomes relating to recurrence (30, 40). Nevertheless, given the benefits to patients, clinicians and wider stakeholders, and high level of clinician engagement, we are optimistic that in time these benefits will be realised.

References

1. Western Australian Cancer Registry. Cancer incidence and mortality in Western Australia. In: Data Integrity Directorate PaSPD, editor. Perth Western Australia,: Department of Health,; 2014.
2. Australian Government. Cancer in Australia: an overview, 2012. In: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries, editors. Canberra: AIHW; 2012.
3. Australian Government. Australian Cancer Database (ACD). In: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries, editors. Canberra: AIHW; 2011.
4. New Zealand Cancer Registry (NZCR). Cancer Data and Stats. In: Health Mo, editor. Wellington: New Zealand Government; 2017.
5. Australian Government. National Mortality Database (NMD). In: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries, editors. Canberra: AIHW; 2011.
6. Jemal A, Ward EM, Johnson CJ, Cronin KA, Ma J, Ryerson AB, et al. Annual report to the nation on the status of cancer, 1975–2014, featuring survival. JNCI: Journal of the National Cancer Institute. 2017;109(9).
7. Husson O, Haak HR, Mols F, Nieuwenhuijzen GA, Nieuwlaat WA, Reemst PH, et al. Development of a disease-specific health-related quality of life questionnaire (THYCA-QoL) for thyroid cancer survivors. Acta Oncologica. 2013;52:447–54.
8. Mendoza A, Shaffer B, Karakla D, Mason EM, Elkins D, Goffman TE. Quality of life with well-differentiated thyroid cancer: Treatment toxicities and their reduction. . Thyroid. 2004;14:133 – 40.
9. Lee JC, Breen D, Scott A, Grodski S, Yeung M, Johnson W, et al. Quantitative study of voice dysfunction after thyroidectomy. Surgery. 2016;160(6):1576-81.
10. Serpell JW, Lee JC, Yeung MJ, Grodski S, Johnson W, Bailey M. Differential recurrent laryngeal nerve palsy rates after thyroidectomy. . Surgery. 2014;156(5):1157-66.
11. Hayward NJ, Grodski S, Yeung M, Johnson WR, Serpell J. Recurrent laryngeal nerve injury in thyroid surgery: a review. ANZ journal of surgery. 2013;83(1-2):15-21.
12. Serpell JW. Preventing hypoparathyroidism after total thyroidectomy. ANZ journal of surgery. 2018;88(3):127-8.
13. Lee JC, Chang P, Grodski S, Yeung M, Johnson W, Serpell J. Temporal analysis of thyroid cancer management in a Melbourne tertiary centre. ANZ journal of surgery. 2016.
14. Nixon IJ, Whitcher MM, Palmer FL, Tuttle RM, Shaha AR, Shah JP, et al. The impact of distant metastases at presentation on prognosis in patients with differentiated carcinoma of the thyroid gland. Thyroid. 2012;22(9):884-9.
15. Hall SF, Irish JC, Groome PA, Urbach DR. Practice patterns in the management of patients with differentiated thyroid cancer in Ontario Canada 2000-2008. Journal of Otolaryngology-Head & Neck Surgery. 2014;43(1):29.
16. Tasevski R. Management Patterns and Outcomes of Differentiated Thyroid Cancer in Ontario: A Population-based Study. (Doctoral dissertation). 2013.
17. Cobin RH, Gharib H, Bergman DA, Clark OH, Cooper DS, Daniels GH, et al. AACE/AAES medical/surgical guidelines for clinical practice: management of thyroid carcinoma. American Association of Clinical Endocrinologists. American College of Endocrinology. Endocrine practice: official journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists. 2001;7(3):202.

18. Pacini F, Schlumberger M, Dralle H, Elisei R, Smit JW, Wiersinga W. European consensus for the management of patients with differentiated thyroid carcinoma of the follicular epithelium. . European journal of endocrinology. 2006;154(6):787-803.
19. Perros P, Colley S, Boelaert K, Evans C, Evans RM, Gerrard GE, et al. British Thyroid Association Guidelines for the Management of Thyroid Cancer. Third Edition. Clinical Endocrinology. 2014;81(Suppl. 1):1-122.
20. Cameron PA, Gabbe BJ, McNeil JJ, Finch CF, Smith KL, Cooper DJ, et al. The trauma registry as a statewide quality improvement tool. Journal of Trauma and Acute Care Surgery. 2005;59(6):1469-76.
21. Australasian Society of Cardiac and Thoracic Surgeons Database Project Steering Committee. Victorian Cardiac Surgery Database Project.
22. Australia and New Zealand Dialysis and Transplant Association (ANZDATA). Australia and New Zealand Dialysis and Transplant Registry [Web Page] [Available from: http://www.anzdata.org.au/.
23. Malycha P, Tyson S. National breast surgery audit. Australian and New Zealand Journal of Surgery. 2000;70(12):834-6.
24. Poelemeijer YQ, Liem RS, Nienhuijs SW. A Dutch Nationwide Bariatric Quality Registry: DATO. Obesity surgery. 2017:1-9.
25. Graves SE, Davidson D, Ingerson L, Ryan P, Griffith EC, McDermott BF, et al. The Australian orthopaedic association national joint replacement registry. Medical Journal of Australia. 2004;180(5):S31.
26. Cancer Institute NSW. NSW Clinical Cancer Registry [Web Page] [Available from: http://www.cancerinstitute.org.au/cancer_inst/programs/registryccr.html.
27. Sweden E. Handbook for Establishing Quality Registries. Karlskrona: Eyenet Sweden. 2005.
28. Australian Commission on Safety and Quality in Health Care. Information Strategy. Sydney: ACSQHC; 2007.
29. Londero SC, Mathiesen JS, Krogdahl A, Bastholt L, Overgaard J, Bentsen J, et al. Completeness and validity in a national clinical thyroid cancer database: DATHYRCA. Cancer epidemiology. 2014;38(5):633-7.
30. Mehra S, Tuttle RM, Milas M, Orloff L, Bergman D, Bernet V, et al. Database and registry research in thyroid cancer: striving for a new and improved national thyroid cancer database. Thyroid. 2015;25(2):157-68.
31. Haugen BR, Alexander EK, Bible KC, Doherty GM, Mandel SJ, Nikiforov YE, et al. 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid. 2016;26(1):1-133.
32. Australian Commission on Safety and Quality in Health Care. Operating Principles and Technical Standards for Australian Clinical Quality Registries [Web Page] [Available from: http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/EA520128CB313DE9CA2573AF007BC590/$File/OP_TS-Nov2008.pdf.
33. Tu JV, Willison DJ, Silver FL, Fang J, Richards JA, Laupacis A, et al. Impracticability of informed consent in the Registry of the Canadian Stroke Network. New England Journal of Medicine. 2004;350(14):1414-21.
34. Cancer Council of Victoria. Cancer Council of Victoria Registry & Statistics 2013 [Available from: http://www.cancervic.org.au/research/registry-statistics.
35. Junghans C, Jones M. Consent bias in research: how to avoid it. Heart. 2007;93(9):1024-5.
36. Buckley B, Murphy AW, Byrne M, Glynn L. Selection bias resulting from the requirement for prior consent in observational research: a community cohort of people with ischaemic heart disease. Heart. 2007;93(9):1116-20.
37. Stub D, Lefkovits J, Brennan AL, Dinh D, Brien R, Duffy SJ, et al. The Establishment of the Victorian Cardiac Outcomes Registry (VCOR): Monitoring and Optimising Outcomes for Cardiac Patients in Victoria. Heart, Lung and Circulation. 2018;27:451-63.

38. Clay-Williams R, Taylor N, Braithwaite J. Potential solutions to improve the governance of multi centre health service research. MJA. 2018;208(4):152-4.
39. Brown WA, Smith BR, Boglis M, Brown DL, Anderson M, O'Brien PE, et al. Streamlining ethics review for multisite quality and safety initiatives: national bariatric surgery registry experience. Med J Aust. 2016;205(200-1).
40. Pearce EN, Lee SL, Weiss R, Magner J, Garber JR, Campion FX, et al. Unique obstacles to establishing thyroid cancer registries. Journal of clinical & translational endocrinology. 2016;3:12-3.

List of Figures

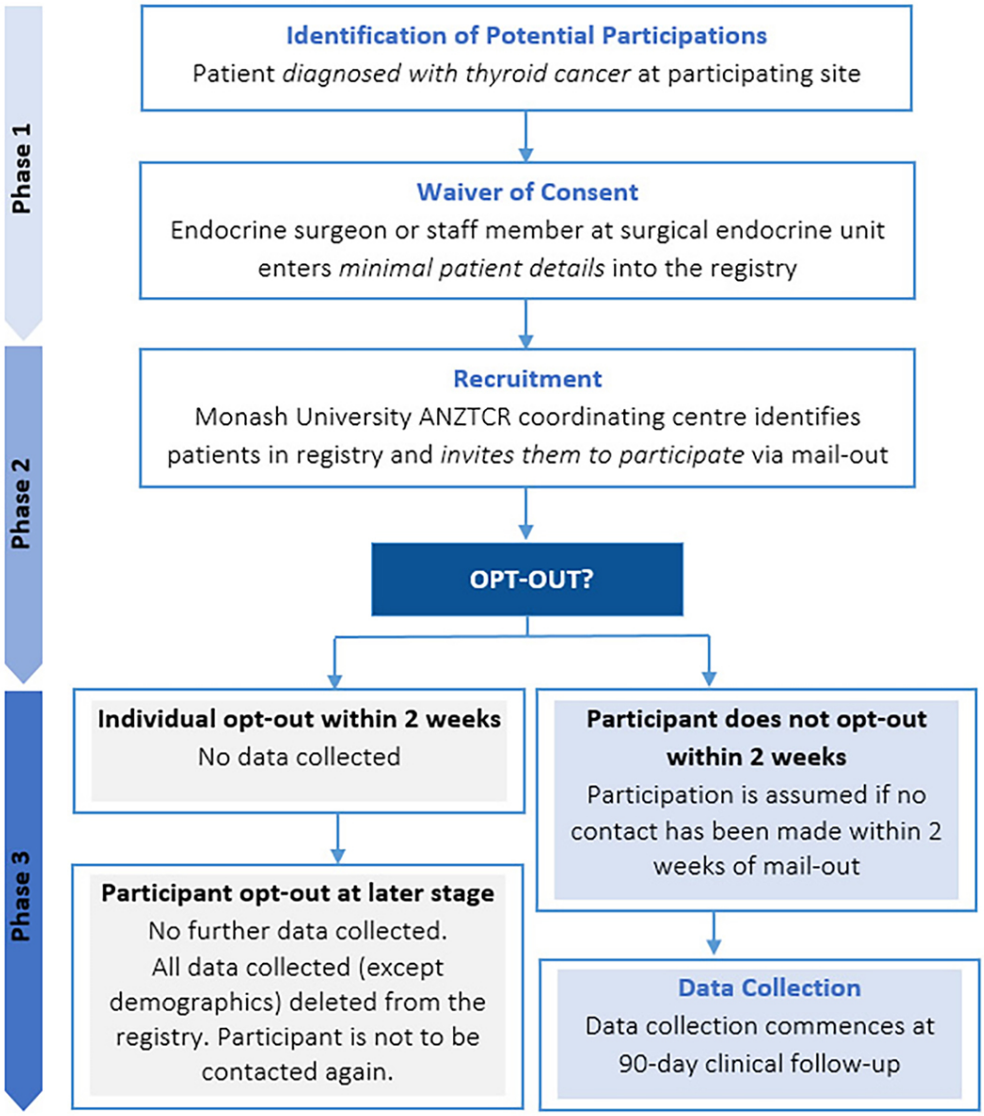

Figure 1. Patient Recruitment Framework

90x102mm (300 x 300 DPI)

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS POLICY

Version: 1
Date: 26 August 2018

Monash University
School of Public and Preventive Medicine
Faculty of Medicine, Nursing and Health Sciences

Statement of Compliance
This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007), Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ASCSQH Operating Principles and technical standards for Australian Clinical Quality Registries, University research policies and procedures and federal laws governing privacy and confidentiality.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

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DOCUMENT VERSION CONTROL

Version	Date	Reason/Comments/Approvals
1.0	21.08.2017	Initial Version Release. Proposed to ANZTCR SC on 25.07.17

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

CONTENTS

This document describes the Australian & New Zealand Thyroid Cancer Registry (ANZTCR) guidelines and policies for governing the release of information for research purposes.

1. PREFACE

The Australian & New Zealand Thyroid Cancer Registry (ANZTCR) encourages the use of its data for a variety of purposes such as quality improvement, research, clinical planning and other activities that may lead to an improvement in care to patients with thyroid cancer. The ANZTCR will only facilitate access to its data for projects that meet appropriate standards of scientific merit and public health importance as determined by the Management and/or Steering Committee. This data access policy defines how data from the ANZTCR may be accessed. The policy includes the criteria and conditions for provision of de-identified individual level data, aggregate data, reports or analyses; and procedures for data request applications. It also outlines the cases in which fees for such access might be applicable, and any associated acknowledgement and publishing responsibilities.

Data collected and collated by ANZTCR is guided by strict protocols and procedures to ensure the security, privacy and confidentiality of all information collected and stored in the registry. All patient and stakeholder information will be handled in accordance with the Commonwealth Privacy Act (1988), the Privacy and Data Protection Act 2014 (Vic) and the Health Records Act 2001 (Vic), similar relevant interstate legislation, and any code of practice or guidelines made under these Acts.

All registry activities have been approved by a National Health Medical Research Council (NHMRC) approved Human Research Ethics Committee (HREC) and other participating site and Monash University Human Research Ethics Committees.

The University Privacy Compliance Framework is available at www.privacy.monash.edu.au.

2. PROJECT INFORMATION

2.1 PURPOSE OF ANZTCR

The Australian & New Zealand Thyroid Cancer Registry (ANZTCR) was developed by the Monash University Breast Endocrine Surgery (BES) Unit in collaboration with the Registry Sciences Unit (RSU). The ANZTCR is a clinical quality registry collecting data on patients diagnosed with thyroid cancer at participating health service sites in Australia to inform best-practice guidelines as well as benchmark performance in Australia with data from comparable international registries.

2.2 PROJECT OVERVIEW

The registry collects data relating to the patient's first presentation, preoperative investigations, cancer diagnosis and surgery, as well as adjuvant treatment and follow-up care up to 90 days post-diagnosis. Data is collected from patient medical records at diagnosis (1-2 weeks post-surgery) and 90 days post-diagnosis (follow-up data).

The registry allows comparison of high quality information, which can be used to develop criteria and procedures to evaluate and improve patient quality of care. Data is analysed to identify which treatments are more successful than others and compare thyroid cancer services across Australia. This will lead to improvement in patient quality of care and thyroid cancer services in the future.

Information held by the registry is used by the ANZTCR in two different ways. The data will be used to monitor:

- Performance of quality of thyroid cancer patient care in Australia;
- Performance of the Australian & New Zealand Thyroid Cancer Registry in collecting data about quality of thyroid cancer outcomes.

3. DEFINITIONS

Management Committee - The ANZTCR Management Committee is responsible for overseeing the daily operations of the registry. The Committee ensures data collection and data quality processes function effectively and complies with ethics committee regulations, legislation and registry policies.

Steering Committee - The ANZTCR Steering Committee is an independent entity which maintains governance and overall management of the ANZTCR. The Steering Committee develops and reviews policies and publications arising from the registry data.

Human Research Ethics Committee (HREC) - HRECs protect the welfare and rights of participants involved in research and they review proposals for research that involves humans. They monitor the conduct of research and deal with complaints that arise from research. Research projects requesting identifiable data and/or intending to contact patients must obtain approval from a National Health and Research Council (NHMRC) registered HREC.

Confidential Data - ANZTCR is responsible for protecting the data from unauthorised access and release by maintaining strict standards of confidentiality. Data that identifies or potentially identifies an individual patient, health care provider, institution or a caseload of a provider or reporting institution is considered propriety and confidential.

Identifiable Data – Data that contains individual identifiers making it possible to identify a specific individual.

Non-identifiable Data - Data that has never been labeled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data may be linked with other data so it can be known they are about the same data subject, although the individual's identity remains unknown.

Re-identifiable Data - Data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.

Disclose or Disclosure - The communication of any ANZTCR information to any individual or organisation other than to the researcher or the ANZTCR.

Research Project - A scientific investigation that has been reviewed by ANZTCR Management Committee.

Researcher - The principal investigator of a research project (as defined above) or the individual requesting data from the ANZTCR.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

4. ACCESS TO DATA HELD BY ANZTCR

ANZTCR data is hosted on a REDCap server that is managed by Monash University. Access to data is subject to applicable privacy laws and principles, and ethics approvals. Specific measures have been put in place to maintain the confidentiality of personal identifying information at the patient and hospital level.

Data access is generally subject to the approval of the ANZTCR Steering Committee. When considering the approval of access to ANZTCR data, the ANZTCR Steering Committee will consider whether the project satisfies the principles of research merit and integrity.

Access to the data is subject to the Data Access Request Process outlined in section 5.

4.1 ELIGIBLE APPLICANTS

Researchers, medical professionals and pharmaceutical professionals working at research institutions, hospitals, private entities, government or other health services within Australia and industry are eligible to request access to data held within the registry. All requests for data are noted in the ANZTCR Steering Committee minutes and logged.

4.2 ACCESS TO ANZTCR DATA

1. Staff who report directly to the ANZTCR Data Custodian will have direct access to the database and for operational purposes Monash University IT staff, directly involved in supporting registry systems have access for upgrades and break fixes, and are bound by Monash University confidentiality agreements.

2. All uses of ANZTCR data, in whatever context, must receive prior approval from the ANZTCR Steering Committee unless a pre-existing funding agreement is in place and has been previously approved by the ANZTCR Steering Committee. Research related requests may require specific ethics committee approval. Use of data for any other purpose will require an additional request.

3. Data access may be subject to conditions in agreements and/or research ethics approvals.

4. Under no circumstances will individually identifiable data in respect to patients, contributing clinicians, or hospitals be made available to parties other than the ANZTCR Steering Committee, authorised ANZTCR personnel, and members of any working group directed by and reporting to the Steering Committee during the course of incident, complaint or outlier management. Requests for ANZTCR data which may potentially identify a cancer patient, their physicians, or institutions involved in the patient's diagnosis and/or treatment, and all research projects which require contact with cancer patients require ethics approval and full review from ANZTCR Management Committee.

5. The ANZTCR will not release participant contact details or identifiable data that can be linked with other data. All contact with registered patients must be conducted by the ANZTCR through the Coordinating Centre. The cost of making such contact is to be borne by the researcher/s requesting the contact.

6. If a third party research or student project requires individually identifiable data for linkage or further research, this cannot be provided by ANZTCR directly. Following ethics approval, sign off by involved Centre Directors or site Principal Investigators and ANZTCR Steering Committee approval, ANZTCR

will provide the required data to the site/s involved to forward the data and patient identifying keys to the third party or student.

7. The ANZTCR will only release data of a sufficiently high level of quality and will release the least sensitive level of data that is practicable in order to fulfil the uses identified in the research proposal submitted with the data request. Tabulated aggregate data with a cell count less than 5 will be suppressed to prevent re-identification of an individual patient, physician or organisation.

8. Where only basic summary data available through public reports is requested, this can be provided by the ANZTCR Coordinating Centre without Steering Committee approval.

9. ANZTCR encourages the independent access of clinician data available through the ANZTCR REDCap Database, however should a contributing clinician request access to their own patient data ANZTCR will provide this. All requests for this category of data should be made in writing to the ANZTCR Management Committee (**Appendix B**).

10. If a hospital executive makes a specific request for its own performance data, ANZTCR will provide this information. Identification of a clinician will not be provided without the written permission of the Centre Director/Principal Investigator. All requests for this category of data should be made in writing to the ANZTCR Data Custodian (**Appendix B**). Such data requests will require Steering Committee approval.

11. For requests from industry, comparative information i.e. market share will not be provided.

12. All requests for access to the ANZTCR data are undertaken in addition to routine ANZTCR workload. As a general rule, following submission of the request form, review by the ANZTCR steering committee will occur within 4 weeks. Requests involving reports or analysis will be provided with a quote and expected time frame for completion. Most data access requests will generally be provided within 2-6 weeks following Steering Committee approval.

13. Requests must be first made to the ANZTCR Management Committee at Monash University who will either table the request at the next ANZTCR Steering Committee meeting or, in some circumstances where the data is required earlier the ANZTCR Management Committee, may circulate the request for out of session approval. Data cannot be extracted until approval is given and relevant ethics approval from participating institutions are in place.

14. All data must only be used for the purposes outlined in the written request, and approved by the Steering Committee. The researcher may only use registry information for the specified research project. If the researcher wants to use registry information for another research project, he/she must first obtain the appropriate approval for the research project. The researcher, and any individual working on the research project, may not disclose registry information to others without the prior written consent of ANZTCR. Moreover, the cancer case information may not be reproduced in any form except for internal use or with prior written consent from the ANZTCR.

15. No data may be passed onto other researchers, clinicians or any other person/entity not explicitly mentioned in the written data request.

16. ANZTCR coordinating centre will perform record-linking tasks at the ANZTCR whenever feasibly possible. Researchers may provide identified data to the registry, and the ANZTCR will return medical

information on records that were found to link. If the research project has the patient's informed consent, then linkage projects will be reviewed by the Management and/or Steering Committee.

17. Requests for access to data must comply with the National Statement on Ethical Conduct in Human Research (2007). Following ethics approval and data access sign off by the ANZTCR Steering Committee, de-identified data will be provided by secure file transfer. Following transfer, security and storage of the data provided will be the responsibility of the requester in accordance with good research practice guidelines.

18. Requests must be made in accordance with the data access policy and provide full disclosure in the request form for proposed access and usage of the data. Data access and usage must comply with all conditions in the approval given for data access.

19. Patient requests for data access to their information will be managed by the Registry Coordinator. Patients will need to provide identifying information prior to data release. (**Appendix C**)

20. If a research project continues beyond the original termination date stated in the proposal, the researcher must notify the ANZTCR in writing of the new termination date, submit corresponding approvals from an ethics committee, and obtain approval in accordance with Section 4.2 (Request for Patient Identifiable Data).

5. REQUESTING DATA

5.1 DATA ACCESS REQUEST PROCESS

1. All data requests must be formally lodged using the relevant Data Request Application Form (**Appendix A** or **Appendix B**) via email, post or fax to:

   Email: SPHPM.ANZTCR@monash.edu

   Post: Dr Liane Ioannou
   Australian & New Zealand Thyroid Cancer Registry
   553 St Kilda Road
   Melbourne, 3004

Upon receipt of the completed and signed form, the ANZTCR Management Committee will present the data request to the Steering Committee at the next scheduled meeting if required under Section 3.2. Meetings are held four times per year.

2. There are three possible outcomes of the data access request. The data access request may be approved; approved subject to amendment; or declined. If the application is declined, a major revision and subsequent resubmission will be required. Approval subject to minor revision will not require a full resubmission. An out of session review of the changes will be organised.

3. Upon approval, the ANZTCR Management Committee will provide a statement of the conditions of its use with a cost estimate if applicable.

   a. The researcher signs the Research Agreement (**Appendix D**).

   b. All project personnel who have access to the confidential data sign the Confidentiality Agreement (**Appendix E**).

c. The Data Custodian releases the data to the researcher.

5.2 REQUEST FOR NON-IDENTIFIABLE DATA

Aggregate data such as incidence, mortality rates and frequencies may be released provided that such disclosure does not include sufficient information that would allow the researcher to identify an individual or organisation. This may include masking cell sizes less than 5 for tabulated data.

The ANZTCR may release non-identifiable tumour-level data, which can include details about the tumour and treatment information. Patient demographic information will not be released and the tumour data will not be identifiable.

The ANZTCR will not release patient contact details.

The researcher must indicate their request for *Non-Identifiable Data* on the Data Request Application Form (**Appendix A**) and submit the application to the ANZTCR Management Committee.

5.3 REQUEST FOR PATIENT RE-IDENTIFIABLE OR DE-IDENTIFIABLE DATA

The ANZTCR will generally not release patient identifiable data.

Hospitals and clinicians may request re-identifiable data for cases reported by their own institution or practice. All patient identifiers are removed and replaced with a code.

The researcher must discuss the approval process with a representative from the Management Committee, including the terms and conditions of the Research Agreement (**Appendix D**) to be signed by the researcher, provisions regarding maintenance of confidentiality, patient contact, and sanctions for violating these provisions.

The researcher must indicate their request for *Re-Identifiable or De-Identified Data* on the Data Request Application Form (**Appendix A**) and submit the application, in addition to their ethics application and letter of ethics approval, to the ANZTCR Management Committee.

It is a requirement of the ANZTCR Management Committee that applications for the release of data for research purposes are submitted and reviewed by a HREC. Section 95A of the Privacy Act 1988 allows the Management Committee to request researchers to submit a proposal to a HREC even if it has received written notification of ethics committee approval from the investigator's institution.

5.4 PATIENT REQUEST FOR DATA ACCESS

Patient requesting access to their data held on the ANZTCR will be required to complete a Data Request Application Form (**Appendix C**) which will be available from the ANZTCR Management Committee. Upon receipt of the completed form the, the ANZTCR coordinator will:

1. Telephone the patient to confirm that they have requested their details
2. Advise the patient that their information will be sent by registered post to the address recorded on their proof of identify documents.

6. DATA SECURITY FOR PATIENT IDENTIFIABLE INFORMATION

The following restrictions apply to the use of confidential information:

Maintenance and Storage of Data by Researcher

Patient identifiable data must be encrypted or kept separate from medical data stored by the researcher. This separation applies for data kept in paper format or on a computer. The medical data will not be identified except by an identifying number with no meaning in any data set other than the researcher's or ANZTCR. The patient identifiable cancer case information will not be attributed to a source that identifies the nature of the records. Identifiable data stored on a computer network must be secured from unauthorised network access by the most effective means that are technically available. If confidential information is lost, it will be reported to the ANZTCR Office and the approving Human Research Ethics Committee.

Penalties for Violations

In addition to terminating the agreement for a violation of this policy, the ANZTCR may impose sanctions on the researcher. Individuals who have witnessed inappropriate use of ANZTCR data or a breach in confidentiality may report violations to the ANZTCR. The ANZTCR recognises that violations may occur to various degrees, however, in all cases the Management Committee will be notified immediately and the research project will be suspended for a minimum of 30 days. During that time, the Management Committee will meet to discuss the magnitude of the violation and the steps needed to rectify the infraction(s). The Management Committee will also determine if the violation(s) should be reported to the proper authorities, including the HREC.

7. PUBLICATION

Any material or manuscript to be published using ANZTCR data must be submitted for review by the ANZTCR Steering Committee prior to release for publication. ANZTCR will have thirty (30) days after receipt of the draft publication to request in writing the removal of any portions of the publication deemed by ANZTCR to inappropriately disclose patient identifiable cancer case information. Upon receipt of such request from ANZTCR, the researcher and ANZTCR will attempt, in good faith, to agree upon the modifications or revisions to the draft publication, which are reasonably necessary to protect the privacy of the subjects of the cancer case information. In no event, however, will the researcher publish identifiable cancer case information.

It must contain appropriate acknowledgement of ANZTCR. Preferred wording for the acknowledgement will be provided with the data. If the data is the primary source for a report or publication, the source of the data must be acknowledged, along with a statement that the analysis and interpretation are those of the author, not the registry. Where a research collaborator has analysed data, ANZTCR, Monash University should be acknowledged as a secondary institution. Where the author is a registry staff member, then the primary attribution should be ANZTCR, Monash University. ANZTCR reserves the right to dissociate itself from conclusions drawn if it deems necessary.

Authorship may be required when ANZTCR makes substantial contribution to the data. Copies of all published abstracts, presentations, and papers that result from the study should be sent to the ANZTCR Management Committee.

8. DATA ITEMS

The ANZTCR Management Committee will provide a list of available data items upon request. It is the policy of ANZTCR that certain data elements are not released under any circumstances.

9. FORMS

The form(s) that must be completed for each data request will vary depending on whether the applicant is a researcher, non-researcher or patient. The forms may be obtained from the ANZTCR Management Committee.

The forms are as follows:

9.1 DATA REQUEST FORMS

1. Request Access to Data - Researcher Form (**Appendix A**). This form should be used for all research-related requests.

2. Request Access to Data – Non-Researcher Form (**Appendix B**). This form should be used for non-research purposes.

3. Request Access to Data – Patient Form (**Appendix C**). This form should be used for patients who would like access to information.

4. Research Agreement (**Appendix D**). This agreement must be signed by the researcher who has been approved to have identifiable information.

5. Confidentiality Agreement (**Appendix E**). Although the Principle Investigator is responsible for assuring that the data are kept confidential, all study staff with access to identifiable ANZTCR data are required to sign a confidentiality agreement. These signed agreements will be kept on file at the ANZTCR.

10. FEES

The ANZTCR does not receive any funding to perform non-routine adhoc data analysis. Therefore, provision of data may be subject to a fee-for-service on a cost recovery basis unless in line with existing funding agreements or MOUs between registry funders/supporters. Fees will be at the discretion of the ANZTCR Steering Committee in consultation with the ANZTCR Management Committee and will be based on the complexity and estimated time taken to complete the request as well as current ANZTCR routine workload. Please see the Data Access Fee Schedule for an explanation of these.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

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APPENDIX A:
DATA ACCESS REQUEST – RESEARCHER FORM

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AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST - RESEARCHER

Please return your application via email or post using the details below:

Australian & New Zealand Thyroid Cancer Registry
533 St Kilda Rd
Melbourne, VIC 3004
Email: SPHPM.ANZTCR@monash.edu
Phone: (03) 9903 0046

PART A: RESEARCHER'S DETAILS

Date of Request: _____

Date required by: _____

Organisation	☐ Research/Academic Institution ☐ Government Department or Agency ☐ Hospital Industry: ☐ Pharmaceutical ☐ Private Health Insurance ☐ Device ☐ Other, *specify* ..... ☐ Professional Medical Organisation ☐ Other *(please specify)*.....		
Short title of data request:			
Principal Investigator :		**Title:**	
Position:			
Affiliation/Organisation:			
Address:			

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

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Telephone:			
Email:			
Other Investigators: (add additional lines for each investigator)		**Title:**	
Are you a student?	☐ Yes ☐ No		
If YES, what degree are you working towards?			
Name and contact details of your supervisor			
Is this a funded research project?	☐ Yes ☐ No		
If YES, who has funded the project?			
Was the ANZTCR formally involved in the grant application?			
Does your project require Human Research Ethics committee (HREC) approval?	☐ Yes ☐ No	**If NO,** proceed to PART B	
If YES have you applied for HREC approval?	☐ Yes ☐ No		
If YES which organisation's HREC did you apply to?	_____		
Have you received HREC approval?	☐ Yes ☐ No	**If YES,** please attach a copy of your approval certificate/s, a full copy of your application and any other relevant documents	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART B: PROJECT DETAILS

Reason for data request. Please note that approval will only be given for the project described in this application. Use of data for any other purpose will require an **additional** request.

Type of data request	☐ De-identified patient level data ☐ Aggregated/summary data ☐ Report/Analysis ☐ Data linkage ☐ Other, specify ……
Title of project	
Background and rationale for the project (500 word maximum plus key references)	
Hypothesis and specific research questions	
Possible outcomes and clinical significance of this research (250 word maximum)	
Methodology of project (500 word maximum)	
Inclusion and Exclusion criteria	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART C: DATA FIELDS REQUIRED

An ANZTCR minimum dataset containing available data fields can be requested. ANZTCR is required to maintain patient privacy. No data will be released that could potentially identify patients, clinicians or hospitals.

Data item required	Justification

PART D: RESEARCHER'S SIGNATURE

I CERTIFY THAT I HAVE READ AND UNDERSTOOD THE ANZTCR DATA ACCESS POLICY. I AGREE TO COMPLY WITH THAT POLICY.
I AGREE TO UNDERTAKE ALL ACTIVITIES DESCRIBED IN THIS REQUEST IN ACCORDANCE WITH THE RESEARCH PROPOSAL, RESEARCH APPROVAL OF THE REVIEWING HUMAN RESEARCH ETHICS COMMITTEE (HREC) AND ALL RELEVANT STATE AND COMMONWEALTH PRIVACY LEGISLATION RELATING TO PATIENT INFORMATION AND HEALTH RECORDS.
I AGREE TO ADHERE TO ALL OF THE CONDITIONS PLACED ON USE AND STORAGE OF THE DATA AS OUTLINED IN ANY ANZTCR DATA ACCESS APPROVAL THAT WILL BE PROVIDED TO ME PRIOR TO COMMENCEMENT OF ANY RESEARCH ACTIVITY,DATA ANALYSIS OR REPORT.
I AGREE THAT THE INFORMATION PROVIDED BY ME TO ANZTCR IS TRUE, ACCURATE, COMPLETE AND WITHOUT MATERIAL OMISSION.
I AGREE THAT INFORMATON PROVIDED WILL NOT BE USED FOR ANY PURPOSE OTHER THAN DESCRIBED IN THE REQUEST FORM.
I AGREE THAT INFORMATION WILL NOT BE DISCLOSED TO ENTITIES OTHER THAT THOSE DESCRIBED IN THE REQUEST FORM.
I AGREE TO PROVIDE MONASH UNIVERSITY WITH A COPY OF ANY FINAL REPORT FOR REVIEW PRIOR TO PUBLISHING AND WILL ANZTCR AS THE DATA SOURCE AND WHERE APPLICABLE, MONASH UNIVERSTY AS HAVING UNDERGONE THE ANALYSIS OR COLLATED THE REPORT.
I ALSO AGREE THAT THE INFORMATION PROVIDED TO ME BY ANZTCR, WHETHER IN THE FORM OF DATA, REPORTS, MODELS, SAMPLES AND REGARDLESS OF HOW COMMUNICATED OR RECORDED, IS CONFIDENTIAL AND CONFIDENTIALITY OF ALL INFORMATION AND COMMUNICATIONS WILL BE MAINTAINED UNLESS OTHERWISE AGREED BY BOTH PARTIES.

Name: _____

Signature _____

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

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AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST - RESEARCHER

FOR OFFICE USE ONLY:

Short Title of Data Access Request: _____ _____	
ANZTCR Steering Committee decision (or delegate)	☐ Approved ☐ Approved – Subject to amendment ☐ Declined
If approved, subject to amendment, please list required changes	
Approved by ANZTCR Steering Committee Chairperson (or delegate): Signature: _____ Date of approval: _____	

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APPENDIX B:
DATA ACCESS REQUEST – NON-RESEARCHER FORM

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

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AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST – NON-RESEARCHER

Please return your application via email or post using the details below:

Australian & New Zealand Thyroid Cancer Registry
533 St Kilda Rd
Melbourne, VIC 3004
Email: SPHPM.ANZTCR@monash.edu
Phone: (03) 9903 0046

PART A: APPLICANT'S DETAILS

Date of Request: _____

Date required by: _____

Organisation	☐ Research/Academic Institution ☐ Government Department or Agency ☐ Hospital Industry: ☐ Pharmaceutical ☐ Private Health Insurance ☐ Device ☐ Other, *specify* ……. ☐ Professional Medical Organisation ☐ Other *(please specify)*……		
Authorised requester's name		**Title**	
Position			
Organisation:			
Address:			
Telephone:			
Email:			

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART B: PROJECT DETAILS

Please note that approval will only be given for the use described in this application. Use of data for any other purpose will require an **additional** request. This information will be reviewed by a committee and may incur a fee depending on the complexity of the request.

Request Title	
Type of data request	☐ Aggregated data/summary data ☐ Report/Analysis
Purpose of the request	
What question/s need to be answered by the information requested	
Description of the type of information required. (Please include the subpopulation, and cross tabulation of the variables of interest required)	
Reference period for the data of interest	
Possible outcomes and potential uses of this request	
Name all entities that the information requested will be disclosed to	☐ Internal use only ☐ Government department/agency, specify…… ☐ Other organisation, specify……
If this request is to be used to support an application for regulatory approval and are there potential implications for the registry? E.g. additional data items to be collected etc.	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART C: DATA FIELDS REQUIRED

An ANZTCR minimum dataset containing available data fields can be requested to ensure the information you require is utilised when requesting a summary report. ANZTCR is required to maintain patient privacy. No data will be released that could potentially identify patients, clinicians or hospitals.

Data item required	Justification

PART D: APPLICANT'S SIGNATURE

I CERTIFY THAT I HAVE READ AND UNDERSTOOD THE ANZTCR DATA ACCESS POLICY AND I AGREE TO COMPLY WITH THAT POLICY. I AGREE TO UNDERTAKE THE ACTIVITIES DESCRIBED IN THIS REQUEST IN ACCORDANCE WITH THE AGREED USE.
I AGREE THAT ANY INFORMATION PROVIDED WILL NOT BE USED FOR ANY PURPOSE OTHER THAN DESCRIBED IN THE REQUEST FORM
I AGREE THAT INFORMATION WILL NOT BE DISCLOSED TO ENTITIES OTHER THAT THOSE DESCRIBED IN THE REQUEST FORM.
I AGREE TO PROVIDE MONASH UNIVERSITY WITH A COPY OF ANY FINAL REPORT FOR REVIEW PRIOR TO PUBLISHING IF REQUESTED AND WILL ACKNOWLEDGE ANZTCR AS THE DATA SOURCE AND WHERE APPLICABLE, MONASH UNIVERSTY AS HAVING UNDERGONE THE ANALYSIS OR COLLATED THE REPORT.I AGREE THAT THE INFORMATION PROVIDED BY ME TO ANZTCR IS TRUE, ACCURATE, COMPLETE AND WITHOUT MATERIAL OMISSION.I ALSO AGREE THAT THE INFORMATION PROVIDED TO ME BY ANZTCR, REGARDLESS OF HOW COMMUNICATED OR RECORDED, IS CONFIDENTIAL AND CONFIDENTIALITY OF ALL INFORMATION AND COMMUNICATIONS WILL BE MAINTAINED UNLESS OTHERWISE AGREED BY BOTH PARTIES.

Name: _____

Signature _____

DATA ACCESS REQUEST – NON-RESEARCHER

FOR OFFICE USE ONLY:

Short Title of Data Access Request:_____ _____	
ANZTCR Steering Committee (or delegate) decision	☐ Approved ☐ Approved – Subject to amendment ☐ Declined
If approved, subject to amendment, list required changes	
Approved by ANZTCR Steering Committee Chairperson (or delegate): Signature:_____ Date of approval: _____	

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APPENDIX C:
DATA ACCESS REQUEST – PATIENT FORM

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AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST – PATIENT

Please return your application via email or post using the details below:

Australian & New Zealand Thyroid Cancer Registry
533 St Kilda Rd
Melbourne, VIC 3004
Email: SPHPM.ANZTCR@monash.edu
Phone: (03) 9903 0046

PART A: PATIENT DETAILS

Date of Request: _____

Date required by: _____

A certified copy of **proof of identity** is supplied as follows: (please tick x boxes) NEEDS TO DISPLAY NAME & ADDRESS AT TIME OF SURGERY	☐ Birth Certificate ☐ Passport ☐ Certificate of Australian Citizenship ☐ Medicare Card ☐ Drivers Licence ☐ Signed letter from General Practitioner verifying proof ☐ Other (utility bill, bank statement etc.)
First Name:	
Family Name :	
D.O.B:	
Address:	
Telephone:	
Email:	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART B: DETAILS REQUESTED

Data details that appear on the Data Capture Form (DCF) are shown in the table below. Please tick those you wish to access.

Surgeon Name	
Hospital/Site	
Date of Diagnosis	
Date of Surgery	
Preoperative Imaging & Tests	
Reason for Surgery	

Surgery Type	
Surgery Details	
Pathology & Staging	
Surgical Complications	
Postoperative Complications	
Recurrence	

I hereby apply for access to information relating to me held by the Australian & New Zealand Thyroid Cancer Registry.

Patient's signature: _____ Date: _____

Please send a copy of my information to above address: ☐

Please send a copy of my information to: _____

_____

PART C: THIRD PARTY RELEASE DETAILS

If your request relates to releasing this information to a third party/surgeon, please complete the following:

Name:	
Position:	
Address:	
Telephone Number:	

I hereby agree for information relating to me, held by the Australian & New Zealand Thyroid Cancer Registry, to be released to the above party.

Patient's signature: _____ Date: _____

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

APPENDIX D:
RESEARCH AGREEMENT

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

RESEARCH AGREEMENT

Name of Study: _____

BY THIS DECLARATION dated the _____ day of _____ 20__

I, _____ of _____

[Name of Investigator] [Institution]

recognise and accept as my responsibility regarding the use of information provided by the Australian & New Zealand Thyroid Cancer Registry (ANZTCR) for the above named study in accordance with the terms and conditions of this Agreement.

1. DEFINITIONS & ABBREVIATIONS

1.1. "Disclose" or "disclosure" shall mean the communication of information to any individual or organisation other than to the Researcher or the ANZTCR.

1.2. "Confidential information". Information accessed under the Public Health Act 2005 and/or information of a sensitive or confidential nature and any extract, derivation, or aggregation of this information that may enable identification of individuals, doctors, public or private facilities, or communities. This includes information derived from data linking or matching with information from other sources.

2. USE OF ANZTCR INFORMATION

The Researcher may use information provided by the ANZTCR only for the Research Project. If the Researcher wants to use such information for another research project, the Researcher must obtain the appropriate approval for the research project from an ethics committee and ANZTCR Management Committee. The Researcher, and any individual working on the Research Project, shall not disclose the ANZTCR information to others without the prior written consent of ANZTCR. Moreover, the ANZTCR information shall not be reproduced in any form except for internal use or with the prior written consent of ANZTCR.

3. PUBLICATION

In the event the Researcher wants to publish the results of the Research Project, the Researcher shall first provide to ANZTCR written notice of Researcher's intent to publish and a draft of the publication. ANZTCR shall have thirty (30) days after receipt of the draft publication to request in writing the removal of any portions of the publication deemed by ANZTCR to inappropriately disclose confidential information. Upon receipt of such a request from ANZTCR, the Researcher and ANZTCR shall attempt in good faith to agree upon the modifications or revisions to the draft publication which are reasonably necessary to protect the privacy of the subjects. In no event, however, shall the Researcher publish confidential information without the written consent of ANZTCR.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

4. CONTACTING PATIENTS

If the Researcher wants to contact patients, the Researcher shall submit a written request to ANZTCR identifying patients the Researcher wants to contact and the purpose of contacting the subjects. If ANZTCR approves such request, ANZTCR shall contact the patients (or the legal guardian of the subject if a guardian has been appointed by a court) and request the patient's written consent to be contacted by the Researcher. In no event shall Researcher contact a patient unless ANZTCR has first obtained such written consent.

5. CONFIDENTIALITY INFORMATION

All confidential data shall remain the property of ANZTCR and shall be destroyed, de-identified or promptly returned to ANZTCR at the end of the project, upon request of ANZTCR, or upon termination of this Agreement.

6. ANNUAL REPORTS

On or before the **[insert date]**, the Researcher shall submit to ANZTCR an annual report regarding the progress of the Research Project, all publications resulting from the Research Project, changes in the Research Project protocol, personnel or any incidents that may have resulted in the disclosure of confidential information, and any other information requested by the ANZTCR Management Committee.

7. REPRESENTATIONS OF THE RESEARCHER

The Researcher represents and warrants to ANZTCR, upon execution of this Agreement and throughout the term of this Agreement, that:

(a) The Researcher has obtained appropriate approval for the Research Project from (i) an ethics committee, (ii) the ANZTCR Management Research Committee.

(b) The Researcher, and any individual working on the Research Project, shall comply with the terms of this Agreement and the Australian & New Zealand Thyroid Cancer Registry's Policy: Requests for Data.

(c) The Researcher, and any individual working on the Research Project, shall conduct the Research Project in accordance with all applicable federal and state laws, rules, and regulations.

8. INDEMNIFICATION

The Researcher shall indemnify, defend and hold harmless ANZTCR against any claims, liabilities, damages, and expenses, including, without limitation, reasonable legal fees incurred by ANZTCR arising out of or related to the acts or omissions of the Researcher in connection with this Agreement.

9. TERM

The term of this Agreement shall commence on the date hereof and shall end on **[insert date]** or on the date the Research Project ends, whichever occurs first, unless sooner terminated as provided herein. This Agreement may be renewed or extended for additional terms by mutual written agreement of the parties.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

10. TERMINATION

(a) For Cause. ANZTCR may terminate this Agreement upon breach by the Researcher of any material provision of this Agreement, provided such breach continues for ten (10) working days after receipt by the Researcher of written notice of such breach from ANZTCR.

(b) Without Cause. Either party may terminate this Agreement without cause by giving the other party at least thirty (30) days' advance written notice thereof.

(c) Effect of Termination. In the event of such termination, the Researcher shall promptly return all ANZTCR information to ANZTCR, in any and all formats. The following provisions shall survive the termination of this Agreement: Paragraphs 3, 4, 5, and 9. Notices to the parties hereunder shall be deemed given if in writing when delivered in person, by registered or express post.

Notices shall be addressed as follows:

Researcher:

_____
_____
_____
_____
_____

Australian & New Zealand Thyroid Cancer Registry
School of Public Health & Preventive Medicine
Monash University
533 St Kilda Road, Melbourne, VIC 3004

(d) Entire Agreement. This Agreement contains the entire understanding of parties with respect to the subject matter hereof and supersedes all prior agreements, written or oral, and all other communications between the parties relating to such subject matter. This Agreement may not be amended or modified except by mutual written agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed and entered into by their authorised representatives as of the date first set forth above.

Australian & New Zealand Thyroid Cancer Registry	Researcher
_____	_____
A/Prof Susannah Ahern Registry Data Custodian	[Name] [Title] [Department]

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

APPENDIX E:
CONFIDENTIALITY AGREEMENT

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

CONFIDENTIALITY AGREEMENT

Name of Study: _____

BY THIS DECLARATION dated the _____ day of _____ 20____

I, _____ of _____

[Name of Appointee] [Address of Appointee]

recognise and accept as my responsibility the following obligations regarding the confidentiality of the information which has been provided to me by the Australian & New Zealand Thyroid Cancer Registry (ANZTCR).

1. DEFINITIONS & ABBREVIATIONS

1.1. "Confidential information". Information accessed under The Public Health Act 2005 and/or information of a sensitive or confidential nature and any extract, derivation, or aggregation of this information that may enable identification of individuals, doctors, public or private facilities, or communities. This includes information derived from data linking or matching with information from other sources.

1.2. "NHMRC". National Health and Medical Research Council

2. ETHICAL OBLIGATIONS

I certify that in my capacity as the holder of this information, I will comply with the guidelines and legislation detailed in the:

2.1. Commonwealth of Australia Privacy Act 1988, incorporating the Privacy Amendment (Private Sector) Act 2000.

2.2 Guidelines approved under Section 95A of the Privacy Act 1988 (National Health and Medical Research Council, December 2001).

2.3 Health Records and Information Privacy Act 2002 (NSW).

2.4 National Statement on Ethical Conduct in Research Involving Humans (National Health and Medical Research Council, 2007)

2.5 NHMRC's Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003).

3. CONFIDENTIALITY OBLIGATIONS

3.1. In the course of using confidential information for research purposes, I acknowledge that I will be exposed to information which if inappropriately used or disclosed may impact on individuals, public or private facilities or communities.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

3.2. I will not disclose confidential information in any released output (eg in reports, publications).

3.3. I will not use this confidential information for purposes other than for performing the specific activities detailed in my application as approved by the Management Committee.

3.4. I will not use the confidential information except during the defined time period for which access to and use of this information was approved.

3.5. I agree to take all the reasonable steps necessary to ensure that the confidential information is kept confidential, including storing or disposing of all data, information, documents and associated correspondence in a secure manner.

3.6. I agree to re-apply for approval from the ANZTCR Management Committee if:

- I require additional confidential information;
- I want to extend the approved time period for access to or use of the confidential information;
- Additional individuals require access to this information as part of the approved research study.

3.7. I acknowledge that unauthorised use or disclosure of confidential information by me may subject me to prosecution under the laws of the relevant state or territory in Australia.

3.8. The declaration of my interests in Research Proposals and associated documents shall be held in strict confidence by the relevant Human Research Ethics Committee and ANZTCR Committee members or employees, and it shall not be used or disclosed to any other person without my prior consent or when it is legally required to be disclosed.

3.9. I agree to dispose of confidential data in a secure manner on completion of the project.

In signing this declaration, I declare that I will adhere to the obligations specified in this document.

_____

Signature

_____ _____

Name (Print) Position

_____ _____

Phone Email

BMJ Open

Development of a Bi-National Thyroid Cancer Clinical Quality Registry: A Protocol Paper

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-023723.R2
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Primary Subject Heading:	Health services research
Secondary Subject Heading:	Surgery, Evidence based practice
Keywords:	Endocrine tumours < DIABETES & ENDOCRINOLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

Development of a Bi-National Thyroid Cancer Clinical Quality Registry: A Protocol Paper

Submission to: BMJ Open

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Conflicts of Interest

All authors declare that they have no relevant conflict of interest in relation to this project.

Author Statement

LI, JD and SA wrote the first draft of the manuscript and developed the registry protocol. JS has led the development of the Australian and New Zealand Thyroid Cancer Registry (ANZTCR) and is the chair of the ANZTCR Steering Committee. The remaining authors, CB, JG, DL, JM, WMR, SS, DT, DW, JZ, are members of the steering committee; were involved in the protocol development; reviewed and provided feedback on various drafts of the manuscript; and approved the final manuscript.

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Abstract

Introduction

The occurrence of thyroid cancer is increasing throughout the developed world and since the 1990s has become the fastest increasing malignancy. In 2014, 2,693 Australians and 302 New Zealanders were diagnosed with thyroid cancer, with this number projected to rise to 3,650 in 2018. The purpose of this protocol is to establish a bi-national population-based clinical quality registry with the aim of monitoring and improving the quality of care provided to patients diagnosed with thyroid cancer in Australia and New Zealand.

Methods & Analysis

The Australian and New Zealand Thyroid Cancer Registry (ANZTCR) aims to capture clinical data for all patients over the age of 18 years with thyroid cancer, confirmed by histopathology report, that have been diagnosed, assessed or treated at a contributing hospital. A multi-disciplinary Steering Committee was formed which, with operational support from Monash University, established the ANZTCR in early 2017. The pilot phase of the registry is currently operating in Victoria, New South Wales and South Australia, with over 20 sites expected to come on board across Australia and New Zealand in 2018. A modified-Delphi process was undertaken to determine the clinical quality indicators to be reported by the registry, and a minimum dataset was developed comprising information regarding thyroid cancer diagnosis, pathology, surgery and 90-day follow up.

Future Plans

The establishment of the ANZTCR provides the opportunity for Australia and New Zealand to further understand current practice in the treatment of thyroid cancer and reasons for variation in outcomes. The engagement of endocrine surgeons in supporting this initiative is crucial. While the pilot registry has a focus on early clinical outcomes, it is anticipated that future collection of longer term outcome data particularly for patients with poor prognostic disease will add significant further value to the registry.

Keywords: thyroid cancer, clinical registry, population health, quality improvement

Article Summary

Strengths & Limitations of this Study

- We outline the establishment of a b-national clinical quality registry (CQR) for thyroid cancer, including the establishment of governance, recruitment framework, clinical quality indicators, minimum data set, data access policy and reporting structure. This CQR was developed as per the Australian Operating Principles for Clinical Quality Registries.
- There are very few established thyroid cancer registries internationally. This a surgeon-driven opt-out CQR for thyroid cancer, with endocrine surgeons contributing data directly to the registry. This can be used a model for researchers developing CQRs.

- Not all thyroid cancer surgery is performed by endocrine surgeons. Currently site participation, although desirable, does not require all surgeons performing surgery for thyroid cancer at a site to participate. This will be an important future activity for the registry.
- The time consuming and labour-intensive site governance approval process in Australia and New Zealand is a major impediment for roll-out of the registry.

Introduction

Thyroid cancer is the 4th most common cancer in Australian males and 3rd most common cancer in Australian females aged 15 to 39 (1). The occurrence of thyroid cancer is increasing throughout the developed world, including Australia and New Zealand, and since the 1990s, it has become the fastest increasing malignancy. Between 1991 and 2009, the number of thyroid cancer cases increased by 250% in Australia (2). In 2018, it is expected there will be approximately 3,300 new cases of thyroid cancer in Australia (3), and approximately 350 new cases in New Zealand (4). From 2007 to 2020 thyroid cancer rates are projected to increase at a slightly lower rate, by 33% in males and 62% in females (3, 5).

The most common types of thyroid cancer have very good long-term prognoses, and of all non-cutaneous cancers, thyroid cancer has the highest five-year survival rate at 98% (6). Patients with thyroid cancer typically undergo surgery with total- or hemi-thyroidectomy. After total thyroidectomy, higher risk patients may undergo thyroid bed ablation with radioactive iodine (RAI), followed by suppressive thyroxine therapy. The removal of the whole thyroid gland and RAI ablation results in a lifelong dependence on pharmacotherapy with thyroid hormone (levothyroxine) (7).

Treatment Complications

Despite highly effective treatments and good long-term outcomes, a number of significant surgical and postoperative complications may occur and be associated with long-term physical and psychological morbidity (8). Specifically, complications of thyroidectomy, such as temporary voice change, may occur in up to 80% of patients, and permanent vocal cord palsy due to injury to the recurrent laryngeal nerve resulting in hoarseness, both potentially affect employment and quality of life (9-11). Postoperative hypocalcemia, due to damage leading to inadequate functioning of remaining parathyroid glands (hypoparathyroidism) may cause symptoms such as severe cramps requiring prolonged inpatient stays on a temporary (in up to 15%) or permanent (in 0.7-3%) basis following surgery (12) and require permanent therapy with calcitriol therapy and calcium supplementation. Haemorrhage; and wound infection is not uncommon (13), and there may be side effects from radioactive iodine (RAI) treatment, such as xerostomia. Depending on cancer pathology and stage of disease, cancer recurrence may occur, requiring additional treatments. Distant metastases may occur in up to 6-20% of cases at follow up and markedly increases the risk of cancer-specific mortality (14).

Variation in Management, Treatment & Outcome

There are significant variations in the management, treatment and outcomes of thyroid cancer, particularly in the role of: diagnostic investigation and pre-treatment scanning; optimal extent of surgery (total or hemi-thyroidectomy); use of active surveillance for small low-risk cancers; central lymph node dissections (therapeutic and/or prophylactic); outcomes following surgery (e.g. recurrent laryngeal nerve palsy, hypoparathyroidism); post-surgical hormone treatment, calcium and vitamin D therapy; and radioactive iodine treatment (provision and dosage) (15). Extent of surgery may be influenced by

surgeon case volume (a measure of surgeon experience) and geographical location (16). Experienced surgeons are more likely to perform central neck dissections, arrange administration of RAI where appropriate, and have lower rates of surgical complications. Thyroidectomies performed by high volume thyroid surgeons have less than a 2% risk of hypoparathyroidism, recurrent laryngeal nerve injury and permanent paralysis (depending on the size of the primary tumour). In contrast, higher rates of complications occur when the procedure is performed by less-experienced surgeons (17, 18). It has therefore been recommended that surgeons operating on patients with thyroid cancer should perform a minimum of 20 thyroidectomies per year (19).

Clinical Quality Registries

A proven strategy to reduce variation in outcomes is to measure and compare high quality disease-specific data using clinical quality registries (CQRs). This strategy has been successfully tested in a range of surgical disciplines including trauma (20), cardiac surgery (21), transplantation (22), breast surgery (23), bariatric surgery (24), joint surgery (25) and cancer care (26). CQRs provide the most effective means of collecting high quality data and are a tool for quality improvement. Where they have been introduced at a state or national level, CQRs have become one of the most clinically valued tools for quality improvement (27). The Australian Commission on Safety and Quality in Health Care (ACSQHC) has advocated development of CQRs, particularly in key high burden areas including cardiac disease, musculoskeletal disease and cancers (28).

Measuring Quality of Care in Thyroid Cancer

To date there are very few thyroid cancer registries internationally. Some of the more notable thyroid cancer registries include a prospective national clinical thyroid cancer database (DATHYRCA) implemented in 1996 by the Danish Head and Neck Cancer Group that collects data from the five Danish centres treating patients with thyroid carcinoma in Denmark; and the Thyroid Cancer Care Collaborative (TCCC) a multi-institution thyroid cancer registry established in the US in 1986 which includes 14 major academic medical centres and follows patients up annually to an average of five years (29). In the US, the American Thyroid Association (ATA) is collaborating with the Medullary Thyroid Carcinoma (MTC) Registry Consortium to establish a database of all patients newly diagnosed with MTC over the next 10-15 years. While single-institution databases have been well published and provided extremely valuable data with regard to understanding thyroid cancer, little data has been published from multi-institution databases and/or registries regarding quality of thyroid cancer care (30).

Rationale

Thyroid cancer management is informed by well-regarded international guidelines (31). However, given the lack of population-level data regarding patient outcomes from thyroid cancer in Australia and New Zealand, it is likely that there is clinician variation in adherence to best practice and therefore, individual patient outcomes of thyroid cancer. Furthermore, while detailed guidelines exist, there remain questions regarding optimal management of patient subpopulations. The Australian and New Zealand Thyroid Cancer Registry (ANZTCR) is a clinical quality registry being developed to provide a comprehensive evidence base regarding the care and outcomes of patients diagnosed with thyroid cancer in Australia and New Zealand. The registry will identify differences in quality of care and outcomes, with the aim to reduce variation and improve patient outcomes and survival. This paper describes the establishment and initial implementation of the ANZTCR.

Methods & Analysis

Establishment of ANZTCR

In Australia, the majority of thyroid surgery is undertaken by specialist endocrine surgeons, represented by the Australian and New Zealand Endocrine Surgeons (ANZES). Long-standing and significant data regarding thyroid surgery has been collected at a number of academic and healthcare institutions across Australia. In 2016, ANZES agreed to lead the evolution of thyroid cancer quality improvement via the establishment of a multi-centre, bi-national CQR for thyroid cancer which would include clinical indicators against which to monitor and benchmark clinical care. Across Australia and New Zealand it is likely that over fifty sites undertake surgery on patients with thyroid cancer including metropolitan, regional and private centres. Although confined to short-term follow-up at the outset, the importance of obtaining patient follow-up information to provide further evidence regarding long-term outcomes following treatment for thyroid cancer has also been identified, and will be implemented in a subsequent phase of the registry.

Patient and Public Involvement

A patient and representative of the Australian Thyroid Foundation (ATF) is a member of the ANZTCR steering committee and was involved in the design of the study. Results will be disseminated to study participants via the ANZTCR website which will have links to all our research output, reports and newsletters. The ATF will also play a role in dissemination of registry output to patients.

Funding

The ANZTCR is funded from industry, philanthropic foundations, and ANZES members.

Ethics

This project has received ethics approval from Alfred Health HREC under the National Mutual Acceptance (NMA) scheme (HREC/16/Alfred/61).

Governance Structure

Coordinating Centre

The ANZTCR Coordinating Centre is located in the Department of Epidemiology and Preventive Medicine (DEPM) at Monash University which manages the registry's core activities under the direction of the ANZTCR Steering Committee. Monash University has custodianship of the data which includes accountability for the privacy, security and integrity of patient information held within the registry.

Site Investigators

The ANZTCR registry is a multi-centred, investigator-driven endeavour. The Primary Investigator (PI) at each site is responsible for ensuring that research activities undertaken at their site are conducted in accordance with Ethics committee approval, the research protocol, site registry agreements and related policy documentation. Site research activities include identification of patients for recruitment and data collection, overseen by the PI at each site.

Steering Committee

The ANZTCR Steering Committee is multi-disciplinary, chaired by the ANZTCR Clinical Lead, and comprises representation of: endocrine surgeons (from each jurisdiction); endocrinologists; ANZES; consumers; the ATF; and Monash University. It meets quarterly and has a significant role in guiding registry strategy and policy, monitoring data collection and quality assurance, reviewing data requests,

and producing data reports and publications, as per the Australian Operating Principles for Clinical Quality Registries (32).

Management Committee

A Management Committee meets fortnightly and oversees the day to day running of the registry. Further subcommittees including a data access subcommittee will be established as required.

Registry Population

All patients with a confirmed diagnosis of primary thyroid cancer ≥18 years of age that have been diagnosed, assessed or treated at a participating site are eligible to participate in the registry.

Opt-Out Process

Recruitment to the registry utilises an opt-out process which has been used successfully in over 75% of CQRs in Australia (33). The rationale for this approach is based on minimising selection bias by achieving near 100% coverage of a population. By limiting the possibility of 'cherry picking' participants or omitting specific groups of patients otherwise not able to be captured by standard consenting processes, clinical validity increases, enabling meaningful analysis and comparison of variation in health outcomes across sites and other geographical areas. The opt-out process enables the full spectrum of public health information to be reported and analysed, increasing capacity to influence and inform clinical guidelines, policy development and funding decisions (34-36).

Participant Recruitment

Patient recruitment at a participating site commences following the appointment of a PI to take responsibility for the registry at the site, and authorisation by the participating site's research governance office. An outline of the recruitment framework is provided in Figure 1.

*** Figure 1 here ***

Phase 1: All patients diagnosed with thyroid cancer, based on histological confirmation (provided approximately 1-2 weeks post-surgery) at a hospital with ANZTCR research governance approval are eligible to participate. The treating endocrine surgeon (or designated staff member) at the surgical endocrine unit will enter minimal patient details into the ANZTCR REDCap Database, in addition to confirming thyroid cancer diagnosis and patient disclosure, at sites where a waiver of consent has been approved for the clinician to provide this information to the registry.

Phase 2: The Monash University ANZTCR coordinating centre will identify patients in the registry and invite them to participate in the study via a mail-out. The mail-out will include an introductory letter explaining the study, including information about the purpose, and possible outcomes of the research (including publication of research results) and a copy of the ANZTCR Participant Explanatory Statement. Using the opt-out process the patient will contact Monash University if they choose to not participate in the study. If the patient does not contact the study coordinator within two weeks participation is assumed.

Phase 3: If the participant has not opted-out of the registry the endocrine surgeon will enter participant diagnosis, surgical, pathology and treatment data into the registry database 90 days post-surgery.

Clinician Engagement

The ANZTCR is an observational study of patients with newly diagnosed thyroid cancer receiving surgical treatment. It collects identifiable patient key diagnostic, clinical, treatment, and complication data from diagnosis to 90-days post-thyroid cancer surgery. The registry is multi-centred operating across participating sites in Victoria, New South Wales, Queensland, Western Australia and South Australia, as well as New Zealand. Since the establishment of the registry we have received interest from almost 30 endocrine surgeons from over 35 sites throughout Australia and New Zealand.

Endocrine surgeons are informed about the registry through ANZES. Quarterly ANZTCR newsletters are distributed to all ANZES members to inform them of the activities and progress of the registry. Registry staff visit clinicians at their participating hospitals to introduce the registry. The primary (PI) and associate investigators (AI) for the registry at each site also act as ambassadors for the registry and promote participation within their site. Clinician participation forms are sent to all endocrine surgeons, outlining the project and inviting clinicians to participate in the registry.

The Monash University ANZTCR coordination centre is responsible for distributing the clinician participation forms to surgeons and collating signed forms prior to the recruitment of patients and data collection. This is a once-only process for clinicians and provides agreement by the surgeon to participate in the registry and enter data on all patients for whom they are listed as the diagnosing or treating clinician in participating hospitals and private practice.

Data Collection

Patient demographic and clinical data is submitted by sites primarily via direct data entry using REDCap, a secure web based database. Clinicians (or their data managers) are responsible for entering their patient data directly into the REDCap database. Opportunities to import data into the REDCap database from existing institutional databases are also being developed. Site staff are trained to use the database and are provided with a data entry manual to assist with good quality data collection. Data to be collected includes demographic and clinical data up to 90 days follow-up. ANZTCR staff will check case ascertainment periodically via each site's Health Information Services unit. The use of agreed definitions of the data elements ensures that the information collected is consistent and uniform, providing reliable and comparable data for analysis. A detailed data dictionary containing the data elements, formats, ranges and validation rules and definitions has been developed and will be maintained under document management with version control.

Minimum Data Set & Quality Indicators

To benchmark clinical care, clinical quality registries require systematic measurement at predefined intervals and the capacity to report back information to participating clinical units. A modified-Delphi approach, informed by international Thyroid Cancer Guidelines and relevant literature, was used to develop a set of thyroid cancer clinical indicators, the parameters of which are shown in Table 1. A detailed methodology of the modified-Delphi process will be published separately. Following the development of the clinical indicators, a minimum data set was developed that included variables relating to the indicators, variables required for patient identification and contact, and other variables of particular relevance to early thyroid cancer management. The selection of data fields and their definitions were derived from national data specifications such as Metadata Online Registry (METeOR) where they exist and from international thyroid cancer registry data dictionaries where terms are not

defined within the Australian context. Once a final list was generated it was then endorsed by the ANZTCR Steering Committee. Data items collected by the ANZTCR are outlined in Table 2.

Data Access Policy

Clinicians can access their own data through the registry database. Researchers may access registry data following approval by the ANZTCR Steering Committee and Ethics Committee as per the ANZTCR Data Access Policy (Supplementary Material). Monash's ANZTCR Coordinating Centre is the point of contact for matters relating to access to registry data.

Reporting

As per the 2008 ACSQHC Operating Principles, the ANZTCR will undergo a period of establishment and on-boarding of participating sites before the commencement of regular reporting. At the conclusion of approximately two years, the ANZTCR will be reviewed regarding its achievement against its aims and suitability for further rollout. Beyond two years and when sufficiently mature data is available, the ANZTCR is anticipated to produce a range of regular reports including: annual reports and benchmarked de-identified reports of clinical quality indicators (with identified data made available confidentially to participating sites).

Table 1. Framework of consensus set of clinical quality indicators

Ref. No.	Clinical Quality Indicator	
Preoperative		
CQI 1	Ultrasound (US)	Process
CQI 2	Fine Needle Aspiration (FNA)	Process
CQI 3	Voice Assessment	Process
Surgery		
CQI 4	Extent of Surgery	Process
CQI 5	Lymph Node Dissection	Process
Surgical Complications		
CQI 6	Recurrent Laryngeal Nerve (RLN) Palsy	Outcome
CQI 7	Hypoparathyroidism (Hypocalcaemia)	Outcome
CQI 8	Haemorrhage Requiring Return to Theatre	Outcome
Staging & Treatment Planning		
CQI 9	Postoperative TNM Staging	Process
CQI 10	Multi-disciplinary Team Meeting (MDM)	Process
Post-Surgical Treatment		

CQI 11	Completion Thyroidectomy	Process
CQI 12	Radioactive Iodine (RAI)	Process

Table 2. Data Items collected by the ANZTCR.

Recruitment	Patient Details	Preoperative	Procedure(s)	Postoperative	Treatment
• Patient ID • Given Name(s) • Surname • Date of Birth • Sex • Country • Street Address • Suburb • State/City • Postcode • Medical Record Number • Surgeon Name • Date of Diagnosis • Basis of Diagnosis • Disclosure of Diagnosis to Patient • Vital Status • Date of Death • Cause of Death	• Contact Number • Email Address • Country of Birth • Preferred Language • Interpreter Required • Aboriginal, Torres Strait Islander Status • Maori Status • Biobank Sample	• Presence of Comorbidities • Medication at Diagnosis • Thyroid Function at First Presentation • Neck Examination • Palpable Lymph Nodes • Family History of Thyroid Disease • Previous Exposure to Radiation • Previous Thyroid Surgery • Preoperative Imaging • Presence of Suspicious Lymph Nodes • Largest Thyroid Nodule Diameter • Fine-Needle Aspiration • Clinical Voice Abnormality • Preoperative Laryngeal Exam	• Date of procedure • Procedure Type • Indication for Procedure • Residual Tumour • Lymph Node Dissection • Lymph Node Dissection Intent • Lymph Node Dissection Levels • Recurrent Laryngeal Nerve • Nerve Integrity Monitor • Primary & Secondary TC Pathology • PTC, FTC, HCC Variants • Incidental Finding of Cancer • Thyroid Benign Pathology • Largest Tumour Diameter • Margin Status • Multifocal Cancer • Lymphovascular Invasion • Extrathyroidal Extension • Lymph Node Metastases • Distant Metastases • Distant Metastases Sites	• Surgical Complications • TNM Staging • Vitamin Supplementation • Genetic Testing	• Maximum Stimulated Tg (ug/L) • Maximum TgAb (U/ml) • Method of TSH Stimulation • Maximum Stimulated TSH (mU/L) • RAI Remnant Ablation (RRA) • Other Adjuvant Therapy

Discussion

Following its national establishment, the ANZTCR will monitor diagnosis, treatment and outcomes allowing for the identification of patterns of care and practices associated with better outcomes through improved compliance with best practice-based guidelines for the management of thyroid cancer. The registry will also be able to identify risk factors that predict favourable and unfavourable treatment outcomes, postoperative complications, and prognosis, leading to the stratification of treatments and follow up. The ANZTCR will highlight risks and benefits of specific approaches to thyroid cancer as well as establish international benchmarks in the routine management of thyroid cancer surgical care. Further, the ANZTCR provides a basis as a platform for longer-term clinical follow-up, sub-studies exploring treatment outcomes, and clinical trials. We believe that the ANZTCR through its accumulation of a significant thyroid cancer cohort will assist in identifying best practice management specifically in complex poor prognostic thyroid cancer cases of low incidence.

One of the key features of the ANZTCR is that it is a surgeon-based CQR, with surgeons entering their patient data directly into the ANZTCR-RCD. While there are a number of benefits to this structure, including reduced data collection costs related to hiring additional staff and subject specific training, there are also a number of potential challenges. One of the major challenges is surgeon engagement. However, due to the registry being funded by the Australian and New Zealand Endocrine Surgeons, a speciality society of endocrine surgeons, we have had high engagement during the establishment phase. In order to maintain this engagement we have circulated quarterly newsletters with updates on the registry and invited the surgeons to be involved in the development of the clinical quality indicators and minimum data set. Continual review and refinement of the dataset will ensure that the data collection burden is kept to a minimum. Additionally, the registry database allows surgeons to run site patient-level and aggregate data reports in real-time for use in clinical care. The registry will also provide surgeons with an 'ANZTCR Valued Contributor' logo for use on their email signature, letterhead and/or website, and has been approved as a clinical audit activity by the Royal Australian College of Surgeons (RACS) Continuing Professional Development (CPD) program.

Data from CQRs generally have strong external validity particularly with regard to generalisability and extrapolation of outcomes, however bias can exist (37), particularly due to the nature of the registry data being surgeon-derived. Initial quality assurance processes will include sample audits of participating surgeon records. In the future to ensure case ascertainment, the ANZTCR could potentially receive monthly data extracts from participating site Health Information Services (HIS) or the Victorian Cancer Registry (VCR), pending approval. As the registry expands it will also consider recruiting non specialist endocrine surgeons who undertake thyroid cancer surgery including head and neck surgeons.

In order to commence patient recruitment the registry needs to seek ethics approval and governance authorisation at the participating site. As CQRs are becoming more common, standard guidelines have been introduced to make the ethics process more manageable. In particular, the National Mutual Acceptance (NMA) scheme has streamlined ethics for all public hospitals in all states except Tasmania (and the Northern Territory). Private hospitals can still choose to participate through the NMA scheme. Nevertheless, the process of obtaining site governance approval remains both time consuming and labour intensive (38, 39). Finally, perhaps the most important challenge faced by CQRs include ongoing funding to ensure their sustainability. Currently the ANZTCR has enough funding to support the registry during the initial pilot phase, however in order to progress to national rollout and implement longer-

term clinical follow-up and patient-reported outcomes additional funding is required. This is particularly relevant as lengthy follow-up is required to ascertain outcomes relating to recurrence (30, 40). Nevertheless, given the benefits to patients, clinicians and wider stakeholders, and high level of clinician engagement, we are optimistic that in time these benefits will be realised.

Future Directions

The registry is currently in a pilot phase to assess feasibility and clinician acceptability. The long-term aims of the registry, following conclusion of the pilot and dependant on funding, are to include longer-term follow-up data from patients, multidisciplinary clinicians and data linkage, with a focus on cancer survivorship issues and the management of poorer prognostic and recurrent cancers.

References

1. Western Australian Cancer Registry. Cancer incidence and mortality in Western Australia. In: Data Integrity Directorate PaSPD, editor. Perth Western Australia,: Department of Health,; 2014.
2. Australian Government. Cancer in Australia: an overview, 2012. In: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries, editors. Canberra: AIHW; 2012.
3. Australian Government. Australian Cancer Database (ACD). In: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries, editors. Canberra: AIHW; 2011.
4. New Zealand Cancer Registry (NZCR). Cancer Data and Stats. In: Health Mo, editor. Wellington: New Zealand Government; 2017.
5. Australian Government. National Mortality Database (NMD). In: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries, editors. Canberra: AIHW; 2011.
6. Jemal A, Ward EM, Johnson CJ, Cronin KA, Ma J, Ryerson AB, et al. Annual report to the nation on the status of cancer, 1975–2014, featuring survival. JNCI: Journal of the National Cancer Institute. 2017;109(9).
7. Husson O, Haak HR, Mols F, Nieuwenhuijzen GA, Nieuwlaat WA, Reemst PH, et al. Development of a disease-specific health-related quality of life questionnaire (THYCA-QoL) for thyroid cancer survivors. Acta Oncologica. 2013;52:447–54.
8. Mendoza A, Shaffer B, Karakla D, Mason EM, Elkins D, Goffman TE. Quality of life with well-differentiated thyroid cancer: Treatment toxicities and their reduction. . Thyroid. 2004;14:133 – 40.
9. Lee JC, Breen D, Scott A, Grodski S, Yeung M, Johnson W, et al. Quantitative study of voice dysfunction after thyroidectomy. Surgery. 2016;160(6):1576-81.
10. Serpell JW, Lee JC, Yeung MJ, Grodski S, Johnson W, Bailey M. Differential recurrent laryngeal nerve palsy rates after thyroidectomy. . Surgery. 2014;156(5):1157-66.
11. Hayward NJ, Grodski S, Yeung M, Johnson WR, Serpell J. Recurrent laryngeal nerve injury in thyroid surgery: a review. ANZ journal of surgery. 2013;83(1-2):15-21.
12. Serpell JW. Preventing hypoparathyroidism after total thyroidectomy. ANZ journal of surgery. 2018;88(3):127-8.
13. Lee JC, Chang P, Grodski S, Yeung M, Johnson W, Serpell J. Temporal analysis of thyroid cancer management in a Melbourne tertiary centre. ANZ journal of surgery. 2016.
14. Nixon IJ, Whitcher MM, Palmer FL, Tuttle RM, Shaha AR, Shah JP, et al. The impact of distant metastases at presentation on prognosis in patients with differentiated carcinoma of the thyroid gland. Thyroid. 2012;22(9):884-9.
15. Hall SF, Irish JC, Groome PA, Urbach DR. Practice patterns in the management of patients with differentiated thyroid cancer in Ontario Canada 2000-2008. Journal of Otolaryngology-Head & Neck Surgery. 2014;43(1):29.

16. Tasevski R. Management Patterns and Outcomes of Differentiated Thyroid Cancer in Ontario: A Population-based Study. (Doctoral dissertation). 2013.
17. Cobin RH, Gharib H, Bergman DA, Clark OH, Cooper DS, Daniels GH, et al. AACE/AAES medical/surgical guidelines for clinical practice: management of thyroid carcinoma. American Association of Clinical Endocrinologists. American College of Endocrinology. Endocrine practice: official journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists. 2001;7(3):202.
18. Pacini F, Schlumberger M, Dralle H, Elisei R, Smit JW, Wiersinga W. European consensus for the management of patients with differentiated thyroid carcinoma of the follicular epithelium. . European journal of endocrinology. 2006;154(6):787-803.
19. Perros P, Colley S, Boelaert K, Evans C, Evans RM, Gerrard GE, et al. British Thyroid Association Guidelines for the Management of Thyroid Cancer. Third Edition. Clinical Endocrinology. 2014;81(Suppl. 1):1-122.
20. Cameron PA, Gabbe BJ, McNeil JJ, Finch CF, Smith KL, Cooper DJ, et al. The trauma registry as a statewide quality improvement tool. Journal of Trauma and Acute Care Surgery. 2005;59(6):1469-76.
21. Australasian Society of Cardiac and Thoracic Surgeons Database Project Steering Committee. Victorian Cardiac Surgery Database Project.
22. Australia and New Zealand Dialysis and Transplant Association (ANZDATA). Australia and New Zealand Dialysis and Transplant Registry [Web Page] [Available from: http://www.anzdata.org.au/.
23. Malycha P, Tyson S. National breast surgery audit. Australian and New Zealand Journal of Surgery. 2000;70(12):834-6.
24. Poelemeijer YQ, Liem RS, Nienhuijs SW. A Dutch Nationwide Bariatric Quality Registry: DATO. Obesity surgery. 2017:1-9.
25. Graves SE, Davidson D, Ingerson L, Ryan P, Griffith EC, McDermott BF, et al. The Australian orthopaedic association national joint replacement registry. Medical Journal of Australia. 2004;180(5):S31.
26. Cancer Institute NSW. NSW Clinical Cancer Registry [Web Page] [Available from: http://www.cancerinstitute.org.au/cancer_inst/programs/registryccr.html.
27. Sweden E. Handbook for Establishing Quality Registries. Karlskrona: Eyenet Sweden. 2005.
28. Australian Commission on Safety and Quality in Health Care. Information Strategy. Sydney: ACSQHC; 2007.
29. Londero SC, Mathiesen JS, Krogdahl A, Bastholt L, Overgaard J, Bentsen J, et al. Completeness and validity in a national clinical thyroid cancer database: DATHYRCA. Cancer epidemiology. 2014;38(5):633-7.
30. Mehra S, Tuttle RM, Milas M, Orloff L, Bergman D, Bernet V, et al. Database and registry research in thyroid cancer: striving for a new and improved national thyroid cancer database. Thyroid. 2015;25(2):157-68.
31. Haugen BR, Alexander EK, Bible KC, Doherty GM, Mandel SJ, Nikiforov YE, et al. 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid. 2016;26(1):1-133.
32. Australian Commission on Safety and Quality in Health Care. Operating Principles and Technical Standards for Australian Clinical Quality Registries [Web Page] [Available from: http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/EA520128CB313DE9CA2573AF007BC590/$File/OP_TS-Nov2008.pdf.
33. Tu JV, Willison DJ, Silver FL, Fang J, Richards JA, Laupacis A, et al. Impracticability of informed consent in the Registry of the Canadian Stroke Network. New England Journal of Medicine. 2004;350(14):1414-21.

34. Cancer Council of Victoria. Cancer Council of Victoria Registry & Statistics 2013 [Available from: http://www.cancervic.org.au/research/registry-statistics.
35. Junghans C, Jones M. Consent bias in research: how to avoid it. Heart. 2007;93(9):1024-5.
36. Buckley B, Murphy AW, Byrne M, Glynn L. Selection bias resulting from the requirement for prior consent in observational research: a community cohort of people with ischaemic heart disease. Heart. 2007;93(9):1116-20.
37. Stub D, Lefkovits J, Brennan AL, Dinh D, Brien R, Duffy SJ, et al. The Establishment of the Victorian Cardiac Outcomes Registry (VCOR): Monitoring and Optimising Outcomes for Cardiac Patients in Victoria. Heart, Lung and Circulation. 2018;27:451-63.
38. Clay-Williams R, Taylor N, Braithwaite J. Potential solutions to improve the governance of multi centre health service research. MJA. 2018;208(4):152-4.
39. Brown WA, Smith BR, Boglis M, Brown DL, Anderson M, O'Brien PE, et al. Streamlining ethics review for multisite quality and safety initiatives: national bariatric surgery registry experience. Med J Aust. 2016;205(200-1).
40. Pearce EN, Lee SL, Weiss R, Magner J, Garber JR, Campion FX, et al. Unique obstacles to establishing thyroid cancer registries. Journal of clinical & translational endocrinology. 2016;3:12-3.

List of Figures

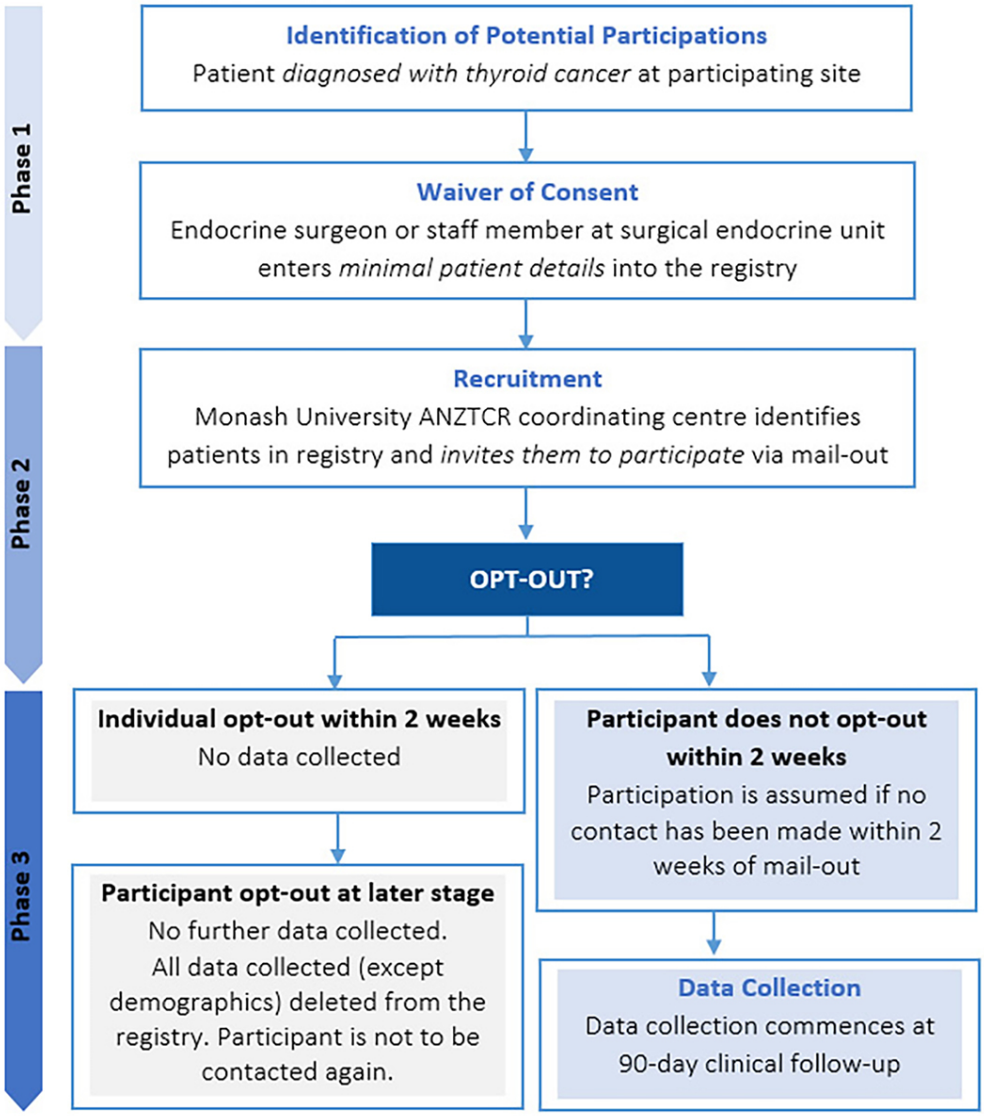

Figure 1. Patient Recruitment Framework

90x102mm (300 x 300 DPI)

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DATA ACCESS POLICY

Version: 1
Date: 26 August 2018

Monash University
School of Public and Preventive Medicine
Faculty of Medicine, Nursing and Health Sciences

Statement of Compliance
This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007), Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ASCSQH Operating Principles and technical standards for Australian Clinical Quality Registries, University research policies and procedures and federal laws governing privacy and confidentiality.

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MONASH University

ANZTCR COORDINATING CENTRE CONTACT DETAILS

Address: Australian & New Zealand Thyroid Cancer Registry
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DOCUMENT VERSION CONTROL

Version	Date	Reason/Comments/Approvals
1.0	21.08.2017	Initial Version Release. Proposed to ANZTCR SC on 25.07.17

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

CONTENTS

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

This document describes the Australian & New Zealand Thyroid Cancer Registry (ANZTCR) guidelines and policies for governing the release of information for research purposes.

1. PREFACE

The Australian & New Zealand Thyroid Cancer Registry (ANZTCR) encourages the use of its data for a variety of purposes such as quality improvement, research, clinical planning and other activities that may lead to an improvement in care to patients with thyroid cancer. The ANZTCR will only facilitate access to its data for projects that meet appropriate standards of scientific merit and public health importance as determined by the Management and/or Steering Committee. This data access policy defines how data from the ANZTCR may be accessed. The policy includes the criteria and conditions for provision of de-identified individual level data, aggregate data, reports or analyses; and procedures for data request applications. It also outlines the cases in which fees for such access might be applicable, and any associated acknowledgement and publishing responsibilities.

Data collected and collated by ANZTCR is guided by strict protocols and procedures to ensure the security, privacy and confidentiality of all information collected and stored in the registry. All patient and stakeholder information will be handled in accordance with the Commonwealth Privacy Act (1988), the Privacy and Data Protection Act 2014 (Vic) and the Health Records Act 2001 (Vic), similar relevant interstate legislation, and any code of practice or guidelines made under these Acts.

All registry activities have been approved by a National Health Medical Research Council (NHMRC) approved Human Research Ethics Committee (HREC) and other participating site and Monash University Human Research Ethics Committees.

The University Privacy Compliance Framework is available at www.privacy.monash.edu.au.

2. PROJECT INFORMATION

2.1 PURPOSE OF ANZTCR

The Australian & New Zealand Thyroid Cancer Registry (ANZTCR) was developed by the Monash University Breast Endocrine Surgery (BES) Unit in collaboration with the Registry Sciences Unit (RSU). The ANZTCR is a clinical quality registry collecting data on patients diagnosed with thyroid cancer at participating health service sites in Australia to inform best-practice guidelines as well as benchmark performance in Australia with data from comparable international registries.

2.2 PROJECT OVERVIEW

The registry collects data relating to the patient's first presentation, preoperative investigations, cancer diagnosis and surgery, as well as adjuvant treatment and follow-up care up to 90 days post-diagnosis. Data is collected from patient medical records at diagnosis (1-2 weeks post-surgery) and 90 days post-diagnosis (follow-up data).

The registry allows comparison of high quality information, which can be used to develop criteria and procedures to evaluate and improve patient quality of care. Data is analysed to identify which treatments are more successful than others and compare thyroid cancer services across Australia. This will lead to improvement in patient quality of care and thyroid cancer services in the future.

Information held by the registry is used by the ANZTCR in two different ways. The data will be used to monitor:

- Performance of quality of thyroid cancer patient care in Australia;
- Performance of the Australian & New Zealand Thyroid Cancer Registry in collecting data about quality of thyroid cancer outcomes.

3. DEFINITIONS

Management Committee - The ANZTCR Management Committee is responsible for overseeing the daily operations of the registry. The Committee ensures data collection and data quality processes function effectively and complies with ethics committee regulations, legislation and registry policies.

Steering Committee - The ANZTCR Steering Committee is an independent entity which maintains governance and overall management of the ANZTCR. The Steering Committee develops and reviews policies and publications arising from the registry data.

Human Research Ethics Committee (HREC) - HRECs protect the welfare and rights of participants involved in research and they review proposals for research that involves humans. They monitor the conduct of research and deal with complaints that arise from research. Research projects requesting identifiable data and/or intending to contact patients must obtain approval from a National Health and Research Council (NHMRC) registered HREC.

Confidential Data - ANZTCR is responsible for protecting the data from unauthorised access and release by maintaining strict standards of confidentiality. Data that identifies or potentially identifies an individual patient, health care provider, institution or a caseload of a provider or reporting institution is considered propriety and confidential.

Identifiable Data – Data that contains individual identifiers making it possible to identify a specific individual.

Non-identifiable Data - Data that has never been labeled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data may be linked with other data so it can be known they are about the same data subject, although the individual's identity remains unknown.

Re-identifiable Data - Data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.

Disclose or Disclosure - The communication of any ANZTCR information to any individual or organisation other than to the researcher or the ANZTCR.

Research Project - A scientific investigation that has been reviewed by ANZTCR Management Committee.

Researcher - The principal investigator of a research project (as defined above) or the individual requesting data from the ANZTCR.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

4. ACCESS TO DATA HELD BY ANZTCR

ANZTCR data is hosted on a REDCap server that is managed by Monash University. Access to data is subject to applicable privacy laws and principles, and ethics approvals. Specific measures have been put in place to maintain the confidentiality of personal identifying information at the patient and hospital level.

Data access is generally subject to the approval of the ANZTCR Steering Committee. When considering the approval of access to ANZTCR data, the ANZTCR Steering Committee will consider whether the project satisfies the principles of research merit and integrity.

Access to the data is subject to the Data Access Request Process outlined in section 5.

4.1 ELIGIBLE APPLICANTS

Researchers, medical professionals and pharmaceutical professionals working at research institutions, hospitals, private entities, government or other health services within Australia and industry are eligible to request access to data held within the registry. All requests for data are noted in the ANZTCR Steering Committee minutes and logged.

4.2 ACCESS TO ANZTCR DATA

1. Staff who report directly to the ANZTCR Data Custodian will have direct access to the database and for operational purposes Monash University IT staff, directly involved in supporting registry systems have access for upgrades and break fixes, and are bound by Monash University confidentiality agreements.

2. All uses of ANZTCR data, in whatever context, must receive prior approval from the ANZTCR Steering Committee unless a pre-existing funding agreement is in place and has been previously approved by the ANZTCR Steering Committee. Research related requests may require specific ethics committee approval. Use of data for any other purpose will require an additional request.

3. Data access may be subject to conditions in agreements and/or research ethics approvals.

4. Under no circumstances will individually identifiable data in respect to patients, contributing clinicians, or hospitals be made available to parties other than the ANZTCR Steering Committee, authorised ANZTCR personnel, and members of any working group directed by and reporting to the Steering Committee during the course of incident, complaint or outlier management. Requests for ANZTCR data which may potentially identify a cancer patient, their physicians, or institutions involved in the patient's diagnosis and/or treatment, and all research projects which require contact with cancer patients require ethics approval and full review from ANZTCR Management Committee.

5. The ANZTCR will not release participant contact details or identifiable data that can be linked with other data. All contact with registered patients must be conducted by the ANZTCR through the Coordinating Centre. The cost of making such contact is to be borne by the researcher/s requesting the contact.

6. If a third party research or student project requires individually identifiable data for linkage or further research, this cannot be provided by ANZTCR directly. Following ethics approval, sign off by involved Centre Directors or site Principal Investigators and ANZTCR Steering Committee approval, ANZTCR

will provide the required data to the site/s involved to forward the data and patient identifying keys to the third party or student.

7. The ANZTCR will only release data of a sufficiently high level of quality and will release the least sensitive level of data that is practicable in order to fulfil the uses identified in the research proposal submitted with the data request. Tabulated aggregate data with a cell count less than 5 will be suppressed to prevent re-identification of an individual patient, physician or organisation.

8. Where only basic summary data available through public reports is requested, this can be provided by the ANZTCR Coordinating Centre without Steering Committee approval.

9. ANZTCR encourages the independent access of clinician data available through the ANZTCR REDCap Database, however should a contributing clinician request access to their own patient data ANZTCR will provide this. All requests for this category of data should be made in writing to the ANZTCR Management Committee (**Appendix B**).

10. If a hospital executive makes a specific request for its own performance data, ANZTCR will provide this information. Identification of a clinician will not be provided without the written permission of the Centre Director/Principal Investigator. All requests for this category of data should be made in writing to the ANZTCR Data Custodian (**Appendix B**). Such data requests will require Steering Committee approval.

11. For requests from industry, comparative information i.e. market share will not be provided.

12. All requests for access to the ANZTCR data are undertaken in addition to routine ANZTCR workload. As a general rule, following submission of the request form, review by the ANZTCR steering committee will occur within 4 weeks. Requests involving reports or analysis will be provided with a quote and expected time frame for completion. Most data access requests will generally be provided within 2-6 weeks following Steering Committee approval.

13. Requests must be first made to the ANZTCR Management Committee at Monash University who will either table the request at the next ANZTCR Steering Committee meeting or, in some circumstances where the data is required earlier the ANZTCR Management Committee, may circulate the request for out of session approval. Data cannot be extracted until approval is given and relevant ethics approval from participating institutions are in place.

14. All data must only be used for the purposes outlined in the written request, and approved by the Steering Committee. The researcher may only use registry information for the specified research project. If the researcher wants to use registry information for another research project, he/she must first obtain the appropriate approval for the research project. The researcher, and any individual working on the research project, may not disclose registry information to others without the prior written consent of ANZTCR. Moreover, the cancer case information may not be reproduced in any form except for internal use or with prior written consent from the ANZTCR.

15. No data may be passed onto other researchers, clinicians or any other person/entity not explicitly mentioned in the written data request.

16. ANZTCR coordinating centre will perform record-linking tasks at the ANZTCR whenever feasibly possible. Researchers may provide identified data to the registry, and the ANZTCR will return medical

information on records that were found to link. If the research project has the patient's informed consent, then linkage projects will be reviewed by the Management and/or Steering Committee.

17. Requests for access to data must comply with the National Statement on Ethical Conduct in Human Research (2007). Following ethics approval and data access sign off by the ANZTCR Steering Committee, de-identified data will be provided by secure file transfer. Following transfer, security and storage of the data provided will be the responsibility of the requester in accordance with good research practice guidelines.

18. Requests must be made in accordance with the data access policy and provide full disclosure in the request form for proposed access and usage of the data. Data access and usage must comply with all conditions in the approval given for data access.

19. Patient requests for data access to their information will be managed by the Registry Coordinator. Patients will need to provide identifying information prior to data release. (**Appendix C**)

20. If a research project continues beyond the original termination date stated in the proposal, the researcher must notify the ANZTCR in writing of the new termination date, submit corresponding approvals from an ethics committee, and obtain approval in accordance with Section 4.2 (Request for Patient Identifiable Data).

5. REQUESTING DATA

5.1 DATA ACCESS REQUEST PROCESS

1. All data requests must be formally lodged using the relevant Data Request Application Form (**Appendix A** or **Appendix B**) via email, post or fax to:

   Email: SPHPM.ANZTCR@monash.edu

   Post: Dr Liane Ioannou
   Australian & New Zealand Thyroid Cancer Registry
   553 St Kilda Road
   Melbourne, 3004

Upon receipt of the completed and signed form, the ANZTCR Management Committee will present the data request to the Steering Committee at the next scheduled meeting if required under Section 3.2. Meetings are held four times per year.

2. There are three possible outcomes of the data access request. The data access request may be approved; approved subject to amendment; or declined. If the application is declined, a major revision and subsequent resubmission will be required. Approval subject to minor revision will not require a full resubmission. An out of session review of the changes will be organised.

3. Upon approval, the ANZTCR Management Committee will provide a statement of the conditions of its use with a cost estimate if applicable.

   a. The researcher signs the Research Agreement (**Appendix D**).

   b. All project personnel who have access to the confidential data sign the Confidentiality Agreement (**Appendix E**).

c. The Data Custodian releases the data to the researcher.

5.2 REQUEST FOR NON-IDENTIFIABLE DATA

Aggregate data such as incidence, mortality rates and frequencies may be released provided that such disclosure does not include sufficient information that would allow the researcher to identify an individual or organisation. This may include masking cell sizes less than 5 for tabulated data.

The ANZTCR may release non-identifiable tumour-level data, which can include details about the tumour and treatment information. Patient demographic information will not be released and the tumour data will not be identifiable.

The ANZTCR will not release patient contact details.

The researcher must indicate their request for *Non-Identifiable Data* on the Data Request Application Form (**Appendix A**) and submit the application to the ANZTCR Management Committee.

5.3 REQUEST FOR PATIENT RE-IDENTIFIABLE OR DE-IDENTIFIABLE DATA

The ANZTCR will generally not release patient identifiable data.

Hospitals and clinicians may request re-identifiable data for cases reported by their own institution or practice. All patient identifiers are removed and replaced with a code.

The researcher must discuss the approval process with a representative from the Management Committee, including the terms and conditions of the Research Agreement (**Appendix D**) to be signed by the researcher, provisions regarding maintenance of confidentiality, patient contact, and sanctions for violating these provisions.

The researcher must indicate their request for *Re-Identifiable or De-Identified Data* on the Data Request Application Form (**Appendix A**) and submit the application, in addition to their ethics application and letter of ethics approval, to the ANZTCR Management Committee.

It is a requirement of the ANZTCR Management Committee that applications for the release of data for research purposes are submitted and reviewed by a HREC. Section 95A of the Privacy Act 1988 allows the Management Committee to request researchers to submit a proposal to a HREC even if it has received written notification of ethics committee approval from the investigator's institution.

5.4 PATIENT REQUEST FOR DATA ACCESS

Patient requesting access to their data held on the ANZTCR will be required to complete a Data Request Application Form (**Appendix C**) which will be available from the ANZTCR Management Committee. Upon receipt of the completed form the, the ANZTCR coordinator will:

1. Telephone the patient to confirm that they have requested their details
2. Advise the patient that their information will be sent by registered post to the address recorded on their proof of identify documents.

6. DATA SECURITY FOR PATIENT IDENTIFIABLE INFORMATION

The following restrictions apply to the use of confidential information:

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

Maintenance and Storage of Data by Researcher

Patient identifiable data must be encrypted or kept separate from medical data stored by the researcher. This separation applies for data kept in paper format or on a computer. The medical data will not be identified except by an identifying number with no meaning in any data set other than the researcher's or ANZTCR. The patient identifiable cancer case information will not be attributed to a source that identifies the nature of the records. Identifiable data stored on a computer network must be secured from unauthorised network access by the most effective means that are technically available. If confidential information is lost, it will be reported to the ANZTCR Office and the approving Human Research Ethics Committee.

Penalties for Violations

In addition to terminating the agreement for a violation of this policy, the ANZTCR may impose sanctions on the researcher. Individuals who have witnessed inappropriate use of ANZTCR data or a breach in confidentiality may report violations to the ANZTCR. The ANZTCR recognises that violations may occur to various degrees, however, in all cases the Management Committee will be notified immediately and the research project will be suspended for a minimum of 30 days. During that time, the Management Committee will meet to discuss the magnitude of the violation and the steps needed to rectify the infraction(s). The Management Committee will also determine if the violation(s) should be reported to the proper authorities, including the HREC.

7. PUBLICATION

Any material or manuscript to be published using ANZTCR data must be submitted for review by the ANZTCR Steering Committee prior to release for publication. ANZTCR will have thirty (30) days after receipt of the draft publication to request in writing the removal of any portions of the publication deemed by ANZTCR to inappropriately disclose patient identifiable cancer case information. Upon receipt of such request from ANZTCR, the researcher and ANZTCR will attempt, in good faith, to agree upon the modifications or revisions to the draft publication, which are reasonably necessary to protect the privacy of the subjects of the cancer case information. In no event, however, will the researcher publish identifiable cancer case information.

It must contain appropriate acknowledgement of ANZTCR. Preferred wording for the acknowledgement will be provided with the data. If the data is the primary source for a report or publication, the source of the data must be acknowledged, along with a statement that the analysis and interpretation are those of the author, not the registry. Where a research collaborator has analysed data, ANZTCR, Monash University should be acknowledged as a secondary institution. Where the author is a registry staff member, then the primary attribution should be ANZTCR, Monash University. ANZTCR reserves the right to dissociate itself from conclusions drawn if it deems necessary.

Authorship may be required when ANZTCR makes substantial contribution to the data. Copies of all published abstracts, presentations, and papers that result from the study should be sent to the ANZTCR Management Committee.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

8. DATA ITEMS

The ANZTCR Management Committee will provide a list of available data items upon request. It is the policy of ANZTCR that certain data elements are not released under any circumstances.

9. FORMS

The form(s) that must be completed for each data request will vary depending on whether the applicant is a researcher, non-researcher or patient. The forms may be obtained from the ANZTCR Management Committee.

The forms are as follows:

9.1 DATA REQUEST FORMS

1. Request Access to Data - Researcher Form (**Appendix A**). This form should be used for all research-related requests.
2. Request Access to Data – Non-Researcher Form (**Appendix B**). This form should be used for non-research purposes.
3. Request Access to Data – Patient Form (**Appendix C**). This form should be used for patients who would like access to information.
4. Research Agreement (**Appendix D**). This agreement must be signed by the researcher who has been approved to have identifiable information.
5. Confidentiality Agreement (**Appendix E**). Although the Principle Investigator is responsible for assuring that the data are kept confidential, all study staff with access to identifiable ANZTCR data are required to sign a confidentiality agreement. These signed agreements will be kept on file at the ANZTCR.

10. FEES

The ANZTCR does not receive any funding to perform non-routine adhoc data analysis. Therefore, provision of data may be subject to a fee-for-service on a cost recovery basis unless in line with existing funding agreements or MOUs between registry funders/supporters. Fees will be at the discretion of the ANZTCR Steering Committee in consultation with the ANZTCR Management Committee and will be based on the complexity and estimated time taken to complete the request as well as current ANZTCR routine workload. Please see the Data Access Fee Schedule for an explanation of these.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

APPENDIX A:
DATA ACCESS REQUEST – RESEARCHER FORM

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST - RESEARCHER

Please return your application via email or post using the details below:

Australian & New Zealand Thyroid Cancer Registry
533 St Kilda Rd
Melbourne, VIC 3004
Email: SPHPM.ANZTCR@monash.edu
Phone: (03) 9903 0046

PART A: RESEARCHER'S DETAILS

Date of Request: _____

Date required by: _____

Organisation	☐ Research/Academic Institution ☐ Government Department or Agency ☐ Hospital Industry: ☐ Pharmaceutical ☐ Private Health Insurance ☐ Device ☐ Other, *specify* ..... ☐ Professional Medical Organisation ☐ Other *(please specify)*.....		
Short title of data request:			
Principal Investigator :		**Title:**	
Position:			
Affiliation/Organisation:			
Address:			

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

Telephone:			
Email:			
Other Investigators: (add additional lines for each investigator)		**Title:**	
Are you a student?	☐ Yes ☐ No		
If YES, what degree are you working towards?			
Name and contact details of your supervisor			
Is this a funded research project?	☐ Yes ☐ No		
If YES, who has funded the project?			
Was the ANZTCR formally involved in the grant application?			
Does your project require Human Research Ethics committee (HREC) approval?	☐ Yes ☐ No	**If NO,** proceed to PART B	
If YES have you applied for HREC approval?	☐ Yes ☐ No		
If YES which organisation's HREC did you apply to?	_____		
Have you received HREC approval?	☐ Yes ☐ No	**If YES,** please attach a copy of your approval certificate/s, a full copy of your application and any other relevant documents	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

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PART B: PROJECT DETAILS

Reason for data request. Please note that approval will only be given for the project described in this application. Use of data for any other purpose will require an **additional** request.

Type of data request	☐ De-identified patient level data ☐ Aggregated/summary data ☐ Report/Analysis ☐ Data linkage ☐ Other, specify ……
Title of project	
Background and rationale for the project (500 word maximum plus key references)	
Hypothesis and specific research questions	
Possible outcomes and clinical significance of this research (250 word maximum)	
Methodology of project (500 word maximum)	
Inclusion and Exclusion criteria	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART C: DATA FIELDS REQUIRED

An ANZTCR minimum dataset containing available data fields can be requested. ANZTCR is required to maintain patient privacy. No data will be released that could potentially identify patients, clinicians or hospitals.

Data item required	Justification

PART D: RESEARCHER'S SIGNATURE

I CERTIFY THAT I HAVE READ AND UNDERSTOOD THE ANZTCR DATA ACCESS POLICY. I AGREE TO COMPLY WITH THAT POLICY.
I AGREE TO UNDERTAKE ALL ACTIVITIES DESCRIBED IN THIS REQUEST IN ACCORDANCE WITH THE RESEARCH PROPOSAL, RESEARCH APPROVAL OF THE REVIEWING HUMAN RESEARCH ETHICS COMMITTEE (HREC) AND ALL RELEVANT STATE AND COMMONWEALTH PRIVACY LEGISLATION RELATING TO PATIENT INFORMATION AND HEALTH RECORDS.
I AGREE TO ADHERE TO ALL OF THE CONDITIONS PLACED ON USE AND STORAGE OF THE DATA AS OUTLINED IN ANY ANZTCR DATA ACCESS APPROVAL THAT WILL BE PROVIDED TO ME PRIOR TO COMMENCEMENT OF ANY RESEARCH ACTIVITY,DATA ANALYSIS OR REPORT.
I AGREE THAT THE INFORMATION PROVIDED BY ME TO ANZTCR IS TRUE, ACCURATE, COMPLETE AND WITHOUT MATERIAL OMISSION.
I AGREE THAT INFORMATON PROVIDED WILL NOT BE USED FOR ANY PURPOSE OTHER THAN DESCRIBED IN THE REQUEST FORM.
I AGREE THAT INFORMATION WILL NOT BE DISCLOSED TO ENTITIES OTHER THAT THOSE DESCRIBED IN THE REQUEST FORM.
I AGREE TO PROVIDE MONASH UNIVERSITY WITH A COPY OF ANY FINAL REPORT FOR REVIEW PRIOR TO PUBLISHING AND WILL ANZTCR AS THE DATA SOURCE AND WHERE APPLICABLE, MONASH UNIVERSTY AS HAVING UNDERGONE THE ANALYSIS OR COLLATED THE REPORT.
I ALSO AGREE THAT THE INFORMATION PROVIDED TO ME BY ANZTCR, WHETHER IN THE FORM OF DATA, REPORTS, MODELS, SAMPLES AND REGARDLESS OF HOW COMMUNICATED OR RECORDED, IS CONFIDENTIAL AND CONFIDENTIALITY OF ALL INFORMATION AND COMMUNICATIONS WILL BE MAINTAINED UNLESS OTHERWISE AGREED BY BOTH PARTIES.

Name: _____

Signature _____

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST - RESEARCHER

FOR OFFICE USE ONLY:

Short Title of Data Access Request: _____ _____	
ANZTCR Steering Committee decision (or delegate)	☐ Approved ☐ Approved – Subject to amendment ☐ Declined
If approved, subject to amendment, please list required changes	
Approved by ANZTCR Steering Committee Chairperson (or delegate): Signature: _____ Date of approval: _____	

AUSTRALIAN & NEW ZEALAND
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APPENDIX B:
DATA ACCESS REQUEST – NON-RESEARCHER FORM

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST – NON-RESEARCHER

Please return your application via email or post using the details below:

Australian & New Zealand Thyroid Cancer Registry
533 St Kilda Rd
Melbourne, VIC 3004
Email: SPHPM.ANZTCR@monash.edu
Phone: (03) 9903 0046

PART A: APPLICANT'S DETAILS

Date of Request: _____

Date required by: _____

Organisation	☐ Research/Academic Institution ☐ Government Department or Agency ☐ Hospital Industry: ☐ Pharmaceutical ☐ Private Health Insurance ☐ Device ☐ Other, *specify* ……. ☐ Professional Medical Organisation ☐ Other *(please specify)*……		
Authorised requester's name		**Title**	
Position			
Organisation:			
Address:			
Telephone:			
Email:			

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART B: PROJECT DETAILS

Please note that approval will only be given for the use described in this application. Use of data for any other purpose will require an **additional** request. This information will be reviewed by a committee and may incur a fee depending on the complexity of the request.

Request Title	
Type of data request	☐ Aggregated data/summary data ☐ Report/Analysis
Purpose of the request	
What question/s need to be answered by the information requested	
Description of the type of information required. (Please include the subpopulation, and cross tabulation of the variables of interest required)	
Reference period for the data of interest	
Possible outcomes and potential uses of this request	
Name all entities that the information requested will be disclosed to	☐ Internal use only ☐ Government department/agency, specify…… ☐ Other organisation, specify……
If this request is to be used to support an application for regulatory approval and are there potential implications for the registry? E.g. additional data items to be collected etc.	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART C: DATA FIELDS REQUIRED

An ANZTCR minimum dataset containing available data fields can be requested to ensure the information you require is utilised when requesting a summary report. ANZTCR is required to maintain patient privacy. No data will be released that could potentially identify patients, clinicians or hospitals.

Data item required	Justification

PART D: APPLICANT'S SIGNATURE

I CERTIFY THAT I HAVE READ AND UNDERSTOOD THE ANZTCR DATA ACCESS POLICY AND I AGREE TO COMPLY WITH THAT POLICY. I AGREE TO UNDERTAKE THE ACTIVITIES DESCRIBED IN THIS REQUEST IN ACCORDANCE WITH THE AGREED USE.
I AGREE THAT ANY INFORMATION PROVIDED WILL NOT BE USED FOR ANY PURPOSE OTHER THAN DESCRIBED IN THE REQUEST FORM
I AGREE THAT INFORMATION WILL NOT BE DISCLOSED TO ENTITIES OTHER THAT THOSE DESCRIBED IN THE REQUEST FORM.
I AGREE TO PROVIDE MONASH UNIVERSITY WITH A COPY OF ANY FINAL REPORT FOR REVIEW PRIOR TO PUBLISHING IF REQUESTED AND WILL ACKNOWLEDGE ANZTCR AS THE DATA SOURCE AND WHERE APPLICABLE, MONASH UNIVERSTY AS HAVING UNDERGONE THE ANALYSIS OR COLLATED THE REPORT.I AGREE THAT THE INFORMATION PROVIDED BY ME TO ANZTCR IS TRUE, ACCURATE, COMPLETE AND WITHOUT MATERIAL OMISSION.I ALSO AGREE THAT THE INFORMATION PROVIDED TO ME BY ANZTCR, REGARDLESS OF HOW COMMUNICATED OR RECORDED, IS CONFIDENTIAL AND CONFIDENTIALITY OF ALL INFORMATION AND COMMUNICATIONS WILL BE MAINTAINED UNLESS OTHERWISE AGREED BY BOTH PARTIES.

Name: _____

Signature _____

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST – NON-RESEARCHER

FOR OFFICE USE ONLY:

Short Title of Data Access Request:_____ _____	
ANZTCR Steering Committee (or delegate) decision	☐ Approved ☐ Approved – Subject to amendment ☐ Declined
If approved, subject to amendment, list required changes	
Approved by ANZTCR Steering Committee Chairperson (or delegate): Signature:_____ Date of approval: _____	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

APPENDIX C:
DATA ACCESS REQUEST – PATIENT FORM

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST – PATIENT

Please return your application via email or post using the details below:

Australian & New Zealand Thyroid Cancer Registry
533 St Kilda Rd
Melbourne, VIC 3004
Email: SPHPM.ANZTCR@monash.edu
Phone: (03) 9903 0046

PART A: PATIENT DETAILS

Date of Request: _____

Date required by: _____

A certified copy of **proof of identity** is supplied as follows: (please tick x boxes) NEEDS TO DISPLAY NAME & ADDRESS AT TIME OF SURGERY	☐ Birth Certificate ☐ Passport ☐ Certificate of Australian Citizenship ☐ Medicare Card ☐ Drivers Licence ☐ Signed letter from General Practitioner verifying proof ☐ Other (utility bill, bank statement etc.)
First Name:	
Family Name :	
D.O.B:	
Address:	
Telephone:	
Email:	

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

PART B: DETAILS REQUESTED

Data details that appear on the Data Capture Form (DCF) are shown in the table below. Please tick those you wish to access.

Surgeon Name	
Hospital/Site	
Date of Diagnosis	
Date of Surgery	
Preoperative Imaging & Tests	
Reason for Surgery	

Surgery Type	
Surgery Details	
Pathology & Staging	
Surgical Complications	
Postoperative Complications	
Recurrence	

I hereby apply for access to information relating to me held by the Australian & New Zealand Thyroid Cancer Registry.

Patient's signature: _____ Date: _____

Please send a copy of my information to above address: ☐

Please send a copy of my information to: _____

_____

PART C: THIRD PARTY RELEASE DETAILS

If your request relates to releasing this information to a third party/surgeon, please complete the following:

Name:	
Position:	
Address:	
Telephone Number:	

I hereby agree for information relating to me, held by the Australian & New Zealand Thyroid Cancer Registry, to be released to the above party.

Patient's signature: _____ Date: _____

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

APPENDIX D:
RESEARCH AGREEMENT

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

RESEARCH AGREEMENT

Name of Study: _____

BY THIS DECLARATION dated the _____ day of _____ 20__

I, _____ of _____

[Name of Investigator] [Institution]

recognise and accept as my responsibility regarding the use of information provided by the Australian & New Zealand Thyroid Cancer Registry (ANZTCR) for the above named study in accordance with the terms and conditions of this Agreement.

1. DEFINITIONS & ABBREVIATIONS

1.1. "Disclose" or "disclosure" shall mean the communication of information to any individual or organisation other than to the Researcher or the ANZTCR.

1.2. "Confidential information". Information accessed under the Public Health Act 2005 and/or information of a sensitive or confidential nature and any extract, derivation, or aggregation of this information that may enable identification of individuals, doctors, public or private facilities, or communities. This includes information derived from data linking or matching with information from other sources.

2. USE OF ANZTCR INFORMATION

The Researcher may use information provided by the ANZTCR only for the Research Project. If the Researcher wants to use such information for another research project, the Researcher must obtain the appropriate approval for the research project from an ethics committee and ANZTCR Management Committee. The Researcher, and any individual working on the Research Project, shall not disclose the ANZTCR information to others without the prior written consent of ANZTCR. Moreover, the ANZTCR information shall not be reproduced in any form except for internal use or with the prior written consent of ANZTCR.

3. PUBLICATION

In the event the Researcher wants to publish the results of the Research Project, the Researcher shall first provide to ANZTCR written notice of Researcher's intent to publish and a draft of the publication. ANZTCR shall have thirty (30) days after receipt of the draft publication to request in writing the removal of any portions of the publication deemed by ANZTCR to inappropriately disclose confidential information. Upon receipt of such a request from ANZTCR, the Researcher and ANZTCR shall attempt in good faith to agree upon the modifications or revisions to the draft publication which are reasonably necessary to protect the privacy of the subjects. In no event, however, shall the Researcher publish confidential information without the written consent of ANZTCR.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

4. CONTACTING PATIENTS

If the Researcher wants to contact patients, the Researcher shall submit a written request to ANZTCR identifying patients the Researcher wants to contact and the purpose of contacting the subjects. If ANZTCR approves such request, ANZTCR shall contact the patients (or the legal guardian of the subject if a guardian has been appointed by a court) and request the patient's written consent to be contacted by the Researcher. In no event shall Researcher contact a patient unless ANZTCR has first obtained such written consent.

5. CONFIDENTIALITY INFORMATION

All confidential data shall remain the property of ANZTCR and shall be destroyed, de-identified or promptly returned to ANZTCR at the end of the project, upon request of ANZTCR, or upon termination of this Agreement.

6. ANNUAL REPORTS

On or before the **[insert date]**, the Researcher shall submit to ANZTCR an annual report regarding the progress of the Research Project, all publications resulting from the Research Project, changes in the Research Project protocol, personnel or any incidents that may have resulted in the disclosure of confidential information, and any other information requested by the ANZTCR Management Committee.

7. REPRESENTATIONS OF THE RESEARCHER

The Researcher represents and warrants to ANZTCR, upon execution of this Agreement and throughout the term of this Agreement, that:

(a) The Researcher has obtained appropriate approval for the Research Project from (i) an ethics committee, (ii) the ANZTCR Management Research Committee.

(b) The Researcher, and any individual working on the Research Project, shall comply with the terms of this Agreement and the Australian & New Zealand Thyroid Cancer Registry's Policy: Requests for Data.

(c) The Researcher, and any individual working on the Research Project, shall conduct the Research Project in accordance with all applicable federal and state laws, rules, and regulations.

8. INDEMNIFICATION

The Researcher shall indemnify, defend and hold harmless ANZTCR against any claims, liabilities, damages, and expenses, including, without limitation, reasonable legal fees incurred by ANZTCR arising out of or related to the acts or omissions of the Researcher in connection with this Agreement.

9. TERM

The term of this Agreement shall commence on the date hereof and shall end on **[insert date]** or on the date the Research Project ends, whichever occurs first, unless sooner terminated as provided herein. This Agreement may be renewed or extended for additional terms by mutual written agreement of the parties.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

10. TERMINATION

(a) For Cause. ANZTCR may terminate this Agreement upon breach by the Researcher of any material provision of this Agreement, provided such breach continues for ten (10) working days after receipt by the Researcher of written notice of such breach from ANZTCR.

(b) Without Cause. Either party may terminate this Agreement without cause by giving the other party at least thirty (30) days' advance written notice thereof.

(c) Effect of Termination. In the event of such termination, the Researcher shall promptly return all ANZTCR information to ANZTCR, in any and all formats. The following provisions shall survive the termination of this Agreement: Paragraphs 3, 4, 5, and 9. Notices to the parties hereunder shall be deemed given if in writing when delivered in person, by registered or express post.

Notices shall be addressed as follows:

Researcher:

_____
_____
_____
_____
_____

Australian & New Zealand Thyroid Cancer Registry
School of Public Health & Preventive Medicine
Monash University
533 St Kilda Road, Melbourne, VIC 3004

(d) Entire Agreement. This Agreement contains the entire understanding of parties with respect to the subject matter hereof and supersedes all prior agreements, written or oral, and all other communications between the parties relating to such subject matter. This Agreement may not be amended or modified except by mutual written agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed and entered into by their authorised representatives as of the date first set forth above.

Australian & New Zealand Thyroid Cancer Registry	Researcher
_____	_____
A/Prof Susannah Ahern Registry Data Custodian	[Name] [Title] [Department]

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

APPENDIX E:
CONFIDENTIALITY AGREEMENT

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

CONFIDENTIALITY AGREEMENT

Name of Study: _____

BY THIS DECLARATION dated the _____ day of _____ 20____

I, _____ of _____

[Name of Appointee] [Address of Appointee]

recognise and accept as my responsibility the following obligations regarding the confidentiality of the information which has been provided to me by the Australian & New Zealand Thyroid Cancer Registry (ANZTCR).

1. DEFINITIONS & ABBREVIATIONS

1.1. "Confidential information". Information accessed under The Public Health Act 2005 and/or information of a sensitive or confidential nature and any extract, derivation, or aggregation of this information that may enable identification of individuals, doctors, public or private facilities, or communities. This includes information derived from data linking or matching with information from other sources.

1.2. "NHMRC". National Health and Medical Research Council

2. ETHICAL OBLIGATIONS

I certify that in my capacity as the holder of this information, I will comply with the guidelines and legislation detailed in the:

2.1. Commonwealth of Australia Privacy Act 1988, incorporating the Privacy Amendment (Private Sector) Act 2000.

2.2 Guidelines approved under Section 95A of the Privacy Act 1988 (National Health and Medical Research Council, December 2001).

2.3 Health Records and Information Privacy Act 2002 (NSW).

2.4 National Statement on Ethical Conduct in Research Involving Humans (National Health and Medical Research Council, 2007)

2.5 NHMRC's Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003).

3. CONFIDENTIALITY OBLIGATIONS

3.1. In the course of using confidential information for research purposes, I acknowledge that I will be exposed to information which if inappropriately used or disclosed may impact on individuals, public or private facilities or communities.

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

3.2. I will not disclose confidential information in any released output (eg in reports, publications).

3.3. I will not use this confidential information for purposes other than for performing the specific activities detailed in my application as approved by the Management Committee.

3.4. I will not use the confidential information except during the defined time period for which access to and use of this information was approved.

3.5. I agree to take all the reasonable steps necessary to ensure that the confidential information is kept confidential, including storing or disposing of all data, information, documents and associated correspondence in a secure manner.

3.6. I agree to re-apply for approval from the ANZTCR Management Committee if:

- I require additional confidential information;
- I want to extend the approved time period for access to or use of the confidential information;
- Additional individuals require access to this information as part of the approved research study.

3.7. I acknowledge that unauthorised use or disclosure of confidential information by me may subject me to prosecution under the laws of the relevant state or territory in Australia.

3.8. The declaration of my interests in Research Proposals and associated documents shall be held in strict confidence by the relevant Human Research Ethics Committee and ANZTCR Committee members or employees, and it shall not be used or disclosed to any other person without my prior consent or when it is legally required to be disclosed.

3.9. I agree to dispose of confidential data in a secure manner on completion of the project.

In signing this declaration, I declare that I will adhere to the obligations specified in this document.

_____

Signature

_____ _____

Name (Print) Position

_____ _____

Phone Email