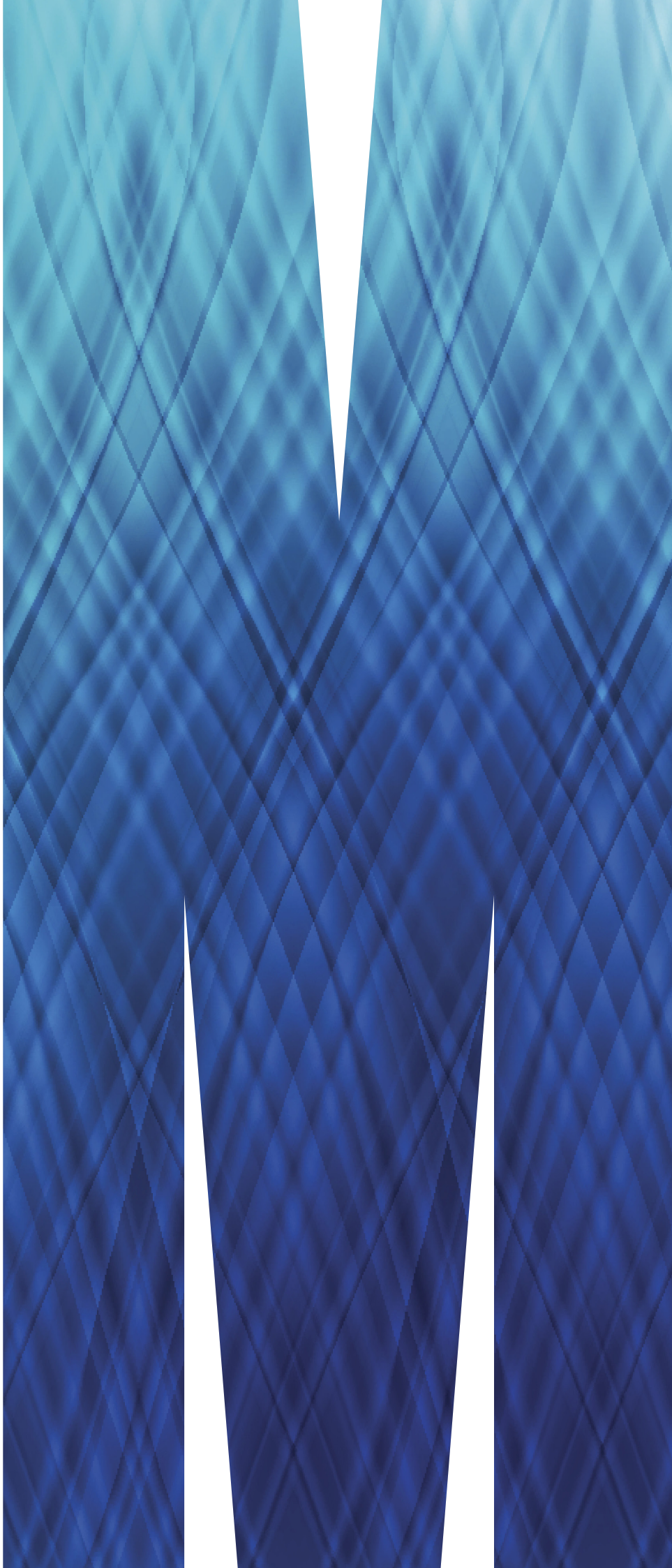
MONASH University

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

2018 ANNUAL REPORT



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AUSTRALIAN & NEW ZEALAND
THYROID CANCER
REGISTRY

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Data Period

The data contained in this document was extracted from the Australian and New Zealand Thyroid Cancer Registry (ANZTCR) on 31 January 2019 and pertains to data that relates to patient events from 25 September 2017 to 31 January 2019. As the registry does not capture data in real time, there may be a lag period between the occurrence of an event and its capture in the registry's database, ANZTCR REDCap Database (ANZTCR-RCD).

AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

MONASH University

AUSTRALIAN & NEW ZEALAND ENDOCRINE SURGEONS

THE AUSTRALIAN THYROID FOUNDATION LTD

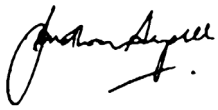
FOREWORD

FROM THE CLINICAL LEAD OF ANZTCR

It is with a great deal of pleasure that I present the first Annual Report of the Australian and New Zealand Thyroid Cancer Registry (ANZTCR) for 2018. That we are in a position to do this is indicative of the strong support and collaboration that has occurred between Australian and New Zealand Endocrine Surgeons (ANZES), endocrinologists, individual endocrine and ENT surgeons and data managers. In particular, I congratulate the 22 hospitals and 31 surgeons contributing to this registry. The primary purpose of a clinical quality registry is to improve outcomes for thyroid cancer patients. I am excited to report these initial results, which although small in number, indicate a high quality outcome for our patients.

I would like to thank Associate Professor Susannah Ahern, Dr Liane Ioannou and Elysia Greenhill from the Registry Science Unit for their management of the ANZTCR and support for the project from Professor John McNeil at Monash University. Additionally, very committed, strong and talented steering committee has been integral to the project's success.

This registry is an important achievement and I would like to express my appreciation to the contributing patients, the Australian Thyroid Foundation and our funders. Thank you for your ongoing support of this key quality initiative for thyroid cancer patients.



Professor Jonathan Serpell
Clinical Lead, Australian & New Zealand Thyroid Cancer Registry

Director, Department of General Surgery, Alfred Health

FROM THE PRESIDENT OF ANZES

As President of Australian and New Zealand Endocrine Surgeons (ANZES), I am delighted to present the first Annual Report of the Australian and New Zealand Thyroid Cancer Registry (ANZTCR).

In Australia, the majority of thyroid surgery is undertaken by specialist endocrine surgeons, represented by 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 clinical quality registry (CQR) which would include clinical indicators against which to monitor and benchmark clinical care. The ANZTCR has been developed to provide a comprehensive evidence base regarding the care and outcomes of patients newly diagnosed with thyroid cancer in Australia and New Zealand.

I would like to thank all those ANZES members and other surgeons who have contributed thus far to the ANZTCR, and to Jonathan for his visionary leadership of the registry. I look forward to seeing the ANZTCR grow and evolve into a tool to support best clinical practice and real-time evidence-based clinical decision-making for thyroid surgeons across Australia and New Zealand.

Associate Professor Julie Miller
President, Australian and New Zealand Endocrine Surgeons (ANZES)

Head, Thyroid and Endocrine Tumour Group, The Royal Melbourne Hospital

FUNDING PARTNERS

The Australian and New Zealand Thyroid Cancer Registry received funding for the pilot of the registry from the Alfred Foundation and its industry sponsor, Medtronic. The registry would also like to acknowledge the Australian and New Zealand Endocrine Surgeons (ANZES) for their ongoing support of the registry.

theAlfred FOUNDATION

Medtronic

SNAPSHOT OF THE ANZTCR

This snapshot provides an overview of the registry recruitment.

31 Surgeons Currently Contributing
There are currently 31 surgeons contributing to the registry with a further 30+ surgeons having expressed interest in contributing and awaiting approval of their site. For a list of participating surgeons please see Appendix E.

22 Sites Currently Participating
Over 20 sites have come on board across Australia in 2018. For a list of approved and participating sites please see Appendix E.

191 Patients Currently Participating
As of 31 January 2019, there were 191 patients registered in the ANZTCR REDCap Database (ANZTCR-RCD). Contributing surgeons enter data for their patients diagnosed with thyroid cancer into the registry.

RATIONALE

The occurrence of thyroid cancer is increasing throughout the developed world and since the 1990s has become the fastest increasing malignancy. Between 1991 and 2009, the number of thyroid cancer cases increased by 250% in Australia.[1] 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% .[2]

However, there are significant variations in the management, treatment and outcomes of thyroid cancer, particularly in diagnostic investigations undertaken; optimal extent of surgery; use of active surveillance; role of lymph node dissections; complication rates following surgery; post-surgical hormone treatment; calcium and vitamin D therapy; and radioactive iodine treatment.[3]

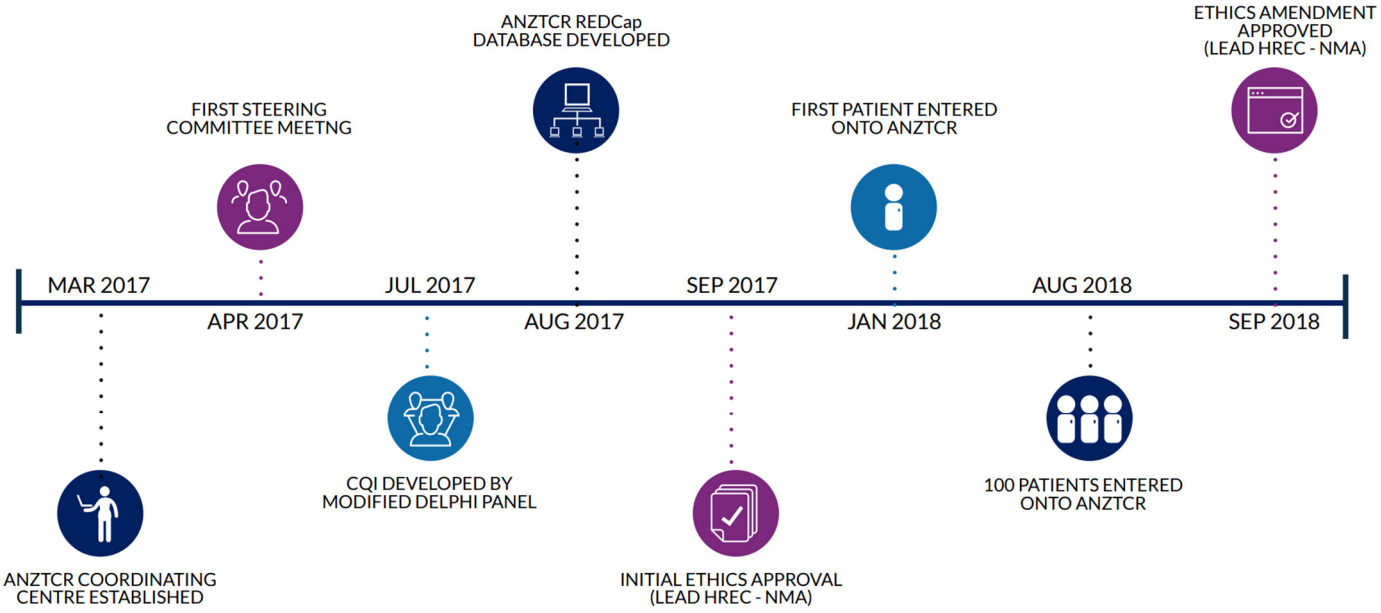
While thyroid cancer management is informed by well-regarded international guidelines, there is a lack of population-level data regarding patient outcomes from thyroid cancer in Australia and New Zealand. Therefore it is likely that there is clinician variation in adherence to best practice and therefore, individual patient outcomes of thyroid cancer. In addition, while detailed guidelines exist, there remain questions regarding optimal management of patient sub-populations.

A proven strategy to reduce variation in outcomes is to measure and compare high quality disease-specific data using clinical quality registries (CQRs). CQRs provide the most effective means of collecting high quality data and are a tool for quality improvement. The Australian Commission on Safety and Quality in Health Care (ACSQHC) has advocated development of CQRs, particularly in key high burden areas including cancers.[4]

'There is a lack of population-level data regarding patient outcomes from thyroid cancer in Australia and New Zealand.'

MILESTONES

The timeline for the development of the ANZTCR is outlined below, highlighting the key milestones since its inception in March 2017.



ANZTCR GOVERNANCE

The ANZTCR conforms to the national operating principles for clinical quality registries as detailed in the 'Operating Principles and Technical Standards for Australian Clinical Quality Registries 2008'[5] and the 'Framework for Australian Clinical Registries 2014'[4] published by the Australian Commission for Safety and Quality in Healthcare (ACSQHC).

Management Committee

A Management Committee oversees the day to day operations of the registry undertaken by the ANZTCR Coordination Centre based at Monash University.

Steering Committee

The ANZTCR is led by a multidisciplinary steering committee which guides registry strategy and policy, monitoring data collection and quality assurance, and producing data reports. Current membership includes representation from the following societies and/or organisations:

- Monash University
- ANZES
- ATF

The committee comprises representation from Australia (each jurisdiction) and New Zealand, and includes representation of the following specialities and/or expertise:

- Surgery
- Endocrinology
- Patient Advocacy
- Data Management
- Registry Science

Some of the key achievements of the Steering Committee have been the establishment of the policies and procedures that underpin the registry, including:

ANZTCR Policies and Procedures
Protocol
Data Dictionary
Data Access & Publication Policy
Privacy Policy
ANZTCR-RCD User Manual

Monash University has custodianship of the data which includes accountability for the privacy, security and integrity of patient information held within the registry. Study data were collected and managed using REDCap electronic data capture tools hosted and managed by Helix (Monash University). REDCap (Research Electronic Data Capture)[6] is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

REGISTRY METHODOLOGY

PARTICIPANT RECRUITMENT

All patients newly diagnosed with thyroid cancer from a participating site are eligible to participate in the prospective registry.

Inclusion criteria

- All newly-diagnosed patients presenting to a participating hospital with a confirmed primary thyroid cancer.
- Patients who are ≥ 16 years of age.

Exclusion criteria

- Patients diagnosed earlier than 1st September 2017 (when the registry commenced).

Recruitment to the registry utilises an *opt-out process* which has been used successfully in over 75% of CQRs in Australia.[7] Patients can opt out of the registry at any time by calling a Monash University free call number or via emailing the ANZTCR. Patient recruitment at a participating site commences following the appointment of a principal investigator to take responsibility for the registry at the site, and authorisation by the participating site's research ethics and/or governance office.

Phase 1 All patients diagnosed with thyroid cancer, based on histological confirmation (provided approximately 1-2 weeks post-diagnosis) at a hospital with ANZTCR research governance approval are eligible to participate. The treating surgeon (or designated staff member) at the surgical unit will enter minimal patient details into the ANZTCR-RCD, 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 surgeon will enter participant diagnosis, surgical, pathology and treatment data into the registry database at approximately 90 days post-surgery.

DATA ELEMENTS

A modified-Delphi approach, informed by international thyroid cancer guidelines and relevant literature, was used to develop a consensus set of clinical quality indicators (CQIs) for the early management of thyroid cancer, the parameters of which are shown below. At the conclusion of 2020, or when sufficiently mature data is available, the ANZTCR will produce regular benchmarked reports of clinical quality indicators to sites.

Preoperative

CQI1 All patients with suspicion of thyroid cancer should have an ultrasound (US) of the primary site before the initiation of treatment.

CQI2 All patients with clinically and/or radiologically suspicious lymph nodes should undergo fine needle aspiration (FNA) to confirm malignancy before the initiation of treatment.

CQI3 All patients with suspicion of thyroid cancer that present with (subjective or objective) evidence of voice abnormality should undergo a laryngeal examination before the initiation of treatment.

Surgery

CQI4 All patients with differentiated thyroid cancer (DTC) who have advanced disease (extrathyroidal extension and/or metastatic disease) or tumour size >4 cm should undergo a total (or near-total) thyroidectomy.

CQI5 All patients with thyroid cancer with indication of lymph node involvement should undergo therapeutic central and lateral neck lymph node dissection in addition to total (or near-total) thyroidectomy.

Surgical Complications

CQI6 Proportion of patients with thyroid cancer who presented with recurrent laryngeal nerve (RLN) palsy at 3 months following thyroidectomy.

CQI7 Proportion of patients with thyroid cancer who present with persisting hypoparathyroidism at 3 months following thyroidectomy, as evidenced by need for ongoing calcium and/or vitamin D.

CQI8 Proportion of patients with thyroid cancer who underwent a thyroidectomy and had postoperative haemorrhage within 48 hours requiring return to theatre.

Staging & Postoperative Treatment Planning

CQI9 Postoperative Tumour Node Metastasis (TNM) staging should be recorded for all patients with thyroid cancer.

CQI10 All patients with thyroid cancer should be reviewed by a multidisciplinary team.

Postoperative Treatment

CQI11 All patients with DTC with tumour >4 cm who had a hemithyroidectomy should undergo a completion thyroidectomy.

CQI12 All patients undergoing surgery for thyroid cancer should have serum thyroglobulin (Tg) recorded postoperatively.

CQI13 All patients with high-risk DTC should undergo radioactive iodine remnant ablation (RRA) following a total (or near total) thyroidectomy.

The ANZTCR minimum data set includes variables relating to the indicators, variables required for patient identification and contact, and other variables of particular relevance to early thyroid cancer management, based on the standard care provided (see Appendix). The use of standardised definitions of data elements ensures data is consistent and uniform providing reliable and comparable data for analysis. 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.

DATA COLLECTION PROCESSES

Data is collected and entered into the ANZTCR-RCD via two methods:

1. Direct data entry into the ANZTCR-RCD by surgeons (or their staff e.g. data manager). ANZTCR-RCD provides a secure online connection to the registry database (primary method of data collection).
2. Data extracts from unit, institution and multi-institution databases held by participating surgeons or electronic medical records where data mapping indicates high levels of data item matching.

RESEARCH ETHICS & GOVERNANCE

The ANZTCR received ethics approval under the National Mutual Acceptance scheme, through Alfred Health in September 2017. In order to commence patient recruitment at a hospital site the registry needs to seek research governance authorisation at public sites and ethics approval at private sites.

CLINICIAN ENGAGEMENT

Potential surgeons are informed about the registry through ANZES and a number of other sources including a quarterly ANZTCR newsletter as well as principal and associate investigators at each hospital site who are ambassadors for the registry and promote participation at their site. Contributing Clinician Agreement forms are distributed to surgeons to invite them to participate in the registry. 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.

The ANZTCR annually acknowledges surgeons who participate in the registry in a number of ways.

CME Audit Points

The ANZTCR is recognised by the Royal Australian College of Surgeons (RACS) as a Continuing Medical Education (CME) audit activity that aims to improve the quality of patient care. Contributing surgeons receive annual CME credit points in Surgical Audit & Australian and New Zealand Audits of Surgical Mortality.

Valued Contributor Logo

A valued contributor logo is provided to contributing surgeons to recognise their valued contribution to the registry. Surgeons are able to use the logo at their own discretion i.e. on their email signature, important documents and letters, and website.

Database Reports

The ANZTCR-RCD allows surgeons to run patient-level and aggregate data reports in real-time. Resources are provided to contributing surgeons with instructions on how to run these reports.

FUNDING

Funding for the pilot of the registry is provided by the Alfred Foundation, Medtronic and ANZES.

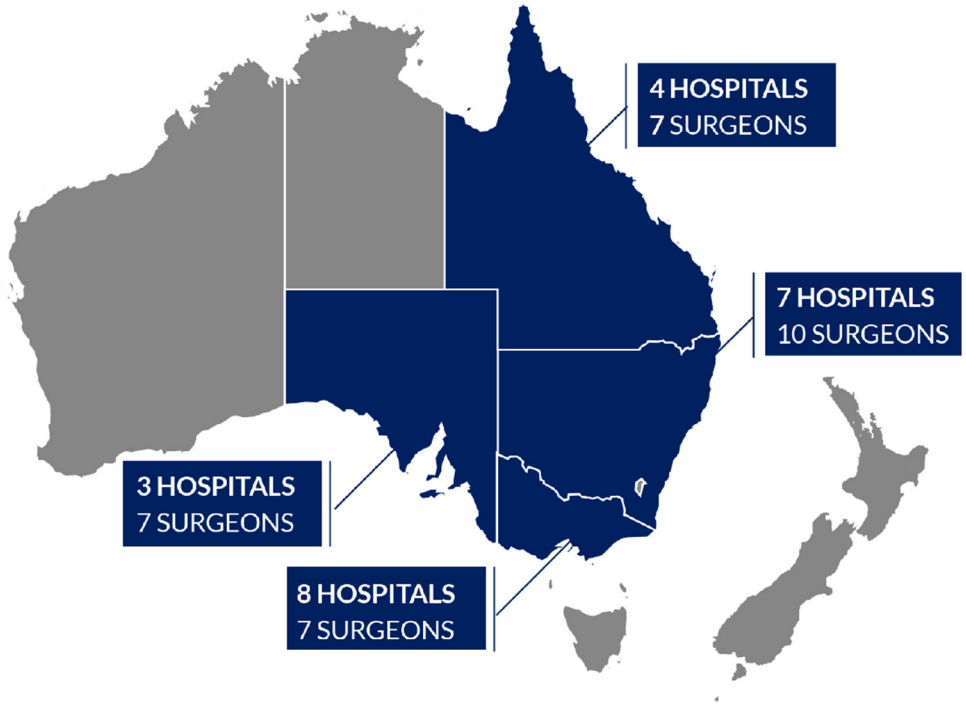
SUMMARY OF THE REGISTRY DATA

SITE & SURGEON PARTICIPATION

In 2017, members of ANZES were informed of the establishment of the registry and, from this, over 50 surgeons across Australia and New Zealand expressed their interest in contributing to the registry. This initial expression of interest helped identify target sites for the pilot phase of the registry.

Figure 1 illustrates this expansion of the registry across Australia since its commencement in early 2018. Over the past 12 months, we have obtained ethics and/or governance approval from 22 hospital sites. This includes 15 public and 7 private hospital sites across Victoria, New South Wales, Queensland and South Australia (Figure 1).

FIGURE 1 NUMBER OF HOSPITAL SITES AND NUMBER OF SURGEONS PER STATE CONTRIBUTING TO THE REGISTRY



Surgery for thyroid cancer is performed by a number of surgeons from different specialities including: endocrine surgeons, general surgeons and Ear-Nose-Throat (ENT) surgeons (otolaryngologists). The registry aims to include all surgeons at a participating site that operate on patients with thyroid cancer. Figure 2 shows the accumulation rates of both sites and surgeons in 2018. Figure 3 displays the speciality area of the 31 surgeons currently contributing to the ANZTCR.

FIGURE 2 SURGEON & SITE ACCUMULATION FOR 2018

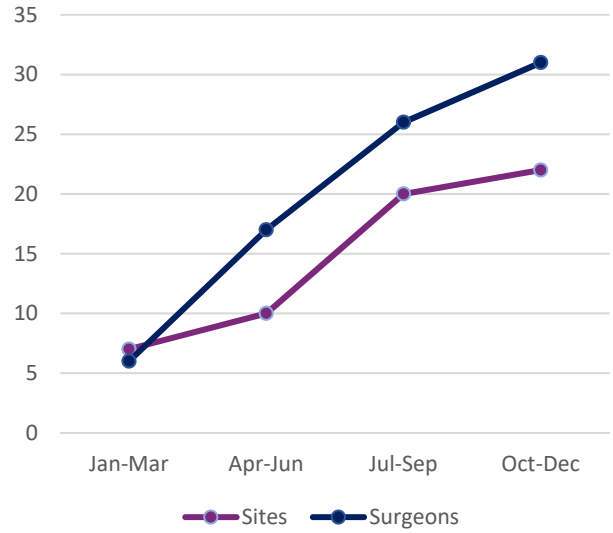
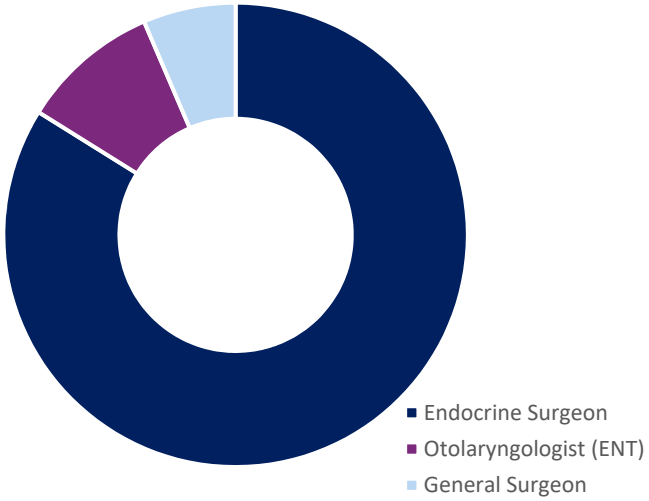


FIGURE 3 AREA OF SURGEON EXPERTISE



REGISTRY PARTICIPATION

As at 31 January 2019, 187 thyroid cancer patients have been recruited to participate in the registry since January 2018. For a patient to be eligible to be included in the registry, they must have had been diagnosed with thyroid cancer on or before 30 September 2017.

A total of 197 patients have been invited to participate in the registry since January 2018. At the time of the data extraction, six (3.0%) of these patients were pending participation status. Of the 191 patients where the opt-out period has elapsed, four (2.1%) have chosen to opt out and two (1.0%) chose to partially opt out, where their data will be kept but no further contact would be made. As at 31 January 2019, the ANZTCR confirmed the participation of 187 thyroid cancer patients and their data.

Table 1 demonstrates patient participation in the ANZTCR from 1 January 2018 to 31 January 2019. The registry has an opt-out rate of below 4%.

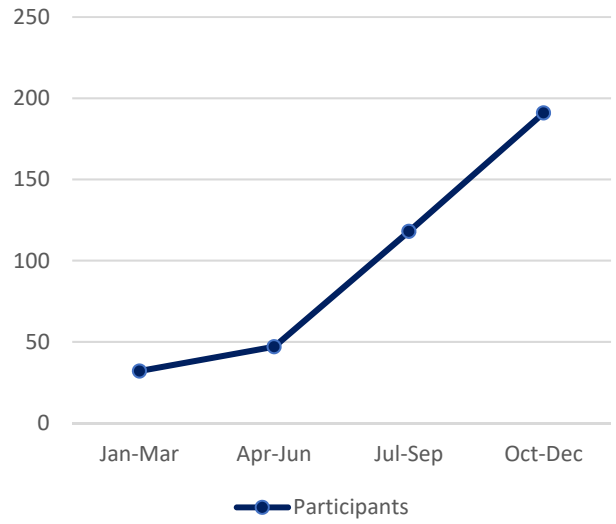
TABLE 1 PATIENT PARTICIPATION IN THE REGISTRY FROM 1 JANUARY 2018 TO 31 JANUARY 2019

	As at 31 January 2019
Invited	197*
Participating	187
Opt-Out	4
Opt-Out Rate	2.1%

*Six patients pending participation status at 31 January 2019.

Figure 4 illustrates the exponential growth of registry participants across Australia since its commencement in January 2018.

FIGURE 4 ACCUMULATION RATES OF PARTICIPANTS IN THE REGISTRY FOR 2018

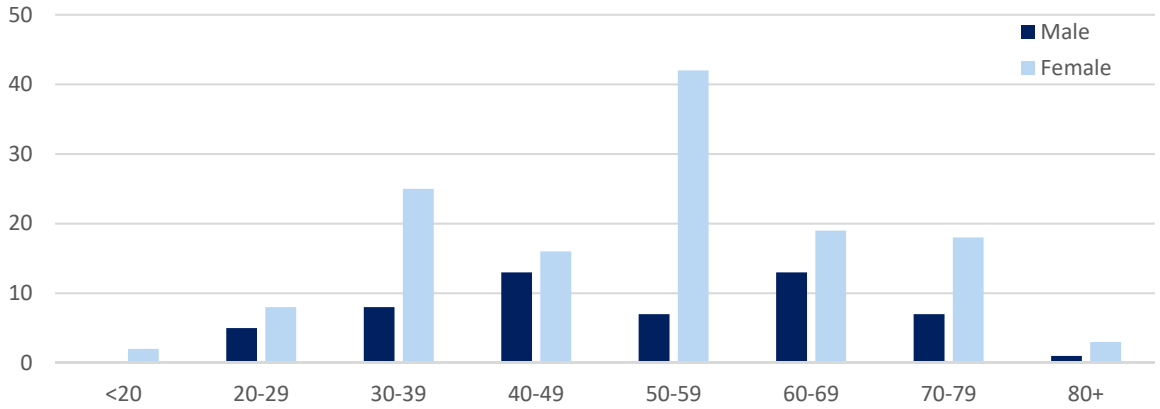


PARTICIPANT CHARACTERISTICS

True to observed population trends, thyroid cancer is more common in female participants. As at 31 January 2019, there were 133 (71.1%) females and 54 (28.9%) males enrolled in the registry who have been diagnosed with thyroid cancer.

The mean age for patients at diagnosis was 52.3 years old, with no difference in mean age between males (52.2) and females (52.3). Figure 5 demonstrates the sex and age of participants in the registry who have been diagnosed with thyroid cancer since September 2017.

FIGURE 5 PARTICIPANTS' AGE DISTRIBUTION AT TIME OF DIAGNOSIS BY SEX



Of the 187 participants, 115 (61.5%) were diagnosed based on histology of primary tumour, 69 (36.9%) based on cytology and 3 (1.6%) based on histology of metastasis.

FOLLOW-UP DATA COMPLETION

Participating surgeons are required to enter follow-up data for all of their patients participating in the registry at 90-days following diagnosis. Of the 187 participants, 176 exceeded the 90-day post-diagnosis period and are therefore eligible for follow-up data collection. From this point forward this report presents data on the patients for which follow-up data has been completed.

Table 2 shows completion rates for follow-up data entry *forms* for patients eligible for 90-day follow-up data collection. Please note, this represents the minimum rate of completion as it does not reflect completion rates for individual data items, which may be higher (please see sample sizes reported for each individual data item).

TABLE 2 COMPLETION OF 90-DAY FOLLOW-UP DATA COLLECTION BY DATA ENTRY FORM

	Preoperative	Initial Procedure	Subsequent Procedure(s)	Postoperative	Postoperative Treatment
N	74	49	78	65	48
Percentage	39.6%	26.2%	41.7%	34.8%	25.7%

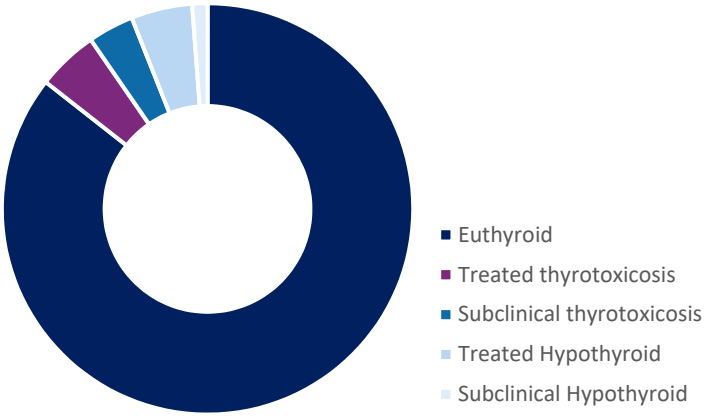
PREOPERATIVE DETAILS CAPTURED BY THE REGISTRY

Previous Medical History

At the time of diagnosis, patients presented with the following comorbidities (n = 85) - obesity (3.2%), smoker (5.9%) and other cancer (4.3%). Three participants (3.7%) had previously been exposed to upper body radiation. Six participants (7.4%) had previous thyroid surgery, four (66.7%) of these were for malignancy.

A patient's thyroid function is assessed at their first presentation to a surgeon prior to diagnosis. Of the 83 participants, 71 (85.5%) presented with a normal functioning thyroid gland (euthyroid), while four had treated thyrotoxicosis (4.8%), four had treated hypothyroidism (4.8%), three had subclinical thyrotoxicosis (3.6%), and one had subclinical hypothyroidism (1.2%) (Figure 9). Four participants (5.6%) were on antiplatelet drugs and four (5.6%) on anticoagulant drugs at diagnosis.

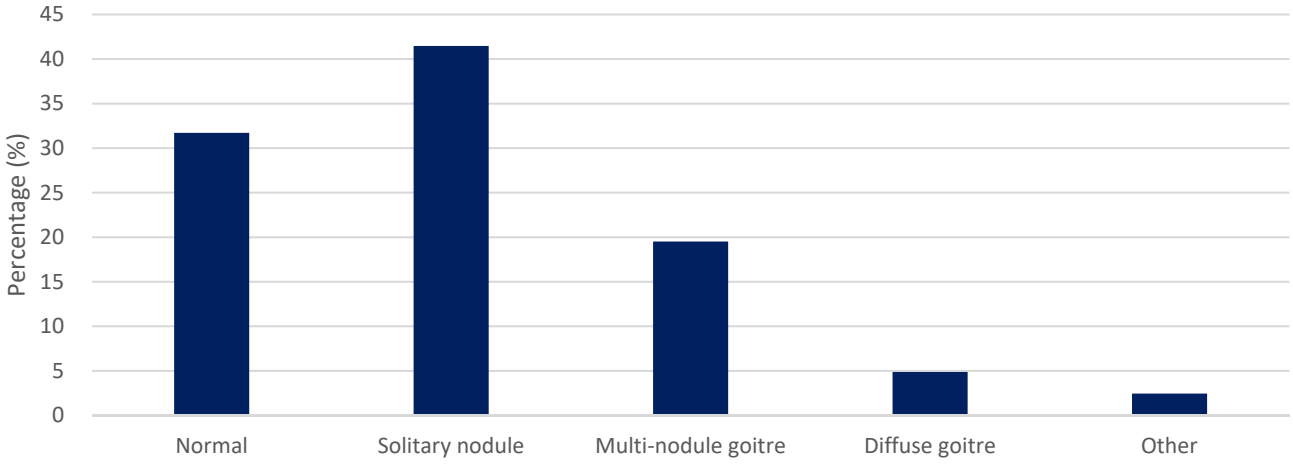
FIGURE 9 THYROID FUNCTION AT PRESENTATION (N=83)



Neck Examination

Of the 82 participants with neck examination information recorded, 34 (41.5%) had a solitary nodule, 16 (19.5%) had a multinodular goitre (MNG), four (4.9%) had a diffuse goitre and 26 (31.7%) had normal findings upon examination (Figure 7). Only 14 participants (17.1%) were reported to have palpable lymph nodes at the time of neck examination.

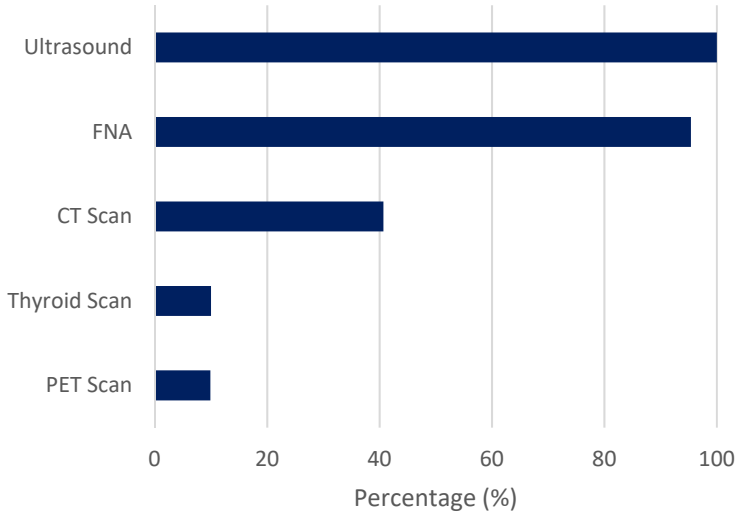
FIGURE 7 NECK EXAMINATION FINDINGS (N=82)



Diagnostic Tests

All participants (n=87) had an US prior to diagnosis. Suspicious lymph nodes were present on US for 22/74 participants (29.7%). Of the 87 participants, 83 (95.4%) underwent a FNA, with 53 (67.9%) having one site, 22 (28.2%) having two sites and three (3.8%) having three sites biopsied. Figure 8 displays the type of preoperative tests conducted and the percentage of patients who underwent each test.

FIGURE 8 PREOPERATIVE TESTS (N=87)



Voice Assessment

Of participants (n=62), eight (12.9%) had evidence of subjective or objective voice abnormality prior to diagnosis. A laryngeal exam was performed prior to any treatment for 65 out of 80 participants (81.3%), with 63 returning a normal result and one indicating right palsy (1.5%) and another one left palsy (1.5%). Table 4 displays the voice assessments conducted on patients in the registry preoperatively.

TABLE 4 PREOPERATIVE VOICE ASSESSMENT

Variable	Response	N (Percentage)
Evidence of Subjective or Objective Voice Abnormality (N=62)	Yes	8 (12.9%)
	No	54 (87.1%)
Laryngeal Exam (N=80)	Yes	65 (81.3%)
	No	15 (18.8%)

PROCEDURES CAPTURED BY THE REGISTRY

Primary procedure

Of the participants who had surgery (n=83), 49 had a total thyroidectomy (56.3%), 31 had a hemithyroidectomy (35.6%), one had a redo unilateral thyroidectomy (1.1%), one had a completion thyroidectomy (1.1%) and five had another type of procedure not defined (5.7%). The main reason for surgery was malignancy (48.2%) and risk of malignancy (38.6%), see Table 5 for more details.

Figure 10 outlines the type of procedure initially performed on patients in the registry.

FIGURE 10 TYPE OF INITIAL PROCEDURE (N=83)

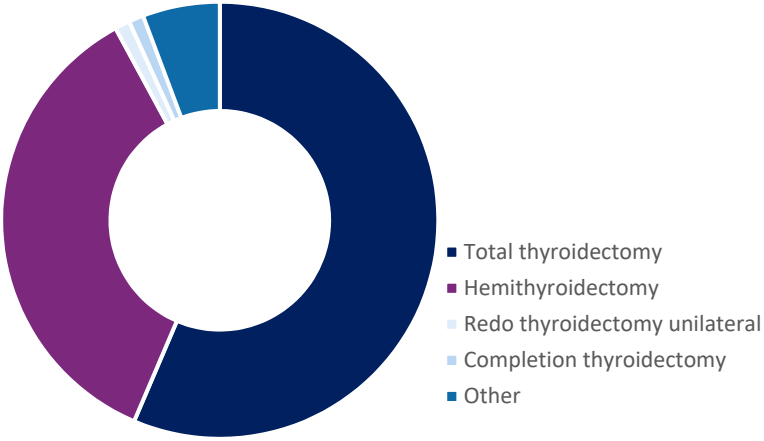


TABLE 5 REASONS FOR INITIAL PROCEDURE

Variable	Responses	N (%)
Reason for Procedure (N=84)*	Malignancy	40 (47.6%)
	Risk of malignancy	32 (38.1%)
	Compression	4 (4.8%)
	MNG nontoxic	4 (4.8%)
	Growth	3 (3.6%)
	Single nodule nontoxic	2 (2.4%)
	MNG toxic	2 (2.4%)
	Graves' disease	1 (1.2%)
	Single nodule toxic	0 (0%)
	Other	4 (4.8%)

*Multiple responses were allowed for this data item.

Lymph node dissection

Of the participants (n=82), 32 (39.0%) had a lymph node dissection, 18 with therapeutic intent (64.3%) and 10 with prophylactic intent (35.7%), see Table 6 below.

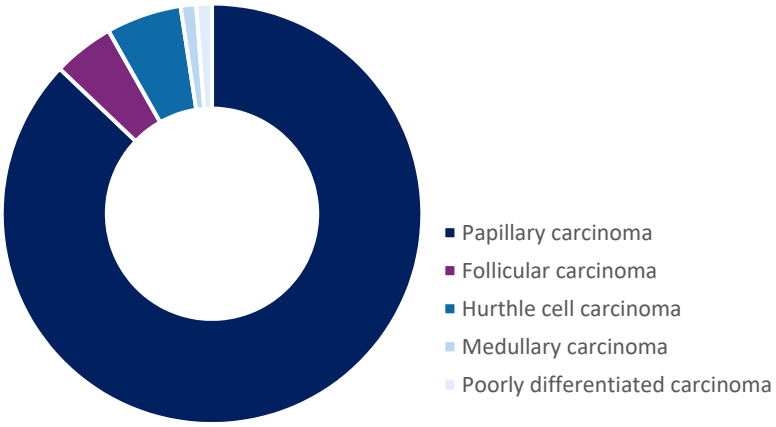
TABLE 6 LYMPH NODE DISSECTION DURING INITIAL PROCEDURE

Variable	Responses	N (Percentage)
Lymph Node Dissection (N=82)	Yes	32 (39.0%)
	No	50 (61.0%)
Type of Lymph Node Dissection (N=28)	Therapeutic	18 (64.3%)
	Prophylactic	10 (35.7%)

Pathology

Of the 86 participants, 84 (97.7%) were diagnosed with DTC, 75 (87.2%) with papillary carcinoma, five (5.8%) with hürthle cell carcinoma and four (4.7%) with follicular cell carcinoma. Two of the 86 patients (2.3%) were diagnosed with undifferentiated thyroid cancer (UTC), one (1.2%) with medullary carcinoma and one (1.2%) with poorly differentiated carcinoma (Figure 11).

FIGURE 11 PATHOLOGY OF PRIMARY TUMOUR (N=86)



In addition to malignant pathology, benign pathology was reported in 37 out of 60 patients, with multinodular goitre and lymphocytic thyroiditis occurring in 30% and 18% of patients respectively. An incidental finding of cancer was observed for 24 out of 74 (32.4%) of patients in the registry undergoing an initial procedure.

Of 71 patients undergoing an initial procedure, 17 were reported to have multifocal cancer with the site of the multifocality reported in the right lobe for eight (47.1%) patients, in the left lobe for eight (47.1%) patients and in both lobes for one (5.9%) patient. See Table 8 for more details. Extrathyroidal extension and lymphovascular invasion were observed in 15 patients (18.5%) and 19 (23.5%) patients, respectively.

For those in which TNM staging was available (N=47), patients were stratified by risk (according to the American Thyroid Association guidelines) with 26 (55.3%) patients being classified as low risk, 20 (42.6%) as intermediate risk and one (2.1%) as high risk. Macroscopic residual tumour (R2) was identified in one patient at the time of surgery and microscopic residual tumour (R1) was pathologically identified in 10 patients (14.3%).

TABLE 8 ADDITIONAL PATHOLOGY FEATURES

Variable	Responses	N (Percentage)
Incidental Finding of Cancer (N=74)	Yes	24 (32.4%)
	No	50 (67.6%)
Additional Benign Pathology (N=60)*	No benign pathology	23 (38.3%)
	MNG (colloid, hyperplastic)	18 (30.0%)
	Lymphocytic thyroiditis	11 (18.3%)
	Follicular adenoma	3 (5.0%)
	Graves' disease	2 (3.3%)
	Hürthle cell adenoma	0 (0.0%)
	Other	7 (11.7%)
Histological Margin Status (N=70)	No residual tumour (R0)	60 (85.7%)
	Microscopic residual tumour (R1)	10 (14.3%)
Multifocal Cancer (N=71)	Yes	17 (23.9%)
	No	54 (64.3%)
Lymphovascular Invasion (N=81)	Yes	19 (23.5%)
	No	62 (76.1%)
Extrathyroidal Extension (N=81)	Sternothyroid muscle; or perithyroid soft tissues	11 (13.6%)
	Subcutaneous soft tissues; larynx; trachea; oesophagus; or RLN	4 (4.9%)
	Prevertebral fascia; encases carotid artery; or mediastinal vessels	0 (0.0%)
	No	66 (81.5%)

*Multiple responses were allowed for this data item.

Recurrent Laryngeal Nerve

During surgery, the RLN was intact on the right for all 66 (100%) participants and the RLN on the left was intact for 62 out of 63 (98.4%) and damaged for one participant (1.6%). During the initial procedure for 85 participants, 74 (88.9%) had a nerve integrity monitor used with a loss of signal reported for the left RLN in two participant procedures (2.9%).

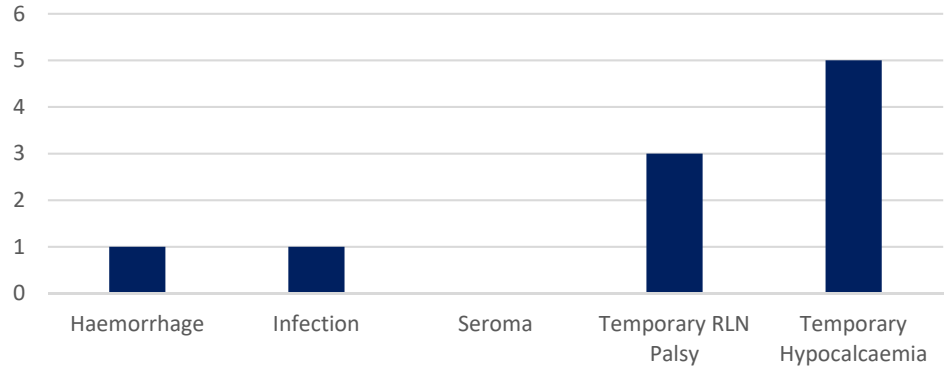
TABLE 7 RECURRENT LARYNGEAL NERVE MONITORING DURING INITIAL PROCEDURE

Variable	Responses	N (Percentage)
RLN Right (N=66)	Intact	66 (84.6%)
	Damaged	0 (0%)
	Sacrificed	0 (0%)
RLN Left (N=63)	Intact	62 (74.7%)
	Damaged	1 (1.2%)
	Sacrificed	0 (0%)
Nerve Integrity Monitor Used (N=85)	Yes	74 (87.1%)
	No	11 (12.9%)

Complications from Surgery

Complications were recorded in a small number of patients at 90-days following initial procedure. Complications included temporary hypocalcaemia (5.9%), temporary RLN palsy (3.5%), haemorrhage (return to theatre within 48 hours) (2.1%), and infection (1.2%) (Figure 12).

FIGURE 12 SURGICAL COMPLICATIONS FOLLOWING INITIAL PROCEDURE (N=85)



Metastatic Disease

Lymph node metastasis were reported in 26 out of 74 (35.1%) patients undergoing initial procedure, with distant metastasis not being reported in any patients (N=72).

POSTOPERATIVE DETAILS CAPTURED BY THE REGISTRY

At 90-days post-surgery, a proportion of patients were receiving thyroxine therapy (84.1%) as well as supplementation with calcium (67.9%) and vitamin D (19.5%) (Table 9).

TABLE 9 POSTOPERATIVE SUPPLEMENTATION & THERAPY

Variable	Response	N (Percentage)
Supplementation with Calcium (N=84)	Yes	57 (67.9%)
	No	27 (32.1%)
Supplementation with Vitamin D (N=82)	Yes	16 (19.5%)
	No	66 (80.5%)
Supplementation with Thyroxine (N=63)	No Thyroxine	10 (15.9%)
	Supplementation	8 (12.7%)
	Replacement	16 (25.4%)
	Suppression	29 (46.0%)

Postoperative Treatment

A total of 67 out of 85 (78.8%) patients were presented at a multi-disciplinary team meeting (MDM) for treatment planning. Postoperative Tg was recorded for 43 out of 44 (97.7%) patients. Of those with differentiated thyroid cancer, 29 out of 67 (43.3%) had RRA following surgery. The main reasons for not having RRA were: the patient had a micropapillary thyroid cancer (<20mm) (53.2%); were at low risk (37.5%); or the patient had a hemithyroidectomy only (25.0%). For more details see Table 10 below.

TABLE 10 POSTOPERATIVE TREATMENT DETAILS

Variable	Response	N (Percentage)
Presented at MDM (N=85)	Yes	67 (78.8%)
	No	18 (21.2%)
Postoperative Tg Recorded (N=44)	Yes	43 (97.7%)
	No	1 (2.3%)
Thyroid Stimulating Hormone (TSH) Stimulation (N=46)	Yes	32 (69.6%)
	No	14 (30.4%)
RRA Following Thyroid Surgery (N=67)	Yes	29 (43.3%)
	No	38 (56.7%)
Reason No RRA (N=32)*	PTC ≤ 10mm	10 (31.3%)
	PTC 11-20mm	7 (21.9%)
	Hemithyroidectomy Only	8 (25.0%)
	Patient Age	3 (9.4%)
	Low Risk	12 (37.5%)
	Comorbidities	1 (3.1%)
	Patient Declined	3 (9.4%)
	Other	2 (6.3%)
	Unknown	3 (9.4%)

*Multiple responses were allowed for this data item.

ACADEMIC OUTPUTS

PUBLICATIONS

Ioannou, L., Serpell, J., Dean, J., Bendinelli, C., Gough, J., Lisewski, D., Miller, J., Meyer-Rochow, W., Sidhu, S., Topliss, D., Walters, D., Zalcberg, J., Ahern, S. Development of a Bi-National Thyroid Cancer Clinical Quality Registry: A Protocol Paper. *BMJ Open*; 9: bmjopen-2018-023723. Doi: 10.1136/bmjopen-2018-023723

PRESENTATIONS

Ioannou, L., Serpell, J., Bendinelli, C., Walters, D., Gough, J., Lisewski, D., Meyer-Rochow, W., Miller, J., Topliss, D., Fleming, B., Farrell, S., Kid, A., Kollias, J., Sywak, M., Aniss, A., Fenton, L., Ghusn, D., Harper, S., Popadich, A., Stringer, K., Watters, D., Ahern, S. Development of a Core Set of Clinical Indicators to Measure Quality of Care for Thyroid Cancer: A Modified-Delphi Approach. 88th Annual Meeting of the American Thyroid Association (ATA), Washington D.C., United States (3-7 October 2018) (Oral Presentation).

Ioannou, L., Serpell, J., Dean, J., Bendinelli, C., Gough, J., Lisewski, D., Miller, J., Meyer-Rochow, W., Sidhu, S., Topliss, D., Walters, D., Zalcberg, J., Ahern, S. Development of a Bi-National Thyroid Cancer Clinical Quality Registry. Alfred Health Research Week, Melbourne, Australia (June 2018) (Poster Presentation).

Ioannou, L., Serpell, J., Dean, J., Bendinelli, C., Gough, J., Lisewski, D., Miller, J., Meyer-Rochow, W., Sidhu, S., Topliss, D., Walters, D., Zalcberg, J., Ahern, S. Development of a Bi-National Thyroid Cancer Clinical Quality Registry. Victorian Comprehensive Cancer Centre (VCCC) Postdoctoral Symposium, Melbourne, Australia (1 June 2018) (Poster Presentation).

Ioannou, L., Serpell, J., Dean, J., Bendinelli, C., Gough, J., Lisewski, D., Miller, J., Meyer-Rochow, W., Sidhu, S., Topliss, D., Walters, D., Zalcberg, J., Ahern, S. Development of a Bi-National Thyroid Cancer Clinical Quality Registry. Royal Australian College of Surgeons (RACS) Annual Scientific Congress (ASC), Sydney, Australia (7-11 May 2018) (Oral Presentation)

FUTURE DEVELOPMENTS

SITE PARTICIPATION

Over the next two years, the ANZTCR will recruit surgeons from a further 20 sites across Australia and New Zealand, bringing the total number of participating sites to over 40 public and private hospitals.

LONGER-TERM FOLLOW-UP

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.

CLINICAL QUALITY INDICATOR REPORTING

As the ANZTCR continues to expand its coverage and recruitment of patients it will be able to undertake reporting back to sites regarding the CQIs. A risk-adjustment process will be established to ensure that these benchmarked reports are adjusted for differences in casemix at different sites. Sufficient caseload is required before these reports can be generated, with a minimum patient volume per site to be determined. The ANZTCR is aiming to generate site benchmarked reports by January 2021. In the interim, participating sites can log onto the database and access their patient information and download data reports at any time.

DATA ACCESS

As the volume of patient data increases, the ANZTCR encourages requests for access to data or for data analyses from clinicians, researchers, governments, industry and others for purposes related to quality improvement, health services research, and epidemiological research. Please contact the ANZTCR for further information regarding our Data Access Policy and Procedure.

ACKNOWLEDGEMENTS

The Australian and New Zealand Thyroid Cancer Registry would not be possible without the leadership and commitment of the Australian and New Zealand Endocrine Surgeons (ANZES). I would like to also gratefully acknowledge funding by the registry's industry partners and the Alfred Foundation, and the support of the Australian Thyroid Foundation (ATF) for the work of the registry.

The registry would not be possible without the input and active participation of our Steering Committee members, and all our participating sites including contributing surgeons, their registry data managers, and their administrative staff.

Most importantly, thank you to our participating patients who generously share their information with us to improve the quality of the management of thyroid cancer in Australia and New Zealand.

Associate Professor Susannah Ahern
Academic Lead, Australian & New Zealand Thyroid Cancer Registry
Head, Registry Sciences & Research Unit, Monash University

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LIST OF ABBRIEVIATIONS

ACSQHC	Australian Commission on Safety and Quality in Health Care
ANZES	Australian and New Zealand Endocrine Surgeons
ANZTCR	Australian & New Zealand Thyroid Cancer Registry
ANZTCR-RCD	ANZTCR REDCap Database
ATF	Australian Thyroid Foundation
CQI	Clinical Quality Indicator
DTC	Differentiated Thyroid Cancer
ENT	Ear Nose Throat
FNA	Fine Needle Aspiration
HREC	Human Research Ethics Committee
MDM	Multi-disciplinary Team Meeting
MNG	Multinodular Goitre
NMA	National Mutual Acceptance
RRA	Radioactive Iodine Remnant Ablation
RLN	Recurrent Laryngeal Nerve
Tg	Thyroglobulin
TNM	Tumour Node Metastasis
TSH	Thyroid Stimulating Hormone
US	Ultrasound

APPENDICES

APPENDIX A: LIST OF TABLES

APPENDIX B: LIST OF FIGURES

APPENDIX C: DATA ELEMENTS CAPTURED

Recruitment

- Patient ID
- Given Name(s)
- Surname
- Date of Birth
- Sex
- Country
- Street Address
- Suburb
- State/City
- Postcode
- Contact Number
- Email Address
- Medical Record Number
- Surgeon Name
- Date of Diagnosis
- Basis of Diagnosis
- Disclosure of Diagnosis to Patient
- Vital Status
- Date of Death
- Cause of Death

Preoperative

- Interpreter Required
- Aboriginal, Torres Strait Islander Status
- Maori Status
- 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

Procedure(s)

- 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 Pathology
- Papillary, Follicular and Hürthle Cell Variants
- Incidental Finding of Cancer
- Thyroid Benign Pathology
- Largest Tumour Diameter
- Margin Status
- Multifocal Cancer
- Lymphovascular Invasion
- Extrathyroidal Extension
- Lymph Node Metastases
- Distant Metastases
- Surgical Complications

Postoperative

- Presented at MDM
- TNM Staging
- Supplementation
- Biobank Sample
- Genetic Testing

Treatment

- Postoperative Tg
- TSH Stimulation
- RAI Remnant Ablation (RRA)
- Other Adjuvant Therapy

APPENDIX D: COMMITTEES & STAFF

Steering Committee Members

Professor Jonathan Serpell	Committee Chair, Endocrine Surgeon
Associate Professor Susannah Ahern	Head, Registry Science Unit, Public Health, Monash University
Associate Professor Julie Miller	ANZES President, Endocrine Surgeon
Professor Duncan Topliss	Endocrinologist
Ms Madeleine Allnutt	Australian Thyroid Foundation, Consumer Advocate
Dr Cino Bendinelli	Endocrine Surgeon
Dr Jenny Gough	Breast and Endocrine Surgeon
Dr James Lee	Endocrine Surgeon
Mr Dean Lisewski	Endocrine Surgeon
Dr Win Meyer-Rochow	Endocrine and General Surgeon
Professor Stan Sidhu	Endocrine Surgeon
Dr David Walters	Breast and Endocrine Surgeon
Professor John Zalcberg	Head, Cancer Research Program, Public Health, Monash University
Dr Chhavi Bhatt	Database Manager

Registry Leads

Professor Jonathan Serpell, Clinical Lead
Associate Professor Susannah Ahern, Academic Lead

ANZTCR Coordinating Centre, Monash University

Dr Liane Ioannou, Registry Coordinator
Ms Elysia Greenhill, Research Assistant

APPENDIX E: LIST OF PARTICIPATING SITES & SURGEONS

Participating Sites

VIC	Alfred Hospital Casey Hospital Dandenong Hospital Frankston Hospital Monash Medical Centre Clayton Monash Medical Centre Moorabbin Peninsula Private Hospital Royal Melbourne Hospital
NSW	Dudley Private Hospital Hornsby Ku-ring-gai Hospital John Hunter Hospital Lake Macquarie Private Hospital Manly District Hospital Royal North Shore Hospital Royal North Shore Private Hospital
QLD	Greenslopes Private Hospital North West Private Hospital Townsville Hospital Wesley Hospital
SA	Royal Adelaide Hospital The Queen Elizabeth Hospital Flinders Medical Centre

Participating Surgeons

Dr Cino Bendinelli
Dr Janne Bingham
Dr Melissa Bochner
Dr Jason Boldery
Dr Jared Chang
Dr Daron Cope
Prof Leigh Delbridge
Dr Robert Eisenberg
Dr Linda Fenton
Dr Anthony Glover
Dr Jenny Gough
Mr Simon Grodski
Dr Andrew Kiu
Dr Jim Kollias
Dr Christine Lai
Mr James Lee
A/Prof Julie Miller
Dr Sally Meade
Dr Teresa Nano
Dr Christine O'Neil
Prof Jonathan Serpell
Prof Stan Sidhu
Dr Anita Skandarajah
Dr Kate Stringer
A/Prof Mark Sywak
Dr Domenika Turkiewicz
Dr David Walters
Dr Robert Whitfield
Dr David Wright
Dr Meei Yeung
Dr Robert Tasevski

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