




BMJ Open Development of an Australia and New Zealand Lung Cancer Clinical Quality Registry: a protocol paper

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ABSTRACT

Introduction Lung cancer is the leading cause of cancer mortality, comprising the largest national cancer disease burden in Australia and New Zealand. Regional reports identify substantial evidence-practice gaps, unwarranted variation from best practice, and variation in processes and outcomes of care between treating centres. The Australia and New Zealand Lung Cancer Registry (ANZLCR) will be developed as a Clinical Quality Registry to monitor the safety, quality and effectiveness of lung cancer care in Australia and New Zealand.

Methods and analysis Patient participants will include all adults >18 years of age with a new diagnosis of non-small-cell lung cancer (NSCLC), SCLC, thymoma or mesothelioma. The ANZLCR will register confirmed diagnoses using opt-out consent. Data will address key patient, disease, management processes and outcomes reported as clinical quality indicators. Electronic data collection facilitated by local data collectors and local, state and federal data linkage will enhance completeness and accuracy. Data will be stored and maintained in a secure web-based data platform overseen by registry management. Central governance with binational representation from consumers, patients and carers, governance, administration, health department, health policy bodies, university research and healthcare workers will provide project oversight.

Ethics and dissemination The ANZLCR has received national ethics approval under the National Mutual Acceptance scheme. Data will be routinely reported to participating sites describing performance against measures of agreed best practice and nationally to stakeholders including federal, state and territory departments of health. Local, regional and (bi) national benchmarks, augmented with online dashboard indicator reporting will enable local targeting of quality improvement efforts.

INTRODUCTION

Lung cancer in Australia and New Zealand

Lung cancer is the fifth most commonly diagnosed cancer in Australia¹ and the fourth in New Zealand,² and provides the

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A binational thoracic oncology registry has strong multisectoral and multiorganisational support based on the established track record of the pilot Victorian Lung Cancer Registry.
- ⇒ Harmonisation of national improvement efforts using a standardised and institutionally contextualised communication strategy addresses an important gap to confirm evidence-based practice, identify evidence to practice gaps and to highlight unwarranted practice variation to focus quality, safety and value improvement efforts.
- ⇒ The registry has strong scalability for comprehensive inclusion of metropolitan, regional and remote centres, in public and private facilities to confirm equity and access to healthcare for populations of diverse indigenous, cultural, linguistic, socioeconomic, regional and remote backgrounds.
- ⇒ A national mandate for institutional participation and reporting is needed to support local governance, to strengthen local infrastructure and data collection, to facilitate data linkage and the creation of a learning health system, and to limit potential inclusion bias of over-representation of high performing centres.
- ⇒ National funding remains to be established and yet there remains a strong need to establish a vehicle to enhance data-driven improvement and the creation of a learning health system to address the leading national cancer burden.

leading cause of cancer-related death in both countries. Australia saw 13 810 newly diagnosed primary lung cancers projected in 2021,³ where indigenous Australians suffer an age-standardised lung cancer rate double that of non-indigenous Australians. Similarly in New Zealand, 2381 new cases of lung cancer were seen in 2018² with a rate nearly threefold higher in the



Maori population. Some 8379 lung cancer deaths were recorded in 2020 in Australia, and survival from lung cancer remains poor in both males and females with a 5-year survival rate of 20.2%,³ and lower in New Zealand at 11%.² Lung cancer imposes the greatest cancer disease burden, chiefly through years of life lost⁴ and direct management costs⁵ and is predicted to increase over time.⁶

Encouragingly, lung cancer research has seen major advances across the multidisciplinary spectrum over the past decade. Molecular pathology has revolutionised understanding of lung cancer pathogenesis and opened the door to targeted treatment.⁷ Endobronchial ultrasound has largely eliminated the need for mediastinoscopy in lung cancer staging.⁸ Surgical enhancements including video-assisted thoracoscopic surgery have led to fewer postoperative complications, reduced length of stay and improved quality of life.^{9,10} Stereotactic body radiotherapy (SBRT) has extended capacity to treat medically inoperable patients with curative intent.¹¹ The breakthrough discovery and availability of almost 20 new systemic therapy agents including targeted therapies and immune checkpoint inhibitors have transformed the treatment landscape for patients with locally advanced and metastatic disease.¹² The importance of early referral to palliative care in improving quality of life, reducing aggressive end-of-life care, and, for some patients, prolonging survival, has also been highlighted.¹³

Additional challenges to modern lung cancer management include the importance of patient-centred and value-based healthcare, rising hospitalisation, management and treatment costs,⁴ and an ageing population predicted to continue to increase.^{5,14,15} The opportunities provided by improved diagnostics and therapeutics are in a phase of rapid evolution and for patients to fully benefit from these advances in research evidence there is need for urgent translation of this evidence to routine clinical practice and to acknowledge population health systems in demanding evidence to confirm and guide this translation [box 1](#).

Challenges

While new diagnostic tools and novel treatments have the potential to improve patient outcomes, optimal management of lung cancer has become increasingly

Box 1 Terri Byrne (Queensland), lung cancer patient advocate

As a woman living with lung cancer in a rural and remote part of Australia, I believe having a National Lung Cancer Registry would help all hospitals deliver the same quality of care. This would make a huge difference and ensure we get a standardisation of information and treatment across Australia, not just in metropolitan areas. Having the same access to treatment in our hometowns would mean no delays and we can have our family close by—giving us the hope we need.

complex, creating challenges for the implementation and monitoring of best practice. There is an urgent need to monitor outcomes related to this disease to improve efficiency, effectiveness and sustainability by ensuring the provision of patient centred, high-quality, evidence-based care that optimises value to the health-care system.

Variation in care

Unwarranted variation in healthcare delivery represents a major opportunity for care improvement. Such variation may present both as gaps between delivered care relative to evidence-based best practice, as well as variation in the use of health services between healthcare providers which are unaccounted for by patients' needs or preferences. The reduction of unwarranted variation in care is a major Australian policy objective to protect patients from harm and to improve the quality of care delivered.¹⁶

There is substantial institutional and regional evidence of unwarranted variation in both processes of care and outcomes for Australians diagnosed with lung cancer ([figure 1](#)). A study of 4854 Victorian NSCLC and SCLC patients revealed guideline concordant treatment delivered to just 60.36% of patients with variation across geographic areas and over time associated with poor performance status, advanced clinical stages, NSCLC subtypes, public hospital insurance, area-level deprivation and comorbidities.^{17,18} Regional variation in 2-year mortality for NSCLC has been demonstrated where those with timely first definitive treatment (OR 0.73; 95% CI 0.56 to 0.94) and multidisciplinary meeting presentation (OR 0.74; 95% CI 0.59 to 0.93) were significantly less likely to die within 2 years of diagnosis.¹⁹ Variation in processes of care is evident in timeliness of care,^{20–22} pathological confirmation of diagnosis,²³ utilisation of multidisciplinary meetings^{23,24} ([figure 2](#)), patterns of care delivery^{25–28} and follow-up after cancer treatment.²⁹ Substantial variation is also evident in key outcomes of care including the utilisation of active anticancer treatment^{17,23,30–32} and survival.^{19,32,33}

Evidence of unwarranted variation in equity and access outcomes is also reported for vulnerable populations including Aboriginal and Torres Straits Islanders,^{34,35} Maori,^{36,37} geographically remote,^{38,39} lower socioeconomic status^{40,41} and the elderly⁴² raising significant concerns regarding equity of access to effective cancer prevention and treatment.

Measurement for quality improvement

Improvement in quality of care is a critical objective in healthcare policy. Clinical performance indicators may be designed to measure the structure, process and quality of care.⁴³ Quality indicators may be used as quantitative measures that provide information about the effectiveness, safety and/or people-centredness of care.⁴⁴ Design of quality indicators enables definition

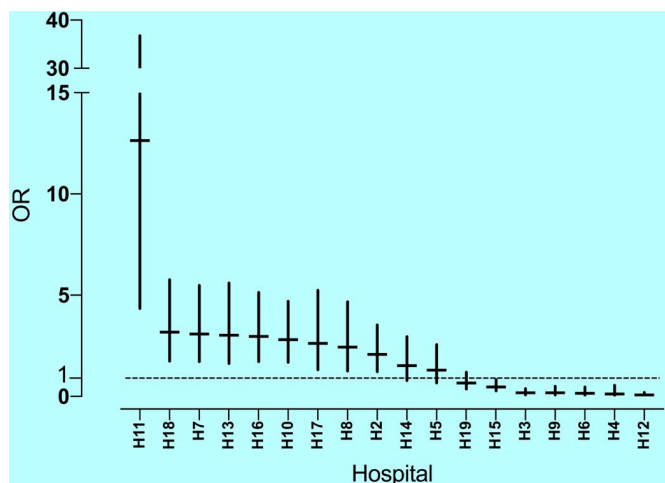


Figure 1 Likelihood of patients having documented screening for supportive care within 18 Victorian health services (OR; 95% CIs) VLCCR 2019 varied between 0.07;0.02 to 0.20 and 12.63;4.34 to 36.79. VLCCR, Victorian Lung Cancer Registry.

of the quality improvement goal, the method for measurement and opportunities for appraisal of quality outcomes. The use of quality measures may be undertaken for quality assurance and demonstration of equity in access to care and outcomes. The examination of unwarranted variation in process and outcomes in care is also critical in meeting stakeholder needs and expectations and to provide accountability for consumers, providers and payors.

The longitudinal measurement and reporting of quality indicators provides opportunities to iteratively improve the quality of care. It also provides and facilitates the integration of novel evidence-based practice knowledge and clinical system performance knowledge

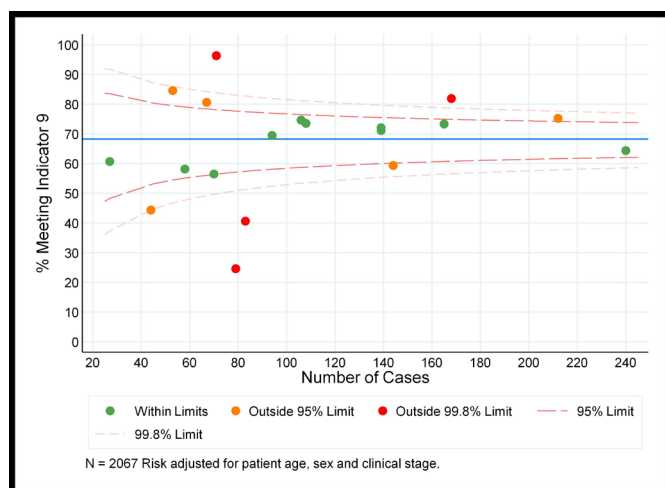


Figure 2 Funnel plot of proportion of patients with documented evidence of presentation to a multidisciplinary meeting, Victorian Lung Cancer Registry 2019, n=2114 subjects. Mean 68% with 95% (heavy dotted line) and 99.8% (light dotted line) CIs. Green dots within confidence limits, red dots represent outlier status.

to improve clinical decision making and to enhance the dissemination and implementation of evidence-based practice in a learning health system.^{45 46} The longitudinal measurement of disease diagnosis, treatment and outcome may further provide critical monitoring during health system shocks, such as those experienced during the COVID-19 pandemic.

Clinical quality registries in measurement of quality of lung cancer care

The feasibility and effectiveness of national lung cancer registries for quality improvement have been demonstrated internationally.⁴⁷⁻⁵¹ The Danish Lung Cancer Registry was established in 2000⁵² with nationally mandated participation, reporting 14 indicators to stakeholders providing both online real-time hospital and annual reports.⁵³ Important improvements following registry development included improved referral to treatment timeliness, improved staging quality, increased lobectomy rates, reduction in 30-day postoperative mortality and improvement in 1-year, 2-year and 5 years survival rates.⁵⁴

The UK National Lung Cancer Audit (UK-NLCA) was established in 2004 providing quarterly feedback reports to hospitals and networks using a 112-item dataset confirmed in 2007 and now captures data from all UK hospitals providing lung cancer care.⁵⁵ Following the commencement of the audit there have been significant changes in process measures including histological confirmation rate (64% in 2005 to 76% in 2009) and multidisciplinary meeting presentation (78% in 2005 to 94% in 2009). The reports confirm wide variation in process and outcome measures including receipt of treatment and survival in participating centres.⁵⁶

Data linkage of the UK-NLCA with administrative, treatment and patient experience datasets has provided important opportunities for evaluation of equity in access⁵⁷ hypothesis generation, gap analysis,^{58 59} confirmation of real-world treatment effectiveness^{60 61} and opportunities for patient experience improvement.⁶² Further, the UK-NLCA has been successfully implemented as an explicit tool for quality improvement in nationally coordinated projects targeting the reduction of unwarranted variation in clinical care outcomes,^{63 64}

The Dutch Lung Cancer registry is comprised of three independent surgery, radiotherapy and systemic therapy subgroups facilitated by the Dutch Institute for Clinical Auditing. Dutch legislation mandates patient inclusion, providing a national consent enabling all Dutch hospitals to contribute to the registry.⁵¹ The Dutch registry has thereby established high level completeness and participation and results for 15 indicators are discussed quarterly and provided to hospitals and made publicly available.

Rationale for registry development

A range of Australian regional and state-based initiatives have been developed for improving outcomes in

lung cancer care through the use of clinical quality indicators^{20 65–68} including the Performance Index of the Cancer Institute New South Wales,⁶⁹ The Queensland Lung Cancer Quality Index,⁷⁰ Cancer Alliance Queensland⁷¹ and the Victorian Lung Cancer Registry (VLCR).⁷² These reports include clinical indicators as tools providing methodologically consistent comparators of service provision across institutions and within various jurisdictions and enable delivery of risk adjusted benchmarking.⁷³

Performance indicators reported by these state initiatives share a broadly aligned purpose, and measure quality of care using the six dimensions of the Institute of Medicine's Quality of Healthcare framework: safety, effectiveness, patient-centred care, timeliness, efficiency and equity.⁷⁴ However, there remains a lack of harmonisation across the states. An opportunity exists to implement an index of standardised and validated indicators to enable nationwide monitoring of clinical practice and benchmarking in lung cancer care.

Braithwaite *et al* describe the 60:30:10 phenomenon in modern medical care where on average 60% of care is in line with evidence or consensus-based guidelines (confirmed in Victorian lung cancer¹⁷), 30% represents some form of waste or low value care and 10% of care leads to patient harm.⁷⁵ The ability to improve evidence-based best practice, to reduce low

value care and to minimise patient harm provides three clear improvement objectives and demands performance measurement, reporting and data availability for knowledge translation, and improvement in quality and value of delivered care.

Proof of concept in the VLCR

The VLCR was developed in 2011⁶⁷ in accordance with the operating principles of the Australian Commission on Safety and Quality in Healthcare (ACSQHC) Framework for Clinical Quality Registry Development,⁷⁶ is registered with the Australian Register of Clinical Registries (ACSQHC-ARCR-432) and is closely aligned with the National Clinical Quality Registry and Virtual Registry Strategy 2020–2030.⁷⁷ The registry has captured data on >14 500 newly diagnosed Victorian cases of NSCLC and SCLC and provides annual risk-adjusted benchmark reports on 21 performance indicator measures to 19 health services, representing 50 hospitals and accounting for >85% of all new diagnoses in Victoria. A dataset has been developed containing key quality process and outcome measures with descriptors of patient, disease, management and outcomes for Victorian patients with lung cancer (figure 3). The registry has provided a framework to facilitate quality improvement collaboratives in a learning health system to drive multisite data-driven

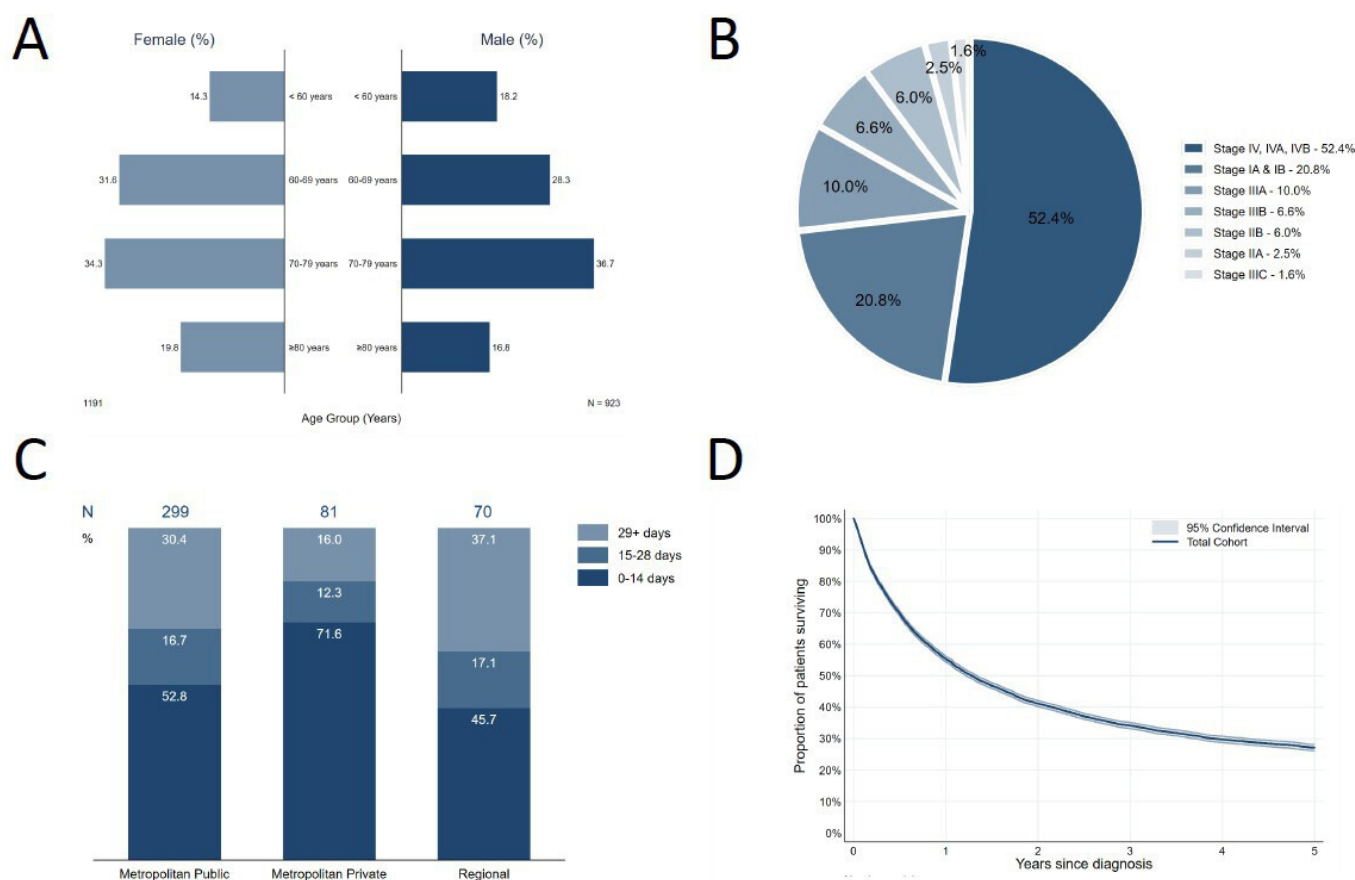


Figure 3 The Victorian Lung Cancer Registry 2019 provides capability to describe patient (A), disease (B), management (treatment timeliness) (C) and survival outcomes (D) for 10552 newly diagnosed patients.

improvement in lung cancer management.⁷⁸ The VLCR is located within the Department of Epidemiology and Preventive Medicine at Monash University which manages the registry's core activities under the direction of the VLCR Steering Committee. The Monash Clinical Registry Unit currently houses 35 clinical quality registries,⁷⁹ including 6 national cancer registries in the School of Public Health and Preventive Medicine, and has established robust protocols for data capture, transmission, security and custodianship, as well as outlier management and accountability for the privacy, security and integrity of patient information held within the registry.

Opportunities in clinical quality registry development

Lung cancer in Australia and New Zealand is characterised by high prevalence, high morbidity and poor survival and comprises the leading national cancer burden. Unwarranted variation in processes and outcomes of lung cancer care are widely demonstrated and demand demonstration and evaluation to address evidence to practice gaps in lung cancer management. Multidisciplinary research evidence in lung cancer care is rapidly evolving and measurement of the integration and translation of this evidence into clinical performance is highly desirable. The provision of harmonised, risk adjusted benchmark reporting of lung cancer management and outcome performance provides the information necessary for an informed national cancer control programme.

METHODS AND ANALYSIS

Australia and New Zealand Lung Cancer Registry objectives

The development of the Australia and New Zealand Lung Cancer Registry (ANZLCR) has four main objectives:

1. Measure and report benchmarked outcomes of clinical quality indicators reflecting the quality of lung cancer management in participating hospitals.
2. Describe unwarranted variation in management and outcomes in lung cancer care.
3. Provide a data infrastructure to enable a learning health system for data-driven improvement in health-care.
4. Develop a clinical data repository to inform collaborative lung cancer research.

COHORT DESCRIPTION

Overview

Established in 2021–2022, the ANZLCR will be a binational, multicentred, population-based clinical quality registry. Confirmation of ethics has been undertaken in Victoria, South Australia, Tasmania and the ACT and further enrolment is facilitated under a National Mutual Acceptance (NMA) agreement.

Governance and oversight

Coordinating centre

The operations of the ANZLCR and coordinating centre location will be determined following consultation with the central governance body, with due consideration of relevant skills, experience and costs required to operate a national registry.

Site investigators

The ANZLCR is a multicentred, investigator-driven endeavour with a local primary investigator(s) at each site responsible for local coordination, including data collection oversight and the feedback and dissemination of report data to institutional stakeholders. Research activities undertaken at their site are conducted in accordance with HREC approval, the research protocol, site registry agreements and related policy documentation.

Governance structure

ANZLCR oversight will be provided by a multidisciplinary steering committee in accordance with the Australian Framework for CQRs.⁷⁶ Chaired by the clinical leads, the group is composed of patient and carer consumers, specialist lung cancer nurses, thoracic surgeons, medical oncologists, radiation oncologists, respiratory physicians, palliative care specialists, pathologists, radiologists, biostatisticians, informaticists, epidemiologists, public health practitioners, health economists, hospital governance and administration staff, and representatives from state and federal departments of health (figure 4). The committee will seek representation from key national organisations with an interest in improving outcomes for those affected by lung cancer including Lung Foundation Australia, Thoracic Oncology Group of Australasia, Medical Oncology Group of Australia, Clinical Oncology Society of Australia, state and federal Cancer Councils, Cancer Australia and tumour biobank services where available. The steering committee will meet quarterly, providing 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.

Management committee

A central management committee comprised of a project manager, data custodian, data collector supervisors and data analysts will meet weekly and oversee the day-to-day running of the registry. Further subcommittees and working groups including a data access subcommittee will be established as required.

Patient and public involvement

No less than two consumers with lived experience of cancer, including lung cancer patients and carers, will inform process as members of the ANZLCR steering committee. A consumer engagement working group will explore opportunities to optimise priorities and measures

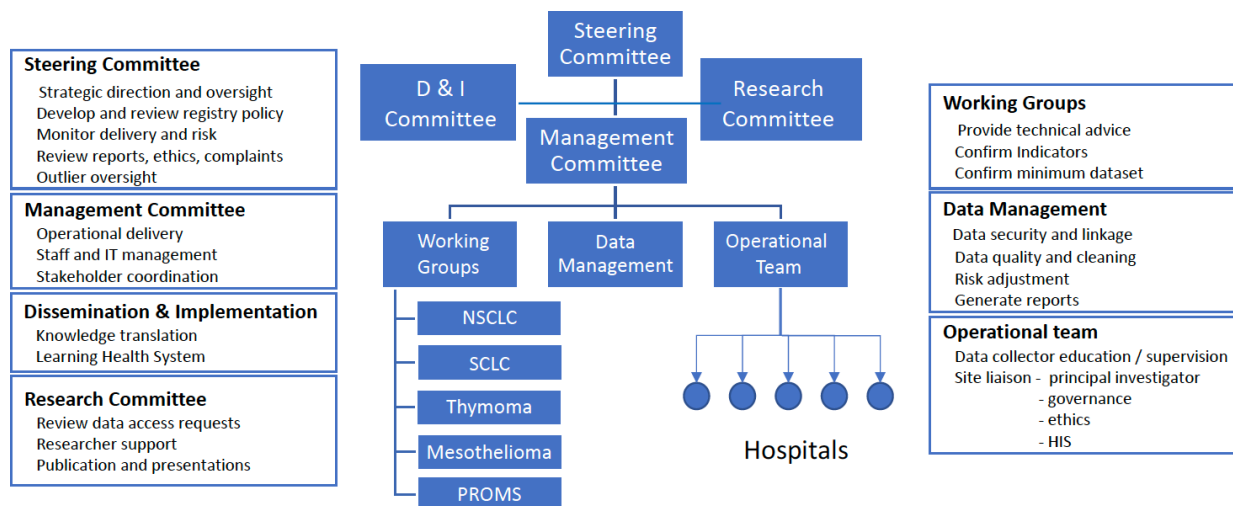


Figure 4 Governance structure for an Australia New Zealand Lung Cancer Registry. HIS, Health Information Services; NSCLC, non-small-cell lung cancer; Patient Reported Outcome Measures (PROMs).

of patient centred care as well as provide direction for registry based collaborative research projects.

Participant recruitment and consent

Registry population

All patients with a confirmed diagnosis of primary thoracic malignancy (NSCLC, SCLC, mesothelioma or thymoma) over ≥ 18 years of age who have been diagnosed, assessed and/or treated at a participating site are eligible to participate in the registry. Participants may be included with either clinically diagnosed or tissue confirmed lung cancer.

Opt-out process

To minimise recruitment bias and achieve whole population coverage, the ANZLCR employs an opt-out process. This approach has been successfully applied in over 75% of CQRs in Australia and accounts for sicker, disadvantaged and minority groups who would otherwise not be included due to their incapacity to consent.⁸⁰ An opt-out process reduces selection bias, which would otherwise be detected by omitting sub-populations, increases clinical validity, thus permitting meaningful outcome assessment with representation from all groups. A waiver of consent applies where patients deemed eligible have died by the time the registry is informed of their diagnosis. The recruitment schema is outlined in [figure 5](#).

Participant recruitment

Eligible patients are identified from institutional discharge lung cancer coding, including International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Australia Modification (ICD-10-AM) codes C34.0–C34.9, Z85.1–Z85.2 and R91 and adopted in New Zealand.⁸¹ Health Information Services (HIS) at each participating health service provide monthly reports, via password-protected secure file transfer, for eligibility screening of potential participants by ANZLCR site data collectors. After notification, patient details are received

and stored in the custom-built ANZLCR database, hosted securely at Monash University. Eligible patients must have a diagnosis confirmed by either pathology examination or imaging, occurring after the institution enrolment and commencement of data capture. On receipt of notification, patient health status is verified before further contact is made.

Following screening for eligibility, a patient explanatory statement and informed consent information is provided with a covering letter explaining the registry, data collection and options for opting-out of participation. Patients are given 2 weeks before their participation is assumed, after which, data collection commences. Participants can subsequently opt-out of the registry at any time. Alignment of consent and ethics across jurisdictions to ensure data sovereignty will be confirmed.

Quality indicators

Quality indicators have been designed and framed with the objective of reflection of the Institute of Medicine targets for quality care, namely that care be safe, timely, effective, efficient, evidence-based, patient-centred and aligned with current clinical practice guidelines.^{74 82–85} Indicators frame the principles of the Lung Cancer Optimal Care Pathways of the Cancer Councils Australia.⁸⁶ Indicators are to be further ratified and extended using a three step Delphi process for national endorsement. This process will specifically consider the inclusion of novel/emerging or under-represented measures eg molecular pathological assessment and subsequent treatment, SBRT in early-stage disease and clinical trial participation. Current NSCLC indicators of the VLCR and 2019 performance are represented in [table 1](#).

Data collection

Data collection is commenced on receipt of consent first informed by electronic data extracts received from HIS departments at each health service. Patient

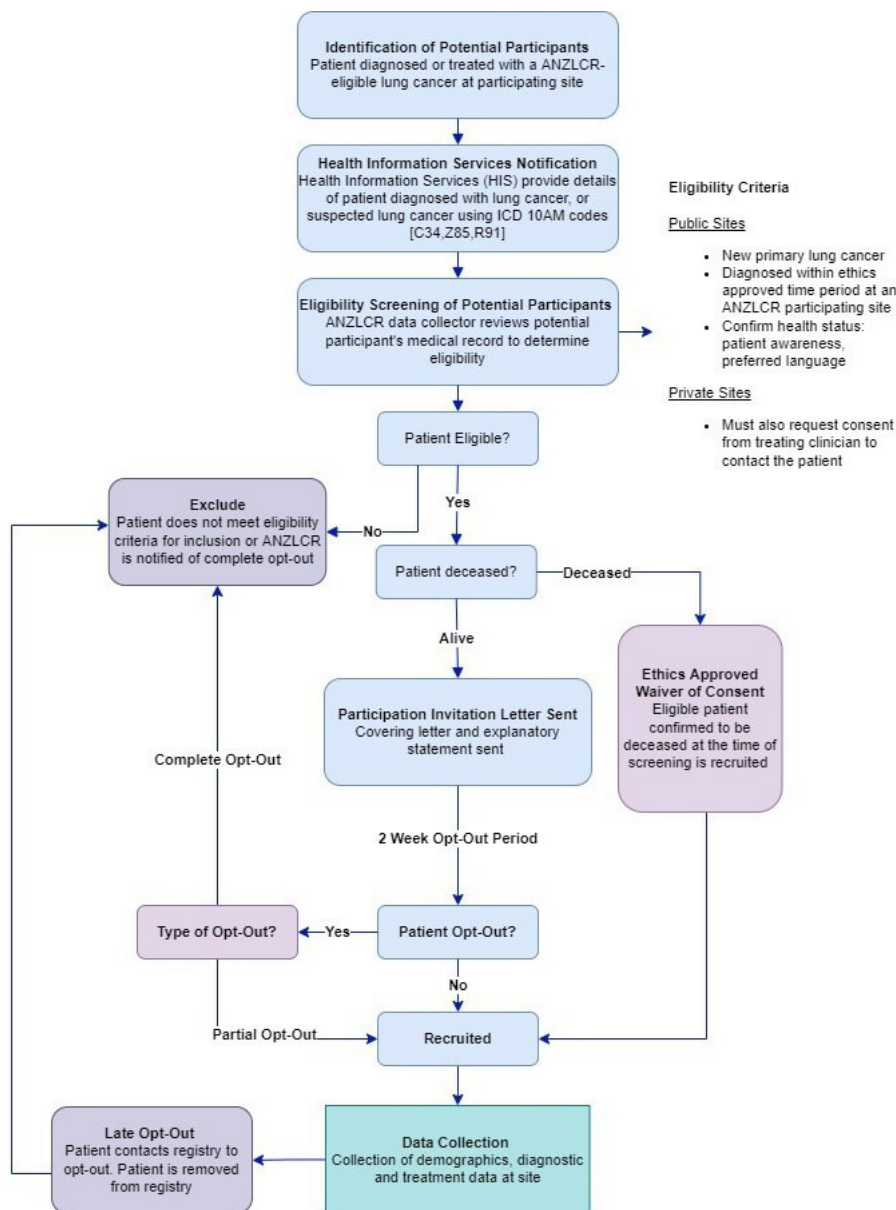


Figure 5 Participant recruitment and data utilisation in the ANZLCR. ANZLCR, Australia and New Zealand Lung Cancer Registry; ICD-10-AM, International Statistical Classification of Diseases, 10th Revision, Australia Modification.

demographics, diagnostic and therapeutic ICD-10-AM coding are captured passively, defined and categorised within the registry database. Clinical treatment and supportive care management data are actively recorded at the site level by data collectors centrally trained and supervised with local direction provided by site principal investigators. Data are primarily submitted via direct data entry using the custom-built secure web-based ANZLCR database. Additional data are obtained from site pharmacy reports, pathology reports and other data sources such as state-level death and cancer-related registries, and government datasets. Site data collectors are trained to use the database, provided with a data dictionary and data entry manual to ensure high-quality data collection. Site data collectors are supported by attendance at quarterly data collection workshops delivered by the central

team to ensure ongoing development, refinement and congruence of data collection skills. Direct data linkage with available multidisciplinary support tools including Queensland Oncology On Line⁸⁷ developed by Cancer Alliance Queensland, and oncology data management systems including CHARM⁸⁸ and MOSAIQ⁸⁹ and state cancer registries⁹⁰ will be explored to further support data linkage.

ETHICS AND DISSEMINATION

Data privacy

Data collected will be stored within Australia at a data centre in Melbourne, managed by eSolutions of Monash University (onshore and private server). To protect sensitive information, data in transit or at rest will be encrypted.

**Table 1** VLCR clinical quality indicators mapped to the optimal care pathway 2019

Step 1: Prevention and early detection	
Step 2: Presentation, initial investigations and referral	
Quality indicators	Mean 2019
Proportion where time from referral for assessment to diagnosis is ≤ 28 days	70%
Proportion with documented screening for supportive care	33%
Proportion with documented ECOG status	69%
Step 3: Diagnosis, staging and treatment planning	
Proportion with confirmed tissue diagnosis (malignant cytology or histology)	92%
Proportion with clearly documented cTNM staging	89%
Proportion undergoing resection with clearly documented PET scan	97%
Proportion with documented presentation at a lung MDM	67%
Proportion where time from diagnosis date to first treatment date (any intent) is ≤ 14 days	41%
Proportion with NSCLC where time from diagnosis date to surgical resection date is ≤ 14 days	53%
Proportion where time from referral date to first treatment (any intent) is ≤ 42 days	47%
Step 4: Treatment	
Proportion with NSCLC (clinical stage I, II) who have had surgical resection	61%
Proportion with NSCLC (clinical stage I or II) and resection with ≥ 5 lymph nodes dissected	70%
Proportion with NSCLC (clinical stage I or II) undergoing resection with VATS approach	80%
Proportion receiving anticancer treatment (surgery, radiotherapy, chemotherapy or systemic therapy)	85%
Proportion with NSCLC (stage IIIB or IV) who have ECOG (0–1) and have commenced chemotherapy	73%
Proportion of NSCLC (pathological stage II) receiving platinum-based chemotherapy after resection	54%
Step 5: Care after initial treatment and recovery	
Proportion of NSCLC undergoing surgical resection with clearly documented pTN	97%
Proportion of NSCLC patients undergoing surgical resection where cTN agrees with pTN	84%
Proportion of patients with NSCLC who have had a surgical resection and died within 30 days of surgery	1.1%
Proportion of patients with NSCLC who have had a surgical resection and died within 90 days of surgery	1.3%
Step 6: Managing recurrent, residual or metastatic disease	
Proportion of patients with NSCLC (stage IV) referred to any palliative care services within 8 weeks of diagnosis	42%
Step 7: End-of-life care	
Proportion of patients with lung cancer where time from chemotherapy start date to death date is ≤ 30 days	5%
Quality indicators are risk-adjusted for clinical stage, age and sex. cTN, Clinival stage TNM staging system; cTNM, Clinival stage TNM staging system; ECOG, Eastern Cooperative Oncology Group Performance Status; MDM, Multidisciplinary Meeting; NSCLC, non-small-cell lung cancer; pTN, Pathological stage TNM staging system; VATS, video-assisted thoracoscopic surgery; VLCR, Victorian Lung Cancer Registry.	

Ethics

Each participating site will require approval from local HRECs. National approval has been granted from the Alfred Health HREC under the NMA scheme (HREC/16/Alfred/84).

Data cleaning, analysis and reporting

Collected data will be cleaned and checked for completeness by central registry data analysts. Quality indicator data will be risk adjusted accounting for sex, age, clinical stage and performance status. Deidentified, risk-adjusted benchmark reports will be distributed to participating site principal investigators, hospital ethics and research

committees and hospital governance and administration on an annual basis with ongoing development of an online QI dashboard for local real time reporting of QI performance. Clinical indicators will be reported using funnel plots,⁹¹ a form of scatter plot in which observed institutional indicator outcomes are plotted demonstrating site volume of activity and outcome (figure 2). Control limits are provided demonstrating 95% and 99.8% CIs and are overlaid on the scatter plot. These control limits represent expected variation in rates assuming random variation and may be used to describe common-cause and special-cause variation.⁹² Funnel plots

allow the identification of ‘outlier status’ for an institution which may represent indicator performance that is statistically superior or inferior to included peers. An outlier management policy developed by the ANZLCR Steering Committee will provide a response management strategy for the verification, investigation and resolution of persisting poor hospital performance against reported indicators.

Data access and release for research

Site principal investigators can request their health services data at any time. In this view, the Registry Coordinator will generate the data ready for secure transfer. The ANZLCR has a data access policy and any researchers wishing to access data will be required to submit a data request form detailing their research proposal to the ANZLCR steering committee. Based on proposal and design, feasibility and impact on healthcare, and following receipt of relevant ethics approval certificates, accepted requests will receive a non-identifiable dataset including the fields specifically requested.

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