

SPEAK – Lung



Survey of Patient Engagement and Attitudes towards Key research priorities in Lung cancer - korero tahi

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Study registration:

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1. SYNOPSIS

Title	Survey of Patient Engagement and Attitudes towards Key research priorities in Lung cancer (SPEAK - Lung)
Background and rationale	Lung Cancer is the leading cause of cancer related death in Aotearoa/New Zealand and disproportionately impacts Māori. Recent advances in lung cancer treatment offer an opportunity to improve outcomes for Māori if delivered in an equitable way. Existing records of patient ethnicity in hospital records needs to be confirmed as accurate, and patient views on topics such as participation in tissue biobanking, enrolment in a lung cancer clinical database and preferred setting to receive treatment are unknown, but have a major influence on advancing lung cancer research in the northern region and developing services to deliver immunotherapy and other cancer treatments suitable to the needs of all patients.
Investigators/collaborators	Dr Laird Cameron Dr Helen Wihongi Dr Mathew Wilson Stella Williams-Terei Dr Kimiora Henare Thomas Hauraki

Aim	To assess lung cancer patient views on key elements of planned lung cancer research in the northern region: self-identified ethnicity, participation in tissue biobanking, participation in a clinical database and preferred location of intravenous treatment
Objectives	<ol style="list-style-type: none"> 1. To accurately describe self-identified ethnicity of lung cancer patients and assess accuracy of current hospital records on ethnicity in lung cancer patients in the Auckland region of New Zealand 2. To assess patient attitudes towards participation in biobanking 3. To assess patient attitudes towards automatic enrolment in a clinical lung cancer database 4. To assess patient preferences on ideal setting to receive immunotherapy
Study population Inclusion/exclusion	<p>Estimated 400-500 participants</p> <p>Lung malignancy of any stage Presenting to clinic on treatment or in follow-up. Included once only Not virtual consults All ethnicities and type/stage of lung cancer</p>
Intervention(s)	Patient Questionnaire
Study design	Observational descriptive study
Outcomes	<p>Outcome 1: Ethnicity</p> <p>1A) Proportion of Māori, and other ethnicities, in the overall study population</p> <p>1B) Proportion of participants with self-identified ethnicity accurately recorded in existing records on Regional Clinical Portal</p> <p>Outcome 2: Attitudes regarding biobanking</p> <p>2A) Proportion of participants who express concern with any aspect of biobanking, and description of principal areas of concern</p> <p>Outcome 3: Lung Cancer Registry</p> <p>3A) Proportion of patients who support establishment of a lung cancer clinical database without individual patient consent, and description of areas of concern</p> <p>Outcome 4: Treatment Setting</p> <p>4A) Proportion of participants who indicate a preference for each potentially possible treatment setting, when asked to imagine an idealised healthcare system</p> <p>4b) present descriptive statistics by ethnicity and travel time from ACH</p>

Data management	Data will be stored in a secure database on-site at Auckland City Hospital and in accordance with the data management plan
Significance Equity impact/MHA	Lung Cancer disproportionately effects Māori in both prevalence and mortality. This study forms part of a larger body of work which seeks to optimise immunotherapy for Māori and delivery of therapies closer to home.
Risks	The investigators feel this study is low risk. <ul style="list-style-type: none"> • Non interventional • Asking a task of a potentially unwell population • Dissemination strategy and cultural safety of encounters needs governance
Funding	Maurice Wilkins Centre Cancer-Theme Funding grant

2. KEY CONTACTS

Name	Role	Affiliation
Investigators		
Laird Cameron	Principal Investigator laird.cameron@auckland.ac.nz	Waipapa Taumata Rau (The University of Auckland) / Te Whatu Ora Te Toka Tumai Auckland
Helen Wihongi	Principal Investigator	Waipapa Taumata Rau (The University of Auckland)
Mathew Wilson	Investigator	Te Whatu Ora Te Toka Tumai Auckland
Stella Williams-Terei	Investigator	Waipapa Taumata Rau (The University of Auckland)
Thomas Hauraki	Investigator	Te Whatu Ora Te Toka Tumai Auckland

3. LAY SUMMARY

Lung Cancer is the leading cause of cancer-related death in Aotearoa New Zealand. This disproportionately affects Māori who have higher incidence of lung cancer and higher rates of mortality due to lung cancer. In recent years the treatment of advanced lung cancer has been transformed by the advent of Immune Checkpoint Inhibitors (immunotherapy), which has led to significant improvements in survival. Immunotherapy for advanced lung cancer in New Zealand has been funded by Pharmac since April 2023. We are still learning how to maximise the benefits of this therapy in a New Zealand context. In the Auckland region, medical oncology services are provided by Te Puriri o Te Ora and immunotherapy can currently only be delivered from a single location in

Auckland City Hospital, central Auckland. This may represent a barrier to treatment from some patients and presents an equity problem for the portion of the patient population who need to travel to receive treatment. The direction of modelling for the northern region cancer service is moving towards care closer to home and with it a new type of workforce.

This study plans to survey all patients attending in-person medical oncology thoracic cancer clinic appointments at Auckland Hospital in a 3 month period. We would like to accurately assess self-identified ethnicity in our patient group, to determine if current hospital records accurately represent this. The survey will ask about patients preference of setting and location to receive immunotherapy. The results will help to inform the planned pilot of delivering community- based immunotherapy with Māori Primary Care Providers. (HRC 24/454)

Ongoing clinical and scientific research is required to continue to improve the equitable access to effective lung cancer treatments such as immunotherapy in New Zealand and infrastructure such as governed biobanking and reliable clinical data are needed for future improvements including discovery of biomarkers for treatment response.

4. ABBREVIATIONS AND GLOSSARY

EHR	Electronic Health Record
GCP	Good Clinical Practice
HDEC	Health Disability and Ethics Committee
NHI	National Health Index
ICI	Immune Checkpoint Inhibitor
ILCWW	Immunotherapy for whanau with Lung Cancer: Who and Where
NSCLC	Non Small Cell Lung Cancer
NZ	Aotearoa New Zealand
SCLC	Small Cell Lung Cancer
Te Aho O Te Kahu	Cancer Control Agency
Te Ira Kawai	Auckland Regional Biobank
Te Pūiri o Te Ora	Auckland Regional Cancer and Blood Service
TWO / HNZ	Te Whatu Ora / Health New Zealand
PIS	Patient Information Sheet
DMP	Data Management Plan

5. BACKGROUND AND RATIONALE

Lung Cancer is the leading cause of cancer related death in New Zealand ^[1] and forms a major priority for cancer research in the Northern region and across New Zealand. Furthermore, lung cancer disproportionately impacts Māori with both higher incidence of disease and greater mortality ^[2]. This presents an urgent equity issue for New Zealand. In recent years the treatment of advanced lung cancer treatment has been revolutionised by the advent of Immune Checkpoint Inhibitor (ICI) therapy, extending typical survival from months to short years ^[3]. Further advances are likely to bring similar improvements to early stage and locally advanced lung cancer in the coming decade. ICI therapy became funded for the treatment of advanced NSCLC lung cancer in the NZ public health system from 1 April 2023 ^[4]. Currently immunotherapy in the northern region is only available in a centralised model delivered in Auckland City Hospital.

In December 2023 a Maurice Wilkins Centre Cancer Theme specific funding round grant was allocated to the project “*Immunotherapy for whanau with lung cancer: who and where*” (ILCWW

Project). This study has several components including extensive stakeholder hui and engagement (whakawhanaungatanga), design of a regional lung cancer clinical database and the administration of a questionnaire in clinic with 4 key questions and which is the focus of this protocol. The areas are – self-identified ethnicity, biobanking, data, preferred site of infusional treatment.

5.1 Ethnicity

For clinical service modelling and research to assess areas of need and outcomes specific for Māori we need to rely on the NHI-linked available ethnicity documented in the EHR. The EHR interface displays a single ethnicity for each patient which is available to clinicians as they meet patients. Although standardised protocols exist for documentation of ethnicity in clinical practice ^[5] it is not clear that this is consistently practiced in a systematic way which has led to under-recording of Māori^[5]. Accurate ethnicity data will form a cornerstone of future work towards improving access to lung cancer treatment for Māori.

5.2 Biobanking

Te Ira Kawai (Auckland Regional Biobank) currently holds no lung tissue, and other New Zealand biobanks hold limited samples of lung cancer tissue. This has been identified as an issue which limits lung cancer research in New Zealand. Further, there is no mechanism to easily identify patients receiving immunotherapy and their relevant molecular biomarkers for the purpose of tissue banking. Current and future translational research requires donations of New Zealand lung cancer samples. All patients receiving immunotherapy will have been diagnosed using a tissue biopsy or cytology sample, and in many cases excess tissue may be available for donation.

5.3 Data

Te Aho O Te Kahu has established CanShare as a national health informatics programme to enhance the timely, relevant and accurate sharing of cancer data ^[6]. However, a regional cancer database does not currently exist. Patients typically undergo a diagnostic journey starting with either investigation of symptoms or follow up of incidental abnormalities found on imaging, this may occur under the care of a GP, Urgent Care doctor or Emergency Department. Thereafter further investigation is typically undertaken by a respiratory physician including cross sectional imaging with CT or PET-CT and Tissue biopsy for histology as well as molecular testing. Cases are discussed at a regional Thoracic Multi-Disciplinary Meeting, and at this point referrals are made to appropriate treating teams such as Medical Oncology, Radiation Oncology, Cardiothoracic Surgery and Palliative Care. Some patients who are referred to Medical Oncology are not ultimately seen in clinic. Reasons for this include clinical deterioration, death prior to meeting oncology, and in some cases patients are offered appointments but do not wish to engage with the service. For this reason, a comprehensive lung cancer database would ideally recruit patients at the time of MDM discussion and decision to refer to medical oncology. This would require data to be entered prior to the patient meeting with medical oncology and would not allow an opportunity for individual consent. Enrolling patients at a later stage risks excluding patients who never make it to an oncology clinic. These patients are likely to include some of the most vulnerable and disadvantaged groups in the lung cancer patient population, and their exclusion risks distorting the outcomes of the lung cancer database.

The question of enrolment without individual consent is a sensitive one, and requires broad consultation with the patient/whanau group involved and the assurance of appropriate data governance including de-identification methods and safe dissemination of data access processes.

5.4 Immune Checkpoint Inhibitor Delivery

Disparities exist in access to diagnostic tests and infusional treatment across New Zealand ^[2] and within the northern region. Centralised delivery of treatment in a single site results in long travel

times for some, and introduces expenses associated with travel. No single site or setting will be optimal for all patients. It is reasonable to assume that many patients will prefer to receive treatment closer to their own home. Others may perceive hospital as a safer environment in which to receive care. A recently approved HRC project (24/454 Wihongi) will pilot immunotherapy for advanced lung cancer with a Māori Primary Care Provider. This questionnaire will begin to explore patient preferences on receiving treatment close to home and in other possible settings. Response will also be useful as the Northern Regional Cancer Service moves towards a new model of care.

6. OBJECTIVES

Objective 1: To accurately describe self-identified ethnicity of lung cancer patients in the Auckland region of New Zealand

- 1.1 Determine the proportion of Māori, and other ethnic groups within the Auckland region lung cancer medical oncology patient cohort
- 1.2 Determine the accuracy of existing hospital records of ethnicity, when compared to self-identified ethnicity

Objective 2: Assess patient attitudes towards participation in tissue biobanking

- 2.1 Identify and quantify patient concerns regarding the concept and practice of biobanking of already available tissue
- 2.1 To identify patients who agree to be contacted regarding use of their tissue for current and future unspecified lung cancer research

Objective 3: To assess patient attitudes towards automatic enrolment in a clinical lung cancer database

- 3.1 Identify and quantify patient concerns regarding establishment of a clinical database of all Auckland lung cancer patients
- 3.2 To assess and quantify patient attitudes towards automatic enrolment of Auckland region lung cancer patients without specific consent

Objective 4: To quantify patient preferences regarding ideal setting and location of immunotherapy for lung cancer

- 4.1 Determine patient preferences for receiving IV immunotherapy in the currently available option of a Tertiary Hospital vs other possible settings including Local hospital, GP Practice, Community centre, Marae, mobile unit or own home.
- 4.2 Presence preferences in the context of home address and ethnicity.

7. OUTCOMES

Outcome 1: Ethnicity

- 1A) Proportion of Māori, and other ethnicities, in the overall study population
- 1B) Proportion of participants with self-identified ethnicity accurately recorded in existing records on the Regional Clinical Portal that is visible to the treating clinician.

Outcome 2: Attitudes regarding biobanking

- 2A) Proportion of participants who express concern with each aspect of biobanking, and description of principal areas of concern

Outcome 3: Lung Cancer Clinical Database

3A) Proportion of patients who support establishment of a clinical lung cancer database without individual patient consent, and description of areas of concern

Outcome 4: Treatment Setting

4A) Proportion of participants who indicate a preference for each potential intravenous treatment setting, when asked to imagine an idealised healthcare system

4b) present descriptive statistics by ethnicity and travel time from ACH

8. STUDY DESIGN and Methods

This is a single arm observational study.

Participants attending an in-person medical assessment will be provided a Patient Information Sheet (PIS) when they check in with the receptionist. The PIS will be provided in the format of a printed leaflet which contains information about participation in the study and a range of contact details to reach study investigators with questions and to access cultural support if required. The patient will retain the PIS for their own records. An investigator will be in attendance at all clinics to provide assistance to participants and answer questions.

Patients who indicate they wish to participate will be offered the survey in an electronic format on a tablet computer. Where the survey is completed electronically, the consent form will also be completed electronically on the same device. Electronic consent will be stored securely as a .pdf document which will be archived and stored securely, separate to the results of the survey, in accordance with the data management plan. A paper consent form and survey, with identical text and content, will also be available and can be offered to any patients who are not able to complete the electronic version. Investigators will preferentially offer the electronic edition whenever possible in order to increase the efficiency and accuracy of data collection. In this survey, the PIS will be provided separately from the consent form, in order that the patient can retain patient information and contact details, whilst allowing for consent to be incorporated into the electronic survey.

The questionnaire contains a total of 8 questions, covering four topics. We anticipate the survey can be completed in 5-10 minutes. It is designed to be completed by the participant themselves, or with assistance from whānau. We anticipate the PIC and questionnaire can be completed whilst in the clinic waiting room, without any impact on standard clinical care. Questions include responses recorded on a Likert scale. Questions which include the option for free text answers will be reviewed by the investigators in order to inform the content and design of future studies but will not be formally assessed with qualitative analysis.

Patients who indicate they do not wish to participate in the survey will not be contacted again by the study team. If a participant has started but not completed their survey, they may receive a **once only** follow up phone call from an investigator who is also a clinician (MW, LC, SWT), and invited to complete the survey. After completion of the survey there are no further activities in this study. There is no study specific follow-up after completion of the survey. Participation will not impact clinical care or decision making. Participants will be provided with contact details of the study investigators should they have any further questions after participation.

It is not anticipated that responses to this survey will include information of clinical significance, however should any clinically relevant information be disclosed in survey responses the participant's usual doctor and / or an appropriate specialist will be notified immediately, and appropriate clinical follow-up will be arranged. The survey is conducted within the clinical setting with the full support

from Te Puriri o Te Ora systems to be able to address any unknown clinical information that arises in completing the questionnaire.

The PIS and Survey will only be available in English. However, all patients who are attending a medical oncology clinic appointment will do so with the expectation of an English language medical consultation. Patients will have access to the same level of language support as is usually provided in clinical care, including from hospital staff (such as the Pacific Health team), and from their own whānau where appropriate. Formal interpreters will be available only when they have already been arranged for the scheduled clinical appointment the patient is attending. Telephone interpreters will not be utilised for this survey. Participants will only proceed with the survey if adequate language support has been provided. We anticipate that most patients who wish to participate in the study will be able to do so. Any patient groups who are overrepresented amongst telephone/virtual consultations may be underrepresented in this study. Importantly, patients completing the ethnicity questionnaire will be blinded to ethnicity documented on their hospital clinical record.

Responses from the electronic survey will automatically populate into a secure REDCap database. Responses to paper surveys will be manually entered into a database by investigators or a member of the Auckland City Hospital research team. The survey will include limited identifiable information: Name, Date of Birth and email address for patients who chose to enter this. Name and date of birth will only be visible to clinical investigators and will be used to view the recorded ethnicity in existing electronic medical records. Email address will only be gathered for patients who indicate they would like to receive a report of the study results. Once data has been collected, identifying data will be removed and a de-identified database will be generated for analysis of results by all investigators.

This protocol may be replicated as a method of safe lung cancer patient engagement for questionnaires with a different focus in the future but that would require a protocol amendment and repeat ethics assessment. For example this project is “korero tahi” and depending on future need “korero rua” may be pursued depending on new areas of research focus.

9. RECRUITMENT AND PARTICIPANT IDENTIFICATION

8.1. Trial Participants

All patients attending an in-person outpatient appointment at a Medical Oncology Thoracic tumour stream clinic with the three-month period of the study will be offered the chance to complete the questionnaire. There are three outpatient clinics per week, occurring at Greenlane Clinical Centre and Auckland City Hospital.

8.2. Inclusion Criteria

- Patients attending an in-person Medical Oncology outpatient appointment in thoracic tumour stream clinic with a diagnosis of Lung Cancer

8.3. Exclusion Criteria

- Clinic attendee with Non-lung cancer diagnosis (eg. Mesothelioma and Thymoma)
- Patients not attending clinic in-person, eg telephone or videoconference appointments
- Unable to provide informed consent
- Unable to participate due to poor performance status or medical instability
- Children aged under 16 are not within the scope of this survey

10. WITHDRAWAL OF PARTICIPANTS

There are no further study activities or follow up after completion of the questionnaire. Participants can withdraw completely from the study and request removal of their data collected up until the point of analysis. If this occurs, collected data would not be used in the final study analysis. The reason for withdrawal will be recorded whenever possible

11. STATISTICS

We estimate our current patient cohort to be around 500. Almost all of these patients will be scheduled for a clinic appointment within the 3 month window of this study. Patients who are only reviewed via telephone call or videoconference will not be included in the study. Patients attending clinic more than once in the 3 month period will only be asked to complete the questionnaire once.

1. Outcome 1 will generate a percentage breakdown of participants by self-identified ethnicity, and the percentage of records correctly documented in electronic medical records
2. Outcome 2 will report the percentage of patients who indicate willingness to participate in biobanking and will report the portion of participants who indicate concern to anticipated domains on a Likert scale. Free text responses will be reviewed by investigators to guide future studies, but will not be subjected to formal qualitative analysis
3. Outcome 3 will report the percentage of patients who indicate that automatic enrolment in a database without individual consent and will report the portion of participants who indicate concern to anticipated domains on a Likert scale. Free text responses will be reviewed by investigators to guide future studies, but will not be subjected to formal qualitative analysis
4. Outcome 4 will report first preference responses for each of the five possible settings for treatment, this will be broken down by ethnicity and distance from hospital.

We do not anticipate adequate numbers of participants in the study period to allow regression analysis by ethnicity but will produce descriptive analysis to generate hypotheses for further investigation.

12. EQUITY AND MAORI CONSULTATION

This study, as part of the ILCWW Project, has been developed in collaboration with Maori Health researchers Dr Helen Wihongi and Stella Williams-Terei. The ILCWW project also involves expertise from Ira Tatai Whakaheke. We have applied and presented this project to the regional established Māori whanau research governance group, Te Rōpu Kawanatanga, and they have agreed to provide further governance over the project, particularly the support of any Māori participants and oversight of findings dissemination. Investigators Williams-Terei and Hauraki and the clinical Māori support service will be available to support Māori patients as needed when approached to complete this survey in the clinical setting.

Previous New Zealand audits have identified that Māori ethnicity is often under-represented in clinical records (5,6) and assessing accuracy of self-identified ethnicity in our regional lung cancer setting is critical to ensure that we understand how to deliver services tailored to the needs of Māori whanau and ensure Māori participation in research to produce Māori-relevant findings.

Patients from Pacific communities are more likely to present with advanced disease and face challenges in accessing the optimal treatment for advanced lung cancer. Pacific patients participating in the survey will have access to all usual clinical supports, including from the Pacific Health team. We will engage the Auckland City Hospital Pacific Health team to provide culturally

appropriate supports for any patient who requires this. We have not undertaken specific consultation with Pacific groups or other communities. However patients of all ethnicities will be included in this study and findings will be relevant to and applicable to all ethnic groups.

Participants with disabilities will be able to access all standard supports available to patients via Auckland City Hospital and Te Whatu Ora. Study investigators will be present in all clinics and available to assist patients with participation and completion of the survey.

13. RECIPROCITY AND DISSEMINATION

All Participants who indicate an interest in study results will receive a report summarising the findings of this study. Findings will also be communicated to Te Puriri o Te Ora leadership, regional governance group Te Rōpu Kawanatanga and a report to Maurice Wilkins Centre as part of project deliverables to stakeholders involved in the wider research project. Authors will seek publication of results in an appropriate peer reviewed journal.

14. DATA MANAGEMENT

Data to identify potential participants from clinic lists and track consent/ questionnaire completion will be administered by clinical staff only. Identifiable information will only ever be visible to clinician investigators who are already involved in patient care. All data will be stored in a secure, password protected Edge or Redcap database. Once all data is collected, patient identifiers will be removed and a study number applied, thereafter the database will be locked. Investigators and project staff will analyse and report on this anonymised data. Governance will sit within the Auckland City Hospital Cancer and Blood system. Data will be managed in accordance with the Data Management Plan.

15. ETHICAL AND REGULATORY CONSIDERATIONS

15.1. Declaration of Helsinki

The Investigator will ensure that this investigation is conducted in accordance with the principles of the Declaration of Helsinki.

15.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this trial is conducted in accordance with relevant regulations and with Good Clinical Practice.

15.3. Approvals

The protocol, informed consent form, participant information sheet and survey will be submitted to an appropriate Research Ethics Committee (REC) written approval. As an observational study this may be within the hospital system rather than regional HDEC.

Locality approval to conduct this study within the Te Puriri or Te Ora clinical services will be sought to make sure there is not an additional demand on the currently stretched clinical workforce.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

15.5. Expenses and Benefits

Patients will not incur any additional costs as a result of participation. Patients will not receive any financial reimbursement for participation.

16. FINANCE AND INSURANCE

This investigation has received funding in the form of a grant from the Maurice Wilkins Centre as part of the larger “*Immunotherapy for whanau with lung cancer: who and where*” (ILCWW) project. The specific funding relevant to this protocol is to cover part of the clinical oncology fellow (NI Wilson) and Māori research nurse (NI Williams-Terei) salaries.

Tablet computers will be purchased using a philanthropic donation from a healthcare consumer intended to benefit lung cancer research in the Auckland region.

17. REFERENCES

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