

Lung Cancer (internet-based) Delphi (LuCiD): Setting the standard for lung cancer care in Australia and New Zealand - a modified eDelphi consensus to determine clinical quality indicators for lung cancer

Protocol

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1 Project Details			
Short title:	LuCiD: Lung Cancer (internet-based) Delphi		
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1.1 Project Summary

Background

Lung cancer represents a major area of unmet need in Australia and New Zealand, with high morbidity and mortality, particularly amongst First Nations people. Unwarranted variations in lung cancer care occur frequently, and these variations are linked to adverse outcomes. Variation persists despite guidelines such as the *Optimal Care Pathway*, which outlines best practice care for lung cancer patients in Australia. A solution exists: the audit and feedback of lung cancer clinical quality indicators (CQIs) is a proven tool to identify and alleviate variation, improve outcomes and increase cost effectiveness. However, Australia and New Zealand do not have agreed CQIs for lung cancer care, which would enable clinical data from institutions across the region to be benchmarked against agreed standards of care.

Objectives

To determine a set of clinical quality indicators applicable to small cell and non-small cell lung cancer care, for use in Australia and New Zealand.

Project plan

Specialist clinicians treating lung cancer, researchers and trained consumers in Australia and New Zealand, will be invited to participate in a modified eDelphi process, which will be completed over three rounds. Panellists will be asked to complete a brief Expression of Interest form, to ensure the panel is appropriately multidisciplinary. There is no pre-defined minimum

panel size, although the intention is to engage at least 100 panellists in the first round, with some attrition likely throughout the process.

A literature review will be performed prior to the first survey round to identify current and potential lung cancer CQIs. In consultation with an advisory panel, these will be synthesised and will then form the basis of the first survey round. The first two rounds will be completed as online surveys using REDCap (online, secure database), during which participants will need to rank the potential indicators on a 7-point Likert Scale. The last round will be conducted as an in-person (or hybrid) consensus meeting, at which time the final list of CQIs will be decided, and their corresponding numeric “quality standard” agreed.

2 Rationale / Background

Lung cancer in Australia and New Zealand

Lung cancer accounts for 15% of all new cancers in the Asia-Pacific region(1); it is one of Australia’s most common cancers, and the leading cause of cancer-related death and cancer-associated burden of disease.(2, 3) Similarly in New Zealand, lung cancer is the fourth most common cancer and the leading cause of cancer-related death.(4) Staging at diagnosis is critical to inform treatment planning and prognostication, and yet is completed in just 65%-72% of lung cancer cases in New Zealand and Australia; this compares poorly to other common cancers (94% in breast and prostate cancer).(5, 6) Most lung cancers in the region are advanced at the time of diagnosis, rendering curative treatment difficult if not impossible.(5, 7)

There is evidence of inequities and variations in lung cancer care and outcomes in Australia and New Zealand. Aboriginal and Torres Strait Islander people are more likely to be diagnosed with lung cancer, less likely to receive active treatment, and more likely to die from lung cancer than other Australians.(8-10) Rates of lung cancer diagnosis are almost four times higher for Māori than non-Māori, they are less likely to undergo lung cancer surgery and they have the lowest survival of all ethnic groups in New Zealand.(11) In both Australia and New Zealand, a lower socioeconomic status (SES) is associated with higher rates of lung cancer.(6, 12) Further, in Australia, individuals living in remote areas are more likely to be diagnosed with advanced lung cancer (or not be staged at all) compared to those living in metropolitan areas, and have a higher age-standardised mortality rate.(6)

There is growing recognition of changing lung cancer epidemiology: up to 25% lung cancers are diagnosed in never smokers(13), and these tumours have distinct clinicopathologic features.(14) Accurate diagnostic investigations and staging are crucial to ensure that patients receive the most appropriate and effective treatment(s). Lung cancer mortality is persistently high despite reduced rates of tobacco smoking and significant therapeutic advances, such as targeted and immunotherapy.(3, 15) This suggests that new treatments may not be enough to improve lung cancer outcomes. It is evident we also need to closely examine the entire care continuum, ensure systems and processes are optimised, and eliminate inequities in lung cancer care.

Quality indicators in lung cancer care

At present, Australia and New Zealand do not have comprehensive CQIs for lung cancer care that are routinely measured and reported.

Australia does not have nationally agreed lung cancer CQIs. The Victorian Lung Cancer Registry, operational since 2012, has defined CQIs against which Victorian lung cancer institutions are audited(16); these CQIs are grouped into domains reflecting the essential components of health care: safety, effectiveness, patient-centredness, timeliness, efficiency and equity.(17) The VLCR indicators were modelled on the approaches taken by international lung cancer registries, and developed locally through “a process of expert consideration and negotiation” without widespread consultation.(18, 19) Clinical guidance can be found in the Australian *Optimal Care Pathway for Lung Cancer*, which outlines evidence-based components of high-quality lung cancer care, although it does not explicitly define quality standards.(20) There is no national infrastructure in place to systematically record and evaluate lung cancer data.

In New Zealand, Te Aho o Te Kahu and the New Zealand National Lung Cancer Working Group established eleven quality indicators for lung cancer care in 2021.(21) Their initial analysis has been published, and reported on eight indicators utilising 2018 clinical data.(11) There is significant work underway in New Zealand to improve the quality of cancer data.(11, 22)

Internationally, CQIs for lung cancer have been established as part of national lung cancer registries, including the United Kingdom, Denmark, and the Netherlands.(23-25) The implementation of these programs has led to highly significant improvements in outcomes, including mortality.(23) Many other countries have lung cancer registries, including Japan, Sweden, Germany, Korea and Czech Republic, although these do not always involve prospective data collection, and their quality standards (when defined) have not been published in English. Other jurisdictions including China and Belgium have developed lung cancer CQIs for research purposes.(26, 27) Numerous professional bodies have published specific lung cancer quality standards, including the American College of Chest Physicians (ACCP), the American Association of Clinical Oncology (ASCO), the National Institute for Health and Care Excellence (NICE) and the International Consortium for Health Outcomes Measurement (ICHOM).(28-32)

The Delphi consensus process

LuCiD will establish lung cancer CQIs for Australia and New Zealand, utilising a process of modified eDelphi consensus, first developed by the RAND Corporation in the 1950s.(33)

The Delphi process is used to achieve consensus amongst an expert group on a particular subject matter. The expert panel often comprises healthcare professionals but can also include consumers and other stakeholders. Consensus is achieved through an iterative series of surveys,

which usually takes place over 2-4 rounds. In a *classical* Delphi, the Round 1 survey contains a series of open-ended questions; in a *modified* Delphi, statements are developed from existing literature. In an eDelphi, survey rounds are conducted via online survey (as opposed to written surveys, or in person discussion). Panellists are asked to indicate their level of agreement with statements, often using a Likert scale. After each survey, results are reviewed and interpreted, with findings fed back to the group until consensus is achieved. Consensus is usually pre-defined, and usually set between 70-80%. Although the Delphi process is commonly used in health research, most parameters – including the number of panellists, number of survey rounds, and definition of consensus – have not been strictly defined.(33)

Summary

Lung cancer in Australia and New Zealand has significant social, clinical and economic impacts. New approaches to lung cancer care are needed to optimise the systems and processes and improve lung cancer outcomes. This project will utilise a modified eDelphi consensus process to establish clinical quality indicators for lung cancer care across Australia and New Zealand.

3 Project Aims / Objectives / Hypotheses

The project objective is to utilise a modified eDelphi consensus process to develop CQIs applicable to small cell and non-small cell lung cancer care. Results will inform future lung cancer research and quality improvement initiatives.

4 Methods

4.1 Project Design

The project will be conducted using a three-round modified eDelphi consensus process. Figure 1, below, outlines the planned project design.

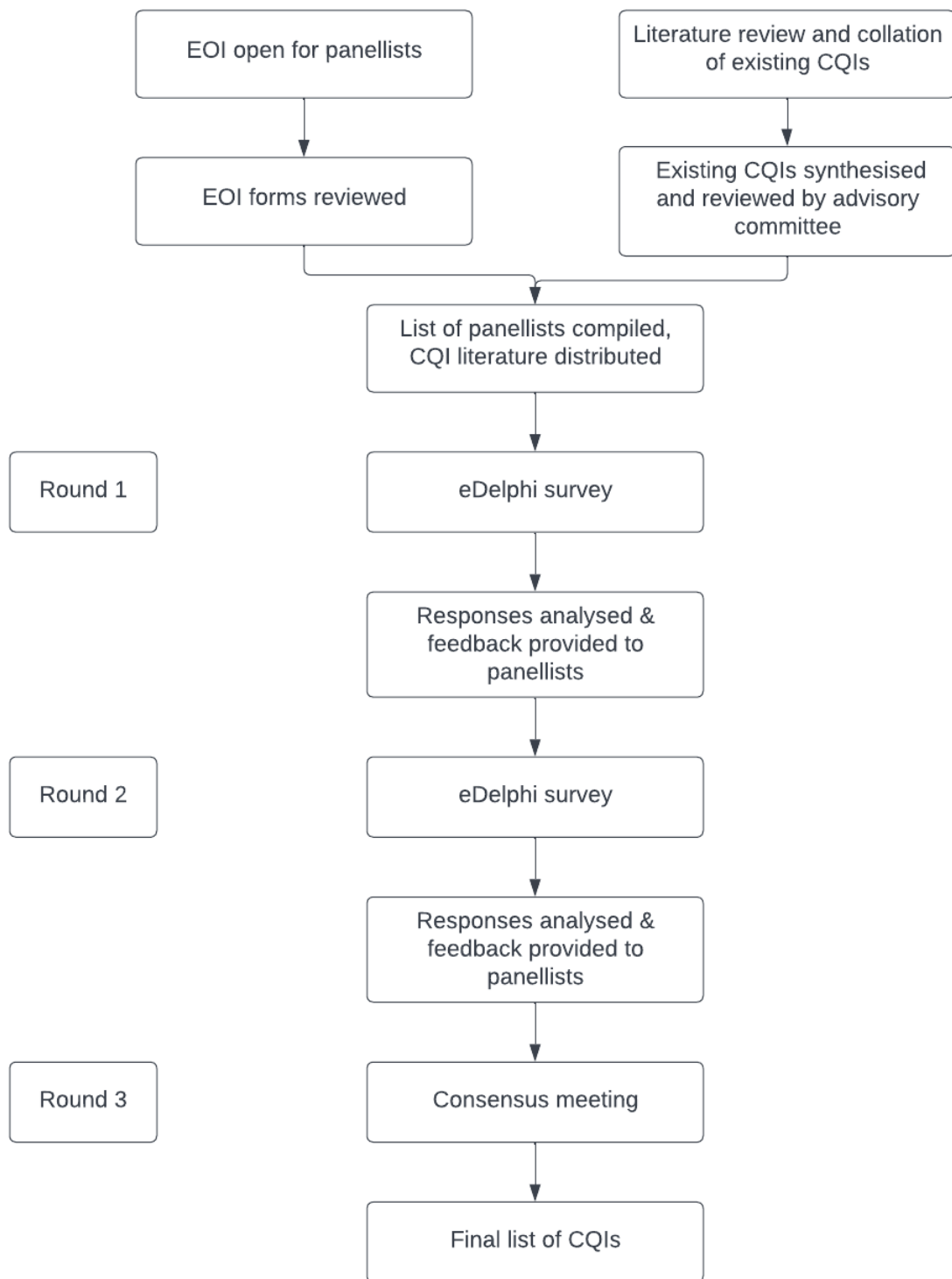


Figure 1 LuCiD Project Design

4.2 Project duration/schedule

After a favourable ethics approval is obtained, Expressions of Interest (EOI) will be sought from potential panellists. This process is expected to begin in August 2022. Table 1 outlines projected timelines for the study.

Timepoint	Event
August 2022	Panellist recruitment begins – EOI open
September 2022	EOI reviewed and final list of panellists compiled Panel for first survey contacted and literature distributed
October 2022	Round one survey distributed – open for three weeks Reminder emails sent at Day 14 and Day 17
November 2022	Round one survey results analysed Feedback from round one survey distributed to panellists Round two survey distributed – open for three weeks Reminder emails sent at Day 14 and Day 17
December 2022	Round two survey analysed
January 2023	Round two survey analysed Feedback from round two survey distributed to panellists
February 2023	Feedback from round two survey distributed (second time) Round three survey – in person meeting, with capacity for virtual attendance if required
March 2023	Round three outcomes finalised Results compiled and final list of quality indicators distributed to panellists and other stakeholders

Table 1: Project timelines

4.3 Source and selection of panellists

4.3.1 Expression of interest (EOI) form

Emails will be sent (see draft text contained in Appendix A), which will contain a link to an electronic EOI form. Emails will be disseminated through existing personal networks and professional groups including the Lung Foundation Australia (LFA), Lung Foundation New Zealand, Thoracic Society of Australia and New Zealand (TSANZ), the Thoracic Oncology Group of Australasia (TOGA), the New Zealand Society for Oncology Lung Oncology Special Interest Group, Medical Oncology Group of Australia, Clinical Oncology Society of Australia, the Trans-Tasman Radiation Oncology Group (TTROG) and the Royal Australasian College of Physicians. Stakeholder representation from government bodies such as the Department of Health, and agencies such as Cancer Australia, will also be sought. Personal invitations will be extended to potential panellists with specific expertise.

The electronic EOI will use REDCap (see PDF in Appendix B). When completing the EOI, participants will be required to state their name and email address, with optional questions

regarding gender, Aboriginal and Torres Strait Islander origin and ethnicity. There will be mandatory questions for clinicians regarding primary institution, discipline, and years of professional experience. Other participants (e.g. researchers, other stakeholder representatives) will be asked to list their primary institution and field of expertise. Consumers will be asked to briefly describe their lived experience of lung cancer, and the research training they have undertaken. Branching logic will be used to minimise the length of the survey, and so that individuals only complete relevant questions (e.g. consumer representatives will not be asked to indicate their years of professional experience).

Submitted EOIs will be screened to ensure diversity, including gender, ethnicity, years of professional experience, discipline, and geographical locations.

4.3.2 Expert panel

Significant debate exists over the definition of “expert” and the optimal way to select “expert” panellists.⁽³³⁾ Our inclusion of health professionals, researchers, consumers and other stakeholders, including First Nations representation, on the panel is intended to ensure diversity of experience and opinions. The broad distribution of the EOI will reduce the risk of bias when selecting panellists. Health professionals will be asked to indicate their years of professional experience.

4.4 Sample Size

There is no prespecified panel size. Panel size for the modified Delphi consensus process can vary considerably – from 10-15 panellists to thousands.⁽³³⁾ We will aim to engage at least 100 panellists for the Round 1 survey, with the knowledge that attrition throughout the process is common.⁽³³⁾

4.5 Inclusion criteria

Clinicians practicing in Australia and New Zealand will be able to participate, including allied health practitioners, General Practitioners, Medical oncologists, Palliative care physicians, Pathologists, Radiation oncologists, Radiologists, Respiratory physicians, specialist lung cancer nurses and Thoracic surgeons. Participation from experienced consumers and other stakeholders (such as First Nations researchers, quality and safety experts, and representatives from Cancer Australia) will also be encouraged.

4.6 Exclusion criteria

Individuals currently training in healthcare disciplines (such as registrars and medical students) will be excluded in order to ensure a highly experienced panel. Consumers without training or lived experience of lung cancer will also be excluded.

4.7 Withdrawal criteria

Panellists may withdraw at any time from the project, including after completing the first or second round surveys. However, their de-identified responses to survey questions will be retained in the event they choose to withdraw.

4.8 Consent

Formal written consent will not be obtained. Consent will be implied by submission of the EOI and the completed survey(s). Participation in the study is voluntary, with no adverse effects for any individual if they choose not to participate, or later decide to withdraw.

In the EOI, participants will be asked if they consent to storage of their email address for future contact. In the Round 1 and 2 surveys, participants will be required to confirm they consent to the storage and analysis of their survey responses.

Participants will be required to provide their name when completing the survey - to avoid duplicate responses and enable the provision of controlled feedback after survey Rounds 1 and 2. This identifying information will be stored separately from their survey responses. All survey responses will be de-identified during data analysis, and only aggregated feedback will be provided to the wider group and in any publications.

4.9 Methods

4.9.1 Advisory committee

An advisory committee will be formed to oversee panellist selection, the list of quality indicators that will form the basis of the Round 1 survey, data analysis, and the running of the consensus meeting.

4.9.2 Definition of consensus

There is no established threshold for defining consensus when conducting a Delphi consensus, although this is usually set between 70-80%.⁽³³⁾ We will define consensus at 70% for the Round 1 and 2 surveys. Therefore, individual indicators rated as 6 or 7 (on a 7-point Likert scale) by $\geq 70\%$ of panellists will be included, and indicators below this threshold will be excluded.

4.9.3 Study procedures

4.9.3.1 Literature review

A literature search will be performed in PubMed prior to the Round 1 survey, using the search terms "lung cancer" and "quality indicators". The aim will be to identify quality indicators used (or recommended for use) on a regional or national level to evaluate the

quality of lung cancer care. Grey literature, reference lists from identified publications, and documents published by government and professional bodies will be reviewed. Publications limited to a specific component of lung cancer care (e.g. thoracic surgery quality indicators) will be excluded.

Based on these publications, a list of established lung cancer CQIs will be compiled. Relevant literature will be sent to panellists prior to the Round 1 survey. The synthesised list of lung cancer CQIs will form the basis of the Round 1 survey.

4.9.3.2 Round 1: eDelphi survey

In the Round 1 survey, panellists will be sent a link to a REDCap survey. They will need to submit their name, to avoid duplicate responses and enable the provision of individualised feedback after each survey round. Panellists will then be asked to review the quality indicators in use, including consideration of their importance, validity and feasibility, and rate them using a 7-point Likert scale. Panellists may also indicate they are “unsure” if a particular indicator is important – as some areas may be outside an individual’s expertise.

For the purposes of the online surveys, CQIs will be structured into domains reflecting the continuum of care, for example “Referral and diagnostic investigations” and “Treatment”. (The definitive approach to the organisation/classification of CQIs will be discussed at the Round 3 consensus meeting.) Panellists will also be able to submit free text responses if they have suggestions for additional quality indicators. Examples of quality indicators may include “proportion of patients who undergo a PET/CT scan prior to surgical resection” or “proportion of patients seen by a lung cancer specialist nurse”.

After Round 1 is completed, responses will be analysed, and panellists will receive controlled feedback in which their individual responses are compared to those from the wider group.

4.9.3.3 Round 2: eDelphi survey

In the Round 2 survey, panellists will be sent a link to a REDCap survey and asked to submit their name (for the same reasons as in Round 1.) They will then be asked to review and rate all quality indicators that did not reach the consensus threshold of 70% in the Round 1 survey, and any new indicators that were suggested by panellists.

After Round 2 is completed, responses will be analysed, and panellists will again receive controlled feedback comparing their responses to the aggregated group. Indicators that have again failed to meet the consensus threshold of 70% will now be definitively excluded.

4.9.3.4 Round 3: consensus meeting

The third round will be conducted as a consensus meeting in February 2023. It is envisaged that this will be conducted as an in-person or hybrid meeting, although a fully virtual meeting

will be facilitated if required. Depending on the level of interest, the number of panellists in attendance may need to be restricted, with attendance via invitation only.

At this meeting, the proposed list of quality indicators will be reviewed. This will be the final opportunity to ensure consensus has been reached and to minimise duplication. Furthermore, if it is felt that too many CQIs have been shortlisted (a preliminary literature review has demonstrated >100 potential CQIs, after removal of obvious duplicates), panellists will be asked to rank the importance of CQIs within each domain. At this time, the numerical quality standard for each CQI will also be determined – for example, “≥90% patients undergo PET/CT scan prior to surgery or radical radiotherapy” or “≥90% patients seen by a lung cancer specialist nurse”.(34)

The preferred approach to the organisation of CQIs will also be decided at this time. Options include categorising CQIs into domains of care (e.g. “Diagnostic investigations” and “Treatment”); the Donabedian approach of structure, process and outcome(35), or the Institute of Medicine framework of safety, effectiveness, patient-centredness, timeliness, efficiency and equity of care.(17)

After this final meeting, the list of CQIs will be collated with a summary report and manuscript for publication generated.

4.9.4 Survey requests and reminders

Panellists will be asked to complete the two pre-planned online surveys prior to attending the consensus meeting. Each survey will be available for three weeks. A total of two reminder emails will be sent to panellists, per survey, during this period.

4.9.5 Panellist retention

Attrition of panellists is common in projects utilising Delphi consensus.(33) We hypothesise that engaging highly motivated members of the lung cancer community will ensure that a core group of expert panellists are involved throughout the entirety of the process. Furthermore, participation will be encouraged by: allowing panellists to opt to only participate in survey Rounds 1 and 2 (and not attend the consensus meeting); facilitating virtual attendance at the consensus meeting; and enabling attendance at the consensus meeting even if the panellist contributed to only one online survey round. These measures are designed to maximise retention and ensure the panel is diverse and representative at all stages.

5 Data Management, Statistical Analysis and Record Keeping

5.1 Statistics and Interim Analysis

Survey responses from Rounds 1 and 2 will be exported from REDCap as a csv file into Microsoft Excel. Data analysis will take place after Round 1 and 2 surveys, with consensus set at 70%.

Statistical software such as SPSS will be used to generate descriptive statistics such as frequency.

All data will be de-identified when statistical analysis is undertaken. Whilst individual panellists will receive their individual feedback, only aggregated findings will be distributed to the wider panel, and in publications.

5.2 Data Management

The EOI, and surveys for Round 1 and 2, will be completed using Curtin University's REDCap. Panellists will be required to supply their name and email address when completing their surveys, so that personalised feedback can be provided to individuals following Round 1 and 2 surveys.

Survey responses from Rounds 1 and 2 will be exported from REDCap as a csv file into Microsoft Excel. Identifying information will be stored separately from the main dataset. All data will be stored securely in a password-protected file on the R: drive at Curtin University. Only the study investigators will have access to this data.

6 Ethics

This project is considered very low risk. Most study participants will be healthcare professionals, and thus able to make an informed decision about their participation. We anticipate our trained consumers will also be able to make an informed decision.

Apart from providing their name and email address, participants will not be asked to provide any personal information, only their opinions. Responses from panellists will be de-identified during analysis and manuscript preparation. Identifying information will be stored securely in a password protected file(s), that only the research team can access. Panellists who take part in the Round 1 and 2 surveys will not know the identity of their co-panellists. They will receive controlled feedback after these surveys that compare their responses to those from the aggregated group. No publications stemming from the project will contain any references to individuals or institutions. Risks to the individual are thus negligible.

7 Budget, financing, indemnity and insurance

Specific funding for this project is not required. CPI Brims' contributions will be in kind. PI Nash has obtained funding from Curtin University (through a Research Training Program scholarship) and Lung Foundation Australia. Access to the RedCap software is via Curtin University. Panellists will not receive payment for their participation. Costs for the planned face to face meeting will

be supported in kind by the Lung Foundation Australia, who are organising the Australian Lung Cancer Conference for February 2023.

8 Publications

At the end of the project, a summary of the results will be shared with all panellists who participated in any of the survey rounds. Results will also be published in a peer-reviewed journal and conference abstract(s) will be generated. Advice will be sought from our consumer representatives about the optimal way to share results with consumers, likely through a report in partnership with the Lung Foundation Australia. The final summary report will also be disseminated to key stakeholders including Cancer Australia, Federal Department of Health, Cancer Council Australia, state Cancer Councils, TSANZ, TOGA, and TROG.

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10 Appendices

Appendix A – Email text (draft) to be distributed to stakeholders

Appendix B – Participant Information and Expression of Interest form

Appendix C – Screenshots Participant Information and Expression of Interest form