REPORT ON THE LUNG CANCER SCREENING ENQUIRY
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FOREWORD

In August 2019 the Hon Greg Hunt MP, Minister for Health, requested that Cancer Australia conduct an enquiry into the prospects, process and delivery of a national lung cancer screening program in Australia.

Cancer Australia has undertaken a multi-faceted body of work underpinned by extensive and inclusive stakeholder consultation to enquire into the national and international evidence of the effectiveness of lung cancer screening, to design a lung cancer screening program appropriate for Australia, and to describe how such a program may be delivered.

Lung cancer is the leading cause of death from cancer for both men and women in Australia. The number of new cases of lung cancer diagnosed is continuing to increase year by year. While survival rates for people with lung cancer are improving, they continue to remain low as many lung cancers are first diagnosed at an advanced stage of disease. The key to improving survival and quality of life of Australians affected by lung cancer is to diagnose lung cancer early.

Based on the national and international evidence, a screening program using biennial low dose computed tomography in asymptomatic high-risk Australians could detect cancers in their early stages when treatment is most likely to be successful. Such a screening program would save lives, reduce lung cancer mortality in Australia by 20% in the screened population, and improve the survival and quality of life of Australians affected by lung cancer.

It is estimated that in the first 10 years of a lung cancer screening program in Australia, over 70% of all screen detected lung cancers would be diagnosed at an early stage, over 12,000 deaths would be prevented and up to 50,000 quality adjusted life years would be gained.

Stakeholders consulted during the enquiry support lung cancer screening in Australia. Cancer Australia, informed by examination of the evidence and in consultation with key stakeholders, has designed an evidence-based lung cancer screening pathway for Australia that will maximise the benefits and minimise the harms of screening.

Lung cancer has a greater proportional impact on Aboriginal and Torres Strait Islander people, people in regional and rural areas, and those of lower socioeconomic status. Through research, analysis and consultation with key stakeholders, Cancer Australia has defined the elements and framework for delivery of a cost-effective and equitable national lung cancer screening program in Australia.

I am pleased to present this report on the enquiry.

Professor Dorothy Keefe PSM MD
Chief Executive Officer
Cancer Australia
October 2020
1. PROPOSAL AND PROCESS

1.1 Introduction

On 1 August 2019, the Minister for Health, the Hon Greg Hunt MP, requested Cancer Australia conduct an enquiry into the prospects, process and delivery of a national Lung Cancer Screening Program (hereafter called the Program) in Australia. Specifically the Minister sought from the enquiry:

- the national and international evidence for lung cancer screening
- the best design for a screening program within the Australian health policy context
- the mechanics of how a lung cancer screening program could be effectively delivered in Australia.

This report outlines the findings of the enquiry and articulates a proposal for Australia to be amongst the first countries in the world to introduce a targeted screening program for people at high-risk of lung cancer. The targeted screening program will support the early detection of lung cancer through the use of Low Dose Computed Tomography (LDCT) in asymptomatic high-risk individuals. LDCT screening aims to diagnose earlier stage lung cancer and enable treatment when the disease is more likely to be curable.

Lung cancer is responsible for the greatest number of cancer-related deaths in Australia and lung cancer has a greater proportional impact on Aboriginal and Torres Strait Islander people, people in regional and rural areas, and those of lower socioeconomic status.

The value proposition of a lung cancer screening program for Australia is supported in three ways. Firstly, the international evidence of effectiveness demonstrates that benefits outweigh harms and improved mortality outcomes result through targeted screening. Secondly, the report describes a feasible delivery model leveraging existing health infrastructure which can be expeditiously and cost effectively rolled out. Finally, the economic evaluation shows that a Program targeting high-risk Australians can be conducted at an acceptable cost per Quality Adjusted Life Year (QALY).

Based on the international evidence, the Program population cohort will be focused on current or former smokers aged 55 to 74 years in the general population and aged 50 to 74 years for Aboriginal and Torres Strait Islander people, who have a younger age at both lung cancer diagnosis and mortality. To maximise access to entry, people may self-refer for risk assessment or be invited to undertake a risk assessment by their GP, Aboriginal healthcare worker, or specialist.

An internationally validated risk assessment tool will be applied to persons entering the Program to assess their suitability for the screening intervention. The risk assessment tool requires an individual’s data on age, ethnicity, education, personal history of cancer, family history of cancer, smoking status and smoking intensity. If a person’s risk assessment meets a threshold level, he or she will be offered LDCT screening following an informed consent process. Once enrolled in the Program, LDCT is offered every two years while they participate in the Program, or until a lesion requiring management is identified.

Those detected with LDCT changes suggestive of high malignancy risk or suspected lung cancer will be referred from the Program to a specialist linked to a multidisciplinary team (MDT) for assessment and treatment.
The Program would align with and complement the other Australian cancer screening programs viz, BreastScreen Australia, National Cervical Screening Program (NCSP), and National Bowel Screening Program (NBSP).

The unique feature of the Program is that it is targeted to high-risk individuals with eligibility for screening largely determined by exposure to a specific carcinogen, tobacco smoking. The Program will also have a strong equity focus because the risk and prevalence of lung cancer is much higher in rural and remote settings, among Australians of lower socioeconomic status and in Aboriginal and Torres Strait Islander people.

The Program will be an Australian Government program delivered with the support and cooperation of State and Territory Governments. The Commonwealth will have overall responsibility for national program management.

1.2 Process

Key activities undertaken by Cancer Australia as part of this enquiry have included:

- a review of national and international evidence to understand the benefits and harms of lung cancer screening, the eligible population for lung cancer screening, its cost-effectiveness, best-practice lung cancer screening clinical pathways, and the key elements of targeted lung cancer screening programs
- research to estimate the expected number of lung cancer cases in Australia that could be attributed to various risk factors, to inform eligibility criteria for a Program
- an analysis of the sociodemographic characteristics of Australians who have died from lung cancer to inform the identification of prioritised groups for targeted communication as part of a potential lung cancer screening program
- the design and operationalisation of a lung cancer screening and assessment pathway, which aims to provide equitable access for all Australians
- the design of a program framework for the effective delivery of a national targeted lung cancer screening program in Australia
- an economic evaluation to understand the economic costs, benefits and outcomes of targeted LDCT lung cancer screening in Australia.

Stakeholder consultation and engagement has been critical to the conduct of the enquiry. Cancer Australia has undertaken comprehensive and extensive stakeholder consultation in the course of the enquiry.

The report that follows:

- outlines the policy context underpinning such a Program
- provides the evidence for screening
- indicates the extent of stakeholder support
- outlines the detail of a national screening program
- examines the cost effectiveness and financial impact
- suggests governance arrangements
- proposes an implementation pathway
- proposes evaluation and a research platform to underpin the Program.
Complementing this report is a more detailed document entitled *Lung Cancer Screening for Australia: A synthesis of evidence, economics and stakeholder perspectives* which summarises the findings of the key activities listed above.

In the first 10 years of the Program it is estimated that over 12,000 lung cancer deaths would be prevented and between 30,000-50,000 quality adjusted life years would be gained. Further, it is estimated that over 70% of all screen detected lung cancers would be diagnosed at an early stage compared to less than 20% of lung cancers currently detected at these early stages in Australia.

The value proposition is clear. A review, commissioned by Cancer Australia concluded that, if implemented, LDCT screening ‘would enable unprecedented changes in clinical management and address the poor outcomes (incidence, mortality, survival, psychosocial and quality of life) for lung cancer that have been observed over many years.’

**KEY POINTS**

- In August 2019 the Minister for Health, the Hon Greg Hunt MP, requested Cancer Australia conduct an enquiry into the prospects, process and delivery of a national lung cancer screening program in Australia.
- This report outlines the findings of the enquiry.
- The value proposition for such a Program is the reduction in mortality and improvement in survival and quality of life of Australians affected by lung cancer.
- In the first 10 years of the Program, it is estimated that over 12,000 lung cancer deaths would be prevented and between 30,000-50,000 quality adjusted life years would be gained.
- The value proposition is supported by:
  - the international evidence of effectiveness and safety
  - a feasible model using existing health infrastructure to roll out a national program
  - the cost-effectiveness of the economic evaluation.
- Australia can be amongst the first in the world to introduce a national lung cancer screening program.
2. CONTEXT

2.1 Lung cancer in Australia

In 2020, over 13,000 Australians are expected to be diagnosed with lung cancer and the number of new cases of lung cases being diagnosed is continuing to increase year by year. While lung cancer is the fifth most commonly diagnosed cancer in Australia (Figure 2.1), it is currently the leading cause of death from cancer for both men and women in Australia (Figure 2.2). In 2020, the Australian Institute for Health and Welfare (AIHW) anticipates there will be over 8,500 deaths from lung cancer – representing 1 in 5 of all cancer deaths. In 2012-2016, 5-year relative survival rate from lung cancer was 18.6% compared to 69.2% for all cancers combined.

The following two figures show significant variations in mortality rates for lung cancer, which demonstrate substantially higher lung cancer mortality rates in regional and remote Australia (Figure 2.3) and amongst lower socioeconomic groups (Figure 2.4).
2.2 Stage at diagnosis

Compared to most other cancers, the survival rate for lung cancer is poor and has improved little over time increasing from 9.5% to 19% between 1987–1991 and 2012–2016. Lung cancer diagnosis in Australians usually occurs once the cancer has spread. Staging is the process of measuring how far a cancer has spread when it is first diagnosed – generally, the later the stage at diagnosis the poorer the survival rate. As shown in Figure 2.7, 42.2% of lung cancer cases were Stage IV at diagnosis and this may be an under-representation, as stage at diagnosis was not able to be derived for over a quarter of cases. This figure of 42.2% Stage IV is in stark contrast to 4.6% for breast cancer, 17.7% for colorectal cancer, 4.2% for prostate cancer and 2.1% for melanoma of the skin.

Figure 2.7 Incidence of select cancers by registry derived (RD) stage at diagnosis

<table>
<thead>
<tr>
<th>Cancer site/type</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
<th>Unknown</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast cancer (females)</td>
<td>43</td>
<td>34.7</td>
<td>12.1</td>
<td>4.6</td>
<td>5.5</td>
<td>100</td>
</tr>
<tr>
<td>% of total cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>22.1</td>
<td>24.3</td>
<td>23.6</td>
<td>17.7</td>
<td>12.3</td>
<td>100</td>
</tr>
<tr>
<td>% of total cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>35.9</td>
<td>46.1</td>
<td>11.2</td>
<td>4.2</td>
<td>2.6</td>
<td>100</td>
</tr>
<tr>
<td>% of total cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung cancer</td>
<td>11.7</td>
<td>6.5</td>
<td>11.2</td>
<td>42.2</td>
<td>28.5</td>
<td>100</td>
</tr>
<tr>
<td>% of total cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melanoma of the skin</td>
<td>78.0</td>
<td>14.1</td>
<td>3.0</td>
<td>2.1</td>
<td>2.9</td>
<td>100</td>
</tr>
<tr>
<td>% of total cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total % of total cases</td>
<td>37.8</td>
<td>28.5</td>
<td>12.5</td>
<td>12.2</td>
<td>9</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: AIHW ACD 2014
This late diagnosis for lung cancer is very important given the significant decline in survival rates from Stage I at diagnosis through to Stage IV. The following figure depicts the incidence distribution and relative survival for lung cancer by stage of diagnosis in Australia. The five-year relative survival for stage IV lung cancer is 3.8%, compared to 67.7% for stage I lung cancer (Figure 2.8).

**FIGURE 2.8 LUNG CANCER INCIDENCE AND SURVIVAL BY STAGE**

### 2.3 Risk factors for lung cancer

There are a range of behavioural, personal and occupational risk factors for lung cancer. Of all these risk factors, the single biggest risk factor is tobacco smoking, whereby 90% of lung cancer in Australian men and 65% of lung cancer in Australian women is estimated to be a result of smoking. The risk of developing lung cancer due to tobacco smoking increases with duration of smoking and the numbers of cigarettes smoked per day.

Smoking rates have been declining in Australia with the proportion of daily smokers decreasing from 19.4% of people aged 14 years and older in 2001 to 11.0% in 2019. Much of this decrease was achieved early in this period and rates have remained relatively steady in recent years. The following are important prevalence factors regarding Australian smokers:

- **sex:** In Australia, 12.2% of men smoke daily, compared to 9.9% of women
- **socioeconomic disadvantage:** 18.1% of people in areas of highest disadvantage smoke daily, compared to 5.0% in the least disadvantaged areas (Figure 2.9)
- **Aboriginal and Torres Strait Islander people:** 24.9% of Indigenous Australians smoke daily, compared with 10.7% of the non-Indigenous population (Figure 2.10)
- **rurality:** Smoking rates are 19.6% for remote areas compared with 9.7% for people located in major cities (Figure 2.11).

There are also differences between culturally and linguistically diverse groups of Australians.

The differences in smoking rates by Indigenous status, remoteness and socioeconomic status is shown diagrammatically in the following three figures. One of the challenges for the Program is to ensure access for the highest risk groups who historically have had the most difficulty of access to health services.
2.4 Policy context

Australia has three national population-based cancer screening programs (BreastScreen Australia, National Cervical Screening Program (NCSP), and National Bowel Screening Program (NBSP)) – all of which have been developed within the guidelines of the Department of Health’s (DoH) Population Based Screening Framework which was co-authored with all States and Territories.

All three have been seen as successful health policy initiatives and effective investments in national cancer control. The AIHW combined report on the efficacy of the breast, cervical and bowel screening programs showed that cancers detected through screening were less likely to cause cancer specific death. For example, the risk of dying from breast cancer was 42% lower for women diagnosed through BreastScreen Australia. Women diagnosed through cervical screening had an 87% lower risk of dying from cervical cancer and for bowel cancer, the risk of dying was 40% lower for people diagnosed through the National Bowel Cancer Screening Program.

WHO Principles of Early Disease Detection

**Condition**

- The condition should be an important health problem.
- There should be a recognisable latent or early symptomatic stage.
- The natural history of the condition, including development from latent to declared disease should be adequately understood.

After smoking, Chronic Obstructive Pulmonary Disease (COPD) accounts for the highest proportion of lung cancer cases (6.2% for the general population; 11.9% for the Indigenous population), however, smoking is the primary cause of COPD.

While other risk factors such as secondhand exposure to tobacco, and occupational exposures are important they account for only a very small proportion of the overall population attributable risk for lung cancer.
**Test**
- There should be a suitable test or examination.
- The test should be acceptable to the population.

**Treatment**
- There should be an accepted treatment for patients with recognised disease.

**Screening Program**
- There should be an agreed policy on whom to treat as patients.
- Facilities for diagnosis and treatment should be available.
- The cost of case-findings (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.
- Case-findings should be a continuing process and not a ‘once and for all’ project.

The proposed design of the Program is in accord with all these principles and also complements and strengthens the Government’s primary prevention strategies, which have contributed to both heightened awareness of the risks of tobacco smoking and decline in smoking rates amongst Australians over the past twenty years.

**2.5 International initiatives**

There is international recognition of both the effectiveness and feasibility of lung cancer screening and acknowledgment of the importance of continuing efforts to reduce deaths from lung cancer. Whilst a number of countries are implementing targeted LDCT screening programs, these tend to be either pilot projects or limited to specific locations within these countries. Examples include:

- In the UK, targeted LDCT screening programs have been recently introduced in Manchester and Liverpool under the title of Lung Health Checks (LHC). These programs specifically target “deprived communities” who have high respiratory morbidity. The community based LHC program was developed as a “one-stop” holistic program with mobile LDCT screening vans (one van for assessment and one van for scans) located next to local shopping centres. In the Manchester LHC, the targeted participants were people aged 55 to 74 years registered at one of 14 general practices who had ever smoked. They were sent an invitation letter to book an appointment with a specialist respiratory nurse. Those who met eligibility criteria and had a risk of lung cancer equal to or higher than the risk threshold were offered an immediate CT scan. Ten more pilot sites are planned.

- The USA has an estimated 2000 screening centres across the country using ‘common elements’ of the American Thoracic Society (ATS) and American Lung Association (ALA) protocols. However, there is no national registry nor are the centres nationally coordinated.

Lung cancer screening is also being trialed or implemented in Poland, South Korea, Israel, Spain, British Columbia (in Canada) and Brazil. Similar to a number of international initiatives, the approach of the Program is designed to focus on high-risk groups and maximise their access and participation.
Lung cancer is the leading cause of death from cancer for both men and women in Australia.

There are substantially higher lung cancer mortality rates amongst rural/remote Australians, amongst lower socioeconomic groups and amongst Aboriginal and Torres Strait Islander people.

Survival rates for people with lung cancer is poor. Many lung cancers are first diagnosed at an advanced stage.

Tobacco smoking remains the single biggest risk factor for lung cancer followed by COPD.

There is mounting recognition of effectiveness of targeted lung cancer screening and the importance of continuing efforts to reduce deaths from lung cancer.
3. EVIDENCE FOR SCREENING

3.1 Benefits and harms

As highlighted in Section 2, survival rates are clearly and substantively higher for early diagnosed lung cancer compared to late stage diagnosed lung cancer. LDCT is the recognised diagnostic tool for early diagnosis of lung cancer - it has low radiation dosage compared to conventional CT scans, and is more sensitive than chest x-rays in the diagnosis of lung cancer.

Two important international clinical trials, the National Lung Screening Trial (NLST) in the United States of America (USA) and the Nederlands-Leuvens Longkanker Screenings Onderzoek (NELSON) Trial, both demonstrate the benefits of LDCT screening. In these two trials, eligibility criteria for LDCT screening were predominantly related to age, smoking history and years since cessation. For example, the key factors for the NLST trial screening eligible cohort were an age range of 55 to 74 years with a smoking history of ≥ 30 pack years (ie. 30 pack years is equal to smoking 1 pack per day for 30 years), and ≤ 15 years since smoking cessation.

The results of the studies showed that LDCT is associated with a larger proportion of lung cancers being diagnosed at an earlier stage compared to control groups.

The NLST demonstrated that LDCT screening reduced lung cancer-specific mortality by 20% while the NELSON trial showed a lung cancer specific mortality reduction of 24% in men and 33% in women. In addition a pooled analysis of randomised controlled trials, including the NLST, indicated a 17% lung cancer specific reduced mortality rate.

Identification and minimisation of potential harms of a targeted lung cancer screening program are important for reducing risks for screening participants. Potential harms of LDCT screening include false positives and consequences of false positives, false negatives, overdiagnosis, radiation exposure, and mortality morbidity or major complications resulting from invasive follow up testing.

With respect to false positives, the use of volumetric assessment of nodules in the NELSON trial appears to have assisted in limiting the rate of false positives (1.2%). Such volumetric measurement is an important element of the Australian Program to reduce the false positive rate, invasive procedures, biopsies, and surgery.

False negative rates reported in international trials are very low, in the order of 0.1 – 1.3% and are therefore not considered a significant limitation of targeted LDCT screening.

Overdiagnosis can be associated with unnecessary follow-up invasive procedures, treatment, psychological impacts, and increased costs that may impact negatively on wellbeing and life expectancy. The current best estimate of overdiagnosis is 8.9% based on extended (11-year) follow-up in the NELSON study. Rates of overdiagnosis will be minimised in the Program by the use of the risk assessment tool to determine eligibility, volumetric analysis, and nodule management protocols coupled with advances in image analytics.

Targeted LDCT screening is associated with exposure to ionising radiation. The level of harm from radiation exposure to patients in an LDCT Screening Program is influenced by the participant’s age at baseline scan, gender, number of scans received, imaging techniques and technologies used, and exposure to other
sources of radiation. However, the approximate dose of radiation delivered in a LDCT scan is about 1.4 millisievert (as reported in the NLST). Based on modelling of dose exposure there are likely to be minimal long-term health impacts for participants from radiation at the level of exposure produced in LDCT screening. The benefits of LDCT screening for lung cancer outweigh several fold any likely harms. Figure 3.1 illustrates the levels of radiation exposure from LDCT, relative to other exposures that the general population experience, with LDCT for lung cancer screening being lower than average background radiation.

**FIGURE 3.1 COMPARISON OF SOURCES OF RADIATION EXPOSURE**

Investigation of screen detected lesions carries potential risks but in the international trials post-procedural mortality is very low in pooled analyses.

Insights from cohort studies and real-world programs show some mild psychological distress, particularly among those concerned about getting lung cancer prior to the screening and among those not expecting a positive finding. However, overall any increases in anxiety seem to be short-term and any adverse effects do not appear to persist long-term.

The compelling evidence supports the conclusion that the benefits of LDCT screening are significant and harms are low risk and manageable. There are clear and substantive improved survival rates resulting from early diagnosis of lung cancer and many of the potential harms can be reduced by careful consideration of the high-risk target population as well as the inclusion of evidence-based quality diagnostic and management processes in the screening and assessment pathway and post screening process.

### 3.2 Targeted screening

Lung cancer screening programs appear to be most clinically effective and cost-effective when targeted to high-risk individuals. Use of age and risk assessment tools have been shown to assist identify individuals at high-risk of lung cancer who would benefit from screening.
The international lung cancer screening trials have all focused on participation of older age cohorts and then applied other inclusion/exclusion criteria. Evidence indicates that screening high-risk individuals of younger ages does not result in a favourable balance of benefits and harms and is not cost-effective.

It is proposed that the population cohort for the Australian Program be people aged 55 to 74 years who are current or former smokers.

For Aboriginal and Torres Strait Islander people, given their higher prevalence of smoking and their lower age for lung cancer diagnosis and mortality, an age range of 50 to 74 is proposed.

Risk assessment tools, which use algorithms to calculate an individual’s risk of lung cancer based on a combination of a variety of established sociodemographic and health-related factors, appear to perform better in the identification of individuals for targeted lung cancer screening than eligibility criteria of age and smoking alone.

To further increase the benefits of the Program for this population group while reducing potential harm, a risk assessment is undertaken with each person to determine eligibility for the screening intervention. The eligible screening population would therefore be Australians aged 55 to 74 years and Aboriginal and Torres Strait Islander people aged 50 to 74 years with a risk assessment exceeding a defined threshold. This risk assessment tool and high-risk threshold are described further in 6.1.

### 3.3 Screening interval

A key component of a targeted lung cancer screening program is for participants, with no significant findings, to have repeat screening at regular intervals. Internationally repeat screening every one or two years has been trialed. The NELSON trial (with a 2.5 year interval) highlighted that an interval longer than two years leads to more interval incident lung cancers and later stage diagnosis. Based on international experience and the balance of benefits and harms a biennial screening program is proposed.

### KEY POINTS

- The compelling evidence is that the benefits of LDCT screening are significant and any harms are low risk and manageable.
- Lung cancer screening programs appear to be most clinically effective and cost-effective when targeted to high-risk individuals.
- Age and risk assessment tools assist in identifying current and former smokers who may be at high-risk of lung cancer.
- Based on international experience and the balance of benefits and harms a biennial screening program is proposed.
- Targeted screening is proposed to be made available to people aged 55 to 74 years, and for Aboriginal and Torres Strait Islander people aged 50 to 74, with a risk assessment exceeding a defined threshold.
- Screening high-risk individuals with LDCT results in significant reductions in lung cancer mortality and diagnosis of a larger proportion of lung cancers at earlier stages.
4. STAKEHOLDER SUPPORT

Stakeholder consultation and engagement has been critical to the conduct of the enquiry. Cancer Australia has undertaken comprehensive and extensive stakeholder consultation activities (Figure 4.1).

This has included:

- public consultation via an online consultation hub. Almost 300 responses were received from all States and Territories and a mix of demographics were represented
- targeted consultation with Aboriginal and Torres Strait Islander community and health professionals. This included consultation with 100 Aboriginal and Torres Strait Islander people and a range of health professionals
- in-depth consultations with Cancer Australia’s key Advisory Groups
- consultation with expert clinicians and health professionals
- consultation with international experts.

There is strong support from the majority of stakeholders consulted for the introduction of a lung cancer screening program in Australia. Some stakeholders go further, reflecting a sense of urgency around the need for such a program. In addition, the majority of formal organisational responses referenced international evidence supporting lung screening.

This strong support amongst stakeholders is due to the acknowledged benefits of earlier detection and the potential for earlier treatment to improve lung cancer outcomes. While citing these benefits, stakeholders highlighted the importance of reducing the potential harms of lung cancer screening.

The few reservations that were expressed principally concerned perceived lack of evidence of cost effectiveness, risk of overdiagnosis/over treatment, and risk of diverting attention from primary prevention. The need to reduce stigma and to implement local initiatives among Culturally and Linguistically Diverse (CALD) communities was also raised. These issues have been addressed in the evidence review and the design of the Program.

The consultation with Aboriginal and Torres Strait Islander community members affirmed strong concern around the impacts of cancer in their community, especially lung cancer, with those consulted having experienced directly or indirectly the impact of lung cancer. Those consulted reflected strong overall support for a targeted lung cancer screening program, particularly referencing the higher incidence of lung cancer and poorer lung cancer outcomes for Aboriginal and Torres Strait Islander people.

Feedback from Aboriginal and Torres Strait Islander organisations and individuals consulted, highlighted a high degree of interest in ongoing collaboration in the implementation of a lung cancer screening program and such co-design was emphasised as essential to ensure appropriate engagement and cultural safety.

Consistent with community perceptions, the overall sentiment from health professionals was that lung cancer screening would be very worthwhile and that the broad health community would strongly support a national screening program.
STAKEHOLDER SUPPORT

Cancer Australia conducted extensive consultation with key stakeholders. There is strong support amongst these stakeholders for the introduction of a targeted lung cancer screening program in Australia.

Similarly, consistent with community perceptions, health professionals also expressed strong support for the Program.

Aboriginal and Torres Strait Islander consultations reflected overall support for a targeted lung cancer screening program.

**KEY POINTS**

- Cancer Australia conducted extensive consultation with key stakeholders. There is strong support amongst these stakeholders for the introduction of a targeted lung cancer screening program in Australia.

- Similarly, consistent with community perceptions, health professionals also expressed strong support for the Program.

- Aboriginal and Torres Strait Islander consultations reflected overall support for a targeted lung cancer screening program.
5. NATIONAL TARGETED SCREENING PROGRAM

5.1 Guiding principles

The design of the Program, as described in this Section, has been guided by the following eight principles.

1. Accessible – Access to the Program for all eligible participants, inclusive of demographic, geographical, socioeconomic, cultural and other factors.

2. Agile - Centred around ongoing application of continuous quality improvement and the implementation of new technologies to ensure the Program adapts to change.

3. Value-based - Underpinned by efficient investment and high-quality care to create benefits for participants in the form of effective, person-centred cancer screening and improved participant engagement.

4. Person-centred - Centred around each individual and delivering benefit to the participant throughout their experience.

5. Culturally safe for Aboriginal and Torres Strait Islander people - Optimal and culturally safe care for Aboriginal and Torres Strait Islander people participating in the Program.

6. Informed by Best Practice - Informed by evidence and guided by best practice methods, processes and techniques in order to ensure the Program is fit for purpose.

7. Evidence-based - Outcomes from research, combined with clinical expertise integrated to underpin scientifically valid recommendations.

8. Research & Data Driven - Data used to monitor and evaluate performance and shape the Program into the future.

The Program is designed to align with these guiding principles. For example, the proposed multi-channel access to the Program, coupled with a strong emphasis on targeting rural/remote Australians/lower socioeconomic groups and Indigenous and other CALD groups is critical to the principle of accessibility.

Similarly, the focus on continuous quality assurance through the management structure, emphasis on ongoing monitoring and adoption of new technologies supported by the research activities will enable the Program to be agile and change over time.
5.2 Screening and assessment pathway

Figure 5.1 below diagrammatically describes the screening and assessment pathway.

**FIGURE 5.1 SCREENING AND ASSESSMENT PATHWAY**

**Identification**
- People aged 55 to 74 years
- Aboriginal & Torres Strait Islander people aged 50 to 74 years
- Current or former smoker

**Risk Assessment**
- PLCO 6 year risk score ≥1.51%
- Assessment of performance status
  - Check eligibility criteria, provide information to enable shared decision-making & informed consent

**Smoking Cessation**

**LDCT**

**No Significant Findings**
- LDCT 24 months
- No

**Low Malignancy Risk**
- LDCT 12 months
- Interval growth?
  - Yes: Rapid access to specialist linked to a MDT (Clinical assessment and appropriate follow-up)
  - No: Continue in screening program

**Moderate Malignancy Risk**
- LDCT 3 months
- Interval growth?
  - Yes: Rapid access to specialist linked to a MDT (Clinical assessment and appropriate follow-up)
  - No: Continue in screening program

**High Malignancy Risk**
- Suspected Lung Cancer
  - Mass lesion of non-infectious aetiology, mediastinal or hilar lymphadenopathy
  - Manage according to relevant clinical guidelines

**Incidental Finding**
- Previously undiagnosed condition(s)
  - Manage according to relevant clinical guidelines

*If interval growth, consider biopsy or PET after appropriate clinical assessment.*
The Program is a radiological screening program encompassing all activities outlined up to the point of referral to a specialist linked to a multidisciplinary team. Subsequent investigation and treatment of lung cancer sit outside of the Program.

Ever-smokers within the eligible age-ranges will be identified and invited to undertake a risk assessment. Those who attend will be assessed to calculate their individual risk of developing lung cancer using the validated risk assessment tool (see Section 5.4). Individuals with a risk over the risk-threshold will be invited for a LDCT scan. Based on the results of the LDCT scan, participants will be classified into different risk profiles which determine their journey through the screening and assessment pathway.

As shown in the above flow chart, participants can be classified into the following risk profiles: no significant findings, low malignancy risk, moderate malignancy risk, high malignancy risk and suspected lung cancer. In addition, incidental findings (unrelated to lung cancer) may also be identified. For the majority of participants (~ 89%) no abnormalities will be found, and they will continue to receive a LDCT scan on a biennial basis. Participants who are established to have a high malignancy or suspected lung cancer risk profile will receive rapid access to a specialist linked to a MDT for further investigation and treatment where appropriate. Participants in the moderate malignancy risk will receive a three-month follow-up scan, those with low malignancy risk will receive a 12-month follow up scan and those with no significant findings will continue with biennial scans. Incidental findings will be managed according to relevant clinical guidelines.

5.3 Participant recruitment

A multi-channel approach that maximises the number of potential participants that can access the Program is proposed. The following access or entry routes will be available to help engage eligible participants and maximise participation including for sociodemographic groups at highest risk of lung cancer.

For new participants:

- **Self-referral** – A potential participant proactively seeks a risk assessment via a primary health care professional of their choice.
- **Facilitated Entry** – A participant is supported to arrange a risk assessment via a primary care professional of their choice.
- **Opportunistic Entry** – An authorised health professional offers to provide a potential participant a risk assessment either during a healthcare consultation that was arranged for other purposes, or at another time.
- **Organised Entry** – A potential participant is proactively identified from existing patient records (Electronic Medical Records (EMR) or Practice databases for example) based on their age and smoking history. Following this, they are invited to participate in a risk assessment.

For existing participants:

- **On-going Access** – An existing participant of the Program is issued with a notification that their next Program screen, and associated performance assessment, is due. The notification is issued by the screening register.

A national information and communication strategy will be a key feature of the Program to aid recruitment to the Program, and retention in it, of the eligible population and to raise awareness amongst the healthcare workforce. The strategy would have culturally appropriate communication and messaging, including information in a range of commonly spoken languages, and would address communication challenges including the stigma of lung cancer.
5.4 Eligible population

A two-step eligibility process is proposed. The former is age and smoking history-based, while the latter is through the application of a risk assessment.

Using the criteria (ages 50 to 74 years for the Aboriginal and Torres Strait Islander population and ages 55 to 74 years for other Australians who are current or former smokers) would result in approximately 2.9 million men and women who have a smoking history and are currently within the age parameters of the Program. Of this population, an estimated 580,000 would be eligible for LDCT upon completion of the risk assessment tool.

The risk assessment tool proposed is called the PLCom2012 (Prostate, Lung, Colorectal, and Ovarian Cancer) model. The PLCom2012 model has consistently performed well in validation studies and is referenced in international screening guidelines and program protocols. It is currently the only risk prediction model which has been validated in an Australian population and has shown positive results in the International Lung Screening Trial (ILST). At present, there is uniform agreement that it is the most feasible risk assessment tool for a national LDCT screening program in Australia.

In order to determine eligibility for the Program, potential participants would complete a risk assessment with a health care professional to determine their PLCom2012 risk score over a six-year period.

If a potential participant aged 55 to 74 years (or for Aboriginal and Torres Strait Islander people aged 50 to 74 years) scores a PLCom2012 risk of ≥1.51% over 6 years, they will be invited to have a LDCT.

The proposed approach which focuses on the population group with the highest known prevalence of lung cancer, and applies a risk assessment tool to that population group, is designed to identify the largest number of cancers in the most cost-effective manner.

5.5 Informed consent

Informed consent is vital in ensuring that Program participants are fully aware of the nature and purpose of the Program, have an understanding of the screening and assessment process, the benefits and potential harms, and the impact of their results. Each participant will be provided with information to enable them to have a genuine understanding of the nature and effects of a procedure or treatment, associated procedural or treatment risks, and any alternatives to the proposed approach.

Informed consent will be obtained prior to participation in the Program and with an emphasis on consent to the following three areas within the screening and assessment pathway:

- the PLCom2012 risk assessment
- data collection to support the participant journey through the screening and assessment pathway, and for audit and research purposes
- inclusion of information in the Screening Register.

It is important to note that if consent is not provided for an individual’s data to be included in national data collection, this will not limit the ability for the participant to take part in the Program.

For most participants, the likely referral pathway for LDCT screening will be through the primary care provider, and, consistent with normal practice, that provider will be responsible for informing the patient and obtaining consent. For participants coming through other recruitment pathways, alternate arrangements for informed consent will be in place.
5.6 Smoking cessation

The Program will complement and reinforce existing primary prevention strategies. Screening presents an opportunity for health education and, thus, smoking cessation is an important and integral component of the Program. It is proposed that smokers entering the Program be offered access to smoking cessation education. Evidence from other trials has shown that trial participants have higher quit rates than normally expected in the general population.

Evidence indicates that compared to an expected general population unassisted quit rate of 3-7% per year, participants in screening trials have shown quit rates of 14-16% at one year follow up, and as high as 24-29% at 5-9 years.

Referral to existing State and Commonwealth smoking cessation in particular Quitline, would be the appropriate pathway for smokers in the Program who express a desire to change their smoking patterns.

5.7 Low Dose Computed Tomography

The screening test for the Program is LDCT with volumetric analysis at 2-yearly intervals. There are currently in excess of 1500 CT scanners in both the public and private sector across Australia which may be suitable for LDCT screening. As part of implementation of the Program (See Section 7) it will be important to assess the scanners ability to meet required standards, including the ability to undertake volumetric analysis.

As this is the first cancer screening program designed in the digital age, LDCT reporting will leverage the use of artificial intelligence (AI) and computer assisted diagnostics. LDCT will employ structured reporting by a radiologist and computer aided detection (CAD). Indeterminate results will be reviewed by a second radiologist. Scans and scan results will be uploaded to the screening register and reports provided to both the participant and their primary care practitioner.

The most appropriate pathway to LDCT will vary across Australia and within implementation sites. In most cases private sector radiology services will be the provider and designation of a specific Program schedule fee item may be appropriate. State radiology services can also provide access to LDCT and in other locations, particularly in remote and very remote locations or correctional facilities, access to LDCT will be by means of mobile vans. Mobile vans will be supported by virtual diagnostic and assessment hubs to enable centralised scheduling of appointments and reading and reporting of LDCT scans.

With some exceptions, the existing infrastructure of LDCTs in each State/Territory is likely to meet the demand generated by the roll out of the Program. Assessment so far indicates shortfalls of infrastructure in Tasmania and in remote locations on the mainland. To rectify this shortfall, it is proposed as part of the capital costs that one fitted mobile van be made available for each State of Australia and the Northern Territory.

The Program will require LDCT providers to adhere to and report against agreed national quality control standards.
5.8 Clinical assessment and management

The post screening clinical assessment and management will be determined by the findings of the LDCT. The clinical management of people with high-risk nodules will be done within existing health care services. It is, however, important that referral protocols be in place prior to implementation of the Program to ensure ready and timely access to such clinical management.

Private specialists, State Health Department Local Health Districts (LHDs) or their equivalents and private hospitals will all play a role in the specialist/MDT referral and any subsequent treatment. Lung Foundation Australia has identified 85 lung cancer MDTs across Australia – predominantly located within public hospitals, but also within the private sector – who could provide ongoing clinical assessment once a participant is referred from the Program.

Any other incidental findings will be managed in accordance with contemporary clinical guidance.

5.9 Screening Register

The establishment of a National Screening Register is a core component of the Program and is essential to ensuring national quality assurance standards are maintained and will support an integrated research program. The Screening Register will have a central role in the effective functioning of the Program, including the collection, storage and issuing of correspondence. The three core capabilities of the Register are:

- data collection and storage: collecting and storing data, information and CT scan images
- correspondence and management of participants: issuing correspondence to participants, such as invitations and reminders at different parts of the screening and assessment pathway
- data sharing and analytics: feeding data and information to support governance, reporting, research and evaluation.

Further, a number of Registry requirements are essential for the initial rollout of the Program. These include:

- issuing participant communication and reminders
- managing rescreening cadence
- storing LDCT images and reports
- capturing, consolidating, managing and presenting data
- allowing for scalability and future-proofing of the Program.

The NBSP and NCSP currently use a common central national screening register. There are synergies/efficiencies that could be achieved through leveraging the common capabilities of this existing register.

The Screening Register will have the capability to monitor and evaluate the overall Program by supporting data collection and reporting on key performance indicators and support the monitoring of Program outcomes. Its data will also be critical to supporting research (see Section 10) to ensure the Program remains evidence-based and contemporary.
### 5.10 Summary policy components

The scope of the policy elements guiding the Program is summarised as follows.

<table>
<thead>
<tr>
<th>Framework Element</th>
<th>Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Screening Program population cohort</strong></td>
<td>General population aged 55 to 74 years and Aboriginal and Torres Strait Islander people aged 50 to 74 years - current or former smoker</td>
</tr>
<tr>
<td><strong>Risk assessment</strong></td>
<td>Australian validated PLCoM2012 risk prediction tool</td>
</tr>
<tr>
<td></td>
<td>A PLCoM2012 6-year risk score ≥ 1.51% makes a person eligible for the screening intervention</td>
</tr>
<tr>
<td></td>
<td>Risk assessment is undertaken by an authorised health professional</td>
</tr>
<tr>
<td><strong>Screening eligible Population</strong></td>
<td>Population aged 55 to 74 years and Aboriginal and Torres Strait Islander people aged 50 to 74 years with a PLCoM2012 6-year risk score ≥ 1.51%</td>
</tr>
<tr>
<td><strong>Entry points into risk assessment</strong></td>
<td>Self-referral (person has seen advertising or is concerned)</td>
</tr>
<tr>
<td></td>
<td>Facilitated entry (person recommended by health professional)</td>
</tr>
<tr>
<td></td>
<td>Opportunistic entry (assessment recommended during a routine medical consultation on other matters)</td>
</tr>
<tr>
<td></td>
<td>Organised entry (person receives an invitation from a health service or authorised health professional as a result of a record review)</td>
</tr>
<tr>
<td><strong>Screening intervention</strong></td>
<td>Low-dose Computed Tomography (LDCT) with volumetric analysis at a 2-yearly interval</td>
</tr>
<tr>
<td><strong>Screening intervention infrastructure</strong></td>
<td>Public and private fixed and mobile CT scanners</td>
</tr>
<tr>
<td><strong>LDCT reporting</strong></td>
<td>Structured reporting by radiologist and computer aided detection (CAD)</td>
</tr>
<tr>
<td></td>
<td>Indeterminate results reviewed by a second radiologist</td>
</tr>
<tr>
<td></td>
<td>PanCan nodule management protocol for baseline scans</td>
</tr>
<tr>
<td></td>
<td>Modified Lung-RADS 1.1 nodule management protocol for subsequent scans</td>
</tr>
<tr>
<td></td>
<td>Scans and scan results uploaded to the screening register</td>
</tr>
<tr>
<td></td>
<td>Scan report provided to GP and participant</td>
</tr>
<tr>
<td></td>
<td>Scans from mobile services reported centrally through a Virtual Diagnostic Hub</td>
</tr>
<tr>
<td><strong>Screening intervention assessment</strong></td>
<td>Scan follow-up interval and other interventions are determined by protocol</td>
</tr>
<tr>
<td></td>
<td>Participant will either continue screening at rate determined by protocol or be referred to a specialist linked with an MDT for investigation and management, and any incidental findings will be managed by the GP in accordance with contemporary clinical guidance.</td>
</tr>
<tr>
<td></td>
<td>Results of lung nodule investigations arising from lung screening are required to be provided to the Screening Register</td>
</tr>
<tr>
<td>Framework Element</td>
<td>Policy</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Screening participant reminder and follow-up</td>
<td>Second and subsequent scan reminders will be issued by the Screening Register using the participant’s preferred method of communication</td>
</tr>
<tr>
<td>Screening cessation age</td>
<td>On turning 75 participants will be invited to join a validation study for screening in older people Australians</td>
</tr>
<tr>
<td>Screening Register</td>
<td>The three core capabilities are:</td>
</tr>
<tr>
<td></td>
<td>- Data collection and storage including CT scans and reports</td>
</tr>
<tr>
<td></td>
<td>- Data sharing and analytics to support governance, reporting, research and evaluation</td>
</tr>
<tr>
<td></td>
<td>- Correspondence and management of participants</td>
</tr>
<tr>
<td>Screening Program principles</td>
<td>An Australian lung cancer screening program will be guided by the following principles:</td>
</tr>
<tr>
<td></td>
<td>- Accessible</td>
</tr>
<tr>
<td></td>
<td>- Agile</td>
</tr>
<tr>
<td></td>
<td>- Value-based</td>
</tr>
<tr>
<td></td>
<td>- Person-centred</td>
</tr>
<tr>
<td></td>
<td>- Informed by Best Practice</td>
</tr>
<tr>
<td></td>
<td>- Evidence-based</td>
</tr>
<tr>
<td></td>
<td>- Research &amp; Data Driven</td>
</tr>
<tr>
<td>Screening Program Governance</td>
<td>The Program sits within the existing Australian health setting</td>
</tr>
<tr>
<td></td>
<td>It is administered by the Australian Government and delivered with the cooperation and support of state and territory governments.</td>
</tr>
<tr>
<td></td>
<td>Program policy decisions will be determined at a national level.</td>
</tr>
<tr>
<td></td>
<td>The involvement of the states and territories in the overarching program is enabled through various forms of state and territory representation at multiple levels in the governance structure.</td>
</tr>
</tbody>
</table>
The Program encompasses all activities from recruitment through to point of referral to a specialist linked to a multidisciplinary team (MDT) for further investigation and treatment where appropriate.

The Program cohort will be the general population aged 55 to 74 years and Aboriginal and Torres Strait Islander people aged 50 to 74 years who are current or former smokers.

A risk assessment tool will then be used to determine eligibility for LDCT screening.

Informed consent will be ensured so that participants are fully aware of the nature and purpose of the Program.

Smoking cessation is an integral component of the Program.

Access to LDCT will, in most places in Australia, be through existing public and private radiology service providers. In some remote and very remote areas, mobile vans will be utilised.

A National Screening Register will be established to ensure that quality assurance standards are maintained and will enable research and effective Program functioning.
6. WORKFORCE

6.1 KEY WORKFORCE GROUPS

A diverse clinical and non-clinical workforce will be required to successfully support and operationalise the lung cancer screening and assessment pathway – drawn from existing public and private sector providers. The categories of workforce are as follows:

- Aboriginal and/or Torres Strait Islander Health Workers, Health Practitioners and/or Hospital Liaison Officers
- GPs and primary care nurses
- Quitline/Tackling Indigenous Smoking Counsellors
- radiologists
- radiographers
- nuclear medicine physicians
- cardiothoracic surgeons
- respiratory physicians
- pathologists
- physicists
- clinical nurse specialists
- medical/radiation oncologists.

The following figure indicates the roles this workforce will play within the Program’s recruitment, eligibility, screening and assessment elements. In addition, there will be key clinical roles in care and management beyond the remit of the Program.
### FIGURE 6.1: HEALTH WORKFORCE ROLES

#### Primary Roles within Pathway

<table>
<thead>
<tr>
<th>Recruitment</th>
<th>Aboriginal and/or Torres Strait Islander Health Worker, Health Practitioner or Hospital Liaison Officer</th>
<th>GP</th>
<th>Primary Care Nurse</th>
<th>Quitline counsellor/ Tackling Indigenous Smoking</th>
<th>Respiratory Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligibility</td>
<td>Aboriginal and/or Torres Strait Islander Health Worker, Health Practitioner or Hospital Liaison Officer</td>
<td>GP</td>
<td>Primary Care Nurse</td>
<td>Quitline counsellor/ Tackling Indigenous Smoking</td>
<td></td>
</tr>
<tr>
<td>Screening</td>
<td>Radiologist</td>
<td>Radiographer</td>
<td>Physicist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment</td>
<td>Radiologist</td>
<td>Respiratory Physician</td>
<td>GP</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Key Roles in Clinical Care and Management (outside of the Program)

<table>
<thead>
<tr>
<th>Management</th>
<th>Primary Care Nurse</th>
<th>Medical Oncologist</th>
<th>Radiation Oncologist</th>
<th>Radiologist</th>
<th>Respiratory Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GP</td>
<td>Pathologist</td>
<td>Nuclear Medicine Physician</td>
<td>Cardiothoracic surgeon</td>
<td>Aboriginal and/or Torres Strait Islander Health Worker, Health Practitioner or Hospital Liaison Officer</td>
</tr>
</tbody>
</table>
6.2 WORKFORCE IMPACT

The degree of impact on each professional group has been estimated by considering two key factors:

- **Demand**: The number of participants or participant related activities required at a national level relevant to each professional group.
- **Capacity**: The size of the professional group impacted (i.e. how many professionals within each group are currently actively working within Australia).

When considering the demand generated by the Program, the likely outcome of each screen has to be considered. As previously mentioned, the majority (~89%) of participants will receive a scan on a biennial basis and no abnormalities will be found. Therefore, the most significant demand generated for this group will be at the recruitment and screening phases, impacting primary care and radiology workforce respectively.

Conversely, around 11% of participants are predicted to have a low risk of malignancy or above – and therefore have the potential to require further LDCT scans or enhanced diagnostic interventions (such as biopsies, PET scans etc.) or require work-up for treatment. This group are therefore likely to impact the secondary care workforce more significantly, such as respiratory physicians.

Currently most people with lung cancer eventually present to the health care system and require some level of treatment. A lung cancer screening program will bring forward the presentation of lung cancers and may lead to an increase in demand for some aspects of care such as surgery and adjuvant chemotherapy and radiotherapy. It will also generate some patients who have other abnormalities detected who will require investigations. The overall impact on service demand is difficult to estimate because people with lung cancer that, without screening, may have presented late with advanced and complicated disease may now present earlier with curable disease. It is likely that overall there will be a low to medium impact on most health professionals currently treating lung cancers. This group would include cardiothoracic surgeons, nuclear medicine physicians, respiratory physicians, pathologists and oncologists.

It is expected that, overall, demand generated by the Program on the key members of the clinical workforce can be met by the existing workforce within Australia. The possible exceptions to this will be on radiologists where adequate access will require careful monitoring.

**KEY POINTS**

- A diverse clinical workforce will be needed to successfully support and operationalise the screening and assessment pathway.
- Overall the roll out of the Program will have a low to medium impact on most health professionals currently treating lung cancers.
7. IMPLEMENTATION

Cancer Australia considered a number of strategies to stage the implementation of the Program such that it is phased appropriately to ensure all the necessary elements of the Program can be developed, tested and, if need be, modified.

The implementation pathway described as follows is preferred phased over a four-year period.

A number of elements will need to be in place prior to commencement of recruitment, including:

- the establishment of the national Register
- appropriate technology to allow data transfer and communication with participants/health providers
- purchase and fit out of the proposed mobile vans for each State and the Northern Territory
- necessary quality assurance measures such as, established clinical pathways, protocols and accrediting of LDCT machines to ensure they are capable of volumetric assessment
- employment of necessary Program management personnel
- information/communication strategies.

The Primary Health Networks (PHNs) could be leveraged as the vehicle for enabling and encouraging population recruitment and primary health care provider participation. In addition to their close involvement with the primary care sector, PHNs have existing working relationships with the States’ public health systems and in many cases the private hospital sector. They also have established formal and informal community networks. Most are already developing clinical pathways with LHDs (or their equivalents) for referred care. The population size of each PHN is suitable for a Screening Program and PHNs have a direct funding and performance relationships with the Commonwealth Department of Health.

In Phase 1, it is proposed that three PHNs are identified for participation. These PHNs would be selected from States/Territories who express interest in early participation.

Parameters which will be important for identification of PHNs for Phase 1 would include:

- strong relationships of the PHNs with LHDs or their equivalent regional health authorities in each State/Territory
- existence of mature clinical pathways and linkages between primary and secondary care providers
- links to existing Regional Cancer Care Centres
- early focus on rural, Aboriginal and Torres Strait Islander, and socioeconomically disadvantaged population groups
- willingness and capacity to provide required performance data.

Subsequent phases would be rolled out in the following three years and, through progressive involvement of other PHNs, expand the Program to a national footprint.

It is also proposed that Aboriginal Community Controlled Health Organisations (ACCHOs) throughout Australia be a key vehicle to promote and enable Program participation by Indigenous Australians.
It is proposed that the Program be implemented in phases such that it is fully implemented across Australia in a four-year timeframe.

Primary Health Networks are proposed as a primary vehicle for implementation with three PHNs identified for Phase 1.

 Aboriginal Community Controlled Health Organisations (ACCHOs) will be also a key vehicle to promote and enable Program participation by indigenous Australians.
8. PROGRAM COSTINGS AND COST EFFECTIVENESS

8.1 Program costings

The following table outlines an indicative costing to the Commonwealth for the first four years of the Program.

<table>
<thead>
<tr>
<th></th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobile screening van set up</td>
<td>$11,200,000</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Promotion and communications (initial)</td>
<td>$11,550,000</td>
<td>$1,550,000</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Annual program costs (recurring)</td>
<td>$20,753,122</td>
<td>$20,753,122</td>
<td>$20,753,122</td>
<td>$20,753,122</td>
</tr>
<tr>
<td><strong>Subtotal Direct costs</strong></td>
<td>$43,503,122</td>
<td>$22,303,122</td>
<td>$20,753,122</td>
<td>$20,753,122</td>
</tr>
<tr>
<td>Risk/performance assessment costs</td>
<td>$31,292,451</td>
<td>$36,410,281</td>
<td>$10,564,016</td>
<td>$10,233,054</td>
</tr>
<tr>
<td>CT costs (biennial and interval)</td>
<td>$52,763,873</td>
<td>$51,473,430</td>
<td>$47,697,694</td>
<td>$45,453,451</td>
</tr>
<tr>
<td><strong>Subtotal MBS costs</strong></td>
<td>$84,056,324</td>
<td>$87,883,711</td>
<td>$58,261,710</td>
<td>$55,686,505</td>
</tr>
<tr>
<td><strong>Total costs</strong></td>
<td>$127,559,446</td>
<td>$110,186,833</td>
<td>$79,014,833</td>
<td>$76,439,627</td>
</tr>
</tbody>
</table>

* A 60% participation rate has been applied to costs.

As can be seen, the direct indicative program costs are $43.5 million in 2021, reducing to $20.8 million in 2024. The remainder of Commonwealth outlays would be absorbed through MBS payments for risk assessments and LDCT costs.

One of the important principles underpinning the Program is the need to access those most at risk of lung cancer – rural/remote, lower socioeconomic and Aboriginal and Torres Strait Islander people. For those reasons, it is important that the risk assessment costs and LDCT costs should not entail any out-of-pocket payments by participants.
The elements of the recurring Program costs ($20,753,000 for 2021) comprise staffing, communications, Register costs and quality assurance/governance.

There are a number of key assumptions underpinning this indicative costing.

- A participation rate of 60% has been applied, whereby 60% of the eligible population (i.e. 60% of the 580,000 ever-smokers in the designated age range meeting the risk threshold) - will actually undergo screening. This participation rate is about 10% higher than the average for the other three Australian cancer screening Programs. This higher rate of participation is predicted because it is believed the targeting of the Program to those most at risk will result in a greater uptake.

- The LDCT costs provided by private radiology clinics are calculated according to the existing MBS schedule fee item of $295 for a CT scan (the recently updated MBS schedule fee is $299.40). Savings could be achieved if a lower designated fee item was introduced.

- The risk/performance assessment costs are greater in 2021 and 2022 and decrease significantly in subsequent years. If a more phased implementation of the Program is preferred (eg. via progressive expansion through the PHNs, these assessment costs would be more evenly spread across the four years).

It is important to note that the total costs for the Program exclude any treatment costs which will be incurred if malignancies/lung cancer are found via the screening. These treatment costs are outside the Program and would be covered through existing health programs.

8.2 Cost effectiveness

In keeping with Australian government policy, a formal assessment of costs and benefits was undertaken using established methods for cost-effectiveness assessment, which is the preferred approach of the Australian Department of Health.

Calculation of the cost effectiveness of the biennial Program was determined using the Microsimulation SCreening ANalysis (MISCAN) lung model. This model was designed to simulate population trends in lung cancer for comprehensive surveillance of the disease, to relate past exposure to risk factors to lung cancer incidence and mortality, and to then estimate the impact of cancer-control interventions. The MISCAN model has been used to evaluate screening programs for breast, cervical, colorectal, prostate and lung cancers worldwide.

The MISCAN-Lung model was populated using detailed data describing smoking patterns over the lifetimes of five different Australian birth cohorts from 1945 to 1969, combined with life tables for these birth cohorts. These inputs were adjusted to enable the model to predict observed lung cancer incidence rates. Cost and quality of life (utility) input parameters were then added to the model to predict the effects of screening on health system and patient costs and Quality Adjusted Life Year (QALYs) gained over the remaining lifetime of the study population (Australian birth cohorts from 1945 to 1969 remaining alive in 2021).

Efficacy of screening and treatment was primarily based on evidence from the US National Lung Screening Trial (NLST), whereas program delivery was informed by preliminary results from the Queensland arm of the International Lung Screen Trial (ILST) and Australia-specific expertise.

The base case results indicate that a biennial screening program for individuals aged 55 to 74 years with a minimum 6-year lung cancer risk 1.5% (using the PLCOm2012) is the most cost-effective form of screening program for the full Australian population, with an estimated incremental cost-effectiveness ratio (ICER) of $83,545 per QALY gained (excluding patient costs).
Indicative costings suggest the following direct Program costs for the first four years of the Program.

- 2021: $43.5 million
- 2022: $22.3 million
- 2023: $20.8 million
- 2024: $20.8 million

In addition, some costs will be incurred through existing schedule items in the MBS – for primary care consultations and radiological services.

Costs could be reduced if a designated MBS schedule item number was introduced for the LDCT scans.

The Program as outlined in this Report would be cost effective with an incremental cost-effectiveness ratio of $83,545 per QALY gained.
9. PROGRAM GOVERNANCE

9.1 Health Ministers’ Endorsement

As with other national health initiatives which impact on State/Territory health services, formal endorsement by Health Ministers of the Program will be important. At the time of preparing this Report, national Health committee structures are under review, but this endorsement would ideally be progressed through the new jurisdictional health structures.

9.2 Governance structure

The Program will be an Australian Government Program delivered with the co-operation and support of State and Territory governments.

The governance structure will consist of a Program Administrator and three core National Program committees, namely:

- Program Delivery Committee
- Program Development and Translation Committee
- Strategic Advisory Committee.

In addition, an Aboriginal and Torres Strait Islander Advisory Group is proposed.

Program Delivery Committee

The Program Delivery Committee will oversee the delivery of the Program including quality, safety and monitoring of the overall Program, and identify risks and issues impacting the Program.

Program Development and Translation Committee

The Program Development and Translation Committee will promote co-ordination, integration and innovation across the overall Program through medical and digital innovation driven by the sector, policy developments, the use of data and technology, and healthcare professional and provider inputs.

Strategic Advisory Committee

The Strategic Advisory Committee will advise on the future policy directions and Program development based on clinical best practice, global evidence and emerging technologies, identify emerging challenges and risks to the Program, and provide information to inform the deliberations of the other core National Program Committees. It is envisaged that this committee will also be responsible for informing research priorities in relation to the Program’s research function.

All three Committees report directly to the Program Administrator.

Aboriginal and Torres Strait Islander Advisory Group

Each of the national Program committees will have representation from up to two Aboriginal and Torres Strait Islander people. These members will form part of a broader Aboriginal and Torres Strait Islander Advisory Group that will provide a platform for advice, support and leadership for the national Program committees.
Program Administrator

The Program Administrator will be responsible for governance of the three core National Program committees, as well as management, development, support, and expenditure of the Program. The proposed Virtual Access and Diagnostic Hub will also be oversighted and managed by the Program Administrator.

KEY POINTS

- The Program will be an Australian Government Program delivered with the cooperation and support of State and Territory Governments.
- Program policy decisions will be determined at a national level.
- State and Territory representation is at multiple levels in the governance structure.
- There are three core national Program committees - a Program Delivery Committee, a Program Development and Translation Committee and a Strategic Advisory Committee. In addition, an Aboriginal and Torres Strait Islander Advisory Group is proposed.
- The Program will be led by a Program Administrator.
10. QUALITY ASSURANCE, EVALUATION AND RESEARCH

10.1 Quality Assurance

For the Program to be safe and effective, both a comprehensive quality and safety framework, and a monitoring and evaluation framework are required.

These have been designed to define how the overall Program, including Program outcomes and performance, are to be measured, monitored and evaluated, and how standards of service and Program delivery will be achieved and maintained.

The Quality and Safety Framework (see Figure 10.1) provides the principles and requirements that define the quality objectives for the Program and the key performance indicators to monitor performance and outcomes.

The Frameworks aim to ensure all service providers and organisations involved in the Program provide value based, quality and safe services including ensuring services are aligned to the following three core elements:

- **Clinically effective & cost-effective**: based on the best available evidence and contribute to research.
- **Person centred**: providing equitable access for all eligible Australians and responsive to the needs of those who access the service.
- **Designed for safety**: both person and Program safety; ensuring greater benefits than harm, delivered by skilled and knowledgeable staff and by accredited providers.

The Frameworks are also designed to ensure agility by supporting continuous quality improvement at a national, State and Territory and provider level. This will lead to accountability and transparency across the Program.

Data collected will be disaggregated by social, cultural, economic and demographic factors to measure the overall effectiveness and reach of the Program. It is integral that data collection of a minimum viable dataset is supported and that processing in close to real time is enabled such that the data are current, accurate and complete.
10.2 Data and research

A Data Governance Framework will be designed and implemented to ensure that the appropriate authority and control is applied to data, and that data are managed in line with legislative and other compliance obligations.

Consultation will occur with the Aboriginal and Torres Strait Islander Advisory Group regarding the appropriate mechanisms to govern the collection, ownership and use of data about Indigenous Australians.

The Program should be future proof and agile; enabled by real time data and reporting on an individual and aggregate level for the benefit of participants and providers. Data collection, data integrity, and data utilisation are core considerations to ensure accurate, high quality data is central to the effective delivery of the Program.

Figure 10.2 shows the different requirements for data storage on the Screening Register as the eligible population proceeds through the Program and into any subsequent treatment.
FIGURE 10.2 PROGRAM DATA

Recruitment

Primary Care Provider Software

Screening Register

Screening

Radiology Provider Software

Assessment

Management

Multidisciplinary Team

Specialist Provider Software

Engagement

Risk Assessment

Performance Status

Reason for Not Being Eligible Based on inclusion criteria

Consent Details

Identification

Referral Details

Low Dose CT Scan (including findings) & PanCan Assessment

Low/Moderate Malignancy

High Malignancy & Suspected Lung Cancer

No Significant Findings

Rescreen

Performance Status

Rescreen, Monitor & Follow up

Lung Cancer Screening program

Management - outside the program
All research activities undertaken within the Program will comply with and follow the principles and drivers of good research. Two core research categories that the Program will enable are:

- research that focuses on the monitoring and evaluation of the effectiveness of the Program and implementation research to apply new research knowledge to current practices in the Program
- research that focuses on novel technologies, taking advantage of technologies as they become available, new clinical guidance, and best practice program management principles. This may involve research on new organisational or operational approaches to improve the screening and assessment pathway.

The Strategic Advisory Committee will have overall oversight of the research directions, and intended research outcomes, and have a defined role in relation to future research. The Program Delivery Committee will have a role from a current state research perspective, particularly around formative evaluation and research (quality assurance and continuous improvement). The Development and Translation Committee (DTC) will play a role in guiding the implementation of research findings that will inform the future direction of the Program.

**KEY POINTS**

- A comprehensive Quality and Safety Framework will be designed to support operational safety, quality and improvement within the Program.
- A Monitoring and Evaluation Framework will be designed to enable regular monitoring of the Program against key performance indicators and determine if the Program is achieving key objectives and outcomes.
- A Data Governance Framework will be designed to ensure that data and information from the Program is managed and utilised consistently and in alignment with the relevant guidelines.
- A detailed research Program is a core component of the Program. This research will ensure the Program remains contemporary by enabling it to be agile and built with a focus on continuous improvement and to strengthen the evidence base of the Program.
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