



**Australian Government**  
**Department of Health**

# **NATIONAL BOWELCANCER**

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## **SCREENING PROGRAM**

### **POLICY FRAMEWORK PHASE FOUR (2015–2020)**

**NOVEMBER 2017**

## National Bowel Cancer Screening Program Policy Framework

The document was reviewed by the National Bowel Cancer Screening Program (the Program) Clinical Advisory Group and the Program Delivery Advisory Group and endorsed by the Standing Committee on Screening on 2 March 2017.

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## Version control and distribution

### Version control (document revision history)

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### Distribution

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## Terms and abbreviations

The following terms and abbreviations are used in this document.

Term	Meaning
ACSQHC	Australian Commission on Safety and Quality in Health Care
AHMAC	Australian Health Ministers' Advisory Council
AIHW	Australian Institute of Health and Welfare
CAG	National Bowel Cancer Screening Program Clinical Advisory Group
CCPHPC	Community Care and Population Health Principal Committee
Health	Australian Government Department of Health
DHS	Australian Government Department of Human Services
GESA	Gastroenterological Society of Australia
GP	General practitioner
Hot zone	A postcode where the average monthly temperature is above 30 degrees Celsius.
iFOBT	immunochemical faecal occult blood test
NBCSP	National Bowel Cancer Screening Program
NCSR	National Cancer Screening Register
NHMRC	National Health and Medical Research Council
Participant	An NBCSP invitee who returns a completed iFOBT for analysis
Participant Details Form	A form sent with the iFOBT kit to be completed by the participant and returned with the completed kit to the pathology laboratory. The form collects information such as Indigenous status, disability, language spoken at home and GP information.
PDAG	National Bowel Cancer Screening Program Delivery Advisory Group
PFUF	Participant Follow-up Function
PI	Performance indicator
Positive colonoscopy	A colonoscopy that has detected tubular adenoma, tubulovillous adenoma, villous adenoma, sessile serrated adenoma, traditional serrated adenoma, adenoma, carcinoma or polyps $\geq 10$ mm.
Program	National Bowel Cancer Screening Program
Quality enablers	'Building blocks' for the required quality across the NBCSP. The quality enablers specify the high-level responsibility assigned to parties involved with implementing elements of the NBCSP.
Register	The National Bowel Cancer Screening Program Register
Screening notice	A letter sent to people in the eligible population inviting them to opt in to receive an iFOBT kit. This letter is sent to people who had a positive colonoscopy result at a previous screen or have a recent colonoscopy recorded in their Medicare records.

## National Bowel Cancer Screening Program Policy Framework

Term	Meaning
Screening pathway	The series of steps an invitee would follow should they participate in the NBCSP, return a positive iFOBT result and undertake follow-up investigations via 'usual care'. It specifies the decision points and health providers' involvement along the way.
Usual care	Health care provided through public and private providers (such as GPs and hospitals). It is generated by, but not specific to, the NBCSP.

## 1 Introduction

### 1.1 Purpose

This document outlines the Policy Framework for Phase Four of the National Bowel Cancer Screening Program (the Program), which covers the phased implementation of biennial screening from 2015 to 2020. This Policy Framework (2015–2020) supersedes the Phase Three Policy Framework (2013–2017) for the Program, due to the Australian Government's decision to accelerate the implementation of biennial screening from 2015.

This document reflects the agreed understanding between the Australian Government and state and territory governments of the high-level policy parameters guiding the implementation of the Program in Phase Four.

It outlines the Program's goals and objectives; key program elements; governance, including key roles and responsibilities; and Program monitoring and evaluation relevant to Phase Four. It also outlines the screening pathway and its key components.

It is intended that the Policy Framework be reviewed in a planned manner unless a review is required ahead of time. The process of planning the review schedule and agreeing changes to the Framework will be managed by the Australian Government Department of Health (Health), with support from the Program Delivery Advisory Group (PDAG) and the Clinical Advisory Group (CAG). Endorsement of significant updates to the Framework will be sought through the Standing Committee on Screening (SCoS) of the Community Care and Population Health Principal Committee (CCPHPC) of the Australian Health Ministers' Advisory Council (AHMAC).

### 1.2 Introduction

In Australia the incidence of bowel cancer has been increasing each year since 1982. The risk of being diagnosed with bowel cancer by the age of 85 was one in 11 for males and one in 15 for females in 2012, with the risk rising sharply and progressively from the age of 50 years.<sup>1</sup> Bowel cancer accounts for almost 9 per cent of all deaths from invasive cancers in Australia, making it the second most common cause of cancer-related death after lung cancer.<sup>2,3</sup>

Randomised controlled trials have clearly established that screening asymptomatic populations for bowel cancer reduces mortality from the disease through early detection. Screening for bowel cancer has the potential not only to allow early diagnosis, thereby reducing mortality rates, but also to prevent the development of bowel cancer. Further details on the rationale and evidence for bowel cancer screening are at [Appendix 1](#).

The National Bowel Cancer Screening Program was implemented in 2006 by the Australian Government to address the rising incidence of and mortality from bowel cancer. A history of the Program and its development is at [Appendix 2](#). The Program is required to be evidence based and aims to be consistent with the [Australian Population Based Screening Framework \(2016\)](#).

The phased implementation of biennial screening for eligible people aged 50 to 74 years commenced in Phase Three and will be completed by 2020 through Phase Four. This will bring the Program in line with recommendations of the National Health and Medical Research Council's *Clinical practice guidelines for the prevention, early detection and management of colorectal cancer (2017)*. The Program's approach to invite eligible people between 50 and 74 years of age to screen every two years is consistent with other bowel cancer screening programs internationally. The upper age of 74 years is based on consideration of the relative risk of bowel cancer in people over 74 years of age who are asymptomatic; the risk to these individuals who undertake screening, in particular from follow-up diagnostic procedures (colonoscopy); and the existence of comorbidities.



## National Bowel Cancer Screening Program Policy Framework

The table below lists the eligible age cohorts from commencement to 2020.

Table1: Eligible NBCSP Age Cohorts by Year

Phase	Start date	End date	Target ages
1	7 August 2006	30 June 2008	55 and 65
2	1 July 2008	30 June 2011(a)	50, 55 and 65
2(b)	1 July 2011	30 June 2013	50, 55 and 65
3	1 July 2013	Ongoing	50, 55, 60 and 65
4	1 January 2015		50, 55, 60, 65, 70 and 74
4	1 January 2016		50, 55, 60, 64, 65, 70, 72 and 74
4	1 January 2017		50, 54, 55, 58, 60, 64, 68, 70, 72 and 74
4	1 January 2018		50, 54, 58, 60, 62, 64, 66, 68, 70, 72 and 74
4	1 January 2019		50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72 and 74

Source: AIHW

(a) Eligible birthdates, and thus invitations, ended on 31 December 2010.

(b) Ongoing NBCSP funding commenced.

Note: The eligible population for all Phase 2 and 3 start dates incorporates all those turning the target ages from 1 January of that year.

Key activities being progressed in Phase Four to support the phased implementation of biennial screening to 2020 and to support the Program to achieve its objectives include:

- reporting against performance indicators and outcomes to enhance program monitoring and continuous improvement
- developing and implementing a Quality Framework and related projects for the Program
- increasing participation in the Program, including improved targeting of invitations, undertaking a national pilot of an alternative pathway for Aboriginal and Torres Strait Islander participants, and improving GP engagement
- addressing issues related to colonoscopy quality, including the implementation of colonoscopy projects to enhance the quality and capacity of colonoscopy services in Australia and support the expansion of the Program
- addressing inadequacies and gaps in data collection, including through the implementation of a National Cancer Screening Register
- undertaking a program evaluation in 2017–18 and reviewing the Program where needed in a systematic and consultative way.

## 2 National Bowel Cancer Screening Program

The Program aims to reduce the incidence of, and illness and mortality related to, bowel cancer in Australia through screening to detect cancers and pre-cancerous lesions in their early stages, when treatment will be most successful.

The Program was implemented in 2006, reflecting the understanding between the Australian Government and state and territory governments to address the rise in incidence of and mortality from bowel cancer. The Program aims to operate in accordance with the Australian Population Based Screening Framework 2016. Projects are underway to support consistency with this framework—for example, the National Indigenous Bowel Screening pilot and the National Bowel Cancer Screening Program Quality Framework.

A biennial screening interval for eligible people aged between 50 and 74 is being progressively phased in from 2015 and will be fully implemented by 2020.

The Program has been expanded in phases since its implementation in 2006.

- **Phase One** commenced from 1 July 2006. The eligible population comprised:
  - people who turned 55 or 65 years of age on or after 1 May 2006 and on or before 30 June 2008
  - people who turned 55 or 65 years of age on or after 1 July 2008 and on or before 31 December 2010
  - pilot participants.
- **Phase Two** commenced from 1 July 2008. The eligible population comprised people who turned 50 years of age on or after 1 January 2008 and on or before 31 December 2010.
- **Phase Three** was triggered by the ongoing funding and expansion of the Program announced in the 2012–13 Budget. The eligible population from 2013–14 comprised:
  - people turning 50, 55 and 65 years of age
  - people who turn 60 years of age on or after 1 January 2013
  - people who turn 70 years of age on or after 1 January 2015.

The then Government also announced that biennial screening for all Australians aged from 50 to 74 years would be phased in from 2017–18 to 2034, commencing with 72-year-olds.

- **Phase Four** commenced with an accelerated expansion of the Program being announced in the 2014–15 Budget. This phase covers 2015 to 2020, during which time the Program is expected to be fully biennial, offering screening to all eligible people between the ages of 50 and 74 every two years.

### 2.1 Objectives

The Program aims to:

1. Achieve participation levels that maximise the population benefit of early detection of bowel cancer in the target population
2. Enable equitable access to the Program for men and women in the target population, irrespective of their geographic, socioeconomic, disability or cultural background, to achieve patterns of participation that mirror the general population
3. Facilitate the provision of timely, appropriate, high-quality and safe diagnostic assessment services for Program participants
4. Maximise the benefits and minimise harm to individuals participating in the Program

5. Ensure the Program is cost effective and maintains high standards of program management and accountability
6. Collect and analyse data to monitor participant outcomes and evaluate program effectiveness.

## 2.2 Key elements of the National Bowel Cancer Screening Program

In Phase Four the Program has the following key features.

### *Eligible population*

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The eligible population in Phase Four (which covers the phased implementation of biennial screening) is outlined in section 2 above.

To receive an invitation to participate in the Program a person must:

- be age eligible (with the exception of alternative invitation projects)
- have a Medicare entitlement type of either:
  - Australian citizen
  - migrant
- have a current Medicare card or be registered as a Department of Veterans' Affairs (DVA) customer
- have a mailing address in Australia
- not be a conditional migrant
- not be a temporary resident
- not be a Reciprocal Health Care Agreement recipient.

People who meet the eligibility criteria are automatically invited at their next eligible birthday to participate in the Program. There are some cases where a person has to be manually registered for the Program (for example, a DVA customer who meets all eligibility criteria except for having a current Medicare card, or an non-invited participant who is age eligible within 12 months).

Alternative invitation projects are run from time to time, including for Aboriginal and/or Torres Strait Islander people, where kits are distributed by the local health service. Over the current period (2015–16 to 2019–20), up to 13.28 million eligible people will be offered free bowel cancer screening through the Program, including 7.1 million Australians in new age groups. It is estimated that when biennial screening is fully rolled out approximately 4 million eligible Australians will be invited annually.

### *Screening test: immunochemical faecal occult blood test*

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An immunochemical faecal occult blood test (iFOBT) is recommended by the National Health and Medical Research Council (NHMRC) guidelines for bowel cancer screening for an asymptomatic population and is the screening test endorsed for Phase Four of the Program. Although no test is 100 per cent, the Program always endeavours to use the most accurate test available for population screening for bowel cancer. The iFOBT detects human haemoglobin and/or its degradation products and is selected for use in the Program on the basis of offering value for money and the best possible balance between:

- a. high specificity and sensitivity

- b. ability to meet Australia's geographic challenges (such as distance and heat)
- c. not requiring dietary or medication restrictions (and therefore being more acceptable to the public)
- d. ease of use
- e. automatic analysis
- f. capability to monitor the test positivity rate to minimise unnecessary colonoscopies.

### **Screening test positivity rate**

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Given the phased implementation of biennial screening in Phase Four of the Program and the oldest age cohorts being added first, the positivity range expected is 4 per cent to 10 per cent. The expected upper level of positivity for the whole cohort was increased from 8 per cent to 10 per cent for Phase Four in recognition of the evidence that older age cohorts demonstrate a higher positivity rate. Test positivity is carefully monitored on an ongoing basis on behalf of the Program by the Australian Institute of Health and Welfare (AIHW) and by the Department of Health (Health) through the relevant performance indicator for positivity (see section 5). In Phase Four, Health is piloting a statistical process control, which involves a set of quantitative positivity rate monitoring rules developed by the AIHW to identify when the positivity rate changes sufficiently from a normal range such that an investigation is warranted. In Phase Four, Health, in consultation with the Program's Clinical Advisory Group (CAG) and Program Delivery Advisory Group (PDAG) and with the support of the AIHW, will review the positivity rate as needed given the addition of the older age cohorts (70- and 74-year-olds).

### **Screening pathway**

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The key components of the participant screening pathway are shown in a flow chart at [Appendix 3](#). This outlines the pathway that Program participants can take from invitation through to diagnosis—generally through a colonoscopy—including the points at which reminder letters will be sent and data collected by the National Bowel Cancer Screening Program Register (the Register). The major components of the participant screening pathway are outlined at [Appendix 4](#). The pathway will be reviewed as needed in consultation with the CAG and PDAG, to support the ongoing effective implementation of biennial screening.

### **Hot-zone policy**

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Australia is unique in some of the physical challenges it poses for the Program and iFOBT testing. The Program must be administered to comply with the Therapeutic Goods Administration (TGA) listing (on the Australian Register for Therapeutic Goods (ARTG)) conditions for the Program's iFOBT kit to meet time-to-analysis and temperature requirements.

Under the TGA's ARTG listing conditions the iFOBT kits are not subject to temperature restrictions when they are being posted or before they are inoculated with faeces. Temperature only affects the stability of the iFOBTs after samples have been taken.

To meet this condition, Health has in place arrangements to provide information to participants on the appropriate usage and storage of the samples and the timing of their return. For example, specific information has been included in the invitation letter, the user instructions in the test kit, and the information booklet. Invitations are also scheduled, through the Register, to be sent in the cooler months of the year for relevant postcodes.

Bureau of Meteorology 30-year data on average monthly temperature has guided the determination of when iFOBT kits should be mailed. Based on this data, there are around 1000 postcodes affected by the hot-zone policy. Of these, there are 130 postcodes where sending

invitations is limited to fewer than six months per year, with some limited to a three-month window. The impact of the hot-zone policy is predominantly on certain areas of the Northern Territory, North Queensland and Western Australia.

The hot-zone policy cannot practicably prevent a participant completing the kit and returning the sample when the average monthly temperature is higher than 30 degrees Celsius. A hot-weather flyer is therefore also included in relevant participants' kits to advise them of the importance of keeping the completed kit cool and how to handle and return kits to minimise heat exposure.

### *Usual care*

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If a Program participant receives a positive iFOBT screening test result they are directed to a general practitioner (GP) for assessment, and necessary follow-up (usually colonoscopy), which is provided through the 'usual care' system. 'Usual care' refers to those health services that are not under the direct responsibility of the Australian Government and that are still an essential part of the Program screening pathway. Participants are able to access both public and private providers within health financing arrangements with states and territories.

As part of the usual care model for the provision of colonoscopy services, state and territory governments manage colonoscopies and related histopathology, and after-care when provided through public hospitals. Participants treated privately receive the current Medicare rebate but retain responsibility for meeting any gap payments charged by private providers.

### *Participant Follow-up Function*

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The Participant Follow-up Function (PFUF) was introduced in Phase One of the Program. The purpose of the PFUF is to provide a follow-up service for Program participants—and/or their health professionals—who are identified through the Register) as requiring follow-up after a positive iFOBT test result. The direct funding of states and territories through the PFUF model recognises the knowledge states and territories have at the local level about how usual care operates in their jurisdiction.

The PFUF is delivered by PFUF officers, whose primary role is to encourage Program participants to progress through the screening pathway where they have received a positive iFOBT result and are not recorded on the Register as having attended the necessary follow-up, including:

- a GP / primary health care provider appointment or
- an assessment colonoscopy or other clinically relevant assessment.

PFUF officers may also perform other activities at the discretion of their state or territory. Funding for the PFUF is provided through a multilateral National Partnership Agreement under the Federal Financial Relations Framework.

### *National Cancer Screening Register*

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An effective register is critical for the Program. In Phase Four, the Program will transition to the new National Cancer Screening Register (the NCSR) in 2018. The NCSR will replace the existing National Bowel Cancer Screening Register administered by the Department of Human Services.

The NCSR offers a national digital health infrastructure for the collection, storage, analysis and reporting of bowel cancer screening data. It will facilitate invitations for screening, mailing of test kits, participant support and follow-up, clinical decision-making, and easier reporting for health care providers.

Participants will be able to view and manage their contact information, screening status and participation in the NCSR through a dedicated web portal accessed through myGov. Health care

providers will be able to send information to the NCSR directly through their clinical information systems\* or through a dedicated health care provider portal. The intended outcomes are improved capture of screening information in the NCSR, and a reduction of the burden on health care providers. In collecting data from clinical information systems, the Register will need to comply with the national *Privacy Act 2008* (and Australian Privacy Principles) and patient–practitioner consent associated with particular transactions.

The *National Cancer Screening Register Act 2016* provides the legislative framework to safeguard protected information in the NCSR. It does so by prohibiting the use and disclosure of that information for purposes outside the requirements for bowel cancer screening; and creating an offence arising from the unauthorised recording, use or disclosure of personal information contained in the Register. The legislation also requires notification to the Information and Privacy Commissioner if there is a data breach.

Access by academic and other researchers to the data held in the Register can be considered for approval in relation to appropriate research projects. The Department of Health assesses and approves applications for access to Register data for these purposes according to the NCSR Data Release Policy.

\*Supported/integrated software systems only

### **Program information**

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Information about the Program and how to participate is available from several sources. The Program Information Line (1800 118 868) is the first point of contact for all public enquiries regarding the Program. Information Line operators are responsible for enquiries received in relation to the Program and the Register.

The contracted pathology provider has an information line (1800 738 365) to answer any queries about the iFOBT kit and to assist people to complete the screening test.

The Program website provides detailed information about the Program, including its history and operation; consumer resources (a 'how to do the test' video, copies of the pre-invitation and invitation letters, brochures and information booklets in English and other languages); testimonials from Program participants; health professional resources (clinical guidelines, practice tools, forms and template letters where appropriate); and program monitoring and evaluation reports. The website can be accessed at [Cancer Screening](#) website.

## 3 Governance, roles and responsibilities

The Program is an Australian Government program that is delivered with cooperation and support from state and territory governments (see [Appendix 5](#)). High-level policy decisions in relation to the Program are made by the Australian Government Minister for Health. Decisions that require the formal agreement of state and territory governments may be managed through multilateral negotiation through the Council of Australian Governments (COAG) structure or through separate bilateral arrangements.

The Department of Health is responsible for program management and governance; policy development; expenditure of program funds (for example, iFOBT screening and partnership follow-up support delivered via states and territories); and Medicare Benefits Schedule support offered to relevant colonoscopy patients on behalf of the Australian Government.

State and territory governments have an advisory role in program policy and management through the Standing Committee on Screening (SCoS) of the Community Care and Population Health Principal Committee and the Program Delivery Advisory Group (PDAG). State and territory governments also have responsibility for providing usual care services for Program participants following a positive screening test; local coordination of the Program, including health system workforce and colonoscopy capacity; and other support activities to improve awareness of the Program and increase participation and follow-up. Details on the participant follow-up function are provided below. A separate Clinical Advisory Group (CAG) provides clinical advice on the Program to Health.

### 3.1 Australian Government Department of Health

The Department of Health has overarching policy development and program implementation responsibility for the Program, including:

- providing advice and recommendations to the Australian Government Minister for Health on the development and implementation of the Program
- effective and high-quality program implementation through measures such as the Quality Framework for the Program, which includes a focus on continuous quality improvement (for example, maintaining a regular monitoring, review and evaluation strategy for the Program)
- conducting/commissioning regular program management related quality audits to assure that contracted service providers are effectively addressing relevant service delivery and quality risks<sup>1</sup>
- establishing and maintaining project agreements with state and territory governments to support the Program's PFUF
- undertaking tender processes and managing contracts for the delivery of services to the Program, such as the development and maintenance of the Register and the supply of screening tests, pathology analysis and associated support services
- developing and implementing a communication strategy and undertaking Program communications for relevant segments of the health workforce and for the general community, including the production of resources
- chairing and providing secretariat services to the Program advisory groups and any established working groups
- providing state and territory program areas with regular Program data to support service planning and implementation.

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<sup>1</sup> It is important to note that pathology laboratory accreditation related quality management responsibilities lie with the National Association of Testing Authorities Australia (NATA).

Most of these responsibilities are managed by the Bowel Screening Section, Cancer and Palliative Care Branch.

Consultation with state and territory governments and other relevant stakeholders on the development and implementation of the Program occurs through:

- the National Bowel Cancer Screening Program advisory groups (CAG and PDAG) and associated working groups
- the SCoS, which reports to the CCPHPC, which in turn reports to the AHMAC.

The Australian Government provides financial support for the above activities and, through the Medicare Benefits Scheme, for consultations with medical practitioners that result from the Program; colonoscopies and histopathology provided in the private sector; and any other follow-up (such as specialist visits) provided in the private sector.

The Australian Government also provides funding to state and territory governments for public hospital services, including colonoscopies, as per relevant funding arrangements with state and territory governments.

### **3.2 State and territory governments**

States and territories play an important role in the effective implementation of the Program in collaboration with the Australian Government. Local coordination of Program implementation, workforce and colonoscopy capacity and communications are essential for the success of the Program. State and territory governments endeavour to:

- provide timely public sector colonoscopy services (and histopathology services if required) to participants with a positive iFOBT result who are referred by their GP
- encourage provision of data to the Register for procedures provided in the public sector to participants with a positive iFOBT result, consistent with related state or territory privacy legislation
- Engage PFUF officers to encourage participants to progress through the screening pathway where they have received a positive iFOBT result, and provide information to the Register on participants to update their pathway status
- work with the Australian Government on:
  - issues such as workforce, training, service capacity and clinical quality
  - communication strategies, to support consistent messages and to avoid duplication of effort
  - local-level initiatives such as communication, public relations and promotional activities, to support increased participation and equitable access for eligible people, particularly related to increasing access for Aboriginal and Torres Strait Islander people, culturally and linguistically diverse (CALD) communities and other harder to reach groups; and engaging GPs to ensure consistent but tailored messaging and to avoid duplication of effort
- participate in advisory structures for the Program.

### **3.3 Health care professionals**

Health professionals such as GPs, gastroenterologists, colonoscopists, surgeons, gastroenterology nurse coordinators, nurse endoscopists and pathologists play a key role supporting Program participants as they progress through the screening pathway. They do this by delivering clinically appropriate advice, services, treatment and care, and by providing data on participants and their outcomes to the Register.



GPs, in particular, have a key role in the prevention, risk assessment, screening, diagnosis and treatment of bowel cancer. The Royal Australian College of General Practitioners (RACGP) *Guidelines for preventive activities in general practice* (the Red Book<sup>2</sup>) recognises this role and identifies that GPs are critical to maximising participation in screening, and to managing participants with a positive screening test. In 2016, the RACGP partnered with MedicineWise to issue guidance to GPs on a range of over-used procedures, including colonoscopies where an iFOBT should have been recommended for screening purposes.<sup>3</sup> In Phase Four, Health is making a concerted effort as part of the accelerated expansion of the Program to work closely with the RACGP, the Australian College of Rural and Regional Medicine, the Association of Practice Nurses and other such organisations to ensure that the support of GPs and practice nurses is recognised and leveraged in supporting the Program. A Primary Health Care Strategy and Action Plan underpins Health's efforts. This approach recognises that within the Program the specific role of the GP is to:

- encourage, where clinically appropriate, those who are sent a screening test through the Program to participate
- assess those with a positive screening test and refer them for further examination as clinically indicated—for example, a colonoscopy
- identify their patients as Program participants when referring them for colonoscopies
- notify the Register of referral/non-referral for colonoscopy or other bowel examination of participants with a positive screening test.

More generally, the role of the GP in relation to bowel cancer screening is to:

- advise patients about bowel cancer, their individual risk of bowel cancer, and bowel cancer screening
- manage individuals identified as being at high risk of bowel cancer, in accordance with the NHMRC guidelines
- inform individuals that the NHMRC guidelines recommend an iFOBT screening test every two years from the age of 50.

### 3.4 National Cancer Expert Reference Group

The National Cancer Expert Reference Group (NCERG) is a panel of experts and jurisdictional and consumer representatives that was established by COAG in 2010. In developing a national work plan for improving cancer care in Australia, the NCERG identified the value of a national approach to delivering consistent and optimal cancer care. As a consequence, the Victorian Department of Health developed *Optimal cancer care for people with colorectal cancer*<sup>9</sup> in 2016. The NCERG has endorsed these new optimal cancer care pathways, which they agree are relevant across all jurisdictions and form a key deliverable from of its program of work.

### 3.5 Primary Health Networks

On 1 July 2015, 31 Primary Health Networks (PHNs) were established to increase the efficiency and effectiveness of medical services for patients, particularly those at risk of poor health outcomes, and to improve coordination of care to ensure patients receive the right care in the right place at the right time. PHNs will achieve these objectives by working directly with general

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<sup>2</sup> <[<sup>3</sup> <\[Version 0.8\]\(http://www.choosingwisely.org.au/recommendations/racgp1></a></p></div><div data-bbox=\)](http://www.racgp.org.au/your-practice/guidelines/redbook/early-detection-of-cancers/Colorectal-cancer-(CRC)/></a></p></div><div data-bbox=)

practitioners, other primary health care providers, secondary care providers and hospitals to facilitate improved outcomes for patients.

PHNs are implementing the HealthPathways project. This is an online manual used by clinicians to help make assessment, management, and specialist request decisions for over 550 conditions. Rather than being traditional guidelines, each pathway is an agreement between primary and specialist services on how patients with particular conditions will be managed in the local context. It is like a 'care map', so that all members of a health care team—whether they work in a hospital or the community—can be on the same page when it comes to looking after a particular person. HealthPathways are designed to be used at the point of care. They are primarily for GPs but are also available to hospital specialists, nurses, allied health and other health professionals. Each health jurisdiction (and participating PHN) can tailor the content of HealthPathways to reflect local arrangements and opinion, and deploys its own version of HealthPathways to its clinical community. The target audience for HealthPathways is the primary care clinicians responsible for managing patients in the community and for initiating requests (including referrals to hospital) for specialist assistance. Further information can be found at the [Health Pathways Community](#) website.

The Australian Government has agreed to six key priorities for targeted work by PHNs. These are mental health, Aboriginal and Torres Strait Islander health, population health, health workforce, eHealth, and aged care. The national headline indicators include:

- potentially preventable hospitalisations
- childhood immunisation rates
- cancer screening rates (cervical, breast, bowel)
- mental health treatment rates (including for children and adolescents).

In the context of the Program, Health will continue to support PHNs to achieve increased cancer screening rates. For example, data at the PHN level to support PHNs is provided through the Australian Institute of Health and Welfare (AIHW) and is available from the [AIHW](#) website.

### 3.6 Australian Institute of Health and Welfare

The AIHW produces comprehensive program monitoring reports for the Australian Government Department of Health, including annual monitoring reports, participation outcomes, operational reports and periodic outcome reporting on key performance indicators. These reports analyse data extracted from the Register and provide an overview of screening participation and outcomes. These reports are integral also to ongoing review and monitoring of the Program. They are available from the [Cancer Screening](#) website. The AIHW is a key partner to the Program.

### 3.7 Register provider

The Program's Register provider is responsible for identifying the eligible screening population using Medicare Enrolment data provided by the Department of Human Services; issuing invitations to screen; supporting the collection of program data; and issuing reminder letters at agreed intervals to people who fail to attend for follow-up procedures, such as GP appointments or an assessment colonoscopy. The Register provider also operates the Program Information Line, which is the first point of contact for all public enquiries regarding the Program and the Register..

### **3.8 Pathology provider**

The contracted pathology provider is responsible for the supply of screening tests and associated support services, including pathology analysis of the screening test kits for the Program and the provision of a specific help line to support participants to complete their kit. This complements the broader Program Information Line.

### **3.9 National Bowel Cancer Screening Program advisory structures**

#### *Clinical Advisory Group*

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The Program's CAG consists of individual experts invited by the Australian Government Department of Health to support the Program. The group provides advice to Health on clinical issues in relation to bowel cancer and bowel cancer screening, including existing, new and emerging screening technologies, clinical issues and developments; the quality of provision of colonoscopy; and the bowel cancer screening pathway. It also provides advice on research and epidemiological evidence.

### **3.10 Program Delivery Advisory Group**

The Program's PDAG currently consists of the Australian Government Department of Health, the Program's Register provider, state and territory governments, the AIHW, and Cancer Council Australia. The group provides advice to Health on bowel cancer screening policy issues and the ongoing implementation of the Program in accordance with the Program Policy Framework. This includes operational aspects of maximising equitable access to the Program for the eligible target group, including people from rural and remote areas; people with a mental or physical disability; CALD communities; Aboriginal and Torres Strait Islander communities; low socio-economic groups or those with a mental or physical disability. It also provides advice on other relevant aspects of the Program, including the monitoring, collection and analysis of data on screening outcomes, and research and epidemiological evidence.

Where relevant and appropriate, joint sessions of the PDAG and the CAG may occur to facilitate consideration of issues relevant to both groups and to facilitate information sharing between the two groups. Information sharing between these groups is also facilitated by the sharing of agenda papers and minutes and, where relevant, through verbal updates by the two chairs.

From time to time Health may need to establish subject-specific and time-limited working groups to progress specific issues of special interest to the Program.

### **3.11 Council of Australian Governments committees**

#### *Standing Committee on Screening*

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The SCoS comprises Australian Government and state and territory government representatives with expertise in and responsibility for screening. The role of the committee includes the provision of advice on emerging population screening issues and other screening issues at the direction of the CCPHPC ; and generic issues related to national screening programs (such as the National Bowel Cancer Screening Program), including, monitoring and evaluation, policy development, implementation, and communication and recruitment strategies.

#### *Community Care and Population Health Principal Committee*

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The role of the CCPHPC is to coordinate the development and implementation of national strategies relating to community care and primary and secondary prevention of chronic disease.

### *Australian Health Ministers' Advisory Council*

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The AHMAC consists of members from the Australian Government and state and territory governments. The role of the AHMAC is to provide effective and efficient support by advising on strategic issues relating to the coordination of health services across the nation and, as applicable, with New Zealand; and operating as a national forum for planning, information sharing and innovation.

### *COAG Health Council*

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The members of the COAG Health Council are the Australian Government, state and territory governments and New Zealand Government ministers with responsibility for health policy, services and program matters; and the Australian Government Minister for Veterans' Affairs.

See [Appendix 5](#) for a pictorial representation of the Program's governance structure.

## 4 Monitoring, review, evaluation and quality

### 4.1 Program monitoring

The Program will be monitored regularly in accordance with screening principles (see the [Australian Population Based Screening Framework \(2016\)](#)) and evaluated periodically.

Data from the Register is used in monitoring and evaluating the quality measures, effectiveness, equity, accountability and performance of the Program. The performance of the Program against the performance indicators (PIs) is reported annually in a monitoring report published by the Australian Institute of Health and Welfare (AIHW), along with six-monthly operational reports to Health and to jurisdictional program managers.

Key performance indicators for the Program were agreed<sup>4</sup> and endorsed by the National Health Information and Performance Principal Committee in 2014. In Phase Four, PIs will be reported against in annual monitoring reports. It is important to note that data reporting is an ongoing challenge for the Program and its Register. Reporting is currently voluntary and manual. This means that clinicians have to fill out relevant forms and send relevant information to the Register, and not all clinicians currently support the Program through reporting such information. The NCSR is expected to enhance reporting by making it easier to report into and out of. Despite reporting challenges, it is considered important to commence reporting against the PIs where meaningful data is available during the progressive expansion to biennial screening. This should make it easier for the Program to track performance and to identify and address (to the maximum extent possible) data gaps and challenges, and will link to the Quality Framework.

The PIs are outlined in the table below. In Phase Four, in consultation with program advisory groups and the AIHW, further work will be undertaken to consider the evidence and feasibility around identifying baseline targets and/or trend expectations for each PI to support continuous quality in the Program and to support the Program in meeting its objectives.

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<sup>4</sup> The AIHW and the Program Data and Monitoring Report Working Group have developed a formal and agreed set of performance indicators for the Program.

**NBCSP Key Performance Indicators**

<b>PBSF step<sup>(a)</sup></b>	<b>No.</b>	<b>Program performance indicator</b>	<b>Related NBCSP objectives</b>
Recruitment	1	Participation rate	2, 5, 6
Screening	2	Screening positivity rate	1, 4, 5
Assessment	3	Diagnostic assessment rate	2, 3, 4
Assessment	4	Time between positive screen and diagnostic assessment	2, 3, 4
Diagnosis	5a	Adenoma detection rate	1, 4
Diagnosis	5b	Positive predictive value of diagnostic assessment for detecting adenoma	1, 4
Diagnosis	6a	Colorectal cancer detection rate	1, 4
Diagnosis	6b	Positive predictive value of diagnostic assessment for detecting colorectal cancer	1, 4
Diagnosis	7	Interval cancer rate	1, 4
Diagnosis	8 <sup>(b)</sup>	Cancer clinic—pathological stage distribution	1, 4
Outcomes	9 <sup>(b)</sup>	Adverse events—hospital admission	3, 4
Outcomes	10 <sup>(c)</sup>	Incidence of colorectal cancer	6
Outcomes	11 <sup>(c)</sup>	Mortality from colorectal cancer	6

(a) Population Based Screening Framework (PBSF).

(b) Indicators 8 and 9 are aspirational performance indicators (performance indicators for which data is not currently available; when data becomes available, it will be reported).

(c) Indicators 10 and 11 are contextual performance indicators (performance indicators that are not specific to the NBCSP but provide context to the burden of bowel cancer in Australia, which may be related to bowel screening activity and outcomes).

## 4.2 Monitoring emerging technologies

Technology is a key driver of the Program. The Program will continue to monitor, including through the support of the Health Policy Advisory Committee on Technology (HealthPACT),<sup>5</sup> research in relation to screening technologies and screening program models.

### *Program review and evaluation*

While sound program management requires an ongoing focus by Health on continuous improvement, there is a need for planned review and evaluation of program policy and elements.

<sup>5</sup> HealthPACT is the national committee for the horizon scanning of new and emerging technologies. It is a sub-committee of AHMAC, reporting directly to the Hospitals Principal Committee. HealthPACT comprises representatives from all Australian state and territory health departments, the Australian Government Department of Health, the Medical Services Advisory Committee, and the New Zealand Ministry of Health.

### *Drivers for program review and evaluation*

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There are a number of drivers for a Program Review:

- Commitment to the phased implementation of biennial screening by 2020 requires the examination of the possible impact of a biennial screening interval on the current program delivery model and service providers. Relevant issues in regard to the implementation of biennial screening include:
  - alignment of the Program with the Population Based Screening Framework, and identification of gaps to be addressed
  - the continued appropriateness and quality of the Program's model and components
  - the continued appropriateness of the clinical pathway
  - options (including costs) for the phased implementation of age cohorts in the implementation of biennial screening
  - participation levels and the involvement of health professionals
  - incorporation of emerging technologies
- Register functions, data collection and dissemination challenges.

The Program's Quality Framework identifies continuous quality improvement as a principle in the maintenance of efficiency and effectiveness within the screening pathway. To implement this, the Program needs to have a structured process for reviewing program elements and proposing appropriate changes.

The Program has been operating since 2006, based on the Australian pilot and published high-quality evidence. National and international research on emerging screening technologies and innovations in program delivery is increasing and needs to be assessed for its relevance, effectiveness and applicability within the Program.

A wide range of existing frameworks and standards inform a program review approach for the Program, including national policy frameworks, clinical guidelines, national safety and quality standards and regulations, craft college guidelines, data standards and NBCSP requirements. These are outlined at Appendix 6.

### *Program review/evaluation plan*

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The Program will be reviewed in a structured and consultative manner to help ensure that key program elements, critical emerging issues and evidence are reviewed and considered in a systematic way. This is consistent with the principles and objectives of the Program's Quality Framework and the Australian Population Based Screening Framework. Such structured reviews will sit under the Policy Framework and complement the Quality Framework.

The Program will use a program review approach that supports regular, five-yearly reviews, preferably undertaken independently. A Program Review Plan will be developed for this purpose in consultation with program advisory bodies. These reviews will consider the program model, key program elements, emerging issues and evidence in a systematic way, in accordance with the principle of continuous quality improvement within the Program and in accordance with program objectives.

Apart from planned review activity, proposals for additional or ad hoc reviews may arise through:

- publication or notification of evidence
- the program advisory groups

- ongoing monitoring of the Program's Quality Framework
- issues or evidence that warrant further structured review, including through research findings.

Where appropriate, depending on the driver for the structured review, Health may establish a specific working group to oversee a review. This may include members from the Program's Clinical Advisory Group and/or Program Delivery Advisory Group and any other relevant advisory bodies. Where the review has significant implications for program policy and delivery, the proposal may also need to be considered by the Minister for Health and, where appropriate, the Standing Committee on Screening (SCoS).

### ***Criteria for conducting reviews/evaluations within the National Bowel Cancer Screening Program***

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1. The Program Review Plan will identify that a review of a program element is due; that a clear issue or question of importance to the Program has arisen; and/or that high-quality evidence suggests a need for a review.
2. Any proposed investigation/review must be ethical and have appropriate ethics clearance, including Department of Health ethics clearance (if required).
3. The proposed investigation/review must comply with relevant legislation and be conducted in accordance with relevant Australian clinical/administrative/research principles and guidelines.
4. The proposed investigation/review must be of benefit to the Program and consistent with the Program's clinical pathway.
5. Consideration of any investigation or review proposal needs to take account of the possible risks to individuals, to health/program systems, to program partners and to the standing of the Program. A risk analysis will be undertaken by Health for each review activity.
6. The investigation/review must be appropriately designed, have robust methods and plan for execution and reporting.
7. The proposed investigation/review must be examined and approved by Health (in consultation with appropriate bodies).
8. The proposed investigation/review must be feasible and timely.

### ***Previous reviews/evaluations/research of relevance***

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Since the commencement of the Bowel Cancer Screening Pilot Program in November 2002 there have been a number of reviews of and research papers on it, including:

- *The Australian Bowel Cancer Screening Pilot Program and beyond—final evaluation report (2005)*<sup>6</sup>
- Initial impact of Australia's National Bowel Cancer Screening Program (Ananda et al. 2009)<sup>7</sup>

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<sup>6</sup> Available from

[http://www.health.gov.au/internet/screening/publishing.nsf/Content/9C0493AFEB3FD33CCA257D720005C9F2/\\$File/final-eval.pdf](http://www.health.gov.au/internet/screening/publishing.nsf/Content/9C0493AFEB3FD33CCA257D720005C9F2/$File/final-eval.pdf)



- Costs and cost effectiveness of full implementation of a biennial iFOBT screening program for bowel cancer in Australia (Pignone 2010)<sup>8</sup>
- *Review of the National Bowel Cancer Screening Program (Phase Two)* (KPMG 2013)<sup>9</sup>
- Optimising the expansion of the National Bowel Cancer Screening Program (Cenin et al. 2014)<sup>10</sup>
- Compelling new data on the effectiveness of Australia's National Bowel Cancer Screening Program: a model for best practice? (APJCO, James St John and Paul Grogan 2016).<sup>11</sup>

The KPMG review of Phase Two of the Program in 2011–12 included the development of an evaluation framework for the Program that highlighted key considerations for future evaluations.

In December 2014, the AIHW released the first analysis of bowel cancer outcomes for the Program.<sup>13</sup> The report showed that bowel cancer mortality rates were lower for Program invitees than for non-invitees. Of people who were diagnosed with bowel cancer in 2006–2008, non-invitees had a 15 per cent higher risk of bowel cancer death by 31 December 2011, accounting for lead-time bias. Among those who were invited to participate in the Program, the risk of death from bowel cancer was over twice as high in those who did not participate but later had a bowel cancer diagnosed, compared with those whose cancer was diagnosed through the Program.

A Phase Three evaluation is planned in 2017–18 to inform the ongoing implementation of biennial screening. It will be based on the evaluation framework developed as part of the Phase Two review of the Program. It is anticipated that the evaluation will include an assessment of the effectiveness of the Program in achieving its objective, the cost-effectiveness of the Program and the effectiveness of the governance structures and the current Program model for the ongoing implementation of biennial screening from 2020.

### 4.3 Quality

The Population Based Screening Framework identifies that a screening program should have an organised quality control program across the screening pathway to minimise potential risks of screening. To achieve the potential benefit of bowel cancer screening, quality must be optimal at each step of the process. Furthermore, an agreed quality management plan should be in place to ensure ongoing management of quality and a continuous quality improvement framework.

#### *National Bowel Cancer Screening Program Quality Framework*

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All Australians expect high-quality and appropriate health care, delivered by trained specialists and provided in a system with a culture of safety. The Program Quality Framework (2016) recognises

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<sup>7</sup> Available from [https://www.mja.com.au/journal/2009/191/7/initial-impact-australia-s-national-bowel-cancer-screening-program?0=ip\\_login\\_no\\_cache%3D78cca90174bf3dfd6a545372967d18ef](https://www.mja.com.au/journal/2009/191/7/initial-impact-australia-s-national-bowel-cancer-screening-program?0=ip_login_no_cache%3D78cca90174bf3dfd6a545372967d18ef)

<sup>8</sup> Available from <https://www.mja.com.au/journal/2011/194/4/costs-and-cost-effectiveness-full-implementation-biennial-faecal-occult-blood>

<sup>9</sup> Available from [http://cancerscreening.gov.au/internet/screening/publishing.nsf/Content/C1EED399C650C2F3CA257D8D001F10E9/\\$File/review-nbcsp-fr-p1.pdf](http://cancerscreening.gov.au/internet/screening/publishing.nsf/Content/C1EED399C650C2F3CA257D8D001F10E9/$File/review-nbcsp-fr-p1.pdf)

<sup>10</sup> Available from <https://www.mja.com.au/journal/2014/201/8/optimising-expansion-national-bowel-cancer-screening-program>

<sup>11</sup> Available from <http://onlinelibrary.wiley.com/doi/10.1111/ajco.12484/full>

## National Bowel Cancer Screening Program Policy Framework

existing safety and quality requirements for health care and draws out specific expectations relevant to the Program. The Quality Framework is based on the Australian Safety and Quality Framework for Health Care (the Health Care Framework) endorsed by Australian health ministers in 2010. It will support the introduction of a systematic approach to review and evaluation activity within the Program, under a principle of continuous quality improvement.

The Program Quality Framework is the first step in supporting the delivery of quality along the screening pathway. The Quality Framework is outcomes based. It states the desired quality outcomes for the different elements of the screening pathway and the actions that are required for these outcomes to be achieved.

The Quality Framework has been developed as part of a suite of documents to support the Program. Recognising the nature of the program model, which comprises a combination of Commonwealth (screening and follow-up delivery) and state and territory responsibilities ('usual care' and PFUF delivery), it is intended to be used by all those involved in the screening pathway, to guide individual and organisational activities, articulate specific responsibilities and highlight interdependencies. It serves as an aspirational framework informed by best practice, and describes the quality the Program aims to achieve. It builds on the collaborative, inter-government and inter-sectoral nature of the Program to promote quality across the screening pathway.

The Quality Framework is a tool for developing procedures to suit different business models. While in some instances its Quality Determinants reference specific guidelines, agreements or contracts, users of the Quality Framework should consider their own circumstances in determining the requirement for tailoring existing standards or developing more specific guidance to operationalise the Quality Framework.

The Australian Government Department of Health is responsible for promoting, reviewing and updating the Quality Framework. The Quality Framework will be subject to regularly scheduled reviews by Health with the support of its stakeholders and advisory groups and may be updated on a needs basis to reflect significant policy change. The Quality Framework is published on the [Cancer Screening](#) Program website.

A Quality Improvement Action Plan will be developed on a needs basis to support quality improvement under the Quality Framework. It may be a single plan that includes all relevant areas of improvement and thus includes other jurisdictions and agencies, or it may comprise specific plans for each party. It will also include any achievements against relevant areas identified previously for improvement. The effectiveness of the plan will be monitored through the SCoS.

## 5 Participation

Increasing participation in the Program remains a key focus in Phase Four.

Under its current design the Program has, in place or underway, most of the measures that are known, through research, to be effective in increasing participation. Key measures already in place or underway include:

- advance notification/pre-invitation letters and free, directly mailed iFOBT kits; and sending postage-paid envelopes to return the samples
- invitation letters signed by a person of trust
- using an iFOBT rather than a guaiac faecal occult blood test
- non-responder reminder letters
- telephone calls in addition to reminder letters (participant follow-up function officers undertake this)
- GP endorsement/support (GP engagement strategy and plan underway)
- patient education to assist informed decision-making
- equitable participation (alternative pathway pilot underway; CALD focused engagement needs consideration)
- communications campaign and evaluation
- multi-component strategies rather than relying on only one means of increasing participation
- improved data collection, monitoring and evaluation (underway)
- a composite model of 'mail out' and opt in (including through primary health care providers)—this is a potential future consideration for the Program once biennial screening is in place and the Register offers the necessary agility to have more than one pathway for the Program.

To increase participation, Health will continue to consult with Program partners, as states and territories play an important role in helping to increase participation.

As part of Phase Four, program materials have been refreshed and a communications strategy for this phase has been implemented to communicate the phased implementation of biennial screening and to promote participation in the Program. The Program has undertaken a significant review of its pre-invitation, invitation and reminder letters to make them simpler and more action-oriented. These letters are considered critical to supporting invited people to make the decision to participate. Similarly, there are opportunities to review forms, the information booklet, the Program website and other such materials to ensure that these are consistent in their messages, are current and are easy to understand as the Program ramps up towards biennial screening.

The Program's communication campaign in 2015 and 2016 and associated public relations activities, including in relation to CALD and Aboriginal and Torres Strait Islander communities, has also given impetus to the Program and its participation levels as it heads towards full biennial screening.

Another key focus in Phase Four will be engaging with GPs and Primary Health Networks to support their important role in encouraging participation in the Program, to communicate program changes and to identify opportunities for local promotion and education about bowel cancer and bowel cancer screening. A key challenge is effectively communicating the phased roll-out of biennial screening, especially to GPs and practice nurses, and assuring their ongoing support for the Program.

As the Program matures into a biennial screening program, future opportunities, such as coordinating communications and engagement activities, particularly in relation to CALD and Aboriginal and Torres Strait Islander Communities, may arise in relation to the other two screening programs (cervical and breast).

### **5.1 Addressing the needs of under-screened communities**

Alternative service delivery approaches for iFOBT screening in Aboriginal and Torres Strait Islander communities were trialled under Phase Two of the Program. These trials involved alternative distribution methods for the iFOBT kits to eligible people aged over 50 years—for example, through local health services rather than direct mail. The trial also included targeted education and recruitment activities and provision of culturally sensitive colonoscopy services.

In Phase Four, Health is funding Menzies School of Health Research (Menzies) to develop and implement a National Indigenous Bowel Screening Pilot to test an alternative approach to increase Indigenous participation in the Program. Menzies has undertaken national consultations and developed consumer resources, health professional training and a pilot implementation plan. In 2018, the Pilot will be implemented in selected Indigenous primary health care services. General practitioners, nurses and Indigenous Health Workers in the participating services will directly offer NBCSP kits to their eligible clients aged 50-74 years and provide follow up support.

Engaging with CALD communities to raise awareness of the Program, bust myths and misconceptions and encourage participation requires a specific focus between now and 2020. While the Program already offers some support to such communities, for example through translated materials and interpreting services, a more strategic approach may be needed given that a significant number of 55- to 70-year-old eligible participants are from CALD backgrounds. In addition to language, cultural barriers and taboos can be a challenge to overcome in relation to bowel cancer screening.

Additional options for improving access to screening by other under-screened and disadvantaged communities—such as people with a disability, low socio-economic groups, rural and remote participants, and those with low literacy or low health literacy—will be further explored in Phase Four, resources permitting.

## 6 Colonoscopy

High-quality and accessible colonoscopy services are important to the Program's success and effective participant care and support. The expansion of the Program over the next five years will result in an increase in the demand for colonoscopy services following a positive iFOBT result from around 20,000 to over 100,000 per year. Access to high-quality, safe and timely colonoscopy procedures is essential to enable bowel cancers to be detected early and to reduce adverse events.

### 6.1 Colonoscopy risks

Colonoscopy is an invasive procedure and has risks associated with it. The NHMRC's 2011 *Clinical practice guidelines for surveillance colonoscopy—in adenoma follow-up; following curative resection of colorectal cancer; and for cancer surveillance in inflammatory bowel disease* identifies that colonoscopy is considered to be a relatively safe procedure for the diagnosis of colorectal disease. However, as with any invasive procedure, there is a risk of adverse events occurring either directly or indirectly as a result of the procedure.

The literature identifies a range of complications and adverse events associated with colonoscopy. The main complications are post-colonoscopy bleeding and post-colonoscopy perforation of the bowel. Other complications include abdominal pain, nausea/vomiting, excess sedation, cardiovascular complications, cerebrovascular complications and pulmonary aspiration. The death rate associated with colonoscopy was 0.01 per cent.

The frequency of perforation is 1 in 1400 for all colonoscopies and 1 in 1000 for therapeutic colonoscopies. These complication figures underpin the need to support Program invitees and participants to be adequately informed about the risks of screening and follow-up diagnostic procedures, such as colonoscopy, and the need for the Program to clearly identify the standards and requirements for these. A current challenge for the Program is the lack of reporting on adverse outcomes into the Register, which means that such data could be under-reported, making it difficult to ascertain the extent of adverse events arising from colonoscopies undertaken on Program participants.

### 6.2 Colonoscopy quality

An effective bowel screening program relies on colonoscopy services that reflect quality, consistency, accessibility and appropriateness. In recognition of this, in 2005, the AHMAC 'agreed to work with the Australian Government, relevant Medical Colleges and other key stakeholders to develop a strategy aimed at improving, over time, the availability, quality and consistency of colonoscopy services in Australia.'

A Quality Working Group was established as part of the Program during Phase One to provide advice on the development of a strategy aimed at improving, over time, the availability, quality and consistency of colonoscopy services in Australia.

The [2009 Quality Working Group report](#) outlined the following recommendations:

- Development of a national accreditation scheme for colonoscopy services using uniform national standards
- Implementation of national accreditation standards, with supporting objectives and performance indicators for colonoscopy services, including clinical indicators
- Development of a formal process to ensure the ongoing competency of proceduralists through a nationally recognised mandatory certification and eventual re-certification system
- Investigation of future training needs and delivery tools for colonoscopy training, especially the practicality and viability of accelerated training programs

- Adoption of agreed minimum reporting systems on procedures and colonoscopy outcomes linked with the accreditation, training, and certification processes.

The Quality Working Group report was endorsed by the AHMAC in 2010. Significant work has been achieved in these areas following the implementation of the National Safety and Quality Health Service Standards (NSQHS) by the Australian Commission on Safety and Quality in Health Care (ACSQHC) in 2011.

During Phase Four of the Program, funding for the following initiatives will support the quality of colonoscopy services:

- revision of the 2005 NHMRC *Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer*;
- revision of the 2011 NHMRC *Clinical Practice Guidelines for Surveillance Colonoscopy—in Adenoma Follow-up; Following Curative Resection of Colorectal Cancer; and for Cancer Surveillance in Inflammatory Bowel Disease (2011)*
- As these guidelines provide the clinical guidance for the operation of the Program, the revisions may impact the current screening pathway
- the Gastroenterological Society of Australia to implement a national colonoscopy re-certification program in Australia including up-skilling and training workshops, travelling endoscopy unit sessions (in urban and rural areas) and intensive one-on-one sessions
- the ACSQHC to lead a national consultation process and develop an implementation strategy for a national safety and quality model for colonoscopy services.

In addition, in May 2016 the Australian Government introduced two Medical Benefits Scheme (MBS) items specifically for NBCSP colonoscopies: 32088 and 32089. If used correctly by clinicians, these will help enable accurate recording of follow-up colonoscopy procedures for participants in the Program within the context of the Australian Government's commitment to expand the Program to a full biennial screening interval by 2020. The new items will also help enable monitoring of quality-related data (including data on proceduralist type and number of procedures, location of procedure, adenoma detection rate and patient age). These new items have the potential to be a useful means of identifying whether appropriate diagnostic assessments are being implemented following positive iFOBT results for Program participants, and the time between positive screen and diagnostic assessment. They may also be able to support identification of the number of bowel cancers being diagnosed in Program participants.

### *Colonoscopy capacity*

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There were 25,242 colonoscopies recorded through the Program in 2014. As the Program expands, it is expected that there will be an increased demand for colonoscopy services. In the expansion of the Program under Phase Four to biennial screening by 2020, approximately 4 million eligible Australians will be invited annually and the Program will generate an estimated 100,000 colonoscopies annually. This will equate to around 9 per cent of all colonoscopies performed in Australia.

Once biennial screening has been fully rolled out, more people will be re-invited to participate in the Program than those invited for the first time (who have a higher rate of positive screening); therefore the number of projected colonoscopies is not estimated to increase at the same rate as the number of people invited to participate.

The increase in the number of colonoscopies is indicative. There are a range of other factors that will impact on the flow-on demand, including a possible drop in positivity due to re-screening and possible increases in colonoscopy surveillance regimens for previously detected abnormalities.

While overall capacity in the private system is not reported as a key issue, the ability of state and territory public systems to provide timely colonoscopy following a positive iFOBT result is reflected in a delay in waiting times.

During Phase Four, Health, with the support of the Program's advisory bodies, will continue to examine the potential impact of the expansion of the Program to biennial screening on colonoscopy capacity.

### **6.3 A cooperative approach**

The Program does not currently have a dedicated communications group. It engages with state and territory program managers and the PDAG for advice and support as needed. There is a need to consider how best to engage regularly on bowel cancer related matters with the myriad Australian organisations (see [Appendix 7](#)) that support an understanding of bowel cancer, support people affected by bowel cancer, and supply non-Program test kits, often on a cost-recovery basis. There is a need for the Program and all relevant organisations to adopt consistent messaging where appropriate, to raise awareness of bowel cancer and the Program, and to support a cooperative approach to addressing the bowel cancer challenges facing Australia. The Program recognises that these organisations are important contributors towards addressing the challenges of bowel cancer, as they can target people who are not eligible for the Program and support people with bowel cancer. A cooperative approach between the Program and these organisations is important so that, where relevant, such organisations channel eligible participants towards the Program. Such a cooperative approach will allow the Program to help save more lives, follow up participants through a structured approach offered through the Participant Follow Up Function and the use of the Register, and, in doing so, improve program effectiveness.

## 7 Appendices and references

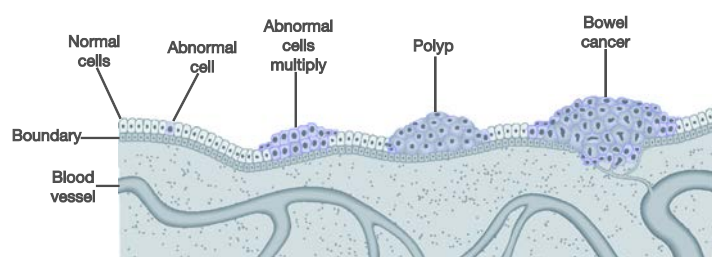
### Appendix 1—Rationale and evidence for bowel cancer screening

#### *What is bowel cancer?*

Bowel cancer refers specifically to cancer of the large intestine (that is, the colon or rectum). It is often referred to as colorectal cancer.

Generally, bowel cancer involves a multistage process in which a series of cellular mutations occur in epithelial cells (the protective layer of surface tissue on exposed bodily surfaces, which also forms the lining of some internal cavities, such as the large intestine) over time.

Early stages of these mutations result in benign polyps that are relatively common in old age. However, a polyp may then undergo additional mutations and become a benign adenoma and, ultimately, a malignant bowel cancer that can invade into deeper layers of bowel tissue and then spread to other sites in the body (Figure 1).



(Illustration adapted from original artwork, courtesy of the Cancer Council Victoria)

These mutations may occur relatively slowly, making early detection and removal of small cancers—and adenomas and polyps that may become cancerous—effective in preventing ill health or death from bowel cancer.

#### *How common is bowel cancer?*

In Australia, the incidence of bowel cancer has been increasing since 1982, with 14,958 new cases diagnosed in 2012 (13 per cent of all cancers). Bowel cancer accounts for almost 9 per cent of all deaths from invasive cancers in Australia, with 4,162 deaths in 2012, making it the second most common cause of cancer-related death after lung cancer.<sup>7, 8</sup>

The risk of being diagnosed by the age of 85 was 1 in 11 for males and 1 in 15 for females in 2012, with the risk increasing sharply from the age of 45 years.

#### *What causes bowel cancer?*

A proportion of bowel cancers (about 20 per cent) are thought to be due to a hereditary component.<sup>9</sup> However, a larger proportion can be attributed to known and unknown environmental and lifestyle factors.

An evaluation of the evidence by the World Cancer Research Fund found there was sufficient evidence that tobacco smoking, obesity and the consumption of alcohol and red and processed meats were risk factors for colorectal cancer, while consumption of foods containing dietary fibre and higher levels of physical activity provided a protective effect from bowel cancer.<sup>10</sup>

Incidence of bowel cancer is also known to increase with age—about 93 per cent of people diagnosed in Australia in 2011 were 50 or older. This is likely to be due to the accumulation of cellular mutations with increasing age.



### **Why screen for bowel cancer?**

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Bowel cancer may be present for many years before showing symptoms such as visible rectal bleeding, change in bowel habit, bowel obstruction or anaemia. Often symptoms such as these are not exhibited until the cancer has reached a relatively advanced stage. However, non-visible bleeding of the bowel may have been occurring in the pre-cancerous stages for some time, and the relatively slow development of bowel cancer makes it a valid candidate for population screening.<sup>11</sup> Randomised controlled trials have clearly established that screening asymptomatic populations with faecal occult blood testing biennially for bowel cancer reduces mortality from the disease through early detection.<sup>12</sup> Screening for bowel cancer has the potential not only to allow early diagnosis, thereby reducing bowel cancer mortality rates, but also to prevent the development of bowel cancer.

The National Health and Medical Research Council's *Clinical Practice Guidelines for the prevention, early detection and management of colorectal cancer* (2017) recommend that organised screening of asymptomatic individuals with iFOBT should be performed at least once every two years, starting at age 50 and continuing to age 74 years.

In December 2014, the AIHW released the first analysis of bowel cancer outcomes for the Program.<sup>13</sup> The report showed that bowel cancer mortality rates were lower for Program invitees than for non-invitees. Non-invitees had a 15 per cent higher risk of bowel cancer death (from 2006–2008 data, corrected, including death by 31 December 2011). Among those who were invited to participate in the Program, the risk of death from bowel cancer was over twice as high in those who did not participate but later had a bowel cancer diagnosed, compared with those whose cancer was diagnosed through the Program.

The report also showed that bowel cancers detected through the Program are more likely to be diagnosed at an earlier stage of cancer spread (121 per cent higher odds) compared with bowel cancers later diagnosed in invitees who did not participate in the Program. Bowel cancers in non-invitees had 38 per cent higher odds of being more advanced than those diagnosed in invitees.

### **Cost of bowel cancer and cost-effectiveness of bowel cancer screening**

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Bowel cancer is one of the most expensive cancers to treat. It is estimated that it costs the health system upward of \$100,000 to treat one case of advanced bowel cancer.<sup>14,\*</sup>

A conservative estimate of the cost-effectiveness of the Program by Pignone et al. (2011)<sup>15</sup> found that full implementation of the Program (i.e. biennial screening of 50–74-year-olds) would have gross costs of \$150 million, reduce bowel cancer mortality by 15–20 per cent and save 3000–5000 life-years annually for an undiscounted cost per life year gained of \$25,000 to \$ 41,667, compared with no screening. Pignone identified six relevant economic analyses, all of which found screening to be very cost-effective (cost per life year gained under \$50,000 per year).

Cenin et al. (2014)<sup>16</sup> published modelling on the impact of various scenarios of roll-out of biennial screening in Australia against baseline five-yearly screening. The model found that with five-yearly screening from age 50 to 70 years (the existing program with 70-year-olds added in 2015), the Program would prevent approximately 35,000 deaths from bowel cancer over the next 40 years. With full implementation of biennial screening by 2020, approximately another 35,000 deaths will be prevented over the next 40 years. Estimates are based on current participation rates. The report also included a sensitivity analysis of what would happen if higher participation rates (60 per cent) were achieved.

### **What is a population-screening program?**

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A population-screening program involves the testing of asymptomatic populations by means of tests, examinations, or other procedures that are acceptable, are cost-effective and can be applied

rapidly. The screening test aims to have high sensitivity (minimal false negatives) and high specificity (minimal false positives).

The Australian Health Ministers' Advisory Council released the Population Based Screening Framework in 2008. The purpose of the framework is to inform on the key issues that should be given consideration when assessing potential screening programs. The framework formally adopts the World Health Organization (WHO) Principles of Early Disease Detection and details the criteria that should be met in Australian screening programs.

### **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.

#### **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 purpose of the Population Based Screening Framework is to inform decision-makers on the key issues to be considered when assessing potential screening programs in Australia. The framework has been divided into two parts:

- the criteria which should be used to assess whether screening should be offered or a screening program introduced for diseases or conditions
- the key principles for the implementation and management of screening programs.

### ***Population Based Screening Framework: screening program criteria***

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The screening program must:

- respond to a recognised need
- have a clear definition of the objectives of the program and the expected health benefits
- have scientific evidence of screening program effectiveness
- identify the target population which stands to benefit from screening
- clearly define the screening pathway and interval
- ensure availability of the organisation, infrastructure, facilities and workforce needed to deliver the screening program
- have measures available that have been demonstrated to be cost-effective to encourage high coverage
- have adequate facilities available for having tests and interpreting them
- have an organised quality control program across the screening pathway to minimise potential risks of screening

## National Bowel Cancer Screening Program Policy Framework

- have a referral system for management of any abnormalities found and for providing information about normal screening tests
- have adequate facilities for follow-up assessment, diagnosis, management and treatment
- have evidence-based guidelines and policies for assessment, diagnosis and support for people with a positive test result
- have adequate resources available to set up and maintain a database of health information collected for the program
- integrate education, testing, clinical services and program management
- have a database capable of providing a population register for people screened that can issue invitations for initial screening, recall individuals for repeat screening, follow those with identified abnormalities, correlate with morbidity and mortality results and monitor and evaluate the program and its impact
- plan evaluation from the outset and ensure that program data are maintained so that evaluation and monitoring of the program can be performed regularly
- be cost-effective
- ensure informed choice, confidentiality and respect for autonomy
- promote equity and access to screening for the entire target population
- ensure the overall benefits of screening outweigh the harm.

The framework is underpinned by the principles of access and equity, fundamental elements of all population-screening programs, and is intended to provide guidance and inform judgement. Importantly, the Australian framework takes into account the need for a strong evidence base in decision-making and the requirement that a program offer more benefit than harm.

Determining the correct balance, whereby disease reduction is maximised with the most effective use of available resources, can be challenging, but should be the aim of any effective screening program.

### *Immunochemical faecal occult blood testing for bowel cancer screening*

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Screening approaches and target populations for screening for bowel cancer vary around the world. International randomised controlled trials have demonstrated that using iFOBTs for screening can reduce mortality from bowel cancer by between 15–25 per cent and reduce incidence by 20 per cent.<sup>17</sup>

An iFOBT is a non-invasive test that detects microscopic amounts of blood in the bowel motion, a common sign of a bowel abnormality such as an adenoma or cancer. The iFOBT identifies spontaneous bleeding that can occur from cancers and pre-cancerous polyps. The presence of blood in the faeces prompts further diagnostic assessment. Positive iFOBT results are usually followed by colonoscopy, which is the most accurate means of visualising the colon. An iFOBT is accepted as the primary screening tool for bowel cancer by a large number of countries.

### *Possible risks of bowel cancer screening*

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Population screening has the potential for both benefit and harm. The possible risks in bowel cancer screening relate to the iFOBT and the risk from follow-up diagnostic tests, usually colonoscopy.

Colonoscopy is an invasive procedure and has a range of risks associated with it. The *2017 NHMRC Clinical practice guidelines for the prevention, detection and management of colorectal cancer* recommend iFOBT screening every 2 years, starting at age 50 and continuing to

## National Bowel Cancer Screening Program Policy Framework

age 74 years, for people at or slightly above average risk (about 95-98% of the population). For people in this group, their bowel cancer risk is not sufficiently high to justify more invasive screening i.e. through colonoscopy.

During Phase Four, Health will continue to monitor the evidence on the risks associated with colonoscopy and will review the upper age limit for bowel cancer screening if required.

No direct adverse events have been observed from iFOBT; however, the test may miss adenomas, as these lesions bleed infrequently. This may falsely reassure participants. As such, there is a need to ensure that participants, and the general public, continue to be aware that a negative iFOBT does not mean that they do not have, or can never develop, cancer or pre-cancerous growths and that they should seek medical advice to determine their level of risk for bowel cancer and if they develop any symptoms. Adverse psychological effects on individuals due to participation in a screening program should also be considered. A positive iFOBT result may cause increased anxiety.

## Appendix 2—History and development of the National Bowel Cancer Screening Program

### *Background*

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In 1996 the Australian Health Technology Advisory Committee<sup>18</sup> systematically assessed bowel cancer screening. As a result the Committee concluded that ‘on the basis of published evidence, and subject to favourable preliminary testing, it is recommended that Australia develop a program for the introduction of population screening for colorectal cancer by faecal occult blood testing for the average risk population’.

The Bowel Cancer Screening Pilot Program was conducted between November 2002 and June 2004 to test the feasibility, acceptability and cost-effectiveness of bowel cancer screening in the Australian community. After the success of this pilot, the Australian Government implemented Phase One of the National Bowel Cancer Screening Program in late 2006.

### *Phase One*

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In the 2005–06 Budget the Australian Government committed to phase in a nationally coordinated, population-based bowel cancer screening program. This was Phase One of the Program, which invited Australians aged 55 and 65 years of age to participate in screening from 2006 to 2008.

### *Phase Two*

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In 2008–09 the Australian Government expanded the Program (Phase Two) to include Australians turning 50 years of age, in addition to those turning 55 or 65, between 2008 and 2011. On 11 May 2009 the Program was suspended following the identification of a fault with the kits in use from December 2008. The Department of Health resumed testing under the Program on 2 November 2009, following the listing on 2 October 2009 of a new iFOBT by the Therapeutic Goods Administration. All participants affected were issued with a replacement iFOBT kit. This process was successfully completed by June 2010.

### *Phase Three*

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In 2011–12 the Australian Government committed to continue the Program and confirmed the ongoing status of the Program. In 2012–13 the Australian Government agreed to expand the Program to screen all 50-, 55-, 60-, 65- and 70-year-olds for bowel cancer. The target cohort was increased to include Australians turning 60 from 2013, and those turning 70 from 2015. The Australian Government committed to the phased introduction of biennial screening for eligible people between 50 and 74 years of age from 2017 through to 2034.

### *Phase Four*

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In the 2014–15 Budget, the Australian Government committed to a further \$95.9 million over four years to accelerate the implementation of a biennial screening interval for eligible people aged 50 to 74 years by 2020.

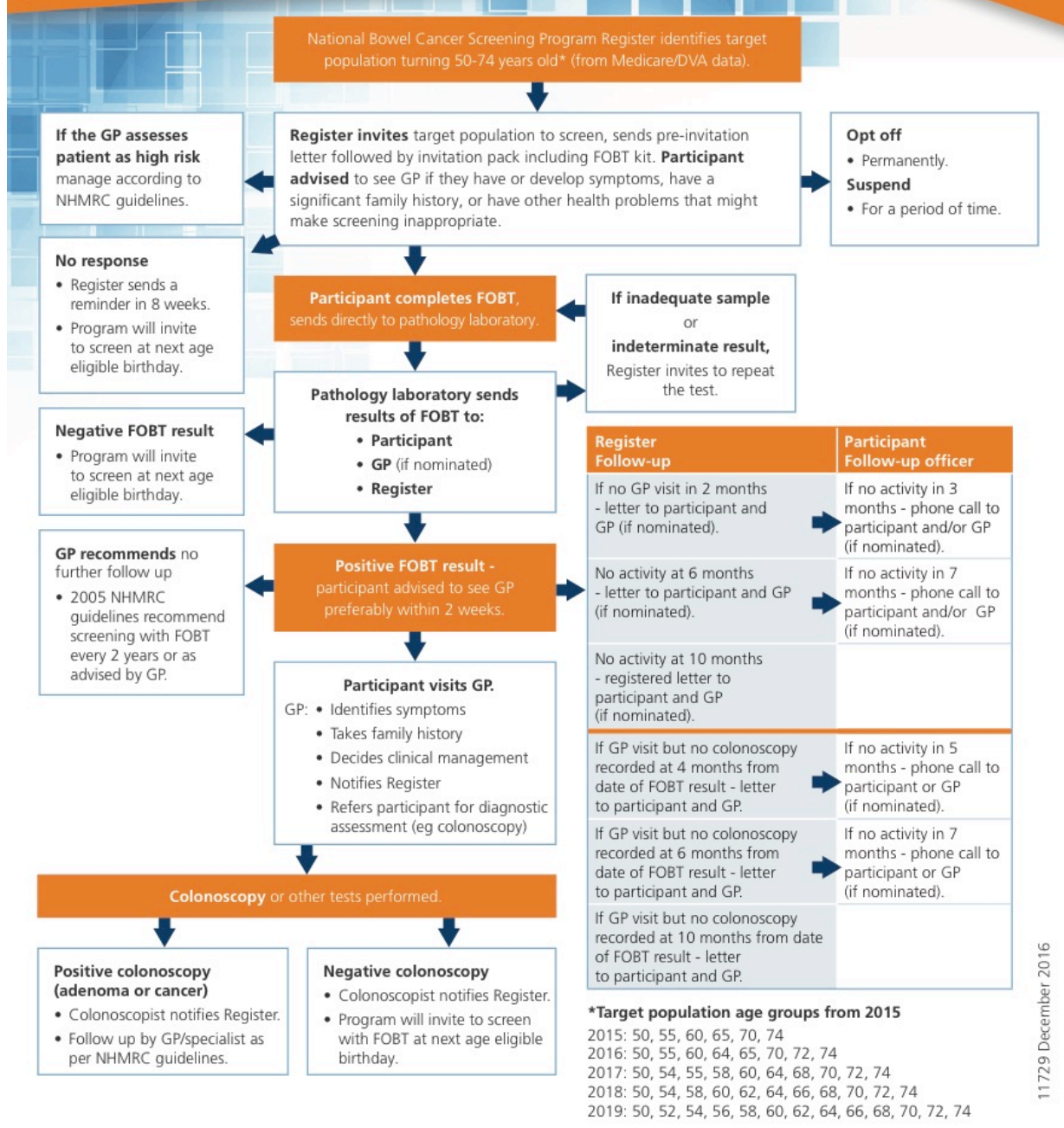
Appendix 3—Screening pathway

**NATIONAL BOWEL CANCER SCREENING PROGRAM**



Australian Government

**PARTICIPANT'S SCREENING PATHWAY**



11729 December 2016

## Appendix 4—Major components of the screening pathway

The major components of the National Bowel Cancer Screening Program screening pathway are:

### *Identification of eligible population*

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The Program Register identifies eligible age cohorts from Medicare and Department of Veterans' Affairs data. In Phase Four of the Program, eligible Australians will be identified based on the calendar year of their birth. They will then be invited to participate from 1 January of that year, with invitations reaching people within six months of their birthday. Where eligible people live in designated hot zones (those postcodes where the average monthly temperature exceeds 30 degrees Celsius for sustained periods of the year), they are invited during the cooler months of the year to decrease possible effects on iFOBT performance due to temperature.

### *Pre-invitation*

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Direct mail from the Register is the primary means utilised by the Program of recruiting eligible people to participate in bowel cancer screening. Eligible people receive a pre-invitation letter to participate in the Program four weeks prior to receiving the test kit. Invitees may opt out<sup>12</sup> or defer participation in the Program if they have had a recent screen or colonoscopy, or if their GP has advised that they do not need to participate.

### *Invitation*

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Eligible people receive a test kit by mail. Participants are encouraged to return the completed test, which will be analysed by the Program's pathology laboratory. The test results are sent to the Register, the GP (if nominated by the participant) and the participant. The participant has the option to opt out of the Program at any point. Additional options for increasing access to screening by people from Aboriginal and Torres Strait Islander, culturally and linguistically diverse, low socio-economic and rural and remote communities are being piloted in Phase Four.

### *Invitation reminder*

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If the participant does not return the screening test, they are sent a reminder letter eight weeks after the invitation date. If a screening test is not returned, the participant is invited to screen at the next eligible age.

### *Screening test pathology analysis*

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A contracted pathology laboratory analyses the screening test samples and sends the result to the participant, the nominated GP and the Register.

### *Negative screening test result*

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If the patient receives a negative screening test result, the result notification advises that it is recommended that they re-screen in two years' time.

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<sup>12</sup> Where a participant chooses to opt out or defer after they have completed a test, their results are still sent to them, their nominated GP and the Register.

### **Positive screening test result**

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If the patient receives a positive screening test result they are advised to visit their GP within two weeks. The GP (if nominated) is also informed of the screening test result. The GP can then discuss the results and the appropriateness of a colonoscopy or other investigative procedure with the patient and refer the patient on where appropriate.

### **Positive screening test result follow-up**

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If there is no follow-up recorded on the register at eight weeks post positive screening test, the participant and the GP (if nominated) are sent a reminder letter by the Register. A further letter is sent at six months. The PFUF will contact the participant and the GP (if nominated) by phone if there is no activity at three months and then at seven months.

If a GP visit is recorded in the Register but no colonoscopy visit is recorded, the participant and GP are sent letters by the Register at four and six months. The PFUF will contact the participant and the GP (if nominated) by phone if there is no activity at five months, and then at seven months.

### **Diagnostic assessment—usual care**

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Once referred by a GP, the participant undergoes further diagnostic assessment, usually a colonoscopy, as part of usual care health services within their state or territory. Best practice guidelines for colonoscopy are outlined in the National Health and Medical Research Council (NHMRC) *Clinical practice guidelines for the prevention, early detection and management of colorectal cancer (2017)* and *Clinical practice guidelines for surveillance colonoscopy—in adenoma follow-up; following curative resection of colorectal cancer; and for cancer surveillance in inflammatory bowel disease (2011)*.

### **Adenoma or cancer**

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Where it is known through reporting to the Register that a participant is diagnosed with bowel cancer or pre-cancerous lesions, including adenoma, following colonoscopy or other procedure, their outcome is recorded by the Register. Further treatment, care and surveillance are provided within the usual care health system. Such participants receive a single notice at their next age/date of eligible screen advising them to discuss screening with their doctor and, if appropriate, to opt in. This is consistent with the surveillance guidelines that some people may return to an 'asymptomatic state' and be eligible again for population screening. Best practice guidelines for clinical management and recommended surveillance are outlined in the NHMRC clinical practice guidelines noted above.

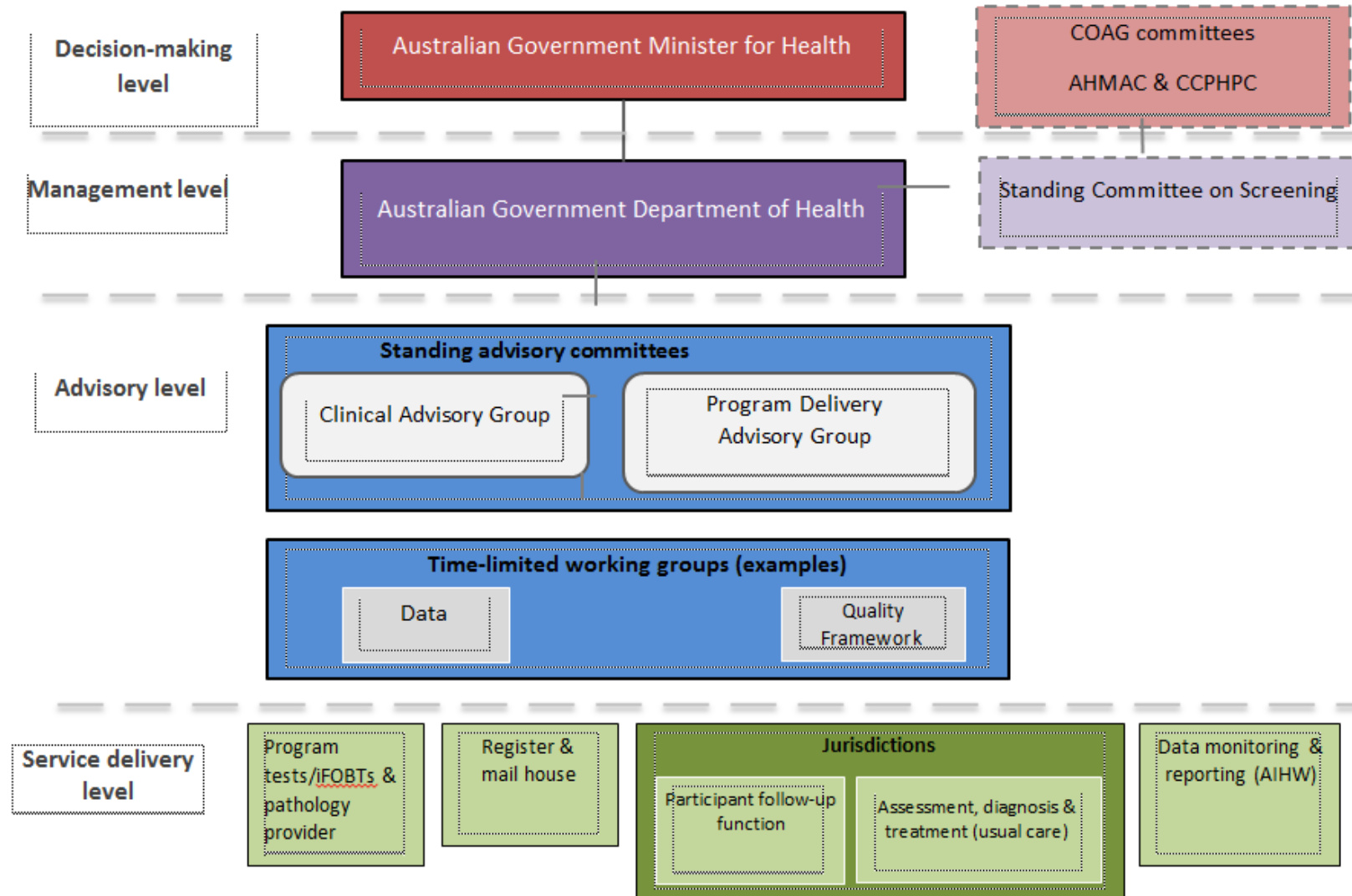
### **Negative colonoscopy**

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Currently, if the patient receives a negative colonoscopy result, their result, where reported, is recorded on the Register and they are invited to re-screen with an iFOBT in five years' time. Unless a participant identifies that they do not wish to participate further in the Program, they will be invited to re-screen at the next eligible age/date according to the re-invitation protocol. Due to the implementation of biennial screening, from July 2017, if a patient receives a negative colonoscopy result they will skip one screening round and be invited to re-screen in four years.



Appendix 5 - Governance structure



## Appendix 6—Frameworks and requirements that inform a structured program review

- Australian Cancer Network Colorectal Cancer Guidelines Revision Committee 2005, *Guidelines for the prevention, early detection and management of colorectal cancer* (approved by the National Health and Medical Research Council on 8 December 2005).
- Australian Institute of Interpreters and Translators 2012, *AUSIT Code of Ethics and Code of Conduct*.
- AHMAC 2016, *Australian Population Based Screening Framework*.
- *National Cancer Screening Register (Consequential and Transitional Provisions) Act 2016*.
- *National Cancer Screening Register Act 2016*.
- Facility- and service-based standards produced by accrediting organisations—for example, Australian Council on Healthcare Standards, 2013 *EQUIP standards*; Quality Improvement Council 2013, *Health and community services standards* (6<sup>th</sup> edition).
- Australian Government Department of Finance 2015, Governance arrangements for Commonwealth Government business enterprises, which apply to Australia Post.
- National Accreditation Authority and Interpreters Ltd (NAATI) guidelines.
- National Bowel Screening Program 2012, *Participant Follow-up Function (PFUF) Guidelines*.
- National Health and Medical Research Council 2011, *Clinical practice guidelines for surveillance colonoscopy—in adenoma follow-up; following curative resection of colorectal cancer; and for cancer surveillance in inflammatory bowel disease*.
- National Health and Medical Research Council 2017, *Clinical practice guidelines for the prevention, early detection and management of colorectal cancer*.
- Australian Commission of Safety and Quality in Healthcare 2012 *National Safety and Quality Health Service Standards*.
- Australian Institute of Health and Welfare 2010, *National best practice guidelines for collecting Indigenous status in health datasets*.
- *Privacy Act 2008*.
- Professional standards that are applied to health care professionals (on either a voluntary or mandatory basis) by regulatory authorities and professional associations such as the professional colleges.
- Gastroenterological Society of Australia 2006 (reprinted 2011), *Standards for endoscopy facilities and services* (3<sup>rd</sup> edition).
- Royal Australian College of General Practitioners 2013, *Standards for general practices* (4<sup>th</sup> edition).
- Australian Commission of Safety and Quality in Healthcare 2004, *Standard for credentialling and defining the scope of clinical practice: a national standard for credentialling and defining the scope of clinical practice of medical practitioners*.
- Therapeutic Goods Administration 2011, *Australian regulatory guidelines for medical devices*. Standards and guidelines.

- Australian and New Zealand College of Anaesthetists, the Gastroenterological Society of Australia and the Royal Australasian College of Surgeons 2008, *Guidelines on sedation and/or analgesia for diagnostic and interventional medical or surgical procedures*. Standards for anaesthesia.
- National Pathology Accreditation Advisory Council pathology standards, including Requirements for Pathology Laboratories (2007), Requirements for the Supervision of Pathology Laboratories (2007), and associated standards and guidance documents.
- NBCSP Quality Working Group 2009, Draft Accreditation Standards for Colonoscopy Services in *Improving colonoscopy services in Australia*.
- World Wide Web Consortium (W3C), Web Content Accessibility Guidelines (version 2.0).

### **Other relevant legislation**

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There is a suite of legislation relating to the Health portfolio that guides research and restricts the disclosure of personal information. This legislation includes the *National Health Act 1953*, the *Health Insurance Act 1973*, the *Aged Care Act 1987*, the *Healthcare Identifiers Act 2010* and, more generally, the *Privacy Act 1988*. There is also legislation that requires the disclosure of information that relates to the health reform process.

### **International work**

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The World Endoscopy Organization is currently developing an international process for the evaluation of new screening tests for colorectal cancer. The draft process being developed by this committee is a step-wise comparative approach that will enable an assessment of the impact of population outcomes through:

1. An initial evaluation of the test in cases of proven cancer
2. A prospective evaluation of performance across the continuum of neoplastic lesions
3. Mass-population studies addressing program outcomes at a prevalent screen on an intention-to-screen basis in unbiased typical screening populations
4. Comprehensive evaluation of ongoing screening over multiple rounds.

## Appendix 7—Non-government organisations promoting screening and/or providing kits

### *Bowel Cancer Australia*

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- Bowel Cancer Australia (BCA) runs its own screening program, *BowelScreen Australia*®, which commenced in 2010 in collaboration with the Pharmacy Guild of Australia and is currently using the Clinical Genomics iFOBT (ColoVantageH kit). The kit can be purchased from pharmacies or the BCA website for \$39.95, including pathology services.
- The BCA website provides information about the Program, including the staged implementation and eligible ages, and directs people to the Program Information Line and the Program website. Those not currently eligible for the Program screening test are encouraged to talk to their GP or pharmacist, or buy a *BowelScreen Australia*® kit.
- BCA's website promotes biennial screening for people aged over 50 according to the NHMRC guidelines, recommending participation in the NBCSP when invited and use of the *BowelScreen Australia*® program in the intervening years.
- One of BCA's campaigns is *Never Too Young*. This campaign has as a key message that rates of bowel cancer are increasing among Australians aged 20–39, and encourages young Australians to act early on symptoms.

### *Rotary Bowelscan*

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- Rotary Bowelscan is the initiative of over 300 Rotary Clubs across Australia.
- The program runs during one month every year to raise awareness of bowel cancer and offer annual screening to people over 40 years of age, using the Clinical Genomics iFOBT (ColoVantageH kit).
- Bowelscan testing kits are distributed to local communities via pharmacies, at a cost of approximately \$30, including pathology services.
- In 2016, Bowelscan testing kits were available from 1 May to 15 June.

### *Jodi Lee Foundation*

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- The Jodi Lee Foundation (JLF) was established by Nick Lee, whose wife, Jodi, was diagnosed with terminal bowel cancer at the age of 39 and passed away two years later. The JLF aims to raise awareness of bowel cancer, promote a healthy lifestyle and encourage screening.
- The JLF encourages screening. Its website directs people to screen through the Program; purchase a ColoVantageH kit via the ColoVantage website or from a pharmacy for \$39.95, including pathology services; or visit their GP.
- Commonwealth funding of \$2.5 million over three years (2012–13 to 2014–15) was provided to the JLF to raise awareness of bowel cancer and encourage participation in the Program via a television commercial that ran in September 2014 and again in April–May 2015. No further funding has been provided to JLF.
- Through its Workplace Prevention Program the JLF works with employers to promote bowel cancer prevention to their employees and provide them with free screening tests. Employers have included the Australian Football League, ANZ Bank, Coates Hire, Hungry Jack's and many others.

### *Cabrini Health*

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- Let's Beat Bowel Cancer (LBBC) is a not-for-profit initiative of Cabrini Health to raise community awareness of bowel cancer and to support medical research into prevention, early detection and treatment.
- LBBC offers screening via the BCA *BowelScreen Australia*® program.
- LBBC has run a number of campaigns for bowel cancer screening awareness, including 'Don't be a fool, test your stool' in 2014.
- In 2015 Cabrini Health developed four videos designed to educate Australian GPs about bowel cancer screening. The Department of Health has provided a link to the videos from the Program website, because they are a useful tool to engage GPs in the Program.

### *The Gut Foundation*

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- The Gut Foundation website encourages screening for all Australians aged 40 or over and offers screening kits at a cost of \$5 to cover postage and handling.

### *Cancer Council*

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- Cancer Council Australia urges all eligible Australians to participate in the Program, and to arrange biennial screening through their doctor if they are not currently eligible.
- Cancer Council Victoria and Cancer Council South Australia offer screening using the Clinical Genomics iFOBT (ColoVantageH kit) via their websites at a cost of \$26 and \$30 respectively, including pathology services.

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