

**Final Evaluation Report of the
Bowel Screening Pilot
Screening Rounds One and Two**

Ministry of Health
Manatū Hauora

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DISCLAIMER

The data analysed for the epidemiological analysis were supplied to the Environmental Health Indicators programme, Centre for Public Health Research, Massey University by the Ministry of Health. The data sources are the Bowel Screening Pilot Register and the Waitemata District Health Board.

Litmus Limited and The Centre for Public Health Research accepts no liability or responsibility for the data or their use.

Preface

This final evaluation report has been jointly prepared for the Ministry of Health by Liz Smith, Litmus; Associate Professor Deborah Read, Mathangi Shanthakumar, and Professor Barry Borman, Massey University; and Dr Tom Love, Sapere Research Group.

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¹ Professor Potter is a member of the Litmus Governance Group and was involved in the peer review of the interim and final BSP evaluation reports from December 2012. Professor Potter became Chief Science Advisor to the Ministry of Health in January 2016, and elected to continue his role as a member of the Litmus Governance Group until the completion of this report.

1. Executive summary

The Ministry of Health funded Waitematā District Health Board (WDHB) to run a Bowel Screening Pilot (BSP) over four years from 2012 to 2015. An evaluation of the BSP was undertaken by Litmus, the Centre for Public Health Research Massey University, and Sapere Research Group. The goal of the evaluation was to determine whether organised bowel screening could be introduced in New Zealand in a way that is effective, safe and acceptable for participants, equitable and economically efficient.

This report is the final evaluation report of the BSP following the completion of the distribution of invitations for screening Rounds 1 and 2 (January 2012 – December 2015).² The report draws from a range of data and information sources and is structured to address the goal and four aims of the pilot as relevant at the completion of screening Round 2.

The New Zealand Health and Disability Multi-region Ethics Committee granted ethical approval for the suite of BSP evaluation activities (reference MEC/11/EXP/119; MEC/11/EXP/119/AM06).

Effectiveness: Is a national bowel screening programme likely to achieve the mortality reduction from bowel cancer for all population groups seen in international randomised controlled trials?

It is probable that the BSP will achieve a reduction in mortality from bowel cancer. However, the magnitude of any reduction cannot be assessed in a five-year evaluation. The full two years of the second round was not analysed due to the timing of data extraction, so the available staging information was insufficient to indicate whether there has been a shift or not towards detection of less advanced cancers as a result of the programme.

Economic efficiency: Can a national bowel screening programme be delivered in an economically efficient manner?

A national bowel cancer screening programme could be delivered in an economically efficient manner. Sapere Research Group (Sapere) modelled fourteen different screening scenarios. All were highly cost-effective both for the whole population and for Māori, and in some cases were delivering direct cost savings.

While bowel cancer screening results in significant cost savings from reduced treatment of bowel cancer, there also are significant resource requirements, particularly in the capacity to provide colonoscopy. These requirements may pose constraints on how a national programme may be delivered.

Equity: Can a national bowel screening programme be delivered in a manner that eliminates (or does not increase) current inequalities between population groups?

There are a number of challenges in delivering an equitable national bowel screening programme. Asians, Māori and Pacific people were all less likely to participate than European/Other people in both rounds. Participation in Round 2 was also lower than in Round 1. Within Round 2, participation varied depending on the screening history of the invited population, with the highest participation among those who had completed Round 1.

² Note: the epidemiological analysis is only for the first 36 months of invites with over eight months allowed for completion of the pathway.

European/Other and Asian participation decreased from Round 1, and was unchanged among Māori. Whilst participation increased for Pacific people in Round 2, it was still low (36.7%). Participation also declined with increasing deprivation in both rounds.

The BSP has demonstrated that, without appropriate systematic and structural approaches together with focused governance and leadership, inequities in bowel cancer outcomes will increase for Māori and Pacific people, and those living in areas of high deprivation.

A national bowel screening programme must lead with an equity focus to avoid increasing existing inequities in bowel cancer outcomes. A national programme needs clearly articulated policies, processes, monitoring and leadership to ensure equity of participation in bowel screening and long-term equity in bowel cancer outcomes. Leading with an equity focus will ensure the programme's design supports and engages those groups known to be least likely to take part and who have a higher risk of cancer.

Safety and acceptability: Can a national bowel screening programme be delivered in a manner that is safe and acceptable?

Safety is defined as the extent to which harm is kept to a minimum, and incorporates multi-dimensional perspectives such as cultural, environmental, and clinical safety (National Screening Unit 2005 p.15). Within the scope of the evaluation, no substantial environmental or clinical safety issues were identified. In Round 2, greater focus has been placed on cultural safety with a more systematic and structural focus on seeking to achieve equity of participation for Māori and Pacific people. However, much more work is needed to address ongoing inequities of access for eligible Māori and Pacific people in the BSP. If the learnings from the BSP are adopted, in particular leading with an equity focus, a national bowel screening programme can be delivered in a manner that is safe.

The evaluation of the BSP has demonstrated that bowel screening can be delivered in a way that is acceptable to most eligible participants provided a systematic focus is applied to addressing barriers to participation for Māori and Pacific people. Acceptability of the BSP and a national screening programme continues to be high amongst national and regional stakeholders, and providers along the screening pathway.

The overall goal is to determine whether organised bowel screening could be introduced in New Zealand in a way that is effective, safe and acceptable for participants; equitable and economically efficient.

The BSP has demonstrated that by maintaining fidelity to and drawing on the learnings from the pilot, an organised quality bowel screening programme could be safely introduced into New Zealand. Sapere's simulations indicate that bowel screening is cost effective and will save lives.

Under most implementation scenarios, bowel screening is cost saving in absolute terms, while bringing health benefits. This result is driven by the savings from avoided costs of treating cancer being large enough to outweigh the costs of screening. This makes bowel screening an exceptionally cost-effective health intervention, given that it both reduces health costs and produces benefits for the population. Bowel screening is a highly cost-effective intervention for Māori, as well as for the New Zealand population overall.

To have a safe, equitable and acceptable bowel screening programme requires the national programme to be equity-led to ensure acceptance and safety for Māori, Pacific and those living in areas of high deprivation. To be safe, a national bowel screening programme requires the involvement of the National Screening Unit, the quality standards to be

finalised and, if used in a national roll-out, a review of the Register's operational functionality. Resolution on the location and funding of the endoscopy governance group is also needed. The impact of a national screening programme on the colonoscopy and histopathology workforces needs to be managed to retain equity between symptomatic and screening services, and ensure surveillance colonoscopies are timely and align with guidelines (New Zealand Guidelines Group 2004).

2. Introduction

2.1 Background to BSP

Bowel cancer in New Zealand

Bowel cancer is a major health issue for New Zealand. As noted by National Bowel Cancer Tumour Standards Working Group (2013) New Zealand has one of the highest bowel cancer rates in the world. In 2012, bowel cancer was the second most common cancer in both men and women and the second highest cause of cancer death for men and women (after lung cancer) (Ministry of Health 2015). For Māori men, bowel cancer is the second most common cause of death from cancer, and it is third for Māori women (Ministry of Health 2015). New Zealand has one of the highest death rates from this cancer in the developed world. In 2012, there were 3,016 new cases and 1,283 deaths (Ministry of Health 2015).

Bowel cancer incidence increases with age – 90% of cases occur in those over 50 years (New Zealand Guidelines Group 2004). The number of new cases of bowel cancer each year is projected to increase by 15% for men and 19% for women to 3,302 by 2016 (National Bowel Cancer Tumour Standards Working Group 2013). Concurrently, age-standardised registration and mortality rates for bowel cancer are declining. Among Māori bowel cancer diagnoses, rates are increasing. The fastest rate of increase is among Māori males (National Bowel Cancer Tumour Standards Working Group 2013).

Estimates of the cost of bowel cancer

On the basis of analysis completed by the Ministry of Health (2011c) (using 2008 incidence data and 2008/09 national prices), the annual public price of registered cancer in 2008 was estimated at \$511 million. Cancers of the colo-rectum and anus made up some 14% of this total, at an estimated annual public price to New Zealand of \$70 million, second only to female breast cancer at 15%. The full cost of treating cancer is likely to be higher than estimated by the Ministry of Health, with an analysis from the Department of Public Health, University of Otago Wellington of \$130 million annually. (Blakely et al 2015, using 2010-2011 incidence and 2011 prices). This is double the estimate from the Ministry of Health.

Further, population growth and structural ageing are dominant forces driving change in cancer registration counts, sometimes overwhelming the effect of changes in cancer risk (Ministry of Health 2002). The Ministry of Health analysis (2011c) incorporated incidence projections from 2011 to 2021, leading to an estimated 23% increase in the total price of cancer to \$627 million by 2021. This increase incorporated a significant growth in price relating to colorectal cancer at \$13 million. This projection assumes the price of cancer per person remains the same; the price will be even higher if newer and more expensive therapies are funded.

The BSP

The Ministry of Health funded Waitematā District Health Board (WDHB) to run a Bowel Screening Pilot programme (BSP) over four years from 2012 to 2015. The BSP began with a 'soft launch' in late 2011, with full operation of the pilot starting in January 2012. Litmus

Limited, the Centre for Public Health Research Massey University and Sapere Research Group have been funded by the Ministry of Health to undertake an evaluation of the BSP, including a cost-effectiveness analysis. The evaluation will contribute to a decision on whether or not to roll out a national bowel screening programme.

The overall goal and underlying objectives of the BSP and its evaluation are the same and have been defined by the Ministry of Health. The overall goal of both is to determine:

Whether organised bowel screening could be introduced in New Zealand in a way that is effective, safe and acceptable for participants; equitable and economically efficient.

The goal comprises four key aims.

1. *Effectiveness*: Is a national bowel screening programme likely to achieve the mortality reduction from bowel cancer for all population groups seen in international randomised controlled trials?
2. *Safety and acceptability*: Can a national bowel screening programme be delivered in a manner that is safe and acceptable?
3. *Equity*: Can a national bowel screening programme be delivered in a manner that eliminates (or does not increase) current inequalities between population groups?
4. *Economic efficiency*: Can a national bowel screening programme be delivered in an economically efficient manner?

Ministry of Health specified ten key objectives of the BSP and its evaluation:

1. *Programme design* – To pilot the use of a population Register closely linked with primary health care services to invite the target population, along with a Coordination Centre and associated information system to manage the screening pathway.
2. *Screening effectiveness* – To assess the early indicators of the effectiveness of bowel screening, including the number and stage of cancers detected, the number and size of adenomas detected, and colonoscopy completion rates.
3. *iFOBT experience* – To assess the performance and acceptability of the chosen iFOBT in the New Zealand context including the positivity rates in New Zealand, positive predictive values for adenomas and cancers, technical repeat rates and false positive rates.
4. *Participation and coverage* – To determine the level of participation and coverage for the eligible and invited populations, including sub-populations (defined by sex, age, ethnicity, socio-economic status and rural representation).
5. *Quality* – To pilot the agreed quality standards and monitoring requirements along the screening pathway and assess the implications for a national programme; in particular to pilot the acceptability and safety of the standards and screening to providers and for different population groups.
6. *Service delivery and workforce capacity* – To monitor the effect, including resource implications of screening activities, on primary care, community health services, laboratory, and secondary and tertiary services and the implications of this for a national programme.
7. *Fair access for all New Zealanders* – To determine whether a bowel screening programme can be delivered in a way that provides fair access for all New Zealanders. In particular, to evaluate the process of adopting a focus in leadership, decision-making processes and implementation of the pilot to provide fair access to all eligible people.

8. *Cost effectiveness* – To determine the costs of all services along the screening pathway to determine the cost effectiveness of a bowel screening programme. To compare this, where possible, with other preventative programmes in New Zealand and bowel screening trials internationally.
9. *Acceptability to the target population* – To pilot provision of information and support to the target population to facilitate informed participation and evaluate the knowledge, attitudes and satisfaction of groups of participants (defined by sex, age, ethnicity, socio-economic status and geographical residence) in the screening pilot, including identifying factors associated with non-participation.
10. *Acceptability to providers* – To evaluate the knowledge, attitudes and acceptability to health professionals and health care providers based in community, primary care and hospital settings.

The interim report (Litmus et al 2015) was structured to address each of these objectives as relevant at the completion of distribution of invitations for screening Round 1 (1 January 2012 – 31 December 2013). Appendix one contains the updated evaluation judgements against six of the evaluation objectives at the end of Round 2.³ To avoid repetition with the interim report, the final evaluation report is structured around the four aims of the pilot. The report concludes by addressing the pilot's goal, and makes recommendations on a national bowel screening programme.

2.2 Uncommon elements of bowel cancer screening

Bowel cancer screening has several specific features that differentiate it from other cancers. Screening for bowel cancer usually involves, either as the first step or as the definitive diagnostic step, direct visualisation of the organ – unlike breast where the organ is imaged. That means, in many cases, definitive diagnosis (cancerous/precancerous lesion or not) and treatment (removal of some precancerous lesions) can be accomplished with the same procedure – again unlike breast.

For a programme that begins, as in New Zealand, not with colonoscopy but with immunochemical faecal occult blood test (iFOBT), there are additional uncommon elements. First, the sample can be collected at home. Second, iFOBT is probably the lowest cost initial screening test for cancer.

Screening for breast and cervix cancers detect and require the treatment of malignant lesions that must then be removed surgically. Some of these cancers would never present clinically, nor cause morbidity and mortality (this is sometimes called 'overdiagnosis'). Thus, screening for each of these two cancers is associated with a rise in incidence, even as there is an accompanying fall in mortality. In contrast, screening for bowel cancer encompasses the removal of some premalignant lesions, some of which would never present as cancers. For bowel cancer therefore, over time both incidence and mortality decline with screening.

³ The evaluation objectives relating to *screening effectiveness, iFOBT experience, participation and coverage and cost effectiveness* have not been updated as these relate to the updated findings of the epidemiological analysis (section 3), costing analysis and cost utility analysis (section 4) presented in this report.

2.3 Description of the BSP

Identification

All men and women aged 50 to 74 who lived in the WDHB area and who were eligible for publicly funded health care were eligible to participate in the BSP. Most people in the eligible population were to be invited to participate in two screening rounds within the four-year BSP period.

Those not eligible to participate in the BSP were people who had a colonoscopy within the last five years, were on a bowel polyp or bowel cancer surveillance programme, have had or were currently being treated for bowel cancer, have had their large bowel removed, were being treated for ulcerative colitis or Crohn's disease, or were awaiting bowel investigations by their doctor (WDHB 2012).

Participation in the BSP was by invitation only. The Coordination Centre invited eligible people to participate in the BSP according to their birth date. In 2012 and 2014, invitations were sent to people with even numbered birth dates. In 2013 and 2015, invitations were sent to people with odd numbered birth dates. People who 'aged in' or moved into the area in 2014 and 2015 were invited in the month following their birth date. There were no referrals into the pilot by a health professional. However, eligible people not on the BSP Register could contact the Coordination Centre to be included or their general practice could request their inclusion.

Identification of the eligible population was undertaken using a purpose-built information system – the BSP Population Register (the Register). Participant details on the Register were taken from the National Health Index (NHI) and individuals who self-registered.

Pre-invitation

In the first screening round, initial contact with the eligible population was through a pre-invitation letter sent by the Coordination Centre four weeks before the invitation.⁴ In the second screening round, pre-invitation letters were only received by eligible people who had never been invited to participate. Pre-invitation letters were being used in the BSP because they have been shown to increase participation in bowel screening internationally (Cole et al 2007). The pre-invitation letter:

- advised people about the BSP and that they were eligible to participate
- included a generic endorsement by prospective participants' General Practitioner (GP)
- advised people that they would receive an invitation and an iFOBT kit from the BSP unless they notified the Coordination Centre they did not wish to participate
- included a detailed booklet to assist people to make an informed decision about participating in the BSP
- advised people who should not participate in the BSP to contact the Coordination Centre.

Pre-invitation letters were sent out to approximately 6,000 eligible participants per month. Some of the incorrectly addressed letters were returned to the Coordination Centre. Action

⁴ In 2014, following feedback from WDHB's Kaitiaki Roopu, the pre-invitation letters were sent two weeks before the invitation.

was taken to identify correct addresses. People could opt out of the BSP at this stage by advising the Coordination Centre and their decision was recorded on the Register.

Invitation

Four weeks after the pre-invitation letter, the Coordination Centre sent an invitation letter to eligible people who had not opted out. The invitation letter was accompanied by:

- a leaflet to assist people to make an informed decision about participating in screening
- an immunochemical faecal occult blood test (iFOBT)⁵
- a consent form
- a Freepost envelope to send their sample to LabPLUS.

Eligible Māori and Pacific people may have received an invitation via attending a community education session or hui and expressing an interest to take part in the BSP. Health promoters notified the Coordination Centre and an invitation letter and iFOBT kit was sent out. It was not known how many Māori and Pacific people received an invitation via attending health promotion activities facilitated by the community awareness raising (CAR) coordinators.

Participation

Participants in the BSP took a single sample at home, using the iFOBT kit. Participants posted the sample to LabPLUS for testing, using the Freepost envelope provided. A completed consent form had to be included with the sample.

If a sample was not received by LabPLUS within four weeks and the person had not opted out of the BSP, a reminder letter was sent from the Coordination Centre to encourage completion. After four weeks, CAR personnel followed up by phone or face-to-face with Māori, Pacific and Asian people who had not responded.

iFOBT test results

LabPLUS tested iFOBT samples and sent positive and negative results to the BSP Register and participants' GPs within three working days of sample receipt. Results were sent electronically, via HL-7 messaging on Healthlink. Results were not sent to participants' GPs if they had indicated this option on their consent form, or where the participant did not have an identified GP.

For a positive iFOBT result, the relevant general practice had to contact their participant within ten working days of receiving a positive result from LabPLUS. The general practice informed their participant of the result, discussed the implications of the result, provided counselling and advice and referred their participant to the Waitakere Hospital Endoscopy Unit (WHEU) for a screening colonoscopy.

Participants with a positive result who did not have an identified GP or who had not been contacted by their general practice within the ten-day period were contacted by the BSP Endoscopy Clinical Nurse Specialist (CNS) within 15 working days of a positive result. If

⁵ A single sample iFOBT, also referred to internationally as a Faecal Immunochemical Test, made by Eiken Chemical Co. Ltd, Tokyo is being used in the BSP. The test is known as OC-Sensor. The sensitivity cut-off for test positivity is 75 ng HB/mL.

WHEU was unable to contact a participant with a positive iFOBT, the CNS sent the participant and their GP a letter, outlining the positive result and encouraging the participant to contact their general practice or the BSP Coordination Centre. If no contact was made, the participant was placed on two-year recall and remains on the BSP Register. A participant with a positive iFOBT could have a colonoscopy at any time in the future.

For a negative iFOBT result, participants were notified in writing by the BSP Coordination Centre within 15 working days of the result being received on the BSP Register. They were advised they would be recalled to screening in two years, if still eligible. GPs were sent negative results but were not required to do anything.

If the sample was spoilt⁶ or documentation was incomplete, the laboratory informed the BSP Coordination Centre and spoilt kit follow-up was triggered. Māori, Pacific and Asian people were followed up with a phone call (if a number was available) or letter the first time they returned a spoilt kit. Other populations received a second test kit and a letter explaining their error, and if they returned a second spoilt kit they were followed up with a phone call.

Diagnostic testing: pre-assessment

All participants with positive iFOBT results were referred for a colonoscopy pre-assessment. The pre-assessment provided an opportunity to assess the participant's fitness for the procedure as well as giving the participant full information about colonoscopy. Pre-assessments included assessment of a participant's medical conditions, bowel condition, discussion of the bowel preparation process, and checking for cultural, mobility or transport problems. If an interpreter was needed, this was noted on the pre-assessment form and the BSP administrator organised an interpreter for the day of the procedure.

Pre-assessments were conducted over the phone by a CNS or endoscopy nurse. If the CNS determined a participant's clinical condition required further investigation, the participant would receive a pre-assessment outpatient consultation. The CNS would arrange this with the participant and the Lead Endoscopist.

If a participant declined a colonoscopy after a positive iFOBT, the participant (and their GP) would receive a letter to confirm this decision, and was informed that they may contact the BSP or their GP at any time in the future if they wished to have the procedure. Otherwise they would be re-invited to participate in the pilot in two years.

Participants deemed fit for colonoscopy were offered an appointment for the procedure during the pre-assessment. Colonoscopy had to be completed within 55 working days of the positive iFOBT result. Participants not deemed fit for colonoscopy (and those who had a failed colonoscopy) were referred for an alternative diagnostic investigation, Computerised Tomographic Colonography (CTC) or to have a colonoscopy under general anaesthetic.

Participants assessed as high risk for colonoscopy (e.g. on Warfarin medication) required certain precautions to be taken to minimise risk during the procedure. Participants could also be deemed high risk due to a significant co-morbidity. In this situation, the WHEU coordinated a multi-disciplinary discussion and facilitated a decision on appropriate management, and kept the participant's GP involved in this process.

⁶ Spoilt kit refers to iFOBT kits where the test was not performed or labelled correctly. Most spoilt kits were due to date and label issues.

Participants assessed as fit and who consented to colonoscopy were sent an appointment letter which contained:

- written confirmation of their positive result⁷
- appointment date and time
- information about bowel preparation and instructions
- information about the procedure
- details of culturally appropriate support available, if required
- information on links to local support services.

Diagnostic testing: colonoscopy

BSP colonoscopies were undertaken at the WHEU.⁸ The procedure was as follows:

- BSP participants arrived at the hospital and were admitted as a day case.
- An endoscopy nurse went through the pre-procedure checklist with the participant.
- The endoscopist met with the participant to get their consent for the procedure.
- The participant's nurse, who would be in the endoscopy room during the procedure, introduced themselves, checked the participant's identity and brought them into the endoscopy room.
- The colonoscopy was conducted under 'conscious sedation'; usually there were two nurses and an endoscopist in the room.
- The participant was taken to recovery where they were kept under observation for a period.
- The endoscopist usually met with the participant at this time to discuss the outcome of the colonoscopy; the endoscopist would always meet with a participant if the outcome was abnormal.
- The participant's nurse reiterated the outcome and talked with the participant about post-procedure risks and what they needed to do in the immediate post-procedure period.
- As sedation was given, the participant was taken home by their responsible adult who remained with the participant for the rest of the day.

Both gastroenterologists and surgeons undertook colonoscopies in the BSP.

Participants with normal colonoscopies were advised they did not need to undergo another iFOBT screening episode for five years and were placed on a five-year recall on the Register. Their GP was informed of this.

Most participants with a family history of bowel cancer were referred to the New Zealand Familial Gastrointestinal Cancer Registry, a service that offers assessment, diagnosis and surveillance of inherited gastrointestinal cancer syndromes.

⁷ In the early implementation stages of the BSP, participants with a positive iFOBT received a separate letter informing them about their positive result. This letter has now been merged with the colonoscopy appointment letter.

⁸ A further seven to eight percent, depending on round, of participants with a positive iFOBT result had their colonoscopy carried out in private health care.

Diagnostic testing: histopathology

LabPLUS was required to provide histopathology results within ten working days. LabPLUS reported histopathology results directly into Concerto (the WDHB patient record system) using a standardised BSP reporting template.

From 2013, the CNS has reviewed the colonoscopy reports and the histopathology results and advised the BSP administrator of the correct letters to send out to participants, their GP, and WDHB notes. The CNS prepared a spreadsheet of actions taken which was reviewed by the WDHB BSP Clinical Director or WDHB BSP Lead Endoscopist. Where there was any concern or uncertainty, the CNS discussed the results with the BSP Clinical Director or Lead Endoscopist. A formal policy was developed (*Histology Results Management*) which set out parameters within which the CNS makes decisions.

Diagnostic testing: alternative investigation

BSP participants assessed as unfit for colonoscopy or with an incomplete colonoscopy were offered a CTC investigation. Occasionally when a colonoscopy failed, the person would proceed to have a colonoscopy under general anaesthetic.

Participants were referred to the Radiology Department by the Endoscopy CNS. Referral was via WDHB's usual referral system. The CTC policy agreed between the BSP and Radiology states that when a BSP colonoscopy fails in the morning, the person will have a CTC that afternoon, and when it fails in the afternoon the person will have one the following morning. The exception to this was when the colonoscopy failed on Friday afternoon. Ensuring same or next day referral to CTC meant the BSP participant did not have to go through bowel preparation twice.

Participants with an incomplete colonoscopy in which a polypectomy was performed were referred to have a CTC between 30 and 50 days later.

Referrals to CTC for BSP participants unfit for colonoscopy were given a unique BSP code by the Radiology Department. This code flagged that the participant must be given a different level of priority to meet the BSP requirement that a date for a CTC must be given within five days and the procedure completed within 20 days.

Results were sent back to the referring clinician (usually the WDHB BSP Clinical Director) using the hospital's usual results system.

Surveillance

Participants requiring ongoing surveillance were exited from the BSP, referred to a surveillance programme, and not recalled for subsequent screening.

WDHB Endoscopy Service was responsible for ensuring participants received their surveillance colonoscopy within the recommended timeframe (according to guidelines in *Surveillance and Management of Groups at Increased Risk of Colorectal Cancer*, Ministry of Health 2004). The BSP WHEU advised participants they had been referred for surveillance and notified participants' GPs. The BSP WHEU recorded surveillance requirements on the BSP Register⁹ and removed the participant from the screening

⁹ The Register has a field for surveillance but not for the recommended surveillance period.

pathway. The BSP WHEU also logged the referral for surveillance in Intelligent Patient Information Systems (iPIMS) where the surveillance period was captured.

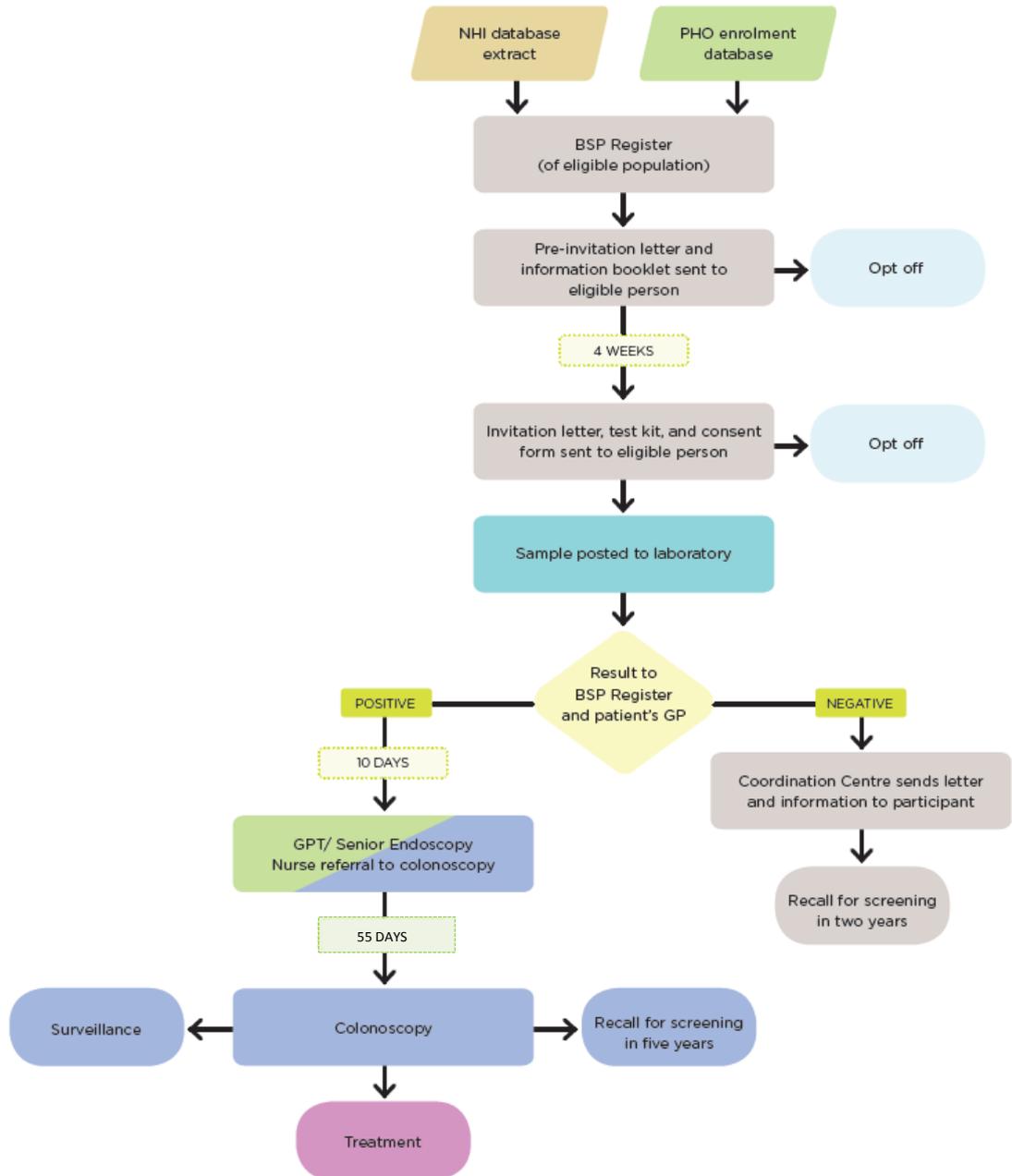
Treatment

Participants diagnosed with cancer or high risk polyps were referred to a colorectal multi-disciplinary meeting (MDM) by the WDHB BSP Clinical Director/WDHB BSP Lead Endoscopist. Referrals were made using a standardised regional bowel cancer MDM form. BSP MDMs were held every two weeks at North Shore Hospital and included representation from medical oncology, pathology, radiation oncology, diagnostic radiology, surgery and nursing. MDMs provided recommendations for culturally appropriate and coordinated care, advice and support. Outcomes of MDMs were communicated to the participant and their GP, and were documented in the medical records.

All participants who required chemotherapy and/or radiation therapy were managed by the Auckland Regional Cancer and Blood Service at Auckland District Health Board. Auckland District Health Board was the regional provider of oncology services for the WDHB population.

Participants diagnosed with cancer were not recalled for screening.

Figure 1: Overview of screening pathway (WDHB 2012)



2.4 Changes in Round 2

The interim BSP evaluation report on screening Round 1 (Litmus et al 2015) highlighted that the BSP, as it was then being delivered, was increasing inequities for Māori and those people living in the most deprived areas due to their low participation and high disease burden. Pacific people had the lowest participation rates and face inequities relating to access; however their disease burden is lower. Screening Round 2 of the pilot was used to trial new initiatives to increase participation by Māori and Pacific people. All initiatives implemented to increase Māori and Pacific participation are described below.

Established initiatives to increase Māori and Pacific participation

The BSP Coordination Centre undertook a range of activities to support Māori and Pacific peoples and others participation in the BSP, namely:

- Since 2013, WDHB's Kaitiaki Roopu provided a Treaty of Waitangi based partnership and participation oversight to the BSP. Kaitiaki Roopu also provided guidance, support, advice and links into the Māori community serviced by WDHB to ensure Māori make informed decisions about the BSP.
- Active follow-up (refer below as this initiative was strengthened in Round 2)
- CAR activities included:
 - Community engagement activities by Māori CAR coordinators with Māori organisations and Māori stakeholder groups such as kaumātua and kuia groups affiliated to Māori health providers.
 - Community engagement activities by Pacific CAR coordinators including presentations in community settings, churches and workplace settings where businesses employed significant numbers of Pacific people.
 - Education sessions by West Fono health promoters conducted in Samoan, Tongan, Niuean, Fijian, Cook Island Māori and Tuvaluan. The sessions focused on the iFOBT, including a demonstration of how to do the test, and key messages about bowel cancer and bowel screening.
- Media targeting the eligible population and their influencers via a monthly advertorial alternating with a poster in the five community newspapers. Advertisements/posters/articles were also published in the Rodney Times, the Village Voice (Wellsford), Maharangi Matters, Hibiscus Matters, Good Neighbour (North Shore and Waitakere). Radio stations targeting Māori and Pacific people also advertised the BSP via regular interviews with Māori and Pacific CAR coordinators.

In 2013, the BSP Coordination Centre revised the pre-invitation letter, kit instructions and consent form to be more accessible to a wider range of literacy levels. These revised documents were introduced in January 2014 (Round 2). The time between getting the pre-invite letter and the iFOBT kit was reduced in January 2014 from four to two weeks, following advice from Māori and Pacific advisors.

New or strengthened initiatives to increase Māori and Pacific participation

In Round 2, the BSP Coordination Centre worked with Kaitiaki Roopu, Māori clinical leaders and Pacific advisors to develop four initiatives to enhance the systems, processes and structures of the BSP. The goal was to increase Māori and Pacific participation in the BSP.

The new initiatives were enabled via enhanced Māori and Pacific partnership and leadership through:

- Representatives from two Pacific providers giving advice to the BSP Coordination Centre via the CAR group. The DHB's Manager, Pacific Health also attended CAR meetings from time to time and was available for ad hoc advice.
- Te Whānau o Waipareira Trust was contracted in August 2015 for two kuia to manage the follow-up calls for four East Tamaki Health Care practices.
- Te Hā o Ngāti Whātua's (Māori health provider) have two BSP funded bowel screening coordinators in Helensville and Wellsford who each work for the pilot two days a week following up all Māori non-responders¹⁰ who live in these areas. Te Hā has worked with the Coast to Coast general practice to support them to encourage participation of their enrolled patients. They have also promoted the programme through community health events.

The four initiatives are described below.

Active follow-up (strengthening initiative)

Since the pilot began, BSP Coordination Centre's CAR coordinators have actively followed up Māori, Pacific and Asian non-responders four weeks after receiving their kit. The purpose of active follow-up is to encourage and enable people to complete their test kit.

CAR coordinators received a list of Māori, Pacific and Asian non-responders and called the person during the day, and then again in the evening if they could not make contact during the day. CAR coordinators talked to non-responders about the BSP and the test kit, and sought to address any concerns. The success of the active follow-up phone calls was constrained by whether a phone number could be identified via the WDHB patient management systems as the BSP Register does not have all phone numbers. CAR coordinators may follow-up with a home visit, if requested.

In 2014, the BSP Coordination Centre's active follow-up process was strengthened by:

- undertaking a minimum of three phone calls within a month of referral to the active follow-up database; at least one of the calls made out of office hours
- reviewing and refining the follow-up call scripts by Workbase (health literacy experts)
- training CAR coordinators in using the revised script as a guideline for their engagement with non-responders. Workbase undertook this training
- increasing the number of people trained to undertake active follow-up calls and using temporary call centre staff to undertake calls. Note: Workforce capacity can be a key limiting factor to complete active follow-up in the 1-month timeframe; for example if staff are ill or on leave.
- monitoring the active follow-up pathway to track work completed (i.e. number of calls per person) and outcomes achieved (i.e. intent to complete kit and whether completed or not)
- referring non-contactable people after three attempts to primary care follow-up (refer DRINFO below)

¹⁰ Non-responders are people who have received a pre-invitation, invitation and reminder letter, have not returned a completed kit, and have not contacted the Coordination Centre to opt out of the BSP.

- developing three key performance indicators (KPIs) to report to WDHB Steering Group and the Ministry on the outputs and outcomes of active follow-up.

Two primary-care initiatives

Until early 2015, promotion of the BSP by general practice was opportunistic. Primary-care practices were unaware of the non-responders in their practice because there was no system to inform general practices of who had received an iFOBT kit and not returned it. In early 2015, two new initiatives were developed and introduced to enable general practices to systematically remind non-responders in their practice to complete and return their kit, and to support opportunistic follow-up of bowel screening.

DRINFO¹¹

The BSP Coordination Centre worked with DRINFO to enable practices to identify, on a quarterly basis, eligible BSP participants in their practice who had received and not completed their bowel screening kit. The intent was to enable practices to send out bulk text reminders via DRINFO SMS or reminder letters on their letterhead to BSP non-responders. Some practices also telephone their patients to encourage participation. The first upload of data to DRINFO occurred at the beginning of July 2015. Quarterly uploads have occurred since then. The BSP Coordination Centre covers the cost of the SMS and postage.

Patient Dashboard

MedTech's Patient Dashboard is a form that displays within MedTech every time a new patient record is opened and shows all key clinical information relevant to routine management of the patient.

The new version of Patient Dashboard prompts general practice to discuss bowel screening with patients when there is no evidence of participation on the clinical record. Dashboard includes the ability to generate a pre-populated form to fax to the BSP Coordination Centre requesting a new kit be sent to their patient. The form can also be given to the patient and the patient can call the BSP Coordination Centre to request a kit.

A staggered roll-out of the new version of Patient Dashboard occurred. Waitemata Primary Health Organisation (PHO) completed the implementation of the new version of Dashboard by October 2014; Auckland PHO by November 2014,¹² ProCare by January 2015, and the National Hauora Coalition by March 2015. The Dashboard initiative was therefore in place across most general practices whose patients are eligible to take part in the BSP by January 2015.

ProCare modified the system by removing the capacity to print fax requests and providing practices with the BSP 0800 number to give to patients to call for a new kit kit. BSP Coordination Centre has no mechanism to record the number of people who phone for a kit as a result of a Dashboard prompted conversation in a ProCare general practice.

¹¹ DRINFO is an audit tool which queries practice data and identifies patients who are 'falling through the gaps' where there is a clinical impact. It helps the practice team by presenting a list of patient names for action, without having to search for them. Examples include patients who are overdue for screening procedures, patients who could be enrolled in funded programmes, patients falling outside guidelines for clinical management, or those whose capitation-based funding is about to expire. In New Zealand, DRINFO is compatible with Medtec32 and My Practice PMS.

¹² Some eligible BSP participants who live in the WDHB area attend a general practice outside of the area.

Non-postal return of completed kit

Research indicated that some Māori and Pacific non-responders dislike posting their completed iFOBT kit due to cultural norms (Litmus 2013). Kaitiaki Roopu and Pacific advisors also noted that posting a faecal sample can be culturally unacceptable. The BSP Coordination Centre sought to identify whether Māori and Pacific participation in the BSP would increase if they offered the option of returning their completed iFOBT kits via a non-postal route.

The BSP Coordination Centre in consultation with LabPLUS and PHOs explored a number of drop-off options. Dropping off completed kits at a community laboratory centre was deemed the best option as it is familiar to participants, maintains the integrity of the sample and ensures the delivery of the sample to LabPLUS.

Between 1 May and 30 September 2015, all eligible BSP participants received a letter with their iFOBT kit informing them of the two options of posting their sample back or dropping off at a collection centre. With statistical analytical support, the BSP Coordination Centre are undertaking an assessment of the changes in participation.

Other changes in Round 2

Workforce changes

The BSP workforce has remained relatively constant in Round 2. Some noted changes include:

- The quality manager resigned in April 2015. The quality monitoring systems for the BSP were set up in Round 1. The focus in Round 2 was on monitoring and audit. The new quality manager started in January 2016; Round 3.
- The BSP Coordination Centre introduced a student panel to develop a flexible workforce to assist with the many manual activities related with the Register.
- Pacific CAR increased from 0.6 FTE to 1.1 FTE, split between two people.
- Two Māori health providers were contracted to support CAR activities and active follow-up of non-responders four weeks after receiving their iFOBT kit.

BSP Register

In Round 2, a number of changes were made to the Register and the staff and processes supporting it. Following the submission of the interim evaluation report (Litmus et al 2015), the Ministry undertook two targeted reviews of the BSP Register to assess data quality and completeness of the eligible population listed in the Register (Karalic 2014, Lee 2014). The Register is discussed in section 6.

Histopathology

In Round 2, the number of pathologists involved in the BSP increased from two to five. Pathologists are joining MDMs via video conference which is more time efficient.

Quality monitoring

Quality indicators are reviewed in every third WDHB Steering Group meeting. The Clinical Governance and Quality Review Groups have therefore been disbanded. The Endoscopy Review group meets monthly (previously fortnightly) to review all issues relating to the endoscopy services, including the readmissions, incidents and clinical performance data.

2.5 Evaluation methodology

This report is the final evaluation report of the BSP following the completion of the distribution of invitations for screening Rounds 1 and 2 (January 2012 – December 2015).¹³ The report draws from a range of data and information sources to address the goal and four aims of the pilot.¹⁴

The following reports and data sources inform the final evaluation report.¹⁵

BSP epidemiology analysis – the Centre for Public Health Research (CPHR) (Read et al 2016)

The scope of the epidemiological analysis was approved by the Ministry of Health (Read et al 2015). It was based on the evaluation of the English bowel cancer screening pilot (Weller et al 2006). The data were extracted by the Ministry of Health from the BSP Register.

The results represent the first (or prevalence) screening round and the first 12 months of the second round. The first screening round began on 1 January 2012 and was completed on 31 December 2013. The second screening round began on 1 January 2014 and was completed on 31 December 2015. The full second screening round could not be analysed due to the timing of data extraction¹⁶ and the need to allow sufficient time to pass for those people who were invited to complete the full screening pathway. Restricting the analysis to the first year of Round 2 allowed participants invited at the end of that year over eight months to complete the pathway. The first round interim analysis found 88% of participants completed the process in about six months (Read et al 2014).

The timing of data extraction before the completion of Round 2 meant that the sensitivity of the iFOBT could not reliably be calculated, so this has been excluded from the analysis.

Logistic regression has been used to investigate associations between demographic variables and screening outcomes. The results are given in the Appendix of the full epidemiology report as odds ratios, both unadjusted and adjusted for all other demographic variables, with 95% confidence intervals.

Key findings are presented and only counts and percentages together with the adjusted odds ratios are discussed. Adjusted odds ratios allow for the effects of all demographic variables other than the one under consideration to be assessed. For example, when considering participation by age group, the results have been adjusted to take account of the potential confounding effects of sex, ethnicity and deprivation (NZDep 2013).

Chi-square statistics were calculated to test for any statistically significant differences between and within the Rounds.

¹³ Note: the epidemiological analysis is only for the first 36 months of invites with over eight months allowed for completion of the pathway.

¹⁴ The Evaluation Plan for the Bowel Screening Pilot 2011–2016 (Litmus, 2011) details evaluation activities undertaken between 2012 and 2014.

¹⁵ Full details of the research methods used and their limitations can be found in each report. Section 2.6 provides a synthesis of evaluation limitations to consider when reviewing the findings.

¹⁶ Data were extracted from the BSP Register in September 2015.

Unless otherwise stated, the results discussed are statistically significant;¹⁷ in this context, differences labelled 'slightly less' or 'slightly more' are statistically different but the adjusted odds ratio is either greater than 0.7 times or less than 1.5 times as much as the reference group, respectively.

Results for the two rounds are presented separately.

Results in the second round are compared with the first round. Where relevant, results for both rounds are also compared with those reported in the pilot population-based screening programme in England¹⁸ (Alexander and Weller 2003; Weller et al 2006, 2007), the European guidelines for quality assurance in colorectal cancer screening and diagnosis (European guidelines) (Seagan et al 2010) and the UK Quality assurance guidelines for colonoscopy (UK guidelines) (Chilton and Rutter 2011).

Appendix 2 contains the full epidemiology report including methodology, analysis, and the possible pathway process of a participant in the BSP.

Costing analysis – Sapere Research Group 2016

For details of the methodology, including definitions of key terms, assumptions and the modelling approach, see Appendix 3 (which provides a full copy of Sapere's costing analysis report). In broad terms, two primary costing approaches are applied:

- Assessment of the cost of the pilot is based on a detailed bottom-up costing model of the screening pathway that determines unit costs for all key programme inputs and applies actual volumes of activity undertaken.
- Estimates of costs associated with treatment of bowel cancers detected as a result of the pilot are based on estimates of average New Zealand lifetime costs of treating bowel cancer diagnosed at different stages.

Primary data sources are:

- Cost data: two detailed six-month samples of actual cost data from the pilot; and cost data from the Ministry of Health.
- Volumes data: information reported by the BSP to the Ministry of Health on a bi-annual basis, identifying activity volumes for key parameters for the full two-year screening round; and data from the Ministry of Health's published BSP monitoring indicators for the period to December 2013.

Appendix 3 contains the complete costing analysis report and provides the results obtained for key input parameters and tables of the variable and fixed cost components of the screening pathway model.

The results present:

- an analysis of the nature and quantum of costs associated with the design, implementation and operation of the pilot to date;
- a forecast of estimated total cost of the BSP for two full screening rounds; and

¹⁷ The result is deemed to be statistically significant if the 95% confidence interval of the odds ratio does not include 1.

¹⁸ The UK bowel screening programme uses the guaiac faecal occult blood test rather than the iFOBT.

- an extrapolation of high-level estimates of the potential ‘steady state’ cost of operating a bowel screening programme on a national basis (excluding development/start-up costs and on the basis of some broad-brush assumptions). This is also presented from a regional perspective.

It is important to emphasise that this costing analysis is not an incremental analysis, but rather takes a ‘snapshot’ perspective of costs incurred to design and run the pilot, with some extrapolation to inform understanding of potential future costs. As such, it does not account, for example, for the fact that some cancers detected as a result of pilot screening, may have been detected symptomatically anyway.

Further, in extrapolating high-level estimates for the operating cost of bowel screening on a national basis, in the absence of key policy decisions about the configuration and implementation approach, we have based our analysis on some broad-brush assumptions about the way a national bowel screening programme may run in ‘steady state’.

Bowel Cancer Screening in New Zealand: A cost-utility analysis based on the findings of the pilot – Sapere Research Group 2016

The cost-utility analysis estimates the cost-effectiveness of bowel cancer screening in New Zealand, with a number of the assumptions informed by the experience in the pilot. For details of the methodology, including definitions of key terms, assumptions and the modelling approach, see Appendix 4 (which provides a full copy of Sapere’s cost-utility analysis report).

Cost-utility analysis is a form of cost-effectiveness analysis. The benefits are measured using quality adjusted life years (QALYs). QALYs take into account improvements in both increased quality of life and increased life expectancy.

Sapere’s analysis was performed using the following process:

- I. Model the natural history of bowel cancer
- II. Estimate the changes in health outcomes from bowel cancer screening
 - using results of the NZ pilot to inform screening parameters
- III. Use QALYs to quantify health benefits
- IV. Estimate the cost savings from screening (i.e. reduction in cancer treatment costs)
- V. Estimate the additional costs from screening
 - i.e. iFOBTs and additional colonoscopies
- VI. Report the cost effectiveness
 - cost-effectives reported as additional cost per QALY gained
 - cost effectiveness under different scenarios.

Sapere used a microsimulation to model the natural history of bowel cancer. The MoDCONZ (Modelling Disease and Cancer Outcomes in NZ) microsimulation model was developed by a team of researchers from the University of Otago. The MoDCONZ model simulates the life histories for a hypothetical sample of people. The sample is defined by age and gender parameters. The model has at its core a natural history of colorectal

cancer, which captures the adenoma-carcinoma sequence, with assumptions based on the probabilities of initiation, progression and response to treatment of colorectal cancers.

Sapere have added a screening intervention model to MoDCONZ to estimate the benefits and costs of bowel cancer screening. The screening intervention estimates the:

- earlier detection of bowel cancer and the resulting changes in bowel cancer mortality
- costs of screening (including surveillance)
- cost offsets from reduced treatment of cancer.

iFOBT participation is based on the experience of the pilot; where iFOBT participation is defined as the proportion of people that are sent an iFOBT kit that return a kit that provide a definite result (96%). iFOBT participation in the first round is based on the first round of the pilot (57%). iFOBT participation in subsequent rounds is based on the second round of the pilot, with 83% for those who participated in the previous round and 24% for those who did not participate in the previous round. After 13 screening rounds, the estimated participation rate is 59%.

The performance of iFOBT is measured as sensitivity and specificity. Our approach to determine the performance of iFOBT was twofold. First we used studies where all participants receive a colonoscopy to determine the sensitivity and specificity at a given cut-off. Secondly we used the results from the pilot to infer how the sensitivity and specificity change for different cut-off levels. The estimate of sensitivity for early stage cancer (stage I or II) is 59.7%, compared with late stage cancer (stage III or IV) with a sensitivity of 85.9%. The sensitivity for adenomas is relatively low with a 7.7% and 25.2% sensitivity for small (< 10mm) and large (≥ 10 mm) adenomas, respectively. The specificity is estimated to be 94.7%, that is a person without an adenoma or cancer has a 5.3% chance of a positive iFOBT (i.e. false positive). Using a higher iFOBT cut-off increases the specificity and decreases the sensitivity.

Those with a positive iFOBT have a 92.5% chance of having a successful colonoscopy; that is, some people may not respond, whereas in some cases a colonoscopy cannot successfully be performed.

Different Quality of Life (QoL) scores were used for the three phases of cancer: initial, continuing care and terminal phase.

- The QoL in the initial phase was dependant on the stage at diagnosis, with more advanced cancer being associated with a lower QoL score. It was assumed that those without bowel cancer would have the QoL of the general population. We used a population average of 0.792, based on the New Zealand population aged 50 and over. The QoL scores for the initial phase cancer were taken from a published cost-utility analysis. The QoL scores ranged from 0.74 for 'stage I rectal or stage I/II colon cancer' and 0.25 for 'stage IV rectal or colon cancer'. These values are used for the stage I and stage IV, respectively; with stage II and stage III as having QoL scores of 0.70 and 0.50, respectively.
- Studies suggest that over time patients' QoL improves and that the QoL is close to the general population. Therefore we assume that in the continuing care phase, after the initial phase, patients QoL improves to that of the general population, i.e. 0.792.
- In the terminal phase, last year of life, the QoL score is assumed to be 0.25. This is based on the assumption that the last year will be similar to being in stage IV.

Bowel cancer is estimated to cost the health sector an additional \$46,000¹⁹ on average per person diagnosed with bowel cancer, with the cost varying substantially by stage of cancer at diagnosis. We base our estimates on work done by the Department of Public Health, University of Otago Wellington (the BODE3 research team: Blakely et al 2015). An excess difference approach was used to estimate the additional cost incurred by those with bowel cancer, compared with the general population. Costs were broken down into three time periods:

- the first year following diagnosis
- remission (time between 1 year and last 6 months)
- 6 months before death.

The costs were estimated by age band, gender and stage of cancer.

The cost of screening used in our analysis is based on the second round of the pilot, since Round 2 is expected to represent steady state costs. Screening costs are described in detail in Appendix 3.

Probabilistic sensitivity analysis was used to model parameter uncertainty. The base microsimulation model addresses the sensitivity of the natural history parameters through a Bayesian calibration with incidence and death data. The screening intervention model introduces new sets of parameters related to the decision points for each individual proceeding through the screening programme and the performance of iFOBTs. Probabilistic sensitivity analysis of these screening parameters was incorporated into the MoDCONZ screening model by performing a random draw on the distributions for these screening parameters at the same time as the draw of natural history parameters for each simulation run over the cohort of individuals.

Research with eligible BSP participants, providers on BSP screening pathway and national and regional stakeholders – Litmus

In Rounds 1 and 2, a range of evaluation activities were undertaken with eligible BSP participants, providers on the BSP screening pathway, and national and regional stakeholders. Activities in Round 1 aligned with the original evaluation plan for the BSP (Litmus 2011). Following the interim evaluation report, it was agreed that screening Round 2 of the pilot would be used to trial new initiatives to increase participation by Māori and Pacific people.²⁰

Following a review of the planned Round 2 evaluation activities, it was agreed to shift the focus to assess the strengthened and new initiatives seeking to increase Māori and Pacific participation in the BSP. A process evaluation of primary care initiatives and a retrospective survey of converted non-responders were undertaken, as well as the final immersion visit (Litmus 2015).²¹ The activities that did not proceed were a clinical pathways study with BSP participants, quality monitoring activities in 2014 and 2015, and a third provider survey.

¹⁹ Reported as \$43,000 in 2011 dollars. Inflation adjusted to 2016 dollars.

²⁰ People living in low deprivation areas also have low levels of participation in the BSP. Towards the end of Round 2, the BSP Coordination Centre started to focus on this group.

²¹ There were no changes in the proposed methodology for the epidemiology and the cost effectiveness analysis for the period 2014–2016 as detailed in the BSP Evaluation Plan (Litmus 2011).

Round 1 participant and provider data collection

Reports on baseline and follow-up surveys of eligible BSP population (Litmus 2012, 2014a)

Computer assisted telephone interviewing surveys measured awareness, knowledge and attitudes towards bowel cancer and the BSP amongst the eligible population. Baseline surveys were conducted in November/December 2011; one with 50–74-year-olds (the eligible screening population) living within WDHB and one with 50–74-year-olds living outside of WDHB. The follow-up survey of the eligible screening population living in WDHB was undertaken in October 2013 to identify changes in awareness, attitudes, knowledge and involvement with the BSP over time.

In 2013, as with the 2011 survey, a main sample of 500 respondents was interviewed, plus a booster sample of 200 respondents (100 Māori and 100 Pacific). Each of the main and booster samples comprised a mix of randomly selected respondents (from the White Pages) and a sample recontacted from the 2011 WDHB survey (who agreed to be recontacted and for whom a name and phone number were available).

Response rates for each survey are shown in Table 1.

Table 1: Achieved response rates, WDHB randomly selected main and booster samples, and main and booster recontact sample 2013 compared with 2011 response rates

| Samples | | Survey 2013 (%) | Survey 2011 (%) |
|---------------------------|----------------|-----------------|-----------------|
| Recontact samples | Main sample | 58.1 | – |
| | Booster sample | 47.3 | – |
| Randomly selected samples | Main sample | 32.0 | 22.4 |
| | Booster sample | 10.1 | 6.6 |

Survey weights were applied to the data to ensure population sub-groups are represented in the correct proportions in the survey results.

Differences between percentages in the 2011 and 2013 WDHB surveys were tested at the 95% confidence level using a *t*-test, adjusted using a conservative design effect for each survey²² and allowing for the average correlation in the recontacted sample used in Kish's weighting approach (Kish 1965). Only statistically significant differences between the two surveys are noted in the report.

Information is reported for key sub-groups (e.g. ethnicity, age group, gender, and household income) where differences within groups are statistically significant.

A qualitative report on the eligible population perspectives of the BSP (Litmus 2013)

In 2012, qualitative research was undertaken with the eligible population to understand participants' experience of the BSP screening pathway, and the factors that facilitated or impeded their progression.

- 12 face-to-face in-depth interviews were conducted with purposively selected BSP participants covering different stages of the BSP screening pathway: four Māori, four

²² The design effects used were 1.67 for the 2011 survey and 1.87 for the 2013 survey. These allow for the selection of one person per household, booster sampling and weighting by age, gender and ethnicity. The true design effect varies between analyses; the values used here are the 90th percentile of design effects calculated for each item gathered in the survey.

Pacific and four Pākehā. Interviews were conducted between 19 and 21 September 2012.

In 2012, recognising that Pacific and Māori were potentially emerging as having lower participation rates, qualitative research was undertaken with non-responders in the eligible Pacific and Māori populations to explore their reasons and the barriers for not taking part in the BSP.

- 12 face-to-face interviews were undertaken with six Māori and six Pacific people who had received a pre-invitation, invitation and reminder letter between April and September 2012, had not returned a completed kit and had not contacted the Coordination Centre to opt out of the BSP (non-responders). Interviews were conducted between 3 and 7 December 2012.

Both studies followed opt-out recruitment and informed consent procedures. Māori and Pacific researchers undertook interviews with Māori and Pacific participants. Participants were invited to bring a support person, and received a koha of \$50.

Reports on the baseline and repeat attitudes survey with providers (Litmus 2012a, 2014b).

The purpose of the surveys was to assess providers'²³ awareness and knowledge of the BSP, attitudes towards the BSP and its delivery mechanisms, and perceived impact of the BSP on normal services. The surveys also aimed to measure attitudes towards a possible national roll-out of a bowel screening programme.

A baseline online provider survey was undertaken between November 2011 and January 2012 before the full implementation of the BSP in January 2012. A total of 88 GPs, 88 practice nurses, eight other general practice staff, 21 endoscopy staff and 30 radiology staff took part in the survey. Response rates for each survey are shown in Table 2.

Table 2: Achieved response rates in 2011

| Provider group | Respondents (n) | Eligible population (N) | Response rate (%) |
|-------------------------------|-----------------|-------------------------|-------------------|
| General practitioners | 88 | 328 [#] | 27 |
| Practice nurses | 88 | 404 [#] | 22 |
| Other general practice staff* | 8 | – | – |
| Endoscopy staff | 21 | 27 | 78 |
| Radiology staff | 30 | 49 | 61 |

[#] Figure based on PHO estimates

* Small number of other general practice staff – combined with practice nurse sample for analysis

The follow-up online provider survey was undertaken from 14 October to 20 December 2013. A total of 80 GPs, 72 practice nurses, 26 other general practice staff, 18 endoscopy staff and 24 radiology staff took part in the survey. Response rates for each survey are shown in Table 3.

²³ Providers include general practitioners (GPs), practice nurses, other general practice staff, endoscopy staff and radiology staff in Waitakere and North Shore Hospitals.

Table 3: Achieved response rates in 2013

| Provider group | Respondents (n) | Eligible population (N) | Response rate (%) |
|-------------------------------|-----------------|-------------------------|-------------------|
| General practitioners | 80 | 328 [#] | 24 |
| Practice nurses | 72 | 404 [#] | 18 |
| Other general practice staff* | 26 | – | – |
| Endoscopy staff | 18 | 26 | 69 |
| Radiology staff | 24 | 47 | 51 |

[#] Figure based on PHO estimates

* Other general practice staff were combined with the practice nurse sample for analysis

Data were analysed by provider group. The small numbers overall and for particular provider groups prevented detailed analysis due to statistical limitations in making comparisons with small numbers.

Comparisons have been made between the results in the 2013 follow-up provider survey and the 2011 baseline provider survey. Significant differences noted for endoscopy staff and radiology staff should be treated as indicative only due to their small sub-sample sizes.

The 2012 and 2013 immersion visit reports (Litmus 2013a, 2014)

In September 2012, an immersion visit was undertaken to gain a detailed understanding of the early implementation of the BSP from those who were involved with its design, implementation and day-to-day operations. Focus was placed on how the BSP was being implemented, what was working well and not so well, and in identifying key process improvements to enhance the BSP, as well as lessons for a national roll-out of a bowel screening programme, should it proceed.

Sixty-two face-to-face, phone interviews and group discussions with providers across the screening pathway were undertaken (including representatives from Ministry of Health, WDHB, LabPLUS, New Zealand Post, Orangebox, Primary Health Organisations (PHOs) and general practices).

In October 2013, a second immersion visit was undertaken which focused on exploring the impact of the BSP on the investigation, surveillance and treatment stages, as well as following up issues identified in the 2012 immersion visit report (Litmus 2013a).

Thirty face-to-face, phone interviews and group discussions with providers across the screening pathway were undertaken (including representatives from Ministry of Health, BSP Coordination Centre, gastroenterologists, CTC, laboratory, endoscopy nurses, BSP colonoscopy surgeons, non-BSP colonoscopy surgeons who do not scope in BSP, oncologist).

All interviews followed an informed consent process.

The role of general practice report (Litmus 2014c)

The role of general practice in informing BSP participants of a positive iFOBT is an uncommon element of the BSP. Findings from the first immersion visit (Litmus 2013a) indicated that although GPs and practice nurses are generally supportive of the BSP, across general practice there is variation in BSP processes and practices undertaken.

Given this uncommon role and noted variation, it was agreed the role of general practice in the BSP needed to be more fully understood, particularly in enhancing participants' experience and considering general practices' role if the Pilot was rolled out nationally. To identify the role and value of general practice in the BSP, a report was developed which drew on the quantitative data from the eligible population and provider surveys (Litmus 2014a & b), interviews with ten general practices including GPs, practice nurses, practice managers and other practice staff as well as face-to-face interviews with five Māori and five Pacific BSP participants.

Fieldwork was undertaken in October 2013. All interviews followed an informed consent process.

Findings from these data sources were used to inform Interim Evaluation Report of the Bowel Screening Pilot: Screening Round One (Litmus et al 2015).

Round 2 participant and provider data collection

Increasing Participation of Māori and Pacific people in the BSP; General practices role in the BSP (Litmus 2016)

In 2015, a computer assisted telephone interviewing survey of general practices with access to Dashboard and/or DRINFO in WDHB was undertaken. The purpose was to determine the perceptions and use of Dashboard and DRINFO to support participation in bowel screening, and identify other activities that may be undertaken to increase participation.

A sample of 96 general practices were identified by the BSP Coordination Centre as having access to Dashboard from ProCare, Auckland PHO, National Hauora Coalition and Waitematā PHO. From 96 contacts, a total of 80 interviews were completed with general practice (Table 4). The response rate achieved was 83%.

Table 4: General practice survey sample profile

| Demographics | No. (n=80) | % (n=80) |
|---------------------------------|---------------|-------------|
| Role | | |
| Practice manager | 34 | 43% |
| Practice nurse | 32 | 40% |
| General practitioner | 7 | 9% |
| Other staff in general practice | 7 | 8% |
| PHO | | |
| Waitematā PHO | 29 | 36% |
| ProCare | 28 | 35% |
| Auckland PHO | 17 | 21% |
| National Hauora Coalition | 3 | 4% |
| Other | 3 | 4% |

BSP monitoring data on the number of faxes received by the BSP Coordination Centre from general practices asking for iFOBT kits to be sent to their patients. This proxy indicator on the use of Dashboard by general practices was analysed for the period January–December 2015.

A case study of a general practice, with a high proportion of enrolled Māori and Pacific patients, who are actively engaged in supporting their patients to take part in bowel screening. The purpose of the case study was to profile the practice and systems used to engage with Māori and Pacific patients that may inform a national bowel screening programme. The case study involved four face-to-face interviews with practice staff, review of relevant system processes and policies for the practice, and interviews with three Māori and four Pacific BSP participants who have had engagement with the general practice about bowel screening.

The case study followed opt-out recruitment and informed consent procedures. Māori and Pacific researchers undertook interviews with Māori and Pacific participants. BSP participants were invited to bring a support person, and received a koha of \$50.

Retrospective survey of converted non-responders. A follow-up computer assisted telephone survey was undertaken with Māori and Pacific non-responders four weeks after receiving their iFOBT kit who are then contacted via active follow-up and go on to complete their kit (referred to as converted non-responders). The primary purpose of the survey was to identify the factors that contributed to Māori and Pacific converted non-responders completing their kit.

A two-staged sampling and interview approach was adopted:

1. Retrospective interviews of converted non-responders who completed their kit and have a negative result between 1 May and 19 July 2015.
2. Fortnightly rolling sample for converted non-responders with negative results recorded between 20 July 2015 and 3 January 2016.

The survey was completed on 1 February 2016. A number of exclusions were applied: Māori and Pacific non-responders who could not be contacted during active follow-up; participants who received a positive result letter.

An opt-out informed consent process was followed. Of the 613 converted non-responder contacts received, a total of 389 interviews were completed: 222 Māori, 167 Pacific people and 10 Other people.²⁴ The response rate achieved for the survey was 65%.²⁵ On completion of the survey, survey weights were calculated to adjust for the sample design and to align the sample with the known population profile. Table 5 shows the demographic profile of the converted non-responder survey respondents.

²⁴ Other includes six European, two Indian, 1 Chinese, and 1 other Asian.

²⁵ The response rate was calculated following the Standard Definitions published by the American Association for Public Opinion Research (2011).

Table 5: Demographic profile of converted non-responder survey respondents

| Variable | Māori n=222 % | Pacific people n=167 % | Total n=389 % |
|-----------|---------------------|------------------------------|---------------------|
| Gender | | | |
| Male | 44 | 45 | 44 |
| Female | 56 | 55 | 56 |
| Age group | | | |
| 50–54 | 33 | 33 | 33 |
| 55–59 | 26 | 26 | 26 |
| 60–64 | 23 | 20 | 21 |
| 65–69 | 12 | 15 | 14 |
| 70–74 | 5 | 6 | 6 |
| 75 plus | 1 | 1 | 1 |

The 2015 immersion visit report (Litmus 2016a)

In November and December 2016, a third immersion visit was undertaken to gain in-depth insight from providers along the screening pathway about the ongoing implementation of the pilot in screening Round 2 (Litmus 2016a).

Forty-two face-to-face, phone interviews and group discussions with providers across the screening pathway were undertaken (including representatives from Ministry of Health, national level stakeholders, WDHB, BSP Coordination Centre, general practice and other primary care organisations, PHOs, gastroenterologists, laboratory, endoscopy nurses, and BSP colonoscopy surgeons). Interviews with general practice and PHOs were reported in Litmus (2016).

All interviews followed an informed consent process.

The New Zealand Health and Disability Multi-region Ethics Committee granted ethical approval for the suite of BSP evaluation activities (reference MEC/11/EXP/119). On July 2015, the Central Health and Disability Ethics Committee approved the amendments to the evaluation plan for the BSP (Litmus 2015) (reference MEC/11/EXP/119/AM06).

2.6 Limitations

This report draws on a mix of qualitative information and quantitative data. The evaluation team is confident that the results presented in the final evaluation report accurately reflect the information and data provided. Table 6 provides a commentary on the quality of the data and information used to inform this report.

Table 6: List of data and information used and their quality

| Data sources | Quality rating | Comments on quality |
|--|----------------|--|
| BSP Register data used for the epidemiology analysis (Read et al 2016) | Medium | There was a marked improvement in the quality of the data in the BSP Register since the interim analysis. However, some data quality issues remain. There is still evidence of a lack of logic checks in some areas. Also, the data dictionary is continuing to evolve, e.g. cancer definitions. |
| The BSP CEA (Love et al 2016) | Medium | Data on pilot activity were supplied by the Ministry of Health, but were not verified directly by the evaluators. |
| The BSP costing analysis report (Blick et al 2016) | High | Data were supplied by the pilot programme, and verified in detail with pilot staff. |
| A survey of general practices on use of Dashboard and/or DRINFO (Litmus 2016a) | High | The survey targeted a sample of 96 general practices identified as having access to Dashboard from ProCare, Auckland PHO, National Hauora Coalition and Waitematā PHO. The response rate achieved was 83%. |
| A case study of a general practice, with a high proportion of Māori and Pacific patients (Litmus 2016) | Medium | Waitakere Union Health was selected as a practice with a high proportion of Māori and Pacific patients who are eligible to participate in bowel screening, and have a range of initiatives and innovations to support their participation. The case had good coverage of clinical staff in the practice. A small number of Māori and Pacific BSP participants were interviewed. Waitakere Union Health has an uncommon positioning of being a low or no cost practice. This positioning may limit the application of their strategies to other general practices. |
| Retrospective survey of converted non-responders (Litmus 2016) | Medium | <p>A census approach was adopted to invite all Māori and Pacific non-responders at four weeks who are contacted via phone by the BSP Coordination Centre's active follow-up and go on to complete their kit, and have a negative iFOBT result for the period 1 May 2015 to 3 January 2016. The period selected aligns with the implementation of a range of initiatives to increase participation by Māori and Pacific people in the BSP. The response rate achieved for the survey was 65%. The survey data was weighted to adjust for the sample design and to align the sample with the known population profile.</p> <p>The main limitation of the survey is respondents' recall of their triggers to act. A fortnightly rolling sampling approach was used to undertake interviews as close as possible to their decision to act.</p> |
| Immersion visit (Litmus 2016a) | Medium-high | Good coverage of providers across the BSP screening pathway. |
| BSP monitoring data on fax requests (Litmus 2016) | Medium | The BSP Coordination Centre provided the data on fax requests received by the BSP for the period 1 October 2014 – 31 January 2016. The data period is in line with the introduction of the pre-populated fax by Waitematā PHO in October 2014 and most practices had the fax facility in place by January 2015. |
| BSP active follow-up data (Litmus 2016) | High | The BSP Coordination Centre provided active follow-up call data for Māori and Pacific non-responders at four weeks for the period 1 January – 31 December 2015. The period selected aligns with the implementation of a range of initiatives to increase participation by Māori and Pacific people in the BSP. In 2015, data quality for active follow-up had improved. 2014 data is excluded as it is incomplete. |

| Data sources | Quality rating | Comments on quality |
|--|----------------|---|
| 2011 Baseline and 2013 follow-up survey of eligible BSP population (Litmus 2012 and 2014a) | Medium-high | <p>In the absence of any other population-level data on awareness and knowledge around bowel cancer and bowel screening, the telephone surveys conducted as part of the BSP evaluation provide useful information. Data limitations:</p> <ul style="list-style-type: none"> ▪ Relatively small sample sizes limit the possibility of extensive sub-group analysis and the reliability of comparisons over time. ▪ Non-respondents may have differed from respondents in unknown ways, which would affect the survey results. Weighting will have helped to mitigate the problem. ▪ The response rates achieved for the two WDHB surveys (using a conservative measure) were reasonable, but not exceptional. |
| The 2011 baseline and the 2013 follow-up survey with providers (Litmus 2012a and 2014b) | Medium | <p>The key methodological limitations of the provider surveys are the low GP and practice nurse response rates and an inability to establish whether GP and practice nurse samples are representative of the wider population of WDHB GPs and practice nurses. Consequently, GP and practice nurse findings are indicative and not definitive.</p> |
| Qualitative interviews with the eligible population – participants (Litmus 2013) | Medium | <p>Findings are dependent on participants' recall of the order of events and experiences on the BSP screening pathway.</p> <p>Undertaking twelve interviews with participants means the diversity of Māori, Pacific and other people may not be covered. On completion of the twelve interviews, no new substantive themes were being identified suggesting that saturation may have been reached.</p> <p>Due to the small sample size, Asian people were not included. Therefore not all experiences of those participating in the BSP have been explored.</p> |
| Qualitative interviews with the eligible population – non-participants) (Litmus 2013) | Medium | <p>Sample size: undertaking six interviews with Māori and six with Pacific people means that not all reasons and barriers for non-participation have been identified. However, it is anticipated that significant themes have been identified.</p> <p>Targeted sub-groups: this approach offers no understanding of the reasons/ barriers for Pākehā and Asian men not participating. Further, it also does not address the diversity of Māori or Pacific people eligible to participate.</p> |
| The 2012 immersion visit report (Litmus 2013a) | Medium-high | <p>The perspective of primary care on the BSP is limited to the participants from six general practices from Waitematā PHO and ProCare.</p> |
| The 2013 immersion visit report (Litmus 2014) | High | <p>Good coverage of providers involved in investigation, surveillance and treatment stages of the BSP screening pathway.</p> |
| Immersion interviews with general practice and WDHB staff (Litmus 2014c) | Medium | <p>The perspective of primary care on the BSP is limited to the participants from ten general practices from Waitematā PHO and ProCare.</p> <p>Variations in processes and opinion on general practice were noted across the ten practices.</p> |

| Data sources | Quality rating | Comments on quality |
|---|----------------|---|
| Qualitative interviews with BSP participants (Litmus 2014c) | Medium | <p>Findings are dependent on participants' recall of the order of events and experiences on the BSP screening pathway.</p> <p>Undertaking ten qualitative interviews means the diversity of Māori and Pacific BSP participants may not be covered, and Asian people and Europeans were not included. Therefore not all experiences of those participating in the BSP have been explored.</p> <p>Two Māori and five Pacific participants were informed about their iFOBT results by the Endoscopy Unit. Participants were not screened as it was assumed that most would have received their positive iFOBT result via their general practice. Further, the pool from which to draw the purposive sample was too small to screen participants out. The sample achieved enabled the exploration of participants' experience of hearing about their results via the Endoscopy Unit and whether they would have preferred to have received their results from their general practice.</p> |

3. Effectiveness

Evaluation aim addressed in this section

Effectiveness: Is a national bowel screening programme likely to achieve the mortality reduction from bowel cancer for all population groups seen in international randomised controlled trials?

Section 3 presents the executive summary findings from the epidemiology report (Read et al 2016). The full report and its appendices are in Appendix 2.

3.1 Acknowledgements

The epidemiological report was prepared for Litmus by Associate Professor Deborah Read, public health physician; Mathangi Shanthakumar, biostatistician and Professor Barry Borman, epidemiologist, Environmental Health Indicators programme, the Centre for Public Health Research (CPHR), Massey University. Litmus was funded by the Ministry of Health to evaluate the bowel cancer screening pilot.

The team thank the Ministry of Health for providing data from the Bowel Screening Pilot Register.

We acknowledge and thank Professor John Potter for providing peer review.

3.2 Introduction

This report is based on the participation in, and outcomes from, the first 36 months. The results describe the first (or prevalence) screening round and the first 12 months of the second round.

The second screening round has been divided into three categories depending on the screening history of the invited population:

1. Completed Round 1

People who successfully completed an iFOBT kit in the first round.

This category is further subdivided into:

a. Negative iFOBT (39.2%)

People with a negative iFOBT result in the first round

This group represents an incidence screening round (i.e., they were screened in Round 2 for newly arisen or previously undetected adenomas and colorectal cancer after a negative iFOBT in Round 1).

b. Positive iFOBT, no colonoscopy (0.1%)

People with a positive iFOBT result in the first round and no colonoscopy done²⁶

²⁶ Details about this subcategory have been excluded from the Executive Summary given that it comprised only 63 eligible people.

2. Did not complete Round 1 (33.2%)
People who did not respond or did not successfully complete an iFOBT kit in the first round
3. Not invited in Round 1 (27.5%)
People who were invited for the first time in the second round (due to being too young or not in the catchment area during the first round).

The results take into account the effects of all demographic factors other than the one under consideration. For example, when considering participation by age group, the results have been adjusted to take account of the potential confounding effects of sex, ethnicity and deprivation (NZDep 2013). Unless otherwise stated, all results are statistically significant; in this context, differences labelled 'slightly less' or 'slightly more' are statistically different but the adjusted odds ratio is either greater than 0.7 times or less than 1.5 times as much as the reference group, respectively.

3.3 Participation

Immunochemical faecal occult blood test (iFOBT) uptake

Round 1

The participation rate²⁷ was 56.9% for the first (or prevalence) screening round.

Participation increased with increasing age for both females and males.

Males were slightly less likely to participate than females. This difference decreased with increasing age.

Asians, Māori and Pacific people were all less likely to participate than European/Other people.

Participation declined with increasing deprivation.

These trends by age, sex, ethnicity and deprivation were the same in Round 2 as in Round 1.

Participation in Round 1 was highest among European/Other (63.0%), followed by Asians (53.7%), Māori (46.1%) and Pacific people (30.6%).

Among European/Other participants, males had lower participation than females (61.1% vs 64.7%). In contrast, Māori male participation was higher than Māori females (48.0% vs 44.7%). Participation was similar among Pacific people and Asians between males and females. This pattern persisted in Round 2, except participation of Māori males and females was similar (45.6% and 46.4%, respectively).

²⁷ This is a proportion rather than a rate, which is occurrence per unit time. 'Rate' has been used synonymously with 'proportion' in this report to improve readability. Participation rate is the percentage of participants with a successfully completed iFOBT kit result out of all those who received an invitation with an iFOBT kit.

Round 2

Participation in Round 2 (51.6%) was lower than in Round 1. Within Round 2, participation varied depending on the screening history of the invited population.

Participation was highest among European/Other (56.6%), followed by Asians (48.8%), Māori (46.0%) and Pacific people (36.7%). The pattern was the same as in Round 1. Although the participation of European/Other and Asians decreased from Round 1, it increased for Pacific people and remained the same for Māori.

Completed Round 1, negative iFOBT

People with a negative iFOBT result in the first round who were invited in Round 2 represent an incidence (as opposed to prevalence) screening round (i.e., they are being screened for new or previously undetected disease). Participation among this group was high – 82.5%.

Participation increased with increasing age for both females and males.

Males were slightly less likely to participate than females.

Participation was highest among European/Other (83.2%), followed by Māori (81.4%), Asians (78.7%) and Pacific people (78.7%).

Asians were slightly less likely to participate than European/Other.

Participation for all age and ethnic groups for both females and males was above 60%.

Participation among people from the most deprived quintile area (NZDep Index 9–10) was slightly lower than among people from the least deprived quintile area (NZDep Index 1–2).

Trends by age, sex and Asian ethnicity were similar to those found in Round 1.

Did not complete Round 1

The participation rate of this group of previous non-responders and people who had not successfully completed an iFOBT kit was very low – 23.5%.

Participation increased with increasing age for both females and males.

Unlike Round 1 and other Round 2 categories, there was no difference in participation by sex.

Asians were slightly less likely to participate and Pacific people and Māori were slightly more likely to participate than European/Other. This pattern of participation for Pacific people and Māori differs from Round 1 and other Round 2 categories.

Pacific people aged 50–59 and 60–69 years were slightly more likely to participate than European/Other of the same age.

Compared to European/Other males, Pacific and Māori males were slightly more likely, and Asian males were slightly less likely, to participate.

Participation declined with increasing deprivation.

Trends by age and deprivation were the same as those found in Round 1.

Not invited in Round 1

The majority (62%) of those being invited for the first time in Round 2 became eligible due to ageing into the target population. The participation rate was low – 41.6%. Participation of the 50–54 years age group, comprising 74.2% of this Round 2 category, was 40.5% compared to 46.1% in Round 1.

Overall participation was lower than in Round 1 and lower for every age group for both males and females.

Participation increased with increasing age from 60-64 years.

Males, particularly those aged 50–54 years, were slightly less likely to participate than females.

Participation was highest among European/Other (46.1%), followed by Asians (44.1%), Māori (35.6%) and Pacific people (28.9%).

Pacific people and Māori were less likely to participate than European/Other.

Participation among both Pacific males and females and Asian and Māori females was lower than for their European/Other counterparts.

Among European/Other and Asians aged 50-54 years, both male and female participation were lower than in Round 1. Pacific participation in this age group was higher than in Round 1; this was of marginal statistical significance. Pacific female participation was higher but there was no difference between rounds for Pacific males. There was no difference in participation by sex among Māori.

Participation generally declined with increasing deprivation.

Trends by age, sex, ethnicity and deprivation were similar to those found in Round 1.

The BSP meets the acceptable level set in the European guidelines: having less than 3% of kits not being successfully completed. Round 2 almost reaches the desirable level of less than 1% of kits not being successfully completed (Moss et al 2010).

The BSP meets the acceptable level set in the European guidelines: having a minimum uptake level of 45% for both rounds (Moss et al 2010). However, it does not meet this level for the newly invited group in Round 2.

Colonoscopy uptake

Colonoscopy uptake was 85.7%²⁸ in Round 1 and 82.3%²⁹ in Round 2.

Males were more likely to have a colonoscopy than females in both rounds.

Asian males were slightly less likely to have a colonoscopy than European/Other males in Round 1.

Colonoscopy uptake increased with increasing deprivation in Round 1. In Round 2, there was no difference in uptake by deprivation apart from those people from the most deprived quintile area (NZDep Index 9–10). This group was over 2.5 times as likely as people from the least deprived quintile area (NZDep Index 1–2) to have a colonoscopy.

Completed Round 1, negative iFOBT

Colonoscopy uptake was 83.7%.

Males were more likely to have a colonoscopy than females.

Pacific people were almost three times less likely to have a colonoscopy than European/Other participants. Pacific males were six times less likely to have a colonoscopy than European/Other males. Pacific males aged 60–69 years were almost five times less likely to have a colonoscopy than European/Other males of the same age.

Colonoscopy uptake increased with increasing deprivation.

Trends by sex and deprivation were similar to those found in Round 1.

Did not complete Round 1

Colonoscopy uptake was 79.0%.

There were no differences in colonoscopy uptake by age, sex or ethnicity.

As in Round 1, colonoscopy uptake increased with increasing deprivation.

Not invited in Round 1

Colonoscopy uptake was 82.5%.

There were no differences in colonoscopy uptake by age, sex, ethnicity or deprivation.

The BSP meets the acceptable level set in the European guidelines: having 85% colonoscopy uptake in Round 1, but not in Round 2 (Moss et al 2010). Round 2 uptake was highest among those who had a negative iFOBT in Round 1, followed by the newly invited group.

²⁸ A further 6.9% (n=361) are recorded as having colonoscopy outside of the BSP.

²⁹ A further 8.2% (n=154) are recorded as having colonoscopy outside of the BSP.

About one percent of participants with a positive iFOBT had CT colonography^{30,31} in both screening rounds.

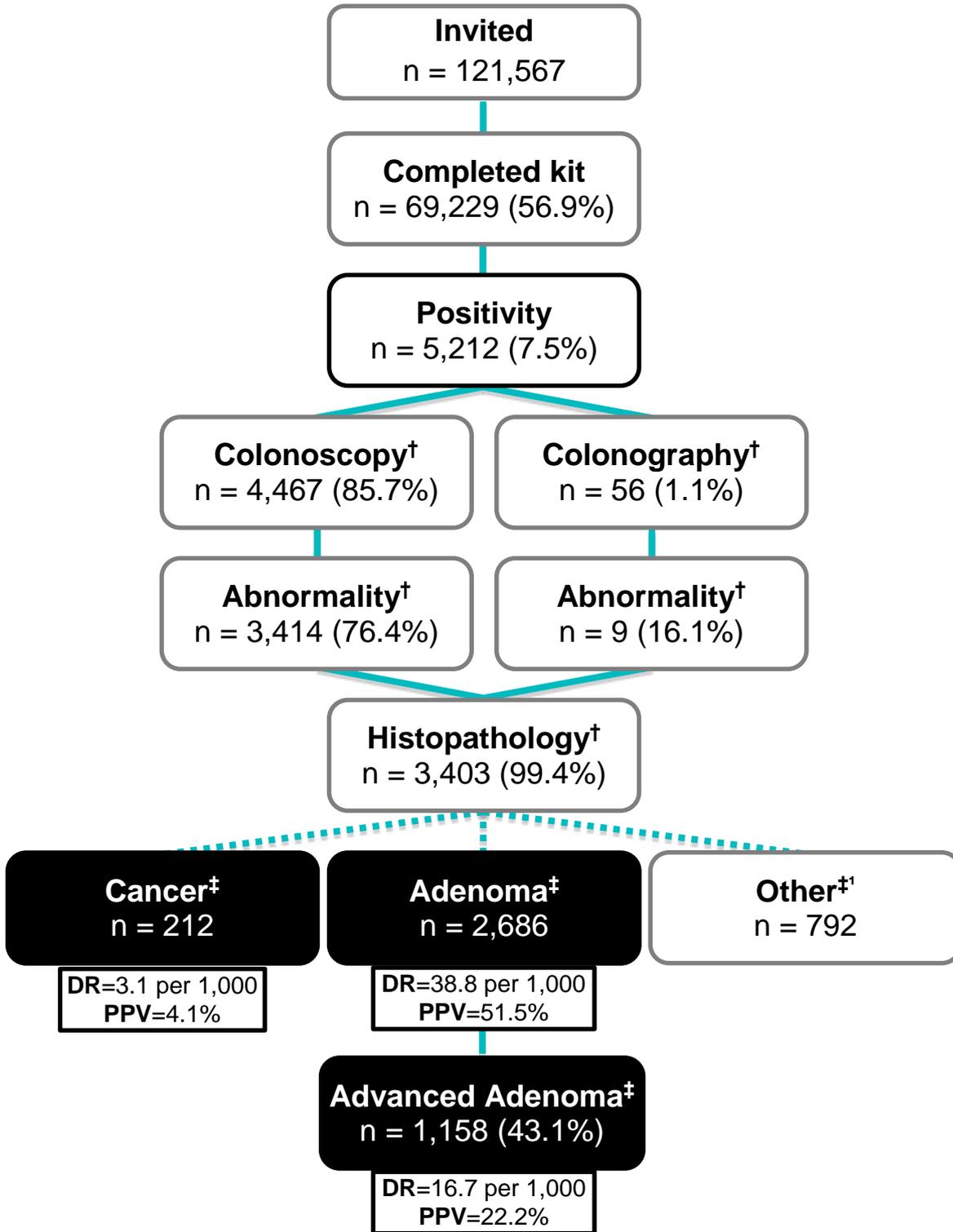
3.4 Outcomes

Figures 2, 3 and 4 summarise the key findings for a) Round 1, b) Round 2, and c) Round 2 in those who completed Round 1 and had a negative iFOBT among those participants who had a positive iFOBT, a completed colonoscopy and histopathology results.

³⁰ CT colonography, sometimes called virtual colonoscopy, is a radiological procedure that uses a CT scanner to visualise the bowel.

³¹ Another two participants had private CT colonography.

Figure 2: Summary of BSP outcomes – Round 1



Key:

DR = Detection Rate = $n / \text{Completed kit} * 1,000$

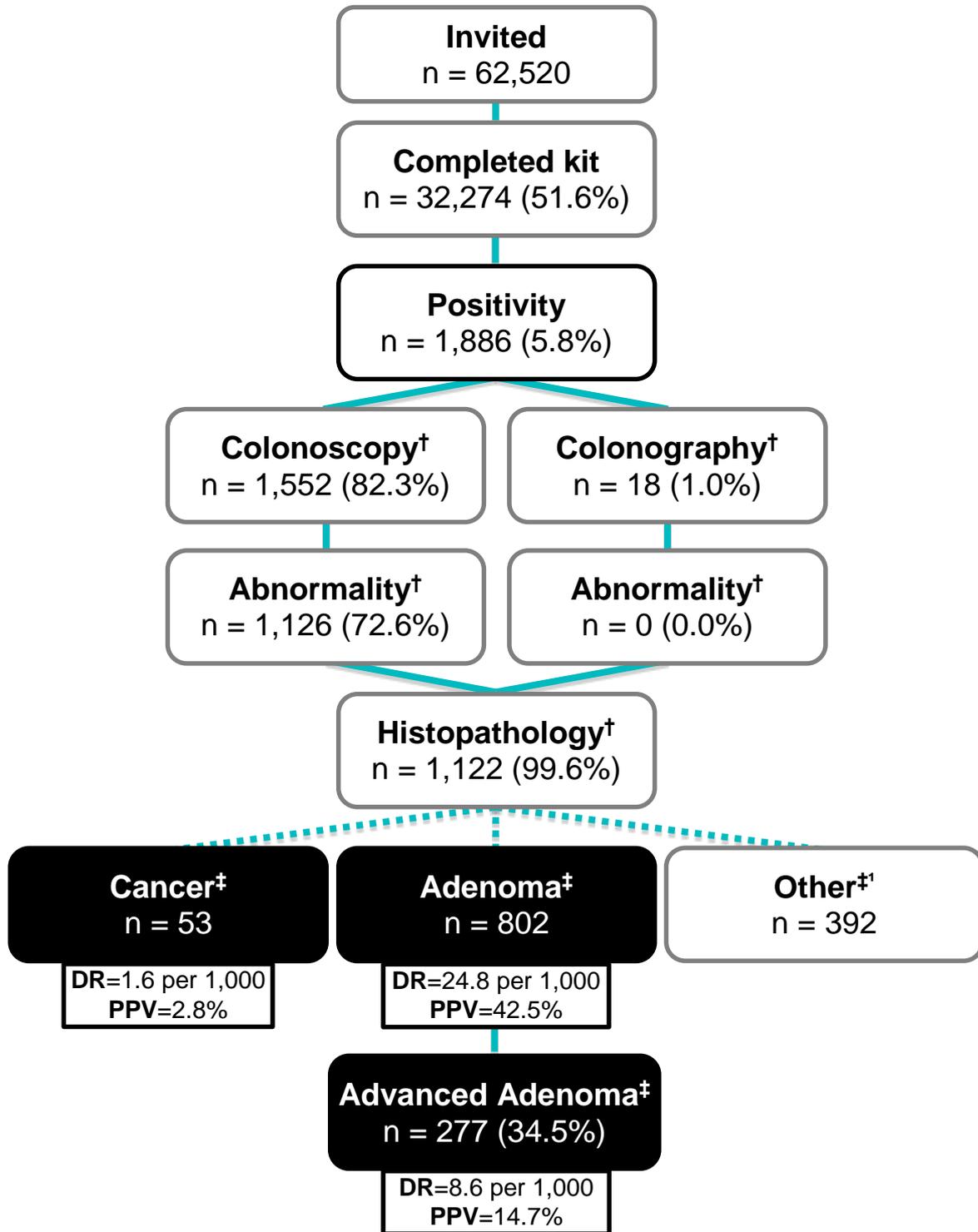
PPV = Positive Predictive Value of iFOBT = $n / \text{Positive iFOBT} * 100$

† : WDHB

‡ : WDHB and other

¹ There are three cases of cancer in situ included in the 'Other' category.

Figure 3: Summary of BSP outcomes – Round 2



Key:

DR = Detection Rate = $n / \text{Completed kit} * 1,000$

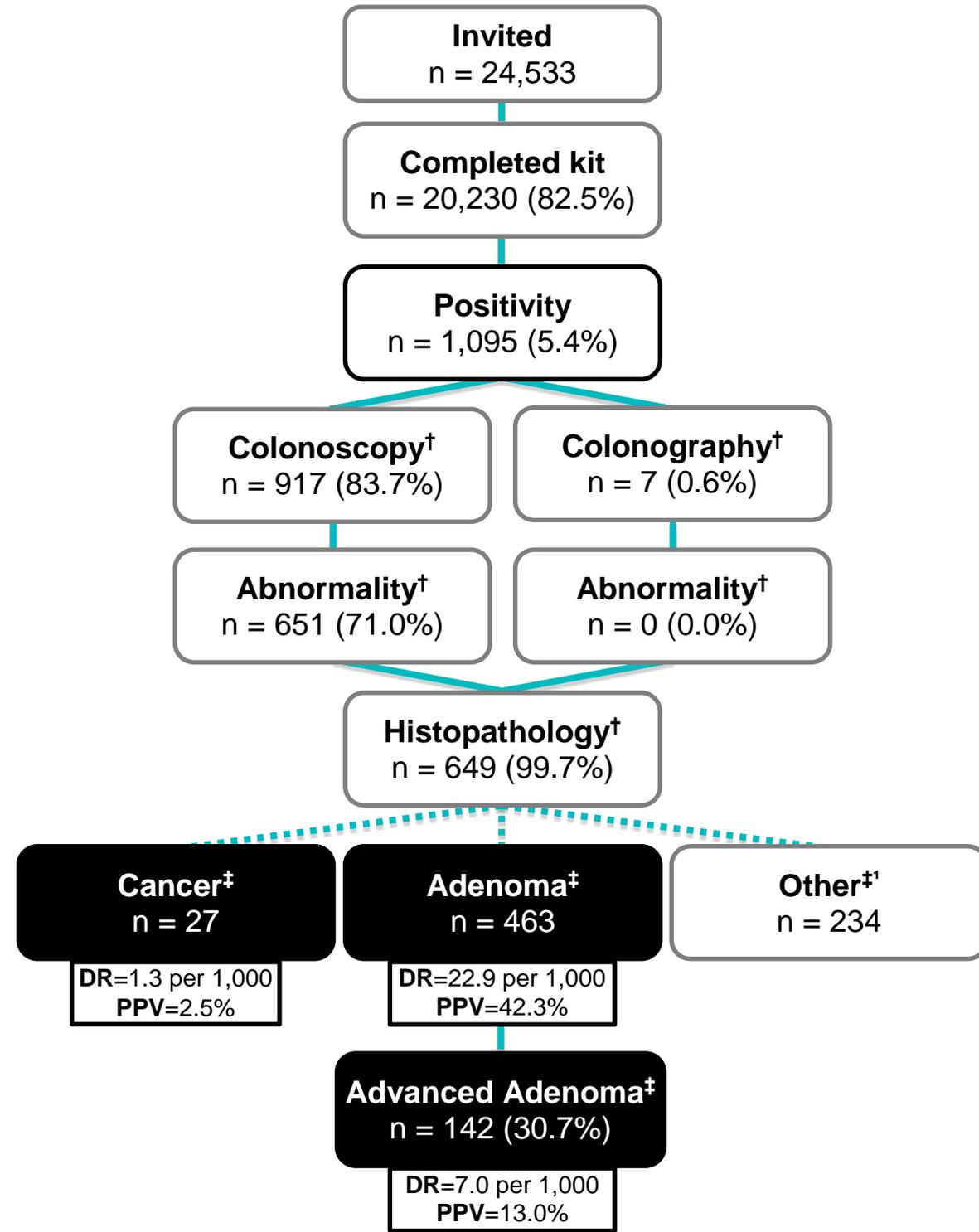
PPV = Positive Predictive Value of iFOBT = $n / \text{Positive iFOBT} * 100$

† : WDHB

‡ : WDHB and other

¹ There is one case of cancer in situ included in the 'Other' category.

Figure 4: Summary of BSP outcomes – Round 2, Completed Round 1, negative iFOBT



Key:
DR = Detection Rate = $n / \text{Completed kit} * 1,000$
PPV = Positive Predictive Value of iFOBT = $n / \text{Positive iFOBT} * 100$
 † : WDHB
 ‡ : WDHB and other

¹ There is one case of cancer in situ included in the 'Other' category.

Immunochemical faecal occult blood test (iFOBT) positivity

Round 1

In Round 1, 7.5% of those who successfully completed a kit had a positive iFOBT result.

Positivity increased with increasing age for both males and females.

Males of every age group were more likely to have a positive iFOBT result than females.

Māori and Asians were slightly more likely to have a positive iFOBT result than European/Other participants.

Female Asians, female Pacific and male Māori were slightly more likely to have a positive iFOBT result than their European/Other counterparts.

Positivity was highest among those from the most deprived quintile areas (NZDep Index 7–8 and 9–10).

Round 2

Positivity in Round 2 was 5.8%; this was lower than in Round 1 (7.5%).

Completed Round 1, negative iFOBT

Of the Round 2 participants who had a negative iFOBT result in Round 1 and successfully completed a kit in the second screening round, 5.4% had a positive iFOBT result.

Positivity increased with increasing age from 55–59 years. Both female and male participants aged 70–74 years were almost twice as likely to have a positive iFOBT result as their 50–54 year-old counterparts.

Males were more likely to have a positive iFOBT result than females.

Māori were more likely to have a positive iFOBT result than European/Other participants.

Male Māori were almost twice as likely to have a positive iFOBT result as their European/Other counterparts.

Māori aged 60–69 years were almost twice as likely to have a positive iFOBT result as their European/Other counterparts.

People from the most deprived quintile areas (NZDep Index 7–8 and 9–10) were more likely to have a positive iFOBT result than people from the least deprived quintile area (NZDep Index 1–2).

Trends by age, sex, Māori ethnicity and deprivation were similar to those found in Round 1.

Did not complete Round 1

Of the Round 2 participants who did not complete Round 1 but adequately completed a kit in the second screening round, 8.4% had a positive iFOBT result.

Positivity increased with increasing age.

Males were slightly more likely to have a positive iFOBT result than females.

Asian males were almost half as likely to have a positive iFOBT result as European/Other males.

Participants from quintile area NZDep Index 7–8 were more likely to have a positive iFOBT result than those from the least deprived quintile area (NZDep Index 1–2).

Trends by age and sex were the same as those found in Round 1.

Not invited in Round 1

Of the Round 2 participants who were not invited in Round 1 and successfully completed a kit in the second screening round, 5.2% had a positive iFOBT result.

Positivity increased with increasing age.

Males were more likely to have a positive iFOBT result than females.

Males of every age group and females aged 70–74 years were about twice as likely to have a positive iFOBT result as their 50–54-year-old counterparts.

Asian and Pacific females were about twice as likely to have a positive iFOBT result as their European/Other counterparts.

People from the second most deprived quintile area (NZDep Index 7–8) were more likely to have a positive iFOBT result than people from the least deprived quintile area (NZDep Index 1–2).

Trends by age and sex were the same as those found in Round 1.

Positive Predictive Values³⁵**Round 1**

The positive predictive value (PPV) of a positive iFOBT for adenoma was 51.5%, advanced adenoma was 22.2%, and cancer was 4.1%. That is, 55.6% of people who had a positive iFOBT had an adenoma or cancer detected, and 26.3% had an advanced adenoma or cancer detected.

There were some age, sex and ethnic differences in the effectiveness of a positive iFOBT in detecting adenoma, advanced adenoma and cancer in Round 1 and Round 2, according to

³⁵ The PPVs have been calculated based on the results of all colonoscopies including those carried out in private health care.

the screening history of the participants. Refer the full report in Appendix 2 for further details.

Round 2

The PPV of a positive iFOBT for adenoma was 42.5%, advanced adenoma was 14.7%, and cancer was 2.8%. That is, 45.3% of people who had a positive iFOBT had an adenoma or cancer detected, and 17.5% had an advanced adenoma or cancer detected.

Completed Round 1, negative iFOBT

The PPV of a positive iFOBT for adenoma was 42.3%, advanced adenoma was 13.0%, and cancer was 2.5%. That is, 44.7% of people who had a positive iFOBT had an adenoma or cancer detected, and 15.4% had an advanced adenoma or cancer detected.

Did not complete Round 1

The PPV of a positive iFOBT for adenoma was 43.8%, advanced adenoma was 18.3%, and cancer was 4.2%. That is, 47.9% of people who had a positive iFOBT had an adenoma or cancer detected, and 22.5% had an advanced adenoma or cancer detected.

The PPV for participants from quintile area NZDep Index 7–8 was about three times higher for advanced adenoma than for those from the least deprived quintile area (NZDep Index 1–2).

Not invited in Round 1

The PPV of a positive iFOBT for adenoma was 41.9%, advanced adenoma was 15.6%, and cancer was 2.4%. That is, 44.4% of people who had a positive iFOBT had an adenoma or cancer detected, and 18.0% had an advanced adenoma or cancer detected.

The PPV for the 50-54 years age group (comprising 74.2 % of those who successfully completed an iFOBT in this round) was 40.0% for adenoma, 20.0% for advanced adenoma and 1.5% for cancer. The PPVs for the same age group in Round 1 were 43.0%, 17.5% and 2.3%, respectively.

Detection rates of adenoma, advanced adenoma and colorectal cancer³⁶

Some of the participants with adenoma, advanced adenoma or cancer would have had more than one type of pathology; only the most serious type was recorded.

Round 1

The overall detection rate per 1,000 screened for adenoma was 38.8, advanced adenoma was 16.7 and cancer was 3.1.

³⁶ The outcomes are for all colonoscopies including those carried out in private health care.

Detection rates increased with increasing age reflecting the natural history of adenomas and colorectal cancer.

Compared to 50–54-year-old participants, detection of a colorectal cancer was more frequent for each age group except 55–59-year-olds. Adenoma and advanced adenoma were detected more frequently with increasing age.

The 70–74-year-old participants were more likely to have an adenoma, advanced adenoma or cancer detected than 50–54-year-old participants.

Males were more likely to have an adenoma, advanced adenoma or cancer detected than females. The difference between males and females existed at every age group for adenoma and advanced adenoma, and in the 65–69 years age group for cancer.

The difference between males and females for adenoma and advanced adenoma decreased with increasing age.

Asians were about 1.5 times less likely than European/Other to have an advanced adenoma detected. The difference was similar for each age group.

Asian males were less likely to have an adenoma or advanced adenoma detected than European/Other males.

Pacific people were less likely than European/Other to have an adenoma or advanced adenoma detected.

Pacific males were over 1.5 times less likely to have an adenoma detected than European/Other males.

Māori were slightly more likely to have an adenoma detected than European/Other.

Māori aged 60–69 years were 1.5 times more likely to have an adenoma detected than European/Other of the same age.

Detection rates were highest among those from the most deprived quintile areas (NZDep 7–8 and 9–10).

Round 2

The overall detection rate of adenoma was 24.8 per 1,000, advanced adenoma was 8.6 per 1,000, and cancer was 1.6 per 1,000.

Completed Round 1, negative iFOBT

The overall detection rate per 1,000 screened for adenoma was 22.9, advanced adenoma was 7.0 and cancer was 1.3.

Adenoma detection rates increased with increasing age.

Males were more likely to have an adenoma or advanced adenoma detected than females. The difference between males and females for adenoma generally decreased with increasing age.

Females aged 70–74 years were more likely to have an adenoma or advanced adenoma detected than 50–54-year-old females.

Males aged 70–74 years were more likely to have an adenoma detected than 50–54-year-old males.

Māori were more likely to have an adenoma detected than European/Other participants.

Māori males were twice as likely to have an adenoma detected as European/Other males.

Pacific people aged 70–74 years and Māori aged 50–59 years were more likely to have an adenoma detected than European/Other of the same ages.

Whilst participants from the most deprived quintile area (NZDep 9–10) were more likely to have an adenoma or advanced adenoma detected than participants from the least deprived quintile area (NZDep Index 1-2), detection of both was similarly increased for NZDep 3–4 participants.

Trends by age, sex and Māori ethnicity for adenoma were similar to those found in Round 1.

Did not complete Round 1

The overall detection rate per 1,000 screened for adenoma was 36.7, advanced adenoma was 15.4 and cancer was 3.5.

Participants aged 70–74 years were more likely to have an adenoma or cancer detected as those aged 50–54 years.

Males were more likely to have an adenoma or advanced adenoma detected than females.

Males aged 55–59 years were more likely to have an advanced adenoma detected than females of the same age.

Asians were less likely to have an adenoma detected than European/Other.

Māori males were more likely to have an adenoma detected than European/Other males.

Asian and Pacific participants were less likely to have an advanced adenoma detected than European/Other participants.

Participants from quintile area NZDep Index 7–8 were more likely to have an adenoma or advanced adenoma detected than those from the least deprived quintile area (NZDep Index 1–2).

Trends by age, sex, Asian and Māori ethnicity for adenoma were similar to those found in Round 1.

Not invited in Round 1

The overall detection rate per 1,000 screened for adenoma was 21.9, advanced adenoma was 8.1 and cancer was 1.3.

Adenoma detection rates increased with increasing age from 60-64 years.

Participants aged 70–74 years were more likely to have an adenoma or cancer detected than 50–54-year-old participants.

Males were more likely to have an adenoma or advanced adenoma detected than females.

Males in every age group were more likely to have an adenoma detected than their 50–54-year-old counterparts.

Māori aged 60–69 years were more likely to have an adenoma detected than their European/Other counterparts. This was also found in Round 1.

Trends by age and sex were similar to those found in Round 1.

The BSP detection rate in Round 1 for adenoma (3.9%) is above the range (1.33–2.23%), and for cancer (0.3%) is towards the lower end of the range (0.18–0.95%) reported in the first screening round of population-based programmes that use the iFOBT (Moss et al 2010).

The BSP markedly exceeds the UK minimum standard and target: having an adenoma detected in at least six and seven participants, respectively, per 1,000 screened by faecal occult blood test (Chilton and Rutter 2011). This is not surprising as the UK programme uses the guaiac FOBT which is less sensitive than the iFOBT.

The BSP meets the UK target of having cancer detected in at least two participants per 1,000 screened (Chilton and Rutter 2011).

3.5 Colorectal cancer

Round 1

Two hundred and twelve participants had cancer detected (3.1 per 1,000 screened; 174.4 per 100,000 invited) –178 were European/Other, 25 were Asian, five were Pacific people and four were Māori.

Colorectal cancer increased with increasing age.

Males were more likely to have cancer than females.

Males aged 60–64, 65–69 and 70–74 years were more likely to have cancer than 50–54-year-old males.

Females aged 65–69 and 70–74 years were more likely to have cancer than 50–54-year-old females.

The extent of spread of a cancer is known as its stage. There are various staging systems and the BSP has adopted Tumour/Node/Metastasis (TNM) staging. The staging ranges from Stage 1, the least advanced, to Stage 4, the most advanced.

Most cancers were Stage I (74.0 per 100,000 invited), followed by Stage II (40.3 per 100,000 invited), Stage III (36.2 per 100,000 invited) and Stage IV (14.0 per 100,000 invited).

About 42% (n=90) of those participants with cancer detected had Stage I (i.e., confined to the bowel inner lining or muscle wall) and eight percent (n=17) had Stage IV (i.e., spread to a distant part of the body).

Twelve (5.7%) cancers were not staged.

Round 2

There were 53 cancers detected in the first year of Round 2.

Completed Round 1, negative iFOBT

Twenty-seven participants had cancer detected (1.3 per 1,000 screened; 110.1 per 100,000 invited): 24 were European/Other, one was Asian and two were Māori.

Nine cancers were Stage I (36.7 per 100,000 invited), three were Stage II (12.2 per 100,000 invited), nine were Stage III (36.7 per 100,000 invited), and one was Stage IV (4.1 per 100,000 invited).

Five (18.5%) cancers were not staged.

Did not complete Round 1

Seventeen participants had cancer detected (3.5 per 1,000 screened; 81.9 per 100,000 invited). This is similar to the cancer detection rate found for Round 1 (3.1 per 1,000 screened). Nine were European/Other, two were Asian, two were Māori and three were Pacific people.³⁷

There were five Stage I and five Stage II cancers (24.1 per 100,000 invited), followed by four Stage III cancers (19.3 per 100,000 invited) and one Stage IV cancer (4.8 per 100,000 invited).

Not invited in Round 1

Nine participants had cancer detected (1.3 per 1,000 screened; 52.4 per 100,000 invited) – six were European/Other and three were Asian.

Five of the nine cancers were detected in the 50–59 years age group.

There were six Stage I (34.9 per 100,000 invited), one Stage II (5.8 per 100,000 invited) and two Stage IV cancers (11.6 per 100,000 invited).

³⁷ Ethnicity was unknown for one participant.

3.6 Colonoscopy completion

Colonoscopy was incomplete³⁸ in less than one percent of cases in both rounds.

3.7 Adverse events

About one percent of colonoscopies in both rounds resulted in readmission, comprising 49 in Round 1 and 15 in the first year of Round 2. Ninety-two percent of readmissions occurred in participants whose colonoscopy included tissue removal.³⁹

In Round 1, the most common cause for readmission was bleeding. The bleeding rate was 7.9 per 1,000 colonoscopies with tissue removal (6.0 per 1,000 total completed colonoscopies).

The perforation rate was 1.2 per 1,000 colonoscopies with tissue removal and 0.9 per 1,000 colonoscopies without tissue removal (1.1 per 1,000 total completed colonoscopies).

The rate for all other complications was 3.8 per 1,000 total completed colonoscopies.

In Round 2, the most common causes for readmission were reasons other than perforation or bleeding. The rate for all other complications was 5.2 per 1,000 total completed colonoscopies.

The bleeding rate was 5.3 per 1,000 colonoscopies with tissue removal (3.9 per 1,000 total completed colonoscopies).

The perforation rate was 0.9 per 1,000 colonoscopies with tissue removal (0.6 per 1,000 total completed colonoscopies).

There was no significant difference between the bleeding and perforation rates from colonoscopies with tissue removal between the two rounds.

Different definitions for adverse events, particularly for bleeding and follow up periods, make direct comparisons with other reported data difficult.

Although the BSP slightly exceeded the UK standard for perforation (less than one in 1,000 colonoscopies) in Round 1, it met the UK standard for perforation of less than one in 500 colonoscopies involving polypectomy. Both standards were met in Round 2. The BSP also met the UK standard of having bleeding in less than one in 100 colonoscopies involving polypectomy (Chilton and Rutter 2011).

³⁸ Incomplete colonoscopy refers to a colonoscopy that does not evaluate the entire colon. Reasons include poor bowel preparation and the individual's general health status. It is possible that the BSP Register has not completely captured these data.

³⁹ Tissue removal refers to biopsy and polypectomy.

3.8 Conclusion

The results provide information for predicting participation in prevalence and incidence rounds of a national bowel cancer screening programme and for targeting resources to increase iFOBT uptake where it is low.

The Ministry of Health's uptake target was 60% by the end of the four-year BSP. The target was met in Round 1 for European/Other females over 55 years and European/Other males over 60 years, Asian females and males aged 70–74 years, and Māori females aged 70–74 years and Māori males over 65 years. Participation for all age and ethnic groups for both females and males was above 60% among those who completed incidence screening in Round 2.

Participation was highest among European/Other, followed by Asians, Māori and Pacific people. The pattern was the same in both rounds. Although Pacific participation was significantly higher in Round 2, the participation of European/Other and Asians significantly decreased in Round 2. For Māori, it was similar in both rounds.

Participation in Round 2 was statistically significantly lower than in Round 1. Within Round 2 participation varied depending on the screening history of the invited population. Those who had previously participated had a high level of participation in marked contrast to those who had previously not responded or not successfully completed the test kit (82.4% versus 23.5%).

Of concern is the statistically significant decrease in first time participation, from the first round to the second. This highlights the challenge of maintaining a satisfactory level of iFOBT uptake over time.

Excluding the group who participated in incidence screening, the low uptake groups were the same in both rounds: younger age groups, males, the more deprived, Māori and Pacific people.

Overall, males participated slightly less than females. The statistically significantly lower participation of Māori females compared to Māori males in Round 1, and the absence of a sex difference in participation in both rounds for Asians and Pacific people, and Māori in Round 2 were all unexpected. Females are generally better informed than males about the benefits of screening as they are targeted by the national cervical and breast cancer screening programmes.

Males were more likely to have an adenoma, advanced adenoma or cancer detected than females in Round 1. They were also more likely to have an adenoma or advanced adenoma detected in incidence screening than females.

Irrespective of age, sex or ethnicity, adenoma, advanced adenoma and cancer increased with increasing deprivation in Round 1 and in one or both of the two most deprived quintile areas in Round 2.

Positivity, PPVs and detection rates for adenoma and colorectal cancer were all lower in Round 2 than in Round 1. This is not unexpected as 62.8% of participants who successfully completed an iFOBT kit in Round 2 had been previously screened.

The detection rates and PPVs in the Round 2 group who did not complete Round 1 are similar to those in Round 1, highlighting the importance of continuing to invite non-responders and those who do not successfully complete a test kit.

Controlling for age, sex and deprivation, there is evidence that Māori have more neoplasia⁴⁰ than European/Other participants. Māori were more likely to have a positive iFOBT result and adenoma detected than European/Other in both prevalence and incidence screening rounds. Māori aged 60–69 years were more likely to have an adenoma detected in prevalence screening⁴¹ than their European/Other counterparts, irrespective of sex and deprivation.

The stage distribution of screen-detected cancers is an important indicator of a screening programme's performance. In incidence screening, the proportion in Stage I is expected to rise and to fall in Stage IV, as cancer is detected earlier. For the first year of Round 2, the number of incident cancers was small and there was no clear decreasing pattern as a third of cancers were Stage III. However, not all cancers were staged.⁴²

Non-completion of colonoscopy and post-colonoscopy readmissions were low as was CT colonography uptake as an alternative to colonoscopy.

The occurrence of interval cancers⁴³ gives an estimate of the iFOBT's sensitivity⁴⁴ in the first round. Sensitivity was not calculated as data were available only for the first year of Round 2. It is recommended that sensitivity and specificity⁴⁵ are estimated after at least six months has passed since the end of Round 2 invitations.

If a national bowel cancer screening programme is implemented it will be important to closely monitor uptake (particularly in the low uptake groups), positivity, PPVs and detection rates, and adverse events. In the short term staging distribution of screen-detected cancers can be used to monitor effectiveness until sufficient data exist to evaluate the programme's impact on colorectal cancer incidence and mortality.

⁴⁰ Neoplasia refers to adenomas (including advanced adenomas) and colorectal cancer.

⁴¹ Round 1 and the Round 2 group who were not invited in Round 1.

⁴² Five cancers were not staged. However, in one instance there may have been insufficient time by the date of data extraction from the Register for surgery and staging to have occurred.

⁴³ Interval cancers are cancers that are diagnosed between the first and second round of screening among people with a negative iFOBT, or positive iFOBT and normal colonoscopy, in the first round.

⁴⁴ Sensitivity is the ability of a test to correctly identify those with disease. A test with high sensitivity will rarely miss those with disease (i.e. have a false negative result).

⁴⁵ Specificity is the ability of a test to correctly identify those without disease.

4. Economic efficiency

Evaluation aim addressed in this section

Economic efficiency: Can a national bowel screening programme be delivered in an economically efficient manner?

4.1 Two aspects of economic efficiency

Two aspects of economic efficiency were considered. The first aspect is whether the programme of screening as implemented in the New Zealand pilot is cost effective. The second is the absolute cost and resources implied by a national implementation of the programme, and particularly the requirement to provide colonoscopies for both screening and ongoing surveillance.

4.3 Summary of cost of screening results

The first component is an analysis of the costs of the BSP as implemented by WDHB. In undertaking this costing analysis, we sought to:

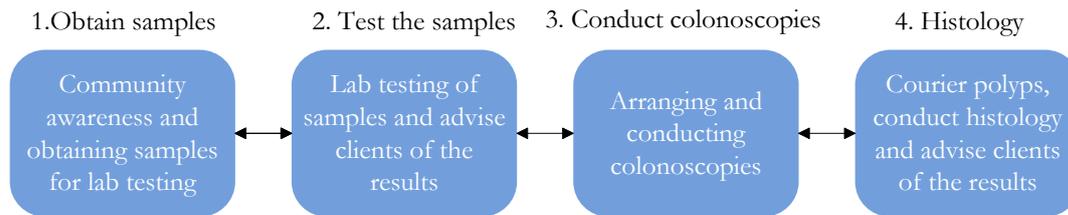
- develop understanding of the nature and quantum of costs associated with the design, implementation and operation of the pilot to date;
- estimate the total cost of the BSP for two full screening rounds (years 1–4); and
- use the results to extrapolate high level estimates of the:
 - ongoing cost of running a bowel screening programme in WDHB; and
 - potential ‘steady state’ cost of operating a bowel screening programme on a national basis.

It is also important to note that the nature of a pilot is that it is continually developing and improving its activity. This means that results calculated over the lifetime of the pilot so far are to some extent based upon a moving target, and it is expected that epidemiological and cost results, in particular, will continue to evolve as the pilot continues.

The model developed to support our analysis involves three key analytical steps. Step one uses data relating to costs incurred over two sample periods (July to December 2012 and January to June 2013) to assess the cost of developing and running the pilot during the first two years. In step two, these costs are used to estimate the total cost of developing and running the pilot for the full four years. Step three estimates the direct costs of running a national screening programme in a ‘steady state’. Estimates do not include development/start-up costs such as workforce development or capital purchases.

Cost of screening in the pilot

The pilot screening pathway has four stages, as shown in Figure 5 below.

Figure 5: Four high-level stages of the screening pathway

Stage three, conducting colonoscopies, absorbs the greatest proportion of resources: █████ S9(2)(i)% of the annual operating cost of the pilot (note that this cost includes overheads assigned to this stage of the pathway, as well as the direct costs of conducting colonoscopies).

The unit cost for particular ‘process outcomes’ have been developed by dividing the annual operating cost for each stage by a key process outcome measure. These unit costs are estimated as follows:

- Average cost of returning a sample to the laboratory – \$████ S9(2)(i) per person, of which \$████ S9(2)(i) per person relates to promotion, outreach and targeted support efforts and \$████ S9(2)(i) per person to mail-outs and sample collection activities;
- Laboratory testing of iFOBt kits (including notification of results) – \$████ S9(2)(i) per sample;
- Average cost of colonoscopy – \$████ S9(2)(i) per person;
- Average cost of histology tests following colonoscopy – \$████ S9(2)(i) per person.

The operating costs for stages one and two were combined and divided by the number of people returning a kit for testing to derive a cost per participant screened of \$████ S9(2)(i). In addition, we derived a cost per participant receiving investigation of \$1,268.76 by combining operating costs for stages 3 and 4 and dividing by the number of colonoscopies conducted (acknowledging that most of these participants go on to have histology).

Across Rounds 1 and 2, the average operating cost (excluding development costs) for key screening outcomes varied in the following ways:

- \$82,100 per person with a cancer detected in Round 1 and \$100,600 in Round 2;
- \$5,600 per person with a lesion detected (adenomas and cancers) in Round 1 and \$5,400 in Round 2.

Note that screening for colorectal cancer includes removing premalignant lesions (adenomas) during the colonoscopy. These adenomas thus never present as cancers, meaning that the incidence of colorectal cancer declines with screening. For this reason, it is important to present the cost of screening per lesion (adenoma and cancer) detected as well as per cancer. These costs exclude cost of surveillance, for example the cost of follow up colonoscopies for those at increased risk of bowel cancer.

The cost per person with a cancer or lesion detected will decrease if participation increases. This reduction is due to some costs, such as promotion, being fixed regardless of the number of people participating. A 6% increase in participation is estimated to result in a 3.5%

increase in total cost, that is the additional participants cost about half the average cost of participants in the base case scenario.

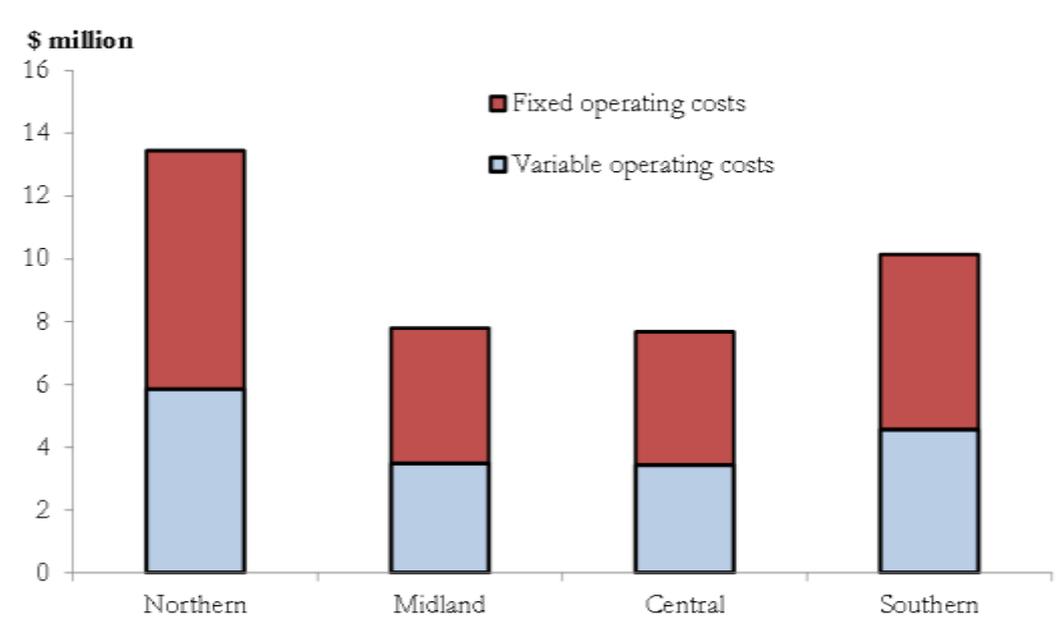
Estimated costs of a national screening programme

In estimating the costs of a national bowel screening programme, this analysis only considered the direct costs of a national screening programme in a 'steady state'. Estimates do not include development/start-up costs such as workforce development or capital purchases. Ministry of Health oversight and governance costs are not included.

There are a number of assumptions, including that the pilot model design is replicated and that all key parameters remain the same. It is assumed that the current models for laboratory services, the coordination centre and the IT register are scaled up to manage the increased volumes required for a national programme. It is also assumed that colonoscopy services will be provided by salaried and contracted colonoscopists, in the same proportion as services provided to the pilot in the second half of year two (July to December 2013).

The annual operating cost of a national screening programme in steady state, excluding development costs and Ministry of Health oversight is estimated at \$39.073 million. This is 7.8 times higher than our estimate of the annual operating cost of \$5.010 million for the pilot in Year 4. Figure 6 shows the estimates for the variable and fixed components of the screening programme for the four regions across New Zealand.

Figure 6: Regional breakdown of screening programme costs



The results of sensitivity testing undertaken suggest a plausible range for the annual operating cost of a national screening programme in steady state as being between \$26.531 million and \$50.623 million (with the base case estimate at \$39.073 million).

4.2 Sources of data and assumptions

The information for our analysis comes from the following sources:

- Existing burden of bowel cancer – Natural history model (MoDCONZ microsimulation)
- Eligible population, e.g. what age group is invited to screening (pilot and the Ministry)
- Participation rates (pilot)
- Performance of iFOBT in detecting adenomas and cancers
 - Sensitivity and specificity (international studies)
 - Different cut-off values (pilot)
- Colonoscopy outcomes
 - Attendance (pilot)
 - Adverse events (international studies and pilot)
 - Sensitivity (international studies)
- Treatment and follow up
 - Health outcomes (MoDCONZ microsimulation)
 - Cost impact (NZ cost data sets, analysed by BODE3 research team).

Table 7 summarises the values and ranges of the key parameters used in the analysis.

Table 7: Cost-effectiveness assumptions

| Parameter | Mean (95% CI) |
|--|---------------------------------|
| Screening | |
| Proportion invited | 96% (94–98%) |
| iFOBT participation, new to screening | Age dependent range: 43% to 70% |
| iFOBT participation, participated in previous round | Age dependent range: 65% to 95% |
| iFOBT participation, did not participate in previous round | Age dependent range: 18% to 30% |
| iFOBT sensitivity adenoma < 10mm | 7.7% (7.1–8.4%) |
| iFOBT sensitivity adenoma ≥ 10mm | 25.2% (22.2–28.2%) |
| iFOBT sensitivity Stage I & II cancer | 59.7% (27–92.5%) |
| iFOBT sensitivity Stage III & IV cancer | 85.9% (67.4–100%) |
| iFOBT specificity | 94.7% (94.4–95%) |
| Rate of successful colonoscopy | 92.5% (90–95%) |
| Colonoscopy specificity | 100% |
| Colonoscopy sensitivity: adenoma <10mm | 76% (72–81%) |
| Colonoscopy sensitivity: adenoma ≥ 10mm | 98% (92–99%) |
| Colonoscopy sensitivity: cancer | 98% (92–99%) |

| | |
|--|---------------------------------|
| Colonoscopy: probability of complication resulting in re-admission | 1% (0.9–1.1%) |
| Quality of life | |
| No diagnoses bowel cancer | 0.792 (0.713–0.870) |
| Initial phase (first year following diagnosis) | |
| Stage I | 0.74 (0.69–0.78) |
| Stage II | 0.70 (0.65–0.75) |
| Stage III | 0.50 (0.44–0.56) |
| Stage IV | 0.25 (0.20–0.31) |
| Continuing care phase | 0.792 (0.713–0.870) |
| Terminal phase – cancer (last year of life) | 0.25 (0.20–0.31) |
| Cost of treating cancer (unweighted average by stage) | |
| Treatment cost: Stage I | \$44,849 |
| Treatment cost: Stage II | \$68,917 |
| Treatment cost: Stage III | \$86,759 |
| Treatment cost: Stage IV | \$54,054 |
| Cost of screening | |
| Eligible to receive a mail-out | \$ [REDACTED] S9(2)(i) |
| Return iFOBT – negative results | \$ [REDACTED] S9(2)(i) |
| Return iFOBT – positive results | \$ [REDACTED] S9(2)(i) |
| Colonoscopy – mode weighted average | \$754.92 (\$639.12 – \$813.08) |
| Histology of samples collected at colonoscopy | \$937.14 (\$793.38 – \$1009.34) |
| Re-admission following colonoscopy | \$5,172 (\$4,655 – \$5,689) |

4.4 Summary of cost-effectiveness results: total population

If bowel cancer screening was rolled out nationally in New Zealand in the same way that it was undertaken in the pilot, it is estimated to dominate no screening – be cost saving with QALY gains. The comparison of the outcomes for screening and no screening is presented in Table 8.

The best estimate of the cost per QALY for this scenario is $-\$1,344$ – be cost saving with health benefits. Since the interpretation of a negative cost per QALY is ambiguous, for interpretation, this is presented as a dominant result, which is preferable to any other state which has a positive cost per QALY.

There is some uncertainty in the result: the cost per QALY is estimated to fall in the range of $-\$5,786$ to $\$4,850$ with 95% confidence.

Table 8: Cost-effectiveness results for pilot screening parameters – whole population

| Treatment | Costs | QALYs | Incremental | | Cost per QALY (95%CI) |
|--------------|---------|--------|----------------------|-------------------|--|
| | | | Costs (95% CI) | QALYs (95%CI) | |
| No screening | \$2,643 | 17.661 | -\$98 | 0.0730 | Dominates* ($-\$5,786 - \$4,850$) |
| Screening | \$2,544 | 17.734 | ($-\$627 - \219) | (0.0451 – 0.1084) | |

Table 9 summarises the cost-effectiveness results for the pilot configuration of screening, and a number of alternative scenarios.

- Table 9 is sorted in order of decreasing cost effectiveness, indicated by the average cost per average QALY column.
- The base scenario implemented in the pilot, is indicated by the highlighted row.
- Alternative scenarios considered here vary the hypothetical implementation of screening with differing participation rates (varying from 50% to 100%), and differing cut-offs for the iFOBT test. The base case cut-off is 75ng. Alternative scenarios range up to a cut-off of 250ng. We have explored scenarios for different age bands for the invited population.

All of the scenarios resulted in similar cost-effectiveness results. The best estimate of each scenario falls within the estimated cost-effectiveness range of the base scenario which reflects the pilot implementation of screening. The range of uncertainty in the estimate is much larger than the range of differences between the point best estimates, suggesting that there is little measurable difference in cost effectiveness across the different scenarios.

Table 9: Cost effectiveness for different implementation scenarios

| Screening age band | Participation rate | iFOBT cutoff (ng) | Avoided cancers | Avoided deaths | Incremental Cost | Incremental QALY | Incremental Cost per QALY - best estimate |
|--------------------|--------------------|-------------------|-----------------|----------------|------------------|------------------|---|
| 50-74 | 100% | 75 | 2,663 | 1,408 | -\$280 | 0.0827 | Dominates |
| 50-74 | 80% | 75 | 2,284 | 1,237 | -\$219 | 0.0786 | Dominates |
| 60-74 | 56% | 75 | 1,396 | 905 | -\$166 | 0.0690 | Dominates |
| 55-74 | 56% | 75 | 1,636 | 974 | -\$158 | 0.0717 | Dominates |
| 50-69 | 56% | 75 | 1,480 | 839 | -\$135 | 0.0701 | Dominates |
| 60-69 | 56% | 75 | 859 | 605 | -\$122 | 0.0631 | Dominates |
| 65-74 | 56% | 75 | 878 | 706 | -\$104 | 0.0626 | Dominates |
| 50-74 | 56% | 75 | 1,738 | 980 | -\$98 | 0.0730 | Dominates |
| 50-74 | 56% | 100 | 1,632 | 941 | -\$79 | 0.0719 | Dominates |
| 50-74 | 50% | 75 | 1,578 | 905 | -\$64 | 0.0713 | Dominates |
| 50-59 | 56% | 75 | 522 | 336 | -\$38 | 0.0607 | Dominates |
| 50-74 | 56% | 150 | 1,412 | 849 | -\$29 | 0.0696 | Dominates |
| 50-74 | 56% | 200 | 1,263 | 794 | \$11 | 0.0681 | \$164 |
| 50-74 | 56% | 250 | 1,159 | 747 | \$34 | 0.0671 | \$511 |

Key elements of these results are:

- In absolute terms, screening dominates non-screening for most scenarios. This means that bowel screening is cost saving in absolute terms, while still bringing health benefits. This result is driven by the savings from avoided costs of treating cancer being large enough to outweigh the costs of screening. This makes bowel screening an exceptionally cost effective health intervention, given that it both reduces health costs and produces benefits for the population. But even for those scenarios where there is a positive incremental cost per QALY, the cost is low. Compared to average levels of cost per QALY funded by PHARMAC in the range of \$16,000 to \$45,000, a cost-effectiveness result of less than \$1,000 per QALY makes bowel screening highly cost effective compared to many other health interventions.
- Narrowing age bands for the eligible population improves the nominal cost effectiveness of the programme, although it decreases the absolute effectiveness across the population. This is because a narrower age band results in fewer screening episodes per person (reducing the cost of screening). Under this scenario the reduced cost of screening outweighs the reduced benefit of the programme, although in absolute terms fewer cancers and cancer deaths are avoided.
- The impact of age bands upon overall cost effectiveness dominates the other variables we have explored in these scenarios.
- Increasing the participation rate improves the cost effectiveness. A higher participation rate results in increased net savings and increased QALY gains. Although the cost of screening increases with increased participation rates, the cost-offsets increase at a greater rate which leads to an increase in net savings.
- A lower iFOBT cut-off is more cost effective than a high cut-off. This is driven by the high avoided cost of cancers, where a higher cut-off leads to fewer avoided cancers and therefore smaller gains, which outweigh the decreased cost of colonoscopy as the cut-off rises.

Figure 7 shows the reduction in people with cancer by age of diagnosis under the screening parameters as implemented in the pilot. There is a bolus effect at the time that screening is begun (age 50), with an increased number of cases diagnosed compared to a base scenario with no screening.

Figure 7: Diagnoses of cancers by age of diagnosis, cohort followed to age 84, whole population

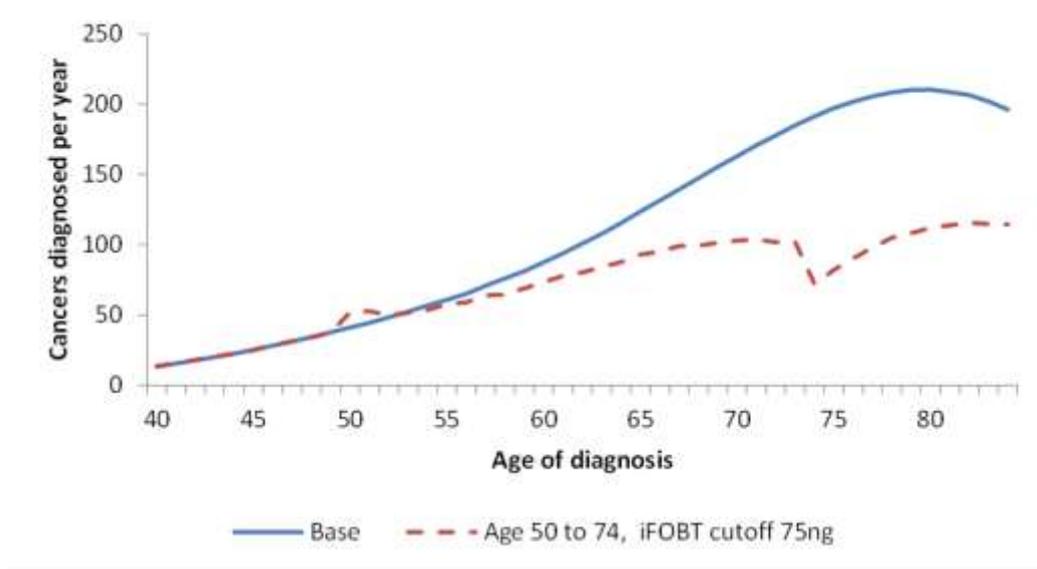
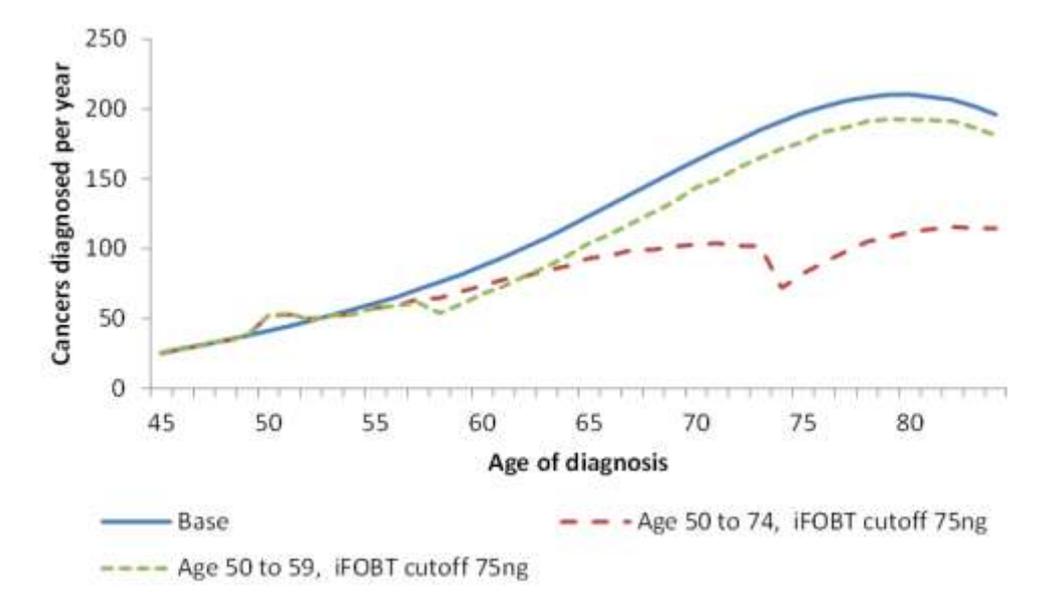


Figure 8 summarises the reduction in cancer achieved with different age groups invited to screening. While the cost effectiveness of using narrower age bands is generally improved, the absolute impact of using narrower bands is decreased, as fewer cancers are avoided across the population. The top line represents the number of cancers diagnosed without screening, by age. The lower lines represent the number of cancers with screening, with the 50–74 scenario represented by the lower line due to the greater reduction in cancers.

Figure 8: Diagnoses of cancers by age of diagnosis, cohort followed to age 84, comparing different age bands, whole population



4.5 Summary of cost-effectiveness results: Māori

The microsimulation model was calibrated separately to the Māori population, to enable subgroup analysis of the effectiveness and cost effectiveness of screening for Māori; that is to estimate Māori specific rate of bowel cancer and bowel cancer mortality. All other parameters are the same – same per event costs and same participation as for the whole population model.

The tables below summarise the cost effectiveness of the same range of scenarios analysed above, for the Māori population, and give further details for the base case as implemented in the pilot. While the broad patterns of cost effectiveness are the same for Māori as for the whole population, the level of cost effectiveness has decreased slightly, with fewer scenarios being cost saving. The difference of \$1,697 in cost effectiveness for Māori compared to the whole population in the base scenario implemented in the pilot is a small one, in the context of cost effectiveness results for health interventions more generally.

Table 10: Cost-effectiveness results for pilot screening parameters – Māori population

| Treatment | Costs | QALYs | Incremental | | Cost per QALY (95%CI) |
|--------------|---------|--------|------------------|-------------------|-----------------------|
| | | | Costs (95% CI) | QALYs (95%CI) | |
| No screening | \$2,233 | 16.901 | \$29 | 0.0759 | \$381 |
| Screening | \$2,262 | 16.977 | (-\$430 – \$307) | (0.0463 – 0.1142) | (-\$3,762 – \$6,288) |

Table 11: Cost effectiveness for different scenarios – Māori population

| Screening age band | Participation rate | iFOBT cutoff (ng) | Avoided cancers | Avoided deaths | Incremental Cost | Incremental QALY | Incremental Cost per QALY - best estimate |
|--------------------|--------------------|-------------------|-----------------|----------------|------------------|------------------|---|
| 50-74 | 100% | 75 | 263 | 183 | -\$83 | 0.0849 | Dominates |
| 60-74 | 56% | 75 | 135 | 112 | -\$64 | 0.0708 | Dominates |
| 60-69 | 56% | 75 | 83 | 75 | -\$53 | 0.0656 | Dominates |
| 50-74 | 80% | 75 | 224 | 159 | -\$46 | 0.0810 | Dominates |
| 65-74 | 56% | 75 | 83 | 84 | -\$38 | 0.0632 | Dominates |
| 55-74 | 56% | 75 | 160 | 123 | -\$36 | 0.0746 | Dominates |
| 50-69 | 56% | 75 | 145 | 107 | -\$12 | 0.0735 | Dominates |
| 50-59 | 56% | 75 | 53 | 44 | \$11 | 0.0652 | \$164 |
| 50-74 | 56% | 75 | 171 | 126 | \$29 | 0.0759 | \$381 |
| 50-74 | 56% | 100 | 160 | 119 | \$38 | 0.0748 | \$514 |
| 50-74 | 50% | 75 | 154 | 116 | \$53 | 0.0743 | \$718 |
| 50-74 | 56% | 150 | 138 | 107 | \$79 | 0.0727 | \$1,086 |
| 50-74 | 56% | 200 | 123 | 100 | \$108 | 0.0715 | \$1,511 |
| 50-74 | 56% | 250 | 114 | 93 | \$124 | 0.0703 | \$1,760 |

4.7 Sensitivity of results to key parameters

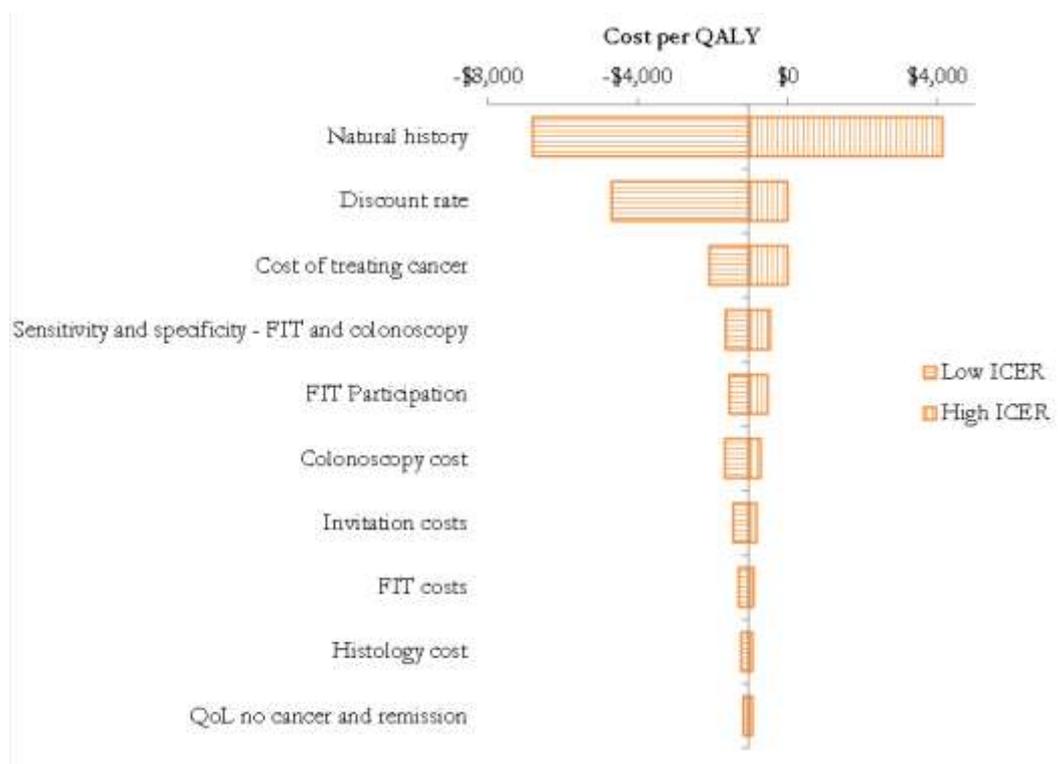
The analysis explored the impact of variation in key parameters within our model upon the overall result using univariate sensitivity analysis and probabilistic sensitivity analysis.

The univariate sensitivity analysis demonstrates that only three variables appear to have any potential for material impact upon the overall cost-effectiveness result:

- Natural history (prevalence of bowel cancer generated within MoDCONZ)
- Discount rate; and
- Cost of cancer.

Even these results have a relatively small impact. The variable which has the greatest effect, Natural History, in the worst case still only increases the incremental cost per QALY to a value of \$4,138, which we consider to be very cost effective. The results of the sensitivity analysis can be seen in the tornado diagram below.

Figure 9: Univariate sensitivity analysis – Tornado diagram



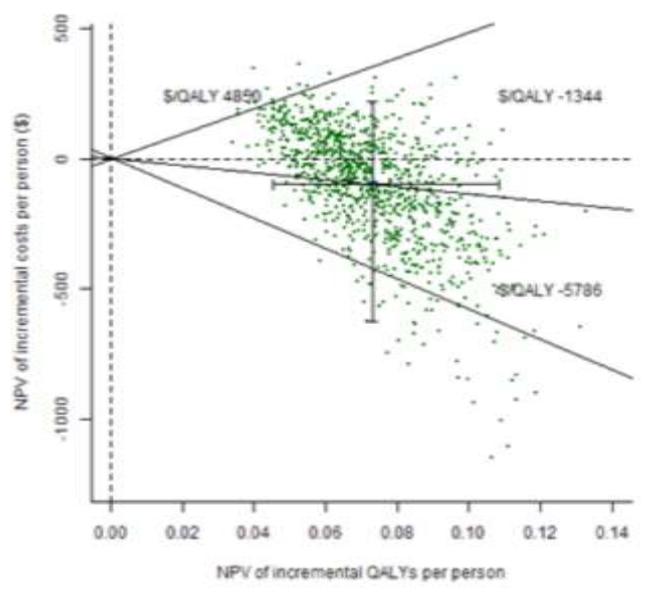
Probabilistic sensitivity analysis was used to estimate the range of the cost per QALY due to parameter uncertainty. This analysis provides us with 1,000 results, with each representing the estimated cost per QALY for the modelled cohort. Each result is based on different values used for each of the parameters.

The 95% confidence interval is cost saving –\$5,786 to \$4,850 per QALY. These values are represented by the lower and upper diagonal lines in Figure 10. The 95% confidence

interval for the net cost of screening per eligible person represented by the vertical error bars is $-\$627$ to $\$297$. The 95% confidence interval for the QALYs gained per eligible person represented by the horizontal error bars is 0.0451 to 0.1084

All of the simulations estimated a positive QALY gain. Sixty-three percent of simulations were cost saving and the remaining 37% had a positive cost; that is in approximately two thirds of the simulations bowel cancer is estimated to be cost saving with QALY gains for the New Zealand population.

Figure 10: Probabilistic sensitivity analysis – pilot base scenario



4.8 Conclusion

A national bowel cancer screening programme could be delivered in an economically efficient manner in New Zealand. Different screening scenarios are all highly cost effective both for the whole population and for Māori, and in some cases were cost saving.

While bowel cancer screening results in cost savings from reduced treatment of bowel cancer, there also are significant resource requirements, particularly in the capacity to provide colonoscopy for those with a positive iFOBT and for those referred for surveillance. These requirements may pose a constraint on how a national programme may be delivered. The policy and clinical decisions involved in planning an implementation of bowel screening will need to trade off cost effectiveness against the sensitivity, specificity and positive predictive value which can reasonably be achieved and supported in a live screening programme on a national basis in absolute resource terms, as well as in effectiveness terms.

5. Equity

Evaluation aim addressed in this section

Equity: Can a national bowel screening programme be delivered in a manner that eliminates (or does not increase) current inequalities between population groups?

5.1 Existing inequities in colorectal cancer

Equity and access is one of the four dimensions of quality in a screening programme (National Screening Unit 2005). The other dimensions of quality are efficiency and effectiveness (refer section 4) and safety (refer section 6). Equity and access is defined as the extent to which people are able to receive a service on the basis of need, mindful of socio-economic factors, ethnicity, age, impairment or gender (National Screening Unit 2005 p.10). Screening programmes should apply the Treaty of Waitangi principles of partnership, protection and participation to ensure that quality standards and activities are explicitly responsive to the specific needs of Māori to reduce inequalities in outcomes (National Screening Unit 2005).

New Zealand has one of the highest bowel cancer rates in the world (National Bowel Cancer Tumour Standards Working Group 2013). For Māori men, bowel cancer is the second most common cause of death from cancer, and third for Māori women (Ministry of Health 2015). Among Māori, bowel cancer diagnosis rates are increasing with the fastest rate of increase among Māori males (National Bowel Cancer Tumour Standards Working Group 2013). Hill et al (2012) note that Māori have poorer survival than other ethnic groups for most types of cancer, including colo-rectum.⁴⁶ Reasons given for poorer survival rates are Māori patients are more likely to be diagnosed with late-stage disease for colorectal cancer⁴⁷ and have higher prevalence of diabetes, cardiovascular and respiratory disease.⁴⁸ Reasons for higher co-morbidity in Indigenous peoples include greater socio-economic deprivation, poorer access to favourable determinants of health, and historical disadvantage through colonisation.⁴⁹ Māori also experience barriers to accessing diagnostic cancer services,⁵⁰ and effective and timely cancer care.⁵¹

Diabetes and obesity are associated with an increased risk for colorectal cancer. Despite a higher prevalence of these risk factors in Pacific people compared with European/Other, Pacific people in New Zealand have consistently had lower rates of colorectal cancer than European/Other. Colorectal cancer is relatively rare in people living in the Pacific Islands⁵² (Meredith et al 2012). However, Pacific people have poorer cancer survival compared with European patients, although their outcomes are better than those of Māori (Hill et al 2012). Meredith et al (2012 p.1182) conclude that Pacific people are facing a critical transition with a new emerging epidemic of cancer associated with diabetes, obesity and physical inactivity.

⁴⁶ Robson et al (2006), Sneyd (2008), Soeberg (2012) cited in Hill et al (2012).

⁴⁷ Robson et al (2006) cited in Hill et al (2012).

⁴⁸ Robson et al (2008) cited in Hill et al (2012).

⁴⁹ Robson et al (2008), Anderson et al (2006) cited in Hill et al (2012).

⁵⁰ Simmonds et al (2008), Taylor et al (2007), National Screening Unit (2005) cited in Hall et al (2012).

⁵¹ Simmonds et al (2008), Stevens et al (2008), Hill et al (2010) cited in Hall et al (2012).

⁵² Paksoy et al (1991), Maraka et al (2010) cited in Meredith et al (2012).

Hill et al (2012) state that inequalities in treatment and survival of Māori and non-Māori cancer patients may arise at three levels: differences in individual patient factors (e.g. existing co-morbidity), differences in health-care processes (e.g. access to diagnostic and treatment services), and differences in the function of the health system as a whole (e.g. location of services, costs and cultural focus of providers). Hill et al (2012) acknowledge that questioning the fairness of the health system is uncomfortable, especially given clinicians' focus on the principle of care based on need. However, it must be recognised that the health system does not provide equal cancer care for Māori and non-Māori, and that these inequities are not inevitable and can be addressed.

As evident, there are existing inequities in the access and treatment of colorectal cancer for Māori and Pacific people. Introducing the BSP created an opportunity to eliminate inequity through a structural and systematic focus on equity for Māori and Pacific people and other groups less likely to participate in bowel screening.

5.2 Inequitable participation in the BSP

In 2015, the interim BSP evaluation report highlighted that the BSP, as it was then being delivered, was increasing inequities for Māori and those people living in the most deprived areas due to their low participation and high disease burden. Pacific people had the lowest participation rates in Round 1, although their disease burden was lower.

After 36 months, patterns of inequitable participation continue. A number of challenges exist in delivering an equitable national bowel screening programme (Read et al 2016). Asian, Māori and Pacific people were all less likely to participate than European/Other people in both rounds. Participation in Round 2 was also lower than in Round 1. Within Round 2, participation varied depending on the screening history of the invited population with the highest participation among those who had completed Round 1 (Read et al 2016).

European/Other and Asian participation decreased from Round 1, and remained the same for Māori. While participation increased for Pacific people in Round 2, it was still low (36.7%). Participation also declined with increasing deprivation in both rounds (Read et al 2016). Controlling for age, sex and deprivation, there is evidence that Māori have more neoplasia than European/Other participants.

Screening Round 2 of the pilot was used to trial new initiatives to seek to increase participation by Māori and Pacific people. Towards the end of Round 2, the BSP Coordination Centre started to focus on people living in high deprivation areas through the active follow-up process. This equity section focuses on assessing the effect of new initiatives on enabling participation by Māori and Pacific people, and then considers the implications for a national bowel screening programme.

Note: More consistent implementation of the new initiatives occurred in 2015, which does not align with the cut-off period for the epidemiological analysis at 36 months. The impact of these initiatives on population level participation therefore cannot be assessed. However, it is possible to comment on their likely contribution to Māori and Pacific participation at an individual level.

5.3 Strengthening the focus on equity

The Ministry and WDHB, in the design and implementation stages of BSP, endeavoured to identify and implement strategies to try and ensure the BSP is delivered in a way that enables access for all with a particular focus on eligible Māori and Pacific people. However, feedback highlights that Māori and Pacific leaders could have been more involved in decision making during the design and early implementation of the BSP (Litmus et al 2015).

The Ministry established the Māori Expert Advisory Group to offer strategic advice on the development of the BSP on how to enhance the effectiveness of the screening pathway for Māori and ensure equity in the BSP. With the establishment of the national Bowel Cancer Working Group, the Māori Expert Advisory Group was disestablished. To ensure consistency and transfer of knowledge, a member of the Māori Expert Advisory Group is on the national Bowel Cancer Working Group. Some of Māori Expert Advisory Group's recommendations were incorporated into the design of the BSP. Advice from Pacific staff at the Ministry and WDHB was sought, on an as-needs-basis through the development and implementation of the BSP.

During the early implementation of the BSP in Round 1, Māori Expert Advisory Group's recommendation of a systematic and structural focus on equity for Māori and Pacific people was not consistently applied. In Round 1, a number of approaches were used to increase participation by Māori and Pacific people in the BSP but their application lacked consistency and resources. Further, the Register did not support active follow-up of non-responders. Towards the end of Round 1, there was evidence of inequities in uptake by eligible Māori and Pacific people, and those living in areas of high deprivation (Litmus et al 2015). The Bowel Screening Advisory Group held a forum to discuss equity in the BSP. As a result of this forum, a more systematic and structural approach was adopted to seek to address the emerging inequities.

Changes included the strengthening of Māori leadership, particularly including those with a depth of clinical, screening and community knowledge, and having representation on key governance groups. Pacific leadership was enhanced, but involvement was ad hoc due to the significant demands on their capacity. Focus was placed on system changes such as reducing the length of time between the pre-invitation letter and receiving the iFOBT kit from four to two weeks, introducing a more systematic and monitored active follow-up process, and reporting progress against KPIs to the WDHB Steering Group and the Ministry of Health on a monthly basis.

In 2013, WDHB's Kaitiaki Roopu was established to address the lack of robust Māori participation and partnership in the overall direction, design and governance of the BSP. The purpose of the Kaitiaki Roopu was to provide a Treaty of Waitangi based partnership and participation oversight to the WDHB BSP. Kaitiaki Roopu also provided guidance, support, advice and links into the Māori community serviced by the WDHB to ensure Māori make informed decisions about the BSP. In Round 2, the role of the Kaitiaki Roopu has waned and needs to be reviewed.

In Round 2, new initiatives were introduced including general practice initiatives, and trialling lab drop-off for completed iFOBT. Other initiatives continue to be explored for Round 3 including pay-for-performance, which is being discussed with PHOs and general practice. Using this approach, general practices will receive funding based on the demographic profile of who they supported to participate (e.g. by age, gender, ethnicity and

deprivation level), and more funding will be received for those known to be less likely to take part.

Feedback from key stakeholders highlights that towards the end of Round 2, there is increasing confidence that an equity focus is a more integral part of the BSP. However, much more work and focus is needed to address ongoing inequities of access for eligible Māori and Pacific people in the BSP.

5.4 Invitation to take part

To take part in the BSP, eligible Māori and Pacific people must receive the invitation letter and kit, open it and engage and understand the information and instructions, decide whether they want to take part and, if they decide to proceed, be able to do the test in their home environment. Taking part in the BSP therefore requires a level of literacy, self-efficacy and physical ability to open and use the small kit. As shown in a number of surveys, the BSP invitation letter and kit is a key source of information on bowel screening (Litmus 2014a, 2016).

In 2013, the BSP Coordination Centre, recognising the inequities emerging in participation, revised the pre-invitation letter, kit instructions and consent form to be more accessible to a wider range of literacy levels. These revised documents were introduced in January 2014 (Round 2). Revisions to the test kit instructions coincided with a notable decrease in the number of people who did not complete their kit correctly on their first attempt. In Round 1, approximately 14% were spoilt on the first attempt, and 6% in Round 2.⁵³ From the outset of the pilot, a basic information brochure was made available in a range of languages including Te Reo Māori, Samoan, Tongan, Korean, Chinese and English.

A review of the Register indicates that most but not all eligible participants are being invited to participate in the BSP (Lee 2014). There are known issues with the currency of addresses which is demonstrated by a return-to-sender rate of around 6% in Round 2 (refer section 6.1). The representation of eligible Māori and Pacific people in those who did not receive a letter is not known. The follow-up eligible BSP population survey (Litmus 2014a) found that 21% of eligible people at the end of Round 1 had not received an iFOBT kit. There was no statistically significant difference noted between Māori, Pacific people and the Other ethnic group on whether or not they had received an iFOBT kit at that stage (Litmus 2014a).

5.5 Awareness and knowledge of bowel cancer and screening

Feedback from those involved in active follow-up highlighted the importance of creating awareness and understanding about bowel cancer and bowel screening amongst the eligible population. Encouraging eligible participants to take part in bowel screening is challenging if they know nothing about bowel cancer and screening and the benefits of doing the test.

⁵³ <http://www.health.govt.nz/our-work/diseases-and-conditions/cancer-programme/bowel-cancer-programme/bowel-screening-pilot/bowel-screening-pilot-results> accessed 27 July 2016.

I find the best responses are when the person already knows what the BSP is. Awareness is really key to them being able to respond and be decisive. Otherwise, my conversations are about what a bowel is. If they already have an idea about what it is then they are more decisive and friendly. Otherwise, it is a mission just to explain why I'm calling and why they should care. (CAR)

The follow-up eligible BSP population survey found that Māori and Pacific people have lower awareness of bowel cancer risk factors, symptoms and bowel cancer tests including the iFOBT compared with non-Māori and non-Pacific people (Litmus 2014a). While awareness of the BSP has increased for eligible Māori and Pacific people since the launch of the BSP, it is not to the same level as non-Māori and non-Pacific people (Litmus 2014a).

The importance of understanding the risks of bowel cancer and the role of screening were further highlighted in a survey of Māori and Pacific non-responders who were contacted via active follow-up and went on to complete their kit (referred to as converted non-responders) (Litmus 2016). When asked unprompted their reasons for completing the iFOBT kit, Māori and Pacific converted non-responders most frequently mentioned doing it as a precautionary measure, that health checks are important, and wanting to know their bowel cancer status. When asked what had the greatest impact on their decision to act, Māori and Pacific converted non-responders mentioned their belief in health checks, followed by concerns about bowel cancer or cancer, and a family history of cancer.

Interviews with Māori non-responders (Litmus 2013) highlighted other barriers to taking part in bowel screening, including more pressing health issues (e.g. cancer or heart disease), poor previous experience of the health system, misinterpretation of their eligibility and dislike of handling faecal matter and mailing the iFOBT sample. Pacific non-responders also faced literacy and language barriers, and appeared to have more environmental barriers that impeded receiving their kit (Litmus 2013).

Supporting Māori and Pacific people to act requires an awareness of bowel cancer and its risks, and understanding of bowel screening. Building this awareness through a range of strategies, such as advertising, CAR and other health promotional activities, is important and enables active follow-up activities. It is also important to consider how to enhance the systems and processes of the BSP to overcome other barriers that stop Māori and Pacific people taking part. More research is needed to fully understand participation barriers for Māori and Pacific people and other low participation groups to inform effective system improvements.

5.6 Assessment of new initiatives to support participation

Strengthening active follow-up

The Register was not designed to capture data to support active follow-up of non-responders. In Round 1, active follow-up with Māori and Pacific non-responders was constrained by a lack of IT infrastructure to monitor and record activities, and limited data management capacity. In Round 2, the BSP Coordination Centre developed a stand-alone active follow-up database to monitor and report on these activities, and the data manager role was increased from 0.5FTE to full time.

In Round 2, active follow-up processes and procedures have also been reviewed and strengthened, and monitoring and reporting on their implementation is reported to WDHB Steering Group and the Ministry. Additional resources have been allocated to active follow-up both within the BSP Coordination Centre and through contracting two external Māori health and community providers as well as the ongoing contracts with two Pacific health and community providers (Litmus 2016).

External Māori and Pacific health and community providers have an important role in gaining access to and supporting people in their communities to act. The Māori and Pacific health and community providers are known and trusted in their community, can engage in face-to-face conversations and share their stories and experiences of bowel screening. The Māori and Pacific community providers noted the importance of training and regular refresher sessions, visiting the different providers on the screening pathway to be able to describe the process to non-responders, and having a Q&A and script developed for the active follow-up to ensure consistent messages. Non-clinicians found the Q&A and script useful in answering any difficult questions. The Māori community provider interviewed summarised their role as seeking to 'normalise bowel screening' (Litmus 2016).

In Round 2, the contract arrangement between the BSP Coordination Centre and external Māori and Pacific health and community providers moved to FTE-based contracts and not outputs (i.e. the number of CAR workshops held). The shift in the contracting model was welcomed by Māori and Pacific providers who can now flexibly deliver services in ways that best meet their community needs (Litmus 2016).

In Round 2, the processes for active follow-up are more clearly defined and monitored. In 2015, the KPI that 95% of Māori and Pacific non-responders on the active follow-up database receive a minimum of three phone call attempts within a month of referral, and at least one of the calls made outside office hours, was consistently achieved. In 2015, 59% of Māori and 54% of Pacific non-responders on the database were contacted through active follow-up, and about four in ten completed their kit. The estimated conversion rate for active follow-up is over 20% for both Māori and Pacific people; taking into account all attempts to contact, whether successful or not. In 2015, 686 out of 2,641 Māori non-responders on the active follow-up database went on to complete their iFOBT kit (26%), and 651 out of 3,010 Pacific people (22%).

At four weeks a reminder letter is also sent out. Consequently, it is not possible to ascertain whether the decision to act was due solely to the active follow-up activities or receiving a reminder letter.

There are three things: first, the message. People need to be informed; second, they need the resources to do it, so the kit is with them; the third is that they are supported. As soon as those things are out of sync... We come in right at the end with the support; if we are supporting them about a kit they never got and bowel screening, which they have never heard of then it is kind of backwards. As long as we have things in place so that they know what it is about, they have a kit, and then they will receive a call about it they can connect all the information. (CAR)

General practice initiatives

Overall, PHOs and general practices interviewed are positive and supportive of the BSP and a national bowel screening programme (Litmus 2016). In 2015, DRINFO and Patient Dashboard were updated to enable opportunistic and systematic patient reminders on completing their iFOBT kit via general practice. Awareness and use of these tools is high

for reminders for screening tests in general. However, they are less frequently used for bowel screening reminders (Litmus 2016).

A survey of general practices with access to Patient Dashboard and/or DRINFO in WDHB found (Litmus 2016):

- In those practices using Patient Dashboard, 71% stated that all clinical staff use it to remind patients to have screening tests (in general). Usage to remind about completing the bowel screening kit was lower with 52% of practices saying that all their clinical staff use it. 16% of practices said that none of their clinical staff use it.
- Strong agreement that Patient Dashboard is a useful tool to identify those who need to be reminded to do bowel screening test (88% strongly agree and agree). Patient Dashboard is also seen as an effective tool to remind Māori and Pacific patients to complete their test kit (79% and 83% strongly agree and agree, respectively).
- 96% were using DRINFO. Two thirds (64%) use DRINFO to remind patients to have their screening tests. In contrast, just over a third of practices interviewed (36%) use DRINFO to identify patients who have received and not completed their bowel screening kit. A third use DRINFO to send text or fax reminders to patients who have not completed their iFOBT kit (32%).

Using Patient Dashboard, general practice can fax the BSP Coordination Centre to send a replacement iFOBT kit to their patients. Between October 2014 and 31 January 2016, the BSP Coordination Centre received 1,622 fax requests from general practice to send out a replacement bowel screening kit to patients, and received back 888 completed iFOBT kits (a return rate of 55%). This demonstrates that general practice has an important role in supporting and increasing participation. Given this contribution, further work is needed to embed into general practice the use of Dashboard and DRINFO for bowel screening.

General practice has an important role in increasing participation in the BSP particularly for eligible Māori and Pacific people, and Others. General practice, when engaged, have a positive contribution of informing their patients about bowel cancer and bowel screening, encouraging the completion of iFOBT kits, informing of positive results, referring for colonoscopy, and supporting if cancer or other health issues are identified through the screening (Litmus 2016). This finding supports international research which also highlights the benefits of having general practice involvement in bowel screening.

Internationally, GP or physician involvement in bowel screening has been shown to have a positive impact on iFOBT screening of participants, although this is subject to high variability (Cole et al 2007, Federici et al 2006, Koo et al 2010, Power et al 2009). Research has found that receiving screening advice from a health care provider was most strongly associated with participation in bowel screening (Courtney et al 2013, Guessous et al 2010, Rees et al 2007, Subramanian et al 2004 as cited in Courtney et al 2013). Further, Duncan et al's (2012) research suggests that continued GP endorsement and family support are important in screening maintenance.

Triggers to action

The importance of multi-faceted and multi-disciplinary approaches to increasing participation for Māori and Pacific people was highlighted in the survey of Māori and Pacific non-responders at four weeks who are contacted via active follow-up and go on to complete their kit (referred to as converted non-responders) (Litmus 2016). The BSP reminder phone call, family/whānau reminders and text reminders from general practice were rated as

important in informing Māori and Pacific converted non-responders' decision to complete their iFOBT kit. Pacific non-responders also rated highly their discussions with general practice.

5.7 Equity along the screening pathway

Once on the screening pathway there is generally no evidence of inequities in service received, particularly in relation to accessing colonoscopy services. The exceptions are in Round 1 where Asian males were slightly less likely to have a colonoscopy than European/Other. In Round 2, in the incidence screening round (i.e. completed Round 1 negative iFOBT) Pacific participants were almost three times less likely to have colonoscopy than European/Other.

Interview feedback from Māori and Pacific participants with a positive iFOBT indicates that once they step onto the BSP pathway their progression is easy, timely and reassuring, and their service experience is overwhelmingly positive (Litmus 2013, 2016).

A number of strategies are used to facilitate participants' journey on the screening pathway following a positive iFOBT. The role of the general practice in informing participants about their positive iFOBT can help overcome reservations about having a colonoscopy, particularly for those anxious or with co-existing conditions. During the pre-assessment phone call the WHEU CNS discusses whether there are barriers that may impede participants from attending a colonoscopy such as language and transport, and action is taken to address them. Participants are able to select an appointment time that best suits them, recognising that eligible participants may be working or have other life situations that need to be accommodated.

5.8 Multi-factor interventions in a national bowel screening roll-out

New Zealand and international research highlights that multiple factors influence bowel screening participation, including cancer characteristics, screening test characteristics, individual factors, and the health system context (Weller et al 2009, Ministry of Health 2010, Senore et al 2010, Reeder 2011, Varlow et al 2014). Reviews undertaken by Senore et al (2010), Power et al (2009) and Christou et al (2010) identified a number of determinants and barriers to participation in bowel screening (summarised in Table 12) and are reflective of the feedback from BSP participants interviewed. However, the relative influence of these factors in achieving or improving bowel screening participation is not known (Senore et al 2010).

Table 12: Summary of enablers and barriers to participation (from the literature)

| Level | Factors that increase participation |
|----------------------------|--|
| Individual | Perceived benefits of screening |
| | Perceived risk of bowel cancer |
| | Previous participation in screening |
| | Health motivation in practising health promoting behaviours or by avoiding unhealthy lifestyles |
| | Having a partner who encourages and supports healthy behaviours |
| System | Support from health care providers/GP, particularly for those with low levels of literacy and less likely to read information provided |
| | Letter sent from GP |
| | Advance notification of screening (may increase participation) |
| | Reminders to take part (with telephone being the most effective and costly) |
| | Involvement of community workers in kit distribution and collection following some general training |
| Level | Factors that decrease participation |
| Individual | Limited knowledge and awareness of bowel cancer and screening |
| | Lack of confidence in screening effectiveness |
| | Anxiety about test, results, fatalistic attitude |
| | Perceived low risk |
| | Low levels of literacy, health literacy and/or self-efficacy |
| | Cultural beliefs – faecal taboos |
| | Embarrassment |
| Presence of co-morbidities | |
| System | Lack of culturally appropriate health promotion material |
| | Low general exposure to health media exposure/bowel cancer media exposure |
| | Distrust of the health system |
| | Discomfort/poor experience with health system |
| | No fixed residence/frequent change of address |
| | Lack of coordination of the screening service |
| | Cost to see general practice including transport; perceived cost for screening and treatment |

Sources: Senore et al 2010, Power et al 2010, Christou et al 2010, Brynum et al 2012.

Successful screening programmes for Māori and Pacific people are systematic, intensive, multi-faceted and multi-disciplinary. Multi-factor interventions that target more than one level at different points of the screening pathway appear to have larger effects than single level interventions (Ministry of Health 2010).

In considering interventions to increase participation by Māori and Pacific people in the BSP, it is useful to consider a framework to promote screening behaviours. International bowel screening studies have used the health belief model to promote health screening behaviours in public health including studies into Indigenous Australian's participation

(Strecher Rosenstock 1997; in Causey and Greenwald 2011, Christou et al 2010). Research found that addressing the six components of health belief model in education sessions empowers participants to take the recommended screening action (Causey and Greenwald 2011). The six components of the health belief model are:⁵⁴

- perceived susceptibility (the belief that they are vulnerable to the disease)
- perceived severity (the belief there are consequences to having the disease)
- perceived benefit (of the efficacy of the recommendations to reduce the seriousness of the disease)
- perceived barriers (the cost to participate in screening)
- cues to action (strategies to promote readiness to take part)
- self-efficacy (the confidence to take the recommended action).

From the converted non-responders survey (Litmus 2016) and the population survey (Litmus 2014a), the findings suggest that factors that have the greatest impact on participation are linked to perceptions of susceptibility and severity of bowel cancer, and the benefits of the test. Increasing understanding of bowel cancer and bowel screening is therefore critical in supporting eligible people to make an informed decision to take part or not. This finding also suggests that the content of the message to non-responders about bowel cancer and bowel screening does not require tailoring across audiences. However, how these messages are communicated will vary depending on the population group.

Active follow-up and a range of other reminders are important as cues to action and work best when non-responders have an understanding of bowel cancer. The use of known Māori and Pacific health providers is also important to gain engagement and potentially overcome distrust and suspicion of unknown mail and callers. Limited health literacy and self-efficacy to complete the iFOBT kit are known barriers in bowel screening (Kobayashi et al 2014). These factors may in part explain why just over half of the re-sent kits are completed, and that around four in ten people contacted by the active follow-up result in completed kits (Litmus 2016).

Health education strategies need to inform about bowel cancer: the risk factors and incidence and effectiveness of treatment as well as demonstrating how the test is done to increase eligible participants' confidence levels (Christou and Thompson 2012). As Javanparast et al (2012 p.523) states, the diversity of eligible participants *suggests that a one-size-fits-all bowel cancer screening program [sic] is not equitable. Tailored approaches need to be developed to ensure equitable participation across populations.*

5.9 Conclusion

Leading with equity

A national bowel screening programme must lead with an equity focus to avoid increasing existing inequities in bowel cancer outcomes. The BSP has demonstrated that without appropriate systematic and structural approaches together with focused governance and

⁵⁴ While the health belief model aligns with research findings in the New Zealand context, consideration is needed on whether this model is appropriate to frame strategies to increase participation for Māori and Pacific people. Discussions with the National Screening Unit highlighted that they do not have a behavioural change model they use for Māori and Pacific participation in screening, and that the health belief model may not be the best to use in this scenario.

leadership, inequities in bowel cancer outcomes will increase for Māori and Pacific people, and those living in areas of high deprivation. A national programme needs to shift the focus from thinking that inequity is an inevitable part of screening to one where *equity is a non-negotiable bottom line*. Leading with an equity focus will ensure the programme's design supports those groups known to be least likely to take part and at higher risk of cancer to be engaged and supported to participate in all stages of bowel cancer screening.

Equity becomes kind of a voluntary option, an added extra instead of being a non-negotiable bottom line, a minimum requirement of where we need to get to.
(Stakeholder)

From discussions with key stakeholders the following principles have been drawn together to support a national bowel screening programme that leads with equity:

Clear equity statement: From the outset, there needs to be a clear and explicit understanding of what is meant by equity in participation and equity of access across the bowel screening pathway. Acknowledgement is needed of the population groups who are known from the BSP to be less likely to take part. Systems need to be put in place to enable their participation. To date, equity initiatives have focused primarily on Māori and Pacific people and recently those living in areas of high deprivation. Consideration is also needed for other groups with lower participation including younger people and males. An intense focus on equity is needed during the design and early implementation for a national programme. A consistent equity approach will be needed on an ongoing basis across the programme.

Leadership and governance: Māori and Pacific leadership at the governance level is needed to ensure that the design, funding and implementation of the programme are informed by expert cultural and clinical advice, and a real-time cultural lens is applied to monitoring of the results of the programme at the governance level.

Dedicated resource: Structural and system approaches to equity need to be appropriately resourced from the outset both to develop an equity strategy and for its implementation.

Really strong analytical power particularly when it comes to equity. Having that resource built into the programme. (Stakeholder)

Structural and system focus: A continuous quality improvement process is required that seeks to strengthen access to screening and the screening pathway to achieve equity. Where appropriate, screening pathways need to be simplified making them easy and stress free so people move easily along them.

System responsibility to deliver a quality programme... using appropriate follow-up systems; that engagement processes and communications were orientated in the right way; that people were ensured that the quality of follow-up and treatment was appropriate; that they have mechanisms to engage that were outside of the 'I will send you a letter and then I will follow-up later' – there are mechanisms to respond to the community and their expectations of services.
(Stakeholder)

Multifaceted and multidisciplinary approaches: A range of approaches are needed to achieve equity such as CAR, letter reminders, active follow-up using phone and face-to-face approaches, opportunistic and systematic reminders by general practice and Māori and Pacific health and community providers. All initiatives undertaken need to be tailored to

the region and local populations and monitored with KPIs for equity along the whole screening pathway, not just at participation.

Approaches used to increase awareness and support participation need to demystify bowel screening as eligible participants can, without engaging with written material received, misunderstand what is required to complete the test. Further, previous experience of Māori and Pacific people in the health system may influence their receptiveness to bowel screening. Recognition is also needed of the wider context of Māori and Pacific lives and the impact on participation. Bowel screening may be a low priority.

*It was about getting my head around it, I mean I've heard other people talk about 'Oh they want me to put my s**t in a bag' ... Cause they think that's what you've got to do; take a whole piece out of the toilet and put it in a bag and send it. (BSP participant)*

Clarity of bowel screening messages and instructions: The distribution of the iFOBT kit and completion requires a level of literacy and self-efficacy to complete. Work has been undertaken in the BSP to improve the accessibility of the letter and kit instructions, and active follow-up scripts. Ongoing focus will be needed to ensure communications at a national level retain a level of rigour on literacy level and clarity and consistency of message.

Integrated Register: The Register needs to be up-to-date and invite all those eligible to take part. The Register needs to inform 'real time' follow-up activities and support reminder processes through interfacing with existing primary care systems. Further, the Register needs to enable the monitoring of uptake and equity across the pathway.

The ability to connect systems and talk across systems so that we can get the best efficiency out of communicating with people and follow-up systems if they are required. So that we are not having to create new systems to do this work. (Stakeholder)

Monitoring data and KPIs: Close monitoring, target setting and accountability is important to determine whether or not equity is being achieved. Ideally, an independent Māori and Pacific monitoring group will be established to assess the KPIs by ethnicity, age, gender and deprivation and receive reports annually. As similar to breast screening, the group will be able to request corrective action where KPIs demonstrate inequity (Hill et al 2012). Using this governance approach to monitoring in breast screening has resulted in a narrowing of screening inequities.

Workforce capability building: All bowel screening providers have a responsibility for equity of access to and participation along the bowel screening pathway. To complement and support the work of Māori and Pacific equity roles, training is important to build the capability of the bowel screening providers to work effectively with Māori and Pacific people across the screening pathway.

Māori and Pacific primary health care and other community providers: A national bowel screening programme needs to connect into a wide range of communities in ways they want to be connected with. The BSP was located in a primarily urbanised community and it is likely that different issues will arise for rural communities. The bowel screening programme needs to determine how it will work with Māori and Pacific primary health care and community providers who have a proven track record with their communities to promote bowel screening and participation through active follow-up and other engagements.

It is unrealistic to think that one person can take on a role, or a small group of people can take on a role for such diverse communities and needs. (Stakeholder)

Symptomatic pathway: An equity focus is also required for the symptomatic pathway to ensure equity in all bowel cancer pathways.

Equity focused and prioritised...We need to look at this wonderful opportunity and lead the world.

6. Safety and acceptability

Evaluation aim addressed in this section

Safety and acceptability: Can a national bowel screening programme be delivered in a manner that is safe and acceptable?

6.1 Safety: can a national bowel screening programme be delivered in a manner that is safe?

Assessing safety in screening programmes

The National Screening Unit (2005 p.10) states that safety, defined as the extent to which harm is kept to a minimum, is one of the four dimensions of quality for a screening programme. The other dimensions of quality are equity and access (refer section 5), efficiency and effectiveness (refer section 4). Safety is multi-dimensional and incorporates perspectives such as cultural (i.e. the screening programme operates in a cultural context that makes sense to participants), environmental (e.g. test, facility, and equipment), and clinical safety (National Screening Unit 2005 p.15). In this context, the screening pathway of the BSP is assessed to determine whether it is safe, and thus addresses whether a national bowel programme can be delivered in a way that is safe.

Assessing safety in the BSP

Governance and leadership

Governance and leadership have important roles in monitoring the safety of the BSP. Feedback indicates the governance and leadership structures of the BSP have worked well across the pilot duration with robust and constructive discussions at the Ministry of Health, WDHB Steering Group and with Bowel Screening Advisory Group and the Bowel Cancer Working Group (Litmus 2016a). In Round 2, Māori leadership in particular was strengthened including those with a depth of clinical, screening and community knowledge, and having representation on key governance groups. Pacific leadership was enhanced, but involvement continues to be ad hoc due to the significant demands on their capacity.

In Round 2, the role of endoscopy governance has been debated at a sector-wide level. For a national screening programme, the Ministry of Health wants to ensure there are consistent quality standards and ways of accrediting and credentialing staff to ensure parity in quality between the symptomatic and screening endoscopies. The Royal Australasian College of Surgeons and the Royal Australasian College of Physicians currently have differing approaches to endoscopy training. There appears to be broad agreement on the need for a comprehensive endoscopy governance group that covers endoscopy training, credentialing and governance, and the management of the Global Rating Scale (GRS).⁵⁵ However, there are differing opinions on where this endoscopy governance group sits in the sector and who funds it, which will require resolution for a national programme.

⁵⁵ GRS is a patient-centred quality improvement and assessment tool for the gastrointestinal endoscopy service across New Zealand.

Quality standards and assurance and improvement processes

Standards are the backbone of quality management in a screening programme (National Screening Unit 2005), and an important tool to monitor safety across the screening pathway. The BSP is a population-based pilot, the design of which draws on the European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis (Seagan et al 2010). The European Guidelines were also used as a guide for the development of the BSP quality standards. Where no standard exists, the Ministry of Health working with the Bowel Cancer Taskforce, Māori Equity Advisory Group and the Bowel Screening Advisory Group reached a consensus decision based on consultation with experts involved in pilots undertaken in Scotland, England, Wales and Australia, and a review of existing evidence.

Five key quality documents were developed for the BSP. These documents are interim, reflecting that they are 'living' documents⁵⁶:

1. BSP Final Service Delivery Model (Ministry of Health 2013a) details the final Service Delivery Model and outlines the screening pathway for the eligible population in the BSP site at WDHB.
2. Policy and Operational Procedures for the BSP (Ministry of Health 2011) provides an overview of business practices and processes for the whole bowel screening process.
3. BSP Interim Quality Standards (Ministry of Health 2012 and 2013) sets out the monitoring, draft quality standards, clinical audit, risk management, and monitoring indicators.
4. BSP iFOBT Draft Performance Quality Standards (Ministry of Health 2011a) identifies requirements for manufacture of the test kit and requirements for laboratory testing.
5. Standards for Endoscopy (colonoscopy) Facilities BSP (Ministry of Health 2011b)⁵⁷ covers service management, quality assurance, participant care, infection control, equipment and participant sedation.

In November 2012, a review of the BSP interim quality standards (Ministry of Health 2012) was jointly undertaken by Ministry of Health, WDHB and LabPLUS. Overall, no substantive issues were identified with the existing quality standards, although refinements and clarifications were made to the interim quality standards (Ministry of Health 2013).

Once a screening programme is established, quality assurance and quality improvement activities are essential to ensure the ongoing safety and effectiveness of the programme (National Screening Unit 2005). In Round 2, the performance of the BSP against the quality standards were reviewed in every third WDHB Steering Group meeting. The Endoscopy Review Group met monthly (previously fortnightly) to review all issues relating to the endoscopy services, including the readmissions, incidents and clinical performance data. All admissions to hospital after a BSP colonoscopy were reviewed at the fortnightly (changed to monthly in late 2015) Endoscopy Review Group meetings. Each admission was categorised as mild, intermediate or severe according to the UK Quality Assurance Guidelines for Colonoscopy (Chilton and Rutter 2011). Readmission analysis was used to inform quality improvements to practices or processes to reduce the number of readmissions.

An issues register is maintained and issues are reviewed at the weekly staff meetings. The three risks identified for the pilot are achieving equity in the pilot, the ability to ensure that all

⁵⁶ Refer the interim evaluation report (Litmus et al 2015) for further detail.

⁵⁷ The standards referring to the quality assurance of the colonoscopy procedure are outlined in the BSP Interim Quality Standards.

eligible people living in WDHB are on the Register, and the impact BSP surveillance numbers will have on symptomatic waiting times and the delay in timing surveillance procedure.

From January 2013, the Ministry of Health has been publishing the results of 15 key monitoring indicators. Appendix 5 provides an overview of the published indicators as at 29 July 2016.

The BSP has a range of quality standards and processes in place that align with international best practice. Quality standards, risks and issues were actively monitored, reported, discussed and actions taken to address risks of breaching quality standards, and mitigated risks emerging. While WDHB noted that reporting against all quality standards was now possible (with exception of the timeliness of the histology result letter), data was not sighted by the evaluation team for all quality standards (Litmus et al 2015, 2016a). Appendix 6 provides an overview of the quality standards and results up to 31 December 2016.

Ensuring all eligible participants are invited

The BSP is a population-based screening pilot which therefore requires the means to identify and invite eligible participants to take part. The BSP Population Register is owned and overseen by the Ministry of Health. WDHB's work on the Register is based at the BSP Coordination Centre and managed by the BSP Data Manager.

NHI numbers were selected as the primary source of eligible participant information for the Register.⁵⁸ NHI information provides a population-based data set from which eligible participants can be identified and subsequently invited to take part in the BSP.

In screening Round 1 using the Register, 136,575 pre-invitation letters and 143,637 iFOBT kits⁵⁹ were distributed, and 83,498 reminder letters were sent at four weeks. In screening Round 2 using the Register, 29,819 pre-invitation letters and 150,355 iFOBT kits were distributed, and 106,228 reminder letters were sent at four weeks (Blick et al 2016). Between rounds 1 and 2, the proportion of participants requiring a reminder letter has increased from approximately 58% to 71%. Consideration is needed on ways to encourage participants to complete their kit in a timely manner.

Having an eligible population database (the Register) is seen by stakeholders as a strength of the BSP. The Register enables the identification of the eligible population, the distribution of kits and monitoring of participation (Litmus et al 2015, 2016a). However, the interim evaluation report questioned the completeness of the Register, data and IT resource to support it, and the ability to effectively assess participation and outcomes (Litmus et al 2015). To address these concerns, the Ministry undertook two reviews of the BSP Register to assess completeness of the eligible population listed in the Register, and data quality.

The review of completeness concluded there are 2–5% of eligible people not on the BSP Register when comparing the population count on the Register to the Census 2013 count and the PHO register count (Lee 2014). This is at the lower end of that estimated in the interim evaluation report (Litmus et al 2015). However, the review also found a lack of currency of participant contact details which may mean some people may not receive an

⁵⁸ It was intended that the NHI numbers would be supplemented by PHO enrolment data, but due to logistical reasons this did not occur.

⁵⁹ Includes iFOBT kits that were resent due to spoilt or expired kits.

invite (Lee 2014). It is estimated that in 2014 the BSP Coordination Centre received 3,528 returned items compared with 5,727 in 2015 (approximately 6% of the 146,131 people who were sent items). In this context, most but not all eligible participants are being invited to participate in the BSP.

Data quality and monitoring of participation and outcomes

Data quality is essential to ensure the effectiveness of the BSP processes and to enable quality monitoring. The 2014 review estimated that 0.03% of records in the Register were affected by a data quality issue (Karalic 2014). The review concluded that this figure is not high and is an *'excellent result'* when placed in the context that this is *'a pilot, operating on newly developed processes and procedures, and using newly developed bespoke software'* (Karalic 2014 p7). The review found that reported quality issues were due to the use of the transactional database for reporting purposes.

The review also identified that a significant Round 2 issue was the lack of a reporting layer, and inability to relate with certainty all events to the screening episode they occurred under. To resolve this issue, a reporting layer was developed for the Register to enable the easy output of a flat file for reporting of participation and screening outcomes. The BSP Coordination Centre and Massey University noted that the reporting template is useful and has made reporting a more efficient process (Litmus 2016a).

Having an operationally efficient Register

The BSP Coordination Centre identified issues relating to the Register's functionality, through its day-to-day operation. The Ministry is informed about the functional issues through Register upgrade requests. Over the course of the pilot, there have been five upgrades to the Register; although due to constrained IT resources at the Ministry not all functional issues have been addressed.

Operationally, the BSP Coordination Centre uses a number of manual processes to deliver components of the screening programme. For example, the Register does not inform or monitor the active follow-up process,⁶⁰ record adverse events or record the surveillance period. The manual nature of the work places more demands on the available BSP Coordination Centre data management capacity.

Not having regular PHO enrolment updates means that contact details on the Register may be out of date or an incorrect GP may be listed. Where an incorrect GP is listed, a result from the lab will not be sent automatically to the GP using the HL-7 message. When a consent form is returned, the BSP Coordination Centre manually checks the consent against the Register. As the information on the Register is not up to date, many changes are being made to update it. As a result, the BSP Coordination Centre has established a student workforce which offers flexible hours on an as-needs-basis for data administration tasks.

The Register does not link on a regular basis to other health systems. As a result, participant eligibility cannot be checked to determine if a person has had a colonoscopy recently and is therefore ineligible to take part. Feedback indicates that updates from the National Cancer Register and Births and Deaths Register are infrequent. People can be invited that have been diagnosed with bowel cancer or who have died. This can be distressing for families and CAR staff who follow-up non-responders.

⁶⁰ The BSP Coordination Centre has developed a local database to support and capture active follow-up activities.

Data should be collected once and validated at source (National Screening Unit 2005 p.21). Data validation does occur at the BSP Coordination Centre but due to limited capacity it is ad hoc. Spot checks are undertaken of data entry by pulling consent forms and checking the data has been entered correctly. Histopathology results are entered by clinicians and no validation is done on the results entered. Stakeholders' perceptions are that data quality is good, as business rules in the Register tend to highlight if issues arise. This reflects the findings of the Ministry's review (Karalic 2014).

Feedback on the operational functionality of the Register highlights the need for a systematic review of its functionality to determine whether it can work efficiently for a national bowel screening programme.

Enabling informed decisions and managing emotional anxiety

All screening programmes face the challenge of ensuring healthy asymptomatic people are aware of the limitations of screening and the uncertainties of false positive and false negative results. All screening programmes create a level of emotional anxiety for participants which needs to be managed as most participants will not have the disease being tested for.

The participation rate in bowel screening is a critical determinant of the magnitude of the screening impact on bowel cancer incidence and mortality (Senore et al 2010). The literature highlights a potential conflict between promoting high participation rates and the need for people to make an informed choice about whether or not they want to be screened. Strategies to promote participation therefore need to be balanced with information on the risks and benefits of screening (Weller et al 2009).

The BSP has in place information and processes that support informed decision making and proactively seek to minimise emotional anxiety for BSP participants. The BSP invitation letter and supporting collateral, CAR and follow-up processes, and result letters make clear both the benefits and the limitations of bowel screening.

In BSP Round 1, general practices were unable to identify the eligible BSP participants in their practice who had received an iFOBT kit and not completed it. In 2015, DRINFO and Patient Dashboard were updated to enable opportunistic and systematic patient reminders on completing their iFOBT kit in general practice. Reflecting their recent introduction, these tools are not yet being consistently used in all general practices. However, when used they are supporting people to consider bowel screening and to take part (Litmus 2016).⁶¹

General practice has the uncommon role in the BSP of informing and discussing positive iFOBT results with their patients and referring to BSP colonoscopy within ten days. General practices in WDHB are mostly undertaking their role as intended (Litmus 2014b). BSP participants interviewed who were anxious, had other health conditions or were reluctant to have a colonoscopy, stated they felt reassured following the consultation with their GP about their positive result (Litmus 2014c).

Where a BSP participant does not have a GP, the BSP endoscopy CNS will contact the participant to inform them of the positive result and will offer reassurance about the result and its implications. Participants with a positive result who do not have an identified GP or who have not been contacted by their general practice within the ten-day period, are

⁶¹ Using Patient Dashboard, general practice can fax the BSP Coordination Centre to send a replacement iFOBT kit to their patients. Between October 2014 and 31 January 2016, the BSP Coordination Centre received 1,622 fax requests from general practice to send out a replacement bowel screening kit to patients, and received back 888 completed iFOBT kits (a return rate of 55%).

contacted by the BSP endoscopy CNS within 15 working days of a positive result. The endoscopy nurse offers reassurance about the result, its implications and the next steps in the screening pathway. If the CNS is unable to contact a participant with a positive iFOBT,⁶² the CNS sends the participant a letter, outlining the positive result, informing that the result is unlikely to mean bowel cancer and encouraging the participant to contact their GP or the BSP Coordination Centre. If no contact is made, the participant is placed on the iFOBT recall system and remains on the BSP Register.

During the pre-assessment phone call and informed consent process for the colonoscopy, reassurance is again offered. To minimise emotional anxiety, quality standards for colonoscopy wait times have been set at 95% of participants receiving their colonoscopy within 55 days. These standards are closely monitored and were met in Round 2. Another example of proactively managing participant anxiety is that on the day of the procedure, the endoscopist usually meets with the BSP participant after the colonoscopy to discuss the outcome; the endoscopist always meets with a participant if the outcome is abnormal.

Feedback from Pākehā, Māori and Pacific BSP participants interviewed with a positive iFOBT results described the communication about their results as reassuring, and their colonoscopy experience as timely and respectful (Litmus 2013, 2014c, 2016)

iFOBT results

WDHB has a Service Level Agreement with LabPLUS (which is an Auckland District Health Board service). The processing and testing of iFOBTs is described by stakeholders as timely with the appropriate quality checks and reporting in place. The relationship between the BSP Coordination Centre and LabPLUS continues to be effective with clear lines of communication (Litmus 2016a). WDHB (2016) notes that LabPLUS continues to meet all quality standards.

During the pilot, the issues of managing incorrectly completed iFOBT kits and expired kits arose. Actions were taken to minimise these occurring, including more pictorial kit instructions and ensuring all kits sent out have at least six months before expiring. Policies were also developed to manage any incorrectly completed or expired kits received (Litmus et al 2015).

BSP participants with a negative iFOBT result are recalled to complete another iFOBT in two years. The negative result letter informs these participants that they will be recalled in two years' time. Around 8 in 10 people with a negative iFOBT result in Round 1, who were invited in Round 2, completed their iFOBT (refer section 3.3). Bobridge et al (2014) highlighted that people who have a negative iFOBT result have a perceived lower bowel cancer risk and thus may be less likely to take part in screening. As indicated in the converted non-responder survey, a third are not aware they need to undertake two-yearly screening if they have a negative result.⁶³ To encourage future participation in bowel screening, more education is needed on bowel cancer risks and the ongoing role of bowel screening across time.

⁶² Extensive efforts are made by the CNS to contact the participant using a range of strategies including phoning at different times of the day and week, finding other contact numbers such as work number or mobile, phoning their general practice for up-to-date contact details, and using community support workers or interpreters, if appropriate.

⁶³ A survey of Māori and Pacific non-responders at four weeks who are contacted via active follow-up and go on to complete their kit found that a third are not aware that it is recommended to do the bowel screening kit every two years (34% Māori and 38% Pacific are not aware). However, 100% of Māori and 99% of Pacific people said they would do the test kit again if sent a kit in two years' time (Litmus 2016).

As noted above, processes and monitoring are in place to ensure BSP participants are informed about a positive iFOBT result by their GP, and there are failsafe mechanisms that occur if there is no GP or the GP cannot contact the patient within ten days. Most general practices interviewed noted that they can usually contact their patients within the ten-day period (Litmus 2014c). Practices with a high proportion of patients living in areas of high deprivation can find the ten-day period challenging if their patients are transient (Litmus 2016).

Diagnostic procedure

In the BSP, key safety considerations for colonoscopy are the acceptance of the test (discussed in section 6.2), capacity to meet demand, avoidance of excessive wait times to minimise anxiety, and monitoring and adherence to quality standards for the endoscopy unit and endoscopists.

Pre-BSP research highlights a significant gap between colonoscopy demand and provision, and that population screening would require a significant increase in colonoscopy capacity (Yeoman and Parry 2007). In Round 1, having adequate colonoscopy capacity to meet BSP quality standards was identified as a key challenge (both for endoscopists and endoscopy nurses). In Round 2, having adequate colonoscopy capacity has continued as a challenge but it is not as great as in Round 1. In Round 2, the BSP Coordination Centre achieved its target of having 80% of colonoscopies provided by WDHB staff, and the remaining 20% are fee-for-service providers. This is a significant reversal from early in Round 1 where 80% were fee-for-service providers. This transition has occurred through the inclusion of the BSP colonoscopy demand into the wider colonoscopy service for WDHB and including BSP colonoscopies within the clinician's job description (Litmus 2016a).

In Round 2, the wait time standard for colonoscopies is being met. In Round 2, between 97% and 99.6% of BSP participants with a positive iFOBT had their colonoscopy within the quality standard of 95% within 55 days (1 July 2014 to 30 December 2015).⁶⁴

Quality standards for colonoscopy continue to be regularly monitored and reviewed by the WDHB BSP Clinical Director and/or WDHB BSP Lead Endoscopist. Quality monitoring also continues for individual endoscopists who receive a copy of their quality results compared in an anonymous format with other endoscopists. The BSP does not have an agreed quality standard for the adenoma detection rate per endoscopist. Quality improvement initiatives are evident and include⁶⁵:

- review of bowel preparation for colonoscopy which resulted in revised afternoon and morning information sheets accompanied by a low fibre diet sheet
- review of readmission data which resulted in further training for endoscopists about polyp removal and the removal of hot biopsies forceps
- review of anticoagulant policy
- BSP participant survey findings being used to identify further improvement areas to enhance participant experience
- the introduction of split bowel preparation to improve bowel preparation (i.e. the participant takes the first dose of Glycoprep-C the day before the procedure and the

⁶⁴ Between January and July 2014, the standards were not achieved with 70% of participants having their colonoscopy within 55 working days (WDHB 2016).

⁶⁵ Other quality initiatives may have been undertaken that are not listed here.

second dose on the day of the procedure). The evidence shows that doing a quality colonoscopy in a well prepared bowel with a good adenoma detection rate is associated with a reduced rate of interval cancer (Anderson and Butterly 2015).

Histopathology

LabPLUS is required to provide histopathology results within ten working days. LabPLUS reports histopathology results directly into Concerto (the WDHB patient record system) using a standardised reporting template. There continues to be an effective working relationship between LabPLUS histopathology, BSP WHEU and the BSP Coordination Centre. Pathologists are supportive of the quality control processes in place including the checking process used by the BSP WHEU of faxing over the list of cases with the number of pots sent, and having one polyp per pot. The latter enables pathologists to easily determine frequency of rescreening by the number, size and type of polyps (Litmus 2016a).

LabPLUS continue to be seen as having quality processes in place, being timely in their delivery, and engaged with the wider BSP screening pathway. WDHB (2016) notes that LabPLUS continues to meet all quality standards. Pathologists are joining MDMs via video conference which is more time efficient.

Ongoing suggested improvements related to histopathology are:

- Proforma reporting required by the Ministry is different from LabPLUS' usual reporting as the form requires reporting on one polyp per page. The report is long and cannot be sent through the standard HL-7 messaging on Healthlink to GPs. The proforma report makes it difficult to find the most relevant information. To address this, pathologists are flagging the most severe polyp and putting a summary of key information on the front of the form to inform clinical decision making. Further, using the proforma approach means it is difficult for LabPLUS to pull collated reports from their system as it is not designed to be a reporting database.
- Streamlining the results letter process as it is labour intensive (e.g. a process that can take up to three weeks with the steps of histology review, information sent to clerk, letter generated on Soprano, approval and then sent out).
- Recording all significant polyps on the Register. Currently, the Register only allows for the histology relating to the most significant polyp to be entered, which can be limiting if a BSP participant has multiple polyps.

From 2013, the clinical nurse specialist (CNS) has reviewed the colonoscopy reports and the histopathology results and advises the BSP administrator the correct letters to send out to participants, their GP, and to WDHB notes. A formal policy has been developed (*Histology Results Management*) which sets out parameters within which the CNS may make decisions. This change has streamlined the workload for the WDHB BSP Clinical Director and WDHB BSP Lead Endoscopist who provide peer review of actions taken. A review has been completed which concluded there was a very high level of compliance with the surveillance guidelines for polyps (New Zealand Guidelines Group 2004).

Treatment available

For the BSP to be safe, participants identified with cancers require timely access to treatment.⁶⁶ 40% of BSP participants requiring clinical follow up have a first specialist

⁶⁶ The quality standards are: 95% of BSP participants requiring clinical follow-up have been referred and seen by an appropriate consultant within 10 working days of diagnosis (2 weeks); 95% of BSP participants diagnosed with cancer are referred to the appropriate consultant for presentation at an MDM within 20 working days from diagnosis (4 weeks).

appointment within 10 days, which is below the standard set of 95% of BSP participants (refer Appendix 5). The BSP Coordination Centre notes this result is mitigated by the endoscopist meeting with participants to discuss abnormal outcomes at the time of the colonoscopy.

Compared to Round 1, the pressure on treatment services has lessened due to lower adenoma detection rates and more colorectal surgeons. WDHB have estimated workforce requirements based on Round 1 BSP findings to determine surgical, CNS, and pathology FTEs, and the theatre time required. In Round 2, the transition from the BSP to treatment is working smoothly. All BSP participants found to have cancer or advanced adenoma continue to be discussed at MDMs (Litmus 2016a), and for 90% this is within 20 working days.

CTC

BSP participants assessed as unfit for colonoscopy or with an incomplete colonoscopy are offered a CTC investigation. Occasionally when a colonoscopy fails, the person may proceed to have a colonoscopy under general anaesthetic. Across the two screening rounds, 104 CTCs and 86 colonoscopies under general anaesthetic have been completed. The interface between WHEU and CTC is working well.

Surveillance

Adherence to surveillance colonoscopy guidelines is important to prevent bowel cancer and unnecessary workload (Schreuders et al 2013). WDHB Endoscopy Service is responsible for ensuring participants received their surveillance colonoscopy within the recommended timeframe (according to guidelines in *Surveillance and Management of Groups at Increased Risk of Colorectal Cancer, Ministry of Health 2004*). The BSP WHEU advised participants they have been referred for surveillance and notified participants' GPs.

At the end of Round 2, feedback from stakeholders continues to indicate that surveillance colonoscopies are impacting on the symptomatic list. Green et al (2012) found that in the first few years of a screening programme the main colonoscopy requirement is for the initial referral after a positive iFOBT. By year seven, surveillance colonoscopies will have built up and account for 40% of the total colonoscopies.

In Round 2, concerns were raised that BSP participants requiring surveillance colonoscopies at one year are not receiving timely appointments.⁶⁷ The Register does not record the surveillance period. The BSP Coordination Centre took an audit of referrals for surveillance late in 2015 to investigate this issue. The purpose was to find out whether people referred for surveillance during Round 1 had a colonoscopy in the required timeframe and the outcome from the procedure.

Stakeholder feedback suggests an area to strengthen is the management of the booking and scheduling process of surveillance colonoscopies for BSP participants. General practice is also seeking greater clarity on the process and responsibility for ensuring BSP participants have surveillance colonoscopies.

Symptomatic services

Introducing a screening programme safely should not impact adversely on symptomatic services nor create inequities between the two services. The BSP Coordination Centre has worked to avoid impacting symptomatic services, particularly in managing colonoscopy

⁶⁷ Only a few participants require a surveillance colonoscopy at one year.

demand in Round 1. Feedback from general practice highlights mixed perceptions about the potential impact of the BSP on symptomatic services. Some perceive there has been an overall enhancement in the symptomatic service with a noticeable decrease in wait times over the last three years. However, it is also noted that the wait times for symptomatic services continue to be longer than for the BSP (Litmus 2016).

Acknowledging the need to avoid inequities between the symptomatic and screening services, a number of Ministry-led initiatives have been undertaken to strengthen the bowel cancer sector and prepare for a possible national bowel screening programme. Wider initiatives include:

- The introduction of colonoscopy wait time indicators which have significantly improved wait times across DHBs, and will require ongoing monitoring.
- Improving the quality of colonoscopies across New Zealand, reflecting that bowel screening colonoscopies tend to be complex with a high incidence of polyps.
- Workforce modelling by Health Workforce New Zealand to look at the impact of a national bowel screening programme on endoscopy, computerised tomographic colonography (CTC), and nurse endoscopy training.
- The introduction of the GRS as a patient-centred quality improvement and assessment tool for the gastrointestinal endoscopy service across New Zealand.

Feedback suggests that the use of the the GRS across DHBs may be waning with the lack of agreement on endoscopy governance. Further, the GRS is not well embedded into the BSP's quality standards. Amongst clinicians the GRS is seen as an important monitoring and audit tool to lift unit quality, productivity and unit utilisation, improve the patient experience and ensure consistent training standards, and avoid creating a two-tiered system.

- Establishing the New Zealand Familial Gastro-Intestinal Service which offers assessment, diagnosis and surveillance of inherited gastrointestinal cancer syndromes.

6.2 Acceptability: can a national bowel screening programme be delivered in a manner that is acceptable?

The assessment of the acceptability of the BSP for eligible participants and providers was made in the Interim Evaluation Report (Litmus et al 2015). Below is a summary of the findings with updated feedback from qualitative interviews with Māori and Pacific BSP participants and providers in 2015 (Litmus 2016, 2016a). For more details on participant and provider acceptability refer to the Interim Evaluation Report.

Acceptability of the BSP to the target population

The acceptability of the BSP (defined by awareness, attitudes and knowledge) varies amongst the eligible population, reflecting it is not a homogenous group. Acceptability of the BSP is higher amongst the eligible European/Other group (non-Māori and non-Pacific), and lower amongst eligible Māori and Pacific people (Litmus 2014a).

Since the launch of the BSP, awareness of it has significantly increased amongst the eligible European/Other group. Knowledge about bowel cancer risk factors, symptoms and bowel cancer tests has also increased. Perceptions of the iFOBT have also become more

positive with significant increases in disagreement that the iFOBT is painful, embarrassing, inconvenient, messy and inaccurate (Litmus 2014a).

Compared with the European/Other group, Māori and Pacific people have lower awareness of bowel cancer risk factors, symptoms and bowel cancer tests including the iFOBT which may reflect their lower levels of participation. However, awareness and knowledge are increasing since the launch of the pilot. Other barriers to participation include a dislike of bowel screening, a preference for seeing their doctor, not being concerned, a fatalistic attitude of 'what will be will be' or not wanting to know, and not wanting to do the test at home. Pacific people also perceive the iFOBT as messy (Litmus 2014a).

BSP participants' experience of the BSP screening pathway is mainly positive. Pākehā, Māori and Pacific BSP participants interviewed in Round 1 consistently described their experience of the BSP as convenient, the iFOBT as easy to do with timely results and progression along the pathway. For those with a positive iFOBT, the communication about their results was reassuring, and their colonoscopy experience was timely and respectful (Litmus 2013). Māori and Pacific BSP participants interviewed in Round 2 also noted that after being supported to complete their iFOBT kit, they found the process easy and not as bad as they had first imagined (Litmus 2016).

Acceptability of the BSP amongst providers and wider stakeholders

In Round 1, the acceptability of the BSP (defined by awareness, attitudes and knowledge) and its design was high amongst providers in the community, primary care and hospital setting. There was support for the BSP to be rolled out as a national screening programme, although there was recognition that further work was required to ensure equity of participation, adequate workforce capacity (particularly colonoscopy capacity), and that bowel screening does not impact on symptomatic services (Litmus et al 2015).

In Round 2, the acceptability of the BSP and a national bowel screening programme continues to be high amongst key national and regional stakeholders and providers interviewed along the screening pathway. No one interviewed was unsupportive of the BSP or a national bowel screening programme. Indications from the Ministry of Health's nationwide consultation also demonstrated wide support for a national bowel screening programme (Litmus 2016a).

In screening Round 1, the BSP was described as having a high functioning multi-disciplinary team working effectively across the screening pathway, linked together via a range of networked meetings and led by respected and motivated clinical leaders at national and regional levels (Litmus et al 2015). In Round 2, this effective teamwork and transitions across the screening pathway continues. The integrated and networked BSP team reflects the work of the BSP Programme Manager supported by the WDHB BSP Clinical Director to ensure all providers on the screening pathway are engaged and their contribution is acknowledged. The BSP Programme Manager's weekly communications have been important in keeping diverse providers informed and engaged with the BSP (Litmus 2016a).

General practices have a role in the BSP of informing participants about a positive iFOBT test within a ten-day window. General practice, when engaged, have a positive contribution to the BSP by informing their patients about bowel cancer and bowel screening, encouraging the completion of iFOBT kit, informing of positive results and supporting if cancer or other health issues are identified through the screening (Litmus 2016).

General practice's engagement with the BSP reflects the intensive work of the BSP Programme Manager and WDHB BSP Clinical Director. It also reflects the BSP Coordination Centre work with PHOs, sought to ensure the BSP dovetailed with existing general practice systems, and that general practices were reimbursed for their involvement.

6.3 Conclusion

Safety

Safety is defined as the extent to which harm is kept to a minimum, and incorporates multi-dimensional perspectives such as cultural, environmental, and clinical safety (National Screening Unit 2005 p.15). Within the scope of the evaluation, no substantial environmental or clinical safety issues were identified. In Round 2, greater focus has been placed on cultural safety with a more systematic and structural focus on seeking to achieve equity of participation for Māori and Pacific people. If the learnings from the BSP are adopted – in particular leading with an equity focus, a national bowel screening programme can be delivered in a manner that is safe.

The evaluation of the BSP has identified areas of consideration to support a safe national bowel screening programme.

Governance and leadership

A national bowel screening programme will need to migrate across to the National Screening Unit to ensure appropriate governance and management structures, a population health focus, and ongoing monitoring of quality standards across New Zealand. The bowel screening programme will also need to be linked to the Bowel Cancer Working Group to continue the ongoing strengthening of bowel cancer pathways in New Zealand. Clinical leadership and programme management will be critical in building on and sustaining a quality programme working with a multi-disciplinary team to maintain fidelity to the bowel screening pathway design across regions, and to collectively resolve any issues arising. An intensity of focus on quality improvement will be required in the early implementation phases to replicate the successes of the BSP.

Resolution is required on where a national endoscopy governance group sits in the sector and who funds it. A national endoscopy group is important as it covers both environment and clinical safety in the BSP WHEU and will assist with achieving greater national colonoscopy consistency for both screening and symptomatic services.

Quality standards

The quality standards in the BSP are interim and need to be reviewed and finalised for a national bowel screening programme. Importantly, those with responsibility for a national programme need to understand their importance in monitoring the screening programme and the actions needed, if they are not achieved.

The Register

Data quality and completeness of Register data are essential to ensure the effectiveness of the BSP processes and to enable quality monitoring. The Ministry's reviews demonstrated the quality of the data on the BSP Register. Feedback on the operational functionality of

the Register highlights the need for a systematic review to determine whether it can work efficiently for a national bowel screening programme.

A systematic review of functionality will clarify the further updates required. Based on stakeholder feedback this may include: ensuring participant and GP information on the Register is up to date, increased operational automation and linkages to other health systems, and enhanced reporting templates. To support the Register in a national programme, clarity is needed on the most appropriate location for the operational data centre. The question was raised of where the responsibility for a national programme Register lies, and whether the Ministry is best placed to manage an operational database. For a national programme, the Register will require a well-resourced development and support team, as well as resourced regional data management and reporting teams to inform decision support teams at DHBs.

To ensure all eligible participants are invited, the Ministry's review of the Register offered a preliminary recommendation that for a national bowel screening roll-out the population register should use the PHO enrolment register as the base and include NHI records verified by use in the National Collections (Lee 2014).

iFOBT testing options

At a national level, the critical workforce issues for testing will be resourcing of the registration process for a much larger number of iFOBT kits. Those managing this process in the BSP advocate for a dedicated team to ensure smooth processing and quality control at registration. Capacity for testing is less of a concern as the testing machine, Diana, can process up to 260 iFOBT samples an hour.

Opinion is mixed on whether iFOBT testing should be centralised nationally in one lab, split across two centres in the North and South Island, or regionalised. Support for a centralised provision of the testing services for iFOBT reflects the efficiencies gained, and the mitigation of the challenges relating to monitoring quality across a number of lab providers. Stakeholders commented that ideally iFOBT testing will have a close working relationship with the Bowel Screening Coordination Centre/s to enable follow-up of issues (e.g. incorrect kit completion, error codes, reporting of tests). The configuration of the lab testing for iFOBT may therefore be determined by the configuration of the Bowel Screening Coordination Centre/s (i.e. national or regional centres). The lab/s will need to be accredited by International Accreditation New Zealand.

Colonoscopy capacity

In the BSP, significant effort was needed to ensure there was adequate colonoscopy capacity to meet the quality standards, particularly in Round 1. Concerns continue about whether this achievement can be replicated sustainably across New Zealand. A key learning from the BSP is having adequate endoscopist capacity to meet the growing demand for colonoscopies in screening Round 1, the need to closely monitor capacity to meet quality wait time standards, and the actions required when these look to be breached. Consideration is also needed on ensuring adequate colonoscopy capacity for symptomatic colonoscopies, which is projected to increase as the programme progresses.

Stakeholders had mixed opinions on whether BSP and symptomatic colonoscopies could be on the same list. Preference tended towards discreet BSP lists, at least in larger centres, with the sharing of resources between the services. It was recommended that pre-assessment phone calls are ring-fenced to ensure they occur (Litmus 2016a).

Ensuring access to colonoscopy for people with positive iFOBT results living in rural areas was also raised.

Histopathology

Key issue for a national programme is adequate histopathology capacity to ensure timely reporting of biopsy specimens from colonoscopies and reporting of specimens from patients who undergo surgery, and attending MDMs. On this basis, more labs will need to be involved. A regional focus is preferred by some stakeholders to build consistent processes, quality monitoring, and interpretations (Litmus 2016a).

Guidelines will need to be developed for histopathology, as per cervical screening, that all labs will need to follow (e.g. how many samples have to be processed to maintain competency, what level of complexity to ensure competency in judging cancer). Quality standards also need to be set for pathologists that can be assessed at an individual level and used to ensure appropriate quality assurance regionally and nationally.

Other learnings from the BSP are the need for an efficient, direct and safe transportation process for histology samples to the lab.

Feedback from LabPLUS highlights that adequate resources, time and priority will need to be given to the development of an IT interface between the national bowel screening information system and laboratory information systems. Ideally, a system like the HL-7 message that GPs can log into to access their patients' results should be used. Currently, labs across New Zealand have different reporting systems. In a national roll-out there will need to be consistency across labs involved in histopathology.

CTC

The role of CTC in a national bowel screening programme requires further clarification.

Surveillance colonoscopies

Surveillance colonoscopies place pressure on symptomatic services, and DHBs are requesting additional funding for surveillance colonoscopies going forward. Given the pressure on colonoscopy, it is important that surveillance colonoscopies are restricted to those most likely to benefit. Internationally, surveillance monitoring guidelines are being researched and reviewed to see if people with low-risk adenomas could be safely returned to screening at two years (Hornung et al 2015). As this evidence base grows, surveillance guidelines will need to be reviewed in New Zealand.

Acceptability

The evaluation of the BSP has demonstrated that bowel screening can be delivered in a way that is acceptable to most eligible participants provided a structural and systematic focus is used to address barriers to participation for Māori and Pacific people (refer section 5). For providers, there was a relatively high level of acceptance of the BSP at the outset of the pilot. To grow and sustain this acceptability, the BSP Coordination Centre through the Programme Manager and WDHB BSP Clinical Director focused intensively on establishing and maintaining provider relationships across the pilot duration. In this context, a national bowel screening programme can be delivered in a manner that is acceptable if it maintains fidelity to the BSP design and operation.

All general practice and PHO stakeholders interviewed are supportive of the roll-out of a national bowel screening programme. General practice can add value to the screening programme across the participant pathway. The following feedback was provided by PHOs and general practices in seeking to gain and maintain general practice involvement a national roll-out of bowel screening:

The PHO role: The need to use existing communication mechanisms within PHOs to roll out the programme.

Involvement in positive result notification: Informing patients of positive results engages general practice in bowel screening, and is likely to enable other opportunistic and systematic general practice reminders to increase participation.

System integration: Reflecting the busy practice setting, a national bowel screening programme will, like the BSP pilot, need to focus on ensuring its systems integrate smoothly with general practices' systems to enable opportunistic reminders, information about iFOBT results, referral to colonoscopy, histopathology results and surveillance. Ideally the systems used will align with general practices' existing audit processes to enable quality improvement processes.

Opportunistic reminders and systematic follow-up: The process to support participation needs to be led from an equity perspective in seeking to increase Māori and Pacific participation. Tools such as Dashboard and DRINFO enable both opportunistic and systematised follow-up. Reflecting use in the BSP, focus is needed on ensuring their widespread and consistent use, and encouraging the use of phone or text reminder processes rather than letter reminders.

Distributing iFOBT kits in practice: From a screening perspective, there are quality control concerns about distributing iFOBT kits in general practice. However, general practice are seeking further exploration of whether this can be operationalised to offer more immediacy and guidance on completion, especially for Māori, Pacific people and people living in areas of high deprivation.

Monitoring data: Providing data on participation and positivity rates at a general practice level relative to other practices would assist with engagement and enable practices to determine responses to encourage participation that are relevant for their populations.

Reimbursement: PHOs and general practice noted that reimbursing general practice for informing participants of a positive iFOBT test was important to maintain engagement and focus in a busy practice setting. Currently, a pay-for-performance initiative is being explored with PHOs to reward practices when Māori, Pacific people and those living in areas of high deprivation complete their iFOBT kit.

7. Conclusion

This section addresses the overall pilot and evaluation goal

The overall goal and underlying objectives of the BSP and its evaluation are the same and have been defined by the Ministry of Health. The overall goal of both is to determine:

Whether organised bowel screening could be introduced in New Zealand in a way that is effective, safe and acceptable for participants; equitable and economically efficient.

The BSP has demonstrated that maintaining fidelity to and drawing on the learnings from the pilot, an organised quality bowel screening programme could be safely introduced into New Zealand. The epidemiological study and cost-effectiveness analysis have demonstrated that it is highly probable that a well managed bowel screening programme will achieve a reduction in mortality from bowel cancer. However, the magnitude of any reduction cannot be assessed in a five-year evaluation.

Bowel screening is cost saving in absolute terms, while bringing health benefits. This result is driven by the savings from avoided costs of treating cancer being large enough to outweigh the costs of screening. This makes bowel screening an exceptionally cost effective health intervention, given that it both reduces health costs and produces benefits for the population. Bowel screening is a highly cost-effective intervention for Māori.

The BSP has done its job of testing a bowel screening pathway design, identifying feasible roles, and risks to translate to a national bowel screening programme. The findings from the BSP have enabled the calculations to estimate colonoscopy, pathology, treatment workloads, and cost-effectiveness parameters to inform a national screening programme. Stakeholders both regionally and nationally strongly support a national bowel screening programme. Importantly, most eligible participants find the BSP acceptable.

In a national bowel screening programme, the National Screening Unit will have a key role to ensure appropriate governance and management structures, a population health focus, and ongoing monitoring of quality indicators across New Zealand. The bowel screening programme will also need to be linked to the Bowel Cancer Working Group to continue the ongoing strengthening of bowel cancer pathways in New Zealand. Clinical leadership and operational management will be critical in building on and sustaining a quality programme and to work with a multi-disciplinary team to maintain fidelity to the bowel screening pathway design across regions, and to collectively resolve any issues arising.

Learnings from the BSP need to be carried forward into a national roll-out. A national roll-out must lead with an equity focus to ensure equitable participation by Māori, Pacific and people living in areas of high deprivation. Equitable participation for other groups such as younger people and males require further consideration. Equity across the bowel cancer pathway for symptomatic and non-symptomatic people will also need to be monitored and maintained. A continuous quality improvement model in a national roll-out will help to address new emerging issues not encountered in the BSP (e.g. for people living in rural and remote locations).

At a population level, the BSP has achieved a participation rate that is higher than that considered internationally to be the minimum participation rate (in most, but not all groups). Maintaining this participation rate in a national roll-out will be challenging, particularly for

people ageing into the programme. The latter is key to sustaining the programme in the long term.

The Register is both the operational driver of the bowel screening programme and its monitoring and reporting tool. Whether the current Register, with its manual work-arounds and support from separate databases, can undertake the day-to-day operation of a national programme has not been determined. For the Register to operationally manage a national bowel screening programme, at least in the interim, a number of enhancements and greater integration with other systems are needed.

The BSP's interim quality standards need to be reviewed and finalised for a national roll-out. Importantly, those with responsibility for a national programme need to understand their importance in monitoring the screening programme and the actions needed, if they are not achieved. With regard to quality, resolution is needed on where a national endoscopy governance group sits in the sector and who funds it, and the ongoing role of the GRS.

The challenges of workforce capacity for endoscopists, endoscopy nurses and pathologists are well known for a national roll-out, as well as the pressure surveillance colonoscopies will place on symptomatic services. Adherence to surveillance colonoscopy guidelines is critical to prevent bowel cancer and unnecessary workload. Workforce requirements will require active monitoring and management particularly in screening Round 1 of a national programme.

Areas for further study include:

- Ongoing monitoring of uptake (particularly in the low uptake groups), positivity, PPVs and detection rates, and adverse events.
- Exploring reasons for lower participation in Round 2, particularly among those newly invited to participate, if this trend persists once participation data for months 37–48 are included.
- Estimating sensitivity and specificity after at least six months has passed since the end of Round 2 invitations.
- Considering the balance between sensitivity and specificity of the iFOBT, given the low PPV for cancer and higher PPV for adenoma in New Zealand (compared to international standards).
- Assessing the staging distribution of bowel cancer diagnosed in incidence screening to evaluate the impact of bowel screening, followed by assessing the impact on bowel cancer-specific mortality once sufficient time has passed (e.g. 10 years).
- Exploring to deliver the programme with maximum efficiency, including managing the costs of histology and colonoscopy.
- Assessing the changing impacts on cost effectiveness as the cost of treating bowel cancer changes in the future, and the incidence of bowel cancer declines.
- Understanding the enablers and barriers for high deprivation populations to take part in a bowel screening programme.
- Gaining a deeper understanding the barriers for Māori and Pacific people to take part in a bowel screening programme
- Identifying strategies to increase participation by younger age groups and males.
- An independent review of the adherence of the BSP to the interim quality standards and their finalisation.

- A functional review of the operation of the Register, if used to support a national bowel screening programme.
- The need to review surveillance monitoring guidelines to see if people with low-risk adenomas could be safely returned to screening at two years.
- A comparison of how uptake in the BSP compares with the early implementation of breast and cervical screening to explore the expected growth trajectory.

Consideration is also needed on the implications of the research findings on the use of non-postal drop-off to increase participation.

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10. Glossary

For clarification, in this report the following abbreviations have been used:

- BSP – Bowel Screening Pilot
- CAR – community awareness raising
- CPHR – Centre for Public Health Research
- CNS – clinical nurse specialist
- CTC – computerised tomographic colonography
- Dashboard – a form that displays within MedTech every time a new patient record is opened and shows all key clinical information relevant to routine management of the patient
- DHB – District Health Board
- DRINFO – an audit tool which queries practice data to identifies patients who require clinical action
- FTE – full time equivalent
- General practice – refers generically to the differing systems and models in which primary care is delivered
- GP – General Practitioner
- GRS – Global Rating Scale
- Hui – A hui is a Māori term for a social gathering or assembly
- iPIMs – WDHB’s Intelligent Patient Information Systems
- iFOBT – immunochemical faecal occult blood test.⁶⁸ A single sample iFOBT test is being used in the BSP. The test is known as OC-Sensor.
- KPIs – key performance indicators
- The Ministry – Ministry of Health
- MDM – multi-disciplinary meeting
- MoDCONZ – Modelling Disease and Cancer Outcomes in NZ – a microsimulation model
- NHI – National Health Index
- Non-responders – people who have received a pre-invitation, invitation and reminder letter, have not returned a completed kit, and have not contacted the Coordination Centre to opt out of the BSP
- QALYs – quality adjusted life years
- PHO – Primary Health Organisation
- PPV – positive predictive value
- Spoilt kits – refers to iFOBT kits where the test has not been performed or labelled correctly. Most spoilt kits are due to date and label issues

⁶⁸ Referred to internationally as Faecal Immunochemical Test for Haemoglobin (FIT).

- The pilot – the Bowel Screening Pilot/BSP
- TNM – tumour/node/metastasis staging
- UK – United Kingdom
- WDHB – Waitemata District Health Board
- WHEU – Waitakere Hospital Endoscopy Unit
- The Register – BSP information system

Appendices

Please note that appendices are available as individual files for download on the Ministry of Health website In the downloads section in the right-hand column of the page: [Final Evaluation Report of the Bowel Screening Pilot: Screening Rounds One and Two](#)

Appendix 1: Updated evaluation judgements against objectives

Updated evaluation findings for Round 2 across the six evaluation objectives. Evaluation objectives on screening effectiveness, participation and coverage and cost effectiveness have not been updated here as they are updated in sections 3 and 4, respectively: [Final Evaluation Report of the Bowel Screening Pilot: Screening Rounds One and Two](#)

Appendix 2: Epidemiology report (Read et al 2016)

The complete epidemiology report: Read D, Shanthakumar M, Borman B. 2016. *The Bowel Screening Pilot Results of the First 36 Months*. Prepared for the Ministry of Health. Wellington, New Zealand: Centre for Public Health Research: [Final Evaluation Report of the Bowel Screening Pilot: Screening Rounds One and Two](#)

Appendix 3: Costing the screening pathway, Rounds 1 & 2 – Sapere

The full report of the BSP costing analysis (Blick et al, 2016) is withheld under S9(2)(i) of the Official Information Act.

Appendix 4: A cost-utility analysis based on the findings of the pilot results – Sapere

The full report of the cost-utility analysis based on the findings of the pilot (Sapere Research Group, 2016a): [Final Evaluation Report of the Bowel Screening Pilot: Screening Rounds One and Two](#)

Appendix 5: BSP monitoring indicators

The Ministry of Health developed a detailed set of monitoring indicators which were drawn up to monitor and evaluate the progress of the BSP. BSP monitoring indicators can be sourced on the following page: [Bowel Screening Pilot results](#). Appendix 5 (Table 13) is a summary of the Ministry of Health's BSP monitoring indicators as sourced on 29 July 2016: [Final Evaluation Report of the Bowel Screening Pilot: Screening Rounds One and Two](#)

Appendix 6: Adherence to BSP quality standards

For the interim evaluation report, analysis was undertaken to identify 1) whether data was available against each of the quality standards and 2) any variance from targets set. Appendix 6 (Table 14) updates this table for the period ending 31 December 2015 drawing from existing data and communications with BSP Coordination Centre: [Final Evaluation Report of the Bowel Screening Pilot: Screening Rounds One and Two](#)