

3 PART A: Introduction

3.1 Background to this Business Case

This business case builds on a series of investigations and reports considering whether and how to implement population screening for bowel cancer in New Zealand.

The primary objective of bowel screening is to reduce the mortality rate from bowel cancer, by diagnosing and treating bowel cancer at an early curable stage. An additional objective is to identify and remove pre-cancerous advanced adenomas from the bowel before they become cancerous, which can, over time, lead to a reduction in bowel cancer incidence.

Principles for Screening Programmes

Screening, in medicine, is a strategy used in a population to identify the possible presence of an as-yet-undiagnosed disease in individuals without signs or symptoms. Screening has the potential to benefit but also has the potential to do harm. Participants in a screening programme should be assured that the screening programme can deliver the potential benefits and minimise the harms and implementation of a screening programme must consider both the harms and the benefits.

There are fundamental principles that should underpin any screening programme. The Core Principles of Screening, as agreed by the National Health Committee are as follows:

- the condition is a suitable candidate for screening
- there is a suitable test
- there is an effective and accessible treatment or intervention for the condition identified through early detection
- there is high-quality evidence, ideally from randomised controlled trials, that a screening programme is effective in reducing mortality or morbidity
- the potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment)
- the health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation
- there is consideration of social and ethical issues
- there is consideration of cost-benefit issues.

Each of these Principles must be evidenced before a screening programme is considered viable, however arguably the most important of these is Principle 5 – that benefit must outweigh harm. The majority of the participants in any screening programme are healthy individuals, and potentially exposing this population to unnecessary harm is always a major consideration. Considerable infrastructure and resource would need to be put in place to ensure the quality of a national bowel screening programme is monitored and kept as high as possible. Safety of participants is of paramount importance. Psychological as well as physical harm must be minimised whilst targeting those most at risk.

These criteria formed the foundation in which development of a national bowel screening programme was established.

In 1998, the report of the Working Party on Screening for Colorectal Cancer did not recommend population screening with faecal occult blood tests (FOBT) because of the “modest potential benefit, the commitment of health sector resources and the small but real potential for harm”². The 1998 report recommended that this decision be reviewed as new information became available.

In April 2005, the National Screening Unit (NSU) of the Ministry of Health established a Colorectal Cancer Screening Advisory Group, to provide the NSU with independent strategic advice and recommendations on population screening for colorectal cancer in New Zealand. In November 2006, the group published a report³ recommending:

- A trial site (or feasibility study) approach using iFOBT.
- That decisions about the use of one-off flexible sigmoidoscopy be deferred until more evidence was available.
- Increased colonoscopy capacity to manage symptomatic and surveillance demand across New Zealand.
- The development of evidence-based guidelines for referral for symptomatic colonoscopy.

In early 2008, the Ministry of Health commissioned a further investigation into the feasibility of colorectal cancer screening. The resulting report⁴ recommended parameters (including age range, threshold for positivity, number of participants) for a colorectal cancer screening pilot in New Zealand, and contributed to the design of the Bowel Screening Pilot. In particular, the report recommended that the study should:

- Aim to determine whether colorectal cancer screening could be introduced in New Zealand equitably, effectively, economically, efficiently and in a way that is safe and acceptable for participants.
- Include a full prevalence and incidence round of screening (therefore be for a minimum of four years’ duration).
- Pilot the use of a population register to identify and invite eligible participants.
- Review the parameters (such as age range) for their implications or inequalities before being confirmed.

A Bowel Cancer Taskforce was established in 2008 to provide advice and support to the Minister of Health on the potential rollout of a national bowel screening programme.

3.2 Bowel Screening Pilot

In 2010, Cabinet approved funding of \$24 million over four years for a Bowel Screening Pilot [CAB Min 10 (12/6B)], to inform future decisions on a national bowel screening programme. Further funding of \$12.4 million was approved in Budget 2015 for a two-year extension of the pilot to December 2017.

Key Recommendations

In preparation for the establishment of a Bowel Screening Pilot, the Bowel Cancer Taskforce made a number of key recommendations, as summarised in Table 4.

Table 4: Key Recommendations for the Establishment of a Bowel Screening Pilot

Area	Key Issues Addressed
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² National Health Committee 1998

³ Report of the Colorectal Cancer Screening Advisory Group November 2006 MoH

⁴ [Next steps towards a feasibility study for colorectal cancer screening in New Zealand](#) University of Otago Department of Public Health March 2008

Area	Key Issues Addressed
Screening Pathway	<ul style="list-style-type: none"> • Key components of the pathway including the eligible age range, inclusions and exclusions, self-referral, treatment of people with a recent colonoscopy, exiting from the programme and the interval between testing. • The development of a larger role for General Practice Teams in the identification and invitation process. • Review and approval of the draft Service Delivery Model.
Choice of iFOBT	<ul style="list-style-type: none"> • Use of an immunochemical (rather than guaiac) test. • Aspects of the use of the test including the criteria for the selection (in the Request For Proposal (RFP)), the number of samples to be collected, the distribution method and the treatment of inadequate samples. • The threshold for positivity to be adopted by the pilot.
Shape of the pilot region/s	<ul style="list-style-type: none"> • Preferred criteria for the selection of the pilot site/s. • Advice on the key areas that the pilot needed to test such as the numbers of coordinating centres and laboratory services or the commitment to a significant role for primary care.
Quality Standards	<ul style="list-style-type: none"> • Participation in the development and subsequent review and advice on quality standards including Pilot Quality and Procedures Manual, colonoscopy standards and endoscopy facility standards. • Review of the draft high level monitoring framework. • The possible role of nurse endoscopists in New Zealand.
Development of existing services	<ul style="list-style-type: none"> • Providing advice and support for initiatives to improve the capability and capacity of the workforce needed to support effective screening, in particular colonoscopy and histopathology. • Support for the development of a national endoscopy quality improvement programme. • Review of the role of Computed Tomography Colonography (CTC) in New Zealand (ongoing).
Miscellaneous	<ul style="list-style-type: none"> • Advice on the Ministry support for the Familial Gastrointestinal Cancer Registry. • Advice and update on Surveillance Guidelines. • Recommending topics the evaluation should address and the time that the evaluation needs to be in place before roll out. • Advice on the options for cabinet papers on a national roll out and subsequently a pilot. • Advice on the IT solution requirements. • Advice on the efficacy of flexible sigmoidoscopy as a screening tool.

Bowel Screening Pilot

The overall goal of the pilot and its 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.

The pilot approach sought to address key questions along the screening pathway and identify likely impacts on diagnostic and treatment services, as well as providing information about the likely cost-effectiveness of a national programme. The pilot was to have a low threshold for positivity (the amount of blood present in the sample to generate a positive result) and a broad age range, in order to obtain the maximum information regarding an appropriate screening programme for New Zealand, as this was the only opportunity to trial the approach in a screening-naïve population.

After a contestable tender process and evaluation of potential pilot sites, Waitemata DHB was selected as the preferred location. It was of an adequate size to analyse impacts of the screening programme on Māori and would include sufficient (approximately 134,000) people in the 50-74 year age range.

The Bowel Screening Pilot (BSP) commenced in Waitemata DHB in late 2011, with the invitation of the 'first 500'. Lessons learned from the 'first 500' were incorporated into the service delivery model for Round 1, which commenced in January 2012 for eligible people aged 50-74 living in the Waitemata area. Round 2 commenced on 1 January 2014.

Round 1 (consisting of those invited from 1 January 2012 to 31 December 2013) and provisional results from Round 2 (1 January 2015 to 31 December 2015) showed results that were consistent with other OECD bowel screening programmes. A summary of the Pilot and findings is attached as Appendix 1.

The executive summary of the final evaluation of the Bowel Screening Pilot⁵ is attached as Appendix 2. This review has concluded that, based on the learning from the pilot, an organised high quality bowel screening programme could be safely introduced into New Zealand. The evaluation found that bowel screening is cost-effective and will save lives. The evaluation by Litmus, the Centre for Public Health Research Massey University, and Sapere Research Group, says that a national bowel screening programme would result in significant cost-savings from reduced treatment of bowel cancer, which outweigh the cost of screening.

The evaluation found a number of challenges in delivering a national bowel screening programme that is equitable, especially for Asian, Māori and Pacific peoples who were all less likely to participate in the BSP. It stressed the importance of an equity focus and appropriate systematic and structural approaches to avoid inequities in bowel cancer outcome increasing for Māori and Pacific people, and those living in areas of high deprivation. The impact of a national screening programme on the colonoscopy and histopathology workforces also needs to be managed, to retain equity between symptomatic and screening services.

International findings suggest that a bowel screening programme using immunochemical iFOBT has the potential to reduce mortality from bowel cancer (after eight to ten years in the population offered screening), by at least 16-22 percent, as documented in the Funen and Nottingham randomised control trials using guaiac FOBT (GFOBT)⁶.

This is consistent with international meta-analysis, which indicates a 15 percent reduction in colorectal cancer mortality in the population offered GFOBT screening over an eight to ten year period⁷. A recent Italian paper stated, "A well implemented screening program adopting biannual iFOBT can decrease colorectal cancer incidence by 10 percent and mortality by 30 percent after 8 years"⁸.

The BSP has performed well according to most monitoring indicators. As expected, the low haemoglobin threshold for triggering a positive iFOBT result has meant that 6-5 percent of participants are referred for colonoscopy. This is at the higher end of what is expected internationally. This has also meant that the number of colonoscopies detecting a cancer is about 4 per 100, which is at the lower end of what is found internationally. The value of the iFOBT is that the threshold for positivity can be altered, thereby changing the ratio of positive results to colonoscopies required and cancers found.

The participation rate of 56.8 percent was higher than the internationally accepted minimum participation rate of 45 percent, although participation was lower for the most deprived population, Māori, males, Pacific and younger age groups. The BSP was acceptable to primary and secondary care providers and many (but not all) people in the eligible population.

⁵ Draft: The Bowel Screening Pilot: Results of the first 36 months. The Centre for Public Health Research. March 2016. Final is due 31 July 2016.

⁶ Kronborg O, Fenger C, Olsen J, et al. Randomised study of screening for colorectal cancer with FOBT. *Lancet* 1996;348: 1467-71.

⁷ Hardcastle JD, Chamberlain JO, Robinson MHE, et al. Randomised controlled trial of faecal-occult blood screening for colorectal cancer. *Lancet* 1996; 348: 1472-7. 95 percent Confidence Interval 6 percent-25 percent.

⁸ Rossi et al. Impact of screening program on incidence of colorectal cancer: a cohort study in Italy. *American Journal of Gastroenterology* 2015

Epidemiology report (CPHR report⁹): The report thoroughly analysed the outcomes from the first screening round (Round 1) and the first year of the second screening round (Round 2) of the BSP. Particular focus was placed on comparing the outcomes of the Pilot with international findings and on equity. The overall report was very positive. With respect to participation outcomes, Round 1 showed good results although participation was less likely for those of younger age groups and for Pacific and Māori.

For those completing their incidence round in Round 2 (taking part in both Round 1 and Round 2) participation was high for all age groups and ethnic groups. For those taking part for the first time in Round 2, it was noted that there was a significantly lower participation than compared to those taking part for the first time in Round 1. This is consistent with international experience, but the report highlighted the challenge of maintaining a satisfactory level of participation over time.

Detection rates and positive predictor values for adenomas were higher than would be expected based on international findings. Detection rates and positive predictor values for cancer were at the lower end of what is usually experienced internationally.

The stage distribution of screen-detected cancers is an important indicator of screening success, and as was hoped, the Pilot found a high proportion of early stage cancers (compared to late stage cancers).

The report noted that non-completion of colonoscopy and post-colonoscopy admissions were low when compared with international findings. This is again a successful outcome for the Pilot.

Cost Effectiveness report (Sapere Research Group¹⁰): The report was extremely thorough and the authors had spent considerable time evaluating international research. The findings of the report were extremely encouraging, with the overall conclusion of the analysis stating that a national bowel screening programme would be economically efficient. The Group modelled thirteen different screening scenarios *“all of which were highly cost-effective both for the whole population and for Māori, and in some cases were directly cost saving”*.

The conclusion also stated that the analysis showed that the Programme would require significant resource requirements, particularly in the capacity to provide colonoscopy, and that this issue would impose a constraint on how the Programme may be delivered.

3.3 Exploration of National Programme Options

It is accepted internationally and by the National Bowel Cancer Working Group (NBCWG) and the Bowel Screening Advisory Group that, because of the stage at which most symptomatic bowel cancer presents, population based screening is the best opportunity to detect bowel cancer at an earlier more treatable stage.

The National Bowel Cancer Working Group has the wider remit of ensuring equitable, timely access to diagnostic investigations and high quality treatment for bowel cancer. As part of this remit, the NBCWG was responsible for advising that Barium Enema should no longer be used as a diagnostic test, developing the National Direct Access Criteria for Colonoscopy and CT colonography, producing equity statements for health professionals regarding treatment for bowel cancer, supporting healthy eating messages, and the distribution of patient information in addition to involvement in the development of the provisional Bowel Cancer Treatment Standards for New Zealand. Most recently, the group has worked with the Health Quality and Safety Commission to produce the Atlas of Variation from treatment for bowel cancer and subsequently proposes to work with DHBs to understand and address variations. The current Chair is Professor Ian Bissett, a colorectal Surgeon.

⁹ Draft: The Bowel Screening Pilot: Results of the first 36 months. The Centre for Public Health Research. March 2016.

¹⁰ Draft: The cost effectiveness of bowel cancer screening in New Zealand: a cost-utility analysis based on pilot results. Sapere research group, 23 May 2016

In July 2015, Cabinet agreed that the Ministry of Health should consult with the health sector on the national service delivery model, service configuration and associated workforce and infrastructure needs, to inform a business case for the delivery of a national bowel screening programme¹¹. Cabinet requested a report back in December 2015 on the outcomes of this sector consultation. Cabinet noted the findings of the consultation on 2 December 2015 [SOC Min (15) 0064].

In August 2015, the Ministry of Health informed DHBs of potential colonoscopy volumes, based on the findings from the Waitemata Bowel Screening Pilot. The Ministry subsequently hosted a national meeting and five regional meetings during August and September 2015, with a combined attendance exceeding 360 people. The meetings explored how a national bowel screening programme could be delivered. This consultation highlighted strong support for the introduction of a national bowel screening programme. The key themes identified during this consultation are summarised in Appendix 3.

DHBs were surveyed in October 2015 to establish:

- The approach each DHB would take to manage the anticipated increase in colonoscopy volumes.
- Estimated additional capital requirements (noting that the Ministry is keen to invest in services and that non-capital approaches should be identified wherever possible).
- Where a requirement for capital investment is identified, what new or extended facilities would be required and what capital plans the DHB already has in place that could contribute to increased colonoscopy volumes.
- Which year the DHB would expect to be ready to commence screening, as part of a national bowel screening programme.

DHBs provided assurance that they could manage the anticipated increase in colonoscopy volumes, if they receive:

- A definitive start date with adequate time to plan and implement the programme.
- Adequate funding to set up and deliver the programme.

The responses from this survey and the subsequent Impact Analysis process undertaken in May/June 2016 informed the proposed rollout approach (tranches and timings) and the financial case.

A programme business case and budget bid for the NBSP was completed in February 2016. In Budget 2016, subject to a re-stated business case due in August 2016, Cabinet approved the next phase of the NBSP [CAB-16-MIN-0189.14]. This provides part-funding for the staged roll-out of the NBSP. This includes funding set-up costs, transitioning the Waitemata pilot, ongoing surveillance and workforce training. The capital funding for the programme was put in a tagged contingency and the remaining funding for the programme's staged rollout is subject to a Budget 2017 bid.

3.4 IT Solution to Support a National Bowel Screening Programme

Good information systems are vital to ensure the optimal, safe and ethical delivery of screening activities. Comprehensive and efficient information systems are pivotal to the successful identification and invitation of eligible people to participate in screening, as well as underpinning failsafe mechanisms and adequate safety provisions for individual participants. The IT solution to support the National Bowel Screening

¹¹ SOC Min (15) 14/7 1 July 2015

Programme would provide the workflow checks and processes to support good business processes for ensuring follow up with quality diagnostic testing and treatment for detected bowel cancers.

The IT solution established to support the pilot site was specifically developed for the Bowel Screening Pilot, within constraints of costs and timeliness and within the context of the relatively small nature of the pilot. Numerous enhancements to the pilot system have since been applied successfully, as new requirements and changes have been identified.

A key assumption is that the business processes that are operating in the pilot site are largely representative of those that are expected in a national rollout. Going forward into the national programme, the assessment of the existing pilot system is that it would not be possible to successfully scale, in its current form, to meet the needs of a national rollout to a further 19 DHBs. This assessment is based on the knowledge gathered from the pilot system, including the identification that approximately 50 percent additional functionality is achieved manually by the Pilot and would need to be automated in a national system.

Learning from other jurisdictions indicates a strong need for flexibility within particular elements of the application such as the ability to change the test technology and associated clinical pathway. The BSP IT system lacks the flexibility in its core components to adapt as required.

3.5 Timing Imperative for Investment

The proposed rollout of a national bowel screening programme over the next two to four years would capitalise on the outcomes of the pilot, as well as the concurrent investment which has been made in colonoscopy services.

Investment in colonoscopy

Since 2013/14, the Government has invested over \$15 million to reduce DHB colonoscopy waiting lists and undertake regional planning to meet long-term colonoscopy demand.

This funding has led to an improvement in colonoscopy provision, in both quantity and quality. Prior to funding (2012/13) 30,122 colonoscopies were performed in a year. Funding received in late 2013/14 has helped achieve a 20% increase in the number of colonoscopies performed with 36,080 colonoscopies performed in 2014/15. Provisional data indicates that 2015/16 colonoscopy achievement will prove to be as high (or higher).

This investment has resulted in a 65 percent drop in the number of people waiting longer than the target time period, from 6,696 in May 2014 to 2,330 in June 2016. In 2016/17, the Government will invest a further \$4 million per annum to further reduce colonoscopy waiting times. The majority of DHBs are meeting their colonoscopy waiting time indicator targets and the Ministry is working actively with those that are not meeting targets. This work has been critical in preparing DHBs to deliver a safe, quality national bowel screening programme.

The percentage of people seen within colonoscopy target times is shown in Table 5.

Table 5: Percentage of people seen within colonoscopy target times

Category	May 2014 (%)	May 2015 (%)	May 2016 (%)	June 2016 (%)
Urgent Colonoscopy (≤ 14 days)	52	70	91	92
Non-Urgent Colonoscopy (≤ 42 days)	32	51	60	68
Surveillance Colonoscopy (≤ 84 days)	37	54	59	65

Timely colonoscopy is a critical factor in enabling a rollout of a bowel screening programme, as this would have an immediate knock-on impact on colonoscopy services. Colonoscopies are required for people identified through screening, with symptoms, as well as surveillance procedures for those with a history or greater risk of bowel cancer. Referral Criteria have been developed for Direct Access Outpatient Colonoscopy and colonoscopy wait time indicators established, with funding to improve the timeliness and volumes of procedures.

It is critical that the momentum that has been gained in this area is not lost. Since consultation on a possible rollout commenced in July 2015, the sector has been 'gearing up' in preparation for a national rollout. DHBs require certainty on when they would be expected to commence bowel screening. Should there be a delay in implementation of a bowel screening programme beyond early 2017, the investment-generated momentum will slow and there may be a loss of focus and expertise, with a resultant delay in planning for capital investment. This could result in growing waiting lists, and the gains that have been made would be lost.

As well as investment in increased colonoscopy capacity (including staff training and retention), there has been investment in reducing system inefficiencies, improving patient flow, development of quality assurance measures and planning for standardised training for colonoscopy and increasing workforce capacity. The likelihood of a national screening programme has allowed for investment in training additional endoscopists, including nurses.

Support for Investment in a National Bowel Screening Programme

There is widespread public and sector support for both a national bowel screening programme and the improvement of existing bowel cancer services. In 2010, the Bowel Cancer Taskforce (whose members were clinical leaders in gastroenterology, colorectal surgery, oncology, general practice and primary health care, public health and gastroenterology nursing) endorsed the implementation of a bowel screening programme in tandem with increasing colonoscopy capacity. This approach was also supported by Cancer Control New Zealand, the New Zealand Society of Gastroenterology, the New Zealand Association of General Surgeons, the Colorectal Surgical Society of Australia and New Zealand (NZ branch), the Royal New Zealand College of General Practitioners and the Cancer Society of New Zealand¹².

Beat Bowel Cancer Aotearoa included bowel screening as one of the 10 key recommendations in their 2015 Call to Action document¹³. CANGO, an alliance of eight major cancer Non-Government Organisations (NGOs), identified a full national bowel screening programme as one of their seven priorities in their manifesto issued in mid-2014, prior to the election.

In 2012, a national baseline survey of people within the eligible screening population (excluding Waitemata DHB) was undertaken as part of the formal evaluation of the Bowel Screening Pilot. Three quarters (76 percent) said they were likely or very likely to participate in a bowel screening programme if they received an invitation letter (stating their doctor's support) in the mail, followed by an iFOBT kit. This finding was comparable to the 2011 baseline survey of Waitemata DHB eligible participants. Over 75 percent of people agreed that 'it is important to check for bowel cancer even if you don't have symptoms'. Over 95 percent agreed that 'treating bowel cancer in the early stages increases a person's chance of survival'.

In early 2015, the Royal Australasian College of Physicians and the New Zealand Society of Gastroenterologists wrote a joint letter to the Minister of Health in support of a national bowel screening programme.

¹² Memorandum to Cabinet Social Policy Committee: Bowel Cancer Screening Programme for New Zealand

¹³ Beat Bowel Cancer Aotearoa 2015 Call to Action April 2011

Bowel Cancer New Zealand, the Cancer Society and leading colorectal surgeons applauded the Budget 2016 announcement and voiced their support for the roll-out of a national programme, reiterating that screening and early detection would save lives and improve New Zealand's high bowel cancer death rates.

In June 2016, the Chief Executives of all 20 District Health Boards confirmed their support in writing, for the implementation of a National Bowel Screening Programme.

Consequence of delay to rollout of a national programme for bowel screening

If the rollout of a national bowel screening programme is delayed, there is a risk that not only momentum but also workforce capacity and capability from current investment will be lost. Each year that the start of the programme is delayed will result in:

- A whole cohort of people aged 74 years (over 36,000 people) not being offered bowel screening in their lifetime.
- Approximately 77 cancers not detected in year one of the phased roll out, for the Tranche 1 DHBs.
- A delay in detecting an estimated 500-700 cancers annually across the whole country in the early rounds.
- An ongoing cost of approximately \$6 million per annum to maintain the Bowel Screening Pilot in Waitemata DHB.
- Continuing bowel screening in just one DHB (Waitemata) with a lower incidence of bowel cancer, once the aims of the pilot have been achieved, would raise ethical concerns.