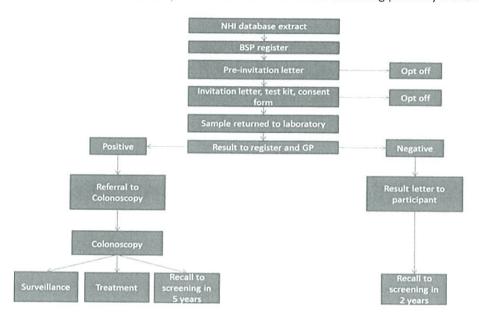


Appendix 1: Initial Findings - Bowel Screening Pilot

The Bowel Screening Pilot (BSP) commenced in late 2011 with the invitation of the 'first 500'. These 500 participants (from a single Primary Health Organisation (PHO) in Waitemata) were invited prior to the BSP officially commencing. Lessons learnt from the 'first 500' were incorporated into the service delivery model for Round 1, which commenced in January 2012. The overview of the screening pathway is shown below.



The first screening Round (lasting two calendar years) invited almost 122,000 people identified from the National Health Index (NHI) database as being eligible. The population register used in the BSP is a first for screening in New Zealand. Other screening programmes use an 'opt on' model, asking potential participants to enrol themselves in the screening programme. The BSP uses an 'opt off' model: identifying and inviting the cohort of people living in Waitemata DHB region who would be aged between 50 and 74 years during the pilot timeframe. These potential participants could opt off at any point along the bowel screening pathway if they chose.

The population register is kept as up to date as possible (via linkages with the NHI database, via manual update by the team at the Waitemata co-ordination centre and through data uploads from the New Zealand Cancer Registry) which ensures demographic information is as reliable as possible.

The first screening round (known as the prevalent round) saw a participation rate of 56.8 percent (Ministry of Health, 2015) for the eligible population (50-74 years), with almost 70,000 people returning a correctly completed iFOBT kit to the laboratory. International guidelines suggest a participation rate of at least 45 percent is acceptable.

Whether an iFOBT kit is positive depends on the amount of Haemoglobin found in the kit's buffer solution. Upon analysis, the average Round 1 positivity rate was found to be 7.5 percent (Ministry, 2015) which was at the higher range of what is found internationally. This equated to 217 people being found to be positive per month.

Participants with a positive iFOBT were then informed (via their GP or through the co-ordination centre) that they may be eligible for a colonoscopy, dependent on eligibility criteria. Approximately 95 percent of all those with a positive screening test went on to have a colonoscopy (or a CT colonography if appropriate).



More than two thirds of people receiving a colonoscopy required bowel polyps to be removed during the procedure. This is a higher proportion than that reported from other population based screening programmes using iFOBT⁵⁵.

4.3 percent of all colonoscopies led to a finding of bowel cancer in Round 1. More than 60 percent of these cancers were identified as being at stage I or stage II, meaning that the cancer had yet to spread to other organs. A recent New Zealand study (Health Research Council and Ministry of Health, 2015) showed that for the unscreened population, approximately 40 percent of bowel cancer patients had a stage at diagnosis of stage I or stage II.

Stage at diagnosis is an important indicator of the success of any screening programme, as finding a cancer at an early stage has a huge impact on the cost-effectiveness of the programme, both in terms of financial benefits to the health system, and in terms of survival and quality of life of affected people.

The numbers of cancers found per colonoscopy in the BSP was at the lower end of the range expected internationally. However, the threshold for positivity of the BSP iFOBT analysis was set at a low level when compared to threshold now being used in other countries with population screening programmes using iFOBT. The threshold for positivity for the pilot was set at this low level (as had been the situation for other pilot studies internationally) to ensure the maximum amount of data was available to make a robust decision regarding the most appropriate and feasible bowel screening options for NZ.

The pilot data demonstrated that If the threshold for positivity of the iFOBT kit was increased to similar levels used in other OECD countries, it would result in both more cancers being found per colonoscopy undertaken and a reduction in the unnecessary risk of colonoscopy for people who had a low level of haemoglobin in their sample and therefore a lower risk of being identified to have cancer or significant polyps.

The pilot data has been analysed, at a variety of different age ranges, to determine the threshold for positivity that maximises the detection of cancer while minimising the number of colonoscopies performed in individuals at a lower risk of having cancer or significant polyps. Elevating the threshold for positivity also substantially reduces the burden on the colonoscopy and pathology workforce and thereby increases the cost effectiveness of the entire programme.

In addition to finding cancers, within the BSP during the first screening round, almost 50 percent of individuals proceeding to colonoscopy were identified to have non-cancerous polyps known as adenomas. Almost half of those with adenomas in the first screening round were reported on histology to have 'advanced' adenomas, which have an increased likelihood of developing into bowel cancer in the future. Consequently the success of the BSP is not confined to detecting cancer because removal of advanced adenomas will reduce colorectal cancer incidence in the long term.

As seen in all international screening programmes, participation reduces in Round 2, and this has also been seen in the New Zealand context. Removal of participants from the population pool due to them testing as positive in Round 1, means that subsequent screening populations slowly move to being, on average, less likely to produce a positive result – i.e. the population pool slowly shifts to a more healthy state.

Round 1 (consisting of all those invited from 1 January 2012 to 31 December 2013) showed results that were anticipated from other OECD bowel screening programmes. Round 2 (all those invited from 1 January 2014 to 31 December 2015) cannot be evaluated fully until all those invited have returned their kit (if they intend to) and have moved through the entire screening pathway. The draft analysis including Round 2 is expected to be available in mid-2016. Indications are that Round 2 is proceeding as expected, with results comparable to those seen in other international programmes.

⁵⁵ European guidelines for quality assurance in colorectal cancer screening and diagnosis (2010).



Three issues identified in the first round of the New Zealand pilot are risks for a national rollout: workforce resource implications for colonoscopy, for pathology and inequitable participation in the programme with respect to ethnicity and deprivation.

Workforce implications for colonoscopy

The positivity rate for the Bowel Screening Pilot was towards the upper end of the expected range of six to eight percent and consequently the number of colonoscopies required was at the upper end of the anticipated range The pilot demonstrated that it took several months to build up to the required steady state of colonoscopy.

Once the BSP moved in to Round 2, and the test positivity rate for the population naturally became lower, there was a resultant reduction in the numbers of colonoscopies.

Lessons from the BSP, with respect to colonoscopy volumes, would be factored into planning for a national service and advice to DHBs regarding monitoring and planning colonoscopy services for the NBSP.

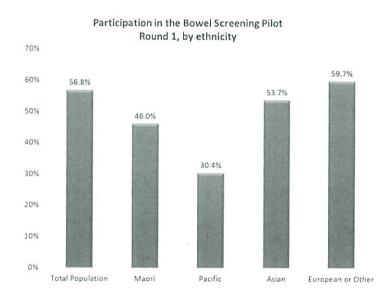
Workforce implications for pathology

The test positivity rate experienced in Round 1 of the Pilot resulted in the need for colonoscopy requirements at the upper end of the anticipated range. In addition, more than two thirds of all those people receiving a colonoscopy required bowel polyps to be removed during the procedure (a higher proportion than that reported from other population based screening programmes using immunochemical faecal occult blood tests). The high number of polyps requiring histological investigation put pressure on the pathological workforce at the contracted laboratory.

The findings from the BSP would be factored into planning for a national service and advice to DHBs around monitoring and planning pathology services for the NBSP.

Inequitable participation

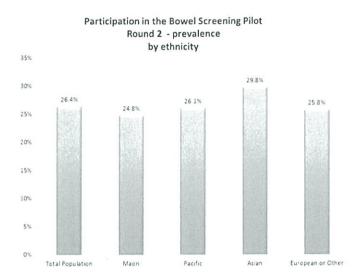
Results from Round 1 of the BSP showed a large disparity in the participation rate of different ethnic groups. The chart below shows that the lowest participation in Round 1 was seen for Pasifica, with a rate of 30.4 percent, followed by a rate of 46.0 percent for Māori.



Source: Ministry of Health 2015



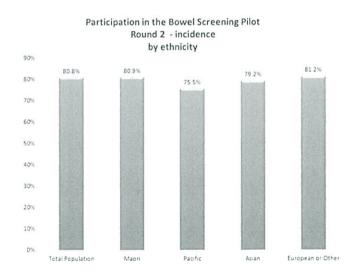
Considerable work has been undertaken since these inequalities were noted in Round 1. A number of initiatives to encourage participation, managed by the Waitemata co-ordination centre, targeted the Māori and Pasifica priority populations. Results from the first year of Round 2 showed no real disparity between ethnic groups for those taking part for the first time (prevalence screen). This can be seen in the following chart.



Source: Ministry of Health 2015

Although participation for those taking part for the first time (prevalence) in the second round is low because the majority of these people had aged in to the screening cohort. Participation is notably lower in the youngest age group (50-55) and this is also seen internationally.

For those who had taken part in Round 1, and had been invited for a second time in Round 2 (participants entering their incident round) the participation was both high and equitable – this was a welcome finding.

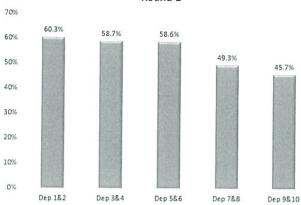


Source: Ministry of Health 2015

When analysed by deprivation group, participation decreases as deprivation increases. Work is now also being undertaken to encourage participation in high deprivation groups.







Source: Ministry of Health 2015

Once on the bowel screening pathway, initial investigations show that disparities between population groups do not exist.

The PIPER study showed that 36 percent of symptomatic colorectal cancers were found in the right side of the colon, and 38 percent were on the left and 25 percent were in the rectum (less than 1 percent had sidedness not stated)⁵⁶. The BSP shows a different site distribution, with 28 percent of colon cancers being found on the right side of the colon, 50 percent on the left side of the colon and 19 percent in the rectum (3 percent had sidedness not stated). This suggests, as previously recognised, that the immunochemical faecal occult blood tests are less sensitive for the detection of right sided cancer. However, this is also true for other bowel screening approaches and there are a number of reasons for this.

Health Research Council and Ministry of Health (2015) PIPER study. Wellington: HRC and MoH; MoH (2-15, September 3) Bowel Screening Pilot Results. Retrieved September 22 2015 from MoH: Health.govt.nz



Appendix 2: Pilot Evaluation Report Executive Summary

The Ministry of Health funded Waitemata District Health Board (WDHB) to run a Bowel Screening Pilot (BSP) over four years from 2012–15. 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 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.

This report is the final evaluation report of the BSP following the completion of the invite distribution for screening Rounds 1 and 2 (January 2012 – December 2015) Note the epidemiological analysis is only for the first 36 months of invites with over eight months allowed for completion of the pathway. 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 thirteen different screening scenarios all of which 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 a constraint on how a national programme may be delivered. Sapere modelled colonoscopy requirements for three potential configurations, showing the estimated number of colonoscopies for a national programme over a decade from implementation.

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.

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.



A national bowel screening programme must lead with an equity focus. 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.

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. 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 very 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, maintaining fidelity to and drawing on the learnings from the pilot, an organised quality bowel screening programme could be safely introduced into New Zealand. Bowel screening is cost effective and will save lives.

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.

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, a review of the Register's operational functionality, resolution on the location and funding of the endoscopy governance group, and the quality standards to be finalised. The impact of a national screening programme on the colonoscopy and histopathology workforces need 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).



Appendix 3: Key Themes from Engagement with the Health Sector

The Ministry of Health hosted one national and five regional meetings during August and September 2015. More than 360 clinicians, managers, private providers and NGO representatives attended the meetings.

There was support for:

- The national coordination of screening invitations and iFOBT screening testing.
- Regional coordination of quality across the bowel screening pathway, in accordance with nationally developed quality standards.
- Local delivery of colonoscopy and health promotion.
- A strong focus on improving equitable participation.
- Involving primary care within the programme.

Other key themes included:

- A keen interest in the model, based on BSP data, used to predict the colonoscopy requirements of a national bowel screening programme followed by requests to access these tools and resources.
- Continuing the existing momentum to improve colonoscopy quality, capacity and wait times an essential requirement to ensure readiness for a national bowel screening programme.
- · Workforce concerns, primarily within endoscopy, pathology and nursing.
- The importance of quality data capture and a robust national bowel screening IT solution to support a national programme.

In June 2016 the Ministry of Health sent all DHBs information about the NBSP, and asked them to complete a high-level impact analysis questionnaire. The themes emerging from this analysis are summarised in Table 51.

Table 51: Key Themes from Engagement with the Sector

Key themes	Next steps
All 20 DHB CEOs sign an agreement in principle to the proposed go live date for a national bowel screening service in their DHBs	Detailed impact analysis carried out with each DHB, by tranche, with an aim to determine actual roll-out order
All 20 DHBs responded to the impact analysis showing commitment and positive engagement for the programme.	 Capitalise on this by continuing regular communication and engagement activities to unpack challenges and issues for DHBs
The 100% response from DHBs on the impact analysis indicates a there is an understanding of the requirements on DHBs for planning and delivery of a national bowel screening service.	Continue engagement activities to further explore DHB challenges and issues identified for implementation.
Improvements in Colonoscopy Wait Time Indicators showing a commitment to improving service delivery in readiness for national bowel screening service.	Continue to work and fund DHBs to meet targets
Challenges for DHBs in recruiting the necessary resources for NBSP, in particular Gastroenterologists, Endoscopy Nurses, Radiologists and Pathologists.	 Work with DHBs and Health Workforce New Zealand to develop recruitment strategies. Explore regional approach through planned regional meetings and relationship management activities.
Some DHBs in the smaller centres have further challenges around recruitment as screening	Work with DHBs and Health Workforce New Zealand to develop recruitment strategies.



Key themes	Next steps
volumes are lower than the larger centres and indicate a portion of FTEs which are harder to recruit and retain	Explore regional approach through the programmes planned regional meetings and relationship management activities.
Additional capital required by some DHBs for endoscopy, CTC and cancer services as a result of increases in volumes due to screening	 Explore regional approach in managing demand through the programmes planned regional meetings and other relationship management activities. Manage DHB expectations in regards to capital funding and ensure there is an understanding that usual business planning approach will be required for capital funding.
DHBs ability to absorb treatment costs during the initial treatment hump due to an increase in bowel cancers being detected as a result of screening	Determine through the detailed analysis carried out at the Implementation Business Case stage likely treatment costs for DHBs using the model developed by Ministry of Health.
The challenge of balancing the out-sourcing and managing colonoscopies locally with minimum capacity and resources available	 Determine through the detailed analysis carried out at the Implementation Business Case stage the regional approach for management of screening volumes. Explore regional approach through the programmes planned regional meetings and relationship management activities.
Further clarity needed for DHBs on the breakdown of funding for implementation and ongoing costs	 Carry out workshops and discussions with DHBs at the programmes planned regional meetings and relationship management activities.



Appendix 4: NBSP Alignment with NSU Core Principles of Screening

The NBSP will align with the National Screening Unit (NSU) core set of six principles. These principles provide a foundation for achieving NSU's strategic vision for achieving high quality, equitable and accessible screening programmes.

1. The overall benefits of screening must outweigh the harm

- There should be regular review of the evidence which programmes are based on.
- There is transparency around significant decisions, major changes to screening programmes and serious adverse events.

2. National screening programmes are people centred

- The screening pathway should be acceptable to individuals, whānau and the populations concerned
- Advisory groups seek appropriate consumer representatives with experience of the condition(s) screened for and the health system
- Screening programmes are delivered in an ethically and culturally competent manner in the New Zealand setting.

3. National screening programmes will work towards achieving equitable access to the screening pathway and equitable outcomes for all population groups

- Screening programmes should incorporate the principles of The Treaty of Waitangi
- Solutions to access are focused on improving processes and adapting systems to meet the needs of individuals and under-screened populations.

4. Informed consent is a priority throughout the screening pathway

- Screening programmes should provide full information to people; this includes detail on benefits and harms of screening
- Screening programmes must ensure that cultural and health literacy differences are addressed when providing information to support informed consent.

5. Screening programmes are monitored and evaluated on a regular basis

- Information systems should be set up to enable timely monitoring, audit and evaluation of screening programmes and providers.
- 6. National screening programmes are committed to continuous quality improvement in programme management and clinical service delivery
 - Policy makers, providers and all those involved in screening programmes are accountable and responsible for maintaining capacity and capability in delivering screening programmes / services of the highest possible quality

The NBSP will align with the **five essential components of organised screening systems** identified as essential to the safe and effective practice of organised screening (adapted from Hale 2012)

- A central agency to lead and coordinate the screening pathway
- Clinical governance
- Infrastructure and systems to manage a screening programme
- Monitoring and evaluation
- Quality Cycle



Appendix 5: Key Programme Risks and Issues

(High/very high only)

Delayin OHBs rol delayed Where th	Delay in roll-out of the first three DHBs roll-out onto the NBSP will be delayed. Where the infrastructure will be brotted and strongland is use to he	L Designation Committee of the Committee	Implementation Possible	Possible Possible	Deveree Service	Park 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	-Good governance and oversight of Programme, strong project managementRigatous management of scope and schedule load statements that the based statement of scope and schedule controlled controlled coleration of project management of scope and schedule controlled colerations of statements and colerations of statements this understood and robust planning is in placeRobust Change-Relationship management with DriBs to agree on expectations regarding roll-out scope and costs with each DriB depending on the state of their If systems that need to be integratedA high level impact analysis of all DriBs has been completed, including II "stock-take"; a detailed impact analysis will be undertaken as past of Tranche 2 and 3 planning will be undertaken as past of Tranche 2 and 3 blanning receiption reportingBoad stakeholder consultation; detailed clear II requirements documented. Robust eineeption reporting project management of scope and schedule. Clear scope control and schedule. Clear scope schedule. Clear scope control schedule. Clear scope schedule.
confirmed and suppression of important and will it is not import at the development. A defendable on hosting location will have a knock or finalising/signing the Supplier contract.	S G S	The infrastructure required will not be in place and cause a delay to T1 delayers as the infrastructure decision and contract is a prerequisite for T1 delayery inneine, it will also delay delayery of the NBSP IT system delayery.	Implementation Possible	Possible	Severe		for the Infrastructure hosting strategy. The chosen infrastructure supplier has the necessary resources and capability to deliver to the project delivery timeframes. The instructure requirements are clear and available as soon as the Governance Board approval has been given. Work within existing convacts and preferred suppliers. Work closely with the programme procurement.
Maon, Pacifica, H andfor other popu participation rates population.	in Deprivation ations have lower han the genetal	if participation rates vary along the pathway between ethnicities, deprivation indewes and/or other populations, then the NBSP has not achieved equity	Programme L	Likely	Major	12 · 14 · 14 · 14 · 14 · 14 · 14 · 14 ·	KPIs for participation along the pathways. Participation rates for different groups monitored. The Programme Business Case lists strategies for driving equal participation. Storing governance and leadership to ensure inequalities are addressed in programme planning and implementation. Ava arene ss rating campaigns, nominate NBSP "Champions" for priority groups, work closely with primary care. DHSs expected to have high level of engagement with Maori & Pacific organisations.
Unable to recruit new staff for the programme team until September 2016. The funding cannot be drawn down for the letter MSPS implementation until the restated Programme. Business case goes to Cabinet for annurul 172 Aurus 27116)		Inadequate resource could cause a delay to all delayed ares, compromise the quality of work produced and limit. Implementation Likely the scope of stakeholder engagement.	Implementation L	ikely	Major	Hg 21	The MoH has approved the memo to recruit staff to the programme team. Programme Director working with HR to develop a recruitment timeline. Key positions will be prioritised.



Risk Containment / Mitigation Plan ▼	Robust RFP process and procurement planning.	Ongoing relationship management with DHBs, regional meetings August 2016 to discuss service model expectations with DHBs and obtain their feedback. Provide data and assistance to help DBs model correctly	There is a quality manual for the Pilot which can be built on using learnings from the Pilot. Option to use GRS as basis for a colonoscopy accreditation tool. Ensure sufficient stalfing levels to support quality	Ensure a strong budget bid is put forward	- Ongoing relationship management with DHBs, regional meetings August 2016 to discuss service model expectations with DHBs and obtain their feedback. - Provide data and assistance to help DHBs model correctly. - DHBs utilise their annual uplift and electives funding.
Current Risk	a g	& FE	H dg	85 HgH	High High
Likelihood Consequence	Severe	Severe	Major	Major	Major
Likelihood	Unlikely	Unlikely	Possible	Possible	Possible
Category	Implementation Unlikely	Implementation Unlikely	Programme	Implementation Possible	Programme
Which may result in_(RISK EFFECT) ▼	Delay in roll-out of the NBSP	Delay in NBSP roll-out	Programme benefits are not fully realised as harms are not minimised/benefits maximised	The roll-out of the NBSP will be delayed. If funds promised to DHBs to deliver the NBSP and Surveillance colonoscopies, DHBs will lose confidence in the Programme and may resisted elay limit their uptake of the NBSP.	- DHB resistance to a NBSP - DHBs seek additional funding from the crown
I here is a risk that_(HISK EVENT) ▼	Delivery of Tranches 2-3 is contingent on a NGC being in place	Detailed set-up plans for the DHBs rely on the BSRCs being in place	An increased risk of adverse events for participants and decreased consistency of participant experience across NZ	Budget 2017 If sufficient funding is not able to be drawn down, the NBSP implementation scope and milestones will be compromised.	- There will be an increased treatment burden on DHBs - DHBs consider funding insufficient for the brought forward treatment costs
In the event that_ [HISK LAUSE]	An appropriate supplier to deliver the National Coordination Centre (INCC) services cannot be identified and/or there is a legal challenge to the supplier of choice	A delay in set up of Bowel Screening Regional Centres	The screening provider does not meet quality requirements	Insufficient funding for the NBSP released in Budget 2017 to continue the roll-out of the NBSP.	The initiation of a NBSP results in a larger than anticipated Round I peak in the number of bowel cancers diagnosed



Risk Containment / Mitigation Plan	Planning for writing the Business Case allows sufficient time for the approvals process. Work to streamline approvals process.	Ensure that the business operational model is clearly defined and agreed in principle with the Programme Governance Board. The business operating model is refined working a single appropriate DHB designated as the first transhe 2 go-live DHB in January 2018. The business operating model is based on the existing Waltemata pilot with minimal changes as required to support multiple locations. Ensure effective use of iterative development methods.	Ensure engagement and commitment across the Sector to achieve the programme objectives. Work closely with the communications team to ensure alignment between business and IT communications.	Health Workforce NZ initiatives to increase name of Gastroenterologists and Surgeons. HWNZ work on nurse endoscopy Ensure NBSP options take into consideration workforce limitations. Detailed impact analysis of DHBs prior to confirmation of roll-out order to identify potential workforce issues and implement plans to address this before go live.
Current Risk Batin	Hgh Hgh	윤년	Hg 48	High dg
d Consequence	Major	Major	Major	Мајол
Likelihood	Possible	Possible	Possible	Possible
Category	Implementation Possible	Implementation Possible	Implementation Possible	Piogramme
Which may result in_(RISK EFFECT)	There will be time slippage for the first key deliverables which will have a knock-on impact on the timeframes for delivering the NBSP by 2020	The IT solution developed may not be fit for purpose.	Sector requirements will be difficult to gather and progress will be constrained	Insufficient colonoscopy, pathology, Some DHB areas will have increased radiology endoscopy and nursing waiting times, poor quality service and workforce may impact on the ability not meet their performance indicators. DMPBs to deliver the NBSP to their Symptomatic services may be population neagtively impacted.
There is a risk that_(RISK EVENT)	Delays in approvals will result in subsequent delays in NBSP implementation	if the business operating model is not defined, documented, then the high level requirements (Vision and Scope) will be unstable leading to IT rework and programme delays	- IT and business communications to, and engagement with, DHBs may not be consistent; engagement and y confidence with the Sector will be Sector equil 3 significantly compromised - DHBrs gather and programme leading to frustration and lack of confidence from DHBs in supporting the NBSP	Insufficient colonoscopy, pathology, radiology endoscopy and nussing workforce may impact on the ability of DHBs to deliver the NBSP to their population
In the event that_(RISK CAUSE)	Delays in Cabinet approval of the restated PBC and/or the ImpBCs for Tranches 1-3	If the business operational model for the national defined, documented, then the high The IT solution developed may not be (Phase 2) IT solution is not clearly defined Scope) will be unstable leading to IT in the purpose.	- IT and business communications to, and engagement with, DHBs may not be consistent; engagement and Change management is not effectively confidence with the Sector will be Sector requirements will be difficult to undertaken for Tranche 1 and Tranche 2 DHB significantly compromised – DHB's gather and progress will be integration Requirements could become confused about the constrained programme leading to frustration and lack of confidence from DHBs in supporting the NBSP	Insufficient workforce capacity e.g. Colonoscopy, Pathology, Endoscopy, Mursing, Radiology





Appendix 6: Summary Programme Long-list Options Assessment

implementation (Timing & staging)
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Option	ပိ	Comment	Outcome
Scale and Scope	a		
	•	Do nothing: This is not a favoured option as it does not address the problems identified and does not support the realisation of the desired benefits.	Carried forward as benchmark
	•	Do minimum: This would achieve a greater mortality reduction for Waitemata DHB residents only. This option failed to achieve a range of IOs and CSFs. It would not be a national programme and would perpetuate inequity between residents of WDHB and other DHBs. The lack of national rollout would result in ongoing adverse events for the population not diagnosed/treated. It does not meet the business needs and would not be value for money, as the age range and specificity threshold are not optimal.	Rejected
	•	Age 60-74, threshold 200ng haemoglobin/ml buffer: This option fully meets all of the CSF, and IOs with the exception of 'promoting equity'. This has been assessed as 'partial', as the Bowel Screening Pilot identified that there was inequity in participation and outcomes between Māori and Other.	Preferred - only viable option
	•	Age 50 & 55-74, threshold 200ng haemoglobin/ml buffer: Both of these options met all of the IOs except 'promoting equity', as above. Both options were assessed as failing the 'supplier capacity and capability' CSF. The volume of colonoscopies required from the extended age range would not be achievable by the majority of DHBs, within existing resources and the proposed timeline for implementation.	Rejected
	•	Age 50-74, threshold 75ng haemoglobin/ml buffer: This option reflects the Bowel Screening Pilot Criteria. It was assessed as failing the 'supplier capacity and capability' CSF, as the volume of colonoscopies required from the extended age range and lower threshold for positivity would not be achievable by the majority of DHBs, within existing resources and the proposed timeline for implementation.	Rejected
	•	Age 55-74 (Māori), 60-74 (other), threshold 200ng haemoglobin/ml buffer: Whilst this option may contribute to reducing inequity between Māori and Other, this is estimated to be a very marginal contribution as the extended age-range would capture very low numbers of cancers. It would not be a nationally equitable service and therefore this option was rejected. Instead the programme would focus on increasing equity by driving equitable participation in the crossing experiment.	Rejected
		occasoring equity by arrying equitable participation in the screening programme.	



Implementation	_ c		
	•	'Big-bang': This option was assessed as failing to meet the 'achievability' and 'supplier capacity and capability' CSFs. Achieving a full rollout across 19 DHBs on the same date would not be possible as it would place too much demand on colonoscopy services and the existing IT solution. Some DHBs require more time to create sufficient colonoscopy capacity to manage the impact of the increased activity arising from the bowel screening programme, and therefore either all DHBs would need to wait until the slowest was ready, or the rollout would compromise patient care in the DHBs with insufficient capacity. The replacement IT solution needs to be developed and implemented progressively to ensure that it is robust. Developing full implementation plans for safe concurrent implementations would require significantly higher programme team staffing.	Rejected
	•	Phased by Tranche: This option was assessed as meeting all of the CSFs, and all IOs with the exception of 'promoting equity', for which it was assessed as 'partial'. The extended timeline for implementation would result in some parts of the population being tested/treated before others, resulting in higher mortality in the later adopters.	Preferred
Service Solution	u		
П	•	See Appendix 7.	
	•	Mail only: This approach has been used successfully in the Bowel Screening Pilot. Whilst it may not be as effective at 'promoting equity' and 'encouraging participation' as mail in conjunction with community targeted distribution, it is a feasible approach. It is based on international best practice and could be implemented immediately, with extension (to community targeted distribution) implemented at a later date if desired.	Preferred
Invitation	•	Mail and community targeted distribution: Feedback from the Pilot indicates that there could be greater uptake in some populations, in particular Māori, if alternative approaches (e.g. distribution on a marae) were added. Whilst this option would therefore be preferable for promoting equity, it was assessed as potentially not meeting 'national consistency' and it would create a potential risk to the programme. It would require barcode scanning of all kits and rigorous monitoring of expiry dates to ensure safety. The option was also 'partial' for 'supplier capacity' and 'achievability', as it would require significantly more investment of time/resource to ensure that it was undertaken effectively. This option was summarised as 'possible', as although it was not taken forward to the shortlist at this stage it could be implemented by the programme at a later date.	Possible
	•	Mail only: This option was assessed as meeting most IOs and CSFs. It was assessed as 'partial' for 'promoting equity' and 'encouraging participation', as findings from the Bowel Screening Pilot indicate that some Māori would be more likely to participate if alternative routes were available for returning samples. Findings may be available from the pilot trial early in 2016. It was also assessed as 'partial' for 'strategic fit/business need', as any reduction in returns would lessen the degree of effectiveness.	Possible
Return	•	Mail with possible future contingency for drop off at laboratories: This option met all of the criteria except 'national consistency', as this would be less viable in some communities, e.g. rural areas. The overall benefits of reaching more Māori/Pacific were assessed as outweighing the potential loss of national consistency and therefore this option was identified as being preferable to mail only. This option also provides a contingency plan should there be any unforeseen (at this time) changes to the postal service. The programme would commence with mail only, with this approach being reviewed throughout implementation (and subsequently through business as usual).	Preferred





	Rejected	Rejected	Rejected	Rejected		Not concluded	Preferred Rejected	
performed by specialists still requires endoscopic resource. Modelling by the Ministry of a one-off flexible sigmoidoscopy in NZ for those aged 56 years, even with a participation rate of 40 percent, reveals that this requires more endoscopy lists to perform both flexible sigmoidscopy and the follow on colonoscopy than does the colonoscopy associated with the proposed national bowel screening programme using iFOBT. Consequently, the Ministry believes that at this stage there is no indication to change the screening test to flexisig or to introduce this as a complement to iFOBT. However adopting an iFOBT policy at this stage will not necessarily exclude other options in future should the evidence support these. Flexisig could be a valuable additional modality for screening and it is important that New Zealand regularly reviews any new evidence in relation to this or other screening modalities.	Colonoscopy: The option was rejected. There would not be enough capacity to offer the population a colonoscopy as a screening test. In addition, there are possible harms associated with colonoscopy and it is a very expensive option as the primary screening test, There is no high-level evidence to support its use in population screening.	Colon Pillcam: This option was rejected as it is expensive, is less accurate than colonoscopy and is currently not used in any population based screening programme.	Faecal DNA testing: This option was rejected as Faecal DNA testing has not yet been trialled in population screening pilots or programmes and is expensive. There is also concern about the stability of the test and the false positive rate.	Computed tomography colonography (CTC): This option was rejected as there would not be enough capacity to offer CTC to a population. The test is also associated with radiation exposure and is an expensive option. CTC may be used as an adjunct to the screening programme where people may not be suitable for colonoscopy e.g. co-morbidities, or inability to tolerate standard bowel preparation.		One Centre/More than one centre: Both options were assessed as being viable, although the option of more than one centre was assessed as only partially meeting a number of criteria. At this stage, no preference has been confirmed and it is planned that the approach will be determined based on the outcomes of the proposed RFP process. International comparisons show that one coordination centre would be sufficient to undertake the processing of iFOBT kits. One centre only would lead to improved efficiencies and would likely cost less.	Regional: This is the preferred option. It was supported by the stakeholder consultation. A regional approach includes awareness raising, health promotion activities, colonoscopy service provision and monitoring quality indicators for the programme and performance of colonoscopy. It allows for strong clinical leadership and more consistency of approach. Having a regional approach to quality systems also allows for improved consistency in monitoring the pathway. Local: This was rejected as the provision of awareness raising, health promotion activities and colonoscopy service provision at a local level with no regional approach is highly likely to lead to significant variation in service provision, unacceptable variations in the screening nathway and compromised quality. One of the key tenants of a population based screening programme is ensuring adherence to quality	standards and consistency of approach.
	•	•	•	•	>	•	• •	
					Service Delivery	Coordination & testing	Screening Centre	



uichte and the second	•	National: This was rejected. The relationships between clinicians and service providers are less likely to develop at a distance. In the face of pathology shortages, having all pathology read centrally would put a significant burden on one laboratory. Transporting diagnostic histology samples in the context of a screening programme would generate an unacceptable risk.	Rejected
nistopatiiology	•	Local/Regional: This was the preferred option. There was strong support during stakeholder consultation that histopathology should be provided in the context of usual care. Hospital specialists and services already have well developed pathways for histology processing, including multi-disciplinary meetings. This provides a safer option.	Preferred
Funding			
	•	DHB funded testing, colonoscopy, treatment, surveillance: The option was assessed as not meeting two CSFs; 'strategic fit/business need' and 'affordability'. The DHBs are not currently funded for this activity and would not afford it within current allocation. The option is not aligned with the approach to other screening programmes, which have been centrally funded.	Rejected
	•	Centrally funded testing, colonoscopy, treatment, surveillance: The option was assessed as also not meeting the 'strategic fit/business need' and 'affordability' CSFs. There is no precedent for central funding of all elements arising from a screening programme and overall it would be less affordable for Government as the DHBs are already receiving funding for treatment/surveillance.	Rejected
	•	Centrally funded testing, colonoscopy, DHB funded treatment, surveillance: This option was assessed as meeting the CSFs and is therefore a viable option.	Possible
	•	Centrally funded testing, colonoscopy, some surveillance, and DHB funded treatment, some surveillance: This option was assessed as a viable option. This option provides more support to DHBs for ongoing surveillance. Over time, the surveillance burden arising from this	Preferred
		programme will grow and there is a significant risk that the symptomatic population would suffer as a result of increased proportion of resources being directed to ongoing surveillance. By centrally funding a proportion of surveillance, this would enable DHBs to maintain service levels for the symptomatic population whilst providing effective surveillance activity. This option has therefore been identified as the preferred option.	



Appendix 7: NBSP IT Solution Assessment

Entire appendix - (29 Pages) withheld under S9(2)(j)



Appendix 8: CBAx Summary of Cost Benefit Analysis and Assumptions

Option 1 – 4 summaries of cost benefit analysis, using CBAX (4 pages) withheld under S9(2)(f)(iv)



Costing the options using CBAx

Option 1 - Do nothing (the counterfactual)

The pilot would discontinue and people would only have access to colonoscopy if they had symptoms or are at increased risk of bowel cancer.

Assumptions:

- 1.1 The CRC incidence rate would remain stable, unchanged from current values. Currently it is unknown whether CRC rates will increase or decrease. The current incidence rate is decreasing slightly year on year, however the obesity epidemic could well reverse this trend at any time. It is difficult to accurately predict CRC rates for the next 20 years without detailed modelling. For simplicity, with regards to this options analysis, the assumption has been made that the CRC incidence rate will remain stable over the next 20 years if there is no screening programme introduced. This model therefore assumes that numbers of cancers will increase, but this would only be a factor of population growth.
- 1.2 There would be no implementation costs or ongoing costs of a programme.
- 1.3 Savings in superannuation based on difference between average life expectancy of 81 years with the average age of CRC deaths of 68 years
- 1.4 People aged 60-74 currently work and pay taxes and also provides a contribution to society. Around 36 percent volunteer (DIA Quarterly Volunteering and Donating Indicator Sep 2014), support their families by being caregiver enabling parents to work or remain in work reducing benefits or providing home support while younger adults work. Children who are well are more likely to attend school, learn and develop in line with their peers, and participate in social activities. The annual loss relating to contribution to society from reduced life expectancy has been estimated at 30 percent of the value of a statistical life divided by the life expectancy.

Option 2 - Basic

The Pilot would continue and all DHBs would come online in 3 tranches. Screening would be offered to people aged 60-74. There would be no primary care involvement in results management.

Assumptions:

- 2.1 The CRC mortality rate would decrease due to more cancers being found earlier, which would impact on survival. This would start to impact mortality rates approximately 8-10 years after the commencement of screening.
- 2.2 The CRC incidence rate would decrease due to pre-cancerous lesions being removed from the population during screening colonoscopies. The decrease in incidence would occur approximately 10 years following the commencement of screening.
- 2.3 Cancer that would have been found without screening would have been found *earlier*. This would result in a stage shift and the corresponding savings in treatment costs. The average first year and remission cost for cancer patient treatment of \$54,018 had been used.
- 2.4 The stage shift is expected to create a short term increase in treatment cost during the first and second round of screening. This has been estimated based on the numbers of cancers identified from screening at 33% of the average first year and remission cost for cancer patient treatment.
- 2.5 As there would be no GP involvement in positive results management, a small reduction in participation in the programme is assumed, compared to Options where there is GP involvement. This is assumed as a percent reduction in participation. This would mean 5 percent fewer colonoscopies being required, 5 percent fewer cancers being found and fewer referrals to



- colonoscopy. It would be logical to assume that the reduced participation would be biased towards Māori and Pacific, which would negatively impact on equity.
- 2.6 Mortality rate assumed to increase by 2 percent as a result of the 5 percent reduction in participation.
- 2.7 QALY gain based on Waitemata pilot study of 0.0607 had been assumed with a 5 percent reduction reflecting the impact of the reduced participation.
- 2.8 Increase superannuation cost based on difference between average life expectancy of 81 years with the average age of CRC deaths of 68 years for the projected reduction in mortality.

Option 3 - Integrated

The Pilot would continue and all DHBs would come online in 3 tranches. Screening would be offered to people aged 60-74. Primary care would be involved in results management with DHBs funding surveillance colonoscopies.

Assumptions:

- 3.1 The CRC mortality rate would decrease due to more cancers being found earlier, which would impact on survival. This would start to impact mortality rates approximately 8-10 years after the commencement of screening.
- 3.2 Mortality rate will be 2 percent higher with the 2 percent reduction in participation.
- 3.3 The CRC incidence rate would decrease due to pre-cancerous lesions being removed from the population during screening colonoscopies. The decrease in incidence would occur approximately 10 years following the commencement of screening. Cancer that would have been found without screening would have been found earlier. This would result in a stage shift and the corresponding savings in treatment costs. The average first year and remission cost for cancer patient treatment of \$54,018 had been used.
- 3.4 The stage shift is expected to create a short term increase in treatment cost during the first and second round of screening. This has been estimated based on the numbers of cancers identified from screening at 33% of the average first year and remission cost for cancer patient treatment.
- 3.5 OPEX costs would be higher (than the counterfactual) to take into account the increased costs to involve GPs in positive results management.
- 3.6 Costs to the Crown for surveillance colonoscopy will be the same as option 4, with funding by DHBs.
- 3.7 QALY gain based on Waitemata pilot study of 0.0607 had been assumed with a 2 percent reduction reflecting the impact of the higher mortality.
- 3.8 Increase superannuation cost based on difference between average life expectancy of 81 years with the average age of CRC deaths of 68 years for the projected reduction in mortality.

Option 4 - Complete (preferred option)

The Pilot would continue and all DHBs would come online in three tranches. Screening would be offered to people aged 60-74. Primary care would be involved in results management and there would be new funding for surveillance colonoscopies.

Assumptions:

4.1 The CRC mortality rate would decrease due to more cancers being found earlier, which would impact on survival. This would start to impact mortality rates approximately 8-10 years after the commencement of screening



- 4.2 The CRC incidence rate would decrease due to pre-cancerous lesions being removed from the population during screening colonoscopies. The decrease in incidence would occur approximately 10 years following the commencement of screening.
- 4.3 Participation rate assumed at 62%.
- 4.4 Cancer that would have been found without screening would have been found earlier. This would result in a stage shift and the corresponding savings in treatment costs. The average first year and remission cost for cancer patient treatment of \$54,018 had been used.
- 4.5 The stage shift is expected to create a short term increase in treatment cost during the first and second round of screening. This has been estimated based on the numbers of cancers identified from screening at 33% of the average first year and remission cost for cancer patient treatment.
- 4.6 OPEX costs would be higher (than the counterfactual) to take into account the increased costs to involve GPs in positive results management.
- 4.7 Costs to the Ministry, regarding surveillance colonoscopy, will increase. Costs to the Crown, however, remain the same.
- 4.8 QALY gain based on Waitemata pilot study of 0.0607 had been assumed.
- 4.9 Increase superannuation cost based on difference between average life expectancy of 81 years with the average age of CRC deaths of 68 years for the projected reduction in mortality.



Appendix 9: HWNZ Support for NBSP



No. 1 The Terrace PO Box 5013 Wellington 6145 New Zealand T+64 4 496 2000

18 April 2016

The Investment Ministers C/- The Treasury No. 1 The Terrace Wellington

Dear Ministers

2016/17 Budget Bid - National Bowel Screening Programme, Workforce Development

Health Workforce New Zealand (HWNZ) and the Ministry of Health Bowel Cancer team have been working closely since the establishment of the bowel screening pilot in 2011.

Since the results of the first screening round became available in late 2014, both teams have developed a comprehensive model showing the impact of various screening variables on workforce. These variables include age range, participation rates and positivity of the screening test

Modelling is comprehensive and incorporates current symptomatic service provision, use of Computed Tomographic Colonography (CTC), and an increase in symptomatic referrals as a result of increased awareness of bowel cancer.

Dr Susan Parry, Clinical Director, Ministry of Health Bowel Cancer Programme, presented the latest modelling predictions at the HWNZ Board meeting on 3 March 2016. This presentation included the impact of a national bowel screening programme on both colonoscopy and laboratory service provision.

A workforce plan has been developed to ensure the delivery of the screening programme will have sufficient workforce capability. Aspects of this plan have already commenced, as follows:

- 1. increasing the number of gastroenterology trainees
- 2. the establishment of a training programme for nurse endoscopists that in the future could potentially be adapted for other non-specialist endoscopists
- 3. discussions with the relevant surgical bodies to consider the increased role that surgical endoscopists may play in the future and the projected impact this would have on the required number of surgical trainees.

The HWNZ Board was very pleased at the progress described, both in terms of workforce developments and the modelling undertaken. The service demand modelling showed that with a restricted age range and higher cut off of the screening test the programme is achievable given workforce projections and the associated training investment. The modelling appears to be rigorous and well considered.





I note that the financial sustainability of the training initiatives referred to above is dependent upon the acceptance of this business case.

Based on the current modelling, HWNZ supports the implementation of a national bowel screening programme.

Yours sincerely

Professor Des Gorman Executive Chair

Health Workforce New Zealand Board



Appendix 10: Tranche Identification

s table sumi	marises the in	dicative allocation	on or UHBS to Ir	ills table summarises the indicative allocation of DHBs to Tranches. This would be tested as part of the Tranche business case development.
DHB	Tranche	Elgible population	Cancer mortality, age specific rate 60-70	Capital/facility Ligent Collpy non Collpy IT Additional comment
Hutt Valley		20,480	27	
Wairarapa	Tench 16 March 2017	8,370	94	
Waitemata		78,660	57	
Auckland		54,580	09	
Canterbury		82,670	73	
Capital and Coast		37,690	64	
Hawke's Bay		26,300	87	
Southern	Tranche 2 2018	49,000	103	
Taranaki		18,460	81	
Waikato		26,900	88	\$9(2)(f)(iv)
West Coast		6,150	95	
Whanganui		11,040	81	
Bay of Plenty		38,350	36	
Counties Manukau		64,650	26	
Lakes		16,150	02	
MidCentral		26,880	7.1	
Nelson Marlborough	Tranche 3 2019	27,230	7.1	
Northland		29,910	91	
South Canterbury		11,120	107	
Tairawhiti		7,085	98	
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