



Service Delivery Model

Bowel Screening Pilot

September 2013

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1. Overview of the Programme

1.1 Purpose

The purpose of this document, the Service Delivery Model (SDM), is to outline the bowel screening pathway for the eligible population in the Bowel Screening Pilot (BSP) site at the Waitemata District Health Board (WDHB). The SDM also identifies roles and accountabilities within the screening pathway.

1.2 Bowel Screening Programmes

An organised bowel screening programme has the potential to reduce bowel cancer incidence and mortality by routinely screening an entire, defined population at regular intervals. A reduction in mortality at a population level depends upon high levels of coverage of the population accompanied by quality screening and follow-up services.

For screening to be effective in meeting its aim it is important that the programme is well organised and focused. An organised approach to screening on a population basis is more successful at reducing the incidence and mortality for bowel cancer compared to ad hoc screening.

The key difference between an ad hoc screening approach and an organised population-based screening approach is that ad hoc screening does not necessarily include the following essential components of an effective screening programme:

1. coordination of all elements of the service
2. a population-based register
3. an invitation and recall system
4. a multidisciplinary team approach to screening
5. close linkages with treatment services
6. specific operational policies, quality standards and on-going monitoring and quality assurance processes.

Bowel cancer screening fulfils several criteria of diseases that are amenable to population-based screening programmes. Bowel cancer is a slow growing tumour with a long pre-clinical phase. Significant adenoma (>10mm) become bowel cancers at a rate of roughly 1% per year and if left in situ, have a cumulative risk of about 24% to become malignant at 20 years. The slow development process from adenoma to cancer makes bowel cancer a good example of where a screening intervention within a non-symptomatic population can save lives.

1.3 Bowel Cancer in New Zealand

Bowel cancer is the most commonly diagnosed cancer in New Zealand and the second most common cause of cancer death. Our death rate from bowel cancer is one of the highest in the developed world. In 2009, 2837 people were diagnosed with bowel cancer, and 1244 people died from the disease. New Zealand has the second highest mortality rate in the OECD for women and the fifth highest for men as of 2008. As of 2009 New Zealand has the sixth highest mortality rate in OECD across the population.

There is a strong association between the stage (extent) of bowel cancer at diagnosis and eventual survival. Those with localised disease have a 95 per cent chance of a five year survival. Those with distant spread (metastases) have only a 10 per cent five year survival rate. There is evidence to suggest that a higher percentage of detected cancers are found at a more advanced stage (greater spread of cancer) in New Zealand than in several countries where there are national or regional screening programmes, including Australia, the United States and the United Kingdom.

Modelling in Ireland has concluded that a screening programme based on a biennial faecal immunochemical test for haemoglobin (FIT) for 55 to 74 year olds could provide a lifetime

reduction in the incidence of bowel cancer by 15 per cent, and reduce mortality from bowel cancer by 36 per cent.

1.4 The Bowel Screening Pilot at Waitemata District Health Board

A BSP commenced at Waitemata DHB in October 2011. Over the following four years, eligible people aged 50 to 74 years who are resident in the pilot region will be invited to participate in one screening round every two years. This means that the eligible population will be involved in two screening episodes over four years. The screening test is a FIT, which is completed in the person’s home then posted back to a designated testing laboratory, LabPlus.

Waitemata DHB serves the populations of four wards: Rodney, Albany, North Shore and Waitakere. Whau ward is shared with Auckland District Health Board (ADHB). In total, this consists of approximately 132,240 eligible participants¹.

Figure 1: Waitemata DHB Territorial Local Authority Boundaries



Table 1: Demographic Characteristics of Waitemata District

| <i>Variable</i> | <i>Category</i> | <i>Sub-category</i> | <i>Eligible Population</i> |
|----------------------|-----------------|---------------------|----------------------------|
| Gender | Male | | 63,710 |
| | Female | | 68,530 |
| Urban / Rural | Urban | | 117,832 |
| | Rural | | 9,159 |
| | Not assigned | | 5,249 |

¹ Projected 2011 population aged 50-74 years as identified in the WDHB RFP Proposal.

| | | | |
|---|------------------|------------------|----------------|
| Ethnicity | European / Other | | 104,360 |
| | Māori | | 6,960 |
| | Pacific | | 5,430 |
| | Asian | Chinese | 7,273 |
| | | Indian | 3,162 |
| | | South-east Asian | 1,760 |
| | | Other Asian | 3,287 |
| Deprivation (NZ Dep 2006) | 1 | 17,994 | |
| | 2 | 20,095 | |
| | 3 | 17,936 | |
| | 4 | 16,125 | |
| | 5 | 14,734 | |
| | 6 | 13,921 | |
| | 7 | 12,810 | |
| | 8 | 10,078 | |
| | 9 | 6,382 | |
| | 10 | 2,165 | |
| TOTAL PROJECTED 2011 POPULATION AGED 50-74 | | | 132,240 |

1.5 Bowel Screening Aims and Objectives

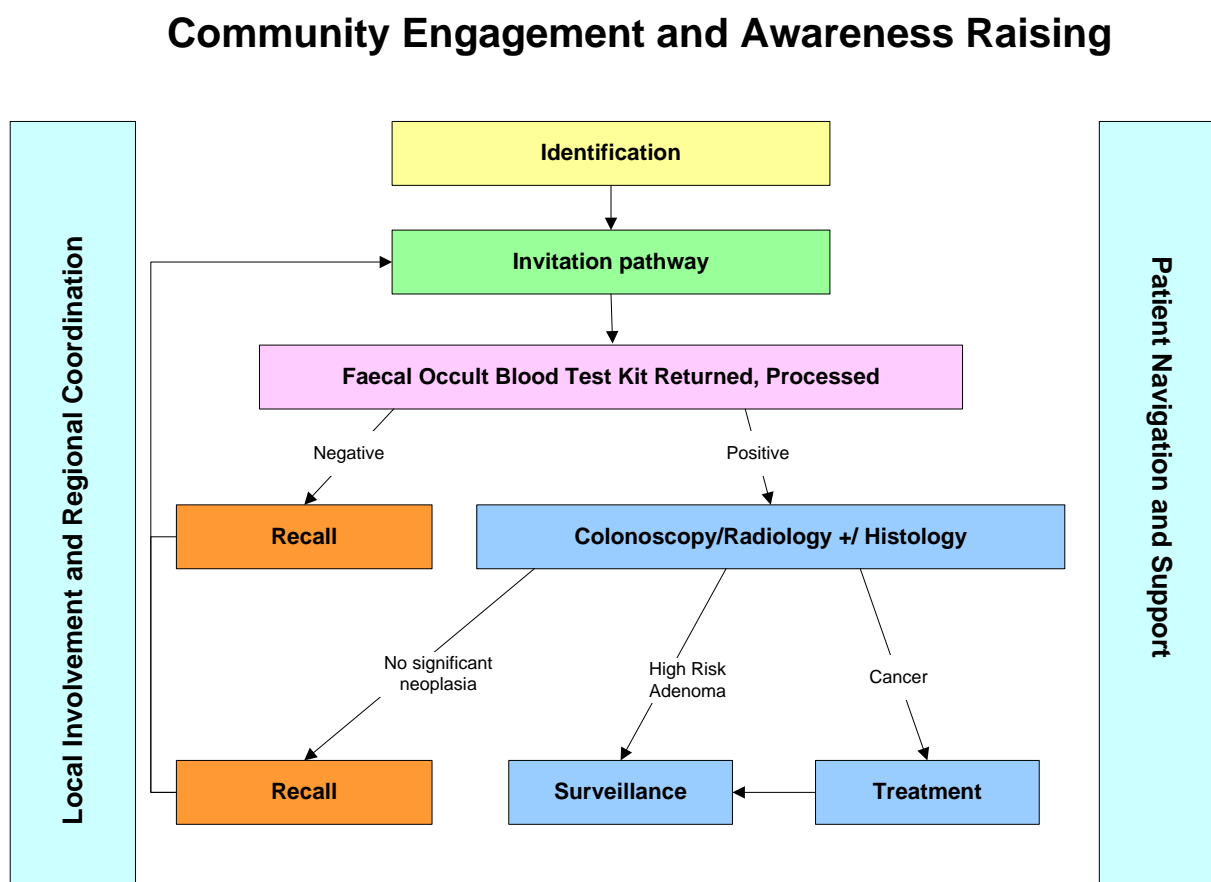
The overall goal of the pilot is to determine whether organised bowel screening could be introduced in New Zealand in a way that is effective, safe and acceptable for the participants, and is both equitable and cost effective.²

The bowel screening pathway requires coordination of services from local and regional health providers, as well as centralised monitoring of participants through a dedicated screening pathway and failsafe mechanisms.

Figure 2 shows the wrap around services for patient navigation and support as well as the requirement for community engagement and awareness raising along the screening pathway.

² International and New Zealand research suggests that uptake for bowel screening programme varies between different population groups. Ethnic minorities, men (of all ethnic groups) and people living in lower socio economic areas are less likely to respond to a bowel screening programme.

Figure 2: The Bowel Screening High Level Pathway



The Pilot has four overarching aims. Their purpose is to assess whether a national bowel screening programme:

1. is likely to achieve the mortality reduction from bowel cancer seen in international randomised controlled trials
2. can be delivered in a manner that is safe and acceptable
3. can be delivered in a manner that eliminates (or does not increase) current inequalities between Māori and non-Māori
4. can be delivered in cost effectively.

The objectives of the Pilot are:

1. *Programme Design.* To pilot the use of a population register, in conjunction with primary health care, to invite the target population for screening. To pilot the coordination centre and the associated information system to manage the screening pathway.
2. *Screening Effectiveness.* To assess the early indicators of the effectiveness of bowel cancer screening, including the number and stage of cancers detected, the number and size of adenomas detected, and colonoscopy completion rates.
3. *FIT Experience.* To assess the performance and acceptability of the chosen FIT 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, socioeconomic status and rurality).

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 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 processes designed to eliminate inequalities in the planning and implementation, including the ability of the pilot site/s to identify factors which eliminate or reduce inequalities.
8. *Cost Effectiveness.* To determine costs of all services along the screening pathway to determine the cost effectiveness of a bowel screening programme. To compare this 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, socioeconomic status and rurality) in the screening pilot, including identifying factors associated with non-participation.
10. *Acceptability to Providers.* To evaluate knowledge, attitudes and acceptability to health professionals and health care providers based in community, primary care and hospital settings.

The Ministry of Health will monitor and evaluate the BSP from identification and invitation of participants through to diagnosis by colonoscopy and referral to treatment where appropriate. Participants who have a cancer or high risk adenoma diagnosed through colonoscopy will be referred to treatment and/or surveillance services. These participants will not be re-invited for screening as they no longer meet the eligibility criteria for the BSP.

1.6 The Bowel Screening Pathway

Overview of the Pathway

A population register has been created that comprises all eligible people living within the BSP district. People aged between 50 and 74 years with a residential address in the BSP district are eligible. People who turn 75 during the life of the pilot will no longer be eligible, and will be exited from the pilot whether or not they have completed two rounds of screening.

The Coordination Centre sends a pre-invitation letter including endorsement from the participant's general practice (where available) on the letter. Advance pre-invitation letters have been shown to increase participation in bowel screening internationally. This letter will:

- explain the purpose of the BSP
- contain an endorsement of the BSP from the participant's general practice
- give people the opportunity to opt out of receiving a FIT if they wish
- advise people that they will receive an invitation and a FIT kit from the BSP unless they notify the Coordination Centre that they are not eligible or do not wish to participate.
- include a pamphlet *All About Bowel Screening* which provides detailed information about the programme

The pre-invitation letter will encourage eligible participants to discuss bowel screening further with their GP if required.

Those people who are not enrolled with a general practice will be sent a pre-invitation letter directly without any general practice endorsement.

Four weeks after sending the pre-invitation letter, the Coordination Centre will mail out the FIT kit along with the consent form and a second, smaller pamphlet (*Your Quick Reference Guide*) about bowel screening. The consent form will be pre-populated with participant and GP details provided by the NHI and PHO register. Participants will be asked to update their contact details as required. The FIT kit is completed at home and then returned (along with the consent form) to the testing laboratory for analysis. The laboratory will electronically forward results to general practices and to the Coordination Centre. The telephone contact details provided on the consent form will be used by the senior endoscopy nurse to contact a participant should they have a positive FIT result.

People with a positive FIT result will be notified by their general practice within 10 working days of testing in the designated laboratory. Participants without a named general practitioner (GP) will be contacted by the senior endoscopy nurse by phone or by letter if a phone number is not provided. All participants with a negative FIT result will be notified by letter by the Coordination Centre.

The Coordination Centre will be responsible for ensuring that all participants with a positive FIT result are identified for colonoscopy pre-assessment. If a participant is deemed fit for colonoscopy during a pre-assessment, they will be offered a date for a colonoscopy. If during colonoscopy pre-assessment it is determined that the participant is unsuitable for colonoscopy they will be referred for an alternative diagnostic investigation, Computerised Tomographic Colonography (CTC), or in exceptional circumstances back to their GP for individual management.

As an outcome from colonoscopy, where individuals are identified as having cancer or at increased risk of developing cancer, they will be offered referral to treatment services or a surveillance programme. Treatment and surveillance will align with WDHB standard practices. These people will no longer be included within the eligible screening population.

Role of Primary Care

Waitemata DHB, Primary Health Organisations (PHOs) and general practices play a fundamental role in the BSP. This is an opportunity to develop a generic model of screening that more closely integrates primary care, whilst retaining within the Coordination Centre overall responsibility for screening the population as a whole.

Key input from PHOs and general practices for the BSP includes:

1. PHOs make a subset of their patient enrolment data available for the purpose of enhancing a district-wide register of the eligible population, and to enable GPs to be informed of their patients' screening results.
2. GPs could assist the BSP Coordination Centre to identify participants who do not meet the bowel screening eligibility criteria (through a documented process).
3. The participant's general practice is identified (if known) on the advance notification letter when it is sent out (although the actual printing and posting is carried out by the Coordination Centre).
4. General practices may provide an additional tier of active follow-up for the entire eligible population by sending out, where participant records permit, an electronic reminder from the practice to those participants who do not respond to either the initial invitation or the first reminder. This may be, for example, a text message, an email or a phone call. This process sits outside the BSP IT system.
5. GPs are advised by the Coordination Centre when their patients are invited to participate in the BSP and have been reminded and not replied to a follow up. General practices could place a flag on the record of those participants who do not return a FIT kit, and undertake any other follow up processes as agreed, with the intention of encouraging them at their next visit to participate in the programme.
6. GPs inform participants who have a positive FIT, and refer these participants to colonoscopy. This represents more appropriate care of the patient and meets established best practice for continuity of care generally. Studies suggest this arrangement is likely to increase patient compliance with further diagnostic investigation and treatment if necessary. The GP informs the participant of a positive result and

makes a referral for colonoscopy within 10 working days of the receipt of the result at the practice. Referrals are forwarded to the WDHB Booking and Scheduling Department through the standard mechanism of facsimile, pending the development and implementation of a regional e-referral system in the second half of 2013. The Coordination Centre, through a relationship with the senior endoscopy nurses, takes responsibility for the 'failsafe pathway'. The senior endoscopy nurses are users of the BSP IT system. If the referral has not arrived by day eleven, a work task to contact the participant for a pre-assessment is assigned to them. A work task for participants who do not wish their GP to be involved, or who are not enrolled in a practice is assigned when the positive result is posted on the register by the laboratory. All participants with a positive FIT are contacted by the senior endoscopy nurse by or shortly after day 11 to conduct a pre-assessment and arrange a colonoscopy appointment.

7. GPs refer patients with a positive FIT to the WDHB endoscopy unit. This referral should include additional clinical information to facilitate a comprehensive pre-assessment by the endoscopy nurse. The e-referral template will specify the information required. The endoscopy nurse conducts a pre-assessment session over the telephone and at the same time she confirms the appointment for the procedure, checks whether an interpreter or other supports are required, and describes the bowel preparation process. The endoscopy unit administrator then mails out a letter of confirmation of appointment and the bowel preparation information and materials.
8. GPs are asked to encourage patients with a positive FIT result to remain within the public system for their colonoscopy, so that their data can be included in the analysis of outcomes. Some patients may choose to make use of the private sector for health services. Their data can be collected but it needs to be analysed separately. The patient consent form includes consent for the collection of colonoscopy outcomes from private providers and WDHB also has access to the regional Testsafe data repository where histology results from public and private health providers are stored.
9. PHOs and general practices collaborate with communications and community engagement activities by having posters and information leaflets available in general practice surgeries and including information about the Pilot in their regular email updates to practices - and their newsletters.

Community Awareness

Processes for district-wide coordination and local involvement have been developed by the BSP to ensure that screening is supported by those who have community knowledge, and in a way that involves them. There is an on-going process of community education within the BSP district to raise awareness of bowel cancer and the need for bowel screening. This takes place prior to participants receiving an invitation to the pilot. Evidence suggests that with these processes in place the BSP is more likely to be successful, in particular for population groups that have been shown to be under-screened by other screening programmes. In the New Zealand setting Māori and Pacific people are under screened populations, who are likely to need extra support to ensure they have fair access to the screening pilot. As monitoring and evaluation of the pilot progresses, the population groups identified as under screened may change to reflect any emerging patterns in participation. International bowel screening programmes have found lower rates of participation for ethnic minority groups, people from lower socio-economic groups and men than other screened groups.

Monitoring

The Coordination Centre is responsible for monitoring the operations of the screening pilot. Operations monitoring and quality oversight is provided by the local BSP Quality Working Group. This includes monitoring timeliness throughout the screening pathway. Data and information to enable monitoring of the BSP against the Quality Standards is collected at all points along the screening pathway through a dedicated IT system, developed by the Ministry of Health and fully accessible to the WDHB pilot team.

The Ministry of Health monitors the quality and performance of the pilot using reporting, monitoring and evaluation processes.

1.7 Coordination of the Bowel Screening Service

WDHB is responsible for establishing a centralised Coordination Centre in the district.

The Coordination Centre is responsible for identifying, inviting and ensuring participants are referred to diagnostic services if they have a positive screening test. The Coordination Centre (through WDHB) is further responsible for ensuring the collection of information necessary for monitoring the quality of the pilot, including diagnostic and treatment outcomes.

The Coordination Centre is responsible for ensuring participants are supported through the screening pathway in a timely and safe way. This will be monitored through the BSP quality requirements.

In this model, the Coordination Centre essentially becomes the agent of the eligible population. They are responsible for ensuring that all Waitemata domiciled residents who are eligible and wish to participate in the BSP are:

- informed about the existence of the pilot, the risks and benefits of participating
- informed about the incidence and risks of bowel cancer, including symptoms
- included on the screening register and flagged when ineligible or opted out
- sent FIT kits and consent forms
- given opportunities to withdraw from the screening programme
- followed up by PHOs and the general practices for participants who do not respond to reminder letter (generated four weeks after FIT kit is sent by the Coordination Centre)
- provided with active follow-up if in under screened segments of the population
- informed promptly and sensitively of negative results of the FIT
- informed promptly and sensitively of the positive result of their FIT, although this function is provided by the GP but ultimate responsibility for ensuring that it happens rests with the Coordination Centre
- provided with timely diagnostic investigation and treatment or surveillance if necessary according to the established protocol.

To achieve this, the Coordination Centre will also develop service specifications, contract and monitor the performance of all of the screening pilot service providers within a robust quality assurance system. This will include communications and engagement partners, PHOs, Māori and iwi providers, Pacific providers, the laboratory, the colonoscopy unit, and the provider arm of the DHB.

In carrying out its responsibilities the Coordination Centre must interface with the Ministry, primary care organisations and providers, colonoscopy services, and the evaluation team appointed by the Ministry.

1.8 Overall Management of the Screening Pathway

For the BSP to be a success it is crucial that overall responsibility and accountability sits with the Coordination Centre. The Coordination Centre itself is administratively accountable to both its 'owner', Waitemata DHB, and the funder and contractor, the Ministry of Health. This responsibility cannot be shared with other organisations or diluted through multiple lines of accountability.

It is important to emphasise that the overall management and responsibility for successful implementation of the pilot rests with the Coordination Centre. The Coordination Centre in turn will

monitor the performance of the other key parties in BSP system. It will be the reference point for all matters relating to the BSP.

Governance arrangements for the BSP should ensure services involved in the delivery of bowel screening have an understanding of what is required from them, and how they must work collaboratively with other parts of the pathway to ensure failsafe measures are in place for the participant.

Roles and Responsibilities

The Coordination Centre will liaise with general practices and PHOs. The Coordination Centre will work with the Endoscopy Unit through a Service Level Agreement that will clearly stipulate the Endoscopy Unit's responsibilities and the quality standards that are to be met.

The roles and responsibilities for the BSP pathway services are detailed in Table 2 below:

Table 2: Roles and Responsibilities of BSP pathway services:

| BSP pathway | Who is responsible | Requirements |
|---------------------------------|--|--|
| Identification | PHOs, BSP and Ministry of Health | Provision of NHI and PHO data extracts to the BSP Population Register in the Coordination Centre. |
| Pre-Invitation letter | BSP Coordination Centre | Centralised printing and sending of pre-invitation letters to eligible participants on the BSP Population Register. |
| FIT invitation | BSP Coordination Centre | Sending of FIT kit, consent form and pamphlet to eligible participants. |
| Testing of FIT kits | Designated laboratory | Receipting and testing of completed FIT kits. |
| FIT results notification | Designated laboratory, BSP Coordination Centre | Electronic messaging of results from the designated laboratory to GPs and the Coordination Centre. The Coordination Centre has responsibility for ensuring all participants have been notified of their results. |
| Endoscopy Services | Waitakere Hospital | Provision of colonoscopy pre-assessment and colonoscopy. Endoscopy Unit staff update the BSP IT system with colonoscopy pre-assessment details and outcomes. |
| Histopathology from colonoscopy | Designated laboratory | Provision of histopathology results for samples taken at colonoscopy. Standardised laboratory reporting is required for the BSP. |
| CT Colonography | WDHB Radiology Department | Perform CTC for participants who are deemed unfit for colonoscopy. Results to be communicated to BSP Coordination Centre and the Endoscopy Unit. |
| Histopathology from treatment | WDHB laboratory | WDHB laboratory will provide histopathology results for patients undergoing treatment. This information will be collected in a standardised format and entered onto the register by Endoscopy Unit staff. |
| Treatment | WDHB and ADHB | Surgery at WDHB and ADHB for radiation/chemotherapy oncology through standard practice. Data from treatment will need to be manually collected by the |

| | | |
|--------------------------|--|--|
| | | Coordination Centre. |
| Colonoscopy Surveillance | WDHB symptomatic endoscopy service for those requiring surveillance within five years. | BSP IT system will capture the effective date the participant moved to 'surveillance' pathway state. |

1.9 The role of Iwi/ Māori and Pacific Providers in the Bowel Screening Pilot

Māori and Pacific interests are represented in the governance and management structures of the BSP. Māori and Pacific provider groups are represented through working groups actively striving to ensure that the detailed delivery of the BSP achieves high coverage rates among both of these under screened populations.

Since the four specifically Māori and Pacific focussed providers serve over a quarter of the total Māori and Pacific eligible registered population, their involvement in and commitment to the BSP is fundamental to its success. Their main role will be to provide active awareness raising, active follow up and spoilt test kit follow up services. The BSP will retain close linkages with these providers to support them to deliver their contracted accountabilities. The WDHB iwi and Māori partners will also play an immensely important role from the beginning in the Community Engagement processes.

1.10 Bowel Screening Policy and Operating Procedures Manual

The BSP Policy and Operating Procedures Manual (the Manual) is interim and will be refined in collaboration with the BSP for the duration of the pilot. The purpose of the Manual is to set out the detailed procedures and processes for implementing and delivering a population based bowel screening pilot, including those designed to achieve equitable participation in services. It is envisioned these processes and procedures could then be applied nationally at a future date if required.

The procedures and processes within the Manual are either measurable or auditable. These will be quality assured and reviewed annually, or when new procedures or changes are introduced. There should be an effective system of document control to ensure the most recent versions are in circulation. Adherence to the requirements of the Manual will be ensured through monitoring, as well as internal and external audit and evaluation processes.

The Quality and Procedures Manual will contain the following:

- policy and process requirements
- operating procedures for management of the participant through the screening pathway
- quality standards
- surveillance management
- monitoring, reporting and evaluation.

Requirements for ensuring equitable access for all New Zealanders within the pilot will be included within each section of the Manual.

Underpinning the requirements in the BSP Manual is the documentation of the day-to-day operating requirements for each part of the screening pathway. These are referred to as Standard Operational Procedures (SOPs) and will be coordinated by the BSP as part of its planning and for the life of the pilot.

2. RAISING AWARENESS OF THE BOWEL SCREENING PILOT

2.1 The Role of the Coordination Centre

The BSP Coordination Centre will develop a comprehensive awareness raising strategy, which includes contracting providers to assist with delivering the BSP message and active follow up services for under screened groups. The Coordination Centre Awareness Raising team will also deliver awareness raising and active follow up services for the Māori, Pacific, Chinese and Korean communities. Coordination with these community groups has the overarching purpose of encouraging people from these population groups to be screened for bowel cancer. Eligible Pacific and Maori people who attend awareness raising activities may request immediate participation in the programme – without waiting to receive the invitation on or about their birth date.

Consideration needs to be given to promotional activities for under screened groups. Invitation processes need to be refined and be flexible to encourage timely education and invitation processes for under screened populations.

2.2 Health Promotion Activity

WDHB funds two community groups, Waitakere HealthLink, which covers West Auckland, and HealthLink North, which covers Rodney and North Shore. Dissemination of information, identification of health issues in the communities, sourcing and training of consumer representatives, community forums and production of newsletters for non-government organisations are all part of the service delivery of these contracts.

Waitemata DHB will work with the NZ Men's Health Trust, the Cancer Society and other community groups (in addition to Māori, Pacific and Asian community providers) primarily through a communications and engagement strategy, and specifically by involving them in the work groups that advise the BSP Steering Group.

The New Zealand Men's Health Trust carries out high profile campaigns to encourage men to make greater use of health services. The Cancer Society is another important community group that already carries out extensive and highly effective work to provide the community with accurate information and to encourage the early detection of cancer. It further provides support for patients suffering from cancer and its consequences, as well as their families. The Auckland Division of the Cancer Society works closely with Waitemata and the Northern Cancer Network through the Northern Cancer Collaborative.

2.2 Iwi/ Māori Providers

The Coordination Centre will develop relationships with key Māori health providers in the district – both within the DHB structures and with iwi organisations and primary care providers. The DHB's Māori Health Gain team (within the Funding and Planning group) and the Māori Health Services team (within the DHB Provider Arm) will be central to the provision of advice and support for the development and implementation of strategies to ensure Māori participation. A Kaitiaki Roopu will be established – consisting of kaumatua and kuia– to support the development of relationships with iwi providers in particular. A Māori Community Coordinator will be employed to deliver awareness raising sessions to as many Māori groups/organisations/whānau gatherings as possible and to follow up Māori who do not participate, or who return a spoilt test kit.

With the support of the Kaitiaki Group, the Coordination Centre will work with iwi organisations to develop contracts for the delivery of BSP education within their communities.

There is one Māori specific PHO within the WDHB district however they do not have the capacity or capability to undertake health promotion activities. The focus of work with this organisation will be on educating their GPs and practice nurses to support their patients to participate.

Practice liaison staff from the two PHOs in WDHB will work with the Coordination Centre to identify practices with high numbers of eligible Māori enrolled and to implement strategies to ensure a high Māori participation. Practices will be informed of their non-participating members and be asked to follow them up and encourage them to do the FIT.

Waitemata District has two providers serving a specifically Pacific population. These are West Fono Health Trust and Pasifika Integrated Health Care. Between them, these two practices have over a quarter of the total eligible enrolled Pacific population in the district. They will play a decisive role in achieving high uptake in this under screened population group.

3. THE BOWEL SCREENING PILOT COMPONENTS OF SERVICE

3.1 The BSP Population Register

The population register contains demographic details of the complete eligible population (people aged 50 to 74 years of age) in the pilot region. Primary identification will be the National Health Index (NHI) with supplementary information provided by PHO registers. Individuals who fit the eligibility criteria, but have not been identified through either the NHI, or on PHO registers will be able to enrol by contacting the BSP Coordination Centre.

In summary the population register for the BSP will be populated from three different sources:

- NHI database
- PHO registers
- Those who enrol in the pilot (have not been identified through the NHI or PHO registers).

The Coordination Centre will make initial contact with the eligible population by sending a pre-invitation letter endorsed by the participant's GP (if known). The pre-invitation letter will also have the BSP branding and the WDHB logo.

It is intended additional information will be supplemented from the Cancer Registry to try to ensure people with a registered bowel cancer are not invited to participate. Eligible people who move into the pilot area or who opt-on (having not been identified through the NHI or PHO registers) will be invited to participate.

The roles and responsibilities at this stage of the screening pathway are:

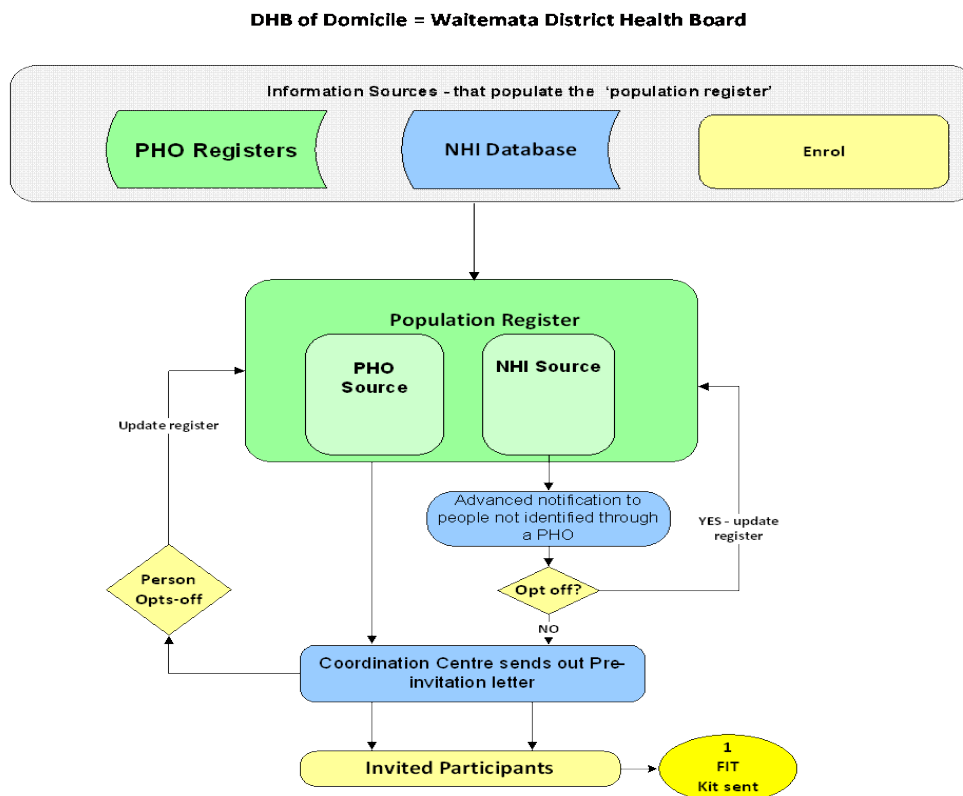
| BSP pathway | Who is responsible | Requirements |
|-----------------------|---|---|
| Identification | PHOs, BSP and the Ministry | Provision of data extracts from the NHI and PHOs to the BSP Population Register at the BSP Coordination Centre prior to the pilot 'go live' date in October 2011, and quarterly thereafter. |
| Pre-Invitation letter | BSP Coordination Centre with endorsement from GPs | Centralised printing and sending of pre-invitation letters to eligible participants on the BSP Population Register. |

3.2 The BSP Programme Register

Once a person sends in a completed FIT they have decided to participate in the pilot. The results of the FIT laboratory test and subsequent monitoring information through the screening pathway is collected within the BSP IT system.

The BSP IT system will allow tracking of a participant's progress through the screening pathway. It will include clinical information on the participant and their screening history (for example, if they have participated in round one of the BSP). The FIT laboratory will electronically notify the Coordination Centre and the participant's GP of the FIT results.

Figure 3: Identification and pre-invitation to screening



The Eligible Population are those men and women age 50 to 74 years domicile in the WDHB.

The opportunity to enrol is for people who:

1. Have moved into the BSP area and are eligible to participate in bowel screening or,
2. have no NHI or are not registered with a PHO (note: a business process will be developed to assign an NHI to eligible participants).

3.3 Screening Pathway 1: FIT Kit Sent – Invitation to participate in FIT Screening

The process for inviting the eligible population will be undertaken in a way that recognises New Zealand’s diverse cultures and provides services that are acceptable to those who receive them. As the first cancer screening programme to invite men and women, the pilot needs to be acceptable to both.

The invitation will include information on the BSP, a consent form and a FIT kit to complete at home.

Once participants have completed the FIT, they return it to the designated FIT testing laboratory. If the participant does not return the completed kit within a four week timeframe they are sent a reminder letter from the Coordination Centre. Participants may request a replacement FIT kit if they have misplaced it. Participants with a spoilt kit will be sent a replacement kit from the

Coordination Centre.³ Participants can also contact the Coordination Centre and request to have no further contact from the pilot at any time. There will be documented procedures to support those participants who are already in the screening pathway who wish to withdraw from the BSP.

Active follow-up is a process to ensure fair access to the BSP for all eligible people in the pilot region. Documented procedures will be developed to contact people from under screened groups who do not participate at any stage in the screening pathway. There will also be procedures to ensure people with a positive FIT continue in the screening pathway. This will be developed locally in partnership with general practices, the Coordination Centre and local communities.

WDHB have identified three tier follow-up of participants:

- All eligible participants who have not returned a kit after four weeks after the invitation and test kit have been mailed, are sent a reminder letter.
- Active follow up occurs for target populations. Subject to the availability of telephone numbers Maori, Pacific and Asian people are contacted between two and three weeks after the test kit has been sent. The purpose of the contact is to check that the kit has been received, to provide answers to questions, and to support participation.
- General Practices are advised of Maori and Pacific people who have not returned a test kit, and asked to support the person to participate. This may be by direct contact, or by flagging the patient record to remind the practice to raise the importance of bowel screening with the patient at his or her next visit.

The roles and responsibilities at this stage of the screening pathway are:

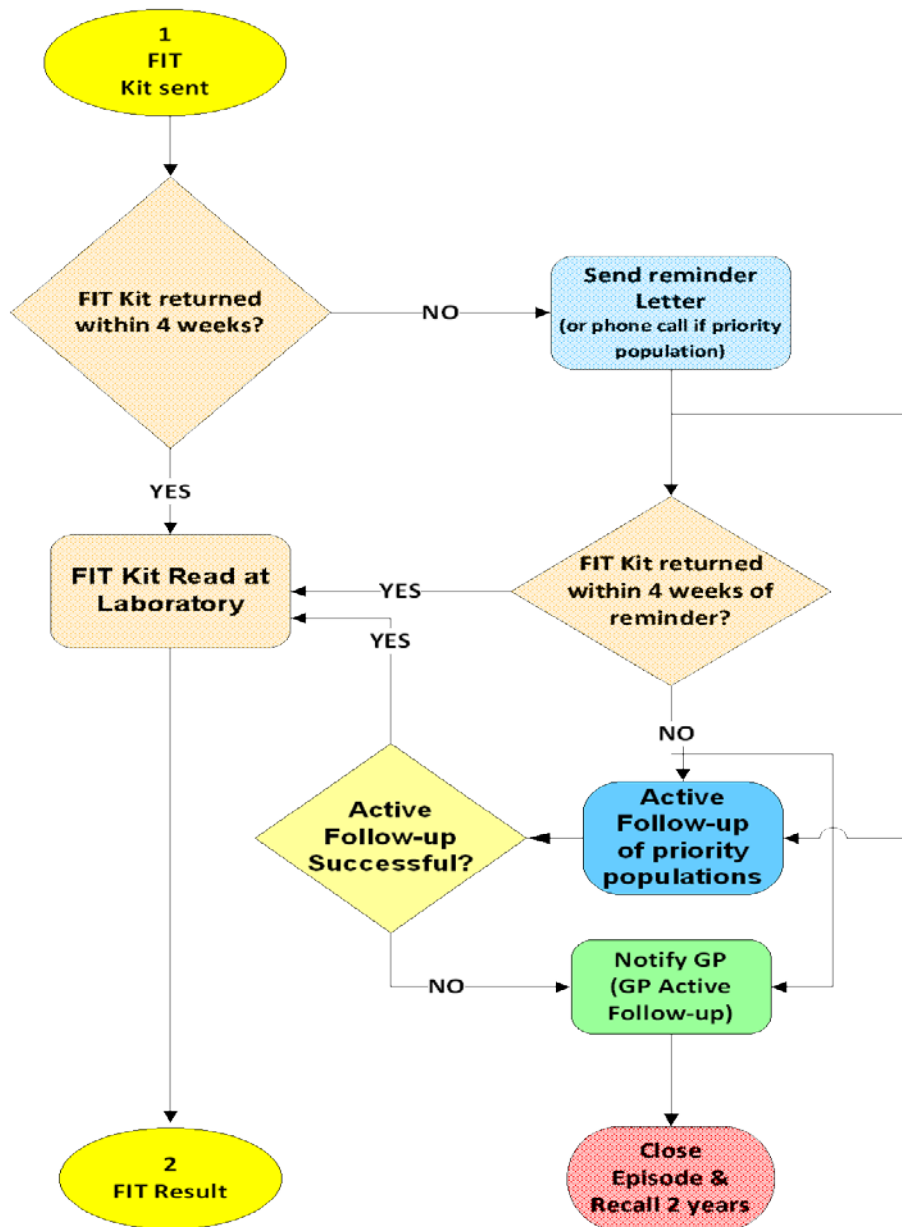
| BSP pathway | Who is responsible | Requirements |
|--|---------------------|--|
| Sending of FIT kits and associated participant information resources | Coordination Centre | <p>Quality assurance for ordering, storing and stock rotation of the FIT kits.</p> <p>Collation of FIT kit packs that include consent form, pamphlet and FIT.</p> <p>Quality control for batching invitations according to the invitation strategy, which addressed the requirement to be aware of colonoscopy capacity.</p> <p>Quality assurance of FIT distribution through mail audit of FIT kit invitations, including spot audit of temperature through temperature loggers (to monitor environmental temperature).</p> |

³ A spoilt test result is where a kit has been returned by a participant, or where the test cannot be used for recording a result according to the programme policy.

This includes but is not limited to:

- where a person cannot be adequately identified according to laboratory protocols
- no collection date has been recorded
- where the specimen was taken more than 7 days before arriving at the lab for analysis.

Figure 4: Screening Pathway 1: FIT Kit Sent and Invitation to Participate in FIT Screening



3.4 Screening Pathway 2: FIT Result - Laboratory and Coordination Centre Management of FIT Kits and Results

Participants mail their completed FIT to the designated testing laboratory for processing. The laboratory will send all results electronically to both the participant's GP (if known) and to the BSP IT system.

The BSP Coordination Centre is responsible for ensuring all participants know their FIT results, and that those with a positive result are offered a colonoscopy. However, the key role of general practices in providing on-going health care for their enrolled population is recognised.

Positive Results

General practices are given a 10 working day period in which to notify their patients of their positive FIT result, and inform them they will be contacted by the Endoscopy Unit to be offered a colonoscopy. It is likely that general practice involvement at this stage in the screening pathway will lead to better colonoscopy attendance, and lower anxiety, for individuals with a positive FIT. All people with a positive FIT, and a GP named on their consent form, will be contacted by the senior endoscopy nurse 11 working days after a positive result is received by the Coordination Centre. Participants with a positive FIT and no GP named on their consent form will be contacted by the senior endoscopy nurse as soon as their result is captured in the BSP IT system (two days from testing in the laboratory). Multiple attempts will be made to contact people with a positive FIT. There will be a documented process for managing participants who are unable to be contacted.

Negative Results

Participants with a negative FIT result will be notified in writing by the Coordination Centre and advised they will be recalled to screening in two years.

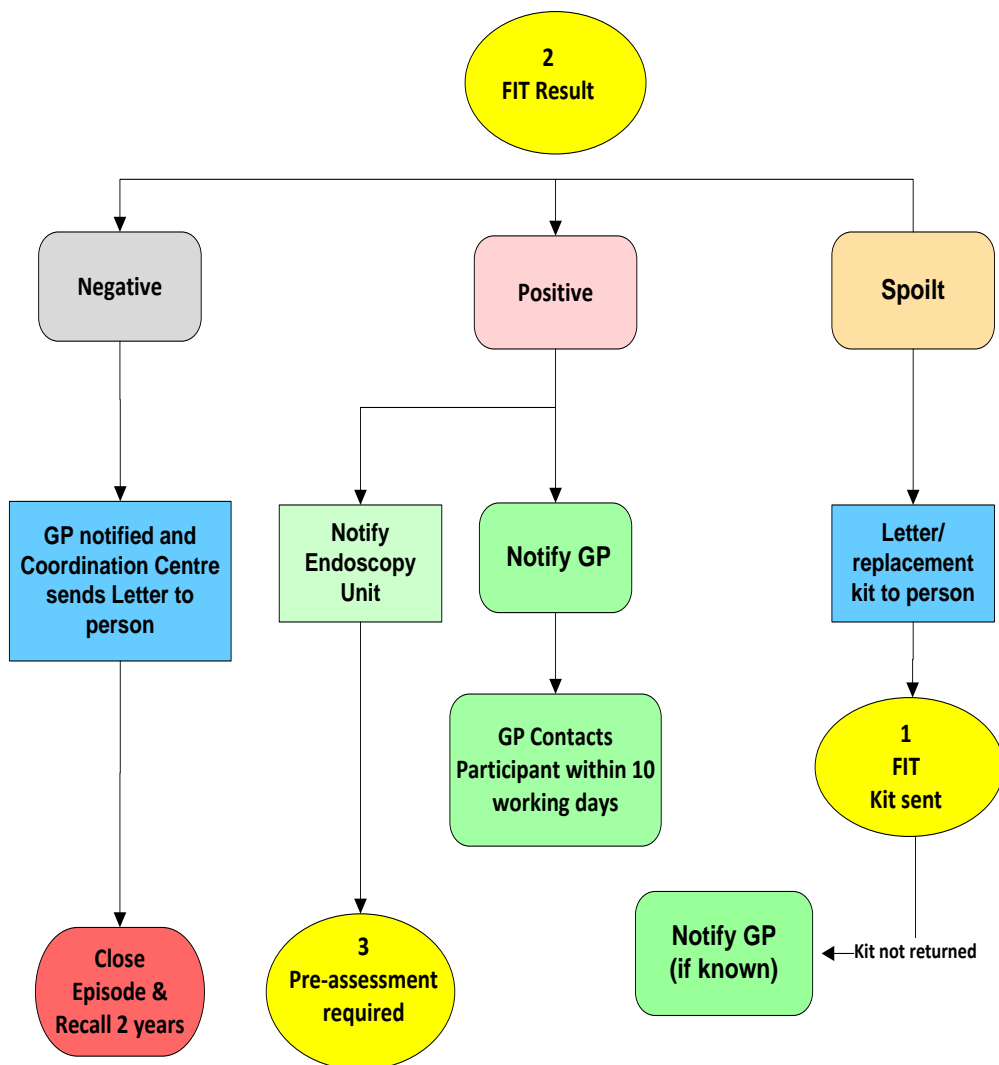
The Coordination Centre will resend a FIT kit to people whose kits are unable to be tested and will also notify the general practice (if known) that a replacement kit has been sent.

The roles and responsibilities at this stage of the screening pathway are:

| BSP pathway | Who is responsible | Requirements |
|---|-----------------------|--|
| Testing and notification of all FIT results | Designated laboratory | Testing of successfully completed FIT kits including checking of participant information on consent forms. Notify Coordination Centre of spoiled kits. Electronic notification of results to GPs and Coordination Centre. |
| Notification of Positive FIT results for participants with an identified GP | GPs/Endoscopy Unit | Notification to their patients with a positive FIT result to advise they will be contacted by the Endoscopy Unit. GPs will contact their patients within 10 working days of receiving the results from the designated laboratory. Endoscopy Unit to notify participants with no GP. A letter will be sent to participants with positive FIT who cannot be contacted by phone. |
| Notification of Negative FIT results | Coordination Centre | Sending negative FIT results letters to all participants. |

| | | |
|--------------------------------------|---|---|
| | | |
| Management of Spoilt Kits | Designated laboratory and Coordination Centre | Send replacement kits to those participants who returned a spoilt kit. |
| Notification of Positive FIT results | Endoscopy Unit | <p>Liaise with practices to ensure all positive FIT participants have been contacted.</p> <p>The senior endoscopy nurse will automatically be notified of positive FIT results and those participants who require a colonoscopy pre-assessment. This will be done through BSP IT system generation of work tasks assigned to the endoscopy nurse.</p> <p>A process will be documented to enable communication between the senior endoscopy nurse and the GP to ensure patient clinical information can be shared prior to the patient undergoing colonoscopy.</p> |

Figure 5: Screening Pathway 2: FIR Result – Management of FIT Kits



3.5 Screening Pathway 3: Pre-Assessment – Management of People with a Positive FIT Result

The Endoscopy Unit will contact the participant with a positive FIT to make arrangements for a pre-assessment prior to colonoscopy. If the participant is assessed as unfit for colonoscopy, or they have a failed colonoscopy, they will be referred for an alternative diagnostic investigation (see Screening Pathway 5 – Alternative Investigation).

Pre-assessment is undertaken by phone or in a face to face meeting, should the person's clinical condition determine that medical input is required. Pre-assessment will be led by appropriately trained nurses with medical back-up as needed. The pre-assessment is an essential step to assess health fitness for the procedure. Some individuals may be assessed as high risk for colonoscopy and certain precautions need to be taken to minimise risk during the procedure. Those include individuals who are:

- receiving warfarin medication
- within insulin dependent diabetes mellitus
- with prosthetic heart valves
- undergoing peritoneal dialysis
- receiving immunosuppressing medication and
- with previous history of endocarditis.

Other individuals may be deemed high risk for a screening colonoscopy due to significant co-morbid disease. The Endoscopy Unit will coordinate a multidisciplinary discussion and facilitate a decision on appropriate management, as well as keeping the person's GP involved in the process.

Nurse-led colonoscopy pre-assessment consultation is required in the pilot site to ensure support for the participant and to coordinate the colonoscopy service across the endoscopy unit and the Coordination Centre. This role is used in the NHS Bowel Cancer Screening Programme (identified as a Specialist Screening Practitioner) and in the Queensland Bowel Cancer Screening Programme (identified as Gastroenterology Nurse Coordinator).

There are also potential risks with provision of bowel cleansing. Death and harm from electrolyte abnormalities, dehydration and serious gastro-intestinal problems have been reported following the inappropriate use of oral bowel cleansing solutions (Picolax®, Citramag®, Fleet Phospho-Soda®, Klean Prep®, Moviprep®) prior to surgery and/or investigative procedures. Frail and debilitated elderly patients and those with contraindications are particularly at risk from these treatments⁴. It is therefore critical that clinical experts who routinely assess patients for colonoscopy provide a dedicated colonoscopy pre-assessment service.

If the participant is assessed to be fit and they accept to undergo a colonoscopy investigation they are given:

- an appointment date and time
- bowel preparation and instructions
- culturally acceptable information about their procedure by the Endoscopy Unit
- access to an interpreter if required
- information on the links to local support services.

Pre-assessment is also an ideal time to obtain a participants family history in relationship to bowel cancer and refer to the NZ Familial Gastrointestinal Service, if appropriate. Systems to capture this

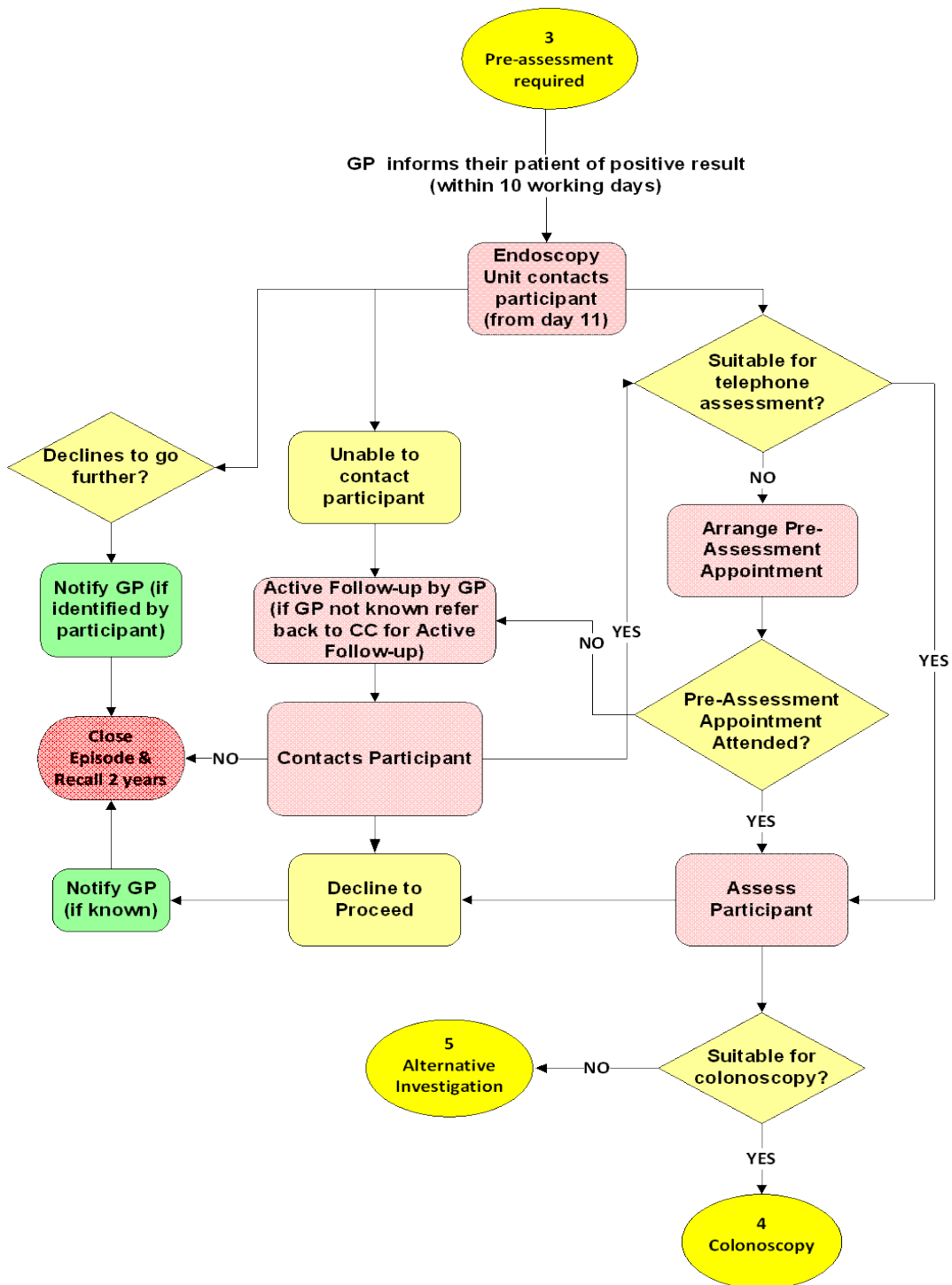
⁴ NHS Rapid Response Report is available at www.npsa.nhs.uk/rrr

information, including the development of a questionnaire and determining the most appropriate point during the pre-assessment process for this information to be obtained , are being finalised.

The roles and responsibilities at this stage of the screening pathway are:

| BSP pathway | Who is responsible | Requirements |
|---|---------------------------|---|
| Arrange colonoscopy pre-assessment | Endoscopy Unit | A senior endoscopy nurse will be responsible for carrying out a colonoscopy pre-assessment. A scheduled date for colonoscopy is made at this time. |
| Ensure participants with positive FIT have undergone a colonoscopy pre-assessment within 15 working days of a positive FIT test | Coordination Centre | The Coordination Centre has ultimate responsibility for ensuring all participants with a positive FIT have undergone a colonoscopy pre-assessment and that they have a scheduled colonoscopy appointment date in the BSP IT system. |
| Ensure exchange of patient clinical information for colonoscopy pre-assessment | General Practices | A process will be documented to enable GPs to inform the Senior Endoscopy Nurse of their patient's relevant clinical information to undergo a colonoscopy. The GP referral will include patient's relevant clinical information. |

Figure 6: Screening Pathway 3: Pre-Assessment – Management of Participants with Positive FIT Result



3.6 Screening Pathway 4: Colonoscopy

Bowel screening colonoscopy will be provided by a dedicated screening colonoscopy unit at the Waitakere Hospital site. Related services, such as Computerised Tomographic Colonography (CTC), will be undertaken by Waitemata DHB. The Screening Colonoscopy Unit will have the capacity to deliver 2,500 colonoscopies a year. This should provide sufficient annual capacity for the screening programme. In the event more are required, there are options available to extend the operating hours of this unit by offering Saturday lists, or utilising spare sessions at the North Shore site should the need arise.

The WDHB Endoscopy Unit will have a documented process to avoid Did Not Attend (DNA) appointments. All participants with a positive FIT result are considered a priority, however the process of follow-up for individuals who DNA for colonoscopy may be different and tailored to meet the needs of the individual.

Processes to avoid DNA are likely to include flexible appointment options, reminders and provision of further information if required. This will be included in the Quality Standards and will be monitored, evaluated, and undergo continuous quality improvement.

Use of a culturally acceptable patient navigation service should also be considered to optimise participation, and interpreters will be made available if required.

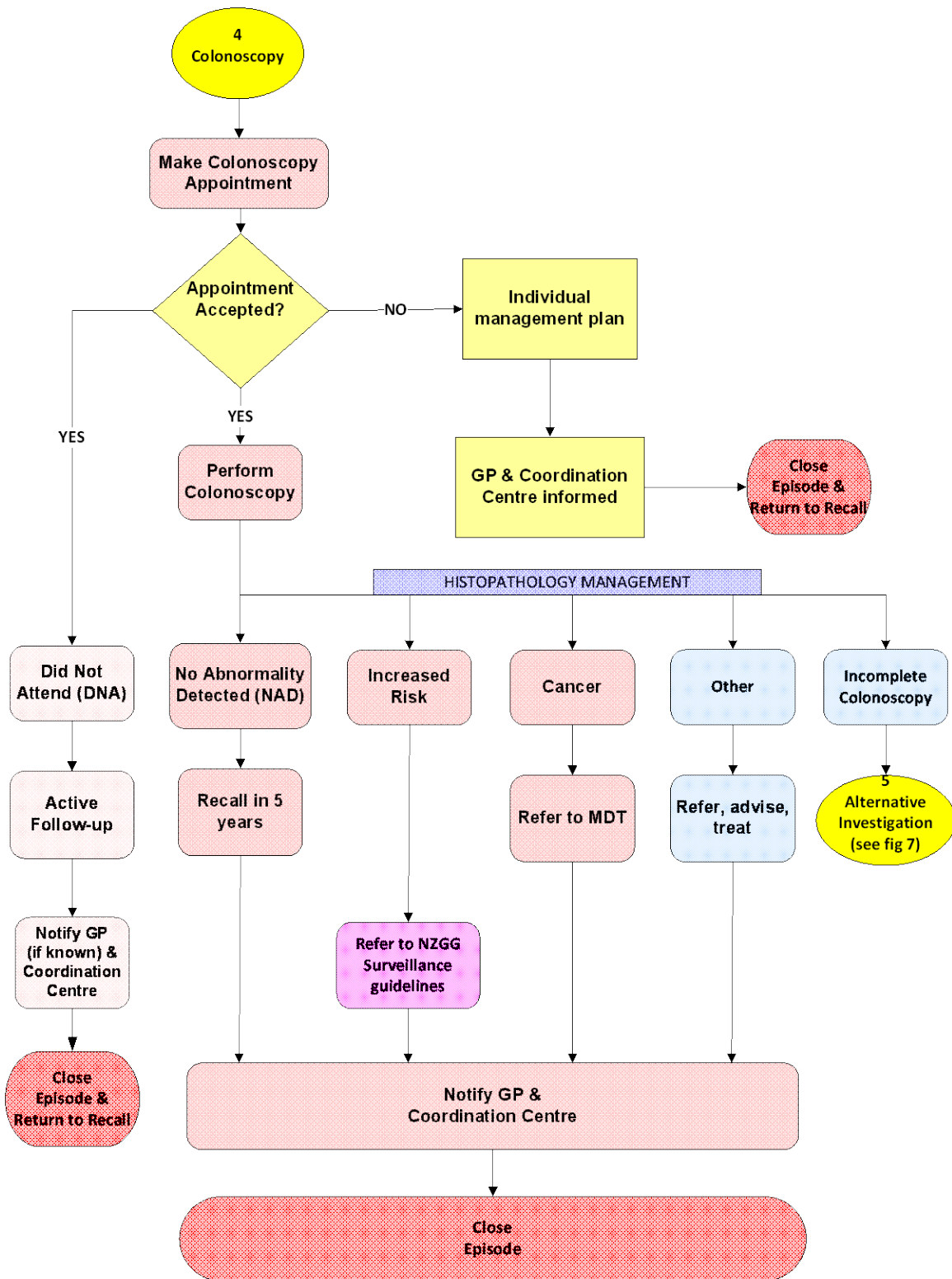
Participants with a 'normal' colonoscopy do not need to undergo another FIT screening episode for five years and will be referred to their GP. If screening is extended beyond the four years of the pilot, those people will be re-invited to participate when they become eligible again.

Those who are diagnosed with bowel cancer or high risk polyps will be referred for treatment and/or surveillance and enter the standard surveillance programme as run by the DHB. The participant's GP will be notified.

The roles and responsibilities at this stage of the screening pathway are:

| BSP pathway | Who is responsible | Requirements |
|--|---|--|
| Colonoscopy | Endoscopy Unit (senior endoscopy nurse/endoscopist) | A scheduled date for colonoscopy is made at colonoscopy pre-assessment. When the actual colonoscopy procedure is undertaken this will be documented in the BSP IT system. |
| Colonoscopy appointment and outcomes | Endoscopy Unit (senior endoscopy nurse) | The senior endoscopy nurse will collect appointment dates (scheduled and actual) and outcomes from colonoscopy. Outcomes from colonoscopy will be collected on a standardised reporting format which will include polyp and biopsy information. Colonoscopy performance data will be collected by the senior endoscopy nurse (using dedicated software) and internally audited and reviewed at the BSP Quality Working Group meetings. |
| Analysis of samples collected at colonoscopy | Designated laboratory | The designated laboratory will report histopathology using a standardised reporting template for polyps and/or biopsy taken at colonoscopy. These results will be forwarded to the BSP IT system. |

Figure 7: Screening Pathway 4: Colonoscopy Investigation



Note: Incomplete colonoscopy due to insufficient bowel preparation may require a repeat colonoscopy and not referral to alternative investigation.

3.7 Screening Pathway 5: Alternative Investigation

Participants assessed unfit for colonoscopy and some who have an incomplete colonoscopy will be offered a Computerised Tomographic Colonography (CTC) investigation.

It is expected that the BSP provider of the CTC service will have, or will develop, a documented process to avoid Did Not Attend (DNA) appointments. All participants with a positive FIT result are considered a priority, however the process of follow-up for individuals who DNA an alternative investigation may be different and tailored to meet the needs of the individual.

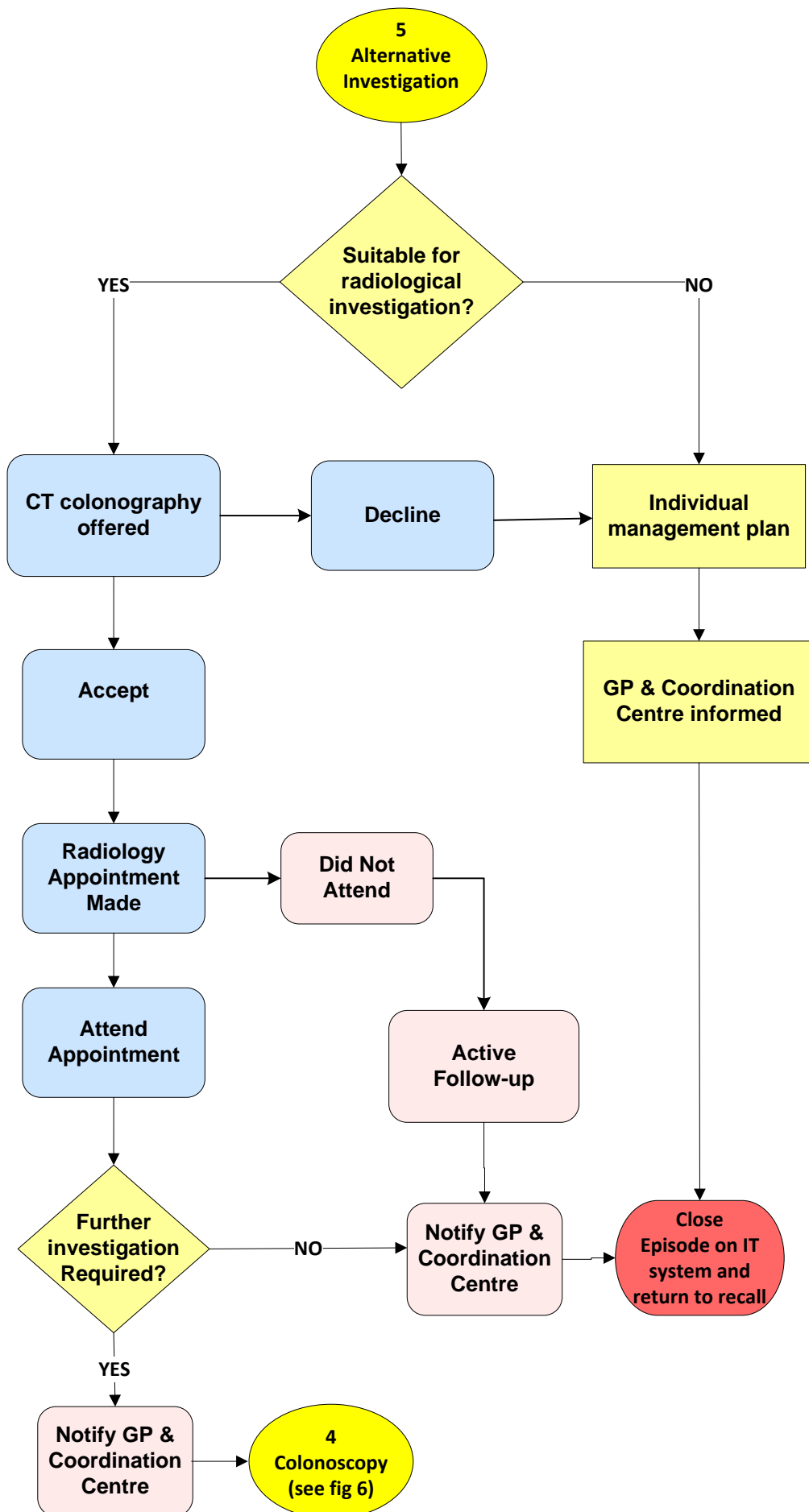
Processes that aim to avoid DNAs are to be developed by the BSP site and the radiology provider. This will include flexible appointment options, reminders and provision of further information if required. These will be included in the Quality Standards and will be monitored, evaluated and undergo continuous quality improvement.

Use of a culturally acceptable patient navigation service and/or interpreters should also be considered to optimise participation and enhance the alternative investigation experience for everyone.

The roles and responsibilities at this stage of the screening pathway are:

| BSP pathway | Who is responsible | Requirements |
|--------------------|--|---|
| CT Colonography | North Shore Hospital, Medical Imaging Department | Provision of CTC within the timeframes and quality requirements of the BSP Quality Standards. |
| CTC outcomes | Coordination Centre | The Coordination Centre will collect appointment dates and outcomes from CTC. |

Figure 8: Screening Pathway 5: Referral to Alternative Investigation



4 SURVEILLANCE

Participants requiring surveillance will not be recalled for subsequent screening and should be referred to a surveillance programme as per the recommended clinical guidelines⁵.

The roles and responsibilities at this stage of the screening pathway are:

| BSP pathway | Who is responsible | Requirements |
|----------------------------|----------------------------|---|
| Refer to Surveillance | Endoscopy Unit | The BSP Coordination Centre will have documented protocols and communications to advise participants they have been referred to surveillance. A notification from the Endoscopy Unit will go to the participant GP for surveillance management. The BSP IT system will capture the date the participant moved to surveillance in the screening pathway. |
| Monitoring of surveillance | BSP Independent Evaluation | The BSP independent evaluation will audit BSP participants who have been referred to surveillance to monitor if participants receive a surveillance colonoscopy within the recommended national guidelines (<i>Surveillance and Management of Groups at Increased Risk of Colorectal Cancer, 2012</i>). |

Patients requiring on-going surveillance (as defined by the New Zealand Guidelines Group guidelines (2012) for the “Surveillance and Management of Groups at Increased Risk of Colorectal Cancer,”) will be referred to Waitemata DHB’s Gastroenterology Unit. This unit currently adheres to these guidelines. Once a patient is referred to the Gastroenterology Unit for surveillance they effectively leave the Bowel Screening Pilot. This patient will be treated in accordance with WDHB existing standards and protocols for surveillance of high risk individuals.

5 TREATMENT

Participants requiring treatment for bowel cancer will not be recalled for subsequent screening and will be referred for consideration to a multidisciplinary meeting (MDM). The BSP Coordination Centre will collect information on the time it takes for patients to see a specialist, the case reviewed at a MDM, and the treatment decision and histology results from surgical resection (through use of a synoptic report from WDHB).

Patients diagnosed with bowel cancer will be referred to the appropriate service through the colorectal multi-disciplinary meeting. These are held weekly at North Shore Hospital and include the surgeons, radiologist, and a pathologist. A medical oncologist and a radiation oncologist attend from ADHB in addition to providing local oncology clinics at North Shore Hospital.

The referral is made using a regional bowel cancer MDM form that has been developed by the Northern Cancer Network Bowel Tumour Work Stream and is currently being piloted by the DHBs.

The MDM should provide culturally appropriate and coordinated care, advice and support. Outcomes of meetings should be communicated to the participant, their GP and be clearly documented in the medical records.

An MDM form is used to act as both a referral form and also a record of the decisions made at the meeting. It captures information in a standardised way to:

⁵ New Zealand Guidelines Group. Surveillance and Management of Groups at Increased Risk of Colorectal Cancer. Ministry of Health. 2012.

- enable efficient presentation of bowel cancer patients in MDM
- enable rapid referral after MDM by using the MDM form instead of dictating a referral letter
- collect data from the MDM forms for real-time performance measurement.

All patients diagnosed with cancer through the bowel screening programme requiring chemotherapy and/or radiation therapy will be managed by the Auckland Regional Cancer and Blood Service at Auckland District Health Board (ADHB).

The roles and responsibilities at this stage of the screening pathway are:

| BSP pathway | Who is responsible | Requirements |
|------------------------------|---|--|
| Refer to Treatment | Endoscopy Unit (senior endoscopy nurse) | Referral of bowel cancer patients to MDM and to treatment services. |
| Collection of treatment data | Coordination Centre | Collection of outcomes from treatment. Standardised reporting will be required for histopathology for bowel surgery. |

GLOSSARY

The following table outlines key terms and definitions used in this document.

| Term | Definition |
|----------------------------|--|
| BCT | Bowel Cancer Team |
| BSP | Bowel Screening Pilot |
| CC | Coordination Centre |
| CTC | Computed Tomographic Colonography |
| DHB | District Health Board |
| DNA | Did Not Attend (an appointment) |
| FTE | Full Time Equivalent |
| GP | General Practitioner |
| FIT | Faecal Immunochemical Test |
| IT | Information System |
| KPI | Key Performance Indicator |
| Ministry | Ministry of Health |
| NHI | National Health Index (unique identifier for each person) |
| NSU | National Screening Unit |
| PHO | Primary Health Organisation |
| SDM | Service Delivery Model |
| Under screened populations | Are defined as those who are traditionally under screened in screening programmes. In the New Zealand setting, Māori and Pacific people are under screened populations that are likely to need extra support to ensure that all WDHB district residents have fair access to the screening pilot. |
| Active Follow-up | Active Follow-up is a process to ensure fair access to the BSP for all people in the pilot region to the benefits of the BSP. Documented procedures will be developed for attempting to contact people from under screened populations who do not continue at any stage in the screening pathway, and for all people with a positive FIT who do not continue in the screening pathway thereafter. This will be developed locally in partnership with local communities, general practices and other first level service providers within the BSP region. The requirements of Active follow-up will be outlined in the Quality and Procedures Manual for the BSP. |
| Advance notification | Advance notification letters have been shown to increase participation in bowel screening internationally. A letter will be sent by the Coordination Centre. This letter will: <ul style="list-style-type: none"> • Endorse the pilot by the GP • Allow people the opportunity to opt out of receiving a FIT if they wish. • Advise people that they will receive an invitation and a FIT kit from the BSP unless they notify the Coordination Centre that they do not wish to participate. |

COLOUR KEY TO FLOW DIAGRAMS

| Colour | Identifier |
|---------------|---|
| Yellow | Participant |
| Light Blue | Coordination Centre |
| Orange | Laboratory |
| Dark Orange | Close current screening episode and/or return to recall |
| Pink | Colonoscopy Investigation |
| Green | GP |
| Bright Yellow | Indicates beginning of part of the screening pathway |
| Magenta | Surveillance |