MINISTRY OF HEALTH
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National Bowel Screening Programme Interim Quality Standards

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Contents

Overview of quality requirements for bowel screening

The National Bowel Screening Programme (NBSP) Interim Quality Standards (the Standards) will be used from 1 July 2017 to support the implementation of the NBSP over the 2017/18 financial year.

These Standards are based on the Bowel Screening Pilot (BSP) interim quality standards, which were reviewed by the Bowel Cancer Taskforce, the Colonoscopy Quality Working Group (CQWG) and the BSP Quality Assurance Group before the BSP commenced in 2012. The BSP quality standards were in turn based on English, Welsh and Scottish bowel cancer screening programmes and the outcomes of the English and Scottish bowel screening pilot evaluation.

These Standards have been reviewed and endorsed by the Bowel Screening Advisory Group (BSAG).

They will be monitored within the NBSP, and progress against them will be monitored by the National Screening Unit (NSU) to ensure best outcomes for NBSP participants and stakeholders.

1 Monitoring and evaluation

Monitoring and evaluation of the NBSP will be undertaken at a local level during the 2017/18 financial year by a quality-focused group at each district health board (DHB). The groups will meet at least quarterly. Nationally, quality will be overseen by the NSU.

Performance monitoring of the NBSP's 2017/18 financial year will be undertaken using the BSP+ IT system reporting layer. Reports will be made available to enable DHBs to view their progress against quality standards.

An independent provider (yet to be appointed) will evaluate the NBSP implementation following the completion of the implementation phase. The NSU will provide oversight of compliance with the monitoring and evaluation processes and indicators and will flag any concerns or matters requiring further investigation.

Full NBSP evaluation, including full benefits realisation, will not take place until at least 10 years after completion of the implementation phase. However, the NSU will regularly evaluate interim benefits realisation (such as monitoring for stage shifts in colorectal cancer and trends in incidence rates).

The NSU has developed an interim monitoring framework (including interim monitoring indicators) for the NBSP's 2017/18 financial year.

2 Interim Quality Standards

The Standards will be monitored to ensure they are appropriate, in particular, to ensure that service providers can meet the specified timeframes.

Interim quality standards specific to endoscopy facilities and the performance of the faecal immunochemical test (FIT) for haemoglobin have also been made available.

2.1 Faecal immunochemical test for haemoglobin performance

Specific quality standards have been developed to monitor the performance of the FIT as part of the laboratory contract with Waitemata DHB through continuous quality improvement (CQI), audit and reporting processes.

2.2 Endoscopy suite (colonoscopy)

The Bowel Cancer Endoscopy Nurse Quality Group provided recommendations on the required standards for endoscopic facilities, guidelines on sedation, scope reprocessing, infection control, audit and training requirements for endoscopy nurses and technicians for the BSP. These Standards have been reviewed and will be monitored through CQI and audit processes.

2.3 Colonoscopy procedures

The Ministry of Health's (the Ministry's) Bowel Cancer Colonoscopy Quality Working Group has evaluated international colonoscopy standards and has consulted with their professional bodies on appropriate colonoscopy quality standards for use in New Zealand. This has resulted in the development of specific interim quality standards relating to colonoscopy. Further to these standards, quality assurance measures of the procedure will need to be collected for all screening participants.

Colonoscopy service providers will collect colonoscopy procedural data and monitor colonoscopy performance for all screening participants. This data will also form part of the NBSP evaluation.

Standardised reporting for colonoscopy will also be developed for the NBSP in collaboration with the DHBs and professional bodies (where required).

2.4 Professional requirements

All staff working in the NBSP will be required to meet existing professional and training requirements and possibly further training requirements as identified by the DHB quality-focused groups. Delivering a quality service relies on enhancing the skills of existing staff through training and development and developing new groups of staff with the right skills and competencies to meet NBSP priorities.

2.5 Histopathology

The Ministry's Bowel Screening Standards Histopathology Working Group, a subgroup of the Bowel Cancer Working Group, has evaluated international pathology standards to help develop these Standards. These Standards still require input from the appropriate stakeholders.

Histopathology service providers will be required to collect and report key quality indicators as part of ongoing monitoring of histopathology service performance following a standardised reporting format.

3 Clinical audit (endoscopy)

Clinical audit will form part of the CQI process. Clinical audit seeks to improve the quality of patient care through a system whereby clinicians examine their practices and compare the results against agreed standards and best practice, modifying their practices where indicated.

4 Risk management

'Failsafe' in a screening programme means that, at any point of the screening pathway, it is possible to identify what stage each participant is at within their screening episode. It also identifies if a participant has 'opted off' or if the system has failed to progress a participant through the screening pathway at any point. It ensures that NBSP participants can be adequately monitored and that there is an identified screening end point for all participants. NBSP providers will be required to have rigorous documented failsafe procedures in place to track every participant along the screening pathway.

5 Monitoring indicators

Monitoring verifies that systems are operating as required. National monitoring indicators for the NBSP are based on European guidelines for QA in colorectal cancer screening and diagnosis.

Scope and purpose

The NBSP will be routinely monitored against appropriate indicators and the Standards. These Standards cover monitoring of the NBSP's financial year 2017/18, commencing July 2017 for three DHBs: Waitemata, Hutt Valley and Wairarapa. The rest of the NBSP implementation will be covered by the national policy and quality standards, which will be developed during 2017 and once completed, will supersede this document.

It is expected that NBSP providers will have QA systems in place, including internal audit processes that ensure adherence to these Standards on an ongoing basis. Ultimate responsibility for these processes will rest with the NSU.

The evaluation processes outlined in these Standards and interim quality standards for other components (for example, interim standards for endoscopy facilities) provide specific protocols to follow within the audit process. It is expected that, where shortcomings are identified as a result of internal auditing, NBSP providers will take steps to meet the required standards and relevant indicators. In addition, an evaluation framework will provide the basis for external assessment and review. The external assessment process enables a verification of adherence to each of the standards. At the time of writing, the exact process for external assessment was yet to be determined.

Terminology used within these Standards includes:

Standard	Each standard is mandatory, specifies the minimum requirements for compliance and, wherever possible, is outcome and quality focused relating directly to NBSP participants. Each standard will always specify the objective that is required. A standard is achieved when all indicators or criteria associated with it are met.
Quality indicators	The quality indicators are measurable elements of service provision. Quality indicators relate to the desired outcome or performance by staff or services.
Essential criteria	The essential criteria are components of service provision that must be in place in order to achieve a quality indicator.
Evaluation process	The evaluation process is the means by which the essential criteria are assessed.
Evaluation target	Evaluation targets are specified where quantitative measures are available. If no target has been set, the expectation is that all criteria will be fully complied with – that is, 'all criteria are met'. The evaluation target identifies the level of compliance required to meet a specific standard, indicator or criterion. The NSU will provide oversight for monitoring the NBSP and ensuring that during the 2017/18 financial year of the NBSP implementation (ie, the timeframe covered by these Standards) the NBSP meets: • the NBSP interim quality standards • the interim endoscopy facility standards (colonoscopy) • the interim FIT performance quality standards.

Data definitions and elements

The NSU has developed data definitions and data elements to enable clear and concise reporting and monitoring of the NBSP. These data definitions have been based on:

- recognised population screening priorities
- consensus between represented stakeholders
- once-only data collection (and agreed responsibility)
- source data based on robust definitions
- acceptable impact/burden on services
- collection with appropriate frequency and timeliness.

The data definitions document will be part of NBSP quality documentation.

Composition/format of quality standards

Each quality standard has been defined according to a standard template, which specifies:

- the name of the standard
- a description of the standard
- the rationale for collection
- achievable and acceptable level of performance (where relevant)
- the quality indicator
- essential criteria required to meet the standard
- the evaluation process
- the evaluation target.

The service providers will have oversight of their specific components of the bowel screening stages to ensure compliance with the quality standards that pertain to them. Although each service provider in the NBSP (such as DHB endoscopy units and laboratories) will be responsible for meeting the standards, the NSU will monitor compliance and lead CQI for the NBSP as a whole.

Performance thresholds

Where possible, performance thresholds have been selected that align with existing screening programme standards and service objectives. These have been based on international evidence and the BSP.

The desirable threshold represents safe and robust performance; screening programmes should budget for and aspire to reach this threshold. However, local constraints may sometimes result in the NBSP failing to meet this threshold. Service improvement plans should focus on delivering a balanced service with as many standards as possible meeting the achievable threshold.

The acceptable threshold is the lowest level of performance considered safe. NBSP providers are expected to exceed the acceptable threshold and to agree on service improvement plans that develop performance towards an achievable level. If a provider is not meeting the acceptable threshold, it is expected to implement recovery plans to ensure rapid and sustained improvement relative to the associated level of risk.

1 Provision of bowel screening

Providing bowel screening to the eligible population Standard 1.1: An effective bowel screening pathway is available to the eligible population of DHBs participating in the NBSP.	
Definition	A high-quality bowel screening service is available to the eligible population in each DHB area.
Rationale	There is evidence that population-based screening can lead to a reduction in mortality from bowel cancer.
Quality indicator	The bowel screening service has all the components of the bowel screening pathway in place to meet the NBSP interim quality standards.
Essential criteria	The NBSP responsible providers must ensure: 1.1.a. they have clearly defined arrangements for governing the NBSP (Overall, the interim coordination centre is responsible for managing NBSP participants.) 1.1.b. they have in place a designated NBSP quality-focused group that meets at least quarterly 1.1.c. they enter the required data into the BSP+ IT system, as detailed in the standard operating procedures 1.1.d. they comply with all NBSP interim quality standards, business processes and operational procedures.
Evaluation process	Information is collected through the BSP+ IT system for monitoring and evaluation purposes. The responsible provider ensures that identified issues are addressed through a CQI process. The external audit process ensures all criteria are complied with along the bowel screening pathway.
Evaluation targets	No quantitative target. All criteria are met.

2 Initial invitation and subsequent recall to bowel screening

Initially inviting and subsequently recalling the eligible population to bowel screening

Standard 2.1: All eligible participants within each of the DHB areas of the NBSP will be offered bowel screening within the first 24 months of becoming eligible and every 24 months following.

Definition	Eligible participants are invited to take part in the screening programme by a mailed pre-notification letter followed by an invitation letter (which includes a FIT kit) every 24 months. The eligible age range for the NBSP is 60–74 years.
Rationale	There is evidence that population-based screening amongst the age range 60–74 years leads to a reduction in incidence and mortality from bowel cancer. There is evidence that effective invitation and subsequent recall maximises these benefits.
Quality indicator	All known potentially eligible participants in each DHB area will be regularly offered (every 24 months) the opportunity to participate in the NBSP. For the initial implementation phase of the NBSP, the cohort of potentially eligible participants will be drawn from the National Health Index (NHI) and primary health organisation (PHO) data. The NSU is responsible for generating this cohort of participants.
Essential criteria	The NSU must ensure: 2.1.a. the eligible cohort is identified 2.1.b. the eligible cohort is sent to the interim coordination centre in a timely manner. The interim coordination centre must ensure: 2.1.c. each known eligible participant is sent their first invitation for screening within 24 months of the NBSP commencing in each DHB area 2.1.d. each participant who becomes eligible after the implementation phase is sent their first invitation for screening within three months of becoming eligible 2.1.e. each eligible participant who completed a FIT kit correctly is recalled after 24 months following the date their negative FIT result was recorded in the BSP+ IT system 2.1.f. each eligible participant who did not complete a FIT kit correctly or who did not respond to an invitation will be recalled 24 months after their previous invitation date.

Evaluation process	Information is collected through the BSP+ IT system for the NBSP for monitoring and evaluation purposes. The internal audit process ensures that all criteria are complied with and identified issues are addressed through a CQI process.
Evaluation targets	100% of known eligible participants are sent an invitation for screening within 24 months of the NBSP commencing in each DHB area. 100% of eligible participants who responded to their invitation with a FIT kit that could be adequately tested are recalled for screening within 24 months of the date their negative FIT result was recorded in the BSP+ IT system. 100% of eligible participants who did not respond to their invitation or who returned a FIT kit that could not be adequately tested are recalled for screening within 24 months of their previous invitation for screening. All other criteria are met.

3 Participation in bowel screening

Participation of the eligible population is high in all population groups Standard 3.1: The number of individuals responding to an invitation to participate in bowel screening is both maximised and equitable.	
Definition	The percentage of eligible participants invited who return a completed FIT kit is maximised. It is essential to ensure that participation is high for all population groups.
Rationale	There is evidence that population-based screening amongst the 60–74 years age range leads to a reduction in incidence and mortality from bowel cancer. A high level of participation for all population groups will maximise these benefits.
Quality indicator	Eligible individuals are invited to participate in bowel screening.
Essential criteria	The interim coordination centre must ensure: 3.1.a. there are mechanisms to identify non-responders and offer them a further opportunity to respond within the screening round 3.1.b. there are mechanisms in place to withdraw or suspend participants from bowel screening at their request 3.1.c. there are failsafe procedures in place, appropriate to the outcome of the screening episode 3.1.d. there is a plan to maximise informed uptake, with particular attention to the local population profile and traditionally under-screened communities, participants from deprived communities, rural communities, Māori, Pacific and men in the eligible age range.
Evaluation process	Information on uptake is collected through the BSP+ IT system for monitoring and evaluation purposes. The provider will use a CQI process to ensure that all criteria are complied with and identified issues are addressed.
Evaluation targets	≥ 60% of all eligible participants invited within each DHB area return a completed FIT kit every 24 months and, when stratified by ethnic group (Māori, Pacific, Asian and 'European & Other') and by deprivation quintile, there is no difference between the total DHB participation rate and the rates for the individual ethnic and deprivation groups.

Informed choice Standard 3.2: The number of individuals responding to an invitation to participate in bowel screening is maximised within the principles of informed choice.	
Definition	NBSP providers must comply with the *Code of Health and Disability Services Consumers' Rights*,[1] in particular: • Right to Effective Communication (Right 5) • Right to be Fully Informed (Right 6) • Right to Make an Informed Choice and Give Informed Consent (Right 7).
Rationale	There is evidence that the mortality rate from bowel cancer can be reduced by a high level of participation in a population-based screening programme, but eligible participants must feel they have been fully informed of the potential harms and benefits of bowel screening.
Quality indicator	Each individual is appropriately informed through the provision of effective information in written and verbal forms as required, enabling them to make an informed choice and provide their informed consent where it is required.
Essential criteria	The bowel screening providers must ensure: 3.2.a. they have a plan to maximise informed participation, with particular attention to the local population profile and groups such as ethnic minority groups and communities 3.2.b. they have a process for reviewing written information and documented verbal communication protocols annually or when a complaint is made, and required changes are made where an issue is identified.
Evaluation process	Information on uptake is collected through the BSP+ IT system for monitoring and evaluation purposes. The information provided to participants meets the requirements of the *Code of Health and Disability Services Consumers' Rights*, rights 5, 6 and 7 and that these are fully met. Participant satisfaction is surveyed throughout the process. The internal audit process ensures that the essential criteria are complied with and identified issues are addressed through a CQI process.
Evaluation targets	100% of participants have their rights met under the *Code of Health and Disability Services Consumer's Rights*. 95% of participants return a signed FIT consent form with their completed FIT kit. All other criteria are met.

[1] Health and Disability Commissioner. *Code of Health and Disability Services Consumers' Rights.* Auckland: Health and Disability Commissioner. URL: www.hdc.org.nz/the-act--code/the-code-of-rights (accessed 9 June 2017).

Failsafe procedures Standard 3.3: Failsafe procedures are in place and appropriate to the outcome of the screening FIT test.	
Definition	Failsafe systems aim to prevent error, minimise risk and maximise follow-up compliance or adherence to standard procedures by sending reminders or applying computer based or other automated checks.
Rationale	Failsafe procedures are important to ensure that participants receive the follow-up appropriate to the outcome of the screening episode. In particular, it is important to ensure that all participants with a positive screening test are provided with every opportunity to undergo colonoscopy or other diagnostic investigation.
Quality indicator	Every participant is advised of the outcome of their screening episode and appropriately referred within the screening process to either timely access to colonoscopy (or other diagnostic investigation) or recall.
Essential criteria	The interim coordination centre must ensure: 3.3.a. there are failsafe protocols to ensure that all eligible participants with a negative screening test result are returned to 24 month routine recall 3.3.b. there are failsafe protocols to ensure all participants who did not respond to an invitation or who returned a FIT kit that could not be adequately tested are recalled 24 months following their invitation date 3.3.c. there are failsafe protocols to ensure GPs, where known, receive notification of positive results 3.3.d. there are failsafe protocols to ensure all participants with a positive FIT result are followed up by their GP or their DHB's endoscopy unit (Note: Those who do not respond are sent a letter (copied to their GP) advising them of their result and asking them to contact their GP or DHB endoscopy unit. The outcome of follow-up is documented in the BSP+ IT system.) 3.3.e. participants can opt out for an indefinite period from the routine recall system by advising the interim coordination centre or through their GP. Individuals opting off are sent the NBSP pro-forma confirmation letter for participants that have withdrawn for the NBSP.
Evaluation process	Information is collected through the BSP+ IT system for monitoring and evaluation purposes. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through a CQI process.

Evaluation targets	100% of eligible participants with a negative screening result are returned to 24-month recall. 100% of eligible participants who did not respond to an invitation or who did not complete a FIT kit correctly are recalled 24 months after their invitation date. 100% of participants with a positive FIT result are followed up by their GP or their DHB's endoscopy unit. All other criteria are met.

4 The screening process

Provision of written FIT information to eligible participants

Standard 4.1: Written information will be sent to all eligible participants within the NBSP with the faecal immunochemical test (FIT) for haemoglobin and invitation letter. The information will give a full explanation of the screening process and provide balanced information on the potential benefits and risks of screening.

Definition	All eligible participants who are being invited for screening for the first time will receive a detailed booklet on the bowel screening process, *Bowel Screening: All about bowel screening* with their pre-invitation letter. Participants will receive the leaflet, *Bowel Screening: Your quick reference guide*, the FIT kit, an instruction sheet on how to complete the FIT kit and a consent form with their invitation to bowel screening.
Rationale	There is a requirement through the *Code of Health and Disability Services Consumers' Rights* to provide accurate information about screening tests and diagnostic investigations in order to allow informed choice and informed consent.
Quality indicator	All eligible participants within the NBSP will receive an invitation letter and bowel screening information in order to consider if they wish to participate in the NBSP.
Essential criteria	The interim coordination centre will provide: 4.1.a. written information on bowel screening to all eligible participants, explaining the potential benefits and risks of screening and the significance of positive and negative results 4.1.b. appropriate bowel screening information to all participants who are invited for screening that explains how to undertake the screening test and return it to the designated FIT testing laboratory 4.1.c. appropriate information to all participants who are invited for screening explaining that a colonoscopy or other diagnostic test will be offered if their screening test result is positive (Note: Participants will also be given information that referral for surveillance may result from a colonoscopy.) 4.1.d. information in different formats and languages appropriate to the needs of the individual, when and where required (this may include a telephone call or face-to-face contact).
Evaluation process	The internal audit process ensures that the criteria are complied with and identified issues are addressed through a CQI process. Participant satisfaction is surveyed.
Evaluation targets	No quantitative target. All criteria are met.

Provision of written FIT results	
Standard 4.2: Written results will be sent to all participants who have returned a faecal immunochemical test (FIT) for haemoglobin kit. The information provided will give a full explanation of the meaning of results and the screening pathway.	
Definition	A formal and complete assessment of the risk of a condition being screened for is provided to a participant, following testing of a satisfactorily completed FIT kit. Usually a result will be 'screen positive' or 'screen negative'. Spoilt and technical failed tests indicate a failure to obtain a result and are not themselves results.
Rationale	There is an obligation through the *Code of Health and Disability Services Consumers' Rights* to provide accurate information about the outcome of screening tests and subsequent diagnostic investigations in order to allow the participant to make an informed decision.
Quality indicator	Bowel screening participants have a full understanding of the screening process, the potential benefits and risks of screening, and the implications of their test results.
Essential criteria	The NBSP providers must ensure: 4.2.a. information is made available in alternative formats and languages appropriate to the needs of the participants 4.2.b. participants receiving a negative result are sent the NBSP pro-forma letter informing them of the limitations of the screening test (Note: Participants are advised to be observant of and report relevant symptoms to their GP.) 4.2.c. the NBSP pro forma letter sent to individuals with a spoilt screening test result contains information that explains the reason and significance of a spoilt result and a further FIT kit 4.2.d. all participants with a positive screening test result are contacted by the NBSP DHB endoscopy nurse to arrange a time for a colonoscopy pre-assessment, by telephone or face to face if clinically indicated. Written confirmation of a positive test occurs once the outcome of the pre-assessment process is known.
Evaluation process	Information is collected through the BSP+ IT system for monitoring and evaluation purposes. The internal audit and external assessment process ensures that the criteria are complied with, and identified issues are addressed through a CQI process.
Evaluation targets	100% of NBSP participants who return a FIT kit (positive, negative or spoilt) are sent written confirmation of their test result. All other criteria are met.

Providing a free telephone helpline Standard 4.3: There is an adequately staffed free telephone helpline for all participants receiving an invitation to participate in the NBSP.	
Definition	A free telephone information line is available to enable further enquiries or information related to the bowel screening pathway.
Rationale	Evidence from other New Zealand screening programmes and international bowel cancer screening programmes indicates that a number of participants require verbal clarification or extra information regarding aspects of the screening process.
Quality indicator	The free telephone information line is fully staffed during business hours and provides information on after-hours assistance if needed (eg, Healthline or the bowel screening website). Helpline operators communicate in a respectful and culturally appropriate manner.
Essential criteria	The NBSP must ensure: 4.3.a. the free telephone information line is staffed continuously during normal business hours between 8.00 am and 4.30 pm, Monday to Friday, excluding public holidays 4.3.b. outside working hours, a recorded message advises callers of the hours the helpline is staffed and acts as a signpost to after-hours assistance (eg, Healthline or the bowel screening website) 4.3.c. all staff involved with the screening information line receive relevant training before undertaking unsupervised work 4.3.d. all staff involved with the screening information line undertake annual update training provided by the bowel screening service provider 4.3.e. the time taken to answer telephone information line calls is internally monitored 4.3.f. the volume of calls and their nature, date and time of day will be monitored to ascertain if the information line is staffed appropriately 4.3.g. gender representation at the interim coordination centre is considered appropriately, in particular in regard to telephone enquiries.
Evaluation process	Participant satisfaction survey across the pathway. The internal audit and external assessment process ensures that the criteria are complied with, and identified issues are addressed through a CQI process.
Evaluation targets	No quantitative target. All criteria are met.

Minimising the time for participants receiving FIT results Standard 4.4: The time between receipt of the faecal immunochemical test (FIT) for haemoglobin kit by the laboratory and receipt of the result by participants and GPs is minimised.	
Definition	The receipt of the FIT kit by the laboratory, sample testing and generation of results for the participant, the register and the GP (if known) is managed efficiently.
Rationale	There is evidence that waiting for a screening test result can cause anxiety.
Quality indicator	All participants returning a screening test are notified of the result of the test by their GP or the NBSP DHB endoscopy unit within the designated timeframes.
Essential criteria	The NBSP FIT testing must ensure: 4.4.a. there is a minimum of one mail delivery to the testing laboratory per day of returned FIT kits 4.4.b. all test kits received by the designated FIT testing laboratory are tested within two working days of receipt in the laboratory, with the first of the two days being when the test kit arrives and is logged at the laboratory 4.4.c. positive results are validated within one working day of being tested 4.4.d. the interim coordination centre and the GP (if known) are notified of a positive result on the day of validation 4.4.e. if a GP is known for a participant, the GP contacts their patient within 10 working days to convey the result and refer the patient to the DHB endoscopy unit for a colonoscopy 4.4.f. if the GP is unknown, or the participant does not wish their GP to receive the result, the endoscopy unit nurse attempts to contact the participant on working day 11 to convey the result and make arrangements for a telephone pre-assessment 4.4.g. if the GP is known but does not refer their patient within 10 working days, the endoscopy unit nurse attempts to contact the participant to convey the result and make arrangements for a telephone pre-assessment on working day 11 4.4.h. The interim Coordination Centre has ultimate responsibility to ensure all participants who submit a FIT kit for testing receive a result of the test within the designated timeframe 4.4.i. all results are captured by the BSP+ IT system.
Evaluation process	Regular reports, including quality control (QC) results, will be generated and reviewed by the laboratory facility as required by the NBSP and as part of the internal QA.

Evaluation targets	100% of FIT kits are logged within one working day of arriving at the laboratory. 100% of correctly completed FIT kits received by the screening laboratory are tested within two working days of arriving at the laboratory. 100% of positive FIT results are validated within one working day of being tested. 100% of positive FIT results are notified to the interim coordination centre and the GP (if known) on the day of validation. 95% of participants returning a correctly completed screening FIT test are advised of their results by their GP or the DHB endoscopy unit (if positive) or via a letter (if negative) within 10 working days. All other criteria are met.

5 The FIT laboratory process

Accreditation of the FIT testing laboratory Standard 5.1: The laboratory providing bowel screening faecal immunochemical test (FIT) for haemoglobin analyses meets recognised professional standards.	
Definition	The laboratory must be accredited by International Accreditation New Zealand (IANZ) against ISO 15189 and any other required standards.
Rationale	There is evidence that laboratories accredited and working against agreed standards achieve the required high level of performance. Accreditation is regarded as an essential element in ensuring good clinical governance and best practice.
Quality indicator	The laboratory providing bowel screening test analyses must have policies, protocols and practices that ensure the quality of FIT analyses. Policies define staff responsibilities, required laboratory procedures and documented internal QC and QA.
Essential criteria	The NBSP FIT testing laboratory must ensure adequate training and ongoing competency. As such: 5.1.a. all laboratory staff must receive relevant training and demonstrate competency before undertaking unsupervised work for FIT testing 5.1.b. all laboratory staff must undertake regular training provided by the laboratory contract holder and undertake competency appraisal and continuous professional development 5.1.c. all laboratory staff must be registered with an appropriate New Zealand registration authority and hold a current APC 5.1.d. laboratory assistants who do not require registration must be supervised in accordance with the registration authority 5.1.e. the FIT testing laboratory must hold current IANZ accreditation.
Evaluation process	The laboratory must inform the interim coordination centre of the IANZ assessment results (both annual surveillance process and the four-yearly peer reassessment). Any change to their accreditation status must be notified immediately. The laboratory must take part in internal and external audit processes.
Evaluation targets	100% of NBSP laboratory staff performing FIT testing must be appropriately qualified and registered with a current APC, receive relevant training and demonstrate competency before undertaking unsupervised work. All other criteria are met.

Quality control and quality assurance of the FIT testing laboratory Standard 5.2: The quality of the bowel screening FIT laboratory test analyses is continually assessed and monitored, and there is evidence of internal quality control, external quality assessment and quality assurance.	
Definition	The laboratory has in place a documented and structured quality framework to ensure QA and QC.
Rationale	Quality control, assessment and assurance are essential when providing independent assessments of the test and laboratory performance.
Quality indicator	The NBSP FIT testing laboratory undertakes CQI activities, and these are evident through internal and external monitoring.
Essential criteria	The NBSP FIT testing laboratory must ensure: 5.2.a. internal QC procedures are undertaken and documented (Note: the QC is reviewed for each run and then monitored for trends by QC sample over time.) 5.2.b. they follow documented procedures for receiving, processing and reporting FIT samples 5.2.c. they demonstrates overall satisfactory performance in an independent external quality assessment scheme (EQAS) 5.2.d. they participate in an independent national quality assessment scheme, where available 5.2.e. QC failure and external QA errors are investigated, documented and show evidence of corrective action and educational activity for up-skilling staff 5.2.f. their quality manager ensures an audit is undertaken annually to ensure continuing compliance with relevant The Royal College of Pathologists of Australasia (RCPA) and IANZ standards (ISO 15189) 5.2.g. they comply with the interim FIT performance quality standards 5.2.h. the FIT test positivity threshold for NBSP is $\geq$ 200ng haemoglobin/ml.
Evaluation process	The NBSP FIT testing laboratory performance is assessed through internal and external monitoring and audit processes. The internal and external audit processes ensure that the criteria are complied with, and identified issues are addressed through a CQI process. QC outcomes are reported monthly through the laboratory contract with Waitemata DHB.
Evaluation targets	100% of all daily and periodic QC is reviewed and documented, and outcomes are reported monthly through the laboratory contract with Waitemata DHB. 100% participation and documentation of results of external QA programmes. 100% monthly reporting through the laboratory contract with Waitemata DHB. All other criteria are met.

6 Pre-assessment for diagnostic investigation (colonoscopy or other diagnostic investigation)

Minimising the interval between a positive FIT and a pre-assessment for diagnostic investigation

Standard 6.1: The interval between receiving a positive faecal immunochemical test (FIT) for haemoglobin result and pre-assessment for colonoscopy (or alternative investigation) is minimised.

Definition	Pre-assessment for colonoscopy (or alternative investigation) requires a formal assessment using a structured process and pro forma to assess the suitability of a participant to undergo diagnostic investigation from their positive FIT.
Rationale	There is evidence that the time interval between receiving a positive result and undergoing a colonoscopy pre-assessment can result in increased anxiety.
Quality indicator	The interval between a participant receiving a positive FIT result and participating in a colonoscopy pre-assessment by telephone is minimised. The interval between the BSP+ IT system receiving a positive result and the participant being first offered a colonoscopy pre-assessment appointment is within NBSP monitoring targets.
Essential criteria	The NBSP endoscopy unit must ensure: 6.1.a. there are arrangements to identify all participants who are unable to be contacted, for example who do not respond to telephone calls or postal letters (Note: Participants who have not responded to a minimum of three attempts by the endoscopy unit to reach them by phone (including at least one phone call out of hours) for a pre-assessment are sent a letter (copied to their GP) advising them that they have a positive result and should contact either their GP or the endoscopy unit to discuss the next steps.) 6.1.b. participants with a positive result are contacted in the first instance by their GP (if known) or the NBSP endoscopy unit (if the GP is not known, the participant does not wish their GP to be notified or the referral has not been received within 10 working days) 6.1.c. they contact the participants within 15 working days of the receipt of the result on the BSP+ IT system to arrange a time for a telephone pre-assessment (Note: If the pre-assessment indicates the need for a face-to-face contact for further assessment, they offer a date for this assessment.) 6.1.d the date of first contact for pre-assessment and actual date of pre-assessment are documented and recorded on the BSP+ IT system for audit purposes.

Evaluation process	The internal and external audit processes ensure that the criteria are complied with, and identified issues are addressed through a CQI process.
Evaluation targets	95% of participants receive initial contact for colonoscopy pre-assessment within 15 working days of a positive FIT result being recorded on the BSP+ IT system. All other criteria are met.

Provision of pre-assessment for colonoscopy	
Standard 6.2: Participants with a positive faecal immunochemical test (FIT) for haemoglobin result are offered pre-assessment for colonoscopy by an experienced endoscopy nurse. They are given appropriate information and an explanation of why, how and when colonoscopy or other investigations could be undertaken.	
Definition	Specific assessment criteria must be met before a participant attends a colonoscopy (or alternative investigation). The endoscopy nurse is the most experienced and competent health professional to undertake this process.
Rationale	There is evidence that providing information about tests, preparation and investigations reduces anxiety and encourages participation.
Quality indicator	Participants who undergo pre-assessment for colonoscopy are fully informed about the colonoscopy procedure or any other diagnostic investigations.
Essential criteria	The DHB NBSP endoscopy units must ensure: 6.2.a. participants with a positive FIT result are offered a colonoscopy and given a full explanation of the process of colonoscopy and the possible risks and outcomes (Note: The opportunity to discuss any concerns is provided at this stage.) 6.2.b. pre-assessment is carried out by an experienced endoscopy nurse with appropriate training, skills and knowledge using documented local protocols 6.2.c. the endoscopy nurse is a registered nurse with a current practicing certificate and the required competencies 6.2.d. pre-assessment identifies participants who need anticoagulant management (Note: The endoscopy nurse will discuss with the lead endoscopist and advise the participant of the required management.) 6.2.e. pre-assessment or pre-admission procedures include completion of the questionnaire relating to the participant's family history in relationship to bowel cancer (refer to Standard 7.2.l) 6.2.f. clear and appropriate pathways are followed and appropriate action is taken for participants with a positive FIT result who do not proceed for colonoscopy 6.2.g. all participants deemed fit and who consent to colonoscopy are offered a date for the procedure at the time of the pre-assessment 6.2.h. written information on colonoscopy, bowel preparation, managing anticoagulant medication (if appropriate) and confirmation of the positive FIT result is sent or given to participants who have been deemed fit and have accepted the offer of colonoscopy

Essential criteria (continued)	6.2.i.	bowel preparation medication is given to participants (free of charge) with documented procedures, including provision of a free telephone helpline for further information
	6.2.j.	information on colonoscopy or other appropriate tests is available in other formats if required, including access to an interpretation service
	6.2.k.	participants are informed of their right to support and advocacy, and staff help any participant who requires assistance to obtain support and/or advocacy.
Evaluation process	Reports that identify the number of participants who have undergone colonoscopy pre-assessment will be generated by the NSU and reviewed by the quality-appropriate policies and internal and external monitoring processes to ensure that the criteria are complied with, and identified issues are addressed through a CQI process.	
Evaluation targets	100% of participants proceeding to colonoscopy in the NBSP are documented to have received a pre-assessment interview. 100% of participants deemed fit and who consent to colonoscopy are offered a date for the procedure at the time of the pre-assessment. 100% of participants with a positive FIT result who do not proceed for colonoscopy have documentation that appropriate pathways were followed. All other criteria are met.	

7 Colonoscopy

Waiting time for colonoscopy Standard 7.1: The interval between notification of a positive faecal immunochemical test (FIT) and colonoscopy is minimised.	
Definition	There is an interval between a positive FIT result being received in the BSP+ IT system and the first offered colonoscopy appointment for that participant.
Rationale	There is evidence that waiting for colonoscopy generates increased anxiety.
Quality indicator	The time between notification of a positive FIT and colonoscopy is minimised and meets the NBSP evaluation target.
Essential criteria	The NBSP DHB endoscopy unit must ensure: 7.1.a. the first available colonoscopy appointment will be offered to the participant 7.1.b. the first offered colonoscopy appointment is within 45 days of the positive result being received by the BSP+ IT system 7.1.c. a record of the first available appointment and the actual attended appointment for colonoscopy is captured on the BSP+ IT system 7.1.d. consent for colonoscopy is captured using the documented service provider consent form.
Evaluation process	Information is collected through the BSP+ IT system for monitoring and evaluation purposes. The internal monitoring and external audit ensures that the criteria are complied with, and identified issues are addressed through a CQI process.
Evaluation targets	95% of participants have a first offered colonoscopy date within 45 working days from the date of the positive screening result being received in the BSP+ IT system. All other criteria are met.

Approval of colonoscopists working in bowel screening Standard 7.2: Screening colonoscopy is only undertaken by screening colonoscopists who meet the NBSP performance standards.	
Definition	Colonoscopists must meet performance standards to work in the NBSP. The DHB NBSP clinical endoscopy lead will monitor individual colonoscopists' performance statistics.
Rationale	Colonoscopy can cause discomfort and clinical complications. Failure to complete colonoscopy or incomplete visualisation of the colonic mucosal surface may result in significant neoplasia being missed.
Quality indicator	All screening colonoscopists are approved to work in the NBSP endoscopy units and meet colonoscopy QA standards. Screening colonoscopists are appropriately qualified, registered with an APC, have received relevant training and can demonstrate competency.
Essential criteria	The NBSP endoscopy unit must ensure: 7.2.a. screening colonoscopists perform more than 250 procedures every five years 7.2.b. a standard four-hour screening endoscopy list comprises no more than five colonoscopy procedures (Note: If mixed screening and symptomatic endoscopy lists are operating, then proportional time allocation should be made.) 7.2.c. they participate in quality reviews and any issues of concern raised are addressed as soon as possible 7.2.d. all adverse events before and during colonoscopy are recorded in the patient's colonoscopy report. Significant adverse events are notified to the NSU immediately and reported according to the NSU incident reporting protocols 7.2.e. they have a robust and auditable system to record and review at a minimum of monthly intervals: • all hospital readmissions[2] within 30 days following performance of colonoscopy within the NBSP • the severity categorisation, root cause analysis and information to be recorded as per the United Kingdom National Health Service (NHS) *Quality Assurance Guidelines for Colonoscopy*[3] • with records available for external audit and the NSU as de-identified data

[2] As per the Ministry of Health standard definition for the OS 8 performance measure.

[3] Chilton A, Rutter M (eds). 2011. *Quality Assurance Guidelines for Colonoscopy*. Sheffield: NHS Cancer Screening Programmes. URL: https://www.gov.uk/government/publications/bowel-cancer-screening-colonoscopy-quality-assurance (accessed 9 June 2017).

Essential criteria (continued)	7.2.f.	they have identified a DHB NBSP endoscopy lead who is responsible for local quality coordination for the endoscopy unit for the NBSP
	7.2.g.	their endoscopy lead records the following data regarding • complications and safety: Perforation rate <1:1000 colonoscopies • post-polypectomy perforation rate <1:500 colonoscopies where polypectomy is performed • post-polypectomy bleeding <1:100 colonoscopies where polypectomy is performed (this includes EMR, endoscopic submucosal dissection and all other polypectomies at colonoscopy) • rate of intermediate or serious colonoscopic complications relating to perforation or bleeding requiring hospital admission within 30 days of performance of colonoscopy within the NBSP <10:1000 colonoscopies (Note: This number is based on the fact that 70% of participants proceeding to colonoscopy in the WDHB pilot have a lesion detected.)
	7.2.h.	their NBSP endoscopy lead ensures that the following data is recorded and the indicated minimum standards attained: • the caecal intubation rate for each proceduralist is 95% or greater for screening patients • the mean colonoscope withdrawal time from the caecum is six minutes or greater for procedures where no polypectomy is performed • the polyp detection rate for each proceduralist is in line with the average polyp detection rate being documented in participants proceeding to colonoscopy within the NBSP • the adenoma detection rate for each proceduralist is ≥35% of screening colonoscopies • the rate of polyp recovery for pathological examination for each proceduralist is more than 95% for polyps >5 mm.
	7.2.i.	screening colonoscopists working in NBSP: • describe each polyp separately in the colonoscopy report (Note: Where polyps are numerous the 'multiple polyps same method' may be used. In text, the number of polyps referred to as greater than (>) the maximum estimated number of polyps.) • send all polyps in separate pathology pots to the lab as an absolute number of polyps is required • ensure information on the histology request form includes for each polyp the pathology pot number and the location, size and shape of the polyp • tattoo the polypectomy site for polyps ≥ 10 millimetres in size • tattoo all cancers or lesions suspicious for cancer distal to the lesion in two positions on opposite sides of the bowel • document all adverse events before, during or immediately after colonoscopy in the colonoscopy report.

Essential criteria (continued)	7.2.j.	for every procedure, the colonoscopist adequately documents the information required in accordance with the Standards in a standardised format
	7.2.k.	the colonoscopist ensures that there is full documentation and reporting of information about patient risk and co-morbidity
	7.2.l.	colonoscopy reports document a participant's family history of bowel cancer (including if not known) based on the participant's completed family history questionnaire (Note: The questionnaire is designed to facilitate on-referral (with participant consent) by the colonoscopist, to the New Zealand Familial Gastrointestinal (GI) Cancer Service, if appropriate and identify those at moderate risk on the basis of a family history of the disease who should be offered colonoscopy surveillance.)
	7.2.m.	the colonoscopist gains written informed consent using a structured pro forma approach from all participants (or the participant's legal guardian where applicable) for all procedures before any procedure is undertaken
	7.2.n.	before leaving the endoscopy unit, participants are given a verbal explanation of the results of their procedure by the proceduralist or senior endoscopy nurse and written information to support the verbal explanation that includes: • colonoscopy findings • when to resume eating • when to resume driving • when to resume or take relevant medications (including anticoagulants) • symptoms to be aware of and which symptoms require prompt presentation to hospital, eg, bleeding, abdominal pain • contact numbers for any other concerns
	7.2.o.	the clinical director/endoscopy lead or designated specialist reviews all pathology reports resulting from the procedure and arranges participant follow-up or referral in line with documented clinical guidelines (Note: If an alternate health professional is designated to review pathology results, the protocol supporting this requires prior approval by the NSU.)
	7.2.p.	participants requiring surveillance are referred in line with the *Guidance on Surveillance for People at Increased Colorectal Cancer*[4]
	7.2.q.	uptake of colonoscopy following a positive FIT is maximised for each population group
	7.2.r.	they have a 'did not attend' (DNA) protocol in place to follow-up participants who do not attend their scheduled colonoscopy
	7.2.s.	all screening colonoscopy results are reported in the BSP+ IT system

4 New Zealand Guidelines Group. 2011. *Surveillance for People at Risk of Colorectal Cancer*. Wellington: Ministry of Health. URL: www.health.govt.nz/publication/guidance-surveillance-people-increased-risk-colorectal-cancer (accessed 9 June 2017).

Essential criteria (continued)	7.2.t.	all screening colonoscopy results (excluding histopathology) are notified within five working days after the procedure to the participant's nominated GP and the NBSP register
	7.2.u.	all participants are notified with the results of all colonoscopy investigations (including histopathology) within 20 working days of the final procedure
	7.2.v.	they have a system for collecting data on overall endoscopy unit and individual colonoscopist performance, and the minimum standards for performance of colonoscopy are met
	7.2.w.	The endoscopy lead performs analysis of overall and individual colonoscopy performance data on a three monthly basis (Note: There is a documented process in place for giving performance feedback and using the data for quality improvement/education.)
	7.2.x.	they have a documented and agreed management strategy for colonoscopists who do not meet the colonoscopy QA standards
	7.2.y.	overall unit and de-identified individual colonoscopist performance data is available for external audit and provided to the NSU on a three monthly basis
	7.2.z.	individual colonoscopists submit colonoscopy audit data as required by the NBSP before performing any colonoscopy within the NBSP: a. Screening colonoscopists working in NBSP are approved to work in the programme by the DHB NBSP endoscopy lead b. Screening colonoscopists participate in local and regional multidisciplinary education sessions and management meetings.
Evaluation process	The internal and external monitoring process ensures that the criteria are complied with, and identified issues are addressed through a CQI process. There is a system for reviewing all adverse events relating to the performance of colonoscopy. There is a system for reviewing individual colonoscopy procedural data at a local, ie, DHB, level. The external audit process ensures individual colonoscopist meet the criteria.	

Evaluation targets	100% of adverse events and all hospital readmissions within 30 days of performance of colonoscopy within the NBSP are documented, appropriately reviewed and de-identified records are made available for external and NSU audit. The rate of intermediate or serious colonoscopic complications relating to perforation or bleeding requiring hospital admission within 30 days of performance of colonoscopy within the NBSP is <10:1,000 colonoscopies. 100% of the minimum standards for performance of colonoscopy are met. 100% of colonoscopy procedure requirements are met. 95% of colonoscopy reports document a participant's family history of bowel cancer (including if not known) based on the participant's completed family history questionnaire. 100% of participants' records have written consent. > 90% uptake for colonoscopy following a positive FIT for each population group. 100% of screening colonoscopy results are reported in the BSP+ IT system. 100% of screening colonoscopy results (excluding histopathology) are notified to the participant's nominated GP and the NBSP register within five working days after the procedure. 100% of participants are notified with the results of all colonoscopy investigations (including histopathology) within 20 working days of the final procedure. 100% of overall unit and de-identified individual colonoscopist performance data is available for external and NSU audit on a three monthly basis. 100% of colonoscopists working in NBSP receive performance feedback from the DHB NBSP endoscopy lead. 100% of colonoscopists working in NBSP are approved to work in the programme by the DHB NBSP endoscopy lead. All other criteria are met.

Quality of bowel preparation Standard 7.3: Bowel preparation is undertaken to a high standard.	
Definition	Bowel preparation is the diet and bowel cleansing procedure carried out by the participant before colonoscopy or computerised tomographic colonoscopy (CTC). This procedure is explained by the endoscopy nurse who will assess individual participants for their suitability to undertake the procedure.
Rationale	Bowel preparation that maximises pathology detection, minimises the need for additional procedures. Effective bowel preparation is key to detailed examination of the bowel. There is much published data to support a variety of regimens with variable tolerability. Good bowel preparation supports improved polyp detection and caecal intubation. Poor bowel preparation is associated with failure to reach the caecum and hinders the detection of lesions.
Quality indicator	The colonoscopist ensures that the participant achieves a high-quality bowel preparation appropriate for their risk factors and preferences. The quality of bowel preparation is documented in the participant's colonoscopy report at the time of the colonoscopy procedure.
Essential criteria	The DHB NBSP endoscopy unit will ensure: 7.3.a. all participants receive bowel preparation education 7.3.b. the type and quality of bowel preparation is documented in all participants' colonoscopy reports 7.3.c. reasons for poor preparation are documented in the participant's colonoscopy report.
Evaluation process	The NBSP DHB endoscopy unit will monitor the quality (effectiveness) of reported bowel preparation at the time of colonoscopy whilst also considering participant acceptability and tolerability.
Evaluation targets	<5% of participants require a repeat colonoscopy examination as a result of poor bowel preparation. All other criteria are met.

Provision of a high-quality endoscopy service Standard 7.4: Colonoscopy is performed in an endoscopy unit that meets the NBSP standards for endoscopy (colonoscopy) facilities.	
Definition	The NBSP endoscopy unit provides a safe, effective and efficient colonoscopy service and meets the interim endoscopy facility standards (colonoscopy).
Rationale	Participants must receive an equitable, high-quality endoscopy service.
Quality indicator	All endoscopy units that perform colonoscopy for NBSP must meet the criteria determined by the requirements in the interim endoscopy facility standards (colonoscopy).
Essential criteria	The NBSP DHB endoscopy units must ensure: 7.4.a. the endoscopy suite meets the interim endoscopy facility standards (colonoscopy) before providing colonoscopy for the NBSP 7.4.b. all endoscopy suites comply with the requirements in the NBSP quality documentation, which includes NBSP interim quality standards and the interim endoscopy facility standards (colonoscopy) 7.4.c. all endoscopy suites submit data requested by the NBSP 7.4.d. all endoscopy suites providing NBSP colonoscopies participate in internal audit and external assessment 7.4.e. all endoscopy suites participate in clinical assessment visits by peer review assessors as part of the external assessment process (Note: Issues raised must be addressed as soon as possible and within timeframes relative to the risk.) 7.4.f. all endoscopy suites facilitate visits from the NBSP when necessary and as requested as part of the external assessment process.
Evaluation process	The internal audit and external assessment processes ensure that the criteria are complied with, and identified issues are addressed through a CQI process.
Evaluation targets	No quantitative target. All criteria are met.

Provision of an alternative diagnostic investigation	
Standard 7.5: If a participant is deemed not fit for colonoscopy by a clinician or had an incomplete colonoscopy, yet might be suitable for radiological investigation, further investigation is carried out to ensure the entire large bowel has been examined.	
Definition	The alternative diagnostic investigation will be by computerised tomographic colonoscopy (CTC).
Rationale	Failure to visualise the large bowel as a result of a positive FIT may result in significant neoplasia being missed.
Quality indicator	All participants who are deemed not fit for colonoscopy by a clinician (the endoscopy nurse or consultant) or have had an incomplete colonoscopy are offered an alternative investigation.
Essential criteria	The NBSP DHB endoscopy unit and the DHB radiology department must ensure: 7.5.a. there is a documented and agreed process for managing all participants deemed unfit for colonoscopy or who have an incomplete colonoscopy 7.5.b. CTC is offered if participants are deemed fit and consent to alternative investigations 7.5.c. participants deemed not fit for colonoscopy are offered the first available appointment for a CTC within 45 working days of a positive result registered on the BSP+ IT system as for colonoscopy 7.5.d. participants with an incomplete colonoscopy and requiring a CTC have the procedure within 10 working days from when they have an incomplete colonoscopy[5] 7.5.e. radiological investigations are reported by a radiologist who is appropriately qualified, registered with an APC, has received relevant training and can demonstrate competency 7.5.f. all providers of CTC comply with *RANZCR Requirements for the Practice of Computed Tomography Colonography (CTC)*,[6] including: • training requirement: 60 cases (50 with endoscopic correlation and 10 'live' cases). See 2.3.1 CTC Training (page 4) • ongoing competency: minimum 30 live cases per year with log book. See 2.3.4 Ongoing Competency (page 5) 7.5.g. radiological results are sent to the participant's nominated GP and the endoscopy unit within seven working days of the CTC procedure 7.5.h. participants are notified of the results of all investigations within 10 working days of the final procedure.

5 Except if they have had a polypectomy as part of the failed colonoscopy and would therefore need to delay the CTC for more than 30 days.

6 RANZCR. 2013. *RANZCR Requirements for the Practice of Computed Tomography, Version 3.1*. Sydney: The Royal Australian and New Zealand College of Radiologists. URL: https://www.ranzcr.com/search/ranzcr-requirements-for-the-practice-of-computed-tomography-colonography-ctc (accessed 9 June 2017).

Evaluation process	The internal audit and external assessment processes ensure that the criteria are complied with, and identified issues are addressed through a CQI process.
Evaluation targets	95% of participants deemed unfit for colonoscopy are offered the first available appointment for a CTC within 45 working days of a positive test result on the BSP+ IT system as for colonoscopy. 95% of participants requiring a CTC after an incomplete colonoscopy have the procedure within 10 working days. For participants who underwent polypectomy, a CTC is to be undertaken after 30 working days but within 50 working days. 100% of participants are notified of the results of all final CTC investigations within 10 working days. 100% of providers of CTC comply with the *RANZCR Requirements for the Practice of Computed Tomography Colonography*. All other criteria are met.

8 Histopathology

Histopathology quality assurance Standard 8.1: Laboratories providing histopathology must be accredited by International Accreditation New Zealand (IANZ) and have appropriate internal and external QA processes in place.	
Definition	All histopathology laboratories participating in the NBSP must hold and retain International Accreditation New Zealand (IANZ) accreditation for providing histology services and adjunct molecular testing. In addition, histopathology laboratories participating in the NBSP must have internal QA policies and practices in place to ensure the quality of histology reporting and participate in an external QA programme to a satisfactory standard.
Rationale	There is evidence that laboratories accredited and working towards agreed standards achieve the required high level of test accuracy. Internal QC systems identify potential sources of and minimise error and allow continued improvements to operational processes. External QAs programmes promote uniformly high standards of diagnostic reporting.
Quality indicators	All NBSP histopathology laboratories must be IANZ accredited. All NBSP histopathology laboratories are enrolled in an external QA programme and demonstrate satisfactory performance. All NBSP histopathology laboratories have appropriate internal QA processes in place.
Essential criteria	The NBSP laboratories must ensure: 8.1.a. every laboratory is supervised by a designated NBSP lead pathologist who provides professional leadership and is responsible for ensuring that the laboratory delivers a quality service in accordance with the NBSP policies and standards (Note: The lead pathologist's duties and responsibilities include, but are not limited to: • reporting bowel screening histopathology • managing an effective internal QA programme for all pathologists within their laboratory • implementing, monitoring and auditing relevant NBSP standards • liaising with clinical colleagues, the NBSP, the NBSP register and regional services • monitoring health and safety within the laboratory • facilitating processes that allow NBSP pathologists to receive adequate training and regular updates.) 8.1.b. all laboratories reporting bowel screening programme pathology have at least three pathologists endorsed to report bowel screening programme pathology, with a nominated deputy for lead roles to ensure a pathologist is available in the laboratory every working day

Essential criteria (continued)	8.1.c.	NBSP screening cases are only undertaken by suitably trained, experienced and registered medical and non-medical staff (ie, medical laboratory scientists and medical laboratory technicians) who achieve and maintain competency in their tasks
	8.1.d	control processes are in place that ensure the reporting requirements of the Cancer Registry Act 1993 are met and all results with an invasive diagnosis are forwarded to the New Zealand Cancer Registry (NZCR)
	8.1.e	satisfactory internal systems for QC and quality improvement are in place
	8.1.f	all participating laboratories are enrolled in the Royal College of Pathologists of Australasia (RCPA) anatomic pathology external QA programme, including the gastrointestinal specialist module, the technical module and the immunohistochemistry technical module (Note: It is preferable for pathologists to be enrolled individually rather than on a laboratory basis. Participation will be ensured by the lead pathologist and individual documentation of participation will be available for audit.)
	8.1.g.	the lead pathologist audits the pathology quality indicators against the screening programme benchmarks.
Evaluation process	The internal and external audit processes ensure that the criteria are complied with and identified issues are addressed through the CQI process. Evidence of current accreditation certification will be required. Laboratories must inform the NSBP of the results of IANZ assessment (both annual and periodic full peer assessment) and any change to the accreditation status. External QA reports, outcome measures and action sheets must be retained and be available for audit.	
Evaluation targets	No quantitative target. All criteria are met.	

Histopathology reporting requirements Standard 8.2: Histopathology must be reported in a timely manner using recognised professional standards.	
Definition	The laboratory meets the turnaround times and reporting requirements of the NBSP.
Rationale	Subsequent management of participants with screen-detected neoplasia must be based on accurate and timely histopathology results. Structured reports ensure all the relevant information is included and allow quicker data retrieval. Timely reporting of results allows participants to progress through the screening pathway in an efficient manner and expedites appropriate therapy as needed.
Quality indicator	Accurate pathological assessment of NBSP biopsies and excised tissue will be provided within the required turnaround times as stated below, using a structured report.
Essential criteria	The NBSP laboratories must ensure: 8.2.a. all histology slides are examined and reported by a qualified, experienced and registered histopathologist (Note: Pathologists in training may undertake gross and microscopic descriptions of screen-detected lesions before review and sign out by a histopathologist, but this must be done in a timely manner. All screening reports must be validated by a named NBSP pathologist.) 8.2.b. histology of both benign and malignant polyps are reported using a structured reporting format based on the most recent RCPA protocol 8.2.c. the size of lesions is generally accepted as that measured by the endoscopist and provided on the request form (Note: If there is a major discrepancy between the provided size and the size of the lesion microscopically, the largest dimension is measured by the reporting pathologist to the nearest millimetre on the haematoxylin and eosin stain (H&E) slide.) 8.2.d. a modification of the Vienna Classification (VCL) is generally used for diagnosis (Note: The term dysplasia will be used in place of neoplasia and two grades of colorectal dysplasia (low and high grade) will be used. The terms intramucosal or in-situ carcinoma should not be used.) 8.2.e. the latest version of the Union for International Cancer Control (UICC) TNM Classification of Malignant Tumours is used and the edition clearly stated in the report 8.2.f. the World Health Organization (WHO) classification of colorectal adenomata into tubular, tubulo-villous and villous is used 8.2.g. all pT1 cancers are reported using the RCPA Polypectomy and Local Resections of the Colorectum Structured Reporting Protocol

Essential criteria (continued)	8.2.h	all adenocarcinomas in patients who meet the modified Bethesda criteria are tested for mismatch repair status as recommended in the RCPA Colorectal Cancer Structured Reporting Protocol
	8.2.i.	all adenocarcinomas (and particularly pT1 cancers) and polyps showing high-grade dysplasia are double-reported or independently second read by another pathologist who reports histopathology for the NBSP, and the name and opinion of the second pathologist is documented in the report
	8.2.j.	no more than 10% of adenomata (including sessile serrated adenomata/ polyps) are reported as high-grade dysplasia by a pathologist
	8.2.k.	a documented mechanism for managing discrepancies is available, and, where there is uncertainty over a histologic diagnosis, opinions may be obtained from: • a second local pathologist • a regional specialist gastrointestinal pathologist or reference panel • a recognised overseas pathologist
	8.2.l.	turnaround times are accordant with the RCPA and RCPA New Zealand Regional Committee guideline and policy (for more detail, see Evaluation Targets below)
	8.2.m.	the referring specialist is informed if it takes more than 15 working days for a histology result to be reported (and noted as a laboratory record) (Note: It is understood and accepted that occasional cases need additional time to allow discussion and referral before issuing a result.)
	8.2.n.	results are collected and submitted to the designated lead endoscopist and the NBSP register, for input into the appropriate IT system, in the agreed codes and electronic format
	8.2.o.	the report and slides of the specimen are made available to the treatment service for review at the pre-operative multidisciplinary team meeting in a timely manner so as to avoid a delay in surgery
	8.2.p.	histopathologists have access to the full screening history of the participant at the time of reporting bowel screening pathology samples.
Evaluation process	The internal and external audit processes ensure that the criteria are complied with, and identified issues are addressed through a CQI process.	

Evaluation targets	100% of histology slides are examined and reported by a histopathologist. 100% of screening results are validated by a named NBSP pathologist. 100% of adenocarcinomas and polyps showing high-grade dysplasia are double reported. ≤10% of adenomata (including sessile serrated adenomata/polyps) are reported as high-grade dysplasia by a pathologist. The RCPA and the RCPA New Zealand Regional Committee quantitative criteria for turnaround times are met, that is: • ≥ 80% of specimens submitted from colonoscopy and/or surgery are reported, electronically authorised and relayed to the referring screening endoscopist/surgeon within five working days of receipt of the specimen in the laboratory. • ≥ 90% of specimens submitted from colonoscopy and/or surgery are reported, electronically authorised and relayed to the referring screening endoscopist/surgeon within 10 working days of receipt of the specimen in the laboratory. • ≥ 98% of specimens submitted from colonoscopy and/or surgery are reported, electronically authorised and relayed to the referring screening endoscopist/surgeon within 15 working days of receipt of the specimen in the laboratory. All other criteria are met.

Laboratory staffing and accreditation requirements Standard 8.3: All laboratories are staffed by suitably qualified, experienced and registered pathologists, scientists and technicians and led by a suitably qualified pathologist.	
Definition	All pathologists, pathologist assistants, medical laboratory scientists and medical laboratory technicians preparing and reporting histology specimens must have appropriate qualifications.
Rationale	The NBSP requires that all pathology specimens are prepared and reported by suitably trained staff.
Quality indicators	Pathologists working in the NBSP must be medically qualified, hold recognised postgraduate qualifications in pathology and be registered to practice in New Zealand. All pathologist assistants, medical laboratory scientists and medical laboratory technicians preparing histology specimens must be qualified and registered to practice in New Zealand.
Essential criteria	The NBSP laboratories must ensure: 8.3.a. all pathologists reporting histopathology for the NBSP are fellows of the RCPA or hold an equivalent recognised postgraduate qualification in pathology 8.3.b. all pathologists reporting histopathology for the NBSP are enrolled on the Medical Council of New Zealand's vocational register in pathology and hold a current APC, and if they are not vocationally registered, they must work under supervision, as required by the Medical Council of New Zealand 8.3.c. all pathologists reporting histopathology for the NBSP have subspecialty training in general or anatomical pathology 8.3.d. all participating pathologists are enrolled in the RCPA Continuing Professional Development Program (CPDP) and complete the appropriate requirements for participating in the programme, and the laboratory keeps a record of the CPDP requirements that have been met 8.3.e. all pathologist assistants, medical laboratory technicians and medical laboratory scientists are registered health practitioners and hold a current APC issued by the Medical Sciences Council of New Zealand (MSCNZ) with a scope of practice indicating subspecialty training in histology or equivalent 8.3.f. each laboratory that reports histology for the NBSP has at least one senior medical laboratory scientists who has a minimum of five years full-time (or equivalent) histology experience.
Evaluation process	The internal and external audit processes ensure that the criteria are complied with, and identified issues are addressed through a CQI process.
Evaluation targets	No quantitative target. All criteria are met.

Ongoing training and competency of histopathology laboratory staff Standard 8.4: Laboratory staff must remain up to date in their field and be appropriately trained and monitored.	
Definition	The laboratory must have documented professional development plans and ongoing training for all staff.
Rationale	Subsequent management of individuals with screen detected neoplasia must be based on accurate histopathology. All laboratory staff require continuing education so that they can maintain and continuously improve their skills.
Quality indicator	All laboratory staff working within the NBSP must meet professional requirements to work in bowel screening. All education and competency activities are recorded and must be relevant to achieving the continuing medical education (CME) and continuing professional development (CPD) requirements of the appropriate health professional bodies. The laboratory must keep a record of the CPD requirements that have been met.
Essential criteria	The NBSP histopathology laboratory must ensure: 8.4.a. all staff involved in processing and reporting bowel screening histology undertake training under supervision 8.4.b. all staff involved in the NBSP reporting participate in regular updates, with documented evidence of attendance by pathologists at internal and/or external teaching programmes in bowel screening pathology comprising at least six educational hours over the preceding three years 8.4.c. all staff have access to the NBSP standards and protocols for laboratories, and all standard operating procedures for pre-analytical and analytical are available and adhered to 8.4.d. all staff have access to current editions of major standard texts, colour atlases and current issues of journals relevant to gastrointestinal pathology 8.4.e. all education and competency activities are recorded and available for any audit body to inspect 8.4.f. all pathologists reporting histopathology for the NBSP have sufficient exposure to relevant material to develop and maintain competence in their reporting of all cases (Note: The lead pathologist should endeavour to make material from larger centres available to pathologists working with smaller volumes as a teaching/learning resource, where required. A regular audit and review among relevant professionals should be undertaken to discuss interesting and difficult cases.) 8.4.g. staff have a balanced workload that allows them to screen a sufficient number of cases to maintain their competence without leading to errors from overwork.
Evaluation process	The internal and external audit process ensures that the criteria are complied with, and identified issues are addressed through a CQI process.
Evaluation targets	No quantitative target. All criteria are met.

Handling of histopathology samples, from collection to reporting and storage	
Standard 8.5: All NBSP tissue specimens retrieved at colonoscopy must be adequately labelled, prepared and examined correctly.	
Definition	Histopathology specimens must be handled in a standardised and appropriate manner.
Rationale	Processes for consistent handling and dissecting pathologic specimens are critical to achieving high diagnostic accuracy. Specimen handling begins at endoscopic removal and ends with the issuing of the final electronic report. A close relationship between endoscopy and the histology laboratory is necessary.
Quality indicator	A written protocol for the labelling of pathology specimens exists. There is a written protocol for handling and potential return of specimens.
Essential criteria	The NBSP histopathology laboratories must ensure: 8.5.a. all steps of sample registration and processing conform to ISO 15189: Specific Criteria for Accreditation: Medical Testing[7] (Note: All samples are clearly identified and permanently marked to ensure accurate matching with the referral form. Both the sample and the referral form include a minimum of two full unique identifiers (ie, name and date of birth or name and National Health Index Number, NHI.) 8.5.b. the clinician performing the biopsy is ultimately responsible for checking correct labelling of specimens before receipt in the laboratory 8.5.c. all NBSP specimens are clearly identified and easily accessible on local pathology IT systems to facilitate activity monitoring, audit and QA 8.5.d. they have a written protocol that details the action to be taken if they receive a mislabelled or unlabelled specimen or incomplete request form 8.5.e. where multiple lesions are biopsied or endoscopically removed, each lesion is clearly differentiated and submitted in a separate container that is consistently labelled and tracked (Note: Biopsies from the same lesion can be submitted in the same container.) 8.5.f. all specimens are submitted with the following clinical and endoscopic information: • size and site of the polyp, morphology (sessile, pedunculated or semi-sessile) • an indication as to whether the lesion was removed (polypectomy) or only sampled (biopsy) 8.5.g. all specimens are fixed in 10% neutral buffered formalin (4% paraformaldehyde concentration as formalin is 30–40% paraformaldehyde) or an appropriate alternative fixative

7 IANZ. 2014. *Specific Criteria for Accreditation: Medical Testing. AS LAB C 7. Second edition*. Auckland: International Accreditation New Zealand. URL: www.ianz.govt.nz/services/accreditation-2/accreditation/laboratories/medical/ (accessed 9 June 2017).

Essential criteria (continued)

8.5.h. polypectomy specimens and biopsies are prepared as follows:

- optimal orientation and the resection margin identification (inked)
- the number and diameter of each tissue fragment is recorded
- the tissue is oriented as appropriate and the resection margin identified, described (broad, dot-like, stalked) and inked
- larger polyps are sliced into 2–3 millimetre slices and embedded with the re-section margin in the appropriate plane, while smaller polyps can be embedded whole
- all tissue is processed and sectioned
- an initial three levels, stained with haematoxylin and eosin (H&E) are examined; at least three further additional levels are performed if the clinical information suggests this or the initial three levels show no abnormality
- additional investigations may be required for difficult lesions

8.5.i. specimens removed by endoscopic submucosal dissection (ESD) are reported as per the RCPA *Polypectomy and Local Resections of the Colorectum Structured Reporting Protocol*[8]

8.5.j. there is an established documented process for returning recognisable body parts/tissues to the participant

8.5.k. they have documented procedures for retaining, indexing, accessing, storing, maintaining and safely disposing of clinical samples (Note: Timeframes for retention are as follows):

Type of record	**Minimum retention period**
Laboratory test results and test reports	A record of the laboratory test results and test reports should be retained for a minimum of 20 years from the date of sample.
Records of histology slides and histology blocks	Histology slides and tissue embedded in paraffin wax or any other permanent embedding medium should be retained for a minimum of 20 years from the date of the final test report.
Records of laboratory referrer test request forms	A copy of each request form or a complete electronic image of each request form should be retained for a minimum of 15 years from the date of the sample.
Specimen pots	The vial or pot should be retained in the laboratory for a minimum of one month following the date of the final test report.

[8] RCPA. 2013. *Polypectomy and Local Resections of the Colorectum Structured Reporting Protocol. 1st edition 2013*. New South Wales: The Royal College of Pathologists of Australasia. URL: https://www.clinicalguidelines.gov.au/portal/2395/polypectomy-and-local-resections-colorectum-structured-reporting-protocol-1st-edition (accessed 9 June 2017).

Essential criteria (continued)		They are aware of and comply with any longer retention period required under law or by any other appropriate body. If they cease to provide histology services, then all specimens and records are to be forwarded to the new service provider.
	8.5.l.	they have written protocols for handling and disposing of human tissue that include cultural considerations.
Evaluation process	The internal audit process ensures that the criteria are complied with, and identified issues are addressed through a CQI process.	
Evaluation targets	100% of requests regarding culturally appropriate methods of handling and disposing of human tissue are treated sensitively and in accordance with local protocols. All other criteria are met.	

Communicating results Standard 8.6: Histology samples are to be reported to the correct recipients in a timely manner.	
Definition	All histology results need to be reported to the NBSP register and discussed at the regional multidisciplinary meeting when appropriate (see also Standard 9.1).
Rationale	Good communication between pathologists, the screening centre personnel and colorectal cancer multidisciplinary teams is essential for participant management.
Quality indicators	Laboratories must have processes in place for ensuring that all histology results are forwarded in the correct format to the NBSP Register. All adenocarcinomas and results showing features suspicious for invasive malignancy must be discussed at a multidisciplinary meeting.
Essential criteria	The NBSP histopathology laboratories must ensure: 8.6.a. histology results are forwarded to the NBSP register in an approved format, within 15 working days of receipt of a specimen 8.6.b. all malignancies and cases suspicious for invasive malignancy are discussed at the regional colorectal cancer multidisciplinary meeting (Note: All pT1 adenocarcinomas will be discussed to determine if surgical resection is recommended and to plan future management.) 8.6.c. reports of unexpected cancers diagnosed by histopathology without prior indication are conveyed to the lead endoscopist and lead nurse or their designated deputies within 24 hours of confirmation of the histology so that appropriate participant counselling and investigations can be instituted 8.6.d. a pathologist who reports bowel screening histology is present at each multidisciplinary meeting to present and comment on relevant pathology 8.6.e. laboratories have a procedure for managing cases where there is a change in diagnosis.
Evaluation process	The internal audit process ensures that the criteria are complied with, and identified issues are addressed through a CQI process.
Evaluation targets	90% of histology results are forwarded to the NBSP register in an approved format within 15 working days of receipt of a specimen. All other criteria are met.

Criterion	Measurement	Standard
Turnaround time	Histopathology specimens are reported, authorised and relayed electronically to the referrer in a timely manner.	Minimum: • ≥80% within five working days of receipt in the laboratory • ≥90% within 10 working days of receipt in the laboratory • ≥98% within 15 working days of receipt in the laboratory
External QA	Pathologists reporting histopathology specimens must participate in the RCPA external QA programme and gastrointestinal diagnostic module.	100%
Accreditation	All histopathology laboratories reporting histology for the NBSP must be IANZ accredited and retain accreditation.	100%
Validation of results	All screening reports must be authorised by a named NBSP pathologist.	100%
Double reporting	There is double reporting of all adenocarcinomas and high-grade dysplasia.	100%
Difficult to interpret polyps	There must be a documented pathway for discussing polyps or lesions that are difficult to interpret.	100%
High-grade dysplasia	Pathologists should not report high-grade dysplasia in more than 10% of adenomata (including sessile serrated adenomata/polyps).	≤10% of adenomata
Qualifications for pathologists	All pathologists reporting bowel screening histology must be qualified.	100%
Senior scientist requirements for laboratories processing histology for the NBSP	Laboratories conducting NBSP screening must employ at least one senior registered medical laboratory scientist who has a minimum of five years full-time (or equivalent) histology experience and who is a named lead senior medical laboratory scientist.	100%

Criterion	Measurement	Standard
Continuing professional development (CPD) for all staff	All staff must meet the CPD requirements and the laboratory must keep a record of the CPD requirements that have been met.	100%
Examining and reporting histology slides	All histology slides must be examined and reported by a histopathologist.	100%
Cultural sensitivity and appropriateness	All requests regarding culturally appropriate methods of handling and disposal of human tissue will be treated sensitivity and in accordance with local protocols.	100%
Sending results to the NBSP register	90% of histology results must be entered onto the NBSP register in an approved format, within 15 working days of receipt of a specimen.	90% within 15 working days
Sending results to the New Zealand Cancer Registry (NZCR)	The laboratory must forward all results with a diagnosis of invasive cancer to the NZCR.	100%
Leadership	Each laboratory reporting for the NBSP will have a designated lead pathologist and deputy. At least three pathologists reporting NBSP histology will be employed at each laboratory.	100%

9 Referral pathways

Multidisciplinary team meetings Standard 9.1: All NBSP participants diagnosed with cancer will be referred to the appropriate consultant for presentation at a multidisciplinary meeting (MDM) in a timely and appropriate manner.	
Definition	Prompt referral to the NBSP multidisciplinary meeting (MDM) will ensure conformity of care in accordance with documented local guidelines or protocols.
Rationale	A small body of evidence indicates that the formation of an MDM and adherence to treatment standards may increase survival for participants with colon cancer. It also appears that MDM discussions may produce more favourable outcomes, in terms of reducing positive circumferential margin rate and harvesting lymph nodes, than if no MDM discussions take place.[9] MDMs help determine best practice and individual quality care.
Quality indicator	A close, cooperative working relationship between all staff involved in the NBSP ensures an effective multidisciplinary approach to care. All NBSP participants diagnosed with cancer and all cases where there is disagreement between the clinical and pathological assessments will be referred to the appropriate consultant to be presented at an MDM.
Essential criteria	The NBSP DHB endoscopy units must ensure: 9.1.a. where a cancer is suspected at colonoscopy, management is coordinated according to local protocol 9.1.b. where a cancer is diagnosed by histopathology without prior indication, the result is conveyed to the NBSP colonoscopist and endoscopy nurse for referral to MDM 9.1.c. there is a local protocol for conveying the result to NBSP participants and referring them to appropriate clinicians within the MDM 9.1.d. local protocols consider the membership of the MDM, which is outlined in *Guidance for Implementing High-quality Multidisciplinary Meetings: Achieving best practice cancer care*[10] 9.1.e. MDMs are minuted and discussions, amendments to pathology or clinical interpretation and the final management course is documented in the participant's record.
Evaluation process	The internal and external audit process ensures that the criteria are complied with, and identified issues are addressed through a CQI process.

[9] New Zealand Guidelines Group. 2011. *Clinical Practice Guidelines for the Management of Early Colorectal Cancer*. Wellington: New Zealand Guidelines Group.

[10] Ministry of Health. 2012. *Guidance for Implementing High-quality Multidisciplinary Meetings: Achieving best practice cancer care*. Wellington: Ministry of Health.

Evaluation targets	95% of NBSP participants requiring clinical follow-up have been referred and seen by an appropriate consultant within 10 working days of diagnosis. 95% of NBSP participants diagnosed with cancer are referred for presentation at an MDM within 20 working days of diagnosis. 100% of participants with cancer or discrepant results are presented for discussion at an MDM. All other criteria are met.

10 Evaluation and performance management

Quality and clinical governance for the NBSP Standard 10.1: Those involved in providing NBSP services must comply with these Standards through the National Screening Unit (NSU).	
Definition	The NSU will provide quality monitoring and clinical oversight of the NBSP.
Rationale	Quality assurance and control are essential to determine performance of the bowel screening service and enable development and improvement.
Quality indicator	Regular reporting to local quality-focused groups ensures these Standards and monitoring indicators are met.
Essential criteria	The NBSP providers must ensure: 10.1.a. they have an agreed mechanism for providing regular feedback on the NSU's monitoring reports to local quality groups and the NBSP 10.1.b. the NSU reviews monitoring reports and identify any deficiencies and/or inequities in performance. Where deficiencies and/or inequities are identified, the DHB clinical lead will develop a remedial action plan, agreed with the NSU.
Evaluation process	Regular reporting and review.
Evaluation targets	No quantitative target. All criteria are met.

11 Risk and complaint management and incident reporting

Managing and reporting on risks, incidents and complaints Standard 11.1: NBSP providers must have appropriate mechanisms in place for managing and reporting risks, incidents and complaints.	
Definition	Reporting of risks, incidents and complaints that occur within the NBSP must be managed and reported using documented processes.
Rationale	To reduce potential risk to NBSP participants, the NSU requires NBSP service providers to use documented risk, incident and complaints management and reporting processes.
Quality indicator	Reports of incidents and complaints are managed according to the NBSP provider documented protocols and reported to the NSU as soon as they occur.
Essential criteria	The NBSP providers must: 11.1.a. adhere to the NSU incident reporting protocols 11.1.b. report incidents and complaints to the NSU using agreed processes 11.1.c. give feedback to all staff involved in the delivery of the NBSP to help them learn from events 11.1.d. write action plans to address any identified deficiencies and agree on those action plans with the NBSP programme director and quality lead 11.1.e. follow written protocols that align with the Privacy Act 1993 for a participant's request to access clinical records, as part of a complaint investigation 11.1.f. have a process in place to review hospital admissions within 30 days post colonoscopy 11.1.g. have a process in place to review morbidity and mortality complications from 30 days post colonoscopy 11.1.h. have rigorous documented failsafe procedures in place to track every participant at all stages of the screening process.
Evaluation process	The internal and external audit processes ensure that the criteria are complied with, and identified issues are addressed through a CQI process.
Evaluation targets	No quantitative target. All criteria are met.

12 Programme statistics

Provision of data to enable the NBSP to be monitored Standard 12.1: Data is captured for monitoring and independent evaluation of the NBSP as required by the Ministry of Health.	
Definition	The interim bowel screening pilot reporting layer technical specification and the data dictionary document identify the required data to enable monitoring and evaluation of the NBSP.
Rationale	Data is captured to monitor and evaluate the effect of the NBSP and assess the need for a changes to practice if required.
Quality indicator	Sufficient data is collected to enable the NBSP to operate at the highest standard and to inform an evaluation of the NBSP.
Essential criteria	The NBSP providers must ensure: 12.1.a. there is a mechanism in place to routinely capture data in the required format and submit it to the BSP+ IT system 12.1.b. there are controlled documented processes in place to ensure quality and accuracy of the data collected 12.1.c. there is a mechanism in place to receive and feed back to the local DHBs/PHOs on monitoring reports delivered by the NBSP 12.1.d. they use monitoring reports as a quality improvement activity 12.1.e. their ethnicity data collection, recording and output protocols comply with the *Ethnicity Data Protocols for the Health and Disability Sector*[11] and self-identified ethnicity is collected and entered at colonoscopy.
Evaluation process	The internal and external audit processes ensure that the criteria are complied with, and identified issues are addressed through a CQI process.
Evaluation targets	No quantitative target. All criteria are met.

[11] Ministry of Health. 2004. *Ethnicity Data Protocols for the Health and Disability Sector*. Wellington: Ministry of Health.

13 IT standards

BSP+ IT system and training Standard 13.1: The NBSP service providers utilise IT equipment that is fit for purpose, reliable, well supported and developed to continue to support the NBSP. Users must be provided with sufficient regular training to maintain expertise in the use of IT systems.	
Definition	NBSP service providers must be assured that the data/information they need in order to monitor the delivery of the NBSP can be provided in a timely way and is of high quality and in a format that can be analysed.
Rationale	IT equipment must be able provide ongoing, effective support for the NBSP.
Quality indicator	Existing information systems within the NBSP must be able to support the delivery of a high-quality NBSP and provide the required data to enable monitoring of its components.
Essential criteria	The NSBP service providers must ensure: 13.1.a. they regularly review equipment and infrastructures and have sufficient equipment and a documented business continuity plan to ensure services are maintained 13.1.b. they have sufficient staff and suitable mechanisms to provide effective and efficient BSP+ IT support to deliver the NBSP 13.1.c. they have suitable maintenance contracts and service-level agreements to ensure equipment and systems are maintained, backed up and developed to meet any changing requirements of the NBSP 13.1.d. they have sufficient resources to provide regular training on key systems to ensure users' expertise is maintained 13.1.e. their staff follow controlled documented procedures for using IT systems that support the NBSP 13.1.f. they review their systems regularly to ensure they align with Ministry of Health IT strategies and standards (eg, security, back up and disaster recovery) 13.1.g. they comply with the Privacy Act 1993 and have written protocols to ensure the privacy of each participant's personal information and data 13.1.h. there are regular reviews and audits to ensure systems meet the Standards New Zealand standard SNZ HB 8169:2002: Health Network Code of Practice information on security standards as well as other legislative requirements such as: • Health and Disability Commissioner Act 1994 • Health and Disability Services (Safety) Act 2001 • Health Information Privacy Code 1994 • Official Information Act 1982 • Public Records Act 2005.
Evaluation process	The internal and external audit processes ensure that the criteria are complied with, and identified issues are addressed through the CQI.
Evaluation targets	No quantitative target. All criteria are met.

Data quality and integrity Standard 13.2: Providers ensure that high-quality data is collected and reported	
Definition	Data collected must be accurate and reliable to enable data-driven decisions for quality outcomes.
Rationale	Quality data is an essential tool in monitoring the NBSP to ensure that it is both safe for participants and provides the projected population benefits.
Quality indicator	All data collected is high quality and as such is accurate, timely, complete and consistent.
Essential criteria	The NSBP service providers must ensure that: 13.2.a. data management protocols are documented and adhered to 13.2.b. data entry protocols include QC requirements and clearly describe staff responsibilities for accurate, timely and complete data entry 13.2.c. data entry staff are adequately trained in line with documented procedures and supported in the process 13.2.d. non-clinical staff are not permitted to interpret individual participant's clinical data 13.2.e. data is de-identified for monitoring purposes unless there is a clear pre-defined need for an identifier, such as in exception (failsafe) reporting 13.2.f. data entry staff have adequate time to allow them to use the system correctly, interruptions are minimised and the environment is conducive to detailed data entry 13.2.g. clinicians, including endoscopy nurses, record screening and diagnostic investigation data and are responsible for its accuracy and completeness 13.2.h. identifiable clinical data is not assimilated into a clinical record without the involvement of a clinician who takes legal responsibility for that inclusion 13.2.i. checks are implemented for errors that may arise during data entry, and an error log is maintained that is regularly audited to identify repeated issues 13.2.j. inconsistencies are investigated and rectified 13.2.k. there is an internal audit process that provides QA of both manually entered clinical records and electronic data 13.2.l. data entry of all manually transcribed records and/or interpretation of data is independently checked for accuracy and completeness.
Evaluation process	The internal audit and external assessment processes ensure that the criteria are complied with, and identified issues are addressed through a CQI process. A statistically significant sample of clinical records is audited monthly. All audited data, errors and investigations are recorded, and outcomes from issues are used for staff education purposes.
Evaluation targets	100% of records are entered correctly into the BSP+ IT system.

Glossary

Term	Description
Adenoma	A colorectal adenoma is a lesion in the colon or rectum containing unequivocal epithelial neoplasia.
Advanced adenoma	In screening programmes, the term 'advanced adenoma' is sometimes used to categorise adenomas for management. In such a context, an advanced adenoma is one that is either greater or equal to 10 millimetres or contains high-grade mucosal neoplasia or a villous component.
Colorectal cancer (CRC)	Colorectal cancer diagnosed by the screening programme, or diagnosed as a direct result of participating in the screening programme. Pathologists working in CRC screening programmes define colorectal cancer as adenocarcinoma (ie, an invasion of neoplastic cells through the muscularis mucosae into the submucosa) in either the colon, rectosigmoid junction or rectum. Only the above are to be reported as cancer in the Programme.
Eligible population	The eligible population are those people in the target population who fulfil the eligibility criteria specified in the NBSP policy.
Faecal immunochemical test (FIT) for haemoglobin	A faecal immunochemical test (FIT) for haemoglobin is an in-vitro stool test that detects hidden blood in stools. The FIT detects human globin, making the test specific for human blood.
Failsafe system	A failsafe system aims to maximise follow-up compliance or adherence to standard procedures by sending reminders or applying computer-based or other automated checks.
Inadequate test	An inadequate FIT is a test returned by a participant, the results of which cannot be reliably determined. The quality is insufficient for processing, and the test cannot be used for recording a result according to NBSP policy.
Invited	Invited are members of the eligible population who have been sent an invitation for screening according to NBSP policy/process, ie, invited by mail. Note: Not all invitations sent may be received.
National Screening Unit (NSU)	The National Screening Unit (NSU) is part of the service commissioning business unit of the Ministry of Health. It is responsible for developing, managing and monitoring nationally organised, population-based health screening programmes in New Zealand.

Term	Description
Offer	An offer is a formal communication made by a bowel screening service, giving a specific participant a realisable opportunity to be tested within an effective timeframe.
Participation rate	Participation rate refers to the number of people who have been screened (for whom an adequate test was received) within a defined timeframe following an invitation, as a proportion of all people who are invited to attend for screening.
Positive test	A positive (ie, abnormal) FIT result is a result based on the last adequate test that, according to NBSP policy, leads directly to referral to follow-up colonoscopy. A positive (ie, abnormal) colonoscopy screening examination is one resulting either directly in diagnosis of cancer or removal of an adenoma or other lesion, or in referral for further investigation according to NBSP policy.
Screening episode	A screening episode is the end-to-end screening process from the perspective of a participant who has accepted an offer of screening. A complete screening episode starts with an offer and ends with the communication of a conclusive result. Some screening episodes may end prematurely, for example if the participant fails to attend a booked screening session.
Screening interval	The screening interval is a fixed interval between routine screenings decided upon in each service.
Screening policy	The NBSP screening policy defines the targeted age group, the geographical area, the screening interval and the screening method.
Surveillance	Surveillance in these Standards relates to continuous monitoring of disease occurrence within a population. The primary aims of colonoscopic surveillance are to reduce the morbidity and mortality from colorectal cancer by removing high-risk adenomas before they have had a chance to become malignant and by detecting invasive cancers at an early, curable, stage.
Target population	The target population is those people of eligible age, according to the NBSP policy, who reside in the area designated to be served by the NBSP.