

8. Protocols

8.1 Clinical Protocols

Background:

Clinical protocols will be locally developed and should closely link with existing colorectal pathways. The exception to this is the pre-assessment for participants with a positive screening test result.

A flowchart of the process can be found at the end of this section.

Process:

8.1.1 Pre-assessment

The Centre will issue positive results to patients and copy to the GP Practice but pre-assessment appointments will be the responsibility of the NHS Board.

Each participant with a positive screening test result will be pre-assessed prior to being offered a colonoscopy.

NHS Boards will ensure quality of pre-assessment is delivered and maintained to meet national bowel screening standards published by NHS Quality Improvement Scotland (NHS QIS).

The nurse or health care professional responsible for pre-assessment will follow the NHS Board pre-assessment protocol.

Pre-assessment will include:

- verbal explanation of the possible causes of the positive result,
- verbal and written explanation of colonoscopy and bowel preparation,
- explanation of the risks of colonoscopy,
- issue bowel preparation, and
- issue colonoscopy appointment.

Where patients defer or refuse colonoscopy the hospital will:

- inform GP Practice of their decision not to proceed / delay to screening investigation,

- ensure there are arrangements in place to identify all individuals who do not participate in pre-colonoscopy assessment and offer them a further opportunity to do so.
- Allow a maximum of 6 months only from screening test result to return for colonoscopy. This 6 month period is essential as recall is dependant on consistent closure of an individual's screening episode. The recall date will be 2 years from positive result so 6 month period for colonoscopy will start from the date of referral but will not affect recall date.

(See Appendices 4 and 5 for information on exclusion criteria, information leaflet, pre-assessment checklist and pre-assessment questionnaire)

8.1.2 Colonoscopy

Background:

Colonoscopy is the first investigation offered following a positive screening test result.

Process:

Following pre-assessment, if appropriate, a colonoscopy appointment is offered at the time of pre-assessment.

NHS Boards will ensure quality of colonoscopy is delivered and maintained to meet national bowel screening standards published by NHS QIS.

8.1.3 Radiology

Background:

Following an incomplete colonoscopy, a referral for a double contrast barium enema or a computed tomography (CT) colonography is made.

Process:

Radiology appointment will be offered.

NHS Boards will ensure quality of radiological procedure is delivered and maintained to meet national bowel screening standards published by NHS QIS.

8.1.4 Pathology

Background:

Cancer resections and polyps/biopsies will be sent to pathology. In the pilot, the workload on pathology was substantial.

Process:

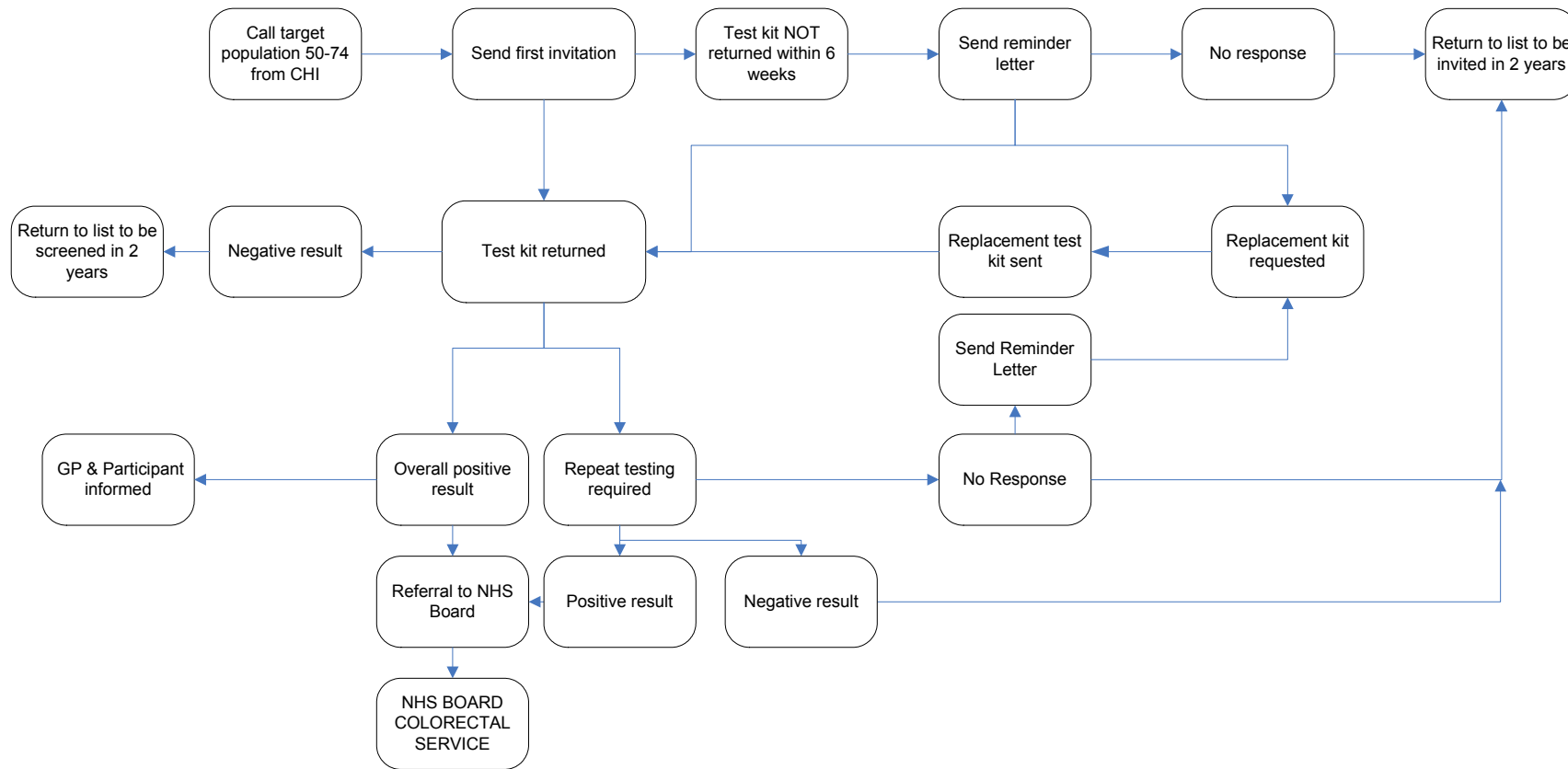
NHS Boards will ensure quality of pathology is delivered and maintained to meet national bowel screening standards published by NHS QIS.

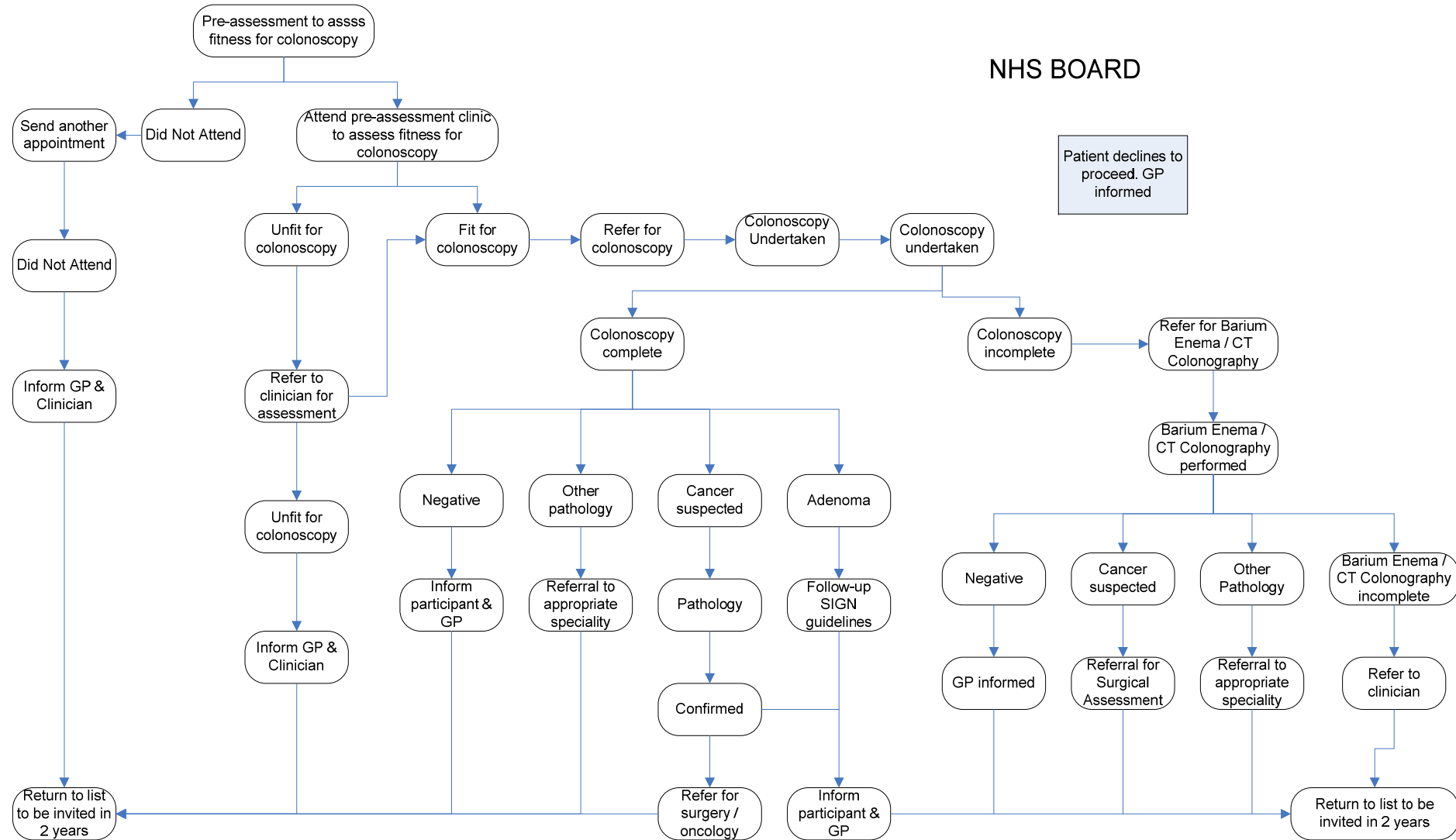
A National QA Pathology process has been established under the umbrella of the Scottish Pathology Network.

1. Pathologists reporting screening specimens are required to participate in the EQA slide circulation. The slide circulation is organised across the UK. This commenced in Spring 2010.
2. Reports on cancers and polypoid cancers issued in the programme will be formulated in accordance with UK guidelines (Royal College of Pathologists www.rcpath.org). The specific bowel screening publication '*Reporting Lesions in the NHS Bowel Cancer Screening Programme*' available from www.cancerscreening.nhs.uk/bowel/publications/index.html .
3. Experience from the pilot programme and early screening rounds has shown that about 15% of new cancers are early stage "polyp cancers" (a cancer focus in a lesion removed as a polyp and potentially cured at the time of endoscopic removal). This is well recognised as a difficult diagnostic area. The governance group of the bowel screening programme has recommended that a referral/review system is instituted. The attached Standard Operating Procedure details the operation of the system. Any polypoid cancer or suspected polypoid cancer (or any case in which there is diagnostic difficulty in this area) should be sent to Anne Park, Department of Pathology, Ninewells Hospital, Dundee DD1 9SY. Each case will be seen by two of a panel of three

pathologists and a report issued to the referring department. A referral form is included with the SOP. The paperwork will also be published on the Scottish Pathology Network (SPAN) website www.pathologyscotland.org.

SCREENING CENTRE





8.2 Other Eligible Groups Protocols

- Individuals with physical incapacity and individuals with consent difficulties
- Long stay institutions and Prisons
- Armed Forces
- People who do not wish to be screened
- Travellers and Homeless

8.2.1 Procedure for dealing with individuals with physical incapacity or consent difficulties.

Physical incapacity

Individuals with all levels of physical ability will be invited by the bowel screening programme. It is important to note that although FOBt sampling may easily be carried out by a carer the next step for positive patients is an invasive procedure. The participant must be fully informed of the consequences of a positive FOBt result and the possible further investigation.

Consent difficulties

The Adults with Incapacity (Scotland) Act 2000 is an Act of the Scottish Parliament that makes provision for the property, financial affairs and personal welfare of adults who are incapable by reason of mental disorder or inability to communicate. The law of Scotland generally presumes that adults (those aged 16 or over) are legally capable of making personal decisions for themselves and managing their own affairs. That presumption can be overturned in relation to particular matters or decisions on evidence of impaired capacity.

The Adults with Incapacity (Scotland) Act 2000 sets out the framework for regulating intervention in the affairs of adults who have (or may have) impaired capacity, in the circumstances covered by the Act. A revised Code of Practice for Part 5 of the Act was issued in 2008 (CEL 11 2008) and was circulated to NHS Board Chief Executives in March 2008. This circular set out the 5 general principles of the Act namely (1) benefit, (2) minimum necessary intervention, (3) take account of the wishes of the adult, (4) consultation with relevant others and (5) encourages the adult to exercise residual capacity.

The Act allows for an intervention but an intervention is only permitted where the adult lacks capacity in relation to the subject matter of the intervention. It is necessary to consider whether the adult lacks capacity in relation to the relevant matter each time a decision or action fails to be taken. The Act also sets out that carers and relatives will have valuable information about the patient's present and past wishes and feelings but care should be taken not to let them simply answer for the adult, or put words into his or her mouth.

Meaning of treatment – Under subsection 47(4) of the Act, 'medical treatment' includes **any procedure or treatment** designed to safeguard or promote physical or mental health. Screening is classed as treatment for the purposes of the Act.

General Authority to treat – Authority to do what is reasonable in the circumstances in relation to medical treatment is set out in section 47 of the Act.

Process

An individual's primary health care provider (this may or may not be a General Practitioner) should be involved to consider what, if any, intervention is required in individual cases. They will be able to assess the situation based on the individual's past and present medical history and consider the best way forward in terms of the Act.

Good practice would also be to provide health care messages about the signs and symptoms to look out for as set out in the Scottish Bowel Screening Know the Facts Leaflet.

8.2.2 Protocol for Long Stay Institutions and Prisons (This protocol is only applicable for those who are in care or serving sentences for over 6 months)

Medical Dictionary Definition for Long-Term Care Facility

A facility that provides rehabilitation, restorative, and / or ongoing skilled nursing care to patients or residents in need of assistance with activities of daily living. Long-term care facilities include nursing homes, rehabilitation facilities, inpatient behavioural health

facilities, and long-term chronic care hospitals. Source: MedicineNet

Background

There may be individuals in long stay institutions that are within the eligible age range. However, careful assessment by health care professionals (HCP) responsible for their care will be essential.

Process:

- NHS Boards should develop protocols to ensure that those in long stay institutions within their area and are eligible to participate can be informed about the programme. The precise mechanism will need to be determined through locally developed protocols.
- NHS Boards will be required to ensure that key HCPs are contacted in each institution within their NHS Board area so that those eligible to be invited to participate in the programme can be identified to the Centre.
- Using the Bowel Screening Call-Recall (BoSS) call on demand module the Centre will issue all invitation packs and result letters to the participants identified HCP.
- For individuals with positive screening test results pre-assessment for colonoscopy should be arranged between the HCPs in the institution and the local NHS Board.
- Following pre-assessment the individuals should be referred to the local hospital for further investigations. Normal procedures for hospital admission will be carried out.
- On closure of this screening cycle the BoSS record will revert to the demographic details held on CHI and will no longer be attached to the BoSS call on demand. The next recall invitation will go to the address held on CHI and will only reach the participant if they have returned to their home address. So recall of the institution will have to restart every two years or when the HCP provides information directly to the Helpline.

The Centre procedure for calling the identified various institutions will follow the same principle for each as follows:

- Procure a list of HCPs responsible as identified by their NHS Board
- Contact these HCPs to ask for:
 - The named HCP to send the invitation packs and results c/o
 - The CHI numbers of eligible individuals who can make informed choice as regards taking part in bowel screening
- The Centre will contact each named institution every two years to request CHI numbers of eligible individuals.

The institution may contact the Centre to ask on behalf of an individual that they be invited for screening. This is in the same way that any non responder who has already been invited contacts the Helpline to request to be screened.

Standard Operating Procedures and flow plans will ensure that once trained all Helpline staff can add participants to this module when they are contacted by a HCP.

This process is the expected pathway.

8.2.3 Protocol for Armed Forces

Background

Service Personnel should request bowel screening via their Service Medical Centre, and the Ministry of Defence should either arrange or commission screening on their behalf.

Work, being led by Scottish Government Health Directorates in partnership with the MoD, is currently underway to issue all forces personnel in Scotland Community Health Index (CHI) numbers by the end of 2010. Forces personnel will then be invited for Bowel Screening using the usual call-recall mechanism.

Process

Information will be provided once a protocol has been agreed.

8.2.4 Protocol for People who do not wish to be screened - Informed dissent

Background and Process

Those who advise that they do not wish to participate in the Programme and sign a “disclaimer” letter to that effect are excluded (see **Annex A, Letter ID 13**). This is currently part of the programme.

A small number of the population strongly object to being invited and refuse from the outset of their conversation with Helpline staff, to receive any further correspondence. It is important that the person wishing to withdraw from the screening programme understands the implications of his or her decision and also understands that he or she can be returned to call/recall at any time on request. The SBSC Helpline Officer will make every effort to obtain written evidence of the informed nature of a person’s decision.

If the decision is communicated by telephone and the person is unwilling or unable to confirm the decision in writing, it is advisable to ask a supervisor to witness the call so that at least two members of staff can independently confirm and document the ceasing instruction.

The caller will also be asked to confirm that their GP can be notified of their decision so that they can be provided with support and advice.

8.2.5 Protocol for Travellers and Homeless

Background

Travellers and homeless people may not have a fixed address in Scotland or be registered with an NHS Scotland GP practice but will be included in bowel screening as long as they have a CHI number.

Process

Minimum expected from NHS Boards

- All NHS Boards should develop protocols to ensure that travellers and homeless people within their area are informed about the programme. The precise mechanism will need to be determined through locally developed protocols – an example of an NHS Board protocol is attached at Appendix 6
- NHS Boards should liaise with housing offices, libraries and community pharmacies and encourage them to display posters
- It is necessary that the individual keeps their details up to date with the GP Practice and / or the Centre for follow-up and recall. The participant will be invited following normal procedure.
- Travellers on static sites are usually registered with a GP and have a postal address therefore will be called using the usual call-recall mechanism.

This process is the expected pathway.

Optional for NHS Boards

- NHS Boards may choose to identify Health Care Professionals (HCP) to raise awareness, provide support and education in travelling and homeless groups. The HCP should encourage registration with a GP and to participate in screening.
- NHS Boards can request that a group of eligible travellers or homeless be added to Bowel Screening Call-Recall System (BoSS) call on demand module. This will allow a HCP to identify participants to the Centre under an allocated name for example 'Meadowfield Travellers Site' or 'Oldtown Homeless Practise'. HCPs will provide an active CHI number

to the Centre. The Centre will call all those identified who are eligible for screening.

Once allocated under this heading the participant invitation packs will be issued on the following day c/o the named HCP. The named HCP will then be responsible for issuing and supporting these individuals through the process. Individuals will return their test kits directly to the Centre in the freepost envelope as per the normal practice. Results will be issued c/o the HCP.

On closure of this screening cycle the BoSS record will revert to the demographic details held on CHI and will no longer be attached to the BoSS call on demand module. The process will be repeated every 2 years or when the HCP provides information directly to the Helpline.

The above can also be used for travellers or homeless requesting bowel screening through Keep Well Nurses.

8.3 Safe Guarding Protocol

Background:

Safe Guarding in a screening programme means that at any point of the screening pathway it is possible to identify what stage each individual is at within their screening episode. It also identifies if an individual defaulted at any point. It ensures that the screening programme can be adequately monitored and that there is an identified end point of screening for all individuals.

Process:

Call-Recall

- Only participants with a valid CHI record and an Area of Residence(AOR) will be invited
- Individuals not listed on CHI must contact a GP Practice to register on CHI.
- All eligible participants with a CHI number but who are not registered with a GP Practice will still be invited. The onus is on them to contact the GP practice if their address changes.
- All eligible individuals with a CHI number but no Area of Residence will not be invited. This is to ensure a point of referral.

Transfers in

- Individuals who are eligible and provide information on previous bowel screening will have their recall date amended.
- When an eligible individual moves from outside NHS Scotland, they will be issued an immediate call-recall date.

Transfers out

- Individuals who transfer to another NHS Board will continue to have their own recall date and be called within 2 years. If they are in the middle of the screening test pathway this will continue until a result is achieved and the results are then sent to their new address (see below - referral to NHS Boards).
- If an individual transfers out of NHS Scotland a summary of their screening episode can be provided on request.

People who default the screening test.

- All individuals who default during the screening test pathway will be sent one reminder after their initial invitation. If they do not

respond to the reminder they will automatically be put back on the 2 yearly recall.

- GP practices will be notified of those people who return a spoiled or out of date screening kit.

Referral to NHS Boards

Background:

All participants with a positive screening test result will be automatically referred to their local NHS Board by SCI Gateway.

Process:

- A participant with a positive screening test result will be referred from the Bowel Screening System (BoSS) via (SCI Gateway) to the participant's NHS Board.
- This referral will be sent directly to a pre-defined point of contact in the Health Board.
- The referral sent will be via a standard protocol-based referral which will be populated automatically from BoSS.
- The IT system will provide a way of confirming that the referral has reached its destination. The Screening Centre will contact an NHS board by fax where the electronic referral is shown to have failed.
- During the programme phasing period, all NHS Boards could receive referrals via BoSS and SCI Gateway before their own NHS Board area goes live. As a failsafe mechanism, if a referral has been sent to a non-active NHS Board and is not actioned promptly by the receiving Board, the Centre staff will contact NHS Board (see Chapter 4 for more information).
- Once the NHS Board is live, it is the responsibility of the individual NHS Board to action positive screening test referrals promptly.
- BoSS will recall all individuals 2 years from invitation date.

NHS Boards

Background:

When an individual is referred to an NHS Board for assessment and investigation it will be essential that each NHS Board can identify the outcome for each participant with a positive screening test result (see extract from NHS QIS standards below).

Process:

- This will be locally agreed but could follow same mechanism as for symptomatic patients and should take into account NHS QIS Bowel Screening Programme Standards.
- Tracking systems and mechanisms for measuring waiting times for bowel screened participants will require to be developed locally. However, previously established waiting times tracking systems could be used.

Extract from Essential NHS QIS criteria:-

Pre-colonoscopy assessment

- The time between the receipt of a positive screening test result by the NHS Board and the offered appointment date for pre-colonoscopy assessment should be within 14 days for at least 80% of individuals.
- Arrangements should be in place to identify all individuals who do not participate in pre-colonoscopy assessment and they should be offered a further opportunity to do so.
- All individuals with a positive screening test result should be offered a pre-colonoscopy assessment and a full explanation of the process of colonoscopy, the possible risks and the possible outcomes. The opportunity to discuss any concern should be provided at this stage and written information provided.
- Pre-colonoscopy assessment should be carried out by a healthcare professional who has appropriate skills, knowledge and experience and national guidance should be followed to identify those at a higher risk than normal from a colonoscopy.

- Clear and appropriate patient pathways are followed for individual with a positive screening test result who do not proceed to colonoscopy.
- GPs are informed of all individuals with a positive screening test result who do not proceed to colonoscopy.
- At least 80% of individuals who undergo pre-colonoscopy assessment and are deemed fit for colonoscopy are offered a date at the time of assessment.

Colonoscopy

- In at least 95% of cases, the interval between the notification of the positive screening test result to the NHS Board and the date offered for colonoscopy is within 31 days.
- In at least 95% of cases, GPs are notified of the results of colonoscopy within seven days.
- A date for a barium enema or a computed tomography (CT) colonography is offered within 31 days of an incomplete colonoscopy.
- The reports for at least 80% of radiological examinations are authorised within seven days of the date of the examination.