

Draft Clinical Standards ~ *July 2006*

Bowel Screening Programme

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First published July 2006

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1 Background on NHS Quality Improvement Scotland

NHS Quality Improvement Scotland (NHS QIS) was set up by the Scottish Parliament in 2003 to take the lead in improving the quality of care and treatment delivered by NHSScotland.

We achieve our objectives through four key functions that link together:

- setting standards
- reviewing and monitoring performance
- providing advice and guidance on effective practice, and
- supporting staff to improve services.

We deliver our commitments to the public and to NHSScotland by following an approach that is:

- **independent** – we reach our own conclusions and report on what we find
- **open and transparent** – we explain what we do, how and why we do it, and what we find, using language and formats that are easy to understand and to access
- **sensitive and professional** – we recognise needs, beliefs and opinions and respect and encourage diversity.

Our work is:

- **partnership-focused** – we work with patients and the public, NHSScotland and many organisations to improve the quality of care and avoid duplication
- **evidence-based** – we base our conclusions and recommendations on the best evidence available
- **quality-driven** – we make sure our own work is monitored and evaluated, internally and externally.

2 Development of NHS Quality Improvement Scotland standards

Basic principles

A major part of our remit is to develop and run a national system of quality assurance of clinical services. Working in partnership with healthcare professionals and members of the public, we set standards for clinical services, assess performance throughout NHSScotland against these standards, and publish the findings. The standards are based on the patient's journey as he or she moves through different parts of the health service. A wide range of diseases and services have already been addressed, including pregnancy and newborn screening, the provision of safe and effective primary medical services out-of-hours, and maternity services.

In fulfilling our responsibility to develop and run a system of quality assurance, we take account of the principles set out in Fair for All and Partnership for Care, to ensure that 'our health services recognise and respond sensitively to the individual needs, background and circumstances of people's lives'.

We will ensure that consideration of equality and diversity issues feature prominently in the design, development and delivery of all our functions and policies.

The standards are developed in accordance with the commitments of the National Health Service Reform (Scotland) Act (2004) which state that 'individual patients receive the service they need in the way most appropriate to their personal circumstances and all policy and service developments are shown not to disadvantage any of the people they serve.'

Process

For each set of standards we develop, we appoint a group representing a range of stakeholders, including healthcare professionals and members of the public to:

- oversee the development of, and consultation on, the draft standards and self-assessment framework, and
- recommend an external peer review process.

The way in which standards are developed is a key element of the quality assurance process. Project groups working on our behalf are expected to:

- adopt an open and inclusive process involving members of the public, voluntary organisations and healthcare professionals
- work within NHS QIS policies and procedures, and
- test the measurability of draft standards by undertaking pilot reviews.

The standards are clear and measurable, based on appropriate evidence, and written to take into account other recognised standards and clinical guidelines. The standards are:

- written in simple language and available in a variety of formats
- focused on clinical issues and include non-clinical factors that impact on the quality of care

- developed by healthcare professionals and members of the public, and consulted on widely
- regularly reviewed and revised to make sure they remain relevant and up to date, and
- achievable but stretching.

Format of standards and definition of terminology

All standards set by NHS QIS follow the same format.

- Each standard has a **title**, which summarises the area on which that standard focuses.
- This is followed by the **standard statement**, which explains the level of performance to be achieved.
- The **rationale** section provides the reasons why the standard is considered to be important.
- The standard statement is expanded in the section headed **criteria**, which states exactly what must be achieved for the standard to be reached. Criteria are **essential**, in that it is expected that they will be met wherever a service is provided. Other criteria are **desirable**, in that they are being met in some parts of the service, and demonstrate levels of quality, which other providers of a similar service should strive to achieve. The criteria are numbered for the sole reason of making the document easier to work with, particularly for the assessment process. The numbering of the criteria is not a reflection of priority.

Clinical governance and risk management standards

Every patient using healthcare services should expect these to be safe and effective. The NHS QIS standards for clinical governance and risk management will ensure NHS boards can provide assurance that clinical governance and risk management arrangements are in place, and are supporting the delivery of safe, effective, patient-focused care and services.

The clinical governance and risk management standards underpin all care and services delivered by NHSScotland and provide the context within which NHS QIS service and condition-specific standards apply. They should be read in conjunction with all our standards.

The clinical governance and risk management standards were effective from November 2005 and are available on request from NHS QIS or can be downloaded from the website (www.nhshealthquality.org).

Assessment of performance against the standards

The framework for the NHS QIS review process is as follows.

- Once the standards have been finalised, each relevant NHS board/service is asked to undertake a self-assessment of its service against the standards.

- A review team visits the NHS board/service on behalf of NHS QIS to follow-up this self-assessment exercise with an external peer review of performance in relation to the standards.
- NHS QIS reports the findings for the NHS board/service, based on the self-assessment exercise and on the external peer review.

Our processes are subject to internal and external evaluation, to help improve the quality assurance system.

3 Development of the draft clinical standards for the bowel screening programme

An introduction to screening services

Screening is a public health service offered to groups of the population to identify risk of a particular condition, or to identify such a risk at an early stage when treatment may be more effective. Screening tests are not compulsory but are offered to help individuals make informed choices about their health, and in the instance of pregnancy and newborn screening, the health of their child. There is an ethical obligation on agencies to ensure that the timely provision of services meets the needs identified through the screening process.

Prior to accepting or declining the offer of a screening test, it is important that individuals receive information about the screening in which they are about to participate. While some screening tests have the potential to save lives, or improve quality of life by making possible the early diagnosis of a serious condition, they are not both 100% sensitive and 100% specific.

Screening is a two-stage process. Usually, the first-line test indicates only a risk or probability that a particular condition is present. A second, diagnostic test is required for confirmation.

Background to the development of the bowel screening programme

The incidence of bowel cancer is high in Scotland; it is the third most common malignancy experienced by men and women and is second only to lung cancer as a cause of cancer death in the combined male and female population. Updated figures state that 3.8% of men in Scotland will develop bowel cancer by the age of 74 and 2.6% of females in Scotland will develop bowel cancer by age 74¹.

The review of a series of randomised control trials (RCTs) in England², Denmark³ and the United States⁴ and a Cochrane Review⁵ demonstrated that faecal screening resulted in approximately a 16% decrease in mortality from bowel cancer in the research populations.

Following review of the evidence from the three RCTs and other published work, the UK National Screening Committee (NSC) recommended that screening for colorectal cancer should be piloted to assess the feasibility, acceptability and practicality of a national programme, and in April 2000, a bowel screening pilot commenced in Scotland in Tayside, Grampian and Fife NHS board areas.

The bowel screening programme overview

In August 2005, the Scottish Executive Health Department (SEHD) announced a new initiative to help tackle bowel cancer, with the roll-out of a national bowel cancer screening programme. The programme will commence in 2007 and will be phased in gradually over a 3-year period to all NHS boards throughout Scotland, targeting all eligible individuals (male and female) aged between 50–74 years.

With the aim to implement a national bowel screening programme, the programme will operate from a screening centre based in Dundee, consisting of a call-recall office, laboratory and helpline telephone service for individuals.

Individuals with an overall positive result will be referred to a local hospital where a pre-assessment will be undertaken by an NHS board-based nurse, and will be offered a colonoscopy examination, if appropriate. This arrangement may differ in some areas, for example in island NHS board areas.

As with all screening services, the national bowel screening programme will require to quality assure the service that is provided and should be integral within existing quality assurance procedures and must meet the programme's nationally set clinical standards.

The development of draft clinical standards for the bowel screening programme

The development of draft clinical standards for the bowel screening programme is the responsibility of NHS QIS, taking into account advice from the NSC and in consultation with NHS organisations. NHS QIS has also developed the quality assurance standards for breast screening, cervical screening, diabetic retinopathy screening, and pregnancy and newborn screening programmes.

NHS QIS established a project group to take this work forward, chaired by Professor Robert Steele. The group first met in February 2006 and its full membership can be found in Appendix 1. The group considered a number of topics surrounding the pilot bowel screening programme pathway (see Appendix 4) and from this starting point seven key areas for clinical standards were identified for the development of standards:

- general principles
- call-recall
- the screening process
- the laboratory process and reporting
- pre-colonoscopy assessment
- colonoscopy and histopathology, and
- neoplasia yield.

Evidence base

During the development of the draft clinical standards for the bowel screening programme, the project group considered a wide range of evidence, which is fully referenced in Appendix 2. The following documents formed the core evidence reviewed by the project group.

- **Cochrane Review: Screening for colorectal cancer using the faecal occult blood test, Hemoccult**

The objective of this review was to determine whether screening for bowel (colorectal) cancer using the faecal occult blood test (FOBT), Hemoccult, reduces bowel cancer mortality, and to consider the benefits and harms of screening. This was established by the systematic review of trials of Hemoccult screening, including meta-analysis of results from RCTs performed in England, Denmark, Sweden and the United States.

Relevance of the Cochrane Review to standards development: Following a review of the evidence, a bowel screening pilot commenced in Tayside, Grampian and Fife NHS board areas. To help tackle bowel cancer, the SEHD subsequently announced a new initiative to roll-out a national bowel screening programme. NHS QIS is tasked with developing clinical standards to meet the quality assurance requirements of the national screening programme.

- **Scottish Executive Health Department Letter: HDL(2006)3⁶**

This HDL outlines the plan for the implementation of the bowel screening programme and the roles and responsibilities following roll-out.

It provides information on the support available to NHS boards and the steps which NHS boards need to take to provide investigations and follow-up care for individuals with positive FOBTs.

Relevance of HDL(2006)3 to standards development: This document guides NHS boards and clinicians to implement measures necessary for the delivery of a successful bowel screening programme throughout Scotland, and ensures the programme quality is delivered and maintained by meeting agreed, national standards.

4 How to participate in the consultation process

NHS QIS may use several different methods of consultation during the development of the draft standards:

- wide circulation of the draft standards document to relevant professional groups, health service staff, voluntary organisations and individuals
- open meetings
- public consultation exercises involving distribution of comments forms and/or questionnaires
- focus group discussions, and
- pilot review visits.

If you would like to know how you can participate in the consultation process, please contact:

Miss Ali McAllister
Project Officer
NHS Quality Improvement Scotland
Glasgow Office
Delta House
50 West Nile Street
GLASGOW
G1 2NP

Tel: 0141 225 6880

Fax: 0141 248 9746

Textphone: 0141 241 6316

Email: ali.mcallister@nhshealthquality.org

Submitting your comments

Responses to the draft clinical standards for the bowel screening programme should be submitted (by post, phone, fax or email) to the above contact details by **Monday, 23 October 2006**.

Consultation feedback

At the end of the consultation period all comments and responses will be collated and the project group will respond to all comments received on the draft standards. The response will explain how the comments were taken into account.

The response will be made available on the NHS QIS website (www.nhshealthquality.org) and from Ali McAllister, Project Officer.

5 Draft clinical standards for the bowel screening programme

Standard 1 General

Standard 2 Call-recall

Standard 3 The screening process

Standard 4 The laboratory process and reporting

Standard 5 Pre-colonoscopy assessment

Standard 6 Colonoscopy and histopathology

Standard 7 Neoplasia yield

Legend:	
BSP	Bowel screening programme
NHS	NHS board
NSC	National screening centre

Standard 1: General

Standard Statement 1a

An effective bowel screening service is available and offered to all eligible Scottish residents.

Rationale

There is evidence that effective population-based screening leads to a reduction in mortality from bowel cancer.

References: 2, 3, 4, 5, 7

Essential Criteria

1a.1 BSP	There are clearly defined arrangements for managing the bowel screening service and the lines of accountability within NHS boards.
1a.2 NHS	There is a designated consultant in public health medicine (CPHM) or registered specialist in public health acting as the bowel screening co-ordinator for each NHS board.
1a.3 NHS	There is a designated lead clinician for each NHS board.
1a.4 NHS	NHS boards will submit complete local datasets to ISD Scotland on all patients with positive screening test results within 6 months of the positive test result.
1a.5 NSC	ISD Scotland will provide regular agreed performance reports nationally and to all individual NHS boards.
1a.6 NHS	Each NHS board has a multidisciplinary bowel screening co-ordinating group with public representation that meets at least annually to review local performance data and address quality assurance recommendations.

Standard 2: Call-recall

Standard Statement 2a

Effective call-recall arrangements are in place to ensure all eligible individuals are invited for screening once every 2 years.

Rationale

There is good evidence that effective call-recall improves uptake and coverage. There is evidence that population-based screening amongst the age range 50–74 years leads to a reduction in mortality from bowel cancer.

References: 2, 3, 4, 5, 7

Essential Criteria

2a.1 NSC	95% of eligible individuals are sent their first invitation for screening before their 52nd birthday.
2a.2 NSC	95% of eligible individuals are recalled for screening within 24 months of their previous invitation for screening.
2a.3 BSP	There are arrangements to maximise the number of known eligible individuals registered on the community health index (CHI), but not registered with a GP, who are invited for screening.
2a.4 NSC	There are arrangements to identify non-responders and offer them a further opportunity to respond within that screening round.
2a.5 NSC	For individuals unable to undertake the screening test, there are arrangements in place to provide an alternative test, on request.

Standard 2: Call-recall (continued)

Standard Statement 2b

The number of individuals responding to bowel screening is optimised within the principles of informed choice.

Rationale

There is evidence that the impact on mortality from bowel cancer is influenced by the level of participation in a population-based screening programme.

References: 2, 3, 4, 5, 8, 9

Essential Criteria

2b.1 NHS	Each NHS board has a plan to maximise informed uptake, with particular attention to special groups and the local population profile.
2b.2 BSP	A minimum of 60% of all invited individuals respond to an invitation to participate in the bowel screening programme and complete the process.
2b.3 BSP	All general practices should be given a summary of their practice uptake annually.

Desirable Criterion

2b.4 BSP	A minimum of 60% of both invited men and women respond to an invitation to participate in the bowel screening programme and complete the process.
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Standard 2: Call-recall

Standard Statement 2c

Failsafe procedures are in place, appropriate to the outcome of the screening episode.

Rationale

Failsafe procedures are important to ensure that individuals receive the follow-up appropriate to the outcome of their screening episode. In particular, it is important to ensure that all individuals with a positive screening test are provided with every opportunity to undergo colonoscopy.

References: 2, 3, 4, 5

Essential Criteria

2c.1 NSC	There are failsafe protocols to ensure that all individuals with a negative screening test result are returned to the routine recall system.
2c.2 BSP	There are failsafe protocols to ensure that all individuals with a positive screening test result are offered pre-colonoscopy assessment.
2c.3 NSC	Individuals can opt out for an indefinite period of time from the call-recall system by signing a disclaimer form which includes information about reinstatement.

Standard 3: The screening process

Standard Statement 3a

The written information sent with the screening test kit and the invitation letter gives a full explanation of the screening process, and provides balanced information on the benefits and risks of screening.

Rationale

There is an obligation to provide accurate information about screening tests and diagnostic investigations.

References: 10, 11, 12, 13, 14, 15

Essential Criteria

3a.1 NSC	All individuals invited for screening are given standardised written information explaining the significance of a positive and a negative screening test result, and the benefits and risks of screening.
3a.2 NSC	All individuals invited for screening are given standardised written information explaining how to undertake the screening test and return it to the screening centre.
3a.3 NSC	All individuals invited for screening are given standardised written information explaining that a colonoscopy will be recommended if their screening test result is positive.
3a.4 NSC	Information can be made available in different formats appropriate to the needs of the target population.

Standard 3: The screening process

Standard Statement 3b

An adequately staffed helpline is available for all individuals receiving an invitation to participate in bowel screening.

Rationale

Evidence from the screening pilot indicates that a number of individuals require verbal clarification or extra information regarding aspects of the screening process.

Reference: 16

Essential Criteria

3b.1 NSC	The helpline is staffed continuously between 8.00am and 8.00pm, Monday to Friday, excluding public holidays.
3b.2 NSC	Arrangements are in place for the provision of additional means of communication to the helpline, eg 24-hour answering service and email.
3b.3 NSC	All staff involved with the screening helpline receive relevant communication skills training before undertaking unsupervised work.

Standard 3: The screening process (continued)

Standard Statement 3c

The time between returning the screening test and receiving the result should be minimised.

Rationale

There is evidence that waiting for a screening test result can cause anxiety.

Reference: 17

Essential Criteria

3c.1 NSC	A minimum of 95% of individuals returning a screening test are sent a result letter within 5 working days of receipt of the test by the screening centre.
3c.2 NSC	Individuals receiving a negative screening test result are given accompanying information highlighting the limitations of the screening test, and individuals are advised to be observant of, and report, relevant symptoms.
3c.3 NSC	The letter sent to individuals with a positive screening test result contains standardised information to explain the significance of a positive screening test result in terms of further investigation and possible outcomes.
3c.4 NSC	In a minimum of 95% of cases, the local NHS board designated contact is informed of individuals with a positive screening test result within 1 working day of the result being validated in the screening centre.
3c.5 NSC	GPs are informed of individuals with a positive screening test result within 5 working days of the result being validated in the screening centre.

Standard 4: The laboratory process and reporting

Standard Statement 4a

The laboratory providing bowel screening test analyses meets recognised professional standards.

Rationale

There is evidence that laboratories accredited and working to agreed standards achieve the required high level of test accuracy. Accreditation is regarded as a key element in ensuring good clinical governance in this important area.

References: 18, 19, 20, 21, 22

Essential Criteria

4a.1 NSC	The laboratory holds accreditation by Clinical Pathology Accreditation (UK) Ltd to ISO 15189 standards.
4a.2 NSC	All bowel screening laboratory staff are either in a training programme or have successfully completed one, and undertake appraisal, personal development and continuing professional development (CPD), when appropriate.

Standard 4: The laboratory process and reporting (continued)

Standard Statement 4b

The quality of the bowel screening laboratory test analyses is continually assessed and monitored, and there is evidence of internal quality control, external quality assessment and quality assurance.

Rationale

Quality control, assessment and assurance are essential to provide an independent assessment of the performance of laboratory test analyses.

References: 18, 19, 20, 21, 22

Essential Criteria

4b.1 NSC	The laboratory demonstrates overall satisfactory performance in an accredited independent national external quality assessment scheme (EQAS).
4b.2 NSC	Internal quality control procedures are undertaken and documented.
4b.3 NSC	The designated quality manager conducts an annual vertical audit to ensure continuing compliance with relevant ISO 15189 standards.

Standard 4: The laboratory process and reporting

Standard Statement 4c

The bowel screening programme follows an evidence-based screening algorithm that combines appropriate tests to identify a population at higher risk of disease.

Rationale

Sensitivity and specificity of screening is influenced by the screening algorithm applied and the performance characteristics of the tests used.

Reference: 23

Essential Criteria

4c.1 BSP	The evidence base for the screening algorithm is documented and any change in the algorithm is approved by the Bowel Screening Programme Board.
4c.2 BSP	There are arrangements to disseminate approved changes to NHS boards when the screening algorithm is changed.

Standard 5: Pre-colonoscopy assessment

Standard Statement 5a

The interval between receiving a positive screening test result and receiving a pre-colonoscopy assessment is minimised.

Rationale

There is evidence that time spent waiting between receiving a screening test result and assessment for colonoscopy can result in significant anxiety.

References: 9, 17

Essential Criteria

5a.1 NHS	The time between sending the appointment letter and the offered appointment date for pre-colonoscopy assessment is no more than 10 working days for all individuals.
5a.2 NHS	There are arrangements to identify all individuals who do not participate in pre-colonoscopy assessment and offer them a further opportunity to do so.

Desirable Criterion

5a.3 NSC	The local NHS board designated contact is informed of all individuals with a positive screening test result within 3 working days of the result being validated in the screening centre.
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Standard 5: Pre-colonoscopy assessment

Standard Statement 5b

Individuals with a positive screening test result are offered pre-colonoscopy assessment and are given an explanation of why, how and when colonoscopy will be undertaken.

Rationale

There is good evidence that providing information about tests and investigations reduces anxiety and encourages participation.

Reference: 24

Essential Criteria

5b.1 NHS	All individuals with a positive screening test result are offered a pre-colonoscopy assessment and are given a full explanation of the process of colonoscopy, the possible risks and the possible outcomes. The opportunity to discuss any concerns is provided at this stage.
5b.2 NHS	Pre-colonoscopy assessment is carried out by a healthcare professional who has undergone appropriate training and has knowledge to identify those who would be put at risk by undergoing colonoscopy.
5b.3 NHS	Clear and appropriate patient pathways should be followed for individuals with a positive screening test result, who have undergone a pre-colonoscopy assessment and do not proceed to colonoscopy.
5b.4 NHS	GPs are informed of all individuals with a positive screening test result, who have undergone a pre-colonoscopy assessment and do not proceed to colonoscopy.
5b.5 NHS	All those invited for pre-colonoscopy assessment are offered a date for colonoscopy at the time of assessment.

Standard 6: Colonoscopy and histopathology

Standard Statement 6a

The time between pre-colonoscopy assessment and the performance of colonoscopy is minimised.

Rationale

There is evidence that waiting for colonoscopy creates anxiety.

Reference: 17, 25, 26, 27

Essential Criteria

6a.1 NHS	The interval between the notification of the positive screening test result to the NHS board and colonoscopy being performed should be no more than 20 working days.
6a.2 NHS	GPs are notified of the results of colonoscopy within 5 working days.

Standard 6: Colonoscopy and histopathology

Standard Statement 6b

Colonoscopy should be performed to an appropriate standard.

Rationale

Colonoscopy has the potential to create morbidity and there is a small mortality associated with the procedure. Furthermore, failure to complete colonoscopy may result in significant neoplasia being missed.

Reference: 26

Essential Criteria

6b.1 NHS	Colonoscopy is carried out by a colonoscopist who has undergone appropriate training and assessment, and meets audited standards.
6b.2 NHS	There is a system to provide individuals, undergoing colonoscopy, an indication of the findings, options and next steps (where appropriate) before being discharged.

Standard 6: Colonoscopy and histopathology (continued)

Standard Statement 6c

A completion investigation of the entire large bowel should be carried out after incomplete colonoscopy.

Rationale

Failure to complete colonoscopy may result in significant neoplasia being missed.

References: 26, 27

Essential Criteria

6c.1 NHS	A barium enema or a computerised tomography (CT) colonography should be undertaken within 20 working days of an incomplete colonoscopy.
6c.2 NHS	The barium enema should be performed and reported by a suitably trained radiologist/radiographer.
6c.3 NHS	CT colonography should be performed by a suitably trained radiologist/radiographer and reported by a suitably trained radiologist.

Desirable Criterion

6c.4 NHS	The barium enema or CT colonography should be carried out on the same day as the incomplete colonoscopy, with the exception that barium enema should not be carried out within 2 weeks of polypectomy.
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Standard 6: Colonoscopy and histopathology

Standard Statement 6d

Histopathology should be carried out to an appropriate standard.

Rationale

Subsequent management of individuals with screen-detected neoplasia must be based on accurate histopathology.

References: 26, 27

Essential Criteria

6d.1 NHS	Pathology reporting is carried out in accordance with the Royal College of Pathologists (RCPATH), Scottish Intercollegiate Guidelines Network (SIGN) and Scottish Pathology Network (SPAN) guidelines. This includes use of a minimum dataset pro forma, if applicable to the specimen type being reported.
6d.2 NHS	The results of a minimum of 80% of the specimens submitted from colonoscopy are reported within 5 working days of receipt of the specimen to the histopathology laboratory.

Desirable Criterion

6d.3 NHS	The histopathology laboratory holds accreditation by Clinical Pathology Accreditation (UK) Ltd to ISO 15189 standards.
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Standard 7: Neoplasia yield

Standard Statement 7a

The number of cancers and adenomas detected in individuals attending for screening is optimised.

Rationale

The aim of the Scottish bowel screening programme is to reduce mortality from bowel cancer in individuals invited for screening.

References: 16, 28

Essential Criteria

7a.1 BSP	There is a minimum detection rate of 2.1 per 1,000 for individuals with invasive cancer(s) attending for prevalent screening.
7a.2 BSP	There is a minimum detection rate of 6.5 per 1,000 for individuals with adenoma(s) attending for prevalent screening.
7a.3 BSP	There is a minimum detection rate of 0.8 per 1,000 for individuals with high risk adenoma(s) attending for prevalent screening.

Standard 7: Neoplasia yield

Standard Statement 7b

The positive predictive value of the screening test should be appropriate.

Rationale

If the positive predictive value of the screening test is low then large numbers of individuals undergo unnecessary colonoscopy.

References: 23, 28

Essential Criteria

7b.1 BSP	The positive predictive value of the screening test for cancer should be at least 12% in prevalent screening.
7b.2 BSP	The positive predictive value of the screening test for total neoplasia should be at least 48% in prevalent screening.

Standard 7: Neoplasia yield (continued)

Standard Statement 7c

Screen-detected cancers should be diagnosed at an earlier stage than symptomatic cancers.

Rationale

The mortality reduction brought about by screening depends on detecting cancer at an early stage.

References: 2, 3, 4, 5, 28

Essential Criterion

7c.1 BSP	In prevalent screening, at least 45% of screen-detected cancers should be diagnosed at Dukes stage A (T1/2, N0, M0).
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Standard 7: Neoplasia yield

Standard Statement 7d

The number of interval bowel cancers diagnosed should be minimised.

Rationale

A high interval cancer rate indicates that the screening test is of insufficient sensitivity.

References: 2, 3, 4, 5, 28

Essential Criterion

7d.1 NSC	No more than 30% of all bowel cancers diagnosed in the population responding to the invitation to be screened should be classified as interval cancers.
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6 Appendices

Appendix 1 Membership of the draft clinical standards for bowel screening project group

Appendix 2 Evidence base

Appendix 3 Glossary

Appendix 4 The pilot bowel screening programme pathway

Appendix 1: Membership of the draft clinical standards for bowel screening project group

Name	Title	NHS board area/organisation
Professor Bob Steele (Chair)	Professor of Surgery	NHS Tayside
Dr Margaret Balsitis	Consultant Pathologist	NHS Ayrshire & Arran
Mrs Linda Colford	Bowel Screening Services Manager	NHS Tayside
Dr Paul Cormie	Macmillan Lead GP, Cancer and Palliative Care	NHS Borders
Mr Jim Docherty	Colorectal Surgeon	NHS Highland
Mr Keith Farrer	Lead Cancer Nurse	NHS Orkney
Dr Callum Fraser	Clinical Leader – Biomedical Medicine	NHS Tayside
Dr Margaret Kenicer	Consultant in Public Health Medicine	NHS Tayside
Mrs Carole Morton	Project Manager (Bowel Screening)	National Services Division, National Services Scotland
Dr Kel Palmer	Gastroenterologist & Chair of Joint Advisory Group	NHS Lothian
Ms Lorna Renwick	Immunisation & Screening Co-ordinator	NHS Health Scotland
Mr Tim Searles	Head of Operations, Bowel Cancer UK	Bowel Cancer UK
Mr Ian Swankie	Public Partner	Bowel Cancer UK
Mr Robert Stewart	Public Partner	NHS Ayrshire & Arran
Dr Steven Yule	Consultant Radiologist	NHS Grampian

Support from NHS QIS is provided by the Standards Development Unit: Mrs Anne Coote (Project Administrator), Ms Hilary Davison (Team Manager), Ms Clare Echlin (Senior Project Officer) and Miss Ali McAllister (Project Officer).

NHS QIS would like to thank the following for their input and support during the development of the draft clinical standards for the bowel screening programme:

- Mrs Maureen Atkinson (Colonoscopy Screening Nurse, NHS Fife)
- Mrs Margaret Briggs (Chair, Scottish Practice Nurses Association), and
- Ms Shelley Dewar (Nurse Endoscopist, NHS Fife).

Appendix 2: Evidence base

- 1 Information Services Division (ISD). Current - online source. *Colorectal Cancer Overview*. Information Services Division of NHS National Services Scotland. www.isdscotland.org/isd/cancer_definition.jsp?pContentID=1425&p_applic=CCC&p_service=Content.show URL accessed 27/06/06.
- 2 Hardcastle J, Chamberlain J, Robinson M, et al. 1996. Randomised Controlled Trial of Faecal Occult Blood Screening for Colorectal Cancer. *The Lancet*, **348** (9040): 1472-1477. www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=PubMed&cmd=Retrieve&list_uids=97098234&dopt=Citation [abstract] URL cited 27/06/06.
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Appendix 3: Glossary

adenoma	An area of the lining of the bowel (mucosa) which is made up of abnormally growing cells. This process is not sinister or life-threatening but benign. However, in a small number of cases it may lead to development of a tumour (carcinoma) that can malignantly spread through the bowel and to other parts of the body.
algorithm	A set of agreed or binding routines by which a process can be carried out.
audit	Systematic review of the procedures used for diagnosis, care, treatment, rehabilitation, examining how associated resources are used and investigating the effect care has on the outcome and quality of life for the patient.
barium enema	Technique for examination of the bowel. The colon is filled with a chalky liquid (barium) so that it will show up on an X-ray.
benign	Non-cancerous. Refers to tumours which grow slowly in one place and which, once removed by surgery, tend not to recur. However, some benign tumours may go on to become malignant. See malignant.
bowel	A tube-like structure running in its upper part from the stomach to the anus. It allows digestion of food and the discharge of waste products.
BSP	bowel screening programme
call-recall	The process used to invite people for a screening test.
cancer	The name given to a group of diseases that can occur in any organ of the body, and in blood, and which involve abnormal or uncontrolled growth of cells.
case review	Re-examination of the diagnosis and management of a person's condition at a defined point in time.
CHI	See Community Health Index.
clinical effectiveness	The extent to which specific clinical interventions, when deployed, do what they are intended to do, ie maintain and improve health, securing the greatest possible health gain from the available resources.
clinical governance	Ensures that patients receive the highest quality of care possible, putting each patient at the centre of his or her care. This is achieved by making certain that those providing services work in an environment that supports them and places the safety and quality of care at the top of the organisation's agenda. Management of clinical risk at an organisational level is an important aspect of clinical governance. Clinical risk management recognises that risk can arise at many points in a patient's journey, and that aspects of how organisations are managed can systematically influence the degree of risk.
Clinical Pathology Accreditation (CPA) UK	An accreditation process which requires laboratories to meet pre-determined standards. Website: www.cpa-uk.co.uk

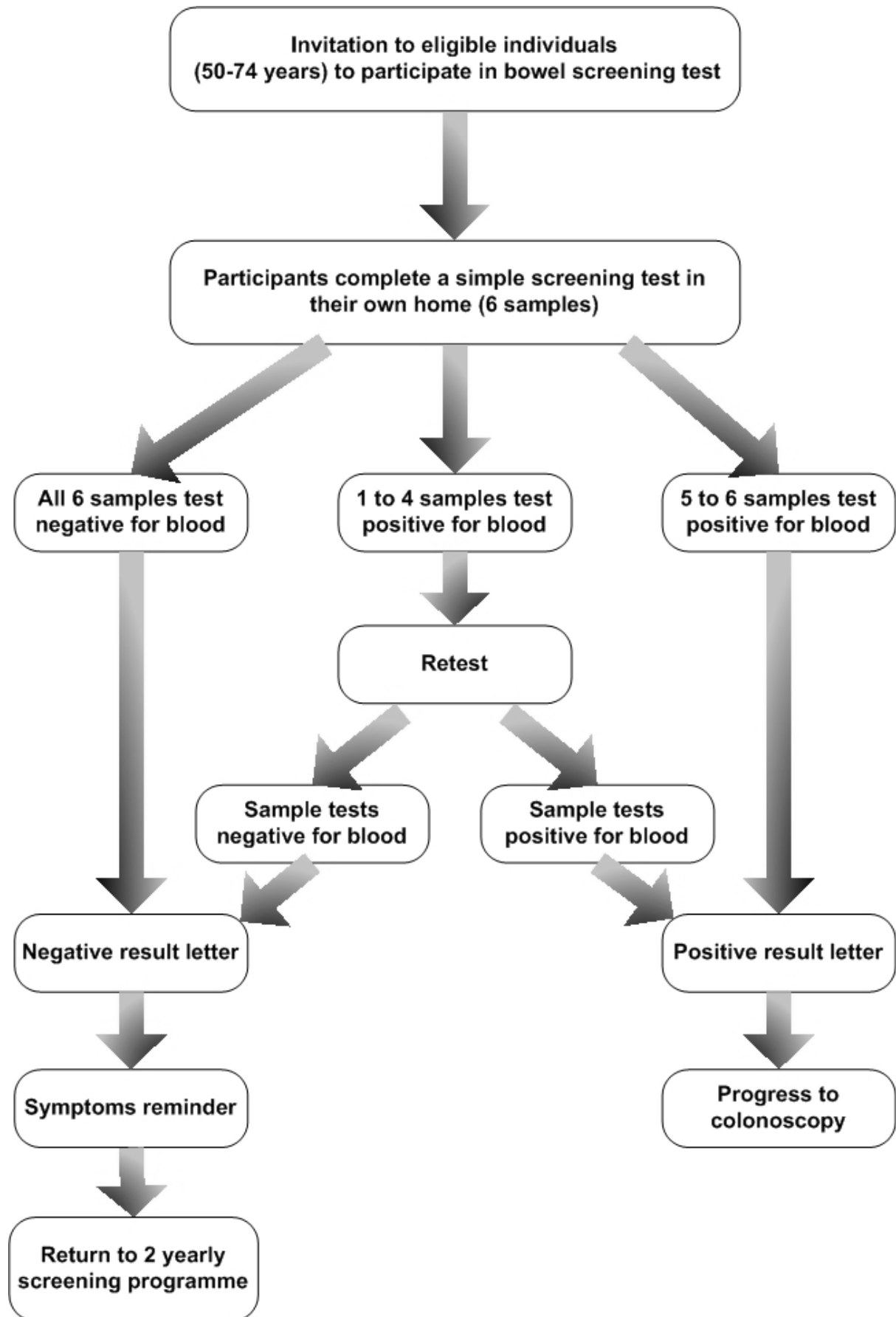
clinician	A healthcare practitioner who specialises in seeing, diagnosing and/or treating patients.
colon	Part of the bowel system. Also called the large intestine. This structure has six major divisions: caecum, ascending colon, transverse colon, descending colon, sigmoid colon and rectum. The total length is approximately five feet in the adult and it is responsible for forming, storing and expelling waste matter.
colonography	Computerised tomography of the abdomen and pelvis that focuses on the colon. See computerised tomography.
colonoscopy	Examination of the interior of the bowel using a long, flexible, instrument (a colonoscope) inserted through the anus. A colonoscope is capable of reaching to the upper end of the large bowel (colon) and can be used to diagnose diseases of the large intestine.
Community Health Index (CHI)	Provides a unique patient identifier that is allocated to every patient registered with a GP in Scotland. This 'CHI number' is entered onto a database that underpins a wide range of patient care processes in Scotland. There are strict controls on access to patient identifiable details.
computerised tomography (CT)	An X-ray imaging technique used in diagnosis that can reveal many soft tissue structures not shown by conventional radiography.
consultant in public health medicine (CPHM)	A senior doctor who specialises in the health of populations.
core competency	Fundamental knowledge, ability or expertise in a specific area or skill set.
criterion(sing)/ criteria(pl)	Provide the more detailed and practical information on how to achieve the standard.
CT	See computerised tomography.
desirable criterion/criteria	Good practice that is being achieved in some parts of the service and demonstrates levels of quality to which other providers of a similar service should strive.
Dukes stage	Category of tumour defined by internationally agreed criteria. Stages defined by Dukes range from Stage A, which is cancer limited to the bowel wall, to Stage C, where the cancer has spread to nearby lymph nodes. Stage D has been added to this system to include cancers with metastatic spread. See also metastasis and staging.
essential criterion/criteria	A criterion that should be met wherever a service is provided.
evidence-based practice	Evidence-based clinical practice is an approach to decision-making in which the clinician uses the best evidence available, in consultation with the patient, to decide upon the option which suits that patient best.
faeces	The waste matter eliminated from the body through the anus (other names are stools and motions).
faecal occult blood test (FOBT)	Test to check for any blood that might be hidden (not visible to the human eye) in the faeces. Blood may arise from bleeding anywhere along the digestive tract, from the mouth to the anus.
failsafe	With reliable back-up.

Health Department Letter (HDL)	A formal communication from the Scottish Executive Health Department to NHSScotland (previously known as a Management Executive Letter – MEL).
histopathology	The study of the structure, composition and function of tissues under the microscope, and of their abnormalities.
incidence	The number of new cases of a disease within a defined group of people over a period of time.
interval cancer	A cancer that occurs in the interval following a screening test with a negative result and before the next routine screening episode.
ISO 15189 standards	A standard from the International Organization for Standardization (ISO) which specifies requirements for quality and competence particular to medical laboratories. Website: www.iso.org
malignant	Tumours which can invade and destroy surrounding tissue and have the capacity to spread. A tumour which is the result of such spread is known as 'secondary' or 'metastatic'.
meta-analysis	Statistical method for the analysis of more than one randomised controlled trial. It allows for a synthesis of summaries and conclusions and may be used to evaluate therapeutic effectiveness or to plan new studies. See randomised clinical trial.
metastasis	Spread of cancer from one part of the body to another.
morbidity	A diseased condition or state. The incidence of a particular disease or group of diseases in a given population during a specified period of time.
mortality (rate)	The number of deaths in a given population during a specified period of time.
multidisciplinary co-ordinating group	A group of people from different disciplines (both healthcare and non-healthcare) who work together to provide care for patients with a particular condition. The composition of multidisciplinary teams will vary according to many factors. These may include the specific condition, the scale of the service provided and geographical/socio-economic factors in the local area.
multi-professional	Consisting of members of more than one profession.
National Services Division (NSD)	The division of NHS National Services Scotland with responsibility for ensuring the provision of national screening programmes and specialist services on behalf of NHSScotland. Website: www.show.scot.nhs.uk/nsd/
national standards	Standards defined at a national level.
negative screening test result	A screening result that is less than the specified cut-off level for a 'positive' result. A positive result indicates a need for further tests or treatment.
NHS	National Health Service
NHS board	There are 22 NHS boards of two types: 14 territorial boards responsible for healthcare in their areas and eight special health boards which offer supporting services nationally. See NHS board (territorial) and special health board.

NHS board (territorial)	There are 14 territorial boards, the mainland being covered by 11 and the island groups (Orkney, Shetland and the Western Isles) by three. They are responsible and accountable for strategic planning, service delivery, performance management and governance within their local areas. Each NHS board uses the organisational building blocks of NHS direct care, such as community health partnerships or operating divisions, in a way which suits its geography and population. NHS boards work together in regional planning arrangements for those services which require that wider perspective. See community health partnership, NHS operating division and single system working. Website: www.show.scot.nhs.uk/organisations/orgindex.htm
NHS Quality Improvement Scotland (NHS QIS)	NHS QIS has been established (January 2003) to lead in improving the quality of care and treatment delivered by NHSScotland. To do this it sets standards and monitors performance, and provides NHSScotland with advice, guidance and support on effective clinical practice and service improvements. Website: nhshealthquality.org
NHSScotland	The National Health Service in Scotland
non-attenders	Eligible people who do not attend following an invitation for screening.
NSC	national screening centre
peer review	Review of a service by those with expertise and experience in that service, either as a provider, user or carer, but who are not involved in its provision in the area under review. In the NHS QIS approach, all members of a review team are equal.
polyp	A growth, usually benign, which protrudes from the lining of the bowel causing a lump or bump.
polypectomy	The surgical removal of a polyp.
population-based screening	An investigation available to all eligible, apparently healthy people. The aim is to identify a disease or abnormality which may be treated, cured or prevented, before symptoms appear.
positive predictive value	The ratio of true positive test results to all positive test results. For example, a positive predictive value of 10% means that 10 individuals are expected to have the disease for every 100 with a positive test result.
positive test result	A screening result that is above the specified ceiling for a 'negative' result. A positive result indicates a need for further tests or treatment.
prevalent screening	A person's first screening for a condition.
primary care	The conventional first point of contact between a patient and the NHS. This is the component of care delivered to patients outside hospitals and is typically, though by no means exclusively, delivered through general practices. Primary care services are the most frequently used of all services provided by the NHS. Primary care encompasses a range of family health services provided by GPs, dentists, pharmacists, optometrists and ophthalmic medical practitioners.

protocol	A set of operational instructions to regulate activity. Protocols may be national, or agreed locally to take into account local requirements.
public partner	A member of the general public who is included in a professional group.
randomised control trial (RCT)	Seeks to measure and compare the outcomes of two or more clinical interventions. One intervention is regarded as the standard of comparison or control. Random allocation means that all participants have the same chance of being assigned to each of the study groups (Alejandro R Jadad).
recall	The part of a screening system whereby a person is recalled for a repeat screen or an assessment appointment. This includes routine recall and early recall.
referral	The process by which a patient is transferred from one professional to another, usually for specialist advice and/or treatment.
Scottish Executive Health Department (SEHD)	The Scottish Executive Health Department is responsible for health policy and the administration of NHSScotland. Website: www.show.scot.nhs.uk/sehd
screening	A public health service offered to groups of the population to identify risk of a particular disorder or disease. This, therefore, involves examination of people with no symptoms, to detect unsuspected disease.
screening episode	A cycle of a person's screening events.
staging	Process of describing whether cancer has spread from its original site to another part of the body. Staging involves clinical, surgical and pathology assessments.
standard statement	An agreed statement of required performance.
T1/2, N0, M0	See TNM classification.
TNM classification	TNM classification provides a system for staging the extent of cancer. T refers to the size of the primary tumour. N refers to the involvement of the lymph nodes. M refers to the presence of metastases or distant spread of the disease. It gives more detail than Dukes staging. See Dukes stage and staging.
vertical audit	Involves randomly selecting a sample or request and following an audit trail to ensure that all procedures are in place to carry out the sample analysis and to determine compliance with the relevant standards.

Appendix 4: The pilot bowel screening pathway



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NHS Quality Improvement Scotland

Edinburgh Office
Elliott House
8-10 Hillside Crescent
Edinburgh EH7 5EA

Phone: 0131 623 4300
Textphone: 0131 623 4383

Glasgow Office
Delta House
50 West Nile Street
Glasgow G1 2NP

Phone: 0141 225 6999
Textphone: 0141 241 6316

Email: comments@nhshealthquality.org
Website: www.nhshealthquality.org

