Northern Ireland Bowel Cancer Screening Programme

Inaugural Report

April 2010 – March 2013

Published: 30 October 2014

(amended: 3 December 2014)

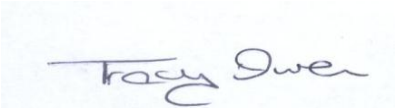
Contents

Foreword

This report describes the experience of the Northern Ireland Bowel Cancer Screening Programme in its first three years of operation to end March 2013. It includes descriptions of how the programme functions, developments which have been introduced, measures of the quality of the service against key standards and reports on the outcomes achieved.

The success of the screening programme to date reflects the hard work and commitment of the many staff who have been involved in its development and operation. From those who answer the calls to the telephone helpline, to the lab technicians who process and report the test kits, to the expertise of the colonoscopy teams. All have embraced the programme with enthusiasm and have strived to provide a high quality service to all participants. Their efforts are also recognised in the positive feedback received from participants, many of whom have taken the time to write letters or send emails to express their thanks for an efficient and positive experience of the health service.

However, there are still challenges to meet as we move forward including how we improve participation rates in the programme through promotion of informed choice among the eligible population. Screening programmes never stand still and we will continue to monitor the quality of the service provided, ensuring that it is benchmarked against similar programmes elsewhere in the UK and adapting to and embracing change and service improvement where required.



Dr Tracy Owen
Consultant in Public Health Medicine,
Lead for NI Bowel Cancer Screening Programme

1 Introduction

The Northern Ireland Bowel Cancer Screening Programme (BCSP) was launched in April 2010 with the aim of reducing the mortality and morbidity from colorectal cancer through early detection and treatment.

Colorectal (bowel) cancer is the second most common cause of cancer death in Northern Ireland. Each year almost 1,200 people are diagnosed with the disease and approximately 425 die from it. However, it is well recognised that when bowel cancer is detected at a very early stage there is a 90% chance of successful treatment.

The screening programme is aimed at people who do not have any symptoms and uses a home collection kit which is then analysed to detect traces of blood in the stools. This is called a guaiac faecal occult blood test (FOBt). The test is simple to do and the sample can be collected within the privacy of the participant's own home.

The presence of hidden blood in the stools is an indicator that further investigations are required as the participant may be at risk of bowel cancer. Those participants who have a positive screening result are offered a colonoscopy procedure to visualise the bowel.

This inaugural report describes the elements of the screening pathway and the monitoring and key performance data to end March 2013.

1.1 The target population and roll out

The screening programme started to issue invitations to the target population from April 2010. The initial eligible population were men and women aged 60-69 years who were registered with a General Practitioner (GP) within Northern Ireland. To participate in screening a participant must be invited by the programme. There is no facility at this time for individuals to self-refer.

A phased roll out was undertaken across Northern Ireland by Health and Social Care Trust area. This roll out was dependent on when each Trust was in a position to provide screening colonoscopy services. The timeline in which screening commenced in each Trust area is shown in Figure 1.

Figure 1: Timeline of phased roll out and significant developments in the NI BCSP

2010	April	screening commenced Northern and Western Trusts
	May	
	June	screening commenced South Eastern Trust
	July	
	August	
	September	
	October	
	November	
	December	
2011	January	
	February	
	March	
	April	high risk surveillance programme commenced
	May	
	June	
	July	
	August	
	September	
	October	
	November	screening commenced Belfast Trust
	December	
2012	January	screening commenced Southern Trust
	February	
	March	
	April	age extension introduced to include 60-71 year olds
	May	
	June	

Invitations for the first round of screening were based on an individual's birthday and the Health and Social Care Trust of their registered GP. Once screening commences in a Trust area, it takes up to two years to invite all of the eligible population in that Trust to participate. The Northern, Western and South Eastern Trusts completed their first round

of screening by March 2012. The Belfast and Southern Trusts completed their first rounds by end December 2013. At April 2012, the eligible age range to participate in the screening programme was extended to include men and women aged up to 71 years.

2 Call recall

2.1 Call recall process

The call recall function of the BCSP is delivered by the Business Services Organisation (BSO) through a team based in Franklin Street, Belfast. The BCSP team are co-located with the Family Practitioner Services (FPS) staff and those who support the call recall function of the Northern Ireland Cervical Screening Programme.

The National Health Authority Information System (NHAIS) records the contact details of all persons registered with a GP in Northern Ireland and is the demographic source used to populate the Bowel Screening Information Management System (BSIMS). Weekly call schedules are set up to identify those eligible for screening and control the volume of participants invited at one time. Invitations and test kits are issued via a contract with a mailing and distribution company.

Once an individual is identified on a weekly call schedule, they commence upon the first of the screening pathways. The detail of the screening pathways can be found on the programme website (www.cancerscreening.hscni.net). The flowchart at Appendix 1 shows a simplified version of the entire screening pathway.

Invitation packs include a personalised invitation letter, a barcoded FOBt kit, six applicator sticks, a foil postage-paid return envelope, and two supporting information leaflets: '*Bowel cancer screening: the facts'* and '*Bowel cancer screening: how to take the test'.* The invitation letter and leaflets give a full written explanation of the screening process. The kit is completed at home and returned in the envelope provided for processing and reporting.

A free telephone helpline is also available to the public to provide them with further advice on completing their test kit if required. The helpline is operated by call recall administrative staff.

Reminder letters are issued to those who do not return a completed test kit within six weeks of the invitation. After a further six weeks the individual is considered a non-

responder and is returned to routine recall to be invited to participate again in two years' time. A letter is issued to the individual and their GP informing them of the process. Should a non-responder submit a completed test kit after twelve weeks their screening episode is reopened and they continue along the screening pathway.

The quality of the demographic data held on NHAIS was found to be poorer than anticipated, with address, name and date of birth discrepancies being discovered when mail was returned undelivered or individuals contacted the helpline. This has resulted in a significant amount of additional administrative work to investigate and correct any discrepancies. The co-location of the BCSP team with the FPS staff has been beneficial in helping to facilitate this process.

2.2 Invitations issued

The BCSP issued over 250,000 invitation packs to end March 2013. As some people are now in their second round of screening, this represents 203,427 individuals. Nearly 100,000 non-responder letters were issued to GPs during that time.

Figure 2: Number of letters issued, April 2010 – March 2013

	Letters issued^
Invitation Pack	250,557
Invite Reminder without kit	146,580
Final Non Responder GP Notification	99,397

^ *Letters issued include first and second round participants*

2.3 Freephone Helpline

The freephone helpline is staffed from 9am to 5pm Monday to Friday, excluding public holidays. The helpline provides advice and reassurance for anxious participants and is a point of contact for general enquiries about the programme. Participants are able to

speak to a member of the call/recall team if they have any questions relating to the screening process, or to ascertain their eligibility for screening. The helpline is also used as the first point of contact for individuals who receive a positive screening test result.

The table below shows the volume of calls received in the last two quarters of 2012/13 and the percentage which were successfully answered. Call handling data is not available prior to October 2012.

Figure 3: Helpline data, October 2012 – March 2013

	Number of screening invitations issued	Number of helpline calls received	% of calls answered
Oct-12	11,275	1,614	92
Nov-12	9,059	1,350	94
Dec-12	9,608	1,048	92
Jan-13	10,555	1,870	90
Feb-13	9,965	1,673	87
Mar-13	10,962	1,531	87

An out of hours message advises callers of the opening times of the helpline. When the helpline was established, calls were directed to another available line, but the data above suggested that a proportion of calls were going unanswered when all the lines were busy. A call messaging service to advise callers that they are in a queue and can hold for an operator will be introduced in 2013/14 to improve this service.

3 Uptake

The method for calculating uptake is adapted from the other UK bowel cancer screening programmes to make the data more readily comparable. The formula used to calculate uptake is set out below.

$$\frac{\text{No. of people in the denominator with a complete screening test result } (\alpha) \text{ available}}{\text{No. of people invited } (\beta) \text{ in a specified period}} \times 100$$

α = FOBt negative, FOBt positive, FIT negative and FIT positive.

β = The number of people invited minus those who have emigrated or have no colon and those whose last kit is still within the compliance period or undelivered.

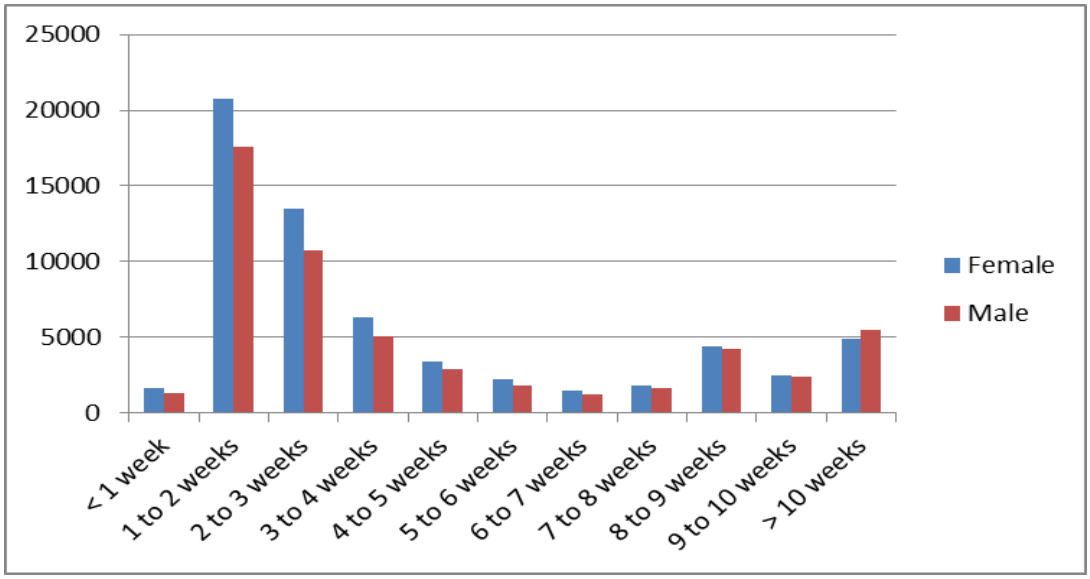
Analysis of uptake is run using a six month compliance period – i.e. the responder status six months after the initial invitation pack is issued.

3.1 Timing of return of kits

The majority of responders returned their test kit within the first few weeks of receiving it: 57% within three weeks and 72% within six weeks. The number of individuals returning kits each week decreased steadily until week seven to eight which coincides with the reminder letter issued at week six. This can be seen in Figure 4, which demonstrates that the reminder letter prompts the return of additional kits..

The vast majority of those who responded returned their test kit within six months from the date of receipt. There was approximately a 3% difference between uptake calculated using a twelve week compliance period and that using a six month compliance period. Kits returned after six months of issue, although processed and reported, were excluded from the uptake calculation.

Figure 4: Number of FOBt kits received by week from invite sent, April 2010 - March 2013



3.2 Uptake rate

DHSSPS Commissioning Directions target 2012/13: achieve uptake rate of 55%

Figure 5 shows uptake of the programme (six month compliance period) by financial year to end March 2013. This suggests there is a slow but upward trend in uptake rates as the programme has become more established in its three years of operation, with an improvement from 45.9% in year 1 to 49.8% in year 3.

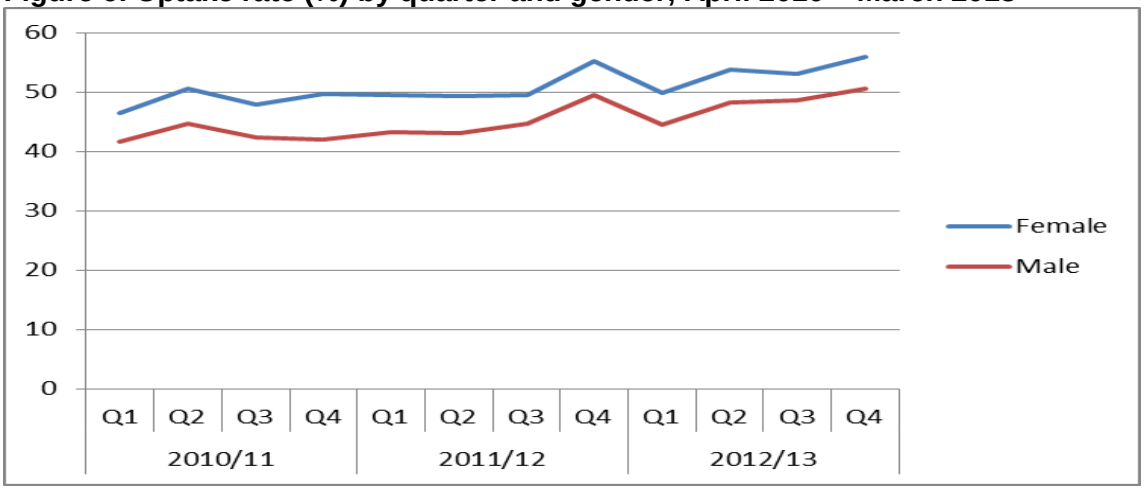
Figure 5: Northern Ireland uptake rate (%) for BCSP, by year

	Uptake rate (%)
April 2010 – end March 2011	45.87
April 2011 – end March 2012	48.30
April 2012 – end March 2013	49.79

3.3 Uptake by gender

Bowel cancer screening is the only cancer screening programme offered to both men and women. The pattern of uptake varies between genders (Figure 6).

Figure 6: Uptake rate (%) by quarter and gender, April 2010 – March 2013



There is a mean difference of 5.7% in uptake rates between genders, with uptake among women being higher. The noticeable peak in uptake rates in quarter 4 of 2011/12 coincides with the launch of a public information campaign to raise awareness of the programme.

3.4 Uptake by HSC Trust

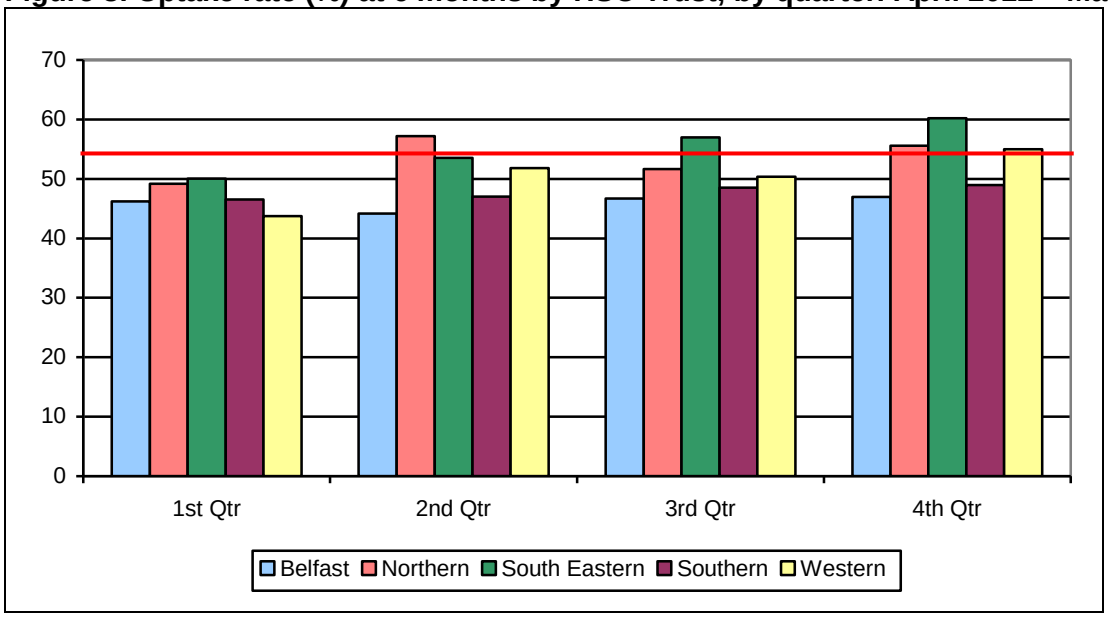
There have been differences in uptake rates between Health and Social Care Trusts. While the constant fluctuation in rates on a monthly basis makes it difficult to identify any sustainable trends, towards the end of 2012/13 uptake was lower in the Belfast and Southern HSC Trust areas. It should be noted that these were the last two Trusts to commence screening and at March 2013 were still in the first round of screening (prevalence round) for their populations.

Figure 7: Uptake rate (%) at 6 months by HSC Trust, by year.

	Belfast	Northern	South Eastern	Southern	Western
April 2010 – end March 2011	-	46.59	48.39	-	42.56
April 2011 – end March 2012	45.90	48.91	50.99	36.60	45.15
April 2012 – end March 2013	46.00	53.40	55.17	47.76	50.22

The Department of Health, Social Services and Public Safety applied a Commissioning Directions target of 55% uptake for the bowel cancer screening programme in 2012/13. At end quarter four of 2012/13, this target had been achieved across three of the five Trusts (Figure 8).

Figure 8: Uptake rate (%) at 6 months by HSC Trust, by quarter. April 2012 – March 2013



There is no published uptake data for the bowel cancer screening programme in England, and Scotland is not directly comparable as it offers screening from age 50. However, published data for the first round of screening in Wales (Oct 2008 – Nov 2010)

showed an overall uptake of 55.2% (female 58.8%, male 51.5%). It should be noted that Wales did not have a phased introduction and undertook a significant public information campaign to raise awareness of the programme before Bowel Screening Wales was launched.

3.5 Improving informed decision making

A number of initiatives were taken forward prior to March 2013 to raise awareness of the bowel cancer screening programme and to promote informed decision making:

- A public information campaign was launched by the Minister in February 2012 to promote the programme. It included television and radio advertising, as well as posters in washrooms and on buses. The campaign ran February/March 2012 and was repeated in 2012/13.
- BCSP was the chosen theme of the PHA stand at the Balmoral Show in May 2012 and PHA staff provided input to stands at other health related events.
- Opportunities were taken to promote the programme at key times, such as bowel cancer awareness month, through PHA media activity.
- Trust staff involved in the delivery of the programme undertook local initiatives to raise awareness, including displaying posters on Trust premises and organising promotional events at local shopping centres in the Western area.

Further work is on-going with the Women's Resource and Development Agency (WRDA) and Cancer Focus NI to promote the programme to population groups who are less likely to participate.

4 Screening Laboratory

4.1 Laboratory process

The screening laboratory is based on the Causeway Hospital site, Coleraine. The laboratory receives, processes and reports all the BCSP test kits for Northern Ireland.

Completed test kits are received by the screening laboratory and logged onto the Bowel Screening Information Management System (BSIMS) for testing. This is supported by the use of a personalised bar coding system to ensure the received test kit matches the details of the individual it was issued to.

The processing and reporting of the FOBt kits is a qualitative manual process which involves laboratory technicians looking for a colour change on the test card when a test solution is applied.

Testing determines one of four possible outcome reports:

Test result	Description
Negative result	0 of 6 wells contain traces of faecal occult blood
Equivocal (unclear) result	1 to 4 wells contain traces of faecal occult blood
Positive result	5 to 6 contain traces of faecal occult blood
Spoilt test kit	Samples not suitable for testing

Individuals with an equivocal or spoilt test result are sent a faecal immunochemical test (FIT) by the call/recall office to provide a further sample.

4.2 Laboratory workload and results

To end March 2013, a total of 116,979 FOBt and 9,620 FIT kits were received by the screening laboratory. Figure 9 describes the validated result for all FOBt kits reported to end March 2013.

Some participants will have more than one test kit result and some will be in their second round of screening. The majority of FOBt kits were reported as negative (91.2%) and these participants were returned to routine recall to be invited for FOBt screening two years from their last result. A small proportion (0.3%) were reported as positive while 8.5% were either equivocal or spoilt and required further definitive testing. Wales reported a 0.4% FOBt positive rate in their first round of screening.

Figure 9: Number of FOBt kits reported by screening laboratory, by result and year

FOBt	Negative	Equivocal	Positive	Spoilt	Total validated tests
2010/11	19,770	1,631	79	306	21,786
2011/12	33,733	2,819	107	380	37,039
2012/13	53,101	4,079	137	740	58,057
TOTALS	**106,604**	**8,529**	**323**	**1,426**	**116,882**
total (%)	***91.21%***	***7.30%***	***0.28%***	***1.22%***	***100%***

Those who receive an equivocal or spoilt result are issued with a FIT kit which requires further stool samples from the participant. FIT kits can only result in a positive, negative or spoilt outcome (Figure 10).

Figure 10: Number of FIT kits reported by result and year

FIT	Negative	Positive	Spoilt	Total validated tests
2010/11	1,215	543	38	1,796
2011/12	2,155	926	36	3,117
2012/13	3,264	1,376	62	4,702
TOTALS	**6,634**	**2,845**	**136**	**9,615**
total (%)	***69.0%***	***29.59%***	***1.41%***	***100%***

Sixty-nine percent of FIT kits were reported as negative with 29.6% producing a positive result. This compares to a FIT positive rate of 30.7% reported by Wales.

The positivity and equivocal rates of the test kits are monitored by the laboratory on an ongoing basis and can fluctuate slightly according to the LOT numbers of the kits being used. The screening laboratory is working closely with colleagues in Scotland and elsewhere to ensure that reported results remain within acceptable control parameters.

4.3 Spoilt kits

Any test kit which is unsuitable for testing is recorded as spoilt. For the period April 2010 to end March 2013 the overall spoilt rate was 1.2% of all kits received for testing. Therefore the vast majority of people who complete a test kit are able to do so to a satisfactory level by following the instructions provided. Participants whose FOBt kit is spoilt are subsequently asked to complete a FIT kit as this requires fewer samples to be collected.

Those whose FIT kit is spoilt will be sent further FIT kits until they submit a testable kit. The reasons recorded for spoilt test kits are described in Figure 11.

The most common reasons for a spoilt test result are that the name or other personal identifiers which the participant has completed on the submitted kit differ to those held on the demographic database (35.7% of cases). While the laboratory and call/recall office make every effort to validate any differences to allow the test to be reported, this is not always possible and the BCSP must ensure that the right result is issued to the right individual. A small number of individuals appear to have on-going problems completing the test kits and in these cases the call/recall staff will make efforts to contact the individual directly to talk through their difficulties and offer advice.

Figure 11: Reason for spoilt result by spoilt code, April 2010 – end March 2013

	Number of test kits	%
Name on kit different to bar code	120	7.7
No dates on samples (received outside 20 days)	85	5.5
No dates on samples (received within 20 days and no positive wells)	90	5.8
No name on kit	191	12.3
Other identifier incorrect (DOB, initials or incomplete name)	244	15.7
Quality Control fail	1	0.1
Returned unused test kit, participant closing episode	59	3.6
Sample not applied correctly	240	15.4
Samples not tested within 20 days of first sample date	142	9.1
Spoilt test kit result (1st) (ie. spoilt FOBt followed by spoilt FIT)	333	21.4
Spoilt test kit result (2nd) (ie. spoilt FOBt followed by 2 spoilt FITs)	5	0.3
Technical fail, kit damaged in lab. Not tested or testing not completed	11	0.7
Test kit expired	10	0.6
Unused kit (no sample), no reason given for not completing in BSIMS or a letter	25	1.6
TOTAL	**1,556**	**100**

4.4 Laboratory turnaround times

NIBCSP standards:

100% of all kits should be tested within two working days of receipt in the laboratory

100% of positive results must be validated within one working day of being tested

Figure 12 documents the turnaround times achieved within the screening laboratory, as the number of days from the kit being logged onto BSIMS to when it was tested. All samples are expected to be logged on BSIMS as received on the day they enter the laboratory. Only 0.02% of kits were not tested and validated within two days of receipt.

Figure 12: Working days between kit logged on BSIMS to report validated, April 2010 – March 2013

No. of days	Number of FOBt kits	Number of FIT kits	Total kits received and tested	Cumulative % of kits tested
0	110,551	9,349	119,900	95.56
1	5,243	156	5,399	99.86
2	142	7	149	99.98
3	16	1	17	99.99
4	8	0	8	100
5	0	1	1	100
6	1	0	1	100
7	1	0	1	100
Total	**115,962**	**9,514**	**125,476**	**100**

Once a kit is tested, the result is validated before a report is issued to the participant. The BCSP standard is that 100% of positive results must be validated within one working day of being tested. The turnaround times for validation of positive results are illustrated in Figure 13. The laboratory met this standard with 97.76% of all positive kits being tested and validated on the same working day and 100% within one working day.

Figure 13: Working days between test logged on BSIMS to report validated for all positive results (April 2010 – end March 2013)

No. of days	Number of positive FOBt kits	Number of positive FIT kits	Total kits with positive result	Cumulative % of positive kits validated
0	316	2,784	3,100	97.76
1	7	64	71	100
Total	**323**	**2,848**	**3,171**	**100**

4.5 Screening test positivity rate

The positivity rate of the screening test measures the number of participants with a positive result as a proportion of all participants with a completed screening test result (i.e. either a positive or negative final result).

Figure 14: Positivity rate for the screening test by HSC Trust, April 2010 - March 2013

Trust	Number of participants with completed test result	Number of positive results	Positivity rate (%)
Belfast	14,206	429	3.02
Northern	36,016	996	2.77
South Eastern	30,971	752	2.43
Southern	12,259	333	2.72
Western	22,945	657	2.86

The positivity rate of the screening test for Northern Ireland, for the period April 2010 to end March 2013 was 2.72%. This compares to an overall positivity rate of 2.8% reported by Wales for their first round of screening.

The screening test positivity rate varied slightly by Trust, with Belfast having the highest rate at 3.02% compared to the South Eastern Trust which had a rate of 2.43%. This may reflect the differing prevalence of colorectal disease in these populations, but may also be influenced by the fact that the second round of screening had commenced in the South Eastern Trust from April 2012. It would be expected that a test positivity rate would be lower in the incident rounds of screening (second round and above) compared to that seen in the prevalent round of screening (first invite).

5 Pre-assessment for colonoscopy

5.1 Pre-assessment process

Once the screening test result is validated on BSIMS a letter is generated and queued for printing and posting by the call/recall office.

Those participants who receive a positive FOBt or FIT result progress onto the next stage of the screening pathway. They receive notification of their result by letter and are advised to call the telephone helpline to make an appointment for pre-assessment for colonoscopy.

Each Trust has one nominated screening colonoscopy centre and the pre-assessment takes place on this site. Each of these endoscopy units required accreditation by the Joint Advisory Group on Gastrointestinal Endoscopy in order to be approved as a bowel screening centre. The screening centres are listed below.

HSC Trust	Screening colonoscopy centre
Belfast	Belfast City Hospital
Northern	Whiteabbey Hospital
South Eastern	Downe Hospital
Southern	South Tyrone Hospital from June 2012 (previously Craigavon Area Hospital)
Western	Altnagelvin Area Hospital

The pre-assessment is carried out by a Specialist Screening Practitioner (SSP): a registered nurse, who will assess the individual's suitability for colonoscopy based on their medical history and current health.

The SSP will take this opportunity to reassure the participant that a positive test kit result will not necessarily result in a diagnosis of cancer at colonoscopy. This is important as although this is addressed in the literature provided with the positive result letter, participants often tend to focus on the potential for negative outcomes. The time

between the participant calling the helpline and their first offered date for SSP appointment should not exceed two weeks.

At pre-assessment the SSP is responsible for relaying the appropriate information regarding screening and colonoscopy so that the participant can make an informed decision whether or not to continue with the screening process. This includes explaining the risks and benefits of screening and ensuring participants are provided with a colonoscopy information sheet (developed by the Northern Ireland Cancer Network: NICAN) to take home and review. Participants are able to withdraw from screening at any stage.

If a participant is determined unsuitable for colonoscopy they will be offered CT Colonography (CTC) as an alternative investigation, as appropriate. SSPs should ensure a request for a CTC is submitted to the radiology department within 24 hours of the pre-assessment appointment.

Both endoscopy and radiology investigations require the use of bowel preparation to evacuate the bowel prior to the procedure. Participants for either procedure will have the use of bowel preparation and how to take it explained to them by the SSP. Where possible they will be able to collect this from the pharmacy department on site.

It is the responsibility of the SSP to record the pre-assessment outcomes onto the correct pro-forma on BSIMS. It is also their responsibility to track the participant through their screening pathway and record the patient journey and management accurately onto BSIMS.

5.2 SSP activity

The activity associated with the SSP clinics is detailed in Figure 15 by Trust. Over 3,000 SSP pre-assessments were offered in the first three years of the programme with an overall DNA rate from SSP appointment of only 1.07%.

Figure 15: SSP activity by HSC Trusts, April 2010 – March 2013

	Belfast	Northern	South Eastern	Southern	Western	Northern Ireland
Number of participants offered SSP appointment	413	918	706	303	672	3,049
Number of SSP appointments attended	406	882	675	299	667	2,966
Number of participants who did not attend their SSP appointment	5	17	5	2	3	32
DNA rate (%)	***1.23***	***1.89***	***0.74***	***0.67***	***0.45***	***1.07***
Number of participants who declined an SSP appointment^	2	19	26	2	2	51
Declines as a % of total offered appointment	***0.48***	***2.07***	***3.68***	***0.67***	***0.30***	***1.67***

^ *Participants who originally declined SSP appointment and then changed their mind and attended SSP appointment have been excluded.*

It is expected that some people who decline an SSP appointment will chose to have a colonoscopy or further investigation in the independent sector. These are undertaken outside the programme and the BCSP does not have any follow up or outcome data for these individuals. Anyone who declines an SSP appointment will remain within the screening pathway and will be invited to complete another FOBt in 2 years' time. They also have the opportunity to change their mind and progress with an SSP appointment at any time.

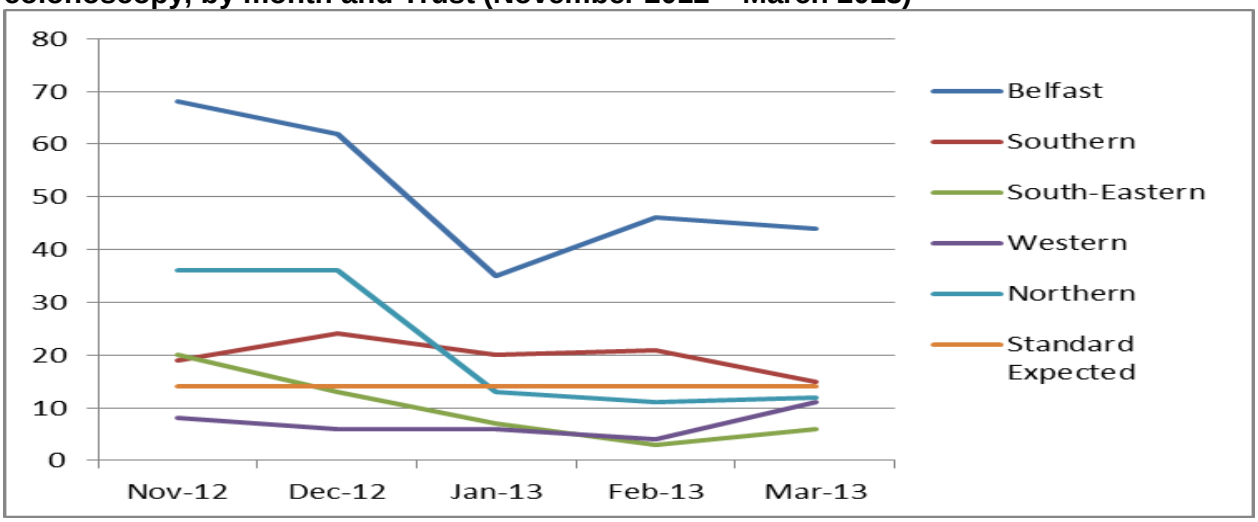
5.3 Waiting time to colonoscopy

NIBCSP Standard: In at least 95% of cases, the interval between the Specialist Screening Practitioner assessment appointment and the first date offered for colonoscopy is within 14 calendar days.

If determined fit for colonoscopy the SSP will immediately offer the participant a date for colonoscopy. This should be within two weeks of the pre-assessment clinic date.

The average number of days between the SSP clinic date and first offered date for colonoscopy is shown by Trust in Figure 16. This data is only available from November 2012. Although this information is captured by BSIMS it is currently not possible to extract it, so a manual recording method is being used as an interim solution.

Figure 16: Average number of days between SSP clinic and first offered date for colonoscopy, by month and Trust (November 2012 – March 2013)



At end March 2013, the average waiting time for screening colonoscopy in all Trusts, except Belfast, was within the 14 days.

5.4 Pre-assessment outcomes

Figure 17 shows the outcome for participants attending SSP pre-assessment clinics from November 2012 to end of March 2013. This data shows that 91.1% of participants attending for pre-assessment (first round and surveillance participants) were referred for colonoscopy. Ten patients (1.6%) decided not to continue on the screening pathway and declined any further investigation. A small but significant number of individuals (3.6%)

declined endoscopy but opted to have a CTC instead. This practice was particularly marked in the Western and Northern Trust areas. It is not recommended practice as CTC is a suboptimal investigation, does not facilitate biopsy and many of these patients are likely to still require endoscopy afterwards if any abnormality is noted at CTC. This has been highlighted to the Trusts and will continue to be monitored.

Figure 17: Outcome for participants attending SSP pre-assessment, Nov 2012 – Mar 2013

	Belfast	Northern	South Eastern	Southern	Western	**Northern Ireland (%)**
Accepted date for endoscopy	126	114	118	106	100	**564 (91.1)**
Unfit for endoscopy (referred for radiology)	3	3	2	2	8	**18 (2.9)**
Declined endoscopy (referred for radiology)	4	7	1	1	9	**22 (3.6)**
Declined further screening (return to routine recall)	3	2	4	0	1	**10 (1.6)**
Endoscopy not required at present (return to routine recall)	1	1	0	0	0	**2 (0.3)**
Temporary unfit (await outcome)	0	1	0	1	0	**2 (0.3)**
Ceased	1	0	0	0	0	**1 (0.2)**
Total participants pre-assessed	**138**	**128**	**125**	**110**	**118**	**619 (100)**

6 Screening colonoscopy

6.1 Screening colonoscopy process

The colonoscopy procedure is carried out in a nominated screening colonoscopy centre by an approved screening colonoscopist. This may be either a consultant or nurse endoscopist, who has completed the Northern Ireland 'Approval of Screening Colonoscopists' training course.

A full colonoscopy procedure visualises the entire large colon from rectum to caecum with the use of a colonoscope; a thin flexible tube with a tiny fibre-optic video camera at the end. Carbon dioxide is used to inflate the large colon to allow the colonoscope to pass through the bowel. The aim of the colonoscopy procedure is to visualise the colon wall to detect polyps. A polyp is an abnormal growth which can be either pedunculated or flat (sessile) against the colon wall. Some polyps can, if left in situ, develop into cancer.

Polyps detected at colonoscopy are excised and/or biopsies taken and submitted for histopathological assessment. There are three types of polyps:

- Benign – known as hyperplastic polyps these are no more likely than normal tissue to eventually become cancer
- Pre-malignant – known as adenomas and may develop into cancer
- Malignant

The pathology of the samples taken, along with their number and size, determine the participant's outcome and screening pathway. As per the guidelines of the British Society of Gastroenterology (BSG) the potential outcomes and further follow up from colonoscopy are:

- Normal colonoscopy (no histopathology taken or benign polyps only) – participant is returned to routine recall and will receive a FOBt kit two years from their last full screening colonoscopy.
- Low risk (1-2 small adenomas <10mm) – participant is returned to routine recall and will receive a FOBt kit two years from the participant's last full screening colonoscopy.
- Intermediate risk (3-4 small adenomas or at least 1 adenoma ≥10mm) – repeat colonoscopy three years from the participant's last full screening colonoscopy.
- High risk (5 or more adenomas or 3 adenomas with at least ≥10mm) – repeat colonoscopy one year from the participant's last full screening colonoscopy.
- Screen detected cancer – participant is referred to the multi-disciplinary team and suspended from screening for five years.

6.2 Screening colonoscopy activity

There are several aspects of the colonoscopy process that are monitored for quality assurance purposes. Due to limitations with BSIMS, data is compiled from an on-going manual SSP audit and is only available in this format from January 2012 onwards.

Figure 18: Number of screening procedures carried out by Trust, Jan 2012 – March 2013

	Belfast	Northern	South Eastern	Southern	Western	Northern Ireland
Colonoscopy (including year 1 surveillance)	310	446	332	258	277	1623
Repeat Colonoscopy	5	34	13	20	13	85
Flexible Sigmoidoscopy	15	47	30	28	28	148
Non endoscopic polypectomy	0	3	2	2	8	15
CTC/barium enema	14	74	12	15	40	155
Totals	**344**	**604**	**389**	**323**	**366**	**2026**

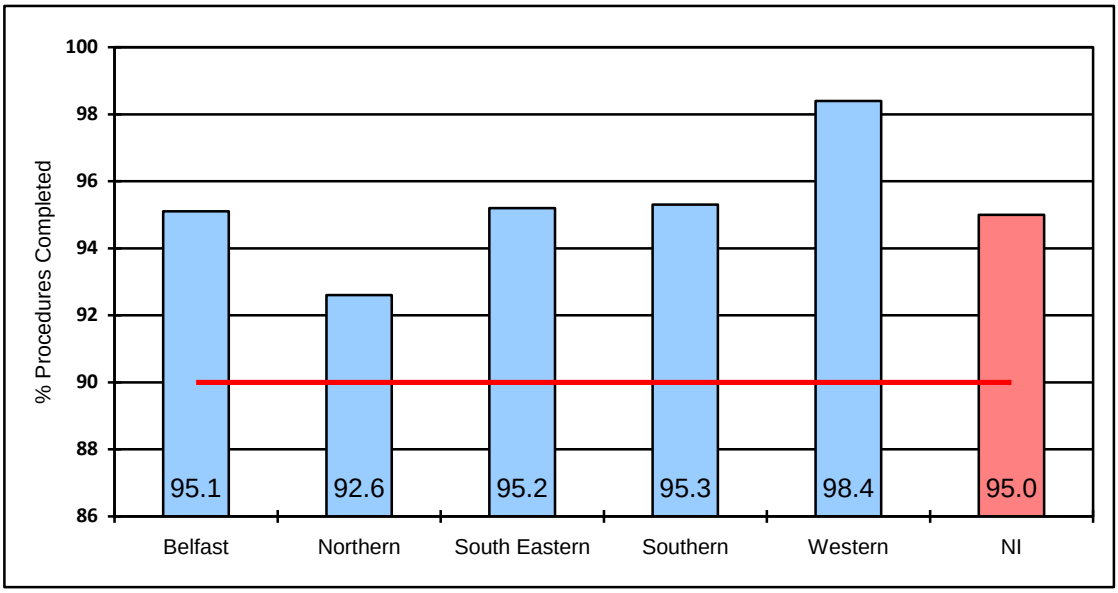
A total of 1,623 screening colonoscopies were undertaken during this period. In a small number of cases a repeat colonoscopy or an alternative flexible sigmoidoscopy may be required. This may occur where there are a large number of polyps involved or if polyps are incompletely excised during the first procedure. In 15 cases, at least one polyp of concern was inaccessible or irretrievable by conventional endoscopy and the participant proceeded to Endoscopic Mucosal Resection (EMR) or surgery to have it removed.

6.3 Caecal intubation rates

NIBCSP Standard: ≥ 90% of colonoscopies should achieve caecal or ileal intubation

Complete examination of the colon is the fundamental objective of colonoscopy and a marker of the quality of colonoscopy.

Figure 19: Caecal intubation rate by Trust, Jan 2012 – March 2013



To ensure that the entire bowel is visualised the standard states that at least 90% of colonoscopies attempted should achieve caecal or ileal intubation. Figure 19 shows the

percentage of all colonoscopies (including surveillance and repeats) successfully achieving caecal or ileal intubation. All Trusts exceeded this standard within the BCSP.

6.4 Polyp retrieval rate

NIBCSP Standard: ≥ 90% polypectomy specimens should be retrieved for histological analysis

The polyp retrieval rate is monitored by Trust and colonoscopist. At least 90% of polypectomy specimens should be retrieved for histological analysis.

Figure 20: Polyp retrieval rate by Trust, Jan 2012 – March 2013

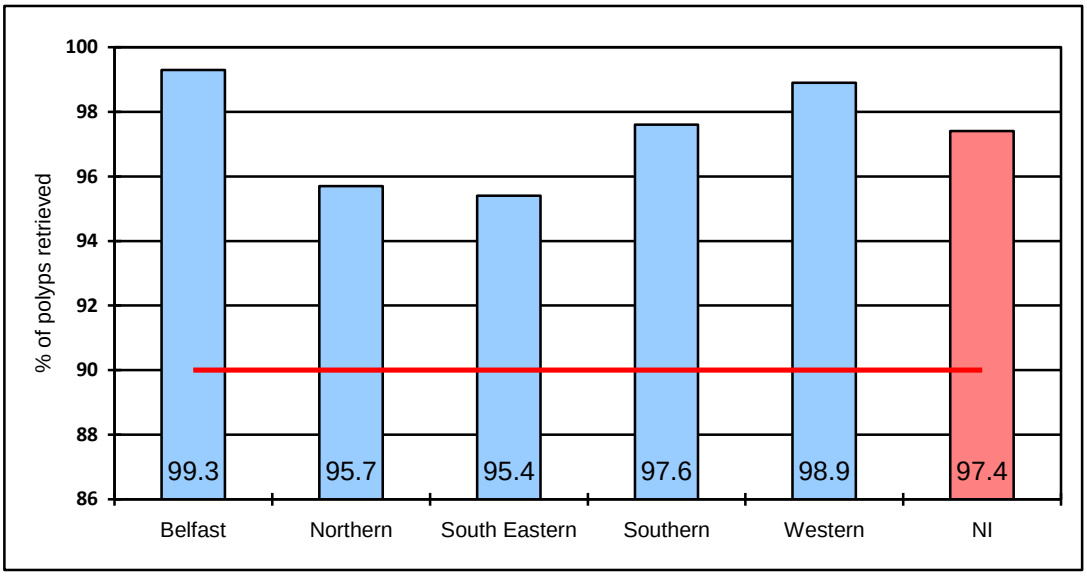


Figure 20 shows the retrieval rate of polyps excised by Trust. This has been calculated as the number of polyps retrieved for histological analysis as a percentage of the number of polyps which were excised. Polyps which were visualised during endoscopy but where excision was not attempted due to mitigating factors have not been included as such polyps would have been subsequently removed surgically and made available for

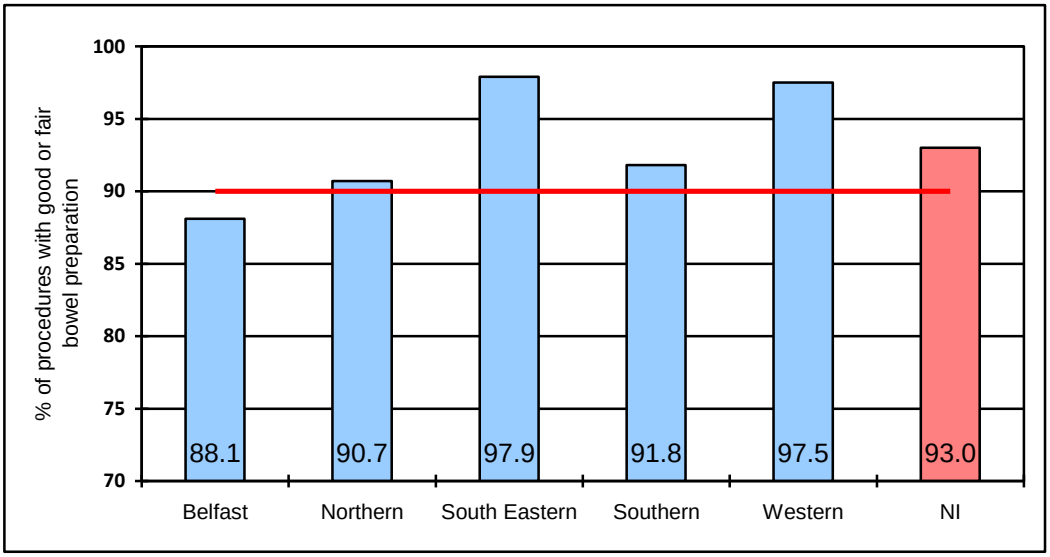
histological analysis by this means. All Trusts exceeded this standard for colonoscopies undertaken within the BCSP.

6.5 Bowel preparation

NIBCSP Standard: ≥90% bowel preparation described as excellent or adequate

A key element in the ability to undertake a satisfactory colonoscopy is to ensure there is adequate bowel preparation or clearance. Adequate bowel preparation maximises pathology detection and minimises the need for repeat procedures.

Figure 21: Percentage of all screening procedures where bowel preparation is categorised as good or fair, by Trust, Jan 2012 – March 2013.



The adequacy of bowel preparation is currently categorised on a three point scale as good, fair or poor. The standard is that 90% or more should be described as excellent or adequate. For the purpose of monitoring against the standard, those categorised as good or fair are regarded as equivalent to excellent or adequate respectively.

The effectiveness of bowel preparation for all screening endoscopy procedures by Trust is shown in Figure 21. Overall, the BCSP met this standard, with Belfast HSC Trust being the only Trust which was slightly below the 90% target.

6.6 Recorded significant events or adverse outcomes

All screening programmes can do harm as well as good. This may be due to over-diagnosis of disease resulting in unnecessary investigations and treatments, or through adverse outcomes linked to the screening process itself.

Colonoscopy is an invasive procedure. It requires the participant to take bowel preparation solutions in advance, they may require minor sedation during the procedure, bleeding can happen at the site where a polyp is removed and on very rare occasions, adverse events such as perforation of the bowel or even death can occur. On occasion the colonoscopist may decide to abandon the procedure (e.g. if the patient is too distressed or uncomfortable) or the patient may request that the procedure is stopped before it is completed.

It is therefore important that the screening programme monitors any significant events or adverse outcomes which occur in screening participants so that we can learn from these in the future.

Figure 22: Number of significant events/adverse outcomes occurring at endoscopy, by Trust. January 2012 - March 2013

	Belfast	Northern	South Eastern	Southern	Western	Northern Ireland
Procedure abandoned - colonoscopist decision	12	25	10	8	4	59
Procedure abandoned – patient request	0	4	2	6	1	13
Bleeding prompting admission	1	3	0	3	0	7
Other	1	0	0	0	0	1
Total	**14**	**32**	**12**	**17**	**5**	**80**

To end March 2013 there were no deaths or bowel perforations associated with bowel cancer screening in Northern Ireland. Figure 22 shows the occurrence of the recorded significant events/adverse outcomes during endoscopy procedures within the screening programme. The data presented here was collated through the SSP colonoscopy audit. Only seven patients required an overnight hospital stay due to bleeding following polyp excision.

A more formal and robust process for recording, reporting and sharing the learning from significant events and adverse incidents across all disciplines within the screening programme was agreed in April 2013. Future reports should include greater detail relating to adverse incidents and learning events.

7 Radiology

7.1 Radiology process

Participants unsuitable for colonoscopy are referred to radiology as appropriate for an alternative investigation. Not all individuals who are unfit for colonoscopy will necessarily be fit for CTC.

Participants should be referred to radiology on the same day they are deemed unsuitable for colonoscopy. They should be offered a date for radiological investigation within 14 calendar days of the clinician's decision that the participant is unfit for colonoscopy. The referrer must receive the results of all investigations within seven calendar days of the final procedure.

There is limited data on the radiology aspect of bowel screening at present. A new audit dataset has been developed and data started to be collected from May 2013. It is anticipated that more information will be available for future reports.

7.2 Radiology activity

A total of 155 radiological procedures were carried out in Northern Ireland as part of the BCSP between January 2012 and end March 2013 (Figure 23). The majority of these were CT Colonographies, with only three double contrast barium enemas being recorded.

Figure 23: Number of radiological procedures carried out, by Trust, Jan 2012 – March 2013

	Belfast	Northern	South Eastern	Southern	Western	NI
CT Colonography	14	74	9	15	40	152
Double Contrast Barium Enema	0	0	3	0	0	3

8 Histopathology

8.1 Histopathology process

Samples submitted for histopathological assessment are reported in accordance with the Royal College of Pathologists guidelines. Each Trust has one named laboratory to which BCSP specimens are sent. The Belfast laboratory also provides a service for the South Eastern Trust. Each laboratory has nominated staff to report on screening specimens.

A specific histopathology database has been developed to support the collection of standardised data on all specimens originating from the BCSP.

8.2 Laboratory turnaround times

NIBCSP Standard: Histopathology reports must be authorised and relayed to the referrer within seven days of receipt of the specimen in the laboratory.

Figure 24 documents the turnaround time of all cases recorded on the laboratory system, LabCentre, as bowel cancer screening specimens between April 2010 and end March 2013.

Figure 24: Number of days from specimen received in laboratory to histology report authorised, April 2010 – March 2013

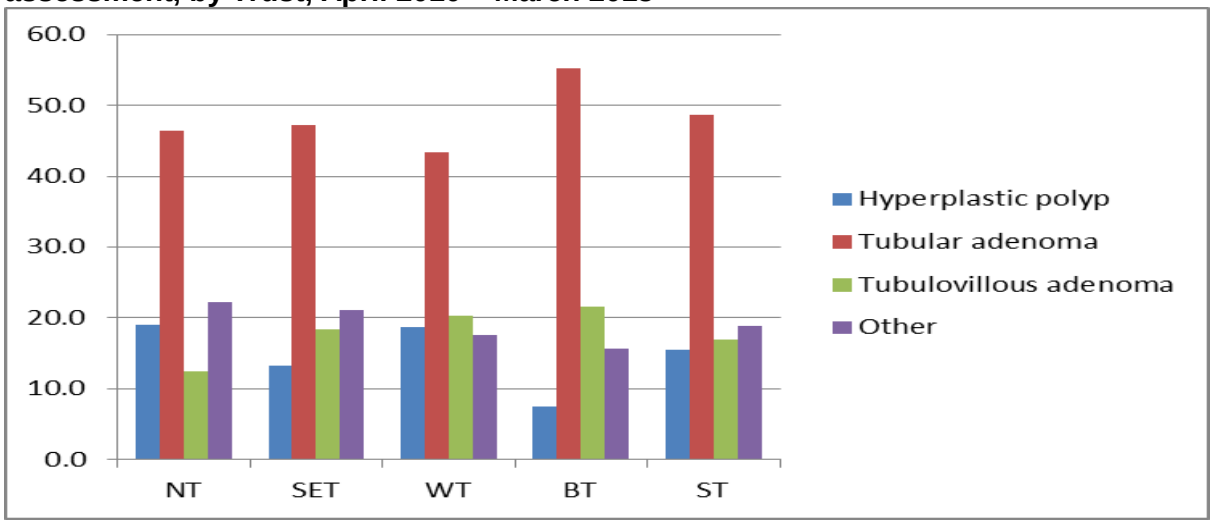
No. of Days	Belfast	Northern	South Eastern	Southern	Western	Northern Ireland	*Cumulative %*
0 – 7	202	457	490	253	242	1644	*95.0*
8 – 14	10	27	31	3	4	75	*99.3*
15 – 21	0	4	2	1	1	8	*99.8*
Over 21	0	4	0	0	0	4	*100*
Total	**212**	**492**	**523**	**257**	**247**	**1731**	***100***

Twelve cases were excluded from the analysis due to incomplete data. Overall, 95% of histology reports for the BCSP were authorised within seven days of the specimen being received in the laboratory.

8.3 Histological diagnosis

Histological analysis of BCSP specimens has uncovered many different diagnoses, including various types of adenomas, benign polyps and inflammation. Figure 25 shows the three most common diagnoses across each Trust, as a percentage of all specimens received for analysis; hyperplastic polyp, tubular adenoma and tubulovillous adenoma. All other diagnoses, including adenocarcinoma, are grouped as 'other'.

Figure 25: Histological diagnosis as a percentage of all specimens submitted for assessment, by Trust, April 2010 – March 2013



A total of 224 screen detected cancers were diagnosed in Northern Ireland from the launch of the programme in April 2010 to end March 2013.

9 Colonoscopy and CTC Outcomes

9.1 Colonscopy and CTC outcomes

Across Northern Ireland 1,665 people underwent further investigations (colonoscopy or CTC) within the bowel cancer screening programme between January 2012 and end March 2013 and had a final outcome recorded. The outcomes following these procedures are set out below. Some participants who were under high risk surveillance may be included twice as the time period is more than one year.

Figure 26: Colonoscopy/CTC outcomes, by Trust, for procedures undertaken Jan 2012 – March 2013.

	Belfast	Northern	South Eastern	Southern	Western	NI	***NI (%)***
Cancer detected	26	42	24	26	21	139	***8.3***
High risk adenoma	22	47	31	37	60	197	***11.8***
Intermediate risk adenoma	74	124	99	36	74	407	***24.4***
Routine recall^	190	270	168	144	150	922	***55.4***
Totals	**312**	**483**	**322**	**243**	**305**	**1665**	***100***

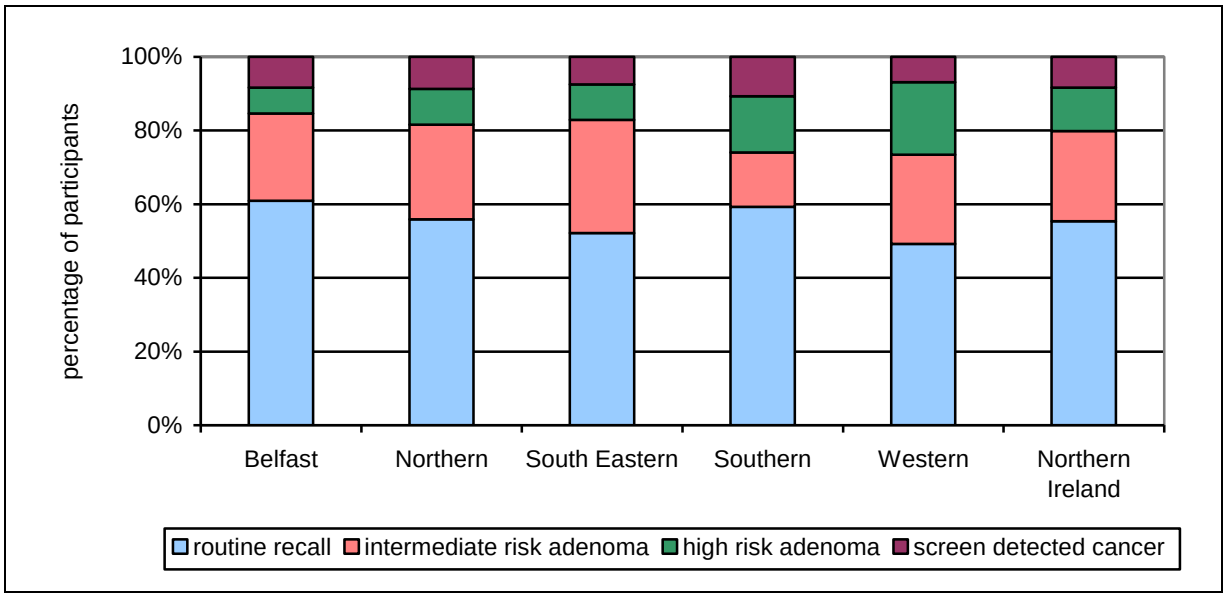
^ *Includes normal colonoscopies and low risk adenoma surveillance outcome*

Some variation in outcomes is seen across Trusts:

- the Western Trust had the lowest proportion of procedures with a final outcome of screen detected cancer - 6.9% which compares to the highest rate of 10.7% in the Southern Trust.
- a higher proportion of procedures in the Western Trust had an outcome of high risk adenoma compared to elsewhere – 19.7% in Western Trust compared to the lowest rate of 7.0% in the Belfast Trust.

- the outcome of intermediate risk adenomas in the South Eastern Trust (30.8%) was more than twice the rate seen in the Southern Trust (14.8%).

Figure 27: Percentage of colonoscopy/CTC outcomes, by Trust, for procedures undertaken Jan 2012 – March 2013.



These data should be interpreted with caution as the numbers of participants included in the analysis is still small. The reason for the above variations is not clear but may include demographic differences in the populations or differences in operator or reporting practice for colonoscopy. As the programme develops, and more colonoscopies and CTCs are undertaken, more robust data will become available at individual operator level.

10 Screen detected cancers

10.1 Number of cancers detected

From the launch of the programme in April 2010 to end March 2013 there were 224 screen detected colorectal cancers in Northern Ireland. These are illustrated below by gender and HSC Trust where the diagnosis was made (Figure 28).

There was a notable difference between genders in the screen detected cancers with 67.9% of all cancers diagnosed in men.

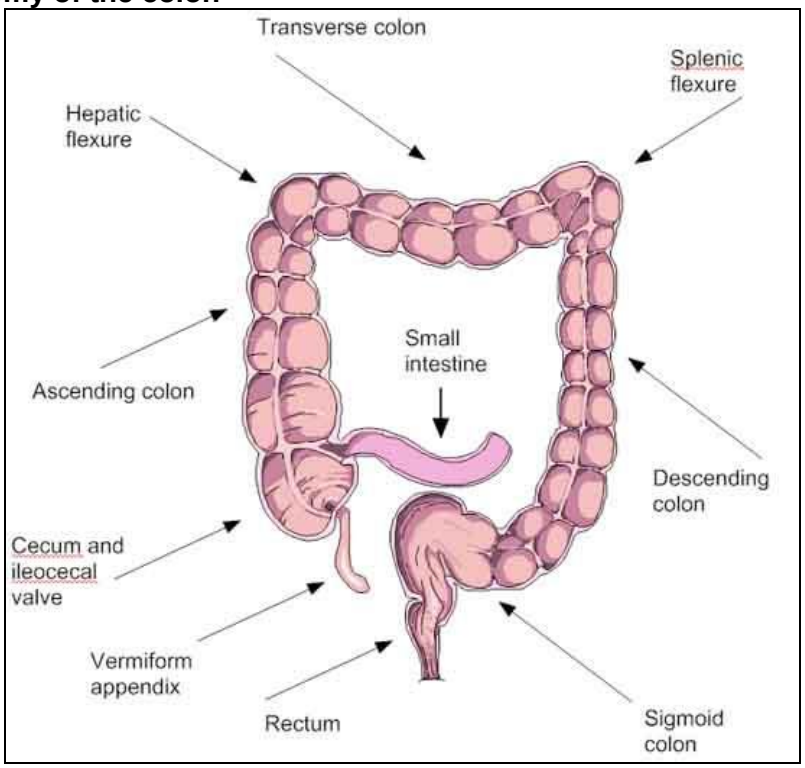
Figure 28: Number of screen detected cancers by Trust of diagnosis, April 2010 – March 2013

	Belfast	Northern	South Eastern	Southern	Western	Northern Ireland	***NI (%)***
Female	11	19	20	7	15	72	***32.1***
Male	13	51	39	13	36	152	***67.9***
Total	**24**	**70**	**59**	**20**	**51**	**224**	***100***

10.2 Site of screen detected cancers

Cancers can occur at any point along the length of the large bowel (colon) which is illustrated in Figure 29. The large bowel runs from the ileocaecal value at the caecum to the rectum. However, cancers are generally more common in the rectum and sigmoid colon areas.

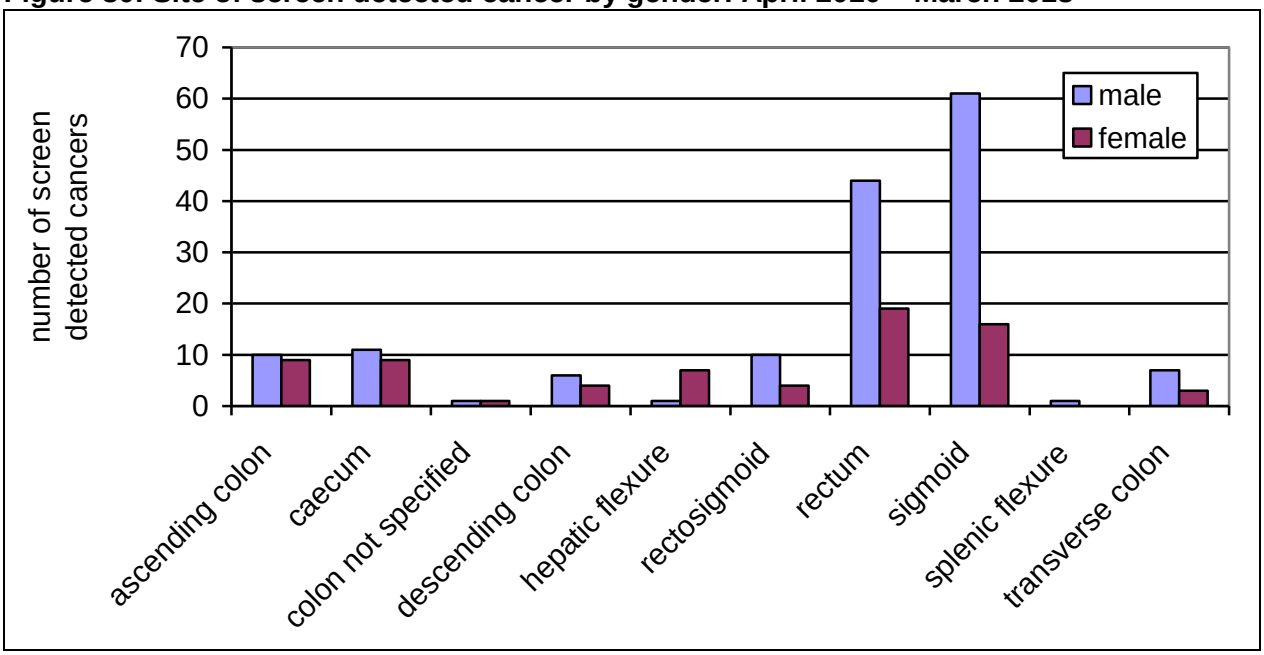
Figure 29: Anatomy of the colon



The site of each screen detected cancer has been recorded, with 68.8% located in the rectum or sigmoid colon (Figure 30).

Gender differences in the site of the screen detected cancers were noted. Men were more likely than women to have their cancer located in the sigmoid colon (40.1% vs 22.2%). While 34.7% of female cancers were detected in the proximal colon (ie. caecum, ascending colon or hepatic flexure) compared to only 14.5% of male cancers located in these sites.

Figure 30: Site of screen detected cancer by gender. April 2010 – March 2013



10.3 Staging

Participants whose sample detected cancer (adenocarcinoma) or adenocarcinoma limited to polyp are suspended from screening for five years and their care managed through the multi-disciplinary team within the Trust.

Bowel cancers are staged according to a classification scale called Dukes Staging. Very early stage cancers, where the disease is limited to a polyp are classified as Dukes A*. Dukes D is advanced disease with other organs involved.

Dukes A*	The cancer is located within the polyp and has not spread to the lining of the colon - no lymph nodes available for evaluation.
Dukes A	The cancer only affects the innermost lining of the colon – no node involvement or metastasis
Dukes B	The cancer has grown through the muscle layer of the colon – no node involvement or metastasis
Dukes C	The cancer has spread to at least one lymph node in the area no metastasis
Dukes D	The cancer has spread to somewhere else in the body

Not applicable (N/A)	Early staged cancers with a Tumour stage of 0 which cannot be graded using Dukes staging method. Cancer has not grown beyond the inner lining of the colon.
Not graded	Dukes staging is undetermined as the participant has been unfit for surgical resection or surgery has been delayed

Of the screen detected cancers in Northern Ireland which were staged, 46.7% of them were considered as early stage bowel cancers at diagnosis – these include Dukes A*, Dukes A and those specimens recorded as staging not applicable (N/A). Only 2.3% of the screen detected cancers were classified as Dukes stage D.

Figure 31: Dukes Staging of screen detected cancers, April 2010 – March 2013

Dukes stage	Female		Male		Total	
	No.	*%*	No.	*%*	No.	*%*
N/A	2	*2.9*	6	*4.2*	8	*3.7*
A*	6	*8.6*	26	*18.1*	32	*15.0*
A	21	*30.0*	39	*27.1*	60	*28.0*
B	26	*37.1*	35	*24.3*	61	*28.5*
C	15	*21.4*	33	*22.9*	48	*22.4*
D	0	*0*	5	*3.5*	5	*2.3*
Total	**70**	***100***	**144**	***100***	**214**	***100***

10.4 Crude cancer detection rate

The crude cancer detection rate is the percentage of all those with a completed screening test result available (i.e. positive or negative FOBt or FIT result) who go on to have a screen detected cancer. For the period April 2010 to end March 2013 the overall crude cancer detection rate for Northern Ireland was 0.21%. This is in line with the predicted modelling which suggested that 0.2% of those completing a screening test would have a screen detected cancer. A breakdown of the crude cancer detection rate

by Trust and gender is tabled below. The crude cancer detection rate in men is over twice that of women.

Figure 32: Crude cancer detection rate (%) by Trust, April 2010 – March 2013

	Belfast	Northern	South Eastern	Southern	Western	Northern Ireland
Female	0.11	0.15	0.14	0.10	0.12	0.12
Male	0.18	0.37	0.34	0.19	0.38	0.29
All	0.14	0.26	0.24	0.14	0.25	0.21

10.5 Positive predictive value

The positive predictive value of the screening test is the percentage of participants with a positive screening test result (positive FOBt or FIT) who subsequently have a screen detected cancer. The positive predictive value of the screening test for Northern Ireland, for the period April 2010 to end March 2013, was 6.8%.

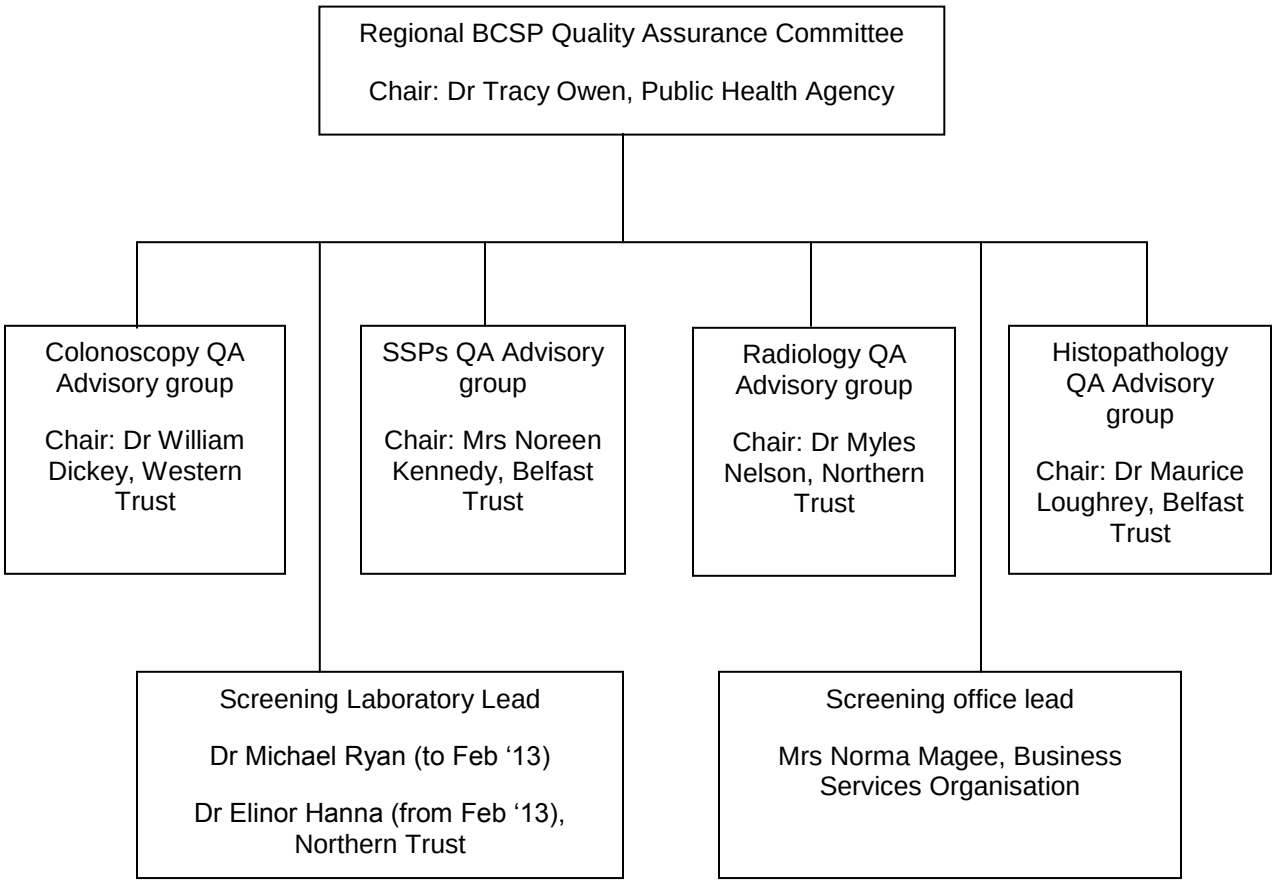
The positive predictive values by Trust and gender are shown in Figure 33, although these should be interpreted with caution, given the small number of screen detected cancers within each Trust.

Figure 33: Positive predictive value of screening test to cancer (%) by Trust. April 2010 – March 2013

	Belfast	Northern	South Eastern	Southern	Western	Northern Ireland
Female	7.6	6.0	6.0	5.6	4.4	5.9
Male	5.2	8.7	8.7	7.7	8.3	7.7
All	6.4	7.3	7.4	6.6	7.9	6.8

11 Quality Assurance

A quality assurance (QA) structure has been established to oversee the performance of the BCSP and provide advice and support on issues relating to quality. This has included the appointment of regional QA professional leads for each discipline and the introduction of a number of QA advisory groups. The QA structure is supported by the cancer screening Quality Assurance Reference Centre (QARC) within the Public Health Agency.



12 Next steps

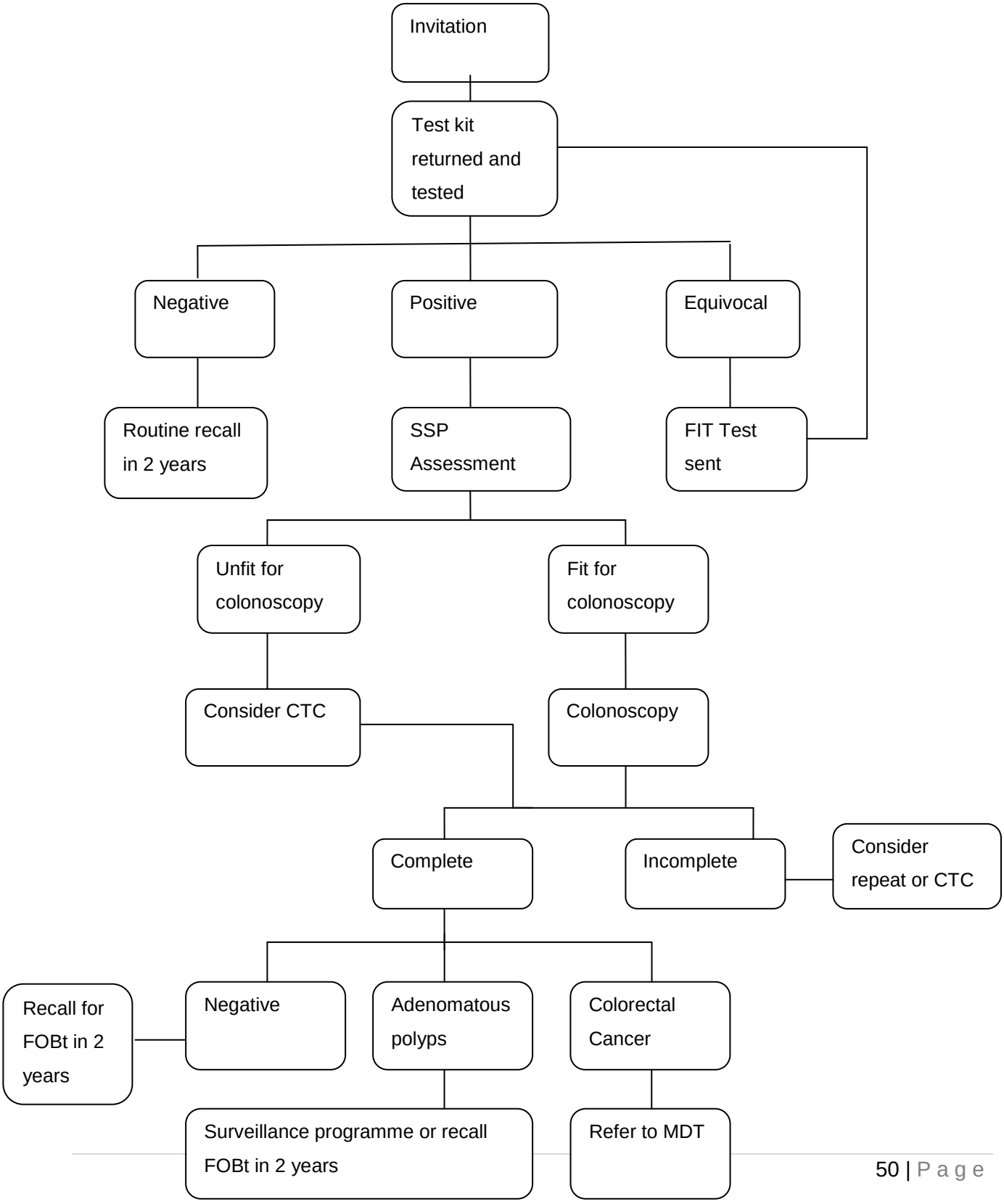
The first three years of the Northern Ireland Bowel Cancer Screening Programme have been challenging but successful. The programme is already demonstrating early detection of colorectal cancers and is having a potentially significant impact on the future incidence of cancers in the Northern Ireland population by detecting and removing premalignant polyps. The key challenges going forward are:

- Improving uptake through informed decision making
- Increasing and maintaining adequate capacity for screening colonoscopy
- Ensuring on-going development of the Bowel Screening Information Management System (BSIMS) to ensure it is fit for purpose to support the programme and its quality assurance
- Establishing systems to monitor and review interval cancers

The next significant change to the programme is to extend the eligible age range up to 74 years from April 2014. Work is on-going across all elements of the programme to ensure this deadline is achieved.

During 2013/14 the QARC intends to host the first multi-disciplinary conference for those involved in delivering the BCSP, continue to support and embed the quality assurance structures within the programme and introduce a patient satisfaction survey to obtain feedback on all aspects of the service provided. We are also working with the Women's Resource and Development Agendy (WRDA) to develop a new bowel screening module for the cancer screening community facilitator programme they currently deliver in the Belfast and South East Trust areas.

Appendix 1: Simplified screening pathway



List of Figures

Report produced by

Quality Assurance Reference Centre
Northern Ireland Cancer Screening Programmes
Public Health Agency
18 Ormeau Avenue
BELFAST
BT2 8HS

Tel: 02890 279381