



Cancer Screening Programmes



NHS Bowel Cancer Screening Programme

Piloting of Flexible Sigmoidoscopy

Advice to the NHS and bidding process

January 2012

NHS Bowel Cancer Screening Programme

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Description	FS is a complementary bowel screening methodology to the current FOB test, and could prevent around 3,000 cancers every year. Improving Outcomes: A Strategy for Cancer set out how we will incorporate FS into the current bowel screening programme, with 60% coverage across England by the end of 2014-15.	
Cross Ref	Improving Outcomes: A Strategy for Cancer (January 2011)	
Superseded Docs	N/A	
Action Required	N/A	
Timing	SHA clusters are invited to nominate pilot sites, with expressions of interest by 29 February 2012 and full bids by 30 March 2012	
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NHS Bowel Cancer Screening Programme

Piloting of Flexible Sigmoidoscopy

Advice to the NHS and bidding process

Contents

1. Introduction	5
Background	5
Flexible sigmoidoscopy (FS).....	6
Next steps.....	7
2. FS pilot sites – criteria	10
3. Practical details.....	13
Funding	13
National actions	13
Local actions.....	13
4. Further details and support	15
Annex A FS Screening Invitation Process	16
8 Week Timeline.....	16
Annex B FS Invitations Overview and Timeline	17
Annex C NHS Bowel Cancer Screening Programme.....	18
Bid for Flexible Sigmoidoscopy Screening pilot or first wave site	18
Annex D Regional Quality Assurance Directors.....	22

1. Introduction

- 1.1. Bowel cancer is a major health problem in England. In 2009, 32,751 people (18,227 men and 14,525 women) were diagnosed with bowel cancer and 12,691 people (6,892 men and 5,799 women) died of bowel cancer.
- 1.2. *Improving Outcomes: A Strategy for Cancer* (January 2011) set out how, in order to save 3,000 lives a year, the Department of Health has committed to invest £60 million between 2011 and 2015 to incorporate Flexible Sigmoidoscopy (FS) into the current bowel screening programme. Pilots will begin in 2012/13 with the aim of achieving 30% coverage by the end of 2013/14 and 60% by the end of 2014/15. It is envisaged that full roll-out will be achieved in 2016.
- 1.3. This document: sets out how the FS pilot programme will work; outlines the criteria for pilot and first wave site selection; and sets out how the four clustered Strategic Health Authorities (SHAs) can bid for their local bowel cancer screening centres to become FS pilot and first wave sites.

Background

- 1.4. Roll out of the original NHS Bowel Cancer Screening Programme using Faecal Occult Blood (FOB) home testing kits began in 2006, and full roll-out (all Screening Centres open) across England was completed in January 2010. The Programme is one of the first national bowel screening programmes in the world, and the first cancer screening programme in England to invite men as well as women.
- 1.5. Research undertaken in Nottingham¹ and Funen² in the 1980s showed that inviting men and women aged 45 to 74 for bowel cancer using the Faecal Occult Blood test (FOBt) could reduce the mortality rate from bowel cancer by 16%³. An independently evaluated pilot in Warwickshire and Scotland showed that this research can be

¹ Hardcastle JD, Chamberlain JO, Robinson MH, Moss SM, Amar SS, Balfour TW, James PD, Mangham CM. Randomised controlled trial of faecal-occult-blood screening for colorectal cancer. *Lancet*. 1996;348(9040):1472-7

² Kronborg O, Fenger C, Olsen J, Jorgensen OD, Sondergaard O. Randomised study of screening for colorectal cancer with faecal-occult-blood test. *Lancet*. 1996;348(9040):1467-71

³ Hewitson P, Glasziou P, Watson E, Towler B, Irwig L. Cochrane systematic review of colorectal cancer screening using the fecal occult blood test (hemoccult): an update. *Am J Gastroenterol*. 2008 Jun;103(6):1541-9

replicated in an NHS setting⁴. Based on the final evaluation report of the pilot and a formal Options Appraisal⁵, the programme in England is screening men and women aged 60 to 69. Experts estimate that by 2025, around 2,400 lives could be saved every year by the FOB testing element of the NHS Bowel Cancer Screening Programme.⁶

- 1.6. The NHS Bowel Cancer Screening Programme is currently being extended to men and women aged 70 and up to their 75th birthday. The Operating Framework for the NHS in England 2011/12 states that the age extensions begun in 2010/11 should continue and be maintained for 2011/12. Those centres whose end of original two-year screening round was in 2011/12 or falls in 2012/13 should implement the extension on immediate completion of the original round. The Operating Framework for the NHS in England 2012/13 stated that all deadlines for full roll-out of programmes highlighted in previous NHS Operating Frameworks should be completed within the established timescale.
- 1.7. Screening Centres must meet the agreed criteria for age extension and be approved by the National Office. As at January 2012, 35 of the 58 local screening centres had implemented the extension. When the age extension is fully rolled out in 2012, around 1 million more men and women will be screened each year.

Flexible sigmoidoscopy (FS)

- 1.8. FS is an alternative and complementary bowel screening methodology to FOBt. Evidence shows men and women aged 55 - 64 attending a one-off FS screening test for bowel cancer can reduce their mortality from the disease by 43% (31% on an invited population basis) and reduce their incidence of bowel cancer by 33% (23% on a population basis).⁷
- 1.9. A randomised controlled trial funded by Cancer Research UK, the Medical Research Council and NHS R&D took place in 14 UK centres, and evaluated screening for bowel cancer using a single FS between

⁴ UK Colorectal Cancer Screening Pilot Group Results of the first round of a demonstration pilot of screening for colorectal cancer in the United Kingdom *BMJ* 2004;329:133-5

⁵ Colorectal cancer screening options appraisal: Cost-effectiveness, cost-utility and resource impact of alternative screening options for colorectal cancer (School of Health and Related Research, University of Sheffield: report to the Department of Health, September 2004) www.cancerscreening.nhs.uk

⁶ Parkin, D.M., Tappenden, P., Olsen, A.H., Patnick, J., Sasieni, P., Predicting the impact of the screening programme for colorectal cancer in the UK. *Journal of Medical Screening*, 2008. 15: p. 163-174

⁷ The Lancet, [Volume 375, Issue 9726](#), p. 1624-1633, 8 May 2010

55 and 64 years of age, removing small polyps by FS and providing colonoscopy for "high risk" polyps.

- 1.10. The study concluded that FS is a safe and practical test and, when offered only once between ages 55 and 64 years, confers a substantial and long lasting benefit. Based on the trial figures, experts estimate the programme would prevent around 3,000 cancers every year. A similar trial with similar results took place in 6 Italian Centres. The UK National Screening Committee (UK NSC) reviewed the evidence, and in April 2011 concluded that screening for bowel cancer using FS meets the UK NSC criteria for a screening test. In England its implementation will be managed by NHS Cancer Screening Programme.

Next steps

- 1.11. In early 2011, pathfinder sites were identified to test organisational arrangements for the operation of FS screening, with particular attention to the invitation and appointment process. This has enabled optimal strategies to be applied in the development of the national pilot. The pathfinder sites were the Tees, South of Tyne and Derbyshire local screening centres. First invitations were issued from the pathfinder sites in January 2011, and the first clinic was held in February 2011. The Pathfinder project ceased in May 2011 as planned.
- 1.12. The valuable learning of the pathfinder sites has now enabled us to begin the pilot process in full. We envisage that the FS pilot will consist of at least five local screening centres (one per Hub), with the first wave of roll-out immediately following.
- 1.13. To achieve 30% coverage of England by March 2014, Wave 1 would consist of a further 15 local screening centres beginning in 2013/14. Similarly, to achieve 60% coverage by March 2015, Wave 2 would consist of a further 20 local screening centres beginning in 2014/15. The remaining local screening centres would begin as Wave 3 in 2015/16.

The Flexible sigmoidoscopy screening process

- 1.14. The FS screening process will be a one-off invitation to people aged 55 years. Screening Centres will need to ascertain the numbers of individuals in that age range over a 12 month period in order to calculate the number of people attending for a FS. The FS screening invitation process is shown at Annex B.

- 1.15. The FS demonstration had a 55% uptake for FS which is similar to acceptance of FOBt in the same areas⁸. The invitation to an individual will have the time, date and place for the FS appointment and will incorporate a reply slip in order for the individual to confirm their attendance. Enemas will be posted to the individuals when they have confirmed their intention to attend.
- 1.16. Screening Centres should therefore plan for an invitation capacity for all the eligible population. However, due to the anticipated acceptance rate the actual FS lists required are expected to be half of that number. The BCSS (Bowel Cancer Screening System) has been set up with this in mind and allows for 'double booking' of FS appointments with subsequent cancellations either explicitly or implicitly due to lack of response within the time limit. It is also anticipated that there will be a large proportion of re-booking of appointments and changes in lists.
- 1.17. A large proportion of this workload will be undertaken by the Programme Hubs but it is expected that there will be a Programme Manager in the Screening Centre who will, together with the administrators, manage this jointly with the Hubs. This will require an increase in and strengthening of the current programme management within Screening Centres in order to co-ordinate the whole of the screening centre's activities. The Clinical Director of the combined FS and FOBt bowel cancer screening programme should be a clinician who is directly involved in delivering part of the service.
- 1.18. Currently the Screening Centres see only 2% of participants who have a positive FOBt result. In future, they will deal with 100% of the invited population. In order to provide the endoscopy capacity to deliver FS across broad geographical areas, consideration will need to be given to potentially using community hospitals, polyclinics, or Independent Treatment Centres. Other options will include running evening and weekend lists, which, together with more local delivery of endoscopy, will make it easier for individuals to attend.
- 1.19. For a total population of 500,000, the anticipated figures for calculating numbers of FS lists (12 individuals per list) would be 10 FS lists required for invitation appointments but approx 5 lists actually will be attended (50% of invited population). Additional screening colonoscopy requirements would be one screening colonoscopy list per week for this total population.

⁸ Robb et al Flexible sigmoidoscopy screening for colorectal cancer: uptake in a population-based pilot programme *J Med Screen* 2010; **17**: 75-78

- 1.20. Screening centres should consider their workforce provision to manage the numbers of lists and to ensure that lists are not cancelled because of lack of endoscopy staff. All endoscopists will be required to undertake an assessment process and meet the minimum criteria before being able to perform FS on the screening population.
- 1.21. Individuals who on sigmoidoscopy examination are found to need full colonoscopy according to set national criteria (based on the FS trial) are to be managed with those requiring colonoscopy within the current programme. Lists can be merged and all current colonoscopy quality requirements will apply. Similarly where imaging is required for a small number of individuals Computerised Tomography (CT) scanning should be offered to the standards currently required in the screening programme.
- 1.22. In order to maximise appropriate use of resources and expertise, it is advised that there should be one central laboratory per screening centre where all polyps arising from the flexible sigmoidoscopy examinations are reported.

2. FS pilot sites – criteria

- 2.1. In order to ensure the quality and safety of symptomatic bowel cancer services and the colonoscopy element of the FOBt programme, the Department of Health and NHS Cancer Screening Programmes have agreed the following criteria for local screening centres expanding or opening in order to participate in both the FOBt and in the FS programme. The operation of FS alone will not be considered.
- 2.2. FS sites would ideally achieve the following criteria:
- i) Sustained operation of the FOBt programme and sustained implementation of the FOBt age extension (70 up to 75th birthday)⁹ while meeting the QA standards of the BCSP including waiting times for SSP appointment and screening colonoscopy
 - ii) Sufficient sustainable endoscopy capacity to deal with the increased workload with the expansion to incorporate FS and continued growth in surveillance
 - iii) Provision of CO2 for insufflation in accordance with European Guidelines for Quality Assurance of Colorectal Cancer Screening and Diagnosis
 - iv) Maintenance of full Joint Advisory Group on GI Endoscopy (JAG) accreditation at each endoscopy unit which offers screening colonoscopy
 - v) Maintenance of GRS scores:
 - waiting times at level A for a minimum of 3 months prior to commencing FS screening at all screening sites
 - waiting times at all other hospitals within the Trust must be at level A before FS screening can commence
 - at least level B for all other GRS scores
 - vi) Sustained achievement of the operational standards for the relevant cancer waiting times commitments:¹⁰

⁹ The Operating Framework for the NHS in England 2011/12, Department of Health (15th December 2010)
www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_122736.pdf

¹⁰ Dear Colleague letter, *Operational Standards for the Cancer Waiting Times Commitments*, Professor Sir Bruce Keogh, Department of Health (30th July 2009, Gateway ref: 12320)

Commitment	Operational Standard
All Cancer Two Week Wait	93%
62-Day (Urgent GP Referral to Treatment) Wait For First Treatment: All Cancers	85%
62-Day Wait For First Treatment From Consultant Screening Service Referral: All Cancers	90%

- vii) Identification of a single pathology laboratory with the capacity to deal with all the polyps arising from FS examinations in a screening centre. The laboratory would need two to four nominated consultant histopathologists who participate in the BCSP External Quality Assurance (EQA) scheme to report these samples. In addition, pathology laboratories which will report suspected colorectal cancers arising in the programme should also have an identified BCSP lead with whom the FS polyp reporting pathologists can liaise.
- viii) Sign off from the Regional Quality Assurance team, Trust Chief Executive and relevant commissioning organisation
- ix) It is envisaged that the population size to deliver FS would be 500,000 as a minimum and up to approx 1,000,000
- x) Confirmation of a commitment to advance equality of opportunity for groups with poor screening uptake, including identifying where difficulties lie in the local population and considering innovative strategies to engage with people who do not respond to their initial invitation.

In addition to the criteria above, the bid must provide the following detail:

- The proposed number of flexible sigmoidoscopy sessions at each of the named sites demonstrating the capacity and demand to deliver FS screening to the Screening Centre's population
- The screening centre weekly timetable for all screening activity identifying the staffing at all clinical sessions delivered locally and the names of the endoscopists and SSPs where available
- Confirmation that the pathology service will be able to meet the current requirements (as in para 2.2 vii)

- Information on the administration of the FS system including appointments and clinic management and links between the Screening Centre and the additional flexible sigmoidoscopy sites where appropriate for colonoscopy, pathology etc
 - Confirmation of the Screening Centre clinical team members with designated sessions in their job descriptions. The Director of the Centre must be a clinician directly involved in delivering the service at one of the sites
 - Identification of programme manager post (WTE and pay band)
- 2.3. Pilot sites should expect and accept that they will begin operations in a developmental phase of the new screening activity. This may involve some of the IT process not being fully developed and working closely with the national team. The national team recognises that additional support might be necessary for the start up period and this will be discussed with the pilot sites. Selection as a pilot site means a site is expected to continue operation into roll-out without any break in the provision of the current screening service.

3. Practical details

Funding

- 3.1. NHS Cancer Screening Programmes will retain and manage the funding of the FS pilot and rollout, which will be provided centrally as set out in *Improving Outcomes: A Strategy for Cancer*. Subject to the passage of the Health and Social Care Bill, Public Health England will be responsible for the piloting and roll-out of FS from April 2013. It is expected that funding will be transferred to the NHS Commissioning Board to commission local elements of the programme from 2016/17 onwards when FS is fully rolled out.

National actions

- 3.2. In addition to this advice and bidding information, NHS Cancer Screening Programmes will follow due process in assessing pilot and Wave 1 bids against the criteria and feeding back to successful and unsuccessful bidders. Ideally a timeline of when services will implement FS will be developed covering Waves 1, 2 and 3.
- 3.3. In addition, NHS Cancer Screening Programmes will develop an FS screening protocol with appropriate accompanying documentation. They will also develop an information pack for pilot sites, a support pack for primary care and national patient materials (eg letters, leaflets).

Local actions

- 3.4. Participation in the FS pilot by local screening programmes is voluntary. So as not to create a geographical inequality, it is desirable to have at least one FS pilot site in each of the four clustered SHAs and ideally one in each of the five hub areas. SHAs are advised to discuss potential pilot and first wave sites with their local Quality Assurance Directors and Cancer Networks. Potential bidders should complete the pro forma at Annex C.
- 3.5. In the first instance, bids to become an FS pilot or first wave site should be sent electronically or by post to :

Professor Julietta Patnick
Director
NHS Cancer Screening Programmes
Fulwood House
Old Fulwood Road
Sheffield S10 3TH
e-mail: Julietta.Patnick@cancerscreening.nhs.uk

- 3.6. Expressions of interest to submitted by **29 February 2012** and full bids should arrive no later than **30 March 2012**. We will aim to make decisions in April 2012.
- 3.7. Once a local screening centre has been confirmed as a pilot or first wave site, other local actions will include:
- i) Splitting current BCSP populations to establish a new screening centre where required in anticipation of the introduction of FS
 - ii) Identifying and resourcing the polyp reporting centre for the new screening programme
 - iii) Working with the local public health teams to raise awareness of the new programmed in the relevant population
 - iv) Educating primary care
 - v) Preparing to deliver the agreed FS screening pathway to the required quality and timeliness standards including establishment of new posts and clinics
 - vi) Participating in evaluation, data collection and quality assurance protocols and procedures as required by the national programme
 - vii) Adhering to clinical governance processes within the host trust
 - viii) Adopting national template letters/leaflets

4. Further details and support

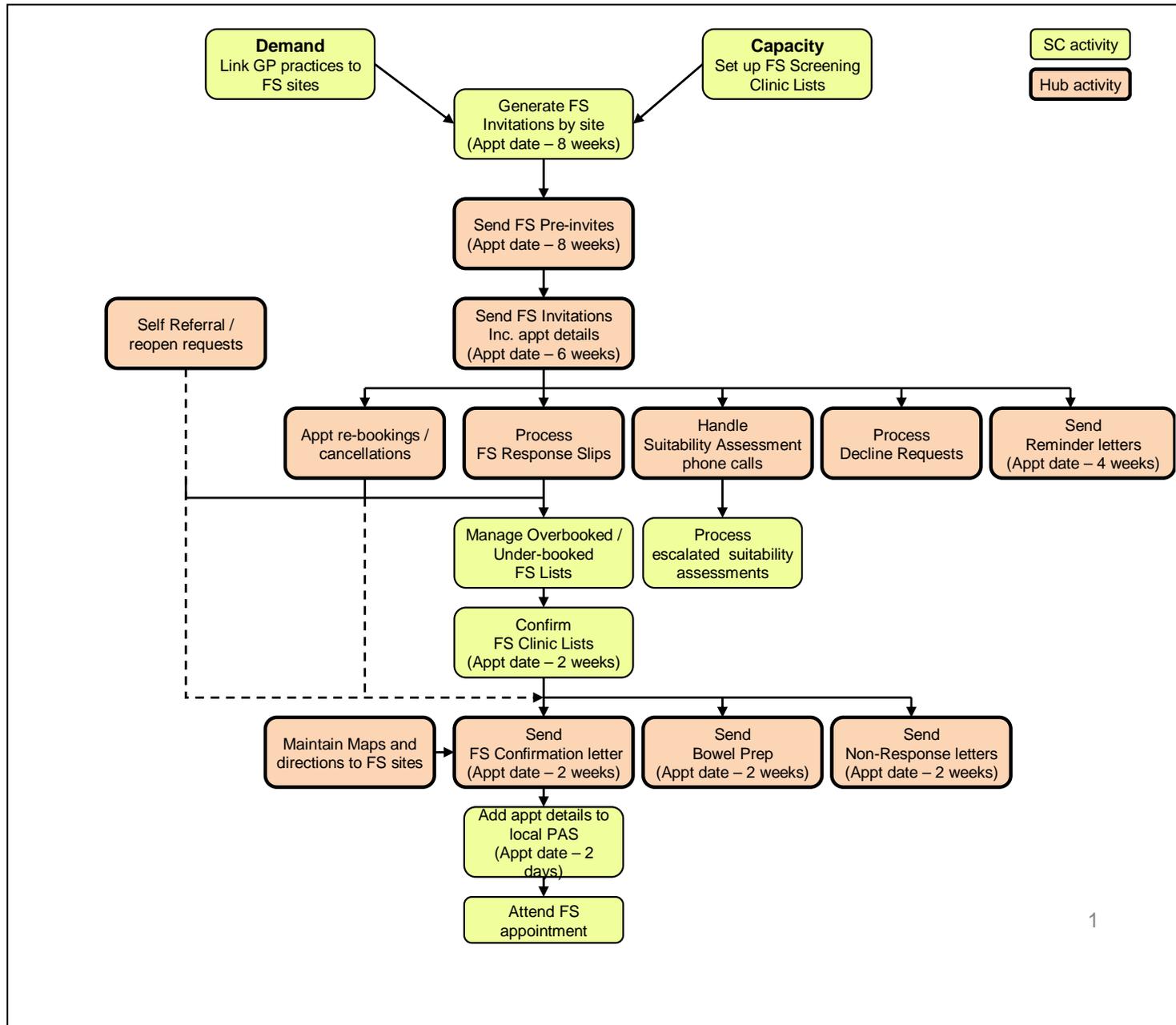
- 4.1. Further support and advice can be obtained directly from the National Office of the NHS Cancer Screening Programmes (tel: 0114 2711060) or from Regional QA Directors (see Annex D).

Annex A FS Screening Invitation Process

8 Week Timeline

	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Week – 8	4 Jul	5	6	7	8	9	10
	←		Selected for FS Screening and matched to appointment Pre-invitation letter generated	→			
Week – 7	11	12	13	14	15	16	17
Week – 6	18	19	20	21	22	23	24
	Full invitation letters generated Full invitation letter sent		Full invitation letter received				
Week – 5	25	26	27	28	29	30	31
Week – 4	1 Aug	2	3	4	5	6	7
	Reminder Letter generated (Appt w/c/ date - 28 days) and sent		Reminder letter received				
Week – 3	8	9	10	11	12	13	14
Week – 2	15	16	17	18	19	20	21
	←		Appointment confirmed by SC Confirmation letter generated Non-response letter generated	→			
Week – 1	22	23	24	25	26	27	28
					Subjects added to PAS		
Appt Week	29	30	31	1 Sept	2	3	4
	←		FS Screening Appointment	→			

Annex B FS Invitations Overview and Timeline



Annex C NHS Bowel Cancer Screening Programme

Bid for Flexible Sigmoidoscopy Screening pilot or first wave site

Planned Screening Centre Name:

Address:

Proposed Start Date (pilot or first wave):

Screening Endoscopy sites to be used (FS or colonoscopy):

Total population served (between 500,000 and 1 million people):

PCTs (please identify cluster and PCTs within it if appropriate):

NHS Bowel Cancer Screening Programme

Criteria to be met	Evidence required to demonstrate compliance	S/C confirm evidence supplied
1. Sustained operation of the FOBt programme and sustained implementation of the FOBt age extension (70 up to 75 th birthday) ¹¹ while meeting the QA standards of the BCSP including waiting times for SSP appointment and screening colonoscopy	Reports demonstrating all SSP appointments and screening colonoscopies are being undertaken within 14 days as required	
2. Sufficient sustainable endoscopy capacity to deal with the increased workload with the expansion to incorporate FS and continued growth in surveillance	Capacity and demand plans for forthcoming 2 years for FOBt and FS screening	
3. Provision of CO2 for insufflation in accordance with European Guidelines for Quality Assurance of Colorectal Cancer Screening and Diagnosis	Confirmation of availability of CO2 at all sites	
4. Maintenance of full Joint Advisory Group on GI Endoscopy (JAG) accreditation at each endoscopy unit which offers screening colonoscopy	JAG accreditation certificates	
5. Maintenance of GRS scores: <ul style="list-style-type: none"> • <u>waiting times at level A for a minimum of 3 months prior to commencing FS screening at all screening sites</u> • <u>waiting times at all other hospitals within the Trust must be at level A before FS screening can commence</u> • <u>at least level B for all other GRS scores</u> 	BCSP waiting times templates completed for active and surveillance waits for the preceding 3 months at all sites/Trusts	

¹¹ The Operating Framework for the NHS in England 2011/12, Department of Health (15th December 2010)
www.dh.gov.uk/prod_consum_dh/groups/dh.digitalassets/@dh/@en/@ps/documents/digitalasset/dh_122736.pdf

NHS Bowel Cancer Screening Programme

Criteria to be met	Evidence required to demonstrate compliance	S/C confirm evidence supplied								
<p>6. Sustained achievement of the operational standards for the relevant cancer waiting times commitments:</p> <table border="1" data-bbox="147 352 1079 697"> <thead> <tr> <th data-bbox="147 352 813 443">Commitment</th> <th data-bbox="813 352 1079 443">Operational Standard</th> </tr> </thead> <tbody> <tr> <td data-bbox="147 443 813 493">All Cancer Two Week Wait</td> <td data-bbox="813 443 1079 493">93%</td> </tr> <tr> <td data-bbox="147 493 813 579">62-Day (Urgent GP Referral to Treatment) Wait For First Treatment: All Cancers</td> <td data-bbox="813 493 1079 579">85%</td> </tr> <tr> <td data-bbox="147 579 813 697">62-Day Wait For First Treatment From Consultant Screening Service Referral: All Cancers</td> <td data-bbox="813 579 1079 697">90%</td> </tr> </tbody> </table>	Commitment	Operational Standard	All Cancer Two Week Wait	93%	62-Day (Urgent GP Referral to Treatment) Wait For First Treatment: All Cancers	85%	62-Day Wait For First Treatment From Consultant Screening Service Referral: All Cancers	90%		Trust data returns
Commitment	Operational Standard									
All Cancer Two Week Wait	93%									
62-Day (Urgent GP Referral to Treatment) Wait For First Treatment: All Cancers	85%									
62-Day Wait For First Treatment From Consultant Screening Service Referral: All Cancers	90%									
<p>7. Identification of a single pathology laboratory with the capacity to deal with all the polyps arising from FS examinations in a screening centre. The laboratory would need two to four nominated consultant histopathologists who participate in the BCSP External Quality Assurance (EQA) scheme to report these samples. In addition, pathology laboratories which will report suspected colorectal cancers arising in the programme should also have an identified BCSP lead with whom the FS polyp reporting pathologists can liaise.</p>		Confirmation of designated laboratory and named histopathologists with job plans identifying sessions for BCSP work and EQA participation								
<p>8. Sign off from the Regional Quality Assurance team, Trust Chief Executive and relevant commissioning organisation</p>		Bid proforma signed by all parties. Minutes of screening centre meetings where FS discussion has taken place and agreement reached.								

Annex D Regional Quality Assurance Directors

Region	QA Director	Contact
East Midlands	Dr D Slater	david.slater@sth.nhs.uk QA Reference Centre Northern General Hospital Herries Road Sheffield S5 7AU
East of England	Dr Jem Rashbass	Jem.Rashbass@esga.nhs.uk QA Reference Centre Compass House Vision Park Chivers Way Histon Cambridge CB4 9AD
London	Dr Kathie Binysh	k.binysh@imperial.ac.uk QA Reference Centre 1 st Floor 51/53 Bartholomew Close London EC1A 7BE
NE Yorks and Humber	Dr Keith Faulkner	keith.faulkner@nhs.net QA Reference Centre Ground Floor North East Strategic Health Authority Waterfront 4 Goldcrest Way Newburn Riverside Newcastle upon Tyne NE15 8NY
North West	Dr Billie Moores	billie.moores@bolton.nhs.uk QA Reference Centre NHS Bolton St Peters House Silverwell Street BOLTON BL1 1PP
South Central	Dr Monica Roche	monica.roche@ociu.nhs.uk QA Reference Centre Oxford Intelligence Unit 4150 Chancellor Court Oxford Business Park South Oxford OX4 2JY
South East Coast	Dr Linda Garvican	linda.garvican@scn.nhs.uk South East Coast QARC 77a High Street

NHS Bowel Cancer Screening Programme

Region	QA Director	Contact
		Battle Sussex TN33 0AG
South West	Dr Jim O'Brien	jim.obrien@southwest.nhs.uk Southwest House Blackbrook Park Avenue TAUNTON Somerset TA1 2PX
West Midlands	Dr Gill Lawrence	gill.lawrence@wmciu.nhs.uk West Midlands Cancer Intelligence Unit The Public Health Building University of Birmingham Birmingham B15 2TT