Evaluation of the UK Colorectal Cancer Screening Pilot

Final Report

(February 2003, revised May 2003)

The UK CRC Screening Pilot Evaluation Team

Address for correspondence:
Professors Freda Alexander & David Weller
Department of Community Health Sciences
University of Edinburgh
Edinburgh EH8 9DX
ph. 0131 6502675
fax 0131 6509519
freda.alexander@ed.ac.uk, david.weller@ed.ac.uk

Contents

Appendices

Acknowledgements

This independent evaluation of the UK colorectal cancer pilot was commissioned by the Policy Research Programme at the Department of Health. The evaluation team required the co-operation and support of a great many individuals in order to produce a report which accurately reflects the experiences and outputs of the Pilot. We are grateful to all personnel in the 2 Pilot sites for accommodating the evaluation into their activities, and providing information required for our report. Thanks also to the National Screening Offices in England and Scotland, the Steering and Executive Groups for the UK Pilot, and the Department of Health's Advisory Group which provided valuable methodological input and feedback on draft materials. The R&D Directorate of the Department of Health provided helpful mechanisms for reporting and feedback. Roma Robertson and Jeremy Walker provided additional research support. Thanks to Morag Edwards and Morag Leitch for their help in report preparation and general administrative support.

The Evaluation Team

(all members of the evaluation team have contributed to the report)

David Weller†	Co-Director; Lead, primary care
Freda Alexander†	Co-Director; Lead, epidemiology and statistics
Sheina Orbell††	Lead, psychosocial component; consultant, ethnicity
Harry Campbell†	Lead, secondary care impact
Ala Szczepura†††	Lead, organisation and management; consultant, ethnicity
John Forbes†	Lead, health economics
Ian O'Sullivan††	Researcher, psychosocial component
Gill Grimshaw†††	Researcher, organisation and management
Jacqueline Price†	Researcher, secondary care impact
Ruth Jepson†	Researcher, primary care
Caroline Round†	Researcher, epidemiological and statistics
Christine Campbell†	Researcher, secondary care impact
Polly Sommerville†	Research support, epidemiological component
Andrew Walker‡	Consultant, health economics
Aileen Neilson‡‡	Consultant, health economics
Malcolm Dunlop†	Consultant, colorectal surgery

† University of Edinburgh
†† University of Essex
††† University of Warwick
‡ University of Glasgow
‡‡ Health Econ, Basel

Executive Summary

1. The UK Colorectal Cancer Screening Pilot was established to determine the feasibility of screening for colorectal cancer in the UK population using faecal occult blood testing. It followed demonstrations of mortality reductions in randomised controlled trials. A key task of the Pilot has been to determine whether outcomes achieved in the trial settings can be repeated in population-based programmes.

2. The Pilot commissioned two sites (one in central England, the other in Scotland), and both sites have achieved their targets for invitation to screening.

3. This evaluation was commissioned independently of the Pilot-site-commissioning process. The evaluation team comprises individuals with expertise in a range of disciplines relevant to colorectal cancer screening. The brief of the Evaluation Group was to produce an independent report for the UK Department of Health, R&D Directorate on the outcomes of screening in the UK Pilot.

4. The Pilot has achieved uptake of screening close to its target of 60% amongst the complete group of invitees. Nevertheless, the evaluation has identified sub-groups in the population with lower uptake, including men, younger people, those from more deprived areas, and individuals of ethnic origin. Uptake was slightly less in Scotland than in England. Practical issues such as ease of completing the kit also appeared important determinants of uptake.

5. Individuals who decline an invitation to undertake FOBt screening exhibit a range of lifestyle factors which potentially increase their risk of colorectal cancer and other diseases. Conversely, participation in the Pilot appeared to have a generally positive effect on health-related behaviours.

6. Adverse events from screening within the Pilot sites were low, despite undertaking several thousand colonoscopies, there was only a very small number of complications relating to perforation, bleeding or abdominal pain. Perceptions of the colonoscopy experience amongst attenders were very positive. Further, psychosocial surveys undertaken as part of the evaluation demonstrated no prolonged psychological effects amongst invitees, regardless of results of their tests or subsequent investigations.

7. Uptake rates for colonoscopy are also influenced by deprivation and ethnicity. Although only 82% of individuals with a positive FOBT had a colonoscopy within the Pilot, significant numbers either had their colonoscopy privately (particularly in England) or were excluded for medical reasons.

8. Outcomes of screening in the two Pilot sites have been compared both with each other and with the Nottingham randomised controlled trial. Test-positivity rates are higher in Scotland (although both sites have higher rates than Nottingham), in men, and in individuals from more deprived areas. Rates of detection of cancers and potentially pre-malignant lesions (eg adenomas) in both sites compare favourably with data from the Nottingham trial.

9. The majority of test-positive results in the UK Pilot have come from repeat-testing; this has caused long screening histories in many participants, and may be overly-burdensome in a national programme. Consideration should be given to tests which provide more definitive results on the first round of screening (eg immunological tests) – these warrant further evaluation. Our evaluation has highlighted the need for rigorous and uniform data collection procedures for pathology detected through FOBT screening programmes. A particular issue which emerged was the classification of cancerous polyps in patients in whom no laparotomy was undertaken (and in whom, therefore, no definitive staging information was available).

10. The predictive value of positive tests (for neoplasia) in both sites compares favourably with the Nottingham trial. Predictive value for neoplasia increases with advancing age, and is higher in males. Staging distribution data also indicate a stage-shift towards less-advanced cancer (eg Dukes A&B) which is similar in magnitude to the Nottingham trial.

11. Observed outcomes of screening in the UK Pilot, and their generally favourable comparisons with results of the Nottingham trial lead us to conclude that benefits observed in the randomised trials of FOBT screening (including CRC-specific mortality reductions) should be repeated in a national roll-out. This would be against the background of falling mortality rates already observed in the absence of screening, and improvements in diagnostic and treatment services.

12. Further, FOBT screening is generally supported by key stakeholders including previous participants and primary care teams. Nevertheless, despite these favourable outcomes, it has become apparent during the course of the Pilot and this evaluation that issues of workload impact and capacity will have a profound influence over the success of a future roll-out of FOBT screening. A national programme would need to very carefully examine existing capacity and potential to accommodate increased activity at both a national and regional level.

13. Our health economics analysis of the UK Pilot suggests that the cost-effectiveness of a national programme of FOBT screening would likely compare well with other forms of cancer screening. This is consistent with previous analyses of colorectal cancer screening.

14. The Pilot has had a modest but discernable impact on workload in primary care. Aspects of workload which appear particularly significant include information provision, paperwork and checking of prior-notification lists. There were slight differences in the scheduling arrangements for nurse visits in each of the two sites, and this possibly had an impact on primary care workload. General practice are entering a period of changing incentives and priorities with new NHS contracts. GPs hold a particularly strong view that CRC screening is likely to impact on workload if rolled out nationally, and that involvement of primary care in this new form of cancer screening should be adequately reimbursed.

15. The UK Pilot has had a considerable impact on workload in secondary care. There has, for example, been an increased demand for non-screening colonoscopy services (discrepancies between waiting times for screening and symptomatic patients have emerged as an important issue). There is general consensus that capacity to provide additional colonoscopy services will be critical in the roll-out of a national programme. There was also a substantial impact on pathology services, and radiological services, while not burdened with large numbers of extra barium enema examinations, would likely increase activity in CT scanning and ultrasound in a national programme.

16. The UK Pilot has demonstrated the importance of formal approaches in developing and implementing cancer screening programmes. It has also underlined the importance of developing rigorous audit and quality assurance procedures alongside programme development. Consideration needs to be given to models of screening nurse provision (including centralised services), and to the employment of data specialists in screening centres.

17. The Pilot has provided some important insights into the commissioning of IT systems for FOBT screening. Browser-based systems appear to hold particular potential for data entry in a national programme.

18. In summary, the UK Pilot has demonstrated that key parameters of test and programme performance observed in randomised studies of FOBT screening can be repeated in population-based pilot programmes. Variations in uptake and test performance according to age, gender, deprivation, nationality and ethnicity lead also to consideration of targeted screening of population sub-groups, perhaps in conjunction with other screening modalities such as flexible sigmoidoscopy.

19. The findings from this report come at the time of new national initiatives to reduce mortality from colorectal cancer. If adopted as part of a national programme, FOBT screening will need to complement other initiatives such as improved diagnostic and treatment services.

1. The UK Pilot and its Evaluation

1.1 Background

The Colorectal Cancer Screening Pilot arose from a recommendation from the National Screening Committee (NSC), following an appraisal of evidence about primary and secondary prevention of colorectal cancer. This appraisal led to the conclusion that the quality of evidence in favour of FOBT screening was sufficiently high for policy recommendations to be made. The NSC recommended the establishment of a Pilot, conducted at two sites, to assess the effectiveness of screening for colorectal cancer using the FOBT. The Pilot has been conducted at Tayside, Grampian and Fife in Scotland and the West Midlands in England. This is the final report from a multidisciplinary inter-university Evaluation Group commissioned by the Department of Health to provide independent evaluation.

Screening began at the Scottish site on 31-March-2000 and at the English site 6-September-2000. Routine data from the Pilot sites are downloaded to the evaluation group on a monthly basis. Up to the times of the last downloads available for this report 486,355 people had been offered screening at the two sites.

The aims of the evaluation and the methodologies to be used have been described in detail in our first year report (February, 2001) and our interim report (July, 2001).

This final report provides results from analyses of routine data downloaded from the Pilot sites and from special surveys conducted by our interdisciplinary team. We consider, in separate chapters: uptake and acceptability; test performance; impact on routine health services, management issues and stakeholder perspectives. Within most of these chapters a multidisciplinary approach has been followed with results from individual disciplines and/or addressing specific topics presented as separate sections, each with its own discussion. Each chapter ends with its own 'Conclusions and Recommendations' section prepared collaboratively by those who contributed to the chapter.

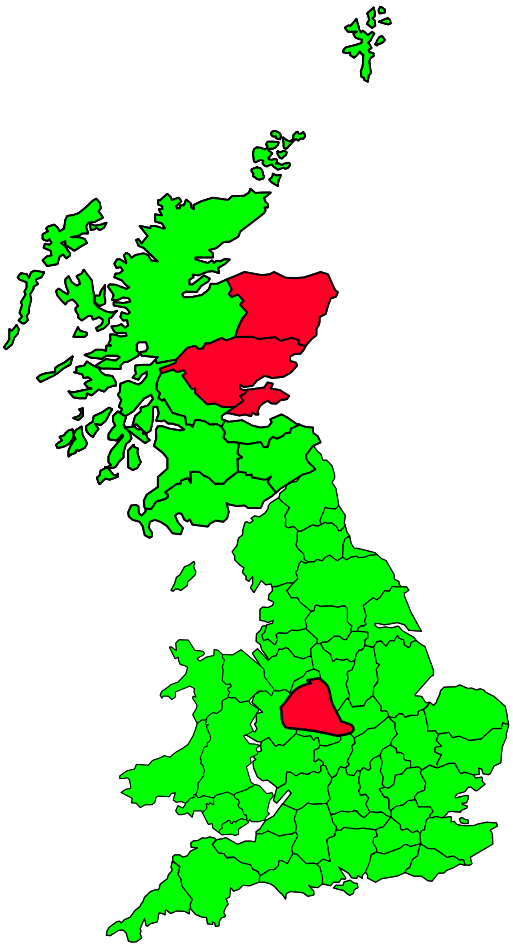
Finally, in chapter 8 we provide a summary of our findings, and a description of work which will be of importance in the future now that this initial phase of the UK Pilot has ended and our evaluation is drawing to a close – this includes follow-up of the cohort of individuals who have been screened in the Pilot to date.

1.2 Structure and functions of the Pilot sites

The Pilot sites were commissioned in 1999, and were required to undertake all of the necessary developmental work to commence screening in early 2000. The Scottish Pilot site commenced screening in March 2000 – it comprises a central laboratory based at King's Cross Hospital in Dundee . The English Pilot site commenced screening in September 2000; it is based at Hospital of St. Cross, Rugby. The two Pilot centres have largely followed the same screening protocol (which was determined as part of the commissioning process, as discussed in Chapter 7). All of the tests and associated information were sent to the target population from the screening Units. All FOB test kits were returned to the Units for testing and results sent to the individual direct from the office. Following an overall positive result individuals were provided with an appointment to see a specialist nurse to explain the result and the implications of further diagnostic investigations. In the first instance this has been colonoscopy, with barium enema undertaken if the colonoscopy has been incomplete.

There were some procedural differences between the two sites, particularly relating to the scheduling of appointments and provision of information on results of tests and investigations. In England, all individuals were invited for an appointment with a nurse, regardless of their FOBT result. However, part-way through the course of the Pilot it was considered that appointments for test-negative individuals were not generally being taken up and, indeed, that the invitation may cause unnecessary anxiety. The protocol was, therefore, changed to only offer appointments to test-positive (or weakly positive) individuals. All participants who underwent colonoscopy (or other investigation) were also given a nurse appointment to provide the results of this procedure.

In Scotland, test results were also sent to participants, and those with 'positive' results were offered a nurse appointment. Nurse appointments were not routinely offered post-colonoscopy.



Location of Pilot sites, UK Colorectal Screening Pilot

Two sites were established following a competitive commissioning process. Both sites have had lead clinician/Directors (Ron Parker in England and Bob Steele in Scotland) and Managers (Pat Ramsell & Sue Elwell in England, and Linda Bradley & Carolyn Smith in Scotland). The screening centres have comprised teams of clinical and support staff including nursing staff, office managers and data managers. Both sites have worked within the framework of their national screening offices. In Scotland, this has been under the direction first of Jan Warner and then Carol Colquhoun and the project manager has been Carole Morton. In England it has been under the direction of Julietta Patnick, and the project manager has been Kathryn Robertshaw.

1.3 The Evaluation

The evaluation team

The Evaluation was commissioned by the R&D Directorate of the UK Department of Health, through a competitive process. The evaluation was a complex task, and required a multi-disciplinary approach. Hence, our evaluation team brought together individuals with the range of expertise necessary to address these complexities; the evaluation includes content from a range of disciplinary and methodological areas, including epidemiology, health services organization, psychology, health economics, primary care and management. The main bulk of the work contained in this report was commissioned in late 1999. A separate component of the work, focusing on issues of ethnicity and cancer screening uptake, was commissioned in 2001, in response to the requirement for more detail in this area. Two members of the evaluation team (AS & SO) led this work.

The evaluation team comprised individuals from, principally, the Universities of Edinburgh, Essex and Warwick. Our geographical and disciplinary diversity meant that considerable effort needed to be invested in maintaining adequate communication and coordination of our activities. Hence, we held face-to-face meetings every several months, and monthly teleconferences to share information and plan.

Accountability and interactions

Despite interacting with a range of groups responsible for the conduct of the Pilot (such as Executive and Steering Groups, and the Pilot sites themselves), our accountability in this process has been to the R&D Directorate, UK Department of Health – this is the third and final report on our activities and findings to the DH.

We have had feedback from the DH's Advisory Group (**see Appendix 8**), which comprises a group of experts with relevant fields of expertise whose activities have included commenting on draft and interim reports, advising on methodological approaches, and providing links and perspectives from their individual disciplinary backgrounds.

It became evident at the outset of the evaluation that we would need to have a carefully-managed relationship with the two Pilot sites; it was critical that this evaluation was independent and unbiased, yet we needed to establish good communication links and workable interactions with the Pilot sites for a variety of reasons – including agreement on definitions and quality standards (**see Appendix 1**), mechanisms for data transfer, and incorporation of our surveying activities into the functions of the Pilot. It was critical, for example, that the methods we proposed – often involving surveying of screenees or Pilot personnel, did not impact adversely with key aspects of Pilot function. For these reasons we developed a 'Terms of Engagement' which aimed to make explicit the competing imperatives of independence and integration (**Appendix 2**) which, over the last 3 years we have found a useful guide for our activities.

We also actively participated in the Executive Group and the Steering Group (**Appendix 8**) of the UK Pilot, by sending in progress reports for these meetings, and having one of the members of the evaluation team present (usually DW or FA). Involvement in these groups was of considerable mutual benefit; we were often able to update on interim results and progress on the evaluation, while we were able to obtain information about the management and conduct of the Pilot which was often of direct relevance to our activities.

Further, we collaborated with the national screening offices in England and Scotland to develop procedures related to screening in the two sites. For example, there needed to be agreement between the Pilot and evaluation about terms and definitions (eg what is meant by a 'polyp' or 'first round of screening'). We needed shared understanding over certain quality standards and test/programme measure – for example uptake and test positivity rates. A number of documents arose from these processes which served as valuable guides for both Pilot and evaluation.

2. Uptake and acceptability of screening

Chapter Summary

- These data largely confirm evidence from our second year report that the Pilot is achieving uptake of FOBt of close to its target of 60%. Age adjusted comparisons with the Nottingham trial show slightly higher uptake in women but slightly lower in men.
- FOBt appears to be less acceptable to men, to younger people, to those from materially deprived areas, to those living in areas with the highest proportions of residents of Indian sub-continent origin, and in Scotland.
- The same groups of people who are reluctant to respond to screening tend, if they have initially responded, to withdraw before completing screening.
- The youngest age group (50-54yrs) may require particular attention, if roll-out occurs, especially in men.
- Information regarding behavioural risk factors indicates that non-responders report a number of health behaviours which could put them at increased risk of bowel cancer.
- Bowel cancer was generally viewed as serious and people considered themselves susceptible to the disease
- Non-uptake may be an avoidant response to fear of a positive result.
- Although public confidence in bowel cancer screening effectiveness was very high, doubts about its effectiveness explained a proportion of variance in non-response; maintaining confidence in screening will be an important consideration for a mass-screening programme
- The most important factors affecting FOBt response are those relating to the ease or difficulty of completing the kit
- We obtained no evidence of psychological distress following FOBt
- There was therefore no evidence that the willingness to be screened differed significantly for different ethnic groups, although numbers were small.
- However, multivariate analyses demonstrated significantly lower rates for uptake and completion of screening for all five ethnic groups studied
- Screening uptake rates amongst ethnic sub-groups were also related to GP attributes (in terms of religion and language characteristics of the clinician)
- Patterns of psychosocial distress amongst non-responders were different amongst ethnic sub-groups

2.1 Analyses of Routine Data

2.1.1 Aims and objectives

To analyse routine data downloaded from the Pilot data sets to estimate uptake and investigate associations of demographic and ethnic variates with different aspects of uptake.

- Decision to respond to the offer of screening
- Completion of phase 1 of screening
- Completion of screening
- Completion of screening in responders

2.1.2 Methods

The data used have been extracted from downloads taken from the English and Scottish Pilot databases by the end of October 2002. The different aspects of uptake considered in this section are each based on the concepts described in the Glossary (**Appendix 1**) but brief descriptions are provided below for ease of reference:

i) Decision to respond to the offer of screening: At least one used kit returned (both adequate and inadequate kits included)
ii) Completion of phase I of screening: An initial adequate kit returned, giving a result of negative, positive or proceed to phase II (weakly positive)
iii) Completion of screening: An overall result of FOB testing available
iv) Completion of screening in responders: Definitions as above with denominator restricted to responders

The analyses of response and phase I completion are both restricted to individuals who were sent their initial screening invitation more than three months before the date of the download, to allow sufficient time for kits to be completed and returned. Only individuals invited more than four months before the download are included in the analyses of screening completion.

Logistic regression was used to investigate associations between the measures of uptake and various demographic and ethnic variables (listed in the Table below). Results are given as odds ratios (ORs) with 95% confidence intervals (CIs). Interactions between age and sex were consistently investigated. Univariate analyses were used to produce unadjusted odds ratios (point estimate and 95% CI) for each demographic factor; where age-sex interaction were statistically significant the 'univariate' analyses take age and sex together; they have been reported as a term for gender and terms for age within each gender. Multivariate analyses of associations with the demographic factors have included them all in the model; thus, ORs give estimated effects of each after adjustment for all the others.

Demographic Variables	Ethnic Variables
Pilot site	**% from Indian sub-continent in census ward**
Age group	
Gender	
Invitation time	
Time from start of screening in Pilot site	

The data on deprivation (Carstairs index) and ethnicity were obtained at 1991 census ward level from the Census Dissemination Unit (MIMAS, Manchester University). These were then linked to the evaluation database using subject postcode (postcode sector within Scotland). For England, it was possible to match current postcodes to those in existence in 1991 and hence to the census wards.

However, as only postcode sectors were available for the Scottish site (due to reasons of confidentiality), this matching was not possible and it was necessary to assume that current postcode sectors are the same as those from 1991. For this reason, it was not possible to assign deprivation to a proportion of Scottish subjects (21%).

For Scotland, pre-calculated deprivation categories based on the Carstairs index are available. The cut-off values for these categories were originally chosen arbitrarily (McLoone, MRC Social & Public Health Sciences Unit, University of Glasgow, 2000). When the Carstairs index was updated after the 1991 census, the cut-off values were chosen to give the same population proportion within each deprivation category as the original classification. This methodology has been applied by us to give deprivation categories for England and Wales based on the Carstairs index. The resultant cut-off values are listed below.

Deprivation Category	Cut-off Value	
	England	Scotland
1	# -3.49	# -4.64
2	# -2.34	# -3.01
3	# -0.70	# -1.19
4	# 2.03	# 1.01
5	# 4.24	# 2.86
6	# 7.45	# 6.02
7	> 7.45	> 6.02

Categorical ethnic variables were calculated for the English Pilot area only by grouping according to quintiles (see Table below). It was clear that the dominant ethnic minority in the English Pilot area is Indian Sub-Continent origin and the analyses we report are restricted to comparison of areas in the highest quintile of Indian sub-continent membership with all others. Few residents in the Scottish Pilot area are from ethnic minorities (data shown in second year report) and analyses with uptake are not considered likely to be informative.

Percentile	England		
	% Afro-Caribbean	% Indian Sub-Continent	% Chinese
20th	0.14	0.40	0.04
40th	0.33	1.08	0.15
60th	0.66	2.36	0.21
80th	1.18	5.85	0.33

2.1.3 Results

From the current downloads we see that 189319 subjects in England and 297036 in Scotland have entered the Pilot in the sense that they have apparently received at least one invitation to participate. Some of these invitations were issued too late for the recipients to be included in any further analyses. Nevertheless, we have applied percentages calculated from more restricted data to estimate the subsequent outcomes for these entire cohorts (**Figures 2.1.1 (a) and (b)**).

We are concerned at the numbers who did not, apparently, complete screening (44.3% in Scotland and 41.4% in England). The majority of these did not, apparently, respond to screening at all.

Although we have analysed the 3 aspects of uptake based on total invitees as denominator, the results are all very similar to each other and we have only presented those for completion of FOBt testing (**Table 2.1.1**). As we observed in the second year report, uptake is higher in the English site, in women and in those living in less deprived areas.

There is a statistically significant age-sex interaction and the trend towards higher uptake in older people, present in both genders, is most marked for men. Uptake decreases significantly with time; this may be a genuine association but there is a possibility of artefact.

Completion of screening by responders (**Table 2.1.2**) while high (98.9%) shows significant associations with gender and age (women and those over 65 being more likely to complete) and deprivation of area of residence.

Analysis of the data from the English Pilot site for associations with Indian ethnicity (**Table 2.1.3**) of area of residence showed significant associations – uptake was lower and completion of screening in initial responders was also lower in areas with the highest proportions of residents from the Indian sub-continent. Both of these persisted after adjusting for deprivation so cannot be explained by confounding with deprivation.

The statistical modelling predicts lowest attendances in younger men from the most deprived areas; we have calculated the actual proportions completing screening for the extreme groups: for the young men in the most deprived areas uptake was 33.9% in Scotland and 37.0% in England; for women aged 60-64 from the least deprived areas the corresponding figures were 69.0% and 71.3% respectively; if the English calculation for the young men was further restricted to areas with the highest population of Indian sub-continent origin then uptake was reduced to 34.1%.

We have compared these Pilot data with corresponding data for the prevalence screen of the Nottingham trial (where exclusion of the Pilot trial is most appropriate) in **Table 2.1.4**. In this Table we have used data for the UK Pilot up to the end of September 2001 to avoid effects of the possible artefact mentioned above. For each age and gender uptake is comparable to that in Nottingham and, indeed, is higher except for the youngest age group.

2.1.4 Discussion

These data largely confirm evidence from our second year report that the Pilot is achieving uptake of FOBt of close to its target of 60%, when considering the total population of invitees . This target figure was based on the Nottingham trial crude data and more detailed comparisons of age- and sex- specific uptake shows that the current Pilot compares very favourably with the Nottingham trial – especially if we focus on data from the downloads to September 2001 or on England.

Within the overall Pilot there are important sub-group differences. In particular, FOBt appears to be less acceptable in Scotland, to men, to younger people, to those from materially deprived areas and to those living in areas with the highest proportions of residents of Indian sub-continent origin. These people are both less likely to accept screening and, once accepted, less likely to complete the testing protocol. The youngest age group (50-54yrs) may require increased attention if roll-out occurs since this is the only group for which uptake is lower than in Nottingham. Men in this age group may be particularly important especially if they live in materially deprived areas and, if in England, live in areas with large proportions of residents of Indian sub-continent origin since uptake in these subpopulations was just over 30%.

Table 2.1.1. Completion of FOBt testing by demographic factors

Demographic Factor		Responder N (%)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
None		259402 (56.8)	/	/
Site	England	105878 (58.6)	1 (-)	1 (-)
	Scotland	153524 (55.4)	0.88(0.87-0.89)	0.75(0.74-0.77)
Sex	Male	118617 (52.1)	1 (-)	1 (-)
	Female	140785 (61.4)	1.46 (1.45-1.48)	1.54(1.49-1.58)
Age-sex	Male: <55	33104 (47.2)	1 (-)	1 (-)
	Male: 55-59	30779 (51.2)	1.17(1.15-1.20)	1.15(1.12-1.19)
	Male: 60-64	26992 (55.0)	1.36(1.33-1.40)	1.37(1.32-1.41)
	Male: ≥65	27742 (57.3)	1.50(1.46-1.53)	1.51(1.46-1.56)
	Female: <55	38964 (58.2)	1 (-)	1 (-)
	Female: 55-59	37054 (62.6)	1.20(1.18-1.23)	1.21(1.17-1.25)
	Female: 60-64	32105 (64.9)	1.28(1.25-1.31)	1.33(1.28-1.37)
	Female: ≥65	32662 (61.7)	1.16(1.13-1.18)	1.22(1.18-1.26)
	p for heterogeneity <0.001, p for age-sex interaction < 0.001			
Invitation Time	Mar - Sept 2000	46445 (58.3)	1 (-)	1 (-)
	Oct 2000 - Mar 2001	65769 (56.6)	0.94(0.92-0.95)	0.89(0.86-0.91)
	Apr - Sept 2001	65997 (58.1)	0.99(0.97-1.01)	0.93(0.90-0.95)
	Oct 2001 - Mar 2002	53864 (54.0)	0.84(0.83-0.86)	0.78(0.76-0.80)
	Apr - Sept 2002	27327 (57.2)	0.95(0.94-0.98)	0.84(0.81-0.87)
	p-value for linear trend < 0.001			
Deprivation Category	1/2	64540 (62.5)	1 (-)	1 (-)
	3	53634 (59.9)	0.90(0.88-0.91)	0.92(0.89-0.94)
	4	57840 (56.5)	0.78(0.77-0.80)	0.77(0.75-0.79)
	5	21187 (51.8)	0.65(0.63-0.66)	0.63(0.61-0.65)
	6/7	19973 (45.6)	0.50(0.49-0.52)	0.49(0.48-0.51)
	p-value for linear trend < 0.001			

Table 2.1.2. Completion of screening for responders by demographic factors

Demographic Factor		Responder N (%)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
None		259402 (98.9)		
Site	England	105878 (98.9)	1 (-)	1 (-)
	Scotland	153524 (98.8)	0.91 (0.84-0.98)	0.90 (0.82-0.98)
Sex	Male	118617 (98.7)	1 (-)	1 (-)
	Female	140785 (99.0)	1.26 (1.17-1.36)	1.42 (1.23-1.64)
Age-sex	Male: <55	33104 (98.4)	1 (-)	1 (-)
	Male: 55-59	30779 (98.7)	1.01 (0.78-1.09)	1.15 (1.00-1.33)
	Male: 60-64	26992 (98.9)	1.03 (0.88-1.11)	1.40 (1.19-1.64)
	Male: ≥65	27742 (99.0)	1.17 (1.04-1.33)	1.61 (1.36-1.89)
	Female: <55	38964 (98.9)	1 (-)	1 (-)
	Female: 55-59	37054 (99.1)	1.22 (1.09-1.36)	1.12 (0.96-1.30)
	Female: 60-64	32105 (99.0)	1.14 (1.01-1.28)	1.34 (0.97-1.33)
	Female: ≥65	32662 (99.1)	1.21 (1.08-1.36)	1.20 (1.02-1.41)
Invitation Time	Mar - Sept 2000	46445 (98.7)	1 (-)	1 (-)
	Oct 2000 - Mar 2001	65769 (98.8)	1.11 (1.00-1.24)	1.09 (0.96-1.23)
	Apr - Sept 2001	65997 (99.0)	1.23 (1.11-1.38)	1.15 (1.01-1.31)
	Oct 2001 - Mar 2002	53864 (98.9)	1.16 (1.04-1.30)	1.12 (0.98-1.29)
	Apr - Sept 2002	27327 (99.0)	1.26 (1.10-1.46)	1.24 (1.03-1.48)
	p-value for linear trend = 0.13			
Deprivation Category	1/2	64540 (99.1)	1 (-)	1 (-)
	3	53634 (99.0)	0.89 (0.79-1.00)	0.89 (0.79-1.00)
	4	57840 (98.9)	0.79 (0.71-0.89)	0.78 (0.69-0.87)
	5	21187 (98.5)	0.56 (0.49-0.65)	0.55 (0.48-0.63)
	6/7	19973 (98.1)	0.45 (0.40-0.52)	0.43 (0.37-0.49)
	p-value for linear trend < 0.001			

Table 2.1.3. Effects of % from Indian Subcontinent – England only

Outcome Measure	% Indian	N (%)	Not Adjusted for Deprivation		Adjusted for Deprivation	
			OR (95% CI)	p-value	OR (95% CI)	p-value
Completion of FOBt testing	1-4	76298 (61.7)	1 (-)		1 (-)	
	5 (high)	17263 (48.5)	0.58(0.57-0.60)	<0.001	0.80(0.78-0.83)	<0.001
Completion of screening by responders	1-4	76298 (99.1)	1 (-)		1 (-)	
	5 (high)	17263 (98.3)	0.52 (0.45-0.60)	<0.001	0.75 (0.62-0.90)	<0.001

Table 2.1.4. Uptake of FOBt screening, split by gender and age, in the uk pilot and the Nottingham trial[1] (n,%)

	UK Pilot		**Nottingham trial**	
Age (Years)	**Men**	**Women**	**Men**	**Women**
50-54	33104 (47.2)	38964 (58.2)	3631 (53.1)	4180(62.1)
55-59	30779 (51.2)	37054 (62.6)	3760 (54.8)	4344(62.0)
60-64	26992 (55.0)	32105 (64.9)	3727 (56.8)	4217 (60.7)
65-69	27742 (57.3)	32662 (61.7)	3179 (56.8)	3634 (56.9)
50-69[2]	118617 (52.1)	140785 (61.4)	14297 (55.1)	16375 (60.6)

[1] Data from personal communication (Moss S and Scholefield J) and Hardcastle et al, 1996
[2] Rates are crude for the UK pilot and age-standardised to the pilot invited population for the Nottingham trial

Figure 2.1.1 (a) Predicted Throughput for Screening Phases (England)

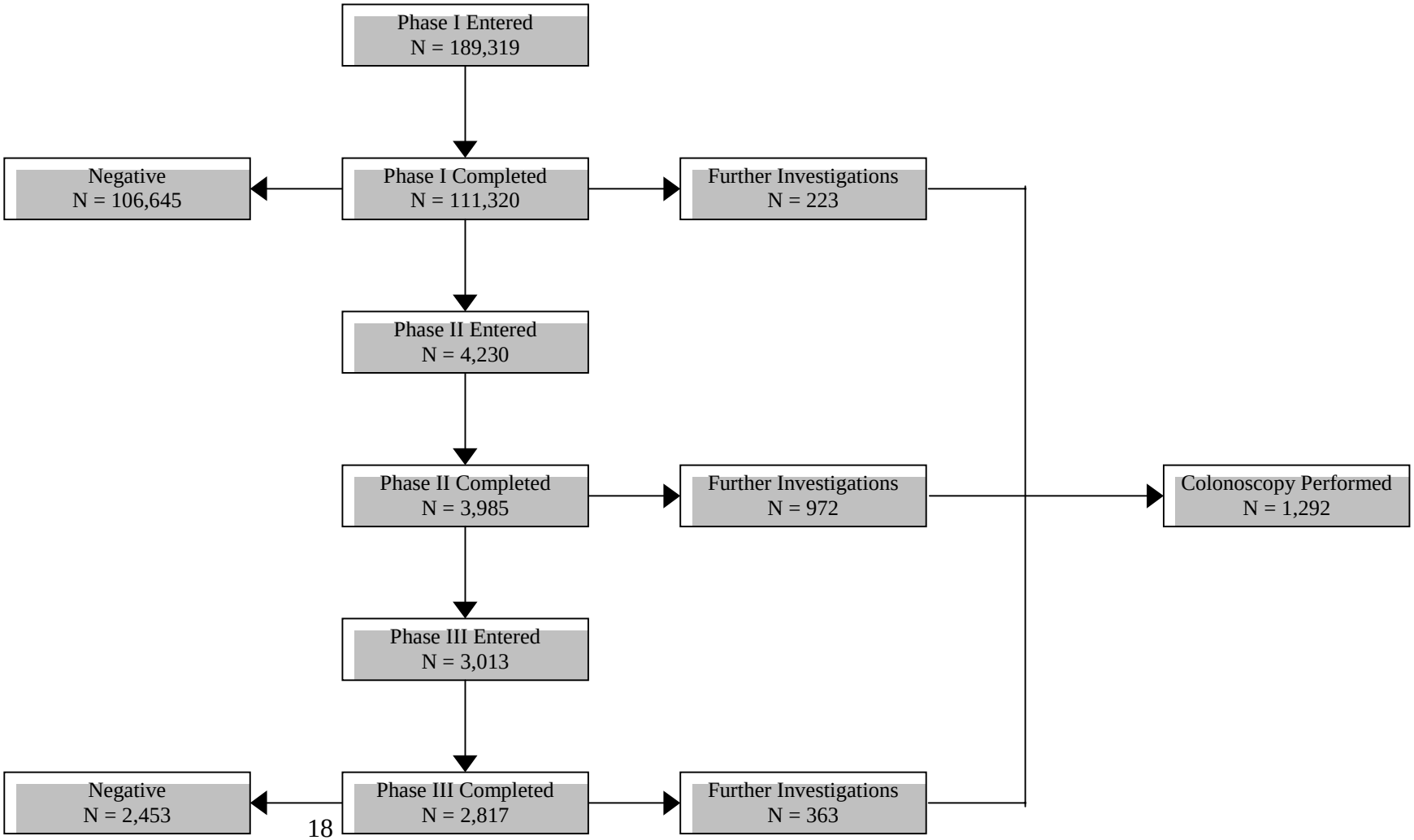
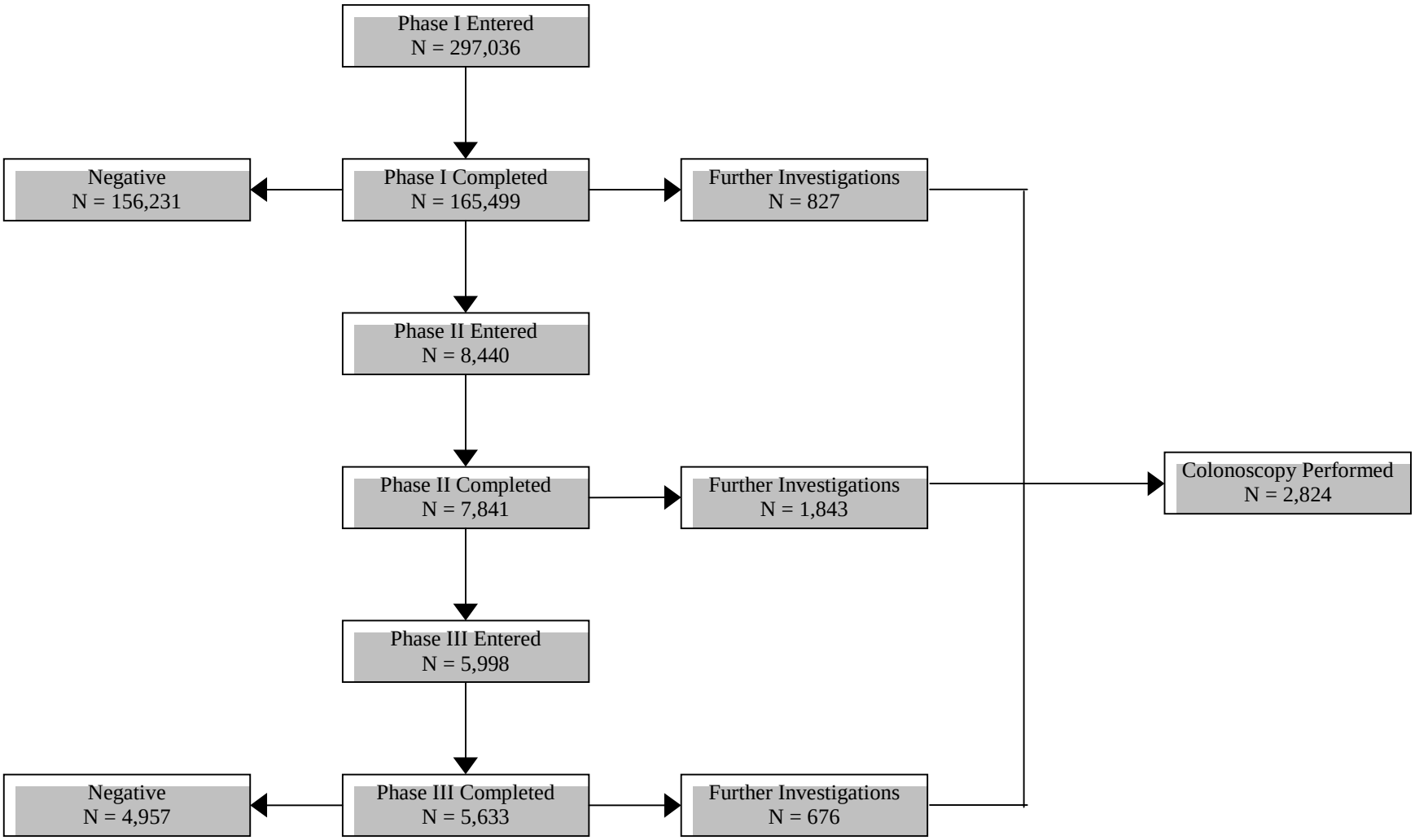


Figure 2.1.1 (b) Predicted Throughput for Screening Phases (Scotland)



2.2 Psychosocial Surveys

2.2.1 Aims and objectives

To conduct a survey of invitees to FOBt utilizing appropriate theoretical models and standard instruments with the objectives of:

1. Understanding beliefs and attitudes concerning response to FOBt versus non-response
2. Evaluating psychological distress following FOBt invitation
3. Evaluating psychological responses to +ve FOBt results and colonoscopy

2.2.2 Methods

2.2.2.1 Sampling

1. Invitees were sampled 8 months following first FOBt invitation
2. Samples have been drawn with the aim of achieving 500 survey participants amongst each of (a) Phase 1 non-responders (b) Phase 1 negatives (c) Phase 3 negatives (d) FOBt +ves and (e) cancer +ves
3. Over-sampling was used to obtain the required number of participants in difficult to reach groups, particularly Phase 1 non-responders
4. Random samples were drawn within each group stratified by Scotland/England, age, gender, deprivation category. Lower deprivation categories were over-sampled. Cancer +ves could not be sampled due to lack of numbers. All Cancer +ves were included in the survey.

2.2.2.2 Protocol

The survey protocol recommended by Dillman (1983) was utilized to maximize participation rates. Those sampled are sent a) a questionnaire booklet and letter b) a reminder letter one week later c) a second booklet and reminder letter two weeks later.

2.2.2.3 Questionnaire

The questionnaire booklet was developed following focus group discussions (see section 2.3) and interviews with Pilot centre staff, particularly those operating the helplines in Rugby and Tayside. A Pilot study with N = 500 sampled (FOBt respond negative) in Scotland has been previously reported to the Advisory group. Changes were made to the questionnaire booklet following the Pilot study. The questionnaire is included in the Report **Supplement S1.**

2.2.2.4 Participation.

Completed questionnaires were obtained from a total sample of N = 2292. (473 Phase 1 non-responders, 697 Phase 1 negatives, 421 Phase 3 negatives, 502 FOBt positives and 199 cancer +ves).

The questionnaire participation rate varied considerably across responder groups. After adjusting the denominator for numbers of people who were unavailable or refused to participate and returned a blank questionnaire, participation rates were (a) Phase 1 non-responders 18% (b) Phase 1 negatives 80.7% (c) Phase 3 negatives 89% (d) FOBt +ves 64.2% (e) Cancer +ves 75.7% (**see Appendix 3 for Tables A2.2.1 and A2.2.2**).

Comparison of questionnaire participants and non-participants showed that non-participants were younger and had higher deprivation category scores (**see Appendix 3 for Table A2.2.3**).

2.2.3 Results: Uptake of FOBt Comparison of non-responders and responders.

*2.2.3.1 Behavioural risk and uptake (**Table 2.2.1**)*

Approximately forty per cent of all survey participants reported never or rarely engaging in physical activity and about 20% were current smokers. More than sixty per cent of all participants were obese/overweight according to the BMI and between forty and fifty per cent of each responder group reported a low fibre intake.

FOBt non-responders were more likely to be current cigarette smokers than all responder groups. They were also more likely to report a low fibre intake than phase 1 negatives and were less likely than all other groups to report knowing someone with bowel cancer or a family history of bowel cancer.

FOBt positives and cancer positives were more likely than all other groups to report a blood relative with bowel cancer. FOBt positives were less likely than cancer positives to engage in regular physical activity.

*2.2.3.2 Perceived susceptibility to bowel cancer (**Table 2.2.2**)*
Approximately forty percent of all groups considered themselves to be at personal risk of developing bowel cancer. Levels of age specific optimism were low; 70% perceived themselves at higher risk of bowel cancer than other people of their own age. Perceived susceptibility was not associated with uptake of the test.

*2.2.3.3 Perceived severity of bowel cancer (**Table 2.2.3**)*
We assessed both perceived physical severity and perceived psychosocial severity. These variables were significantly associated with uptake of FOBt. Non-responders were more likely to perceive that bowel cancer would lead to death and pain, and would limit their social and personal relationships and put their financial security at risk. This suggests that non-uptake may be an avoidant response to threat of a positive result.

Higher perceived severity was also higher amongst men, amongst younger people and amongst those with a higher deprivation index, suggesting that this belief may be important in explaining demographic differences in uptake reported in section 2.1.

Cancer +ves, who have direct personal experience of cancer, perceived bowel cancer as less severe than all other groups.

*2.2.3.4 Perceived efficacy of FOBt in reducing cancer risk (**Table 2.2.4**)*
Public confidence in the effectiveness of FOBt was very high across all groups. FOBt was viewed by over ninety percent of participants as likely to prevent death from bowel cancer, lead to earlier treatment, prevent drastic treatment and reduce worry about bowel cancer. However, we did obtain significant differences between non-responders and responders. Non-responders were less likely than all other groups to believe that taking part in FOBt would give them peace of mind and less likely to believe that FOBt would reduce the chances of dying from bowel cancer.

*2.2.3.5 Perceived self-efficacy and barriers to completing FOBt (**Tables 2.2.5 and 2.2.6**)*
Nearly 100% of responders perceived the FOBt kit as easy to complete and were confident in their ability to do so. However, non-responders were significantly less confident. **Table 2.2.6** shows specific difficulties in completing the kit. Thirty percent of non-responders reported that constipation or diarrhoea made it difficult to complete the kit. Physical disability, lack of time and storage difficulties were also reported.

Specific barriers were also associated with age and with deprivation index, but were not associated with being male. Constipation, lack of time and storage difficulties were more likely to be reported by younger people. Physical disability and bowel movement irregularities were more likely to be reported by those from areas with a lower deprivation index.

*2.2.3.6 Perceived psychological costs of completing FOBt (**Table 2.2.7**)*
Psychological barriers to completing an FOBt were important discriminators of non-respondents. Non-responders to FOBt were more likely to view completing the kit as an invasion of privacy (34%), embarrassing (50%), disgusting (36%) or unhygienic (30%). Non-responders were also more likely than all other groups to expect that completing an FOBt would lead to unpleasant treatment.

We also obtained specific associations between perceived psychological costs and demographic variables. People from areas with a higher deprivation index were more likely to perceive completing the kit as 'disgusting' (21.5%) compared with those from a lower deprivation area (15.3%). Younger people were also more likely to view the kit as embarrassing or disgusting and found the prospect of having to go to hospital and having unpleasant treatment aversive.

*2.2.3.7 Perceived social encouragement for performing an FOBt (**Table 2.2.8**)*
People often take the opinions of others into account when deciding whether to perform a behaviour. Nearly all FOBt responders perceived high social support for taking part in screening. However, nearly twenty percent of non-responders considered that their partner, children or friends would not want them to do the FOBt. For this group, perceived social encouragement from a doctor was considered more likely than encouragement from friends or relatives.

People living in an area with a high deprivation index were slightly, but significantly less likely to perceive that their partner or their doctor would encourage them to do the FOBt, compared with people living in areas with a low deprivation index.

*2.2.3.8 Multivariate analysis of uptake of FOBt (**Table 2.2.9**)*
Multivariate analysis of variables associated with uptake of FOBt screening demonstrated that participation was associated with lower perceived psychosocial (financial) severity of bowel cancer, high self-efficacy and low barriers particularly in relation to visual impairment, lack of time and storage problems, low psychological costs (embarrassment) and high social encouragement from a partner.

*2.2.3.9 Summary of gender differences (**Table 2.2.10**)*
Men were less likely than women to take up FOBt (section 2.1). (It should be noted that this finding is consistent with previous studies of FOBt. However, previous research suggests that women are less likely than men to take up flexible sigmoidoscopy). Men perceived bowel cancer as more serious, both in terms of physical impacts such as pain and sickness, and in psychosocial terms. Men were more likely to perceive impacts on their social lives, relationships and financial security.

*2.2.3.10 Summary of deprivation index differences (**Table 2.2.11**)*
People from areas of higher social deprivation were less likely to take up FOBt. (section 2.1). Findings from the psychosocial surveys indicate that social deprivation was associated with perceived threat of bowel cancer and with barriers to completing the kit. These people perceived themselves at higher risk of developing bowel cancer and perceived bowel cancer as more serious, in terms of physical pain and damage to financial security. This higher perceived threat was co-existent with low perceived ability to complete the kit. Physical disabilities and irregular bowel habits were significant barriers to completion of the kit for this group, who were also more likely to view the kit procedure as disgusting. Finally, people from areas of lower social deprivation perceived lower social support for taking part from their partner or doctor.

*2.2.3.11 Summary of age group differences (**Table 2.2.12**)*
Younger people were less likely to take up FOBt (section 2.1). The survey showed that younger people were more likely to perceive bowel cancer as a threat to financial security. They also perceived the kit as difficult to complete in terms of lack of time, storage problems and constipation and found the kit embarrassing and disgusting. Younger people also perceived higher outcome costs in terms of having to go to hospital and unpleasant treatment.

*2.2.3.12 Summary of employment status differences (**Table 2.2.13**)*
People who were employed (full/part-time) were less likely to take up FOBt than those who were not employed (section 2.1). Findings from the survey demonstrate that people who were employed perceived bowel cancer as more serious in terms of threat to financial security, important relationships, and the ability to live life as normal. Lack of time, and current treatment for bowel disease were significant barriers to completion of the kit for the employed, and they also felt that doing the kit would lead to unpleasant treatment. Self-confidence in ability do the FOBt kit was however, higher amongst the employed.

*2.2.3.13 Multivariate analysis of intentions to take up FOBt in the future (**Table 2.2.14**)*
72% of non-responders and virtually all responders intend to take part in screening if it is offered to them again in the future. Multivariate analysis of variables associated with intention showed that intention was associated with high perceived efficacy of screening, high self-efficacy and low barriers, low psychological costs and previous screening history.

2.2.4 Results: Psychological Distress after FOBt (**Table 2.2.15 and 2.2.16**)

Since invitees were surveyed only once for this evaluation, psychological distress was assessed in the same survey 8 months after first FOBt invitation using standard validated measures of anxiety, depression and anger which have been used in previous studies of colorectal cancer, breast and cervical cancer screening impact. Thus data relating to distress assess whether there is any sustained impact of screening on the population. Comparison of screening +ves and –ves facilitates assessment of whether a positive result has any sustained impact on distress compared to a control group.

Levels of anxiety and depression for all survey participants were not significantly different from population norms. Anxiety and depression were higher amongst younger people, women and those with higher deprivation indexes. Non-responders to FOBt reported more symptoms of anxiety and depression than those who did complete the kit.

There was no evidence of elevated distress amongst FOBt positives or cancer positives. These groups reported lower anxiety and depression than either non-responders or respond-negatives.

2.2.5 Discussion

Although FOBt uptake was reasonable, reaching almost 60% in the whole invitee group (whilst considerably less in certain sub-groups), achieving adequate levels of uptake would clearly be a major issue in a national programme. Moreover, uptake was associated with gender, age, deprivation and employment status. The psychosocial survey may provide information which could assist in addressing both inequality in uptake and promote uptake generally. Information regarding behavioural risk factors indicates that non-responders report a number of health behaviours which could put them at increased risk of bowel cancer.

Bowel cancer was generally viewed as serious and people considered themselves susceptible to the disease, indicating that this disease and its prevention are salient issues for this age group. Perceived severity, particularly in terms of financial consequences, discriminated the non-responder group and was also associated with being younger, male and more deprived. The importance of financial concerns may relate to loss of earnings or employment or to concerns about life insurance and other forms of long term financial security. The threat to physical well-being posed by bowel cancer is also notable with non-responders, males and those in lower socio-economic groups viewing the disease as more severe. These finding suggests that non-uptake may be an avoidant response to fear of a positive result.

Public confidence in bowel cancer screening effectiveness was very high. However, doubts about its effectiveness in preventing death from bowel cancer and in providing peace of mind about bowel cancer did explain a proportion of variance in non-response. Maintaining confidence in screening will be an important consideration for a mass screening programme. This variable was not associated with demographic variables.

The most important factors affecting FOBt response are those relating to the ease or difficulty of completing the kit. Self-efficacy, specific barriers and psychological costs also accounted for age group differences and social deprivation differences in uptake. Constipation, lack of time and storage problems were more commonly reported amongst younger people. Those in employment were more concerned about the negative implications of bowel cancer for their financial security, and were also more likely to report that lack of time was a barrier to completing an FOBt. People from areas of higher deprivation were more likely to report physical disabilities and a range of bowel irregularities as barriers. Non-response was also associated with finding the process of completing the kit disgusting or embarrassing. These emotional reactions may be linked to complaints of constipation or diarrhoea, whilst embarrassment may arise from storage difficulties. It may be possible to address these barriers in communications sent to people with their kits.

We obtained no evidence of psychological distress following FOBt. It should be noted that it is entirely likely, based on findings from other screening programs (eg Orbell et al., 2003), that anxiety was elevated at the time of receipt of a positive result and immediately prior to colonoscopy. The findings reported here relate only to sustained impact, 8 months following initial invitation.

2.3 Focus Group Studies

2.3.1 Aim

The aims of the focus group discussions were:

- to explore people beliefs and views about colorectal/bowel cancer
- to identify the psychological issues that might be associated with acceptability and uptake of FOBt screening for colorectal/bowel cancer.

2.3.2 Methods

Four focus groups were conducted with pre-existing, rather than specially convened groups. Two of the discussion groups were conducted with senior citizen lunch clubs, one was conducted with a group of Rotary club members and the other with an occupational group in a large manufacturing plant. The groups were guided by a moderator and audio-recorded. The questioning and discussions were broadly structured around the components of the theory of planned behaviour (Ajzen, 1988), the health belief model (Becker, 1974; Janz & Becker, 1984), and protection motivation theory (Rogers, 1975; Rippetoe & Rogers, 1987). The recordings were transcribed verbatim and following review the data was categorised according to three broad topic areas; awareness and understanding of colorectal/bowel cancer, perceptions of colorectal/bowel cancer, and acceptability of FOBt screening.

2.3.3 Results

Awareness of the disease amongst the group participants was good and for many was related to personal experience of the disease. Participants were also aware of the symptoms associated with the disease, however no one mentioned that blood loss associated with colorectal/bowel cancer is very often occult. Diet was recognised by most participants as the main cause of the disease, and in terms of treatment alternatives, colostomy was suggested most frequently. While there was an acknowledgement amongst participants that they were vulnerable to colorectal/bowel cancer because of their age, understanding of personal risk factors was poor.

With regard to perceptions of colorectal/bowel cancer, there was widespread acceptance of the serious threat to mortality and morbidity presented by the disease. The findings show that the participants perceived colorectal/bowel cancer as also having serious psychosocial threats. Colostomy was viewed as having very serious social and psychological consequences.

The findings demonstrated a high level of support for FOBt screening and most participants (men and women) were positively inclined towards doing the test. The simplicity and convenience of the FOBt were highlighted as particularly appealing features. Being able to do the test oneself and in the privacy of one's own home was perceived as beneficial as it imbued a sense of personal autonomy over the behaviour. Participants also did not perceive doing the FOBt as embarrassing, or as something that would compromise their personal standards of hygiene. Finally, doing the FOBt and participating in colorectal/bowel cancer screening was not perceived by the participants as something that would cause them major psychological upset. Receiving a positive result was however, something that several participants viewed as distressing.

2.3.4 Discussion

The participants in the focus groups demonstrated good awareness of colorectal/bowel cancer, in terms of causation, consequences, and treatment alternatives. The disease was perceived as one that presents a serious challenge to one's physical well-being, but also as one that can have serious psychosocial consequences. Finally, while the majority of participants perceive the FOBt as an acceptable screening technique with very specific benefits, the discussions did not elicit a great understanding of personal vulnerability to colorectal/bowel cancer.

See Report **Supplement S2** for detailed focus group paper.

2.4 Ethnicity

2.4.1 Analyses of Routine Data

Data used for analysis of ethnic uptake were extracted from a screening data download taken from the English Pilot site on 1/6/02; a total of 179,305 records were downloaded. These also formed the basis of the samples drawn for the ethnic psychosocial survey. In addition, a data download of individuals' names, full postcodes and NHS numbers was arranged with the NHSIA. This enabled a religion and language ('ethnicity') indicator to be identified based on each individual's name using the *Nam Pehchan* software package, and a deprivation indicator (Carstairs index) to be obtained from each subject's residence. Five distinct religion-language groups were identified for the South Asian community: Hindu-Gujerati, Hindu-Other, Muslim, Sikh and Other Asian; and 7 deprivation categories were identified, using the same cut-off values as those applied in the Main Evaluation.

The aspects of screening uptake measured were identical to those developed for the Main Evaluation: (i) response to offer of screening; (ii) completion of phase I of screening; (iii) completion of screening; and (iv) completion of screening in responders. Similarly, analyses of screening uptake only included individuals who had been sent their initial screening invitation more than three months before the date of the download; and analyses excluded subjects who were withdrawn for various reasons. Logistic regression analysis was used to explore associations between the measures of uptake and various attributes of the population, including gender, age, invitation time, ethnicity and deprivation category. Both univariate and multivariate analyses were undertaken to produce respectively unadjusted and adjusted odds ratios with 95% confidence intervals.

Screening uptake analysis for the whole population showed 1.4% had declined the offer of screening. In general, a lower proportion of Asians declined the offer of screening (0.53% – 1.13%) than Non-Asians (1.43%), except for Hindu-Gujeratis (1.97%). There was therefore no evidence that the willingness to be screened differed significantly for different ethnic groups, although numbers were small.

In terms of a decision to respond to screening [i.e. at least one kit returned (adequate or inadequate) allowing at least 3 months from invitation], the response rate for the overall population was 62.2%. However, significantly lower levels were recorded for all ethnic groups (ranging from 31.9% for Muslims to 43.7% for Hindu-Others); versus 63.7% for non-Asians. Multivariate analyses also produced adjusted odds ratios which demonstrated a significantly lower uptake, even once other factors were taken into account, for all five ethnic groups at the $p<0.01$ level.

The overall level of completion of phase I screening (i.e. initial adequate kit returned, giving a result of negative, positive or weakly positive, allowing at least 3 months from invitation), was 61.3%. Once again, significantly lower levels were recorded for all ethnic groups (ranging from 30.0% for Muslims to 42.4% for Hindu-Others); versus 62.9% for non-Asians. Multivariate analysis once again demonstrated a significantly ($p<0.01$) lower completion rate for all ethnic groups. Non-responder rates were, of course, higher in all ethnic groups (ranging from 53% for Muslims to 36.1% for Hindu-Gujerati), compared to 29.1% for non-Asians. However, ethnic groups also all demonstrated a higher percentage of cases still 'under process' (range 16.5% Muslim, 21.6% Hindu-Gujerati to 27.7% Other-Asian) compared to 6.6% for non-Asians. Linked to the latter finding, analyses identified that ethnic group were also all being sent more kits (between 6.8% and 27.7% were being sent 4 or more kits, compared with 3.4% for non-Asians). These results may be indicative of problems with kit use.

In terms of the influence of age and gender, analyses also show different uptake patterns among Asians versus non-Asians. Asian uptake was generally higher among younger invitees (the reverse of the pattern observed for non-Asians). Uptake among males and females varied, with Muslim and Sikh groups exhibiting similar uptakes for both sexes; Hindu-Gujerati males a higher uptake than females; and the other two groups a lower male uptake (as observed in the non-Asian population).

In terms of completion of screening (i.e. an overall result of FOB testing available, allowing at least 4 months from invitation), once again lower uptake levels are observed for all ethnic groups (ranging from 32.1% for Muslims to 45.4% for Hindu-Gujeratis); versus 63.7% for non-Asians. Multivariate analysis once again demonstrated a significantly ($p<0.01$) lower uptake for all ethnic groups, even with

other factors taken into account. Furthermore, the rates of completion of screening in responders (i.e. in those who returned at least one test kit) indicated that Sikh and Muslim groups continued to demonstrate significantly lower uptakes (adjusted odds ratios 0.22 and 0.31 respectively versus 1.0 for non-Asians); for other ethnic groups, although rates were lower (0.53 – 0.86 adjusted odds ratios) these differences were not significant at the p=0.1 level.

Finally, because there is evidence from the literature that the role of the clinician can be particularly important in influencing screening uptake in ethnic groups, screening uptake rates of subjects were also related to GP attributes (in terms of religion and language characteristics of the clinician). Uptake rates were found to be much lower for subjects registered with an Asian GP (regardless of the subject's ethnic origin), especially when the practitioner was Muslim. Rates were lowest for Muslim subjects registered with a Muslim GP (only 22.8% returned a kit).

2.4.2 Psychosocial Surveys

Psychosocial questionnaires were sent to 4,000 people identified as Hindu-Gujerati, Hindu-Other, Moslem and Sikh-Punjabi. Response rates ranged from 61.3 to 44.7 per cent across groups of FOBt responders, and from 11.1 to 4.4 per cent across groups amongst Phase I non-responders.

Comparisons of FOBt responders and non-responders across all ethnic groups suggest that the principal determinants of non-uptake were lower perceived efficacy of screening, higher perceived psychological costs, and higher perceived barriers and lower levels of encouragement from children or a partner. These findings indicate that determinants of uptake *per se* are very similar for Asian and non-Asian groups. Since uptake was lower amongst Asian groups, we examined absolute differences between Asians and non-Asians and between different Asian sub-groups on these determinants of uptake. Analyses showed that all Asian groups collectively perceived screening as less efficacious and as having higher psychological costs and higher barriers. The Hindu-Gujerati group also perceived higher costs in terms of embarrassment, disgust and hygiene than all other Asian groups; and perceived lower levels of encouragement for participation from all sources. Moslems reported lower self-confidence about completing the kit (i.e. perceived it as more difficult to complete) but this was not related to differences in specific barriers. 14% of Asian non-responders considered that FOBt should not be rolled out, compared with 6.3% of non-Asians. Amongst FOBt responders, 4.1% of Asians and 0.7% of non-Asians considered that it should not be rolled out.

The pattern of psychological distress observed was similar to that obtained amongst non-Asians, in that FOBt non-responders were more distressed than FOBt respond negatives. However, absolute differences in psychological distress were observed such that all Asians reported higher anxiety, depression and anger than non-Asians and Asian rates were above population norms. Sikhs reported the highest levels of depression and anger, compared to other Asian groups.

2.4.3 Focus Group Studies

Focus Group interviews were conducted with members of Sikh-Punjabi, Gujerati, Pakistani/Urdu, Bengali, Vietnamese/Chinese, and African-Caribbean communities by bilingual, trained community workers who followed an agreed topic guide, based on that used in the Main Evaluation. Examples of the circulated FOB test kit were used in these groups and information given about the disease and screening process, as part of the stimuli for the discussions. These were phased to ensure that un-forced comments were recorded first, and that subsequent discussion could be based on some knowledge – especially as many of the discussion groups had to be held in locations outside the screening Pilot, where communities had not been sent postal materials. Where focus group interviews were held with groups within Warwickshire/Coventry, enquiries were made as to receipt of the formal invitations to participate. It appeared that some at least of the eligible participants reported that they had not yet seen the postal invitation.

As a general rule, there was (at least theoretical) support and even enthusiasm for the principle of screening among most minority ethnic communities. Few people, once the principle had been explained, thought that there was, or should be, a problem with completing the test. Many suggested that 'doing it at home' was a more convenient and acceptable method than having to report to a hospital. However, at the same time, it was clear that many members of minority groups would not respond to postal invitations unless prior warning had been given and community-relevant sources had alerted them to the value of the activity. Low levels of literacy meant low awareness or reliance on

others (such as children) to advise about postal material, and some said that their children protected them against intrusive surveys and the like. We did not find the anticipated level of resistance to FOBt screening on the grounds of hygiene or religion, although there were some questions about 'storage'.

2.5 Conclusions and recommendations

While the Pilot has achieved close to its target uptake of 60%, there are important sub-groups in which uptake is low. FOBT appears to be less acceptable to men, to younger people and to those from materially deprived areas, to those belonging to certain ethnic sub-groups. Uptake was also lower in Scotland: this may be a reflection of the relatively dispersed and rural nature of the Scottish Pilot population, although it is difficult to conclude this with certainty. Uptake in people from ethnic minorities is also likely to be influenced by GP attributes including religion and language, and this may lead to further need for targeted recruitment efforts.

We recommend that in a national programme efforts are directed towards improving uptake in these groups; they may need to be the focus of tailored recruitment strategies which address the apparent barriers to uptake in these groups.

Psychosocial and lifestyle factors will also be important in the implementation of a national programme; those who do not respond to invitations for FOBT screening would appear to exhibit a number of lifestyle characteristics which put them at risk of colorectal cancer (and other lifestyle-related diseases). While colorectal cancer is considered to be a serious disease, to which people consider themselves susceptible, practical issues such as ease of completion of a FOBT still influence their decisions to participate in screening.

While it is likely that many participants in the UK Pilot experienced short-term anxiety, we were not able to detect sustained adverse psychological sequelae. This suggests that provided the standard of information provision and other programme elements of the UK Pilot can be repeated in a national programme, adverse psychological effects in the population would be minimal.

Table 2.2.1 Comparison of FOBt outcome groups on measures of colorectal cancer risk factors.

	Phase I Non-Responder		Phase I Negative		Phase III Negative		FOBt Positive		Cancer Positive	
	Total N = 473		Total N = 697		Total N = 421		Total N = 502		Total N = 199	
Proportion of people agree with each item.	N	%[1]	N	%	N	%	N	%	N	%
Exercise "Over a 7-day period during my leisure-time, I never/rarely engage in any regular activity long enough to work up a sweat."	186	41.8	255	38.7	152	37.5	216	45.3 a	62	33.7 a
Smoking[2] "Yes, I am a smoker."	138	29.7 abcd	144	21.3 a	78	18.9 b	95	19.0 d	18	9.2 c
Weight (assessed by BMI) Underweight Desirable Overweight/Obese[3]	12 153 277	2.7 34.6 62.7 a	20 245 379	3.1 38.0 58.9 bc	16 114 261	4.1 29.2 66.8 b	8 128 330	1.7 27.5 70.8 ac	7 57 123	3.7 30.5 65.8
Fibre Intake[4] Low Moderate High	224 123 97	50.5 ab 27.7 21.8	265 240 156	40.1 a 36.3 23.6	169 128 100	42.6 32.2 25.2	222 150 121	45.0 30.4 24.5	71 60 61	37.0 b 31.3 31.8
Fat Intake[4] Low Moderate High	227 123 88	51.8 28.1 20.1	362 178 116	55.2 27.1 17.7	221 95 78	56.1 24.1 19.8	266 130 83	55.5 27.1 17.3	106 52 31	56.1 27.5 16.4
Family History "I know someone personally who has had bowel cancer." "A member of my family (a blood relative) has had bowel cancer."	156 55	33.6 abc 11.8 ab	263 105	39.0 d 15.6 cd	166 64	40.5 ae 15.7 d	207 98	41.7 b 20.1 ace	110 52	56.7 cde 27.1 bde
Contraceptive Pill (% of Women only) Never/< 12 months 1-5 years > than 5 years	**N = 158** 32 46 80	**%** 20.3 ab 29.1 50.6	**N = 205** 32 58 115	**%** 15.6 cde 28.3 56.1	**N = 119** 37 31 51	**%** 31.1 c 26.1 42.9	**N = 140** 60 29 51	**%** 42.9 be 20.7 36.4	**N = 45** 22 6 17	**%** 48.9 ad 13.3 37.8

[1]. % within a row sharing the same subscript differ significantly at $p < .05$

a. Figures indicate proportion endorsing each item.
b. In the UK , smoking prevalence in the adult population is around 27% (Walker, Maher, Coulthard, Godard, & Thomas, 2001).
c. Levels of obesity amongst the adult population in the UK are estimated to be around 20% (National Audit Office, 2001)
d. Fibre and fat intake was assessed by the DINE (Dietary Instrument for Nutrition Education- Roe, Strong, Whiteside, Neil, & Mant, 1994). The low fat category is designed to represent a fat intake of 83 g/day or less and the high fat category an intake greater than 122 g/day. The low fibre category is designed to correspond to a dietary fibre intake of 20 g/day or less, and the high fibre category to more than 30 g/day.

Table 2.2.2 Comparison of FOBt outcome groups on specific items assessing perceived susceptibility to colorectal Cancer.

	Phase I Non-Responder		Phase I Negative		Phase III Negative		FOBt Positive		Cancer Positive	
	Total N = 473		Total N = 697		Total N = 421		Total N = 502			
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
"In comparison to other people my age, my chances of developing bowel cancer are high."	250	57.2 a	315	47.5 abc	234	57.9 b	257	54.0 c	-	-
"I am at more of a risk of developing bowel cancer than other people my age."	315	72.2	432	67.7	280	70.4	329	68.5	-	-
"I think that my chances of developing bowel cancer are high."	172	39.5 a	223	34.0 b	163	40.8 bc	149	31.1 ac	-	-
"I feel personally at risk of developing bowel cancer."	176	39.1 a	276	41.3 b	192	47.5 abc	195	40.0 c	-	-
"It is likely that I will develop bowel cancer."	142	35.4	203	33.6	119	32.2	154	32.2	-	-
"I agree that my chances of developing bowel cancer are very high."	176	41.0	275	42.6 a	179	45.0 b	172	36.6 ab	-	-

* % within a row sharing the same subscript differ significantly at $p < .05$

[1] Figures indicate proportion of people who responded to the item endorsing it.

Table 2.2.3 Comparison of FOBt outcome groups on specific items assessing perceived severity of colorectal cancer

	Phase I Non-Responder		Phase I Negative		Phase III Negative		FOBt Positive		Cancer Positive	
	Total N = 473		Total N = 697		Total N = 421		Total N = 502		Total N = 199	
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
"I am certain that if I were to develop bowel cancer it would limit my social life."	363	77.6 abcd	488	71.1 aef	294	70.7 bgh	292	59.2 cegi	80	42.3 dfhi
"If I develop bowel cancer it is likely that my financial security would be at risk."	321	69.3 abcd	430	62.5 aefg	233	56.3 behi	214	43.4 cfh	75	39.5 dgi
"I am certain that if I were to develop bowel cancer it would damage important relationships in my life."	259	55.7 abcd	336	49.1 aef	195	47.4 bgh	159	32.6 cegi	41	22.3 dfhi
"If I develop bowel cancer it is likely that I would have to stop living my life the way that I want to."	355	76.8 ab	507	74.9 cd	311	74.9 ef	315	63.6 aceg	85	45.0 bdfg
"If I develop bowel cancer I am certain that I would experience a lot of physical pain."	313	68.5 abcd	385	57.9 ae	243	59.3 bf	287	59.1 dg	63	33.3 cefg
"If I develop bowel cancer I am certain that I would experience a lot of physical sickness."	285	63.6 abcd	359	54.9 ae	228	56.2 bf	247	50.6 dg	51	27.4 cefg
"If I develop bowel cancer is it likely that I will die."	358	80.1 abcd	472	72.5 ae	294	72.4 bf	302	62.3 dg	82	43.6 cefg
"If I develop bowel cancer, it could almost certainly cause my death."	260	59.1abcd	343	53.2 ae	204	50.5 bf	238	49.2 dg	51	26.8 cefg

* % within a row sharing the same subscript differ significantly at $p < .05$

[1] Figures indicate proportion endorsing each item.

Table 2.2.4 Comparison of FOBt outcome groups on specific items assessing the efficacy/benefits of performing fobt.

	Phase I Non-Responder		Phase I Negative		Phase III Negative		FOBt Positive		Cancer Positive	
	Total N = 473		Total N = 697		Total N = 421		Total N = 502		Total N = 199	
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
"Doing an FOBt in the future would reduce my chances of dying from bowel cancer."	380	86.4 ab	592	90.4 a	357	89.0	443	91.7 b	168	90.3
"Doing an FOBt in the future would help find any abnormalities I may have before they become cancerous."	425	96.8	647	96.4	387	95.8	475	98.3	180	96.3
"Doing an FOBt in the future would increase my chances of getting treatment earlier."	412	93.8 ab	653	98.0 a	394	97.0	477	98.6 b	181	97.3
"Doing an FOBt in the future would help me avoid having to have drastic treatment if I had bowel cancer I didn't know about."	415	94.3	633	96.1	387	96.3	463	95.9	174	94.1
"Doing an FOBt in the future would put my mind at rest about bowel cancer."	397	91.3 abc	651	97.6 a	394	97.0 b	471	97.5 c	175	94.6
"Doing an FOBt in the future would reduce any worries I might have about getting bowel cancer."	391	89.5 abc	629	95.7 a	391	96.8 b	462	95.9 c	172	93.0
"Doing an FOBt in the future would increase my confidence about not getting bowel cancer."	386	88.7 abcd	628	94.7 a	382	95.5 b	459	94.8 c	175	94.6 d
"Doing an FOBt in the future would reduce any worries I might have about having any 'non-cancerous' abnormalities."	384	88.3 abcd	618	93.6 a	383	94.6 b	465	96.7 c	176	96.2 d

* % within a row sharing the same subscript differ significantly at $p < .05$

[1] Figures indicate proportion endorsing each item.

Table 2.2.5 Comparison of FOBt outcome groups on specific items assessing confidence in performing an FOBt.

	Phase I Non-Responder		Phase I Negative		Phase III Negative		FOBt Positive		Cancer Positive	
	Total N = 473		Total N = 697		Total N = 421		Total N = 502		Total N = 199	
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
"If I am invited to do an FOBt in the future, I am certain that I could do it."	333	71.6 abcd	665	96.4 a	408	97.6 b	467	94.3 c	187	98.9 d
"If I am invited to do an FOBt in the future, I would feel very confident in my ability to do it."	351	76.0 abcd	663	98.4 a	408	98.8 b	470	95.1 c	187	98.9 d
"If I am invited to do an FOBt in the future, I believe that I would be able to do it."	366	80.1 abcd	654	97.3 a	408	99.0 b	475	96.3 c	184	97.9 d
"If I am invited to do an FOBt in the future, I am capable of doing it."	394	85.3 abcd	659	96.3 a	405	97.1 b	469	94.0 c	184	97.4 d
"If I am invited to do an FOBt in the future, I could easily do it if I wanted to."	370	79.1 abcd	686	99.3 a	416	99.0 b	485	97.2 c	195	99.5 d
"If I am invited to do an FOBt in the future, it is easy for me to do it."	326	69.5 abcd	679	98.0 a	404	96.4 b	455	91.9 c	187	96.4 d

* % within a row sharing the same subscript differ significantly at $p < .05$

[1] Figures indicate proportion endorsing each item.

Table 2.2.6 Comparison of FOBt outcome groups on specific items assessing difficulties in performing FOBt.

	Phase I Non-Responder		Phase I Negative		Phase III Negative		FOBt Positive		Cancer Positive	
	Total N = 473		Total N = 697		Total N = 421		Total N = 502		Total N = 199	
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
"Constipation is likely to stop me from doing an FOBt if I am asked to do one in the future."	124	29.9 abcd	120	18.5 a	77	19.9 b	14	7.8 c	69	14.9 d
"Physical disability is likely to stop me from doing an FOBt if I am asked to do one in the future."	95	23.2 abcd	113	17.1 a	67	17.2 b	13	7.3 c	66	14.0 d
"Visual impairment is likely to stop me from doing an FOBt if I am asked to do one in the future."	64	15.9 abc	97	14.7	45	11.5	4	2.2 b	36	7.7 c
"Irregular bowel movements are likely to stop me from doing an FOBt if I am asked to do one in the future."	98	23.7 abcd	63	9.4 a	50	12.7 b	4	2.2 c	47	9.9 d
"Diarrhoea is likely to stop me from doing an FOBt if I am asked to do one in the future."	122	30.0 abcd	142	21.8 a	87	22.4 b	13	7.3 c	89	19.1 d
"Current treatment for bowel cancer is likely to stop me from doing an FOBt if I am asked to do one in the future."	98	25.1 abc	149	23.2	88	23.8	13	7.2 b	62	14.0 c
"Other bowel disease is likely to stop me from doing an FOBt if I am asked to do one in the future."	89	22.6 abcd	87	13.6 a	59	15.7 b	13	7.2 c	56	12.3 d
"Other illness is likely to stop me from doing an FOBt if I am asked to do one in the future."	78	19.6 abcd	55	8.5 a	31	8.1 b	10	5.5 c	54	11.6 d
"Lack of time is likely to stop me from doing an FOBt if I am asked to do one in the future."	95	23.5 abcd	20	3.0 a	6	1.6 b	4	2.2 c	20	4.3 d
"Having no where to store the test is likely to stop me from doing an FOBt if I am asked to do one in the future."	75	18.5 abcd	23	3.5 a	15	3.9 b	4	2.2 c	20	4.4 d

* % within a row sharing the same subscript differ significantly at $p < .05$

[1] Figures indicate proportion endorsing each item.

Table 2.2.7 Comparison of FOBt outcome groups on specific items assessing the psychological costs of Performing an FOBt.

	Phase I Non-Responder		Phase I Negative		Phase III Negative		FOBt Positive		Cancer Positive	
	Total N = 473		Total N = 697		Total N = 421		Total N = 502		Total N = 199	
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
"Doing an FOBt in the future would be an invasion of my privacy."	145	34.0 abcd	70	10.8 a	33	8.5 be	68	14.4 ce	24	13.4 d
"Doing an FOBt in the future would be embarrassing."	216	50.0 abcd	118	18.4 ae	58	14.9 bf	122	25.7 cefg	32	17.7 dg
"Doing an FOBt in the future would be disgusting."	149	35.9 abcd	94	14.9 ae	48	12.5 b	61	13.0 cf	13	7.2 def
"Doing an FOBt in the future would be unhygienic."	121	29.5 abcd	80	12.7 ae	33	8.7 be	43	9.3 c	14	7.9 d
"Doing an FOBt in the future would lead to unpleasant treatment if abnormalities were present."	311	74.2 abcd	387	61.3 ae	231	60.5 bf	253	53.6 cef	102	55.7 d
"Doing an FOBt in the future would lead to me having to go to hospital if abnormalities were present."	363	85.0 a	527	80.8 b	315	81.2 c	357	75.2 abc	148	80.4
"Doing an FOBt in the future would lead to blood being found in my bowel motion if abnormalities were present."	327	77.3	476	74.0 a	315	81.2 a	377	78.7	146	81.1

* % within a row sharing the same subscript differ significantly at $p < .05$

[1] Figures indicate proportion endorsing each item.

Table 2.2.8 Comparison of FOBt outcome groups on specific items assessing social influences on performing an FOBt.

	Phase I Non-Responder		Phase I Negative		Phase III Negative		FOBt Positive		Cancer Positive	
	Total N = 473		Total N = 697		Total N = 421		Total N = 502		Total N = 199	
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
"My partner is likely to want me to do an FOBt in the future"	313	82.6 abcd	555	96.7 a	344	96.6 b	408	95.8 c	160	97.6 d
"My children are likely to want me to do an FOBt in the future"	320	84.7 abcd	546	94.6 a	318	93.5 b	398	94.3 c	156	98.7 d
"My doctor is likely to want me to do an FOBt in the future"	354	89.4 abcd	601	96.8 a	356	96.7 b	417	96.1 c	178	97.3 d
"My friends are likely to want me to do an FOBt in the future"	314	81.1 abcd	542	88.7 a	312	89.9 b	393	91.0 c	171	96.6 d

* % within a row sharing the same subscript differ significantly at $p < .05$

[1] Figures indicate proportion endorsing each item.

Table 2.2.9 Multivariate logistic regression analysis – significant predictors of uptake of FOBt screening.

		FOBt non-respond		FOBt respond		Multivariate odds ratio
	N[1]	N	%	N	%	
Severity of Bowel Cancer						
1) "If I develop bowel cancer it is likely that my financial security would be at risk."	1,273	321	25.2	952	74.8	
"If I develop bowel cancer it is unlikely that my financial security would be at risk."	975	142	14.6	833	85.4	0.501 (0.328, 1.597)
Difficulties In Performing a FOBt						
1) "Visual impairment is likely to stop me from doing a FOBt if I am asked to do one in the future."	246	64	26.0	182	74.0	
"Visual impairment is unlikely to stop me from doing a FOBt if I am asked to do one in the future."	1,851	338	18.3	1,513	81.7	0.355 (0.162, 0.778)
2) "Lack of time is likely to stop me from doing a FOBt if I am asked to do one in the future."	145	95	65.5	50	34.5	
"Lack of time is unlikely to stop me from doing a FOBt if I am asked to do one in the future."	1,953	310	15.9	1,643	84.1	5.504 (2.609, 11.612)
3) "Storage problems are likely to stop me from doing a FOBt if I am asked to do one in the future."	137	75	54.7	62	45.3	
"Storage problems are unlikely to stop me from doing a FOBt if I am asked to do one in the future."	1,949	331	17.0	1,618	83.0	2.840 (1.191, 6.773)
Psychological Costs Of Performing a FOBt						
1) "Doing a FOBt in the future would be embarrassing."	546	216	39.6	330	60.4	
"Doing a FOBt in the future would not be embarrassing."	1,573	216	13.7	1,357	86.3	2.194 (1.301, 3.699)
Confidence in Performing an FOBt						
1) "If I am invited to do an FOBt in the future, I could easily do it, if I wanted to."	2,051	326	15.9	1,725	84.1	
"If I am invited to do an FOBt in the future, I could not easily do it, if I wanted to."	219	143	65.3	76	34.7	0.474 (0.244, 0.921)
2) "If I am invited to do a FOBt in the future, I am certain that I could do it."	2,060	333	16.2	1,727	83.8	
"If I am invited to do a FOBt in the future, I am not certain that I could do it."	197	132	67.0	65	33.0	0.312 (0.128, 0.762)
3) "If I am invited to do an FOBt in the future, I would feel very confident in my ability to do it."	2,079	351	16.9	1,728	83.1	
"If I am invited to do an FOBt in the future, I would not feel very confident in my ability to do it."	153	111	72.5	42	27.5	0.349 (0.138, 0.883)
Social Encouragement for Performing a FOBt						
1) "My partner is likely to want me to do an FOBt in the future"	1,780	313	17.6	1,467	82.4	
"My partner is unlikely to want me to do an FOBt in the future."	119	66	55.5	53	44.5	0.331 (0.139, 0.788)

[1] Total number of participants endorsing item options.

Table 2.2.10 Gender differences on specific items.

	Gender				Chi-square
	Female		Male		
	Total N = 1,107		Total N = 1,275		
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**χ^2, p**
Perceived Severity of Bowel Cancer					
"If I develop bowel cancer… …I am certain that it would limit my social life."	648	65.0	869	69.2	4.560, p < .05
…I am certain I would experience a lot of physical pain."	547	56.0	744	60.5	4.542, p < .05
…I am certain my financial security would be at risk."	508	51.2	765	61.0	21.669, p < .000
…I am certain it would damage important relationships in my life."	397	40.2	593	47.6	12.119, p < .000
…I am certain I would experience a lot of physical sickness."	483	50.1	687	56.4	8.589, p < .00
…I am certain I would have to stop living my life the way that I want to."	667	67.3	906	72.7	7.564, p < .00
"If I develop bowel cancer is it likely that I will die."	635	66.0	873	71.9	8.613, p <.00
Barriers					
"If asked to do an FOBt in the future… …physical disability is likely to stop me from doing it."	174	19.2	180	15.0	6.470, p < .01
…visual impairment is likely to stop me from doing it."	141	15.6	105	8.8	22.779, p < .000
…irregular bowel movements are likely to stop me from doing it."	140	15.1	122	10.1	12.245, p < .000
…lack of time is likely to stop me from doing it."	79	8.8	66	5.5	8.680, p < .01
…storage problems are likely to stop me from doing it."	71	7.9	66	5.6	4.302, p < .05
Efficacy/Benefits					
"Doing an FOBt in the future would increase my chances of getting treatment earlier."	925	96.3	1,192	97.7	3.974, p < .05
"Doing an FOBt in the future would put my mind at rest about bowel cancer."	929	97.0	1,159	95.2	4.561, p < .05
Psychological Costs					
"Doing an FOBt in the future would be embarrassing."	292	31.6	254	21.3	29.163, p < .000
"Doing an FOBt in the future would be disgusting."	181	20.1	184	15.6	7.014, p < .01
"Doing an FOBt in the future would lead to unpleasant treatment if abnormalities were present."	589	64.9	695	58.9	7.906, p < .01
Confidence					
"Doing an FOBt in the future is easy for me."	882	87.6	1,169	92.6	4.726, p < .05
Social Influence					
"My friends are likely to want me to do an FOBt in the future."	782	90.8	950	86.9	15.880, p < .000

[1] Figures indicate proportion endorsing each item.

Table 2.2.11 Deprivation category differences on specific items.

	Deprivation Category				Chi-square
	Depcat 1/2/3		Depcat 4/5/6/7		
	Total N = 1,068		Total N = 1,026		
Proportion of people agree with each item.	N	%[1]	N	%	χ^2, p
Perceived Vulnerability to Bowel Cancer					
"In comparison to other people my age, my chances of developing bowel cancer are high."	449	49.4	522	57.0	10.562, p < .000
"I feel personally at risk of developing bowel cancer."	360	39.0	412	44.1	4.987, p < .05
Perceived Severity of Bowel Cancer					
"If I develop bowel cancer…					
… I am certain I would experience a lot of physical pain."	578	56.0	602	61.2	5.682, p < .05
…I am certain my financial security would be at risk."	577	55.4	603	59.8	4.040, p < .05
…I am certain it would damage important relationships in my life."	443	42.6	478	47.7	5.290, p < .05
…I am certain I would experience a lot of physical sickness."	527	51.9	553	56.7	4.601, p < .05
Barriers					
"If asked to do an FOBt in the future… …physical disability is likely to stop me from doing it."	151	15.2	177	19.0	5.053, p < .05
…visual impairment is likely to stop me from doing it."	102	10.3	130	14.1	6.626, p < .01
…irregular bowel movements are likely to stop me from doing it."	106	10.6	138	14.5	6.820, p < .01
…constipation is likely to stop me from doing it."	174	17.6	199	21.4	4.484, p < .05
…diarrhoea problems are likely to stop me from doing it."	185	18.7	229	24.8	10.571, p < .000
…current treatment for bowel cancer is likely to stop me from doing it."	164	17.3	217	24.0	12.738, p < .000
…other bowel disease is likely to stop me from doing it."	114	12.0	166	18.2	14.225, p < .000
Psychological Costs					
"Doing an FOBt in the future would be disgusting."	149	15.3	199	21.5	12.088, p < .000
Confidence					
"If I am invited to do an FOBt in the future, I am capable of doing it."	998	95.6	922	91.3	15.614, p < .000
Social Influence					
"My partner is very likely to want me to do an FOBt in the future."	877	94.7	746	92.1	4.835, p < .05
"My doctor is very likely to want me to do an FOBt in the future."	908	96.4	834	93.9	6.101, p < .01

[1] Figures indicate proportion endorsing each item.

Table 2.2.12 Age-group differences on specific items

	Age-groups								Chi-square
	50-54 years		55-59 years		60-64 years		65-69 years		
	Total N = 609		Total N = 552		Total N = 508		Total N = 623		
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**N**	**%**	**N**	**%**	**χ^2, p**
Perceived Severity of Bowel Cancer									
"If I develop bowel cancer I am certain my financial security would be at risk."	440	73.0	347	63.6	266	53.6	220	36.5	177.655, p < .000
Barriers									
"If asked to do an FOBt in the future…									
….constipation is likely to stop me from doing it."	151	26.4	84	16.6	73	15.4	96	17.6	26.362, p < .000
…. current treatment for bowel cancer is likely to stop me from doing it."	128	22.9	113	22.6	81	18.0	88	17.1	8.590, p < .07
…. lack of time is likely to stop me from doing it."	61	10.7	36	7.0	22	4.7	26	4.8	19.989, p < .000
…. storage problems are likely to stop me from doing it."	53	9.2	29	5.7	18	3.8	37	7.0	13.274, p < .01
Benefits/Efficacy									
"Doing an FOBt in the future would reduce my chances of dying from bowel cancer."	530	90.9	476	90.7	435	90.8	499	86.3	9.100, p < .05
Psychological Costs									
"Doing an FOBt in the future would be embarrassing."	178	31.2	136	26.1	117	24.9	115	20.6	16.866, p < .000
"Doing an FOBt in the future would be disgusting."									
"Doing an FOBt in the future would lead to unpleasant treatment if abnormalities were present."	121	21.4	80	15.8	74	16.2	90	16.5	7.814, p < .05
"Doing an FOBt in the future would lead to me having to go to hospital if abnormalities were present."	389	69.0	307	60.2	269	58.6	319	57.6	18.885, p < .000
	487	84.8	404	78.3	372	79.8	447	78.4	10.167, p < .05
Confidence									
"Doing an FOBt in the future is easy for me."	532	88.1	490	89.3	468	93.6	561	90.9	10.622, p < .01

[1] Figures indicate proportion endorsing each item.

Table 2.2.13 Employment status differences on specific items.

	Employment Status				Chi-square
	Employed (full/part-time)		Other		
	Total N = 1,001		Total N = 1,232		χ^2, p
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	
Perceived Vulnerability to Bowel Cancer					
"In comparison to other people my age, my chances of developing bowel cancer are high."	447	50.4	580	55.3	4.724, p < .05
Perceived Severity of Bowel Cancer					
"If I develop bowel cancer I am certain my financial security would be at risk."	773	78.1	474	39.3	333.149, p < .000
"If I develop bowel cancer I am certain it would damage important relationships in my life."	482	49.1	481	40.0	18.070, p < .000
"If I develop bowel cancer I am certain I would have to stop living my life the way that I want to."	719	72.8	820	68.2	5.695, p < .05
Barriers					
"If asked to do an FOBt in the future current treatment for bowel cancer is likely to stop me from doing it."	208	22.2	195	18.5	4.016, p < .05
"If asked to do an FOBt in the future lack of time is likely to stop me from doing it."	92	9.6	48	4.3	22.323, p < .000
Psychological Costs					
"Doing an FOBt in the future would lead to unpleasant treatment if abnormalities were present."	611	65.2	658	58.7	9.151, p < .01
Confidence					
"If I am invited to do an FOBt in the future, I have control over whether or not I do it."	967	97.4	1,160	95.5	5.631, p < .05
"If I am invited to do an FOBt in the future, I feel capable of doing one."	945	95.3	1,122	92.7	6.086, p < .05
"If I am invited to do an FOBt in the future, I would feel very confident in my ability to do it."	932	94.7	1,108	92.0	6.207, p < .05

[1] Figures indicate proportion endorsing each item.

Table 2.2.14 Multivariate logistic regression analysis – significant predictors of future intention to participate/non-participate in FOBt screening.

		Non-Intend		Intend		Multivariate odds ratio
	N[1]	N	%	N	%	
Difficulties In Performing a FOBt						
1) "Physical disability is likely to stop me from doing a FOBt if I am asked to do one in the future."	352	53	15.1	299	84.9	
"Physical disability is unlikely to stop me from doing a FOBt if I am asked to do one in the future."	1,741	82	4.7	1,659	95.3	0.049 (0.003, 0.725)
Efficacy/Benefits Of Performing a FOBt						
1) "Doing a FOBt in the future would reduce my chances of dying from bowel cancer."	1,921	112	5.8	1,809	94.2	
"Doing a FOBt in the future would not reduce my chances of dying from bowel cancer."	224	38	17.0	186	83.0	0.095 (0.016, 0.551)
2) "Doing a FOBt in the future would put my mind at rest about bowel cancer."	2,074	113	5.4	1,961	94.6	
"Doing a FOBt in the future would not put my mind at rest about bowel cancer."	85	31	36.5	54	63.5	0.001 (0.000, 0.050)
3) "Doing a FOBt in the future would reduce any worries I might have about other non-cancerous abnormalities."	2,011	110	5.5	1,901	94.5	
"Doing a FOBt in the future would not reduce any worries I might have about other non-cancerous abnormalities."	135	35	25.9	100	74.1	138.68 (2.69, 7149.56)
Psychological Costs Of Performing a FOBt						
1) "Doing a FOBt in the future would be disgusting."	361	72	19.9	289	80.1	
"Doing a FOBt in the future would not be disgusting."	1,698	61	3.6	1,637	96.4	13.422 (2.315, 77.836)
Confidence in Performing an FOBt						
1) "It is very likely that I could do a FOBt in the future, if I want to."	2,132	69	3.2	2,063	96.8	
"It is very unlikely that I could do a FOBt in the future, if I want to."	122	97	58.4	25	1.2	0.013 (0.001, 0.119)
2) "If I am invited to do a FOBt in the future, I am certain that I could do it."	2,051	32	1.6	2,019	98.4	
"If I am invited to do a FOBt in the future, I am not certain that I could do it."	194	129	66.5	65	33.5	0.077 (0.014, 0.416)
3) "If I am invited to do a FOBt in the future, I am capable of doing it."	2,097	104	5.0	1,993	95.0	
"If I am invited to do a FOBt in the future, I am incapable of doing it."	138	58	42.0	80	58.0	16.483 (1.363, 199.356)
4) "If I am invited to do a FOBt in the future, I believe that I would be able to do it."	2,072	66	3.2	2,006	96.8	
"If I am invited to do a FOBt in the future, I do not believe that I would be able to do it."	134	93	69.4	41	30.6	0.019 (0.002, 0.155)
Past Behaviour						
1) "I have participated in the FOBt screening Pilot."	1,803	38	2.1	1,7653	97.1	
"I have not participated in the FOBt screening Pilot."	462	129	27.9	33	72.1	5.124 (1.331, 19.728)

[1] Total number of participants endorsing item options.

Table 2.2.15 Psychological distress 8 months after first FOBt screening invitation.

	HADS Depression			HADS Anxiety			STAI -Anxiety			STAI-Anger		
	N	Mean	Sd	N	Mean	Sd	N	Mean	Sd	N	Mean	Sd
All Questionnaire Respondents	2,182	3.47	3.20	2,185	5.95	4.26	1,769	32.75	10.56	1,982	7.31	2.63
Group												
Phase I Non-Responder	454	4.09 a b c	3.48	455	6.53 a b	4.43	352	33.22	10.52	402	7.61 a	2.93
Phase I Negative	655	3.77 d e	3.18	652	6.36 c d	4.15	534	33.31	10.72	598	7.22	2.31
Phase III Negative	397	3.40 a	2.96	400	5.80	4.11	330	31.58	10.49	364	7.32	2.76
FOBt Positive	190	2.76 b d	2.81	189	5.16 a c	4.32	153	33.28	11.51	174	7.41	3.28
Positive Cancer	486	2.80 c e	3.10	489	5.28 b d	4.20	400	32.33	10.02	444	7.10 a	2.34
Gender												
Female	966	3.66 a	3.23	967	6.97 a	4.29	759	33.75 a	10.78	860	7.30	2.49
Male	1,216	3.32 a	3.17	1,218	5.15 a	4.06	1,010	31.99 a	10.34	1,122	7.31	2.74
Age-group												
50-54 years	579	3.85 a	3.55	581	6.85 a	4.57	502	33.99 a	11.32	551	7.31	2.63
55-59 years	534	3.55 b	3.32	533	6.14 a b	4.43	435	32.92	10.56	483	7.27	2.60
60-64 years	475	3.48	3.14	477	5.68 a	3.83	369	32.34	10.03	433	7.43	2.77
65-69 years	594	3.01 a b	2.68	594	5.12 a b	3.92	463	31.56 a	10.00	515	7.23	2.55
Deprivation Category												
Depcat 1/2	558	3.22 a	3.19	558	5.56 a	4.22	468	31.80 a	10.04	526	7.06 a	2.29
Depcat 3	468	3.07 b	2.90	466	5.57 b	4.04	386	32.15	9.94	431	7.10 b	2.17
Depcat 4	450	3.66	3.26	453	6.05	4.22	381	33.77	11.19	414	7.47	2.98
Depcat 5	306	4.04 a b	3.39	305	6.84 a b	4.53	230	33.98	11.43	267	7.73 a b	3.10
Depcat 6/7	214	4.25 a b	3.56	218	6.65 a b	4.42	156	34.60 a	11.08	180	7.65	3.15
Population Norms												
Female	-	-	-	-	-	-	106	32.02	8.67	-	-	-
Male	-	-	-	-	-	-	382	34.51	10.34	-	-	-
(*Spielberger et al., 1983)*												
Other Colorectal Cancer Studies												
1) Colonoscopy Positive (polyps) 3 months post exam	-	2.7	-	-	3.6	-	-	-	-	-	-	-
Colonoscopy Negative (no polyps) 3 months post exam	-	2.5	-	-	3.2	-	-	-	-	-	-	-
Colonoscopy Positive (polyps) 17 months post exam	-	2.9	-	-	3.6	-	-	-	-	-	-	-
Colonoscopy Negative (no polyps) 17 months post exam	-	2.8	-	-	3.5	-	-	-	-	-	-	-
(*Thiis-Evensen et al., 1999*)												
2) Colorectal Cancer – Newly Diagnosed	37	2.7	2.6	37	1.8	2.2	-	-	-	-	-	-
(*Nordin & Glimelius, 1997)*												
Colposcopy Studies												
1) Immediately after colposcopy	-	-	-	-	-	-	31	33.35	-	-	-	-
(*Wilkinson et al., 1990)*												
									-	-	-	-
2) Immediately after colposcopy	-	-	-	-	-	-				-	-	-
3-5 months after positive smear result	-	-					102	38.49	13.15	-	-	-

2-6 months after colposcopy (just prior to treatment) (*Orbell, et al., 2002)*	-	-	-	-	-	-	38	39.57	11.49	-	-	-
3) 4 weeks post colposcopy (G*ath et al., 1995)*	-	-	-	-	-	-	99	32.91	-	-	-	-
4) 24 weeks post colposcopy examination (*Richardson et al., 1996)*	-	-	-	-	-	-	109	39.2	-	-	-	-
36 weeks post colposcopy examination (*Gath et al., 1995*)	-	-	-	-	-	-	96	30.90	-	-	-	-
Breast Cancer Screening Studies	102	2.54	2.97	102	2.93	2.75	-	-	-	-	-	-
1) 8-10 weeks post breast screening – clear result	65	2.80	3.93	66	4.29	3.68	-	-	-	-	-	-
8-10 weeks post breast screening – false positive result	226	3.13	3.10	226	4.27	3.54	-	-	-	-	-	-
Control group – women aged 50-69 yet to be screened (*Scaf-Klomp et al., 1997)*	104	4.23	-	-	-	-	103	4.43	-	-	-	-
	202	4.25	-	-	-	-	202	4.32	-	-	-	-
2) 6 weeks post breast screening – clear result	49	3.82	-	-	-	-	49	4.27	-	-	-	-
6 weeks post breast screening – false positive 1												
6 weeks post breast screening – false positive 1 (*Bull & Campbell, 1991)*												

* Means within a column sharing the same subscript differ significantly at $p < .05$

Table 2.2.16 Distribution of survey participants in 'normal', 'borderline' and 'abnormal' categories of the hospital anxiety and depression scale by FOBt outcome group

	Phase I Non-Responder		Phase I Negative		Phase III Negative		FOBt Positive		Cancer Positive	
	N = 473		N = 697		N = 421		N = 502		N = 199	
	N	%[1]	N	%	N	%	N	%	N	%
HADS Depression[2]	377	83.0 abc	573	87.5	352	88.7 a	446	91.8 b	176	92.6 c
Normal	50	11.0	56	8.5	36	9.1	27	5.6	10	5.3
Borderline	27	5.9	26	4.0	9	2.3	13	2.7	4	2.1
Abnormal										
HADS Anxiety[2]	291	64.0 ab	421	64.6 c	269	67.3 d	344	70.3 a	144	76.2 bcd
Normal	82	18.0	126	19.3	81	20.3	90	18.4	21	11.1
Borderline	82	18.0	105	16.1	50	12.5	55	11.2	24	12.7
Abnormal										

* % within a row sharing the same subscript differ significantly at $p < .05$

[1] Figures indicate proportion endorsing each item.
[2] Subscales of the HADS range from 0 (no distress) to 21 (maximum distress). Zigmond and Snaith (1983) suggested a score of 7 or less as indicative of a 'non case' of anxiety and depression, 8-10 as a 'borderline case', and scores of 11 or more as an 'abnormal case'.

References – Chapter 2

Ajzen I. Attitudes, personality, and behaviour. Milton Keynes, UK: Open University Press; 1988.

Becker MH. The health belief model and sick role behaviour. *Health Education Monographs* 1974; 2: 409-419.

Bull AR, Campbell MJ. Assessment of the psychological impact of a breast screening programme. *British Journal of Radiology* 1991; 64: 510-515.

Dillman DA. Mail and telephone surveys: the total design method. New York: Wiley; 1978.

Gath DH, Hallam N, Mynors-Wallis L, et al. Emotional reactions in women attending a UK colonoscopy clinic. *Journal of Epidemiology and Public Health* 1995; 49: 79-83.

Janz N, Becker MH. The health belief model: a decade later. *Health Education Quarterly* 1984; 11: 1-47.

National Audit Office. Tackling obesity in England. London: The Stationery Office; 2001.

Nordin K, Glimelius B. Psychological reactions in newly diagnosed gastrointestinal cancer patients. *Acta Oncologica* 1997; 36: 803-810.

Orbell S, Hagger M, Brown V, et al. (under review). Cognitive appraisal and emotional sequelae of first visit to colposcopy amongst women with abnormal cervical smears; a comparison of "See and Treat" versus "Diagnose and Defer Treatment".

Richardson PH, Doherty I, Wolfe CDA, et al. Evaluation of cognitive-behavioural counselling for the distress associated with an abnormal smear result. *British Journal of Health Psychology* 1996; 1: 327-338.

Rippetoe PA, Rogers RW. Effects of components of protection motivation theory on adaptive and maladaptive coping with health threat. *Journal of Personality and Social Psychology* 1987; 52: 596-604.

Roe L, Strong C, Whiteside C, et al. Dietary intervention in primary care: validity of the DINE method for diet assessment. *Family Practice* 1994; 11: 375-381.

Rogers R. A protection motivation theory of fear appeals and attitude change. *The Journal of Psychology* 1975; 91: 93-114.

Scaf-Klomp W, Sanderman R, van de Wie, HBM, et al. (1997). Distressed or relieved? Psychological side effects of breast cancer screening in the Netherlands. *Journal of Epidemiology and Community Health* 1997; 51: 705-710.

Spielberger CD, Gorsuch RL, Lushene RE. *Manual for the State-Trait Anxiety Inventory (Self-evaluation questionnaire).* Palto Alto, CA: Consulting Psychologists Press; 1970.

Thiis-Evensen E, Wilhelmsen I, Hoff GS, et al. The psychologic effect of attending a screening program for colorectal cancer. *Scandinavian Journal of Gastroenterology* 1999; 34: 103-109.

Walker A, Maher J, Coulthard, M, et al. Results from the 2000 General Household Survey. London: The Stationery Office; 2001.

Wilkinson C, Jones JM, McBride, J. Anxiety caused by abnormal result of cervical smear test: a controlled trial. *British Medical Journal* 1990; 300:400.

Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica* 1983; 67: 361-370.

3. Uptake and acceptability of colonoscopy

Chapter summary

- Uptake of colonoscopy amongst FOBt positives was 82.2%. Only 1.5% did not undergo colonoscopy because they were deemed medically unfit. The remainder, 16.3%, did not attend (DNA) – or had not attended prior to the data download.

- However, further data scrutiny revealed that the apparent DNAs included those under therapy or polyp follow-up (20%), who had had recent endoscopy (8%), with no colon (2%) and who intended to have a private colonoscopy (6%). Correcting for these gives an alternative estimate of colonoscopy uptake of 87%.

- DNA was higher in England (20.8%) than in Scotland (14.0%), higher amongst all ethnic minorities (over 25%) (particularly Hindu-Gujeratis and Muslims) and amongst those from areas of higher deprivation. Deprivation and ethnicity effects persisted after adjusting for mutual confounding.

- After correcting for the factors above, DNA remained higher in England (17.6%) than Scotland (10.3%) but further data artefacts may influence the figure of 15.3% for England.

- The main reason for non-uptake appears to be unwillingness, and this may result from a variety of participant and provider characteristics. Evidence from our psychosocial surveys shows that people undergoing colonoscopy in England were more likely to have consulted a clinic nurse, whilst those in Scotland were more likely to have consulted their GP. Further psychosocial research may be required to understand specific beliefs associated with non-uptake.

- Perceptions of the colonoscopy experience amongst attenders were very positive. More than 90% of people attending colonoscopy felt they had adequate information about the meaning of their FOBt result and the colonoscopy procedure prior to attendance. Over 90% reported that they had felt in control and able to deal emotionally with what happened whilst at the hospital.

- We obtained no evidence of psychological distress amongst FOBt positives or cancer positives 8 months after first invitation. Levels of anxiety and depression in these groups were within the normal population range and lower than amongst the non-responder and respond negative groups at the same time point.

- Forty-five percent of cancer positives and 24% of FOBt positives reported that their result had had major consequences on their lives. Notably, in view of the role of the perceived financial severity of bowel cancer in accounting for FOBt non-uptake, 15% of cancer positives and 9% of FOBt positives reported serious financial consequences of their diagnosis.

- The most common beliefs concerning the cause of their condition were that it was attributable to chance, ageing, diet/eating habits and lack of exercise. Cancer positives were also likely to attribute their cancer to heredity.

- Cancer positives felt very confident that treatment would cure their illness. In contrast, FOBt positives were less confident of treatment, but more likely to believe that they could personally make behaviour changes which would control their problem. The screening process appears to have had a generally positive impact, in that a substantial proportion of survey participants reported smoking less, eating more fibre and less fat since receiving their result. If sustained, such behaviour changes might reinforce the preventive impact of the screening programme amongst FOBt positives.

- In roll-out and/or further piloting, attention must focus on data collection and coding for FOBt positives not colonoscoped within the programme.

3.1 Analyses of Routine Data

3.1.1 Aims and objectives

- To analyse routine data downloaded from the Pilot data sets to investigate uptake among the test positives and associations with demographic and ethnic variates.
- To describe reasons for failure to have colonoscopy.

3.1.2 Methods

The data used have been extracted from downloads taken from the English and Scottish Pilot databases at the end of October 2002.

Colonoscopy in FOBt-positives is deemed to have occurred if the database contains evidence from colonoscopy and/or pathology datasets that a colonoscopy has been performed. Following the issue of our second year report, in which it was not possible to determine why a colonoscopy had not been performed in an individual who was test-positive, the Pilot sites have computerized all their nurse data sets. We are, therefore, able to determine whether failure to perform colonoscopy was due to the subject's medical unfitness or other reasons. This was initially interpreted as presumed patient non-compliance. However, following discussions with the Pilot site staff, we have conducted an alternative analysis which distinguishes amongst this group those who

- expressed the intention of having colonoscopy performed privately (presuming it was done)
- were currently under therapy and/or polyp follow-up
- had had a recent diagnostic evaluation
- have no colon
- were genuine 'DNA' (did not attend)

The analysis has been restricted to individuals for whom more than three months elapsed between completion of FOB testing and the download.

Logistic regression was used to investigate associations between uptake and various demographic and ethnic variables (listed in section 2.1.2). Univariate analyses were used to produce unadjusted odds ratios (point estimate and 95% CI) for each demographic factor. Associations with proportion of Indian sub-continent residents (England only) have been presented with and without adjustment for deprivation; these latter analyses are, however, both adjusted for age and sex. Multivariate analyses with all demographic factors included in the model were used to produce adjusted odds ratios.

Methods relating to deprivation and ethnicity are as described in Section 2.1.2.

3.1.3 Results

Table 3.1.1 gives numbers of FOBt-positives in whom colonoscopy was and was not performed as part of the screening programme and before the final download. The percentage (82.2) who had had a colonoscopy within the time frame of the analysis is almost the same as the figure given in the second year report (81.3%). However, in this report we have the remainder broken down by their fitness for colonoscopy (the protocol specified that those unfit should not be offered DCBE and this appears to have been followed); a very small percentage of FOBt positives (1.52%) attended a nurse appointment at which they were deemed medically unfit for colonoscopy (and/or were classified as unfit by the colonoscopist).

Logistic regression analysis of uptake (**Table 3.1.2**) confirms that the higher uptake in Scotland seen in **Table 3.1.2** is statistically significant. Analyses by age and sex have been presented showing age patterns in each sex (to be consistent with the tables in section 2.1.3) but the age-sex interaction is no longer statistically significant. There is a suggestion that uptake of colonoscopy declines in the oldest subjects, especially for females. It also declines significantly with increased area deprivation.

Analyses of the English data set (**Table 3.1.3**) show that uptake reduces markedly in areas with the highest proportions of residents from the Indian sub-continent. This is not attributable to confounding

by deprivation; indeed, the OR in the adjusted analysis differs from unity more than in the unadjusted analysis.

Examination of free text fields in the nurse data sets, conducted at the request of the Pilot site teams, (**Table 3.1.4**) shows that the group who were initially classified as DNA can be split into several categories: those who may be assumed to have had colonoscopy performed privately, those for whom it was not applicable and those for whom there was no evidence in the downloaded data against their DNA status.

We have, therefore, constructed an alternative version of **Table 3.1.2** in which the first group are re-interpreted as having taken up colonoscopy and the second group are omitted from numerator and denominator (along with the small number previously classified as unfit). The results (**Table 3.1.5**) provide substantially higher estimates of uptake of colonoscopy (overall 87%) but the difference of approximately 7% between England and Scotland persists. However, the English Pilot staff have informed us of further potential data artefacts (see footnote to **Table 3.1.4**) and uptake in England may be as high as 85%.

3.1.4 Discussion

Uptake of colonoscopy is a potential cause for concern, especially in England though the alternative estimates of **Table 3.1.5** give a much higher figure than in the 2nd year report. It is now clear that this is due to unacceptability of the diagnostic procedure for an important proportion of the subjects who test positive. The associations with deprivation (and, possibly also age and sex) are consistent with increases in co-morbidity – but if so, this generally makes subjects less willing to attend for nurse appointments and/or colonoscopy rather than medically unfit. The data indicate as strongly as analyses of this sort of data can do (i.e. where personal information on ethnicity is not available) that colonoscopy is markedly less acceptable to those who have Indian sub-continent origin.

Collection of data to address the question of colonoscopy uptake has been extremely difficult using the routine data sets developed for the Pilot.

The first difficulty arises from the ambiguous status of those who 'have not yet' had a colonoscopy performed. Use of a longer time gap (ie. longer than 3 months) from completion of screening to data download as an eligibility criteria for the analysis would help but only at the expense of excluding large amounts of data. We recommend that attention is always placed (in, for example, quality standards) on the status of the outcome variable as colonoscopy performed and computerised up to a fixed point in time.

The remaining difficulties came to us as data which had not been coded and were recorded as free text fields. These related to people for whom colonoscopy was not appropriate and those who had expressed the intention of having it performed privately.

Selection for invitation to screening in a large (or national) population must be simple. It is not possible to select out before the issue of the invitation those for whom it is not appropriate because of absence of a large bowel or current/recent therapy or diagnostic procedures. Nevertheless, screening is not appropriate for these people and modification of the invitation letter would be a useful refinement of the screening procedure. We understand that this is being implemented in the second rounds of the Pilots. Clearly some individuals will enter therapy and/or have diagnostic tests between their decision to accept screening and their positive result. For these, and others who are not selected out as a result of the invitation letters, we recommend that the screening data sets include a coded field indicating eligibility for colonoscopy. This should record information from several sources including telephone contacts and nurse visits.

Most UK screening programmes seek to deliver diagnostic tests as part of the screening procedure and this is, almost certainly, optimal. Elsewhere, some screening procedures cease with the indication of routine recall or a recommendation for diagnostic tests (organised, for example, by the GP). Where this occurs, major attention is focussed on the collection of evidence that the tests have been performed and of their results. The important numbers of people choosing private colonoscopy (especially in the English Pilot area) indicate that this will be required in any roll-out situation.

In general, clear classification of the FOB test positives as we have provided in **Table 3.1.1** and **Table 3.1.4** must be readily available in future from the routine data sets held by the screening offices.

Taking all of these factors into account, it remains the case that around 13% of all those found positive in the Pilots and for whom colonoscopy is appropriate have not yet (at time of download) received it. The people involved are more likely to live in deprived areas and (if English) in areas with high proportions of Indian sub-continent residents. This may be more common in men and in certain age groups. We recommend that further research is directed at making diagnostic tests more acceptable to members of these demographic groups.

Table 3.1.1 Colonoscopy attendance within the screening programme

	Colonoscopy Attendance (N, % of FOBt positives)		
	England	**Scotland**	**Total**
Attended	1227 (77.5%)	2463 (84.3%)	3690 (81.9%)
Unfit, had DCBE	2 (0.1%)	0 (0%)	2 (0.0%)
Unfit, no DCBE	14 (0.9%)	51 (1.7%)	65 (1.4%)
Did not attend (initially presumed unwilling)	341 (21.5%)	408 (14.0%)	749 (16.6%)

Table 3.1.2 Uptake of colonoscopy in FOBt positives by demographic factors

Demographic Factor		**Responder N (%)**	**Unadjusted OR (95% CI)**	**Adjusted OR (95% CI)**
None		3690 (81.9)		
Site	England	1227 (77.5)	1 (-)	1 (-)
	Scotland	2463 (84.3)	1.56 (1.34-1.82)	1.62 (1.33-1.96)
Sex	Male	2272 (82.2)	1 (-)	1 (-)
	Female	1418 (81.4)	0.94 (0.81-1.10)	1.30 (0.86-1.94)
Age-sex	Male: < 55	436 (80.3)	1 (-)	1 (-)
	Male: 55-59	524 (84.5)	1.24 (0.98-1.57)	1.29 (0.92-1.82)
	Male: 60-64	610 (84.0)	1.20 (0.96-1.48)	1.22 (0.88-1.70)
	Male: ≥ 65	702 (80.3)	0.88 (0.73-1.06)	0.84 (0.62-1.14)
	Female: <55	278 (85.8)	1 (-)	1 (-)
	Female: 55-59	321 (80.9)	0.93 (0.71-1.21)	0.74 (0.48-1.14)
	Female: 60-64	362 (80.4)	0.90 (0.70-1.15)	0.73 (0.49-1.11)
	Female: ≥ 65	457 (79.9)	0.86 (0.69-1.07)	0.75 (0.50-1.12)
Invitation Time	Mar - Sept 2000	803 (82.2)	1 (-)	1 (-)
	Oct 2000 - Mar 2001	976 (82.2)	1.00 (0.80-1.25)	1.25 (0.96-1.63)
	Apr - Sept 2001	935 (82.5)	1.02 (0.82-1.28)	1.26 (0.96-1.65)
	Oct 2001 - Mar 2002	836 (82.4)	1.02 (0.81-1.28)	1.15 (0.86-1.53)
	Apr - Sept 2002	140 (72.2)	0.56 (0.39-0.80)	0.94 (0.62-1.44)
	p-value for linear trend = 0.245			
Deprivation Category	1/2	761 (83.0)	1 (-)	1 (-)
	3	727 (85.1)	1.17 (0.91-1.51)	1.10 (0.85-1.43)
	4	873 (82.9)	0.99 (0.79-1.26)	0.98 (0.77-1.24)
	5	370 (78.1)	0.73 (0.55-0.96)	0.74 (0.56-0.98)
	6/7	330 (74.8)	0.61 (0.46-0.80)	0.66 (0.49-0.88)
	p-value for linear trend = 0.002			

Table 3.1.3 Effects of % from Indian Subcontinent - England Only

		Uptake of Colonoscopy	
		% Indian	
		1-4	5 (High)
	N (%)	850 (79.7%)	277 (71.4%)
Not adjusted for deprivation	OR (95% CI)	1(-)	0.64 (0.49-0.84)
	p-value		p-value = 0.001
Adjusted for deprivation	OR (95% CI)	1(-)	0.60 (0.40-0.88)
	p-value		p-value = 0.010

Table 3.1.4 Further classification[1] of those who did not receive colonoscopy within the screening programme

	England	Scotland
No evidence against DNA[2]	267 (78.3%)	294 (72.0%)
Currently under therapy and/or polyp follow-up	42 (12.3%)	62 (15.3%)
Recent diagnostic procedure	6 (1.8%)	35 (8.6%)
No colon	4 (1.2%)	7 (1.7%)
Intended to have colonoscopy performed privately	22 (6.5%)	10 (2.4%)

[1] Data taken from free text fields in the nurse data sets

[2] No evidence from any of the downloaded data; some of these will undoubtedly have had a colonoscopy performed since the download and/or awaiting one and the English Pilot are aware of 10. In addition, the English Pilot has informed us of 30 in this group whose screening result was incorrectly classified as positive from the downloaded data; the procedure was prolonged and still, apparently, inconclusive at the time of download

Table 3.1.5 Uptake of colonoscopy in FOBt positives by demographic factors – alternative version[1]

Demographic Factor		Responder N (%)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
None		3722 (87.1)		
Site	England	1249 (82.4)	1 (-)	1 (-)
	Scotland	2473 (89.7)	1.86 (1.55-2.23)	1.86 (1.48-2.34)
Sex	Male	2287 (86.9)	1 (-)	1 (-)
	Female	1435 (87.5)	1.06 (0.88-1.27)	1.65 (1.01-2.69)
Age-sex	Male: 50-54	441 (84.3)	1 (-)	1 (-)
	Male: 55-59	527 (88.9)	1.21 (0.92-1.59)	1.32 (0.89-1.95)
	Male: 60-64	611 (88.9)	1.23 (0.95-1.59)	1.40 (0.96-2.05)
	Male: 65-69	708 (85.3)	0.83 (0.67-1.03)	0.88 (0.62-1.23)
	Female: 50-54	282 (90.7)	1 (-)	1 (-)
	Female: 55-59	327 (86.7)	0.97 (0.71-1.32)	0.65 (0.39-1.10)
	Female: 60-64	366 (86.1)	0.91 (0.68-1.22)	0.65 (0.39-1.07)
	Female: 65-69	460 (87.3)	1.02 (0.78-1.34)	0.81 (0.49-1.34)
	Differences by age group and age-sex interaction: not statistically significant			
Invitation Time	Mar - Sept 2000	804 (88.3)	1 (-)	1 (-)
	Oct 2000 - Mar 2001	982 (86.8)	0.88 (0.67-1.14)	1.08 (0.78-1.49)
	Apr - Sept 2001	945 (87.0)	0.89 (0.68-1.17)	1.12 (0.81-1.56)
	Oct 2001 - Mar 2002	848 (88.1)	0.98 (0.74-1.30)	1.10 (0.77-1.56)
	Apr - Sept 2002	143 (78.6)	0.49 (0.33-0.73)	0.94 (0.58-1.54)
	linear trend: not statistically significant			
Deprivation Category	1/2	773 (89.0)	1 (-)	1 (-)
	3	734 (90.3)	1.15 (0.84-1.58)	1.08 (0.79-1.49)
	4	877 (87.3)	0.85 (0.64-1.13)	0.86 (0.65-1.14)
	5	372 (83.2)	0.62 (0.44-0.85)	0.63 (0.46-0.88)
	6/7	332 (79.4)	0.48 (0.35-0.66)	0.53 (0.38-0.74)
	p-value for linear trend <0.001			

[1] Private colonoscopies included as colonoscopy attended, those unfit for colonoscopy or for whom it was not applicable

3.2 Psychosocial surveys

3.2.1 Methods

The methods and response rates to the psychosocial survey are reported in section 2.2.2. The questionnaire sent to FOBt positives and cancer positives included additional questions concerning the meaning of their abnormal result, their experience of colonoscopy and psychological distress. Questions regarding the meaning of the abnormal result referred to 'the problem with your bowel motions (that is small amounts of blood being found in them by the bowel cancer screening test)'. Data were obtained from a total of 502 FOBt positives and 199 cancer positives.

3.2.2 Results

*3.2.2.1 Psychological distress associated with FOBt positive result (**Tables 2.2.14 and 2.2.15**)*

Findings relating to psychological distress are reported more fully in section 2.2.3. Eight months following first invitation to take part in screening, FOBt positives and cancer positives reported levels of anxiety and depression within the normal population range and lower than that in the non-responder and respond-negative groups.

*3.2.2.2 Meaning of an abnormal FOBt result (**Tables 3.2.1 and 3.2.2**)*

The most commonly held beliefs regarding the cause of an abnormal result for both groups were chance/bad luck, ageing and diet/eating habits, each being endorsed by at least 45% of survey participants. We also obtained significant differences between the two groups. Cancer positives were more likely than FOBt positives to attribute their result to heredity (33.9% versus 25%), or chance (64.4% versus 47.5%). FOBt positives were more likely than cancer positives to attribute their result to their diet (60.3% versus 50%), their lack of exercise (35.8% versus 21.4%) and their own behaviour (17.5% versus 11.0%). Thus FOBt positives viewed their result as largely a product of their behaviour whereas those with a cancer positive diagnosis preferred to attribute the cancer to heredity and chance.

As might be expected, nearly 75% of cancer positives reported that their condition was serious, with major consequences for life (45.4%) and 27.5% reported that the problem with their bowel motions causes difficulties for close relationships. Notably, almost 35% of FOBt positives also reported that the problem with their bowel motions was serious, and 24% felt that it had major consequences on their lives. In view of the importance of the perceived financial severity of bowel cancer in accounting for differences in uptake of FOBt (section 2.2.2), it is interesting to note that 14.6% of cancer positives and 9% of FOBt positives reported serious financial consequences.

An interesting pattern of findings emerged regarding perceptions of timeline and controllability of the bowel problem. FOBt positives were more likely to view their problem as permanent rather than temporary (50% compared with 37.9% of cancer positives). Relatedly, whereas cancer positives considered that treatment can cure the problem (94.1%), FOBt positives were less confident of effective treatment (76.8%). However, FOBt positives were more likely to consider that they could personally do things to control their problem (75.5%) compared to cancer positives (59.3%).

*3.2.2.3 Relationship of beliefs about illness to psychological distress (**Table 3.2.3**)*

People who perceived their condition as more chronic and having serious consequences were more likely to score above the 'case' threshold on anxiety and depression. Those suffering from borderline/abnormal depression were also more likely to report that treatment would not be effective in curing their problem.

*3.2.2.4 Information received prior to colonoscopy (**Tables 3.2.4 and 3.2.5**)*

The most common sources of information prior to colonoscopy were leaflets and nurse consultation at the screening centre, with over 90% or survey participants reporting these sources of information. A significant minority (22% cancer +ves and 28.4% FOBt positives) also apparently consulted their GP.

People screened in England were more likely to have received a leaflet and consulted a nurse prior to colonoscopy, whereas people screened in Scotland were twice as likely to have consulted their GP (32.1% versus 15.9%).

Overall, 90.3% of people considered that they had as much information as they wanted to about their result prior to colonoscopy and 94.2% felt prepared regarding the colonoscopy procedure.

*3.2.2.5 Experience of colonoscopy (**Table 3.2.6**)*

The majority of people (89.7%) acknowledged that their visit to the hospital for colonoscopy was very important to them. Less than 15% of people felt that undesirable things happened to them during their colonoscopy, however cancer +ves reported that significantly more undesirable things happened, than did FOBt positives (24.1% versus 10.8%). Over 90% of people felt confident that they could handle (emotionally) what happened at the hospital and that they had control over the way the examination went. Finally, 61% of people felt responsible for what happened to them during their colonoscopy, however FOBt positives were significantly more likely to feel that they were responsible.

Substantial numbers of people changed their smoking, dietary, and exercise behaviours after attending for a colonoscopy (**Table 3.2.7**). The greatest changes were observed in smoking behaviour (38.5% smoking less) and in eating behaviour (36.9% eating less fatty food and 26.7% eating more fibre). Significant differences were only observed between Cancer +ves and FOBt positives in terms of fat and fibre consumption, FOBt positives eating less fatty food (39.3% versus 30.9%) and more fibre (29.2% versus 20.4%).

3.2.3 Discussion

We obtained no evidence that abnormal FOBt screening results may lead to long term psychological distress. Both in absolute terms and in comparison to non-responders and respond negative groups respond positive groups did not report elevated anxiety or depression at 8 months after screening. It should be noted that it is entirely likely, based on findings from other screening programs (eg Orbell et al., 2003), that anxiety was elevated at the time of receipt of a positive result and immediately prior to colonoscopy. The findings reported here relate only to sustained impact, 8 months following initial invitation.

The vast majority of respondents had received leaflets about colonoscopy and consulted a nurse and were satisfied with the information they had received prior to colonoscopy. Analyses comparing Scotland and England revealed an important trade-off in information sources used. In Scotland nurse consultations were fewer and this was reflected in a rate of GP consulting that was twice that of England.

Unsurprisingly the requirement for colonoscopy was viewed by most people as important and as one they felt they could cope with. This is important given that the majority of people who are invited for colonoscopy do not end up with a diagnosis of cancer. That more FOBt positives than Cancer +ves felt responsible for what happened to them during their colonoscopy is interesting given that FOBt positives viewed their result as largely a product of their own behaviour. Positive health behaviour change following colonoscopy is good, and is perhaps a reflection of recommendations made at the clinic.

Analysis of illness representation showed that FOBt positives tended to view their condition as having behavioural causes, being likely to last a long time and being personally controllable. Cancer positives were more likely to attribute their condition to heredity, to view their condition as relatively short-lived and to consider treatment highly effective in providing a cure. These findings suggest that screening may have the potential to encourage preventive behavioural change amongst those with FOBt positive results.

3.3 Ethnicity

3.3.1 Analyses of Routine Data

For analyses of colonoscopy uptakes, a restriction of 3 months between completion of screening (i.e. FOB test result) and the download was applied, as in the Main Evaluation.

In terms of the decision to undergo further procedures following a positive FOB test result, 72.8% of subjects had undergone such procedures, applying the 3 months restriction. Multivariate analysis produced an adjusted odds ratio which demonstrated that the colonoscopy uptake rate for the combined Asian group (all Asians) was half that of non-Asians, significant at the $p<0.01$ level. Within the Asian population also, Hindu-Gujerati and Muslim groups demonstrated significantly ($p<0.05$) lower uptakes with adjusted odds ratios 0.31 and 0.37 respectively versus 1.0 for non-Asians; for other ethnic groups, uptake rates were also lower (0.27 – 0.82 adjusted odds ratios), although these differences were not significant at the $p=0.1$ level.

Analysis of routine data therefore demonstrates significantly lower colonoscopy uptake rates for ethnic groups, allowing at least 3 months follow up period for a positive FOB test result, even once other factors such as deprivation are taken into account. Colonoscopy uptake rates for the whole population were found to be significantly lower in those with a more recent positive FOBt result. It may be, therefore, that the low level of colonoscopy uptake in ethnic groups is partly due to delays in making a firm decision about further procedures.

3.3.2 Psychosocial Surveys

There were very few questionnaires (8 in total) from people who were FOBt positive (all cancer negative); 4 were from invitees who were Asian and 4 from African-Caribbeans. It was not possible, therefore, to consider colonoscopy uptake using this approach.

3.3.3 Focus Group Studies

Low levels of knowledge about cancer, and a high level of fear of the disease, meant that it was sometimes hard to ask detailed questions in respect of colonoscopy. However, it became apparent that in many groups there was one (or sometimes more) person who had personal – or close indirect – experience of at least colonoscopy (‘a camera put inside you’). When such testimony was presented to the groups, a lively discussion ensued. It would appear that cancer screening and health promotion/ preventive work could be built on the use of personalised narratives which raise the salience and accessibility of the issue

3.4 Conclusions and recommendations

Uptake of colonoscopy is an important issue in a FOBT screening programme. It is undesirable for screening participants to reach the point of a positive test and then not proceed with definitive investigations (both in terms of cost-effectiveness and potential adverse effects on individuals’ health). While estimates of non-uptake of colonoscopy are likely to be considerably less than those suggested by the crude data from the Pilot sites (approximately 20%), this issue will still need to be addressed in a national programme. We recommend that ‘informed consent’ for FOBT screening should include adequate information provision about colonoscopy. Ideally, at the outset, participants should be aware of the procedure and its potential adverse effects, and be prepared to have the procedure if they test positive. Further, it is critical that in a national programme there is adequate attention to data collection and coding for FOBT positives not colonoscoped within the programme.

In common with FOBT uptake, there are sub-groups in whom colonoscopy uptake is particularly low, and this should be addressed in targeted/tailored recruitment and informed consent procedures in a national programme.

Participation in the UK Pilot appears to have had a generally positive effect on participants; colonoscopy attenders were very positive about their experiences - this, coupled with low complication rates from colonoscopy (Chapter 4) suggests that good quality assurance procedures were in place for colonoscopy in both Pilot sites. Further, participation in FOBT screening appears to have had positive

effect on lifestyle factors. This supports the existence of a ‘halo effect’ of cancer screening – that is, benefits of screening may stretch beyond those immediately attributable to the screening process. We recommend that in a national programme standards of service delivery of FOBT testing and colonoscopy (such as information provision and co-ordination of screening processes) should match those achieved in the UK Pilot.

.

Table 3.2.1 Comparison of phase IV participate-negatives and phase IV participate-positives in terms of causes of the problem with their bowel motions.

	FOBt Positive		Cancer Positive		Chi-square
	Total N = 502		Total N = 199		
Proportion of people suggesting particular causes.	**N**	**%[1]**	**N**	**%**	**χ^2, p**
Stress/worry	185	44.3	63	37.5	2.242, ns
Heredity	101	25.0	59	33.9	4.821, p < .05
Germ/virus	74	20.1	35	22.0	0.245, ns
Altered immunity	77	21.2	22	15.2	2.409, ns
Chance/bad luck	191	47.5	114	64.4	14.071, p < .000
Poor medical care in the past	39	10.1	9	5.4	3.177, ns
Pollution in the environment	87	23.2	48	29.6	2.485, ns
Ageing	310	74.0	120	68.6	1.811, ns
Mental attitude eg thinking about life negatively	41	10.8	8	5.0	4.540, p < .05
Family problems/worries	96	24.4	34	20.7	0.883, ns
Overwork	74	19.2	28	17.5	0.220, ns
Smoking	91	23.2	31	18.3	1.647
Alcohol	117	29.2	36	22.1	2.948, ns
Emotional state eg feeling down, lonely, anxious, empty	88	22.5	24	14.7	4.320, p < .05
Accident/injury	30	7.9	7	4.3	2.308, ns
Personality	34	9.0	7	4.3	3.442, ns
Diet/eating habits	255	60.3	86	50.0	5.286, p < .05
Lack of exercise	143	35.8	36	21.4	11.365, p < .001
Own behaviour	67	17.5	18	11.0	3.663, p < .05

[1] Figures indicate proportion endorsing each item.

Table 3.2.2 Comparison of FOBt positives and cancer positives in terms of beliefs about the problem with their bowel motions.

	FOBt Positive		Cancer Positive		Chi-square
	Total N = 502		Total N = 199		
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**χ^2, p**
Emotional Representation					
"Having this problem with my bowel motions makes me feel anxious."	274	60.2	133	71.1	6.789, p < .01
"When I think about the problem with my bowel motions I get upset."	113	25.9	73	40.3	12.744, p < .000
"The problem with my bowel motions does not worry me."	194	44.4	484	26.7	16.806, p < .000
Timeline acute/chronic					
"I expect the problem with my bowel motions to last the rest of my life."	201	44.9	51	27.9	15.649, p < .000
"The problem with my bowel motions will improve in time."	153	36.0	41	22.3	11.131, .001
"The problem with my bowel motions is likely to be permanent rather than temporary."	217	50.0	69	37.9	7.533, p < .01

[1] Figures indicate proportion endorsing each item.

Consequences					
"The problem with my bowel motions has major consequences on my life."	107	24.4	83	45.4	23.617, p < .000
"The problem with my bowel motions strongly affects the way others see me."	24	5.6	22	12.3	8.196, p < .001
"The problem with my bowel motions causes difficulties for those who are close to me."	62	14.4	49	27.5	14.600, p < .000
"The problem with my bowel motions has serious financial consequences."	39	9.0	26	14.6	4.082, p < .05
"The problem with my bowel motions is serious."	147	34.7	137	74.5	81.602, p < .000
"The problem with my bowel motions does not have much effect on my life."	292	65.8	93	51.7	10.774, p < .001
Treatment Control					
"There is nothing that can help the problem with my bowel motions."	61	13.9	14	7.7	4.662, p < .05
"There is very little that can be done to improve the problem with my bowel motions."	77	17.7	10	5.5	15.872, p < .000
"My treatment will be effective in curing the problem with my bowel motions."	325	76.8	177	94.1	26.628, p < .000
"Treatment can control the problem with my bowel motions."	385	87.1	176	94.6	7.767, p < .01
Personal Control					
"There is a lot I can do to control my symptoms."	339	75.5	108	59.3	16.373, p < .000
"The course of the problem with my bowel motions depends on me."	306	69.1	109	60.9	3.842, p < .05
Illness Coherence					
"I have a clear understanding or picture of the problem with my bowel motions."	312	71.1	145	79.7	4.896, p < .05

Table 3.2.3 Relationship between psychological distress and beliefs about illness.

	Anxiety				Depression			
	Normal Anxiety		Borderline/abnormal Anxiety		Normal Depression		Borderline/abnormal Depression	
	Total N = 488		Total N = 190		Total N = 622		Total N = 54	
Proportion of people agree with each item.	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Emotional Representation								
"Having this problem with my bowel motions makes me feel anxious."	262	58.5	136	77.3	356	62.3	39	78.0
"The problem with my bowel motions makes me angry."	35	8.1	54	32.5	65	11.8	24	52.2
"I get depressed when I think about the problem with my bowel motions."	67	15.4	80	47.1	118	21.2	29	60.4
"The problem with my bowel motions makes me afraid."	149	34.4	99	57.9	220	39.8	27	56.3
"When I think about the problem with my bowel motions I get upset."	92	21.3	90	52.6	151	27.5	30	58.8
"The problem with my bowel motions does not worry me."	193	44.2	42	25.8	324	58.7	39	86.7
Timeline acute/chronic								
"The problem with my bowel motions will last a long time."	169	40.1	88	53.3	226	42.1	30	65.2
"I expect the problem with my bowel motions to last the rest of my life."	160	36.4	85	48.9	212	37.9	32	62.7
"The problem with my bowel motions will improve in time."	-	-	-	-	157	29.0	27	57.4
"The problem with my bowel motions will pass quickly."	161	38.9	47	29.6	-	-	-	-
"The problem with my bowel motions is likely to be permanent rather than temporary."	183	42.9	94	55.0	245	44.7	29	61.7

Consequences								
"The problem with my bowel motions has major consequences on my life."	105	24.2	79	46.5	156	23.8	27	56.3
"The problem with my bowel motions strongly affects the way others see me."	22	5.1	21	13.0	35	6.4	8	18.2
"The problem with my bowel motions causes difficulties for those who are close to me."	64	15.0	45	27.4	90	16.5	17	37.8
"The problem with my bowel motions has serious financial consequences."	35	8.3	26	15.5	50	9.3	12	24.0
"The problem with my bowel motions does not have much affect on my life."	139	32.0	93	54.7	357	64.1	14	30.4
"The problem with my bowel motions is serious."	181	42.7	94	56.3	247	45.6	27	57.4
Treatment Control								
"There is nothing that can help the problem with my bowel motions."	-	-	-	-	61	11.1	12	24.0
"The negative effects of the problem with my bowel motions can be prevented/avoided by my treatment."	-	-	-	-	458	84.2	29	61.7
"Treatment can control the problem with my bowel motions."	-	-	-	-	505	90.5	38	79.2
Illness Coherence								
"I don't understand the problem with my bowel motions."	162	37.5	81	49.1	215	39.2	29	61.7
"The problem with my bowel motions doesn't make any sense to me."	133	30.7	79	48.2	186	34.1	25	52.1
"The symptoms of the problem with my bowel motions are puzzling to me."	157	36.6	92	54.8	216	39.6	33	67.3
"The problem with my bowel is a mystery to me."	166	38.6	89	53.6	227	416	29	61.7
"I have a clear understanding of the problem with my bowel motions."	336	77.1	112	66.3	418	75.6	25	52.1

Table 3.2.4 Information given prior to colonoscopy.

	FOBt Positive		Cancer Positive		Chi-square
	Total N = 502		Total N = 199		
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**χ^2, p**
Before you went to the hospital for your colonoscopy examination, did you discuss the result of your bowel cancer screening test with a nurse from the screening centre?	459	92.2	180	91.8	0.021, ns
Before you went to the hospital for your colonoscopy examination, did you receive a leaflet explaining what traces of blood in the bowel motion meant?	462	93.1	179	92.3	0.163, ns
If you did receive a leaflet explaining what traces of blood in the bowel motions meant, did you read it?	469	98.1	180	96.3	1.981, ns
Did you obtain information from any other source about what traces of blood in the bowel motions meant, before you went into hospital for your colonoscopy examination?	132	26.6	59	30.3	0.958, ns
Before you attended your colonoscopy examination, did a nurse at the screening clinic explain to you what was involved in the colonoscopy examination?	496	99.0	194	98.5	0.344, ns
Before you attended for your colonoscopy did your GP explain to you what was involved in the colonoscopy examination?	141	28.4	42	22.0	2.877, ns
Did you obtain information from any other source about what was involved in a colonoscopy examination, before you had your colonoscopy?	91	18.5	43	22.3	1.261, ns
Before you attended for your colonoscopy examination did you receive a leaflet explaining what was involved in the colonoscopy examination?	449	90.9	165	86.4	3.007, ns
If you did receive such a leaflet, did you read it?	447	97.6	164	97.6	0.000, ns
"Before I attended for my recent colonoscopy examination at the hospital I felt that I had as much information as I wanted about what my positive bowel cancer screening test result meant."	448	90.5	176	89.8	0.081, ns
"Before I attended for my recent colonoscopy examination at the hospital, I felt that I had as much information as I wanted about the procedure."	465	93.6	188	95.9	1.436, ns

[1] Figures indicate proportion endorsing each item.

Table 3.2.5 Information seeking prior to colonoscopy.

	Overall		Scotland		England		Chi-square
	Total N = 701		Total N = 465		Total N = 236		
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**N**	**%**	**χ^2, p**
"Before you were asked to attend the hospital for a colonoscopy examination, did you discuss the result of your bowel cancer screening test with a nurse from the screening centre?"	639	91.2	412	89.8	227	96.6	9.952, p < .01
"Before you went to the hospital for your colonoscopy examination, did you receive a leaflet explaining what traces of blood in the bowel motion meant?"	641	91.4	416	91.2	225	96.2	5.688, p < .05
"If you did receive a leaflet explaining what traces of blood in the bowel motions meant, did you read it?"	649	92.6	422	96.8	227	99.1	3.494, ns
Did you obtain information from any other source about what traces of blood in the bowel motions meant, before you went into hospital for your colonoscopy examination?	191	27.2	131	28.6	60	25.6	0.680, ns
"Before you attended for your recent colonoscopy examination at the hospital, did a nurse at the screening clinic explain to you what was involved in the colonoscopy examination?"	690	98.4	456	98.7	234	99.2	0.281, ns
"Before you attended for your recent colonoscopy examination at the hospital, did your GP explain to you what was involved in the colonoscopy examination?"	183	26.1	146	32.1	37	15.9	20.734, p < .000
"Did you obtain information from any other source about what was involved in a colonoscopy examination, before you went into hospital for your colonoscopy examination?"	134	19.1	84	18.6	50	21.4	0.736, ns
"Before you attended for your recent colonoscopy examination at the hospital, did you receive a leaflet explaining what was involved in the colonoscopy examination?"	614	87.6	394	87.0	220	94.8	10.181, p < .001
"If you did receive a leaflet explaining what was involved in the colonoscopy examination before you attended for your recent colonoscopy examination, did you read it?"	611	87.2	391	97.0	220	98.7	1.636, ns
"Before I attended for my recent colonoscopy examination at the hospital I felt that I had as much information as I wanted about what my positive bowel cancer screening test result meant."	624	90.3	406	88.5	218	94.0	5.348, p < .05
"Before I attended for my recent colonoscopy examination at the hospital, I felt that I had as much information as I wanted about the procedure."	653	94.2	426	93.0	227	96.6	3.665, ns

[1] Figures indicate proportion endorsing each item.

Table 3.2.6 Experience of colonoscopy

	Overall		FOBt Positive		Cancer Positive		Chi-square
	Total N = 701		Total N = 502		Total N = 199		
Proportion of people agree with each item.	**N**	**%[1]**	**N**	**%**	**N**	**%**	**χ^2, p**
"My visit to the hospital for colonoscopy was important to me."	620	89.7	440	88.7	180	92.3	2.043, ns
"Undesirable things happened during my hospital visit for colonoscopy."	84	14.5	45	10.8	39	24.1	19.915, p < .000
"Desirable things happened during my hospital visit for colonoscopy."	190	35.3	148	38.2	42	27.8	5.893, ns
"When I went to the hospital for colonoscopy, I was confident that I could handle (emotionally) what was happening, no matter how it worked out."	675	96.5	478	95.6	197	99.0	4.972, ns
"When I went to the hospital for colonoscopy, I was confident that I could make things go the way that I wanted them to during the examination."	648	93.1	463	92.8	185	93.9	0.739, ns
"I am responsible for what happened during my visit to the hospital for colonoscopy."	415	61.5	317	65.6	98	51.3	12.584, p < .01
"Somebody else is responsible for what happened during my visit to the hospital for colonoscopy."	404	62.7	289	62.6	115	63.2	0.500, ns

[1] Figures indicate proportion endorsing each item.

Table 3.2.7 Behaviour change after colonoscopy.

	Overall		FOBt Positives		Cancer Positives		Chi-square
	Total N = 701		Total N = 502		Total N = 199		
Proportion of people agree with each item.	**N**	**%**	**N**	**%**	**N**	**%**	**χ^2, p**
"Since being told that there was a problem with my bowel motions I have been smoking more/less than I used to…							
…more than I used to	14	7.3	10	6.8	4	8.9	
…less than I use to	74	38.5	57	38.8	17	37.8	0.222, ns
…the same as I used to	104	54.2	80	54.4	24	53.3	
"Since being told that there was a problem with my bowel motions I have been eating more/less fatty food than I used to…							
…more than I used to	33	5.0	26	5.6	7	3.7	
…less than I used to	243	36.9	184	39.3	59	30.9	6.064, p < .05
…the same as I used to	383	58.1	258	55.1	125	65.4	
"Since being told that there was a problem with my bowel motions I have been eating more/less fibre than I used to…							
…more than I used to	172	26.7	133	29.2	39	20.4	
…less than I used to	18	2.7	14	3.1	4	2.1	6.218, p < .05
…the same as I used	456	70.6	308	67.7	148	77.5	
"Since being told that there was a problem with my bowel motions I have been taking more/less mild exercise than I used to…							
…more than I used to	148	23.2	103	22.8	45	24.1	
…less than I used to	37	5.8	20	4.4	17	9.1	5.672, ns
…the same as I used to	453	71.0	328	72.7	125	66.8	
"Since being told that there was a problem with my bowel motions I have been taking more/less moderate exercise than I used to…							
…more than I used to	133	20.4	90	19.5	43	22.4	
…less than I used to	24	3.6	15	3.3	9	4.7	1.638, ns
…the same as I used to	496	76.0	356	77.2	140	72.9	
"Since being told that there was a problem with my bowel motions I have been taking more/less strenuous exercise than I used to…							
…more than I used to	109	17.1	78	17.3	31	16.5	
…less than I used to	45	7.0	27	6.0	18	9.6	2.588, ns
…the same as I used to	484	75.9	345	76.7	139	73.9	

4. Outcomes of Screening

Chapter summary

- As detailed in our previous reports the proportions positive on the FOB test are higher in Scotland The overall proportions positive are 1.6% (England) and 2.1% (Scotland). These differences are statistically significant.
- Positivity increases with age, is higher in men and in more deprived areas. In England, positivity rates have increased with time but not in Scotland.
- Age-adjusted positivity rates in the Pilot (2.42 men, 1.81 women) are higher than those in the Nottingham trial (2.05 men, 1.62 women). Age-and sex-specific rates are also higher than reported from Nottingham.
- Most test-positive results came from re-testing; this means that involvement in the screening process is often extended and many participants have complex screening histories. More research is required to examine the use of tests where re-testing is not generally necessary (such as immunological tests, which don't require dietary restriction and involve lower rates of re-testing)
- Detection rates are lower in England than Scotland. Age-adjusted rates in both Pilot sites (1.26/1000 and 1.99/1000 respectively) compare favourably with those reported from the Nottingham trial for the same age group (1.61/1000).
- Age-adjusted Positive Predicted Values (PPVs) also compare favourably with those from Nottingham when denominators are people for whom colonoscopy was performed. The substantial proportion not receiving colonoscopy leads to low PPVs when calculated for test positives.
- There is a strong association between neoplasia detection rates and increasing age and gender, the higher rates being seen in males. Weaker associations appear with deprivation (rates higher in more deprived areas).
- Higher PPV rates are seen with increasing age, in males rather than females. Little association is seen with deprivation but PPVs are lower in more deprived areas.
- The staging distribution for both sites is similar to that for the Nottingham trial with that for Scotland being particularly favourable.
- Within the Asian community neoplasia detection rates were much lower, although the statistic is based on a very small number of cases. Analyses of Asian ethnicity using census data classifications do not confirm this.
- We recommend that PPV calculations for quality standards should take as denominator subjects who have diagnostic evaluation results present in the data set.

4.1 FOB Test Results

4.1.1 Aims and objectives

To analyse routine data downloaded from the Pilot datasets to:

- describe the results of FOB testing in the two Pilot areas, for each phase of screening, separately and overall;
- compare the results for each site with those seen in the Nottingham trial;
- explore any associations of results with the demographic and ethnic factors considered in chapter 2.

4.1.2 Methods

As described in Section 2.1.2 of this report, the data used have been extracted from downloads produced by the end of October by the Pilot sites. All available data on results are used in these analyses (i.e. no time restrictions are applied) as we believe that bias in early screening results towards positive or negative outcomes is unlikely.

In addition to the overall results of FOB testing, a breakdown is given by phase of screening, where the individual phases are briefly described below (**see Appendix 1** for full descriptions):

Phase I
Interval between invitation and receipt, by the Screening Unit, of a first adequate test kit (or a decision to give up)

Phase II
Begins with an initial weak positive result and ends with the result of a dietary re-test (or a decision to give up)

Phase III
For individuals who are initially weak positive and then negative on dietary re-test, this phase begins with the decision to start the process of re-testing and ends with the result of a follow-up re-test (or decision to give up)

Logistic regression was used to explore any associations between the overall FOB test result and the demographic and ethnic factors; these methods and a list of the variables studied are described in section 2.1.2.

4.1.3 Results.

Table 4.1.1 and **Table 4.1.2** give the results of FOB testing in the two Pilot areas (for explanation of terminology used in the tables see Appendix 1). As detailed in our previous reports the proportions positive are higher in Scotland. The overall proportions positive are 1.6% (95% CI: 1.37-1.81, England) and 2.1% (95% CI: 2.03-2.17, Scotland). These differences are statistically highly significant.

We discussed possible explanations for this in our previous report. It could reflect differences in the casemix of the population screened and we noted last year that age- and sex- specific incidence rates of colorectal cancer are lower at every age in the area of the English Pilot than those for the Scottish Pilot area. We investigated reports of a previous RCT of sigmoidoscopy compared with FOBt which was conducted in an area which overlapped with that of the English Pilot and had the potential to make the English Pilot screen more like an incidence than a prevalence screen; we showed that the effect of this trial must be, at most, marginal.

Associations of positivity proportions with demographic factors (**Table 4.1.3**) show that positivity increases with age, is higher in men and is higher in more deprived areas. In England, positivity rates have increased with time but not in Scotland.

Although the rates for the Nottingham trial have been described as 2.08% this describes the whole trial at a broader age range than the current Pilot; age- and sex- specific rates for the Nottingham trial are shown in **Table 4.1.4** and are not higher for the age group 50-69 than the UK Pilot.

As reported in our previous report, the majority of subjects who test positive reach this conclusion during phase II and very few are found to be positive during phase I (see **Figures 2.1.1(a) and (b**)).

4.1.4 Discussion.

The present results confirm our previous observations (in the first year report, the interim report and the second year report) that the vast majority of individuals who are FOBt positive reach this status via a route which involves being classified as weak-positive and then completing at least one dietary restricted re-test. This involves several tests, a lengthy time in reaching a conclusion and, we anticipate, increased anxiety. These data support those who recommend that there should be research into alternative methods of reaching test-positive/ test-negative status; one possibility is the use of immunological tests and this is being explored by the Scottish Pilot team in collaboration with members of the evaluation group.

The FOBt-positive proportions in the English Pilot are significantly lower than in the Scottish Pilot but they are not lower than the Nottingham trial when age is taken into account. The effect of an earlier trial (removing adenomas from part of the population offered screening in the English Pilot) has been effectively excluded. Lower underlying rates of bowel cancer must form part (possibly all) of the explanation for English-Scottish comparisons. An experimental study within the Pilot using random allocation of English-Scottish reading to kits from both sites was considered unethical by the Pilot Executive Group. Alternative plans to compare reading sensitivity and specificity at the two sites using quality control samples were considered but did not come to fruition. Thus we have no prospect of experimentally excluding differences in methodology in the two sites but these appear to be extremely unlikely explanations.

The statistically significant trends towards higher proportions of FOBt positivity in older people and in males are consistent with the observed differences in colorectal cancer incidence. By contrast, the higher proportions in people resident in more deprived areas are not reflected in incidence rates for colon (or rectum for females) cancer.

Table 4.1.1 Test results for English pilot site.

		6-Mth Period in which Invited										Overall	
		Mar-Sept 2000		Oct 2000 - Mar 2001		Apr - Sept 2001		Oct 2001 - Mar 2002		Apr - Sept 2002		No.	%
		No.	%	No.	%	No.	%	No.	%	No.	%		
Phase I Results	Negative (R1a)	2942	95.9	29512	96.2	33931	95.8	18000	94.8	21094	96.2	105479	95.8
	Strong Positive (R2a)	4	0.1	63	0.2	76	0.2	50	0.3	43	0.2	236	0.2
	Positive with DR (R2b)	2	0.1	29	0.1	39	0.1	41	0.2	29	0.1	140	0.1
	Weak Positive (Enter P2)	119	3.9	1088	3.5	1382	3.9	887	4.7	770	3.5	4246	3.9
Phase II Results	Negative (Enter P3)	92	78.6	771	76.3	1020	77.2	603	72.7	518	73.9	3004	75.5
	Positive (R2c)	25	21.4	239	23.7	302	22.8	226	27.3	183	26.1	975	24.5
Phase III Results	Negative (R1b)	77	89.5	606	86.7	815	86.2	506	88.0	412	86.9	2416	86.9
	Positive (R2d)	9	10.5	93	13.3	130	13.8	69	12.0	62	13.1	363	13.1
FOBt Result	Negative	3019	98.7	30118	98.6	34746	98.5	18506	98.0	21506	98.5	107895	98.4
	Positive	40	1.3	424	1.4	547	1.5	386	2.0	317	1.5	1714	1.6

Table 4.1.2 Test results for Scottish pilot site.

		6-Mth Period in which Invited										Overall	
		Mar-Sept 2000		Oct 2000 - Mar 2001		Apr - Sept 2001		Oct 2001 - Mar 2002		Apr - Sept 2002		No.	%
		No.	%	No.	%	No.	%	No.	%	No.	%		
Phase I Results	Negative (R1a)	41106	94.0	33299	93.8	29161	94.4	33407	95.1	16878	94.0	153851	94.3
	Strong Positive (R2a)	179	0.4	138	0.4	117	0.4	94	0.3	67	0.4	595	0.4
	Positive with DR (R2b)	68	0.2	57	0.2	26	0.1	41	0.1	15	0.1	207	0.1
	Weak Positive (Enter P2)	2357	5.4	1988	5.6	1571	5.1	1582	4.5	1000	5.6	8498	5.2
Phase II Results	Negative (Enter P3)	1699	77.5	1403	76.5	1123	77.3	1112	75.0	644	73.7	5981	76.3
	Positive (R2c)	492	22.5	432	23.5	330	22.7	370	25.0	230	26.3	1854	23.7
Phase III Results	Negative (R1b)	1343	87.2	1164	89.5	954	89.2	926	87.4	468	83.9	4855	87.8
	Positive (R2d)	198	12.8	137	10.5	116	10.8	134	12.6	90	16.1	675	12.2
FOBt Result	Negative	42449	97.8	34463	97.8	30115	98.1	34333	98.2	17346	97.7	158706	97.9
	Positive	937	2.2	764	2.2	589	1.9	639	1.8	402	2.3	3331	2.1

Table 4.1.3 Positive test result by demographic factors

		England			Scotland		
		No. positive (%)	**Unadjusted OR (95%CI)**	**Adjusted OR (95%CI)**	**No. positive (%)**	**Unadjusted OR (95%CI)**	**Adjusted OR (95%CI)**
None		1714 (1.56)			3331 (2.06)		
Age	<55	335 (1.12)	1 (-)	1 (-)	618 (1.36)	1 (-)	1 (-)
	55-59	388 (1.26)	1.12 (0.97-1.30)	1.13 (0.97-1.31)	755 (1.87)	1.38 (1.24-1.53)	1.31 (1.15-1.49)
	60-64	481 (1.88)	1.69 (1.47-1.94)	1.67 (1.45-1.92)	836 (2.30)	1.71 1.54(1.90-)	1.64 (1.44-1.85)
	≥65	510 (2.18)	1.97 (1.71-2.26)	1.92 (1.67-2.21)	1122 (2.81)	2.09 (1.90-2.31)	1.93 (1.71-2.71)
		p-value for linear trend <0.001			p-value for linear trend <0.001		
Gender	Male	1026 (2.01)	1 (-)	1 (-)	2057 (2.81)	1 (-)	1 (-)
	Female	688 (1.17)	0.58 (0.52-0.64)	0.58 (0.53-0.64)	1274 (1.43)	0.50 (0.47-0.54)	0.51 (0.47-0.56)
Invitation Time	Mar – Sept 2000	40 (1.31)	1 (-)	1 (-)	937 (2.16)	1 (-)	1 (-)
	Oct 2000 - Mar 2001	424 (1.39)	1.06 (0.77-1.47)	1.09 (0.79-1.52)	764 (2.17)	1.00 (0.91-1.11)	0.95 (0.85-1.07)
	Apr – Sept 2001	547 (1.55)	1.19 (0.86-1.64)	1.27 (0.91-1.76)	589 (1.92)	0.87 (0.80-0.98)	0.85 (0.76-0.96)
	Oct 2001 - Mar 2002	386 (2.04)	1.57 (1.13-2.19)	1.48 (1.06-2.06)	639 (1.83)	0.84 (0.76-0.93)	0.88 (0.78-1.00)
	Apr – Sept 2002	317 (1.45)	1.11 (0.80-1.55)	1.14 (0.81-1.60)	402 (2.27)	1.05 (0.93-)1.18	0.96 (0.79-1.18)
		p-value for linear trend = 0.001			p-value for linear trend =0.067		
Deprivation Category	½	410 (1.28)	1 (-)	1 (-)	600 (1.70)	1 (-)	1 (-)
	3	292 (1.37)	1.08 (0.93-1.25)	1.08 (0.93-1.26)	627 (1.86)	1.10 (0.98-1.23)	1.11 (0.99-1.25)
	4	479 (1.61)	1.27 (1.11-1.44)	1.26 (1.10-1.44)	626 (2.18)	1.29 (1.15-1.44)	1.30 (1.15-1.46)
	5	225 (2.06)	1.63 (1.38-1.92)	1.55 (1.31-1.83)	254 (2.47)	1.47 (1.27-1.70)	1.48 (1.27-1.72)
	6/7	266 (2.10)	1.66 (1.42-1.94)	1.54 (1.31-1.82)	192 (2.63)	1.56 (1.32-1.84)	1.57 (1.32-1.86)
		p-value for linear trend <0.001			p-value for linear trend <0.001		
% Indian sub-continent	Low/Medium	1133 (1.4)			1		

Table 4.1.4 Positivity rates (n,% of those screened) by gender and age in the pilot and the Nottingham trial[1]

Age	Pilot: Scotland[2]			Pilot: England[2]			Pilot: Both[2]			Nottingham trial		
	Male	**Female**	**Both**	**Male**	**Female**	**Both**	**Male**	**Female**	**Both**	**Male**	**Female**	**Both**
50-54	374 (1.91)	205 (0.88)	579 (1.35)	182 (1.38)	127 (0.83)	309 (1.08)	556 (1.69)	3.32 (0.86)	888 (1.24)	43 (1.18)	34 (0.81)	77 (0.97)
55-59	432 (2.52)	269 (1.28)	701 (1.84)	206 (1.53)	147 (0.92)	353 (1.20)	638 (2.08)	416 (1.13)	1054 (1.56)	54 (1.44)	46 (1.06)	100 (1.24)
60-64	477 (3.10)	291 (1.53)	768 (2.24)	271 (2.36)	176 (1.35)	447 (1.82)	748 (2.78)	467 (1.46)	1215 (2.06)	72 (1.93)	84 (1.99)	156 (1.96)
65-69	623 (3.63)	412 (1.98)	1035 (2.73)	287 (2.72)	188 (1.58)	475 (2.12)	910 (3.28)	600 (1.84)	1510 (2.50)	80 (2.52)	83 (2.28)	163 (2.39)
50-69[3]	1906 (2.74)	1177 (2.01)	3083 (2.24)	946 (1.96)	638 (1.52)	1584 (1.65)	2852 (2.42)	1815 (1.81)	4667 (2.00)	249 (2.05)	247 (1.64)	459 (1.77)

[2] Data restricted to people who completed screening 3 months before download (so as to be comparable with Tables in 4.2)
[3] Age-standardised or age-sex standardised to the total pilot population who completed screening

4.2 Cancer and Adenoma Detection Rates

4.2.1 Aims and objectives

To analyse routine data downloaded from the Pilot sites to:

- estimate the detection rates for each Pilot site of neoplasia and colorectal cancer in subjects completing FOB testing;
- estimate the PPVs for the same outcomes for subjects testing positive;
- explore associations of detection rates and PPVs with demographic and (England only) Indian sub-continent proportions;
- describe the stage distribution of screen-detected cancers
- compare the estimated detection rates and PPVs with those seen in the Nottingham trial;

4.2.2 Methods

The data downloads previously described in Section 2.1.2 have again been used. However, to allow time for further investigations to be undertaken, subjects completing FOB testing less than three months before the date of the download have been excluded.

A subject has been classified as having colorectal cancer only if there is pathological confirmation from either a resection specimen or a biopsy/polyp removed at colonoscopy or, rarely, clear clinical indication of malignancy. In our second year report we confirmed that the computer algorithm was accurately identifying colorectal cancers for the English site by conducting a systematic audit with them. Pathological confirmation of lack of malignancy and of polyp type are required for classification as having adenoma(s). Subjects with more than one lesion have been classified according to their most severe condition.

Polyp cancers are those which are confined to one or more polyps. The initial procedure was to identify these as those which were known from pathology data to have been completely removed at colonoscopy. This is, we believe, successful in Scotland but led to the classification of many polyp cancers as being more extensive in the English data. This is partly, but not entirely, attributable to

- complete removal field being missing in pathology forms
- situations where complete removal was coded as ‘no’ but surgery found no evidence of malignancy

We have cross-checked the data on polyp cancers with staff at the English site.

Abnormalities classified as colorectal cancer or adenoma are grouped as neoplasia.

Some individuals had their status unknown; these include including non-malignant polyps of unknown type, malignancy status not known, malignancy suspected at colonoscopy but no pathology. Individual checking has revealed that some of these people are still undergoing repeat diagnostic tests.

All remaining individuals who were FOBt positive are conservatively classified as not having neoplasia detected; this group is comprised of the following three distinct types:

- no neoplasia (confirmed by pathology)
- no neoplasia reported at colonoscopy (no tissue removed for pathology)
- colonoscopy not reported as being performed

Table 4.2.1 gives a breakdown of all FOB test positive subjects into the above categories by Pilot site. It can be seen that the proportion of individuals falling into the group ‘no neoplasia reported at colonoscopy’ is higher for Scotland (27.0% versus 20.0%). We have confirmed that none of these had records of tissue having been removed at colonoscopy for pathological examination. We have presented alternative versions of the cancer and neoplasia detection rates and PPVs in which the unknown outcomes are treated differently. Specifically, for PPV we use two alternative denominators: all subjects who test positive (Method 1) and all who had evidence in the data base that a colonoscopy

had been performed. [See 3.1 for further discussion of the absence of colonoscopy in subjects who tested positive].

As previously described, logistic regression was used to investigate associations between neoplasia and malignancy detection rates and PPVs and demographic and ethnic factors (see Section 2.1.2 for details). In the logistic regression results for PPV we have used as alternative denominators (1) all subjects who tested positive and (2) all subjects who tested positive and had colonoscopy performed.

The majority of the staging information presented in **Table 4.2.6** was extracted from the routine downloads. However, a small amount of additional data was supplied by the Screening Units directly. Subjects who were unstaged because no surgery was performed for a polyp cancer are referred to as 'presumed stage A'.

4.2.3 Results

Altogether, the data contain evidence of 92 people with cancers confirmed to one or more polyps, 460 with other cancers and 1354 with adenomas (**Table 4.2.1**). The final row of this Table (colonoscopy not performed) includes subjects for whom a colonoscopy was not appropriate and these who expressed the intention to have one performed privately (See 3.1).

Age- and sex- adjusted detection rates for neoplasia and invasive cancer by Pilot site are given in **Table 4.2.2**. Detection rates are lower in England than Scotland and the differences are statistically significant. We note, however, that the English site are now aware of 11 additional cancers for whom relevant data were not contained in the download. Comparing the Pilot results with those from the Nottingham trial it can be seen that overall cancer detection rates are somewhat lower in England and higher in Scotland than in the Nottingham trial. After age-adjustment, and bearing in mind that the Nottingham figures are based on a small number of cases, the Pilot rates are comparable (England) or higher than (Scotland) the Nottingham trial. However, detection rates in the Pilot for women do appear to be genuinely lower. Cancers and neoplasias amongst the group with 'neoplasia status unknown' would increase the Pilot rates by an amount which cannot be quantified.

A somewhat different pattern of results is seen when looking at PPVs. If the conservative approach of Method 1 is applied (**Table 4.2.3 (a)**), these are both significantly less than those reported in Nottingham; if, however, Method 2 is used (**Table 4.2.3 (b)**) the results are comparable to or better than those for Nottingham.

Relationships between neoplasia detection rates in individuals who completed screening and the demographic factors are examined in **Table 4.2.4**. For both Pilot sites, there is a strong association (in both univariate and multivariate analyses) with increasing age and with gender, the higher rates being seen in males. There is a significant relationship with deprivation category in England and an association of borderline statistical significance in Scotland – higher rates being seen in more deprived areas.

Similar analyses are presented in **Table 4.2.5** and **Table 4.2.6** for PPV (where the denominators are restricted to subjects who were FOB test positive and those with colonoscopy performed respectively). The results exhibit similar associations though with reduced magnitude: higher rates are seen with increasing age, in males rather than females. At the Scottish site only, there is a statistically significant effect with deprivation in **Table 4.2.5** but this does not retain statistical significance in **Table 4.2.6**; category 6/7 have lower PPV rate than any of the other groups.

Analyses of detection rates and PPV for the English site by Indian sub-continent proportions are given in **Table 4.2.7**. The univariate analysis shows higher neoplasia detection rates in areas with a greater proportion of residents from the Indian Sub-Continent, but this loses statistical significance in the multivariate analysis. There is some evidence of an association in the opposite direction for PPV but this does not retain statistical significance after adjustment for deprivation.

Table 4.2.8a gives a summary of the available proportions by stage and compares this to the Nottingham trial. The staging distribution for both sites is similar to that for the Nottingham trial. More detailed staging information for the Pilot is provided in **Table 4.2.8b**. The slightly lower proportions of presumed Stage A cancers in England (and the correspondingly higher proportion of

Stage A cancers) appears to be largely attributable to more frequent surgery given for polyp cancers in the English Pilot.

Finally, **Table 4.2.9** gives counts, for subjects with adenomas, by size of largest polyp and number of polyps. This is essential data in planning workload resulting from adenoma follow-up.

4.2.4 Discussion

The most important problem with the data on which the analyses in this section are based relates to the absence of information from diagnostic evaluation for substantial numbers of subjects who tested positive for FOB. The possible reasons and explanations for this are presented and discussed in 3.1 and are not relevant here. What is, however, of major relevance is the effect of this on the denominators used in the calculation of PPVs. Although we have presented results which take all FOBt positives as denominator we strongly recommend that attention is focused on those which restrict the denominator to subjects with diagnostic evaluation reported in the data-set (ie. **Tables 4.2.3(b), 4.2.6**). We also recommend that calculations of PPV used in quality standards, especially if roll-out occurs, should take the same denominators.

Further data problems related to the identification from the Pilot downloads of polyp cancers, adenomas and neoplasia status. The distinction between polyp cancer and other colorectal cancer may, indeed, not be important; it may be that management (ie. laparotomy: yes/no) is what is most important both for the patient and for NHS resource allocation. Before any roll-out is planned and, preferably, as soon as possible, it will be necessary for specialists in different relevant disciplines to decide which are the key outcomes and how the data collection can be simplified while at the same time making ascertainment of the key outcomes straightforward and unambiguous.

The pathology data sets adopted for the Pilot were complex and missing data in individual fields were common. Concentration on fewer fields but inclusion of all those relevant to the identification of cancers and adenomas is essential. We are, however, confident that, after manual checking with the Pilot sites (which is unlikely to be practicable if roll-out occurs) our data are reliable.

Diagnostic and pathological data necessarily take time to accrue and patience is required when reporting screening parameters such as detection rates, PPV and %s by Duke's stage. That is, valid data cannot be entirely that of the present moment; our restriction here to subjects with FOBt results available at least 3 months before the download may not be quite enough.

One of our most important results is that the cancer detection rates achieved in this service setting compare very favourably with those reported from the Nottingham trial. It is possible that female detection rates in the Pilot are genuinely lower. Detailed modelling of colorectal cancer incidence and mortality by age, sex, time period and both cohort has been published for England and Wales and for Scotland. This shows that incidence for males has increased markedly over the last 20 or so years while that for females has remained relatively stable. This could contribute, in part, to the gender differences we have observed. The neoplasia detection rates are less easy to compare since we lack Nottingham data restricted to the prevalence screen, the main trial and the Pilot age group. However, overall neoplasia detection rates for Nottingham are 9.80/1000 which is higher but not enormously higher than those we report.

A second key result is that PPVs in the Pilot compares well with those from Nottingham provided we take as denominators subjects with diagnostic results available. This problem regarding choice of denominator does not appear to have arisen in the research setting.

The third key result is that the Duke's state distribution of the cancers detected in the Pilot is almost identical to that reported from the Nottingham trial.

We have also examined associations with demographic factors. The associations for detection rates concern the same factors and in the same direction as for FOB positivity: higher rates in men, in older people and, though less strong, in areas where deprivation is highest. A possible association, in England, with areas of highest Indian sub-continent residence does not persist after adjustment of depcat.

Associations of PPV with age and gender are evident and in the same direction as those for detection rates. However, associations of PPV with deprivation and with Indian sub-continent proportions are modest and in the opposite direction. There is, thus, some evidence of increased false-positive results here.

In conclusion, these analyses indicate areas where attention to data definition and collection is required but the present data are reliable and indicate that FOBt screening conducted in the service context achieves process parameters similar to, and at times better than, those achieved in the Nottingham trial.

Table 4.2.1 Identifying neoplasia and malignancy from existing data

(Restricted to subjects testing positive[1])

	Pilot Site				Overall	
	England		Scotland		No.	%
	No.	%	No.	%		
Polyp cancer[2]	26	1.6	66	2.3	92	2.0
Other Colorectal Cancer	105	6.6	232	7.9	460	9.9
Adenoma	473	29.9	881	30.2	1354	30.0
No Neoplasia Reported at Colonoscopy	306	19.3	790	27.0	1096	24.3
No Neoplasia (Confirmed by Pathology)	271	17.1	404	13.8	675	15.0
Neoplasia Status Not Known	46	2.9	90	3.1	136	3.0
Colonoscopy Not Performed[1]	357	22.5	459	15.7	816	18.1

[1] See 3.1 for discussion of the test positive subjects without evidence that colonoscopy has been performed
[2] Includes those for whom surgery was performed

Table 4.2.2. Detection rates/1000 for pilots and the Nottingham trial

	Males[1]			Females[1]			Both[2]		
Outcome	**England**	**Scotland**	**Nottingham[3]**	**England**	**Scotland**	**Nottingham[3]**	**England**	**Scotland**	**Nottingham[3]**
Colorectal cancer	1.80	2.91	1.74	0.81	1.21	1.11	1.26	1.99	1.61
Neoplasia	8.28	12.36		3.69	4.39		5.79	8.03	

[1] Rates are age-standardised to the population screened in the total Pilot (with FOB testing complete) up to 3 months before data download.

[2] Rates are age-and sex-standardised using the same standard population

[3] Using the prevalence screen for the main trial (personal communication, Moss S and Scholefield J); cancer includes some but probably not all polyp cancers

Table 4.2.3(a) Positive predictive values (PPVs) as percentages of test positives for the pilots and the Nottingham trial

	Males[1]			Females[1]			Both[2]		
Outcome	**England**	**Scotland**	**Nottingham[3]**	**England**	**Scotland**	**Nottingham[3]**	**England**	**Scotland**	**Nottingham[3]**
Colorectal cancer	9.11	10.67	10.06	7.14	8.68	8.54	8.34	9.90	9.47
Neoplasia	42.09	45.15		32.38	31.61		38.31	39.88	

[1] Rates are age-standardised (total Pilot population of FOB+ves taken as standard).

[2] Rates are age-and sex-standardised using the same standard.

[3] Nottingham data for the main trial, prevalence screen 50-69 yrs; data for invasive cancers includes some but not all polyp cancers. Personal communication: Moss S and Scholefield J

Table 4.2.3(b) Positive predictive values (PPVs) as percentages of those with colonoscopy performed for the pilots and the Nottingham trial[a]

	Males[1]			Females[1]			Both[2]		
Outcome	**England**	**Scotland**	**Nottingham[3]**	**England**	**Scotland**	**Nottingham[3]**	**England**	**Scotland**	**Nottingham[3]**
Colorectal cancer	11.59	12.69	10.06	9.94	10.27	8.54	10.18	11.75	9.47
Neoplasia	53.69	53.60	-	36.12	37.28		46.85	47.29	-

[1] Rates are age-standardised (total Pilot population of FOB+ves taken as standard).

[2] Rates are age-and sex-standardised using the same standard population.

[3] Nottingham data for the main trial, prevalence screen 50-69 yrs; data for invasive cancers includes some but not all polyp cancers. Personal communication: S. Moss

Table 4.2.4 Neoplasia by demographic factors (subjects completing FOB testing)

		England			Scotland		
		No. positive (%)	**Unadjusted OR (95%CI)**	**Adjusted OR (95%CI)**	**No. positive (%)**	**Unadjusted OR (95%CI)**	**Adjusted OR (95%CI)**
Age	<55	91 (0.32)	1 (-)	1 (-)	174 (0.43)	1 (-)	1 (-)
	55-59	121 (0.41)	1.29 (0.98-1.70)	1.27 (0.97-1.68)	248 (0.70)	1.63 (1.35-1.98)	1.63 (1.30-2.06)
	60-64	183 (0.75)	2.35 (1.83-3.03)	2.29 (1.78-2.94)	315 (0.98)	2.29 (1.90-2.76)	2.39 (1.92-2.97)
	≥65	209 (0.94)	2.94 (2.30-3.77)	2.89 (2.26-3.70)	442 (1.24)	2.91 (2.44-3.48)	2.94 (2.38-3.62)
		p-value for linear trend <0.001			p-value for linear trend <0.001		
Gender	Male	399 (0.82)	1 (-)	1 (-)	822 (1.27)	1 (-)	1 (-)
	Female	205 (0.37)	0.44 (0.37-0.52)	0.44 (0.37-0.52)	357 (0.45)	0.36 (0.31-0.40)	0.36 (0.31-0.41)
Invitation Time	Mar - Sept 2000	20 (0.66)	1 (-)	1 (-)	366 (0.85)	1 (-)	1 (-)
	Oct 2000 - Mar 2001	193 (0.63)	0.97 (0.61-1.54)	0.96 (0.60-1.52)	291 (0.83)	0.98 (0.84-1.14)	0.97 (0.81-1.16)
	Apr - Sept 2001	212 (0.60)	0.92 (0.58-1.46)	0.97 (0.61-1.54)	243 (0.79)	0.94 (0.80-1.10)	0.90 (0.75-1.09)
	Oct 2001 - Mar 2002	99 (0.53)	0.81 (0.50-1.31)	0.75 (0.46-1.22)	279 (0.80)	0.95 (0.81-1.11)	0.96 (0.79-1.17)
	Apr - Sept 2002	80 (0.47)	0.71 (0.43-1.16)	0.69 (0.42-1.13)	0		
		p-value for linear trend = 0.043			p-value for linear trend = 0.76		
Deprivation Category	1/2	147 (0.49)	1 (-)	1 (-)	246 (0.76)	1 (-)	1 (-)
	3	102 (0.51)	1.03 (0.80-1.32)	1.04 (0.81-1.34)	217 (0.68)	0.90 (0.75-1.08)	0.90 (0.75-1.08)
	4	195 (0.67)	1.35 (1.09-1.67)	1.35 (1.08-1.67)	239 (0.87)	1.14 (0.96-1.37)	1.15 (0.95-1.38)
	5	67 (0.62)	1.26 (0.95-1.69)	1.29 (0.96-1.72)	93 (0.91)	1.20 (0.94-1.52)	1.20 (0.94-1.53)
	6/7	83 (0.68)	1.37 (1.05-1.80)	1.55 (1.16-2.06)	62 (0.86)	1.13 (0.85-1.49)	1.11 (0.83-1.47)
		p-value for linear trend = 0.008			p-value for linear trend = 0.06		

Table 4.2.5 PPV: Neoplasia by demographic factors (subjects testing positive)

		England			Scotland		
		No. positive (%)	**Unadjusted OR (95%CI)**	**Adjusted OR (95%CI)**	**No. positive (%)**	**Unadjusted OR (95%CI)**	**Adjusted OR (95%CI)**
Age	<55	91 (29.45)	1 (-)	1 (-)	174 (31.18)	1 (-)	1 (-)
	55-59	121 (34.28)	1.25 (0.90-1.74)	1.23 (0.88-1.73)	248 (37.35)	1.32 (1.04-1.67)	1.40 (1.06-1.86)
	60-64	183 (40.94)	1.66 (1.22-2.26)	1.67 (1.21-2.29)	315 (43.21)	1.68 (1.33-2.12)	1.91 (1.46-2.51)
	≥65	209 (44.00)	1.88 (1.39-2.55)	1.88 (1.38-2.57)	442 (45.52)	1.84 (1.48-2.30)	2.03 (1.57-2.64)
		p-value for linear trend < 0.001			p-value for linear trend < 0.001		
Gender	Male	399 (42.18)	1 (-)	1 (-)	822 (45.24)	1 (-)	1 (-)
	Female	205 (32.13)	0.65 (0.53-0.80)	0.66 (0.53-0.82)	357 (32.31)	0.58 (0.49-0.68)	0.56 (0.47-0.68)
Invitation Time	Mar - Sept 2000	20 (50.00)	1 (-)	1 (-)	366 (39.06)	1 (-)	1 (-)
	Oct 2000 - Mar 2001	193 (45.52)	0.84 (0.44-1.60)	0.77 (0.39-1.50)	291 (38.09)	0.96 (0.79-1.17)	0.99 (0.79-1.25)
	Apr - Sept 2001	212 (38.90)	0.64 (0.34-1.21)	0.61 (0.32-1.20)	243 (41.33)	1.10 (0.89-1.36)	1.08 (0.85-1.38)
	Oct 2001 - Mar 2002	99 (25.98)	0.35 (0.18-0.68)	0.35 (0.17-0.70)	279 (44.08)	1.23 (1.00-1.51)	1.17 (0.90-1.52)
	Apr - Sept 2002	80 (41.24)	0.70 (0.36-1.39)	0.67 (0.33-1.37)			
		p-value for linear trend < 0.001			p-value for linear trend =0.61		
Deprivation Category	1/2	147 (40.27)	1 (-)	1 (-)	246 (44.57)	1 (-)	1 (-)
	3	102 (39.08)	0.95 (0.69-1.32)	0.99 (0.71-1.38)	217 (36.59)	0.72 (0.57-0.91)	0.71 (0.56-0.91)
	4	195 (42.58)	1.10 (0.83-1.45)	1.09 (0.82-1.45)	239 (40.17)	0.84 (0.66-1.06)	0.84 (0.66-1.08)
	5	67 (30.45)	0.65 (0.46-0.93)	0.76 (0.53-1.09)	93 (36.61)	0.72 (0.53-0.98)	0.72 (0.52-0.98)
	6/7	83 (33.33)	0.74 (0.53-1.04)	0.97 (0.67-1.40)	62 (32.29)	0.59 (0.42-0.84)	0.57 (0.40-0.82)
		p-value for linear trend = 0.401			p-value for linear trend = 0.009		

Note: This version codes neoplasia to "no" if FOBt +ve and colonoscopy result not known to be positive.

Table 4.2.6 PPV: Neoplasia by demographic factors (subjects with colonoscopy performed[1])

		England			Scotland		
		No. positive (%)	**Unadjusted OR (95%CI)**	**Adjusted OR (95%CI)**	**No. positive (%)**	**Unadjusted OR (95%CI)**	**Adjusted OR (95%CI)**
Age	<55	91 (37.60)	1 (-)	1 (-)	174 (36.86)	1 (-)	1 (-)
	55-59	121 (43.84)	1.30 (0.91-1.84)	1.27 (0.88-1.83)	248 (43.59)	1.32 (1.03-1.70)	1.41 (1.05-1.89)
	60-64	183 (53.20)	1.89 (1.35-2.64)	1.91 (1.35-2.70)	315 (50.16)	1.72 (1.35-2.20)	2.02 (1.52-2.69)
	≥65	209 (57.26)	2.22 (1.59-3.10)	2.27 (1.61-3.20)	442 (55.67)	2.15 (1.70-2.72)	2.46 (1.87-3.24)
		p-value for linear trend <0.001			p-value for linear trend <0.001		
Gender	Male	399 (53.77)	1 (-)	1 (-)	822 (53.73)	1 (-)	1 (-)
	Female	205 (42.27)	0.63 (0.50-0.79)	0.63 (0.50-0.80)	357 (38.26)	0.53 (0.45-0.63)	0.51 (0.42-0.62)
Invitation Time	Mar - Sept 2000	20 (57.14)	1 (-)	1 (-)	366 (47.66)	1 (-)	1 (-)
	Oct 2000 - Mar 2001	193 (55.94)	0.95 (0.47-1.92)	0.83 (0.40-1.75)	291 (46.12)	0.94 (0.76-1.16)	0.92 (0.72-1.18)
	Apr - Sept 2001	212 (49.30)	0.73 (0.36-1.46)	0.67 (0.32-1.39)	243 (48.12)	1.02 (0.81-1.28)	0.98 (0.76-1.28)
	Oct 2001 - Mar 2002	99 (35.74)	0.42 (0.20-0.85)	0.39 (0.18-0.83)	279 (49.91)	1.09 (0.88-1.36)	1.02 (0.77-1.35)
	Apr - Sept 2002	80 (57.14)	1.00 (0.47-2.11)	0.90 (0.41-1.98)	0		
	Oct - Dec 2002	0	/	/	0		
		p-value for linear trend <0.001			p-value for linear trend = 0.885		
Deprivation Category	1/2	147 (52.50)	1 (-)	1 (-)	246 (51.14)	1 (-)	1 (-)
	3	102 (47.44)	0.82 (0.57-1.17)	0.87 (0.60-1.25)	217 (42.38)	0.70 (0.55-0.90)	0.71(0.54-0.91)
	4	195 (53.87)	1.06 (0.77-1.44)	1.06 (0.76-1.46)	239 (46.77)	0.84 (0.65-1.08)	0.84 (0.65-1.10)
	5	67 (40.61)	0.62 (0.42-0.91)	0.71 (0.47-1.06)	93 (45.37)	0.79 (0.57-1.10)	0.80 (0.57-1.12)
	6/7	83 (45.60)	0.76 (0.52-1.10)	0.92 (0.61-1.39)	62 (41.89)	0.69 (0.48-1.00)	0.67 (0.45-0.99)
		p-value for linear trend = 0.329			p-value for linear trend = 0.074		

Table 4.2.7 Neoplasia by % from Indian Subcontinent - England Only

Outcome Measure	% Indian	N (%)	Not Adjusted for Deprivation		Adjusted for Deprivation	
			OR (95% CI)	p-value	OR (95% CI)	p-value
Neoplasia detection (Subjects Completing FOB testing)	1-4	433 (0.57)	1 (-)		1 (-)	
	5 (high)	121 (0.71)	1.23 (1.01-1.51)	0.044	1.13 (0.86-1.47)	0.38
Neoplasia (PPV) (Subjects Testing Positive)	1-4	433 (40.58)	1 (-)		1 (-)	
	5 (high)	121 (31.19)	0.68 (0.53-0.87)	0.002	0.74 (0.52-1.05)	0.09
Neoplasia (PPV) (subjects with further diagnostic results available)	1-4	433 (50.94)	1 (-)		1 (-)	
	5 (high)	121 (43.68)	0.76 (0.57-1.00)	0.048	0.89 (0.60-1.32)	0.57

Table 4.2.8a Duke's Stage summary by pilot site and for the Nottingham trial

		England		Scotland		Nottingham	
		No.	%	No.	%	No.	%
Stage Available[1]	No	7	5.3	28	9.4	0	0.0
	Yes	124	95.3	270	90.6	83	100.0
Stage	A/B[2]	89	71.8	197	73.0	59	71.1
	C/D	35	28.2	73	27.0	24	28.9

[1] 'Yes' include polyp cancers presumed to be Stage A.
[2] Includes those presumed to be Stage A.

Table 4.2.8b Detailed Duke's Stage by pilot site (N,%)

Stage	England	**Scotland**
Presumed Stage A (unstaged polyp cancers)	22 (16.8%)	66 (22.1%)
A	33 (25.2%)	68 (22.8%)
B	34 (26.0%)	63 (21.1%)
C	33 (25.2%)	71 (23.8%)
D	2 (1.5%)	2 (0.7%)
Other unstaged	7 (5.3%)	28 (9.4%)

Table 4.2.9 Adenoma details: counts for people by size (of largest polyp) and number of polyps

Size[1] (mm)	England				Scotland			
	Number of Polyps				Number of Polyps			
	n=1	n=2	n ≥ 3	Total	n=1	n=2	n ≥3	Total
None given	17		3	20	35	6	7	48
1-3mm	67	19	6	92	159	59	65	283
4-6mm	62	31	34	127	133	62	69	264
7-10mm	74	21	25	120	123	72	105	300
11-19mm	48	22	27	97	87	46	97	230
≥20mm	90	35	66	191	126	54	127	307
Total	358	128	161	647	663	299	470	1432

[1] Categories are based on quintiles of the Scottish data

4.3 Ethnicity

Detection rates were calculated as in the Main Evaluation. Abnormalities were classified as: *non-malignant adenoma* (polyp where lack of malignancy is confirmed by pathology data); *malignancy* (polyp cancer which is known from pathology data to have been completely removed); *invasive colorectal cancer* (all other cancers whose removal is incomplete or not known); and *neoplasia* (i.e. sum of all three categories above). Subjects with more than one polyp and/or cancer were classified according to their most severe condition.

The overall neoplasia rates in those with a positive FOB test result was 402 per 1,000. Within the Asian community this figure was much lower (158 per 1,000 FOBt positives), although the statistic is based on a very small number of cases. The association between neoplasia detection rates among FOBt positives and demographic and ethnic factors showed strong association in both univariate and multivariate analyses with increasing age. The detection rate was lower among females, among those with a positive FOBt result in the recent past, and among the Asian community as a whole. The deprivation category was found to be insignificant in determining the variation in neoplasia rates among FOBt positives.

The rates of malignancy and invasive colorectal cancer calculated from the data download are currently being compared with a manual audit list maintained by the English Pilot site.

4.4 Adverse Sequelae of Screening in the UK Pilot

All screening has the potential to cause harm – it has been important in this evaluation to document any adverse events caused by screening in the two Pilot sites. We focus on immediate effects of tests and investigations; data on complications from surgery and other treatments in Pilot invitees found to have significant pathology have not been routinely available for the evaluation. There was a clear protocol for mandatory reporting of adverse events, and sharing of this information between the sites.

The complications of particular concern in screening for colorectal cancer is perforation or hemorrhage following colonoscopy. The major complications are directly related to the procedure itself – they occur at the time of the procedure due to the mechanical presence of the endoscope itself or due to therapeutic manipulations of the instrument. It is generally a relatively safe procedure. While rates vary worldwide, perforation rates for diagnostic colonoscopies occur in approximately 0.2% (eg 2 per 1000) of cases, rates being lowest amongst most recent audits (Araghizadeh et al, 2001).

Various mechanisms may result in perforation – it may the result of direct mechanical trauma, from force at the tip of the endoscope (especially when there is poor visualisation). Further, the scope may be passed through a diverticulum, penetrate the side of a tight flexure, or tear the mucosa of a narrowed stricture. Perforation may also result from pneumatic distension.

In general, rates of perforation in therapeutic colonoscopy/poypectomy are about double the incidence of diagnostic colonoscopy – that is, approximately 4 per 1000 procedures, although again rates are lower in the most recent studies (Araghizadeh et al, 2001). In polypectomy or biopsy there is a deliberate mucosal injury produced; the actual polypectomy may directly result in perforation if the mechanical force overcomes the tensile strength of the colon. If the lesion has thinned the colonic wall, perforation may also result from full-thickness biopsy.

Post-colonoscopy hemorrhage is also a rare complication in centres which perform large numbers of colonoscopies. A systematic review of five studies demonstrated hemorrhage rates of 0.03% for colonoscopy with biopsy, and 1.9% for colonoscopy with polypectomy (Kavic & Basson, 2001).

Overall, there were very few adverse incidents in either site, and this is likely to be related to the rigorous quality assurance procedures that were in place for tests and investigations conducted within the Pilot.

England

- 6 patients admitted and observed overnight for post-colonoscopy bleeding or abdominal pain, and discharged the following day
- 11 patients re-admitted for bleeding or abdominal pain
- 1 patient with perforation at colonoscopy performed as a therapeutic procedure
- 1 patient died post-colonoscopy; this patient had an undiagnosed underlying illness which only became apparent in the post-colonoscopy period, and death was not attributed to the colonoscopy itself.

Scotland

- 4 patients admitted and observed overnight for post-colonoscopy bleeding, and discharged the following day
- 2 patients re-admitted for bleeding (1 on warfarin, bleeding probably not caused by the biopsy at colonoscopy)
- 1 perforation at colonoscopy surgery – fully recovered
- 3 post-operative deaths following surgery indicated by colorectal screening (all attributed to known cardiac conditions).

Based on the data available for this evaluation, approximately 1200 individuals underwent colonoscopy in England, and 2400 in Scotland (the actual numbers for the whole of the screening period will have been higher; adverse effect information has been gathered for the whole of the period). This gives rates for

perforation which compare extremely well with those in the published literature. Rates for post-colonoscopy hemorrhage also compare very favourably.

Further, as detailed in Chapter 2, we did not detect persistent adverse psychological sequelae amongst screening participants.

In summary, these are very favourable findings. It is important, nevertheless, to follow them up and ensure that all important adverse events in the period following screening, investigations and treatments are captured. Accordingly, the Evaluation team plan to perform record linkages in future to identify more delayed adverse sequelae of colonoscopy. Specifically, we shall, firstly, link all those who have had a colonoscopy performed in the Scottish Pilot with the Scottish Health Departments SMR1 data base to ascertain all inpatient and outpatient admissions in this population; secondly, we shall link the same people in both sites to death registries to ascertain all-cause mortality. Both of these will be performed for the six month period following colonoscopy but, since the populations involved are likely to have substantial comorbidity, a comparison group will also be linked; this group will be a systematically selected control sample of people of the same sex, age-group and depcat level screened negative at the same time. This method of selecting controls matches for age, sex, depcat, site and other unidentified factors which influence the decision to be screened.

4.5 Conclusions and Recommendations

In this chapter we have reported the process parameters of screening for bowel cancer using the FOB test and compared them with those reported from the Nottingham trial conducted in a research setting (Hardcastle et al, 1996). In addition, we have itemised the adverse sequelae and commented on issues of data collection.

Test positivity has, as expected, increased by age and is higher in men and in more deprived areas. Positive proportions are comparable to, though somewhat higher than, those from Nottingham. The proportions (1.6-2.1%) are entirely acceptable for a population screening programme.

Further research to refine the testing protocol, including, for example the use of immunological testing is strongly recommended. In addition, we advise the use of record linkage to identify interval cancers and examination of stage of cancers detected at the second screen to see whether other groups within the initial weak-positive category should be selected for colonoscopy.

Cancer detection rates are also higher with increasing age, in men and in residents of more deprived areas. They, too, are similar to those reported from Nottingham; rates for the Scottish Pilot were somewhat higher and, for the English Pilot, somewhat lower, than those reported in Nottingham for the same age group.

Positive predictive values are a further parameter which was higher in men and increased with age but there is no evidence that it was higher in the more deprived areas; indeed, there was a suggestion that it might be lower in these areas. PPVs for cancer were around 9% which is acceptable for population screening, even when the diagnostic evaluation procedure is, as here, invasive and with potentially serious complications; PPVs for neoplasia (including both cancers and adenomas) were around 40%. The remainder of the test positives are classified as false positives; monitoring of these by record linkage for interval colorectal cancers and other GI cancers is strongly recommended, if only to confirm the initial verdict that they have no significant pathology.

The Pilots had, from the outset, a firm protocol in place to ensure that adverse sequelae were ascertained and reported. Nevertheless, very few have been identified. This evidence of absence of harm is critical for a programme which may be rolled-out.

We have identified aspects of data definitions, collection and coding which require attention before roll-out could occur. We do not envisage problems here but emphasise that the kind of detailed audit which we were forced to undertake with the Pilot sites would not be appropriate after roll-out. Accurate calculation of process parameters from routine data is essential if quality standards are to be useful when applied in practice.

In conclusion, the process parameters from the Pilot are acceptable for population screening and are similar to those reported from the Nottingham trial for the same age group. It is, therefore, reasonable to assume that the long-term benefits reported by the randomised trials in terms of mortality reductions (Hardcastle et al, 1996, Mandel et al, 1993, Kronberg et al, 1996) and eventual reduction in incidence (Mandel et al, 2000) should be realised in service screening by FOB testing. One minor caveat arises from the different population experience of colorectal cancer mortality and survival in the UK today where reductions in colorectal cancer mortality and increases in colorectal cancer survival with time have been reported in the absence of screening (Hayne et al, 2001, Dunlop, 2001). It is possible that a 'halo' effect will emerge as was seen when service mammographic screening for breast cancer was introduced and improved stage distributions as well as mortality benefits were observed outside the screening age range; this requires investigation. Finally, we emphasise that in making a decision for or against roll-out, or as research after roll-out takes place, it will be necessary to compare FOB testing with flexible sigmoidoscopy should positive results emerge from ongoing randomised trials (Atkin et al, 2002).

References – Chapter 4

Atkin WS, Cook CF, Cuzick J, et al. *Single Flexible Sigmoidoscopy Screening To Prevent Colorectal Cancer: Baseline Findings Of A UK Multicentre Randomised Trial.* Lancet 2002; 359: 1291-1300.

Araghizadeh FY, Araghizadeh MD, Timmcke et al. Colonoscopic perforations. *Dis Colon Rectum* 2001; 44: 713-716

Dunlop MG. Colorectal Cancer. In Scottish Executive Health Department. Cancer Scenarios: An Aid To Planning Cancer Services In Scotland In The Next Decade, Pp 49 - 62. Edinburgh: The Scottish Executive; 2001.

Hayne D, Brown RSD, McCormack M, et al. *Current Trends In Colorectal Cancer: Site, Incidence, Mortality And Survival In England And Wales.* Clinical Oncology 2001; 13: 448-452.

Jorgensen OD, Kronborg O, Fenger CA. Randomised Study Of Screening For Colorectal Cancer Using Faecal Occult Blood Testing: Results After 13 Years And Seven Biennial Screening Rounds. *Gut* 2002; 50: 29-32.

Kavic SM, Basson MD. Complications of endoscopy. *Am J Surgery* 2001;181: 319-332.

Mandel JS, Bond JH, Church TR, et al. *Reducing Mortality From Colorectal Cancer By Screening For Fecal Occult Blood.* New England Journal Of Medicine 1993; 328: 1365-1371.

Mandel JS, Church TR, Bond JH, et al. The *Effect Of Fecal Occult-Blood Screening On The Incidence Of Colorectal Cancer*. New England Journal Of Medicine 2000; 343: 1603-1607.

5. Health Economics

Chapter summary

- We constructed a model of the lifetime costs and benefits of FOB screening drawing on work that had previously been validated as part of the largest UK randomised trial in Nottingham.
- We used values for the screening test performance from the pilot study. It was not always possible to use resource data because were estimating the lifetime costs and benefits of the programme, so some values were derived from other sources.
- Our model suggests that over the expected lifetime for a 50-year old male, the estimated net cost per QALY gained is around £2,600. While there is no official "cut-off" for societal willingness-to-pay for a QALY, NICE has recommended technologies that have a net cost of round £30,000 per QALY gained.
- We ran the model with different compliance rates for screening and reduced attendance at each subsequent screening round but the effect of the net cost per QALY gained was relatively small. When treatment costs were doubled the cost per QALY fell below £2,000.
- When a 60-year old male cohort is considered as the target screening group, the cost per QALY increases roughly three-fold, ranging from just below £6,000 to nearly £8,000 depending on the assumptions made for the key cost effectiveness drivers.
- We conclude that under most circumstances FOB screening every two years in the age range considered has a net cost per QALY gained that falls within the usually acceptable limits. This confirms the findings of the MRC trial.

This section describes the economic analysis complementing the evaluation of the CRC pilots. The work was led by Aileen Neilson (HealthEcon, Basel), Andrew Walker (Robertson Centre for Biostatistics, University of Glasgow) and John Forbes (University of Edinburgh).

5.1 Introduction

The aim of this component of the evaluation was to assess the likely economic efficiency of screening for colorectal cancer using the pilot study protocol. To achieve this we estimated the lifetime NHS costs and health benefits (measured in quality-adjusted life-years, or QALYs) for two groups:

- a cohort who are not offered screening but treated according to current practice;
- a cohort who are offered screening as per the protocol used in the pilot study, with repeat invitations every two years.

The net cost per QALY gained was thus calculated by calculating the additional costs of screening, after allowing for treatment cost savings, and the gain in survival and quality of life. The purpose of this is to assess whether colorectal cancer screening using the pilot study protocol is a good use of resources (defined as giving more QALYs) compared to other possible interventions.

Attempts to proceed in this way are somewhat hampered by the fact that the upper limit on what society is prepared to pay for health gains in general and QALYs in particular has not been clearly defined (not should we expect it to be in the near future). However, recent decision-making by the National Institute for Clinical Excellence (NICE) reveals some limited information about willingness-to-pay in this context. It has been suggested that £30,000 per QALY might represent a threshold: below this level health technologies have a good chance of being funded, but above this they are often restricted to a limited

population of those who might possibly benefit. The key question was thus how the net cost per QALY for FOB testing in the general population aged 50 and over compared to this perceived threshold.

The QALY has several shortcomings, of which we are fully aware. However, there is no other common metric for use across health care programmes that allows us to address the question posed. We could have calculated cost per cancer detected or cost per person screened, but we did not feel this to be useful as it does not allow valid comparisons with other uses of resources. Only QALYs go beyond interim outcomes, such as cancers detected, to estimate what this means for the patient in terms of health gain.

The following section reports the main findings of the literature review. Section 5.3 then describes how the economic model was constructed, reports the data used and the main results. A sensitivity analysis was carried out to show the findings were robust and this is reported too. The final section presents our conclusions and recommendations.

5.2 Review of previous economic analyses

We conducted a systematic review of previous economic analyses of CRC screening programmes in order to inform our understanding of the study designs and findings reported by previous investigators working in this field. Using a range of overlapping search strategies applied to MEDLINE, EMBASE and NHS EED and careful review of corresponding citations/related literature we identified several hundred references that addressed (often tangentially) some element of the economics of CRC screening programmes. However, just under 30 studies satisfied at least two of the following characteristics:

- Related to an average risk population
- Based on a UK population
- Using FOBT as its primary screening modality
- Published within the last 5 years

We are confident that these search and filtering strategies captured the main contributions in this field. More restrictive combinations of these characteristics with the additional constraint of being based in whole or part on the evidence base derived from randomised controlled trials of CRC screening would condense the literature even further to a very small set of studies.

Each paper was scored across the characteristics noted above with one point awarded for each satisfied characteristic. Full details of the search strategy, citations and related information is available on request for those interested in replicating our review.

The field is dominated by a small number of studies that have incorporated the results of CRC screening trials. Given the consistency of the trial findings with respect to the reduction in mortality associated with screening, the corresponding results obtained from integrating the efficacy estimates alongside a range of assumptions and estimates of economic consequences offer a convincing case in support of CRC screening using FOBT. The main UK contribution has been the results of the MRC trial, which showed that FOB screening at around £2000 per QALY appears relatively cost effective compared to the baseline of no population screening. Although a higher range of cost per life year or cost per QALY figures have been reported in other studies, most of these are largely a reflection of differences in service intensity and price levels across different health care systems.

A further prominent and consistent observation from this review is that several CRC screening strategies (such as flexible sigmoidoscopy combined with faecal occult blood testing) may offer a more cost effective approach when assessed against a screening strategy restricted to FOBT alone. However, this conclusion depends on compliance and the cost of specific elements of the screening regime.

5.3 Modelling CRC screening

The model we constructed was based on our previous experience of evaluating the MRC trial. The model that had been developed and validated for that study was reworked to include the following data:

- pilot study data on screening compliance, positive rates an detection of neoplasia;
- the most recent and generalisable sources of resource use and costs; and
- information drawn from what we believe is one of the most robust modelling studies reported to date (Frazier et al, 2000).

We ported and rewrote the original model from Excel to DATA 4.0 to enable more statistically sophisticated and informative analyses to be carried out.

Model and baseline parameter values

The primary transition states were modelled using a Markov model. In terms of updating the previous model we integrated the relevant epidemiological findings from the CRC screening pilots (short-run screening "effects" observed in the study populations) within the model design and coupled this with relevant population and epidemiological characteristics and a new set of resource parameters (**Appendix 4**). Where data were not readily available from the pilot study, we used assumptions based on the Nottingham experience; for example, we assumed surveillance after polypectomy and surveillance colonoscopy every three years only for those found with a "high risk polyp". The baseline parameter values are presented in the **Table 5.1**. More details of the model are available on request.

Calibration issues

We have validated the logical structure of the model and its reliability using another reported model (calibrated with North American data) in addition to our previous work. We checked the model's dynamics against cancer incidence/detection rates, cancer stage distributions, cancer mortality rates etc. The proportion of cancers by stage and other detection rates (neoplasia vs. no neoplasia) predicted by the model should be comparable at least with pilot study data on the first round of screening. Unfortunately, the nature of the pilots means that there are no data on (i) subsequent rounds of screening, and (ii) rates in the absence of screening. Where these were not available we used MRC trial-based estimates.

One important check on the model calibration is to compare the CRC incidence and mortality estimates. For example, the MRC trial reported a 15% reduction in CRC mortality from FOBT every 2 years in persons aged 50-74 (based on an average follow-up of 2-3 rounds of screening and a maximum of 5-6). Screening a 50-year old male to aged 75 (followed-up to aged 80) should result in a higher reduction in mortality from CRC than the MRC trial. The model predicts a 50-year old male screened in this way, will experience a 31% reduction in CRC incidence and a 39% reduction in CRC mortality. This estimate lies within the range reported by other recently published economic models of CRC screening which evaluate FOBT screening every year rather than every 2 years. For example, Frazier et al estimate screening a 50-year old male ***annually*** to aged 85 would reduce CRC incidence by 39% and CRC mortality by 55%.

We conclude that our model was consistent with other models and, more importantly, with observed trial data.

Cost effectiveness estimates

Analysis of the components of the lifetime cost for a 50-year old man shows that with FOB screening, 49% of lifetime costs relate to screening itself (£126), 12% relate to investigation of test results (£31), and 40% relate to treatment (£103). By contrast, the lifetime cost without screening is £143. In other words, over the lifetime of a 50-year old man there will be an additional cost of £157 on screening and investigation, less a saving of £40 on treatment, giving a net cost of £117.

While the cost is not high, the benefits might seem modest to at first sight. We estimated that a 50-year old man offered FOBT every two years will live an average of 16 days more as a result. This is actually

towards the upper end of most of the reported life (day) gains for similar screening regimes which tend to cluster around 10 – 14 days (see **Table 5.2**).

While this is not a dramatic change in length of life, the costs are low as well, so overall the net cost per QALY gained is only £2,650. Most of the density of the "net cost per QALY" distribution is between £2,000 to £3,000.

We considered the impact of changing base case values for key parameters (see **Tables 5.3 and 5.4**). Three of these are presented below to illustrate our findings:

- Changing compliance rates (with a fall in attendance at each subsequent round of screening) had a relatively small effect on net cost per QALY. This may be because some costs depend upon the number of people being screened, so a reduced number attending reduces the costs of the programme as well as the total benefit.
- When CRC treatment costs are doubled this has the effect of reducing the incremental cost per QALY to below £2,000, reflecting the net impact on resource consequences when FOBT screening is compared with a strategy of no screening.
- When a 60-year old male cohort is considered (rather than 50-year old men) as the target screening group, the cost per QALY increases roughly three-fold, ranging from just below £6,000 to nearly £8,000 depending on the assumptions made for the key cost effectiveness drivers.

We used a baseline estimate of £5 per FOB test (including the test being despatched and processed when returned) - this is almost certainly an overestimate and including this in the sensitivity analysis would have reduced the net cost per QALY gained even further. This suggests that our results are robust. Although the results vary depending on the age/sex of the target screening group, alternative surveillance regimes, costs of surveillance and estimated lifetime therapy costs, it is difficult to construct likely scenarios where the cost per QALY would even begin to approach a threshold such as £30,000.

At this point we decided further refinements to our relatively crude analysis would not be required. We could have proceeded to estimate out-of-pocket expenses to those screened and investigated or to include resource use data from the pilot study areas. However, we believe that we have demonstrated that this would not have affected the policy conclusion. Further detail would have satisfied intellectual curiosity but would not have served a useful purpose.

Table 5.1 Baseline parameter values

Parameter	Baseline value
Initial probability of having a polyp at age 50 yr	0.26
Initial probability of having (asymptomatic) stage A&B cancer at age 50	0.0008
Initial probability of having (asymptomatic) stage C&D cancer at age 50	0.0012
Proportion of polyps that are high risk (e.g. >1cm, neoplastic)	0.02
Annual CRC-specific mortality rate	
A&B (1 year to 5 years into treatment?)	0.002
C&D (1 year to 5 years into treatment?)	0.3
Annual transition probabilities	
Polyp, cancer free to low-risk polyp	0.01
Low-risk polyp to high-risk polyp	0.02
High-risk polyp to Stage A/B cancer	0.05
Stage A/B to Stage C/D cancer	0.40
Probability CRC will be diagnosed due to symptoms (i.e. patient seeks medical care)	
Stage A&B cancer	0.25
Stage C&D cancer	0.7
Utility adjustment for quality of life	0.96
Annual probability of developing a low-risk polyp after polyp removal given history of low-risk polyp	
First year	0.06
Year 2+	0.18
Annual probability of developing low-risk polyp after polyp removal given history of high-risk polyp	
First year	0.075
Year 2+	0.25
Test performance characteristics	
FOB test	
Sensitivity for polyps	0.10
Sensitivity CRC	0.33
Specificity	0.97

Colonoscopy	
Sensitivity for low risk polyps	0.85
Sensitivity for high risk polyps	0.95
Sensitivity for CRC	0.95
Specificity	1.00
Probability of perforation due to diagnostic colonoscopy	0.0004
Probability of perforation due to therapeutic colonoscopy	0.0022
Probability of death following a colon perforation	0.073
Compliance rates, %	
FOBT screening	60
Colonoscopy after positive FOBT	80
Colonoscopy surveillance after polyp removal	80
Costs, 2002 £	
FOB test	£5
Diagnostic colonoscopy	£127
Therapeutic colonoscopy	£138
Screen detected Stage A/B cancer, estimated lifetime costs	£7,005
Non screen detected Stage A/B cancer, estimated lifetime costs	£7,228
Screen detected Stage C/D cancer, estimated lifetime costs	£6,547
Non-screen detected Stage C/D cancer, estimated lifetime costs	£6,655
Treatment for Colonic Perforation	£6,500
Number of FOBT test kits mailed to invitees	
FOBT test result negative/ positive/ no FOBT results (including non-responders)	Assume at least 2 test kits mailed
Annual discount rate: Costs, %	6
Annual discount rate: QALYs, %	1.5

Table 5.2 Base case

Strategy	No FOBT	FOBT every 2 years
Lifetime cost	£143	£259
Incremental cost	£117	
Effects (QALYs)	20.47	20.51
Incremental effects	0.04	
Incremental C/E (£/QALY)	£2,650	

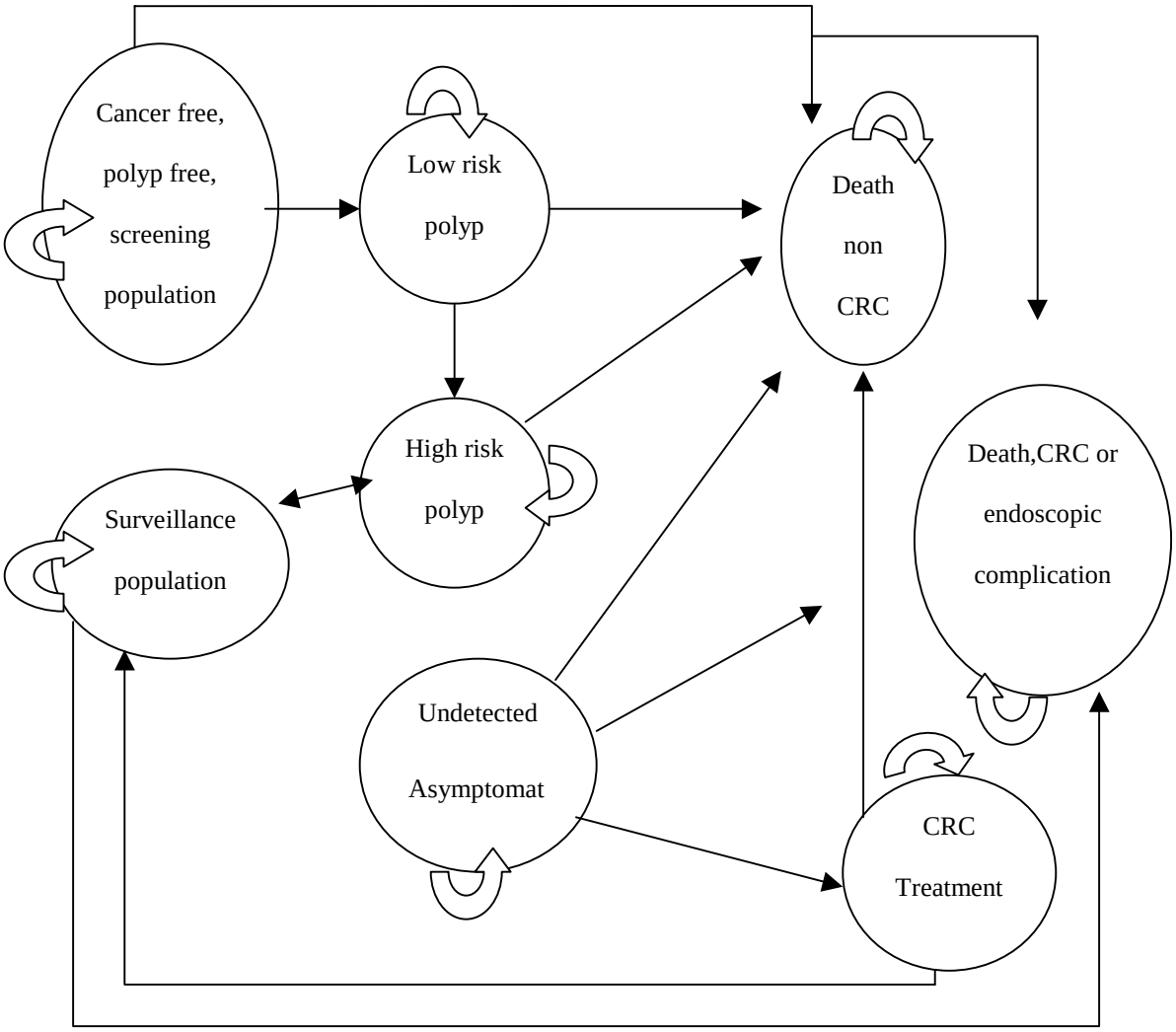
Table 5.3 Sensitivity analysis for 50-year old male cohort

50-year old male cohort	Costs (£) screening minus no screening	Effects (QALYs) screening minus no screening	Net cost	Net effect	Net cost/QALY
Base case	259-143	20.51-20.466	117	0.044	2,650
Compliance with FOBT 50% (60% in base case)	260-143	20.504-20.466	118	0.038	3,110
Ditto 70%	259-143	20.516-20.466	116	0.050	2,325
Compliance with follow-up colonoscopy after a positive FOBT 70% (80% in base case)	260-143	20.505-20.466	118	0.039	3,010
Ditto, 90%	259-143	20.564-20.515	116	0.049	2,370
Fall in attendance at each subsequent screening round of 5% (0% in base case)	260-143	20.503-20.466	118	0.036	3,216
Double CRC treatment costs	362-282	20.51-20.466	80	0.044	1,823
Costs of treating screen-detected cancers equal to cost of non-screen detected	262-143	20.51-20.466	119	0.044	2,707
Double colonoscopy cost	289-146	20.51-20.466	143	0.044	3,240

Table 5.4 Sensitivity analysis (60-year male cohort)

60-year old male cohort	Costs (£) screening minus no screening	Effects (QALYs) screening minus no screening	Net cost	Net effect	Net cost/QALY
Base case	263-143	20.484-20.466	120	0.018	6,623
Compliance with FOBT 50% (60% in base case)	263-143	20.481-20.466	121	0.015	7,839
Ditto 70%	262-143	20.487-20.466	120	0.021	5,756
Fall in attendance at each subsequent screening round of 5% (0% in base case)	263-143	20.482-20.466	120	0.016	7,465
Compliance with follow-up colonoscopy after a positive FOBT 70% (80% in base case)	263-143	20.482-20.466	121	0.016	7,518
Ditto, 90%	262-143	20.486-20.515	120	0.020	5,927
Double CRC treatment costs	384-282	20.484-20.466	102	0.018	5,621
Costs of treating screen-detected cancers equal to cost of non-screen detected	266-143	20.484-20.466	123	0.018	6,784
Double colonoscopy cost	278-146	20.484-20.466	132	0.018	7,263

Figure 5.1 CRC model primary transition states



5.4 Conclusions and recommendations

The main message from our modelling work is that the results from the pilot study reinforce the conclusion from the MRC trial i.e. that FOB testing of the general population aged 50-74 yields health gain at what is generally regarded as an acceptable cost.

However, this evaluation only considered FOBT and it is possible that screening by some alternative modality might be even more cost-effective. In other words, if we consider the pilot protocol in isolation and compare it to no screening then it is cost-effective. However, it might not be the most efficient way to screen for colorectal cancer in the general population.

Recommendations

The most important subject is whether colorectal cancer screening should be funded according to the pilot study protocol. The estimate of net cost per QALY gained is low compared to other common health services. The figures compare favourably with statins in secondary prevention of heart disease, screening for breast and cervical cancer, recent estimates of the likely cost of screening for aortic aneurysms, and so on. By any reasonable economic criterion it would be a high priority for future funding. However, the remit for this evaluation meant that other forms of colorectal cancer screening have not been evaluated and it is conceivable that they may be even more cost-effective.

There are several ways in which our model could be refined. For example:

(i) Refine the resource estimates, for example by including the latest UK audit data on resource use during lifetime treatment of the disease; and integrating other research on (for example) differences in participation rates and the reassurance value of screening (through willingness-to-pay).

(ii) The prognostic significance of adenoma detection and excision is likely to be of critical importance in determining the most cost-effective approach to this disease yet very little is known about it. The field should be reviewed and indirect evidence on the malignant and health-affecting potential of adenomas should be gathered.

(iii) The impact of the introduction of screening on waiting times in terms of the impact upon endoscopy resources and use of theatre time should be studied, including evaluation of ways in which capacity could be increased (e.g. through the use of nurse practitioners).

(iv) Consider using a different approach to modelling. In common with many recent economic publications in this field we chose a Markov design to model the health transitions alongside the expected use of resources over the lifetime of the screening programme. An alternative approach would have been discrete event modelling and simulation, which has been used recently in a cost-utility study of one-time colonoscopic screening for colorectal cancer and may offer some advantages. However, we decided to continue with our original modelling strategy and interpret our findings against a wider methodological stage.

However, the similarity between the results of the present modelling exercise and that carried out based upon the MRC trial in Nottingham suggest there is limited added value to further clinical trials or pilot work restricted to FOBT regimes alone. In other words, further work seems simply to repeat what we have already found. While this is reassuring, it is also expensive in terms of research time and effort and at some point a policy decision must be made on how to proceed. Thus the most important extension may be:

(v) estimate the costs and benefits of other screening modalities (e.g. by including data from the UK flexible sigmoidoscopy screening trial) (UK Flexible Sigmoidoscopy Screening Trial Investigators, 2002)

Our literature search also identified several problems with the existing literature as follows:

- The time horizon often chosen for the calculation of the incremental costs and effects of CRC screening (typically around 30 years) stretches well beyond the evidence base derived from the trials where follow-up is typically less than 15 years. It is not unusual to encounter modelling studies that use trial results as a short to medium term foundation for what is essentially a very long-term forecasting exercise. The direction and magnitude of forecast errors for the key model parameters is rarely addressed. Perhaps the most uncertain element of the forecast is the nature and impact of novel therapeutic options on the anticipated health outcomes for screening participants and non-participants alike. Moreover, the future cost of new patterns of treatment may be poorly calibrated by simply rolling over current styles and components of care. It is not clear whether sensitivity analyses that rather simplistically vary the level of (current) resource costs offer any degree of insight into the eventual magnitude of realised resource consequences over the medium to long term. Indeed, the recent introduction of new, much more costly (and perhaps less efficient) therapeutic options in the management of advanced colorectal cancer are a case in point.

- Another difficult issue is the handling of real resource constraints (service capacity) within an economic evaluation. The realistic capacity of a "live" service to accommodate the diagnostic workload generated by a screening programme clearly needs to be carefully integrated into any programme of service delivery. All modelling studies are by construction dealing with idealised scenarios, sometimes stretching over several decades, where it is virtually impossible and arguably not sensible to engage in forecasts or predictions of future capacity. Even measuring existing capacity within a national service framework is itself likely to be problematic as regional and local variation in resource deployment and use are the relevant binding constraints.

- A related issue is the partial nature of all economic evaluations of CRC screening to date in so far as they do not attempt to analyse the likely impact of screening within a more general framework capturing implications for other components of the health service system. One obvious implication is the extent to which a reallocation of resources in favour of CRC screening "crowds out" other services or introduces unanticipated indirect effects that cascade throughout the service. Again, the relevant literature in this field is silent on this issue.

A final point is that the assessment of cost effectiveness should not be confused with calculations which seek to establish the budgetary implications of introducing CRC screening on a population basis using FOBT or other screening modalities. However, there is a lack of data on how resources are being used now: this makes detailed estimates of how resource use would be affected by screening in the long-term difficult to estimate and hard to monitor.

References – Chapter 5

Frazier L, Colditz G, Fuchs C, et al. *Cost-effectiveness of screening for colorectal cancer in the general population.* JAMA 2000; 284: 1954-1961.

UK Flexible Sigmoidoscopy Screening Trial Investigators. *Single flexible sigmoidoscopy screening to prevent colorectal cancer: baseline findings of a UK multicentre randomised trial* Lancet 2002; 359: 1291-1300.

6. Workload and Impact on Routine Services

Chapter Summary

A national FOBT screening programme will have a workload impact well beyond the immediate services resourced through the programme. The introduction of a national programme will need to carefully examine existing capacity and potential to accommodate increased activity, at both a national and regional level. It will also need to take into account implementation of new NHS contracts for consultant and GP services over the next two to three years – these contracts, and other elements of health service reform, are likely to alter incentives and patterns of health service provision in primary and secondary care

Primary Care

- Our surveys and audit demonstrate that the Pilot has had a discernable, albeit modest, impact on workload in primary care
- Aspects of this increased workload which appear to be of particular significance to primary care personnel include increases in paperwork, administration and information provision to patients
- There is a strong perception, particularly amongst GPs, that a national programme of FOBT screening will impact significantly on workload in primary care, and that primary care-based activities generated through screening should be adequately resourced.
- The issue of checking of prior-notification lists requires specific attention, as it is a significant component of workload – more information is required on the cost-effectiveness of PNL-checking, and the consequences of inappropriate screening invitations

Secondary Care

- The UK Pilot has generated considerable additional workload for secondary care
- Relevant staff almost universally agree that adequate resourcing (particularly in the area of colonoscopy provision) will be critical to the success of a national programme
- The Pilot has led to increased demand for symptomatic colonoscopy services
- 'Screening doctors' and 'nurse endoscopists' are potential responses to the increased workload from screening
- Discrepancies between colonoscopy waiting times for screening and symptomatic patients are undesirable; ideally, waiting times for symptomatic patients should be reduced to 2 to 4 weeks before commencement of screening
- Our data suggest that at least one additional colonoscopy session for every dedicated screening session might be required in the first five years of a programme, with requirements increasing after that due to a cumulative effect. There will also be a need for additional consultant sessions for dealing with pathology detected at screening colonoscopy
- There will be increases in workload for pathology, radiology, oncology and at least initial increases in the requirement for surgery
- Screening has a potentially positive effect on the quality of delivery of colonoscopy services

A key task of this evaluation has been to determine the impact of FOBt screening on primary and hospital acute services, both directly and indirectly. We have examined the capacity of the health service to respond to the new demands from FOBt screening, in order to make predictions about the level of investment in new service provision which would be required should FOBt screening be rolled out. Information for this section comes from surveys of key personnel involved in the provision of primary and secondary care services, as well as examination of key indices of workload impact such as waiting times for investigation and treatments in the Pilot regions. We present results from our analyses of workload impact on primary and secondary care, then examine the specific issue of follow-up of adenomas detected through FOBt screening.

6.1 Primary care

6.1.1 Aims and Objectives

To evaluate the impact of FOBt screening on workload in primary care, and how primary care might best accommodate FOBt screening.

6.1.2 Methods

The workload impact on General Practice was assessed by the inclusion of questions in the Primary Care Questionnaire (see Report **Supplement S3**) and the Prospective Workload Audit (also in **Supplement S3**). Questionnaires and audit sheets were piloted in Scotland, and then sent firstly to Scottish practices and then to English practices. Feedback was received from primary care reference groups in both England and Scotland.

The questionnaires were sent to a sample of practices in Scotland and England (see **Table 6.1.1**). There were slightly different versions of the questionnaire for GPs, practice nurses, receptionists and practice managers. The questionnaires also differed slightly according to time since recruitment of the practice, with questionnaire 1 being sent to those practices recently involved in the Pilot, and questionnaire 2 being sent to those involved in the Pilot between four months and one year ago at time of sending. The audit relied on prospective documentation of activity by primary care staff, and was conducted in practices as they were recruited to the Pilot.

Selection of GP practices
Lists of practices were obtained from the Pilot sites in both England and Scotland.

Sampling frame for audit
Where possible, **all** prospective practices were invited to take part in the audit. If they were unable to do so, they were invited to take part in the questionnaire survey.

Sampling frame for questionnaire survey
Starting from practices which had most recently taken part in the Pilot, all practices which had been involved (but not included in the audit) were sent retrospective questionnaires, until a total of 30 in England and 30 in Scotland had been sampled. All regions in both countries were sampled.

Selection of staff within GP practices
Within practices, general practitioners (GPs), practice nurses, receptionists and practice managers were all sent questionnaires or audits. To identify sampling frames for both the questionnaire survey and the audit, the practice manager in each practice was contacted by a member of the evaluation team (RJ). Lists of GPs and other staff present during the period of practice involvement were confirmed. Part-time GPs and GP registrars were included, but the practice manager was asked to make a judgement in excluding other staff whose appointments were fractional, or whose level of involvement in Pilot-related activities would, for any reason, be expected to be minimal. No receptionists working less than 0.25 full time equivalent (FTE) were included.

Content of the questionnaires
The questionnaires are divided into eight sections:

1. *Views on workload issues related to colorectal cancer screening*

This section asked questions on whether a national programme would impact substantially on workload in primary care, and respondents' views on remuneration (this section is omitted in the questionnaire for receptionists).

2. The meeting between screening Pilot team and practice
This section asked whether the respondent attended the meeting, how long the meeting lasted, how many staff from the practice attended, impressions of the meeting, and if they would have liked a meeting after screening for feedback.

3. Pre-screening checking of patient lists
This section asked about whether practices devoted time to the task of checking patient lists, which staff groups were involved, how much time the respondent spent on the task, whether they thought it was a useful exercise and any other comments they had.

4. Workload impact
Questions included in this section ask about how often the practice staff were involved in activities relating to the CRC Pilot such as answering telephone enquiries; consultations; discussions with staff; paperwork; queries from the Pilot unit. Questions are also asked on an estimate of the percentage of time that was spent on the above activities, and any other comments on workload impact. For *questionnaire 1* practice staff were asked to think about any extra activities that occurred during what they regarded as the *busiest* week of the Pilot period. For *questionnaire 2*, practice staff were asked to recall the same activities during the *whole* screening period.

5. Nature of the enquiries
Respondents are asked to think of the enquiries they have received since patients became involved in the screening project. They are asked to detail what type of information need they have responded to such as instructions on how to perform the test, advice on whether or not participate, and concern/fear arising from a positive result. This section is not included in the Practice managers' version of the questionnaire.

6. Organisational factors (results in section 7.2)
This section included questions relating to the communication and co-ordination between the practice and the screening centre and endoscopy unit. Respondents were asked about their satisfaction with information provided regarding the screening Pilot, the outcomes of patient's involvement in the initial screening and follow-up investigations, and how well enquiries were dealt with if they rang the Pilot site. Receptionists were not asked these questions, and practice managers and practice nurses were only asked questions relevant to them.

7. Views on colorectal cancer screening in general (results in section 7.2)
This section was for GPs and practice nurses only and asked whether they considered a national programme should be introduced, and whether they thought the screening Pilot was a valuable and positive experience for patients.

8. Demographic details
This section was also for GPs and practice nurses only and asks for details of gender, working hours (full-time or part-time), and number of years since graduation or since they qualified.

Content of the audit forms
Audit sheets were sent to individual GPs and practice managers. Receptionists and practice nurses filled out a collective form or individual ones on request.

The audit was divided into two sections:

1. Nature of the enquiries
Practice staff were asked to note down any enquiries from patients. They were asked to provide details of the date, time, mode of enquiry (e.g. telephone call or consultation) and a brief description of the nature of the enquiry.

2. Other activities arising from the CRC Pilot

Participants in the audit were also asked to give details of any other activities arising from the Pilot such as meetings, organisational activities, discussions with staff and paperwork, queries from the Pilot unit and time spent with patients undergoing further investigations. There was an option to tick a box if they did not receive any enquiries or undertake any other activities. There was also a space where they can provide more general feedback on the Pilot.

Statistical methods
The data were been entered into an Access database, and then analysed using SPSS and SAS statistical packages.

6.1.3 Results

Questionnaire Survey

Table 6.1.2 provides detail about response rates. In summary 67% of GPs, 82% of Practice managers, 69% of Practice nurses and 70% of Practice receptionists responded. A total of 856 questionnaires were returned (347 from Scottish practices, and 509 from English practices). The results which follow are generally presented separately for each staff type.

Impact on workload from FOBt screening

1. Time commitment
Respondents were asked to estimate the time spent on activities relating to the colorectal cancer screening Pilot during the time of their practice's involvement in the Pilot (**Table 6.1.3**).

Most GPs and other staff indicated they spent 2% or less of their time during this period on Pilot-related activities. The proportions of respondents spending 2% or less of time were broadly similar (ranging from 76% to 86%) across all staff categories.

These impressions of impact on personal workload from the Pilot were supplemented with views on the likely impact on workload should FOBt screening be rolled out. Forty percent of GPs thought that a national colorectal cancer screening programme would substantially impact on the workload in primary care, although this proportion was slightly lower amongst practice managers and markedly lower among nurses (**Table 6.1.4**). Amongst GPs, a majority (55%) felt that general practice should be remunerated for this additional workload (**Table 6.1.5**), as did a similar proportion of practice managers.

2. Types of activities
Respondents were asked about their frequency of involvement in various Pilot-related activities (**Tables 6.1.6 to 6.1.12**).

Telephone enquiries (**Table 6.1.6**)
Few respondents were involved "often" or "very often"; 45% to 57% were involved "sometimes".

Enquiries arising during consultations (**Table 6.1.7**)
65% of GPs reported this occurred "sometimes", and 24% "often" (the corresponding values for practice nurses are 57% and 21%).

Extra consultations specifically arising from the Pilot (**Table 6.1.8**)
57% of GPs reported this happened "sometimes", 36% "never" (32% and 67% for practice nurses).

Involvement in discussions with other staff re procedures for the Pilot (**Table 6.1.9**)
63% of GPs reported this happened "sometimes", 26% "never".

Extra paperwork (**Table 6.1.10**)
11% of GPs reported this happened "very often", 33% "often" and 49% "sometimes". Frequencies were generally lower for other staff categories.

Involvement in queries from the Pilot Unit (**Table 6.1.11**)
Most respondents reported either "sometimes" (12%-37%) or "never" (54%- 87%).

Spending time with patients undergoing further investigations (**Table 6.1.12**)
13% of GPs reported "often", 71% "sometimes" and 15% "never" (corresponding values for practice nurses are 5%, 30% and 64%).

*3. Pre-checking of patient lists (**Tables 6.1.13 and 6.1.14**)*
More detailed enquiry was made about pre-checking of patient lists. Respondents were asked to estimate the amount of time spent checking, and whether they thought it was a useful process. The majority of respondents (77% of GPs, 72% overall) spent one hour or less on this process. Between 57% and 81% felt that it was a useful process (63% of GPs). Practice managers were the ones who spent most time on this task and were also the respondents who thought that it was most useful.

4. Nature of enquiries
Tables 6.1.15 to 6.1.21 show the nature of enquiries from patients participating in the CRC Pilot. Amongst GPs, enquiries about whether or not to participate, concerns over positive results and questions about bowel symptoms prompted by the Pilot were the most common type of enquiry. Less common were advice on how to perform the test, confusion over information provided by the Pilot site, questions about the risks and benefits of screening and explanation about subsequent stages in the screening process.

There was a broadly similar pattern for practice nurses, although they were more likely to become involved in discussions over how to perform the test.

5. Meeting between screening Pilot team and practice
Tables 6.1.22 and 6.1.23 summarise responses for items relating to the meeting between the screening Pilot team and the practice.

Table 6.1.23 summarises responses to the item *Would you have liked a meeting after screening was over for feedback?*. Respondents were evenly split over this issue.

6. Free text comments
Additional views on workload were obtained in the free-text sections of the questionnaire for primary care personnel. The questionnaire elicited comments on remuneration if a screening programme was introduced, the workload impact of individuals participating in the Pilot, and views on whether a national programme of FOBt screening should be introduced. A summary of the comments is provided below, and a full text version of these comments has been included in the Report **Supplement S.4.**

The comments were coded by one person, and several themes were identified which are outlined in **Table 7.2.7**. Although the total number of comments on each of these themes was calculated, this number is not necessarily indicative of the relative importance of the issues.

Practice staff were asked for comments on remuneration. The first question they were asked was, 'Do you think that a national programme would impact substantially on workload in primary care?' If they had answered 'Yes', they were then asked if general practices should be remunerated for the additional workload and any comments. Two hundred and thirty nine respondents commented in response to this question (out of a total of 836 respondents), but not all of these were relevant to the question, and are discussed in a later section. All those who specifically commented on the issue of remuneration did think that some remuneration was necessary. For example, a typical comment was *'It is not practical to expect more & more tasks without adequately funding them.'(GP, England)* However, the most common theme to emerge when asked about remuneration was the impact on workload and resources. In particular, practice staff were concerned that they would not have the resources available to cope. For example, one Scottish GP commented, '*It is an issue of workload rather than money. If we do manage this, what do we take out instead?* Another related comment was, *'There is now no spare capacity in primary care - at GP/nurse or administrative staff level.*
All new initiatives must be followed by resource.' (Scottish GP). Several respondents commented on the need for additional staff, such as nurses or clerical staff.

A further question asked people to comment on the workload impact of the pilot, and there were 134 comments. Combined with the comments on workload asked in the previous question, 72 comments related to the small or insignificant impact of the pilot, compared with 29 reporting a significant impact. Comments ranged from, '*Virtually no impact' (Practice Manager, England)* to *'The paperwork generated by the screening pilot was EXCESSIVE - will need to be reduced if ongoing screening*

system'(GP, Scotland). Many of the comments on workload issues related to the increase in administrative tasks such as checking patient list before screening began and filing results. However, some practices reported no increase in administrative tasks, whilst others reported a significant increase. They may be several explanations for the differences in the reporting of additional workload. The pilot was organised differently in England and Scotland, and these organisational differences may have impacted on the workload in general practice. For example, in Scotland, practices were asked to check patient lists before invitations were sent out. In addition, several GPs commented on the workload of other members of the practice (e.g. receptionists), which may not have been an accurate reflection of the actual workload involved.

The other area of additional workload often mentioned was the increase in patient discussions and extra consultations. Several practice staff specifically commented on the additional time involved with patients who were anxious following a test result, and awaiting further tests or results. A typical comment was, '*Main workload was due to anxiety re positive results. (GP, England)*'

Audit

Of 60 practices contacted, 41 agreed to take part in the prospective workload audit. Of these 41 practices, 38 returned completed 'workload impact audit' forms; the total number of returned audit forms was 195. **Table 6.1.24** summarises these 195 returns by: (a) staff type; (b) proportions reporting 'no enquiries' during the audit period; and (c) proportions reporting 'no other activities' during the audit period. **Table 6.1.25** shows the distributions of (a) the number of individual enquiries reported among the 195 returned forms; and (b) the number of individual 'other activities' reported. From this, it appears that 69% of returned audit forms reported no enquiries related to the CRC Screening Pilot, and 86% of forms reported no other activities. The total number of reported enquiries was 111, and the total number of other activities was 65.

The average duration of enquiries was 4.2 minutes (standard deviation: 3.7 minutes, range 0.5 minutes to 20 minutes). The mean length of other activities was 7.6 minutes (standard deviation: 11.3 minutes, range 0.3 minutes to 60 minutes).

Categories of enquiry recorded are summarised in **Table 6.1.26**; categories of other activities are shown in **Table 6.1.27**.

6.1.4 Discussion

Based on data available so far, FOBt screening would appear to have a modest yet discernible impact on workload in primary care. While primary care has not been responsible for recruitment and delivery of screening in the UK CRC Screening Pilot, it has generated extra work, mainly in the form of responding to information needs of invitees. Many primary care personnel, particularly GPs, hold strong views about the capacity of primary care to accommodate a further form of cancer screening without additional dedicated resources. The specific issue of PNL checking is of particular interest – clearly this imposes a significant burden on some practices, while others do not find it troublesome. This is likely to partly reflect the relative effort different practices invest in this process.

Table 6.1.1 Sampling period and sample size for questionnaires and audit

	Sampling period	Sampling frame	Sample to date
Retrospective questionnaire (1)	Not less than six weeks after the practice had been sent the last initial invitations and no more than four months after the practice had been sent the last of the invitations.	30 practices in Scotland and 30 practices in England	31 practices in Scotland and 29 practices in England
Retrospective questionnaire (2)	Not less than four months after the practice had been sent the last initial invitations and no more than 12 months after the practice had been sent the last of the invitations.	30 practices in Scotland and 30 practices in England	28 practices in Scotland and 31 practices in England
Audit	No less than one week, and no more than 2 weeks after the last of the initial invitations have been sent out	30 practices in Scotland and 30 practices in England	30 practices in Scotland and 11 practices in England

Table 6.1.2 Response rates, by country and type of practice staff

staff function	questionnaires sent	questionnaires returned	% returned
SCOTLAND[1]			
GP	255	192	75.3
Practice Manager[2]	56	43	76.8
Practice Nurse	81	55	67.9
Receptionist	87	57	65.5
ALL STAFF FUNCTIONS	479	347	72.4
ENGLAND			
GP	235	137	58.3
Practice Manager[2]	59	51	86.4
Practice Nurse	130	91	70.0
Receptionist	323	230	71.2
ALL STAFF FUNCTIONS	747	509	68.1
ALL AREAS			
GP	492	329	66.9
Practice Manager[2]	115	94	81.7
Practice Nurse	211	146	69.2
Receptionist	410	287	70.0
ALL STAFF FUNCTIONS	1,228	856	69.7

NOTE 1: Country is not recorded for two GPs.
NOTE 2: Not all practices employ a practice manager.

Table 6.1.3 Percentage of time spent on activities relating to screening pilot

	staff function: number (%)				
SCOTLAND					
percentage of time	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
0-1	61 (34.1)	19 (48.7)	27 (67.5)	23 (51.1)	130 (42.9)
1-2	77 (43.0)	13 (33.3)	10 (25.0)	13 (28.9)	113 (37.3)
2-5	29 (16.2)	3 (7.7)	2 (5.0)	4 (8.9)	38 (12.5)
5-10	2 (1.1)	4 (10.3)	0 (0.0)	2 (4.4)	8 (2.6)
10-20	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	2 (0.7)
>20	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
not applicable	9 (5.0)	0 (0.0)	1 (2.5)	1 (2.2)	11 (3.6)
ENGLAND					
0-1	52 (43.3)	13 (54.2)	40 (58.8)	72 (69.2)	177 (56.0)
1-2	46 (38.3)	3 (12.5)	16 (23.5)	11 (10.6)	76 (24.1)
2-5	19 (15.8)	7 (29.2)	8 (11.8)	10 (9.6)	44 (13.9)
5-10	1 (0.8)	1 (4.2)	3 (4.4)	7 (6.7)	12 (3.8)
10-20	1 (0.8)	0 (0.0)	1 (1.5)	3 (2.9)	5 (1.6)
>20	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.0)	2 (0.6)
not applicable	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ALL AREAS					
0-1	113 (37.8)	32 (50.8)	67 (62.0)	95 (63.8)	307 (49.6)
1-2	123 (41.1)	16 (25.4)	26 (24.1)	24 (16.1)	189 (30.5)
2-5	48 (16.1)	10 (15.9)	10 (9.3)	14 (9.4)	82 (13.2)
5-10	3 (1.0)	5 (7.9)	3 (2.8)	9 (6.0)	20 (3.2)
10-20	1 (0.3)	0 (0.0)	1 (0.9)	5 (3.4)	7 (1.1)
>20	2 (0.7)	0 (0.0)	0 (0.0)	1 (0.7)	3 (0.5)
not applicable	9 (3.0)	0 (0.0)	1 (0.9)	1 (0.7)	11 (1.8)

Table 6.1.4 Do you think a national programme would substantially impact on workload in primary care?

	staff function: number (%)			
SCOTLAND				
response	**GP**	**Practice manager**	**Practice nurse**	**ALL**
Yes	88 (47.1)	19 (46.3)	14 (34.2)	121 (45.0)
No	75 (40.1)	14 (34.2)	22 (53.7)	111 (41.3)
Not sure	24 (12.8)	8 (19.5)	5 (12.2)	37 (13.8)
ENGLAND				
Yes	40 (30.8)	15 (31.3)	15 (19.5)	70 (27.5)
No	73 (56.2)	25 (52.1)	44 (57.1)	142 (55.7)
Not sure	17 (13.1)	8 (16.7)	18 (23.4)	43 (16.9)
ALL AREAS				
Yes	128 (40.4)	34 (38.2)	29 (24.6)	191 (36.5)
No	148 (46.7)	39 (43.8)	66 (55.9)	253 (48.3)
Not sure	41 (12.9)	16 (18.0)	23 (19.5)	80 (15.3)

Table 6.1.5 Do you think that general practice should be remunerated?

	staff function: number (%)			
SCOTLAND				
response	**GP**	**Practice manager**	**Practice nurse**	**ALL**
Yes	92 (53.8)	19 (57.6)	14 (37.8)	125 (51.9)
No	4 (2.3)	1 (3.0)	0 (0.0)	5 (2.1)
Not sure	9 (5.3)	2 (6.1)	2 (5.4)	13 (5.4)
Not applicable	66 (38.6)	11 (33.3)	21 (56.8)	98 (40.7)
ENGLAND				
Yes	58 (57.4)	21 (53.9)	22 (40.0)	101 (51.8)
No	6 (5.9)	2 (5.1)	5 (9.1)	13 (6.7)
Not sure	6 (5.9)	3 (7.7)	7 (12.7)	16 (8.2)
Not applicable	31 (30.7)	13 (33.3)	21 (38.2)	65 (33.3)
ALL AREAS				
Yes	150 (55.2)	40 (55.6)	36 (39.1)	226 (51.8)
No	10 (3.7)	3 (4.2)	5 (5.4)	18 (4.1)
Not sure	15 (5.5)	5 (6.9)	9 (9.8)	29 (6.7)
Not applicable	97 (35.7)	24 (33.3)	42 (45.7)	163 (37.4)

Table 6.1.6 Involvement in telephone enquiries

	staff function: number (%)				
SCOTLAND					
frequency of involvement	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
Often	25 (13.4)	1 (2.5)	7 (17.5)	7 (14.3)	40 (12.7)
Sometimes	115 (61.8)	22 (55.0)	15 (37.5)	23 (46.9)	175 (55.6)
Never	42 (22.6)	17 (42.5)	18 (45.0)	19 (38.8)	96 (30.5)
Not applicable	3 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.0)
ENGLAND					
Very often	3 (2.4)	0 (0.0)	1 (1.3)	4 (3.0)	8 (2.2)
Often	14 (11.1)	3 (11.5)	8 (10.5)	6 (4.6)	31 (8.6)
Sometimes	64 (50.8)	12 (46.2)	37 (48.7)	61 (46.2)	174 (48.3)
Never	45 (35.7)	11 (42.3)	30 (39.5)	61 (46.2)	147 (40.8)
Not applicable	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ALL AREAS					
Very often	4 (1.3)	0 (0.0)	1 (0.9)	4 (2.2)	9 (1.3)
Often	39 (12.5)	4 (6.1)	15 (12.9)	13 (7.2)	71 (10.5)
Sometimes	179 (57.4)	34 (51.5)	52 (44.8)	84 (46.4)	349 (51.7)
Never	87 (27.9)	28 (42.4)	48 (41.4)	80 (44.2)	243 (36.0)
Not applicable	3 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.4)

Table 6.1.7 Involvement in enquiries during consultations

	staff function: number (%)				
SCOTLAND					
frequency of involvement	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	9 (4.9)	**	0 (0.0)	**	9 (4.0)
Often	44 (23.8)	**	10 (25.0)	**	54 (24.0)
Sometimes	120 (64.9)	**	23 (57.5)	**	143 (63.6)
Never	11 (6.0)	**	7 (17.5)	**	18 (8.0)
Not applicable	1 (0.5)	**	0 (0.0)	**	1 (0.4)
ENGLAND					
Very often	5 (4.0)	**	5 (6.6)	**	10 (5.0)
Often	29 (23.2)	**	14 (18.4)	**	43 (21.4)
Sometimes	81 (64.8)	**	43 (56.6)	**	124 (61.7)
Never	10 (8.0)	**	14 (18.4)	**	24 (11.9)
Not applicable	0 (0.0)	**	0 (0.0)	**	0 (0.0)
ALL AREAS					
Very often	14 (4.5)	**	5 (4.3)	**	19 (4.5)
Often	73 (23.6)	**	24 (20.7)	**	97 (22.8)
Sometimes	201 (64.8)	**	66 (56.9)	**	267 (62.7)
Never	21 (6.8)	**	21 (18.1)	**	42 (9.9)
Not applicable	1 (0.3)	**	0 (0.0)	**	1 (0.2)

Table 6.1.8 Involvement in consultations specifically relating to the crc pilot

	staff function: number (%)				
SCOTLAND					
frequency of involvement	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	2 (1.1)	**	0 (0.0)	**	2 (0.9)
Often	13 (7.0)	**	0 (0.0)	**	13 (5.8)
Sometimes	103 (55.7)	**	13 (33.3)	**	116 (51.8)
Never	66 (35.7)	**	26 (66.7)	**	92 (41.1)
Not applicable	1 (0.5)	**	0 (0.0)	**	1 (0.5)
ENGLAND					
Very often	1 (0.8)	**	0 (0.0)	**	1 (0.5)
Often	5 (4.1)	**	1 (1.4)	**	6 (3.1)
Sometimes	72 (59.5)	**	23 (31.9)	**	95 (49.2)
Never	43 (35.5)	**	48 (66.7)	**	91 (47.2)
Not applicable	0 (0.0)	**	0 (0.0)	**	0 (0.0)
ALL AREAS					
Very often	3 (1.0)	**	0 (0.0)	**	3 (0.7)
Often	18 (5.9)	**	1 (0.9)	**	19 (4.6)
Sometimes	175 (57.2)	**	36 (32.4)	**	211 (50.6)
Never	109 (35.6)	**	74 (66.7)	**	183 (43.9)
Not applicable	1 (0.3)	**	0 (0.0)	**	1 (0.2)

Table 6.1.9 Involvement in discussions with other staff about pilot-related issues

	staff function: number (%)				
SCOTLAND					
frequency of involvement	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.7)
Often	14 (7.8)	6 (15.8)	3 (7.9)	3 (7.0)	26 (8.7)
Sometimes	121 (67.2)	30 (79.0)	17 (44.7)	23 (53.5)	191 (63.9)
Never	43 (23.9)	2 (5.3)	17 (44.7)	17 (39.5)	79 (26.4)
Not applicable	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (0.3)
ENGLAND					
Very often	1 (0.8)	1 (4.4)	1 (1.4)	0 (0.0)	3 (0.9)
Often	15 (12.2)	5 (21.7)	4 (5.7)	6 (5.5)	30 (9.2)
Sometimes	71 (57.7)	11 (47.8)	35 (50.0)	51 (46.8)	168 (51.7)
Never	36 (29.3)	6 (26.1)	30 (42.9)	52 (47.7)	124 (38.2)
Not applicable	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ALL AREAS					
Very often	3 (1.0)	1 (1.6)	1 (0.9)	0 (0.0)	5 (0.8)
Often	29 (9.6)	11 (18.0)	7 (6.5)	9 (5.9)	56 (9.0)
Sometimes	192 (63.4)	41 (67.2)	52 (48.2)	74 (48.7)	359 (57.5)
Never	79 (26.1)	8 (13.1)	47 (43.5)	69 (45.4)	203 (32.5)
Not applicable	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.2)

Table 6.1.10 Involvement in pilot-related paperwork

	staff function: number (%)				
SCOTLAND					
frequency of involvement	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	30 (16.4)	1 (2.6)	1 (2.6)	0 (0.0)	32 (10.4)
Often	72 (39.3)	6 (15.4)	1 (2.6)	20 (42.6)	99 (32.1)
Sometimes	74 (40.4)	19 (48.7)	8 (20.5)	19 (40.4)	120 (39.0)
Never	7 (3.8)	13 (33.3)	28 (71.8)	8 (17.0)	56 (18.2)
Not applicable	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (0.3)
ENGLAND					
Very often	5 (4.0)	3 (11.1)	0 (0.0)	4 (3.7)	12 (3.6)
Often	30 (24.0)	8 (29.6)	3 (4.2)	10 (9.2)	51 (15.3)
Sometimes	76 (60.8)	11 (40.7)	13 (18.1)	33 (30.3)	133 (39.9)
Never	14 (11.2)	5 (18.5)	56 (77.8)	60 (55.1)	135 (40.5)
Not applicable	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (0.6)
ALL AREAS					
Very often	35 (11.4)	4 (6.1)	1 (0.9)	4 (2.6)	44 (6.9)
Often	102 (33.1)	14 (21.2)	4 (3.6)	30 (19.2)	150 (23.4)
Sometimes	150 (48.7)	30 (45.5)	21 (18.9)	52 (33.3)	253 (39.5)
Never	21 (6.8)	18 (27.3)	84 (75.7)	68 (43.6)	191 (29.8)
Not applicable	0 (0.0)	0 (0.0)	1 (0.9)	2 (1.3)	3 (0.5)

Table 6.1.11 Involvement in queries from the pilot centre

	staff function: number (%)				
SCOTLAND					
frequency of involvement	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	1 (0.6)	1 (2.6)	0 (0.0)	0 (0.0)	2 (0.7)
Often	4 (2.2)	1 (2.6)	0 (0.0)	1 (2.4)	6 (2.0)
Sometimes	63 (35.2)	15 (38.5)	4 (10.3)	17 (40.5)	99 (33.1)
Never	111 (62.0)	22 (56.4)	34 (87.2)	24 (57.1)	191 (63.9)
Not applicable	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (0.3)
ENGLAND					
Very often	0 (0.0)	3 (11.5)	0 (0.0)	2 (1.9)	5 (1.5)
Often	5 (4.1)	1 (3.9)	0 (0.0)	6 (5.6)	12 (3.7)
Sometimes	33 (27.1)	9 (34.6)	9 (12.7)	34 (31.5)	85 (26.0)
Never	83 (68.0)	13 (50.0)	62 (87.3)	65 (60.2)	223 (68.2)
Not applicable	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.9)	2 (0.6)
ALL AREAS					
Very often	1 (0.3)	4 (6.2)	0 (0.0)	2 (1.3)	7 (1.1)
Often	9 (3.0)	2 (3.1)	0 (0.0)	7 (4.7)	18 (2.9)
Sometimes	96 (31.9)	24 (36.9)	13 (11.8)	51 (34.0)	184 (29.4)
Never	194 (64.5)	35 (53.9)	96 (87.3)	89 (59.3)	414 (66.1)
Not applicable	1 (0.3)	0 (0.0)	1 (0.9)	1 (0.7)	3 (0.5)

Table 6.1.12 Involvement in spending time with patients undergoing further investigations

	staff function: number (%)				
SCOTLAND					
frequency of involvement	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	2 (1.1)	**	0 (0.0)	**	2 (0.9)
Often	24 (13.2)	**	2 (5.1)	**	26 (11.8)
Sometimes	135 (74.2)	**	15 (38.5)	**	150 (67.9)
Never	21 (11.5)	**	21 (53.9)	**	42 (19.0)
Not applicable	0 (0.0)	**	1 (2.6)	**	1 (0.5)
ENGLAND					
Very often	1 (0.8)	**	1 (1.4)	**	2 (1.0)
Often	17 (13.8)	**	3 (4.2)	**	20 (10.3)
Sometimes	80 (65.0)	**	18 (25.4)	**	98 (50.5)
Never	24 (19.5)	**	49 (69.0)	**	73 (37.6)
Not applicable	1 (0.8)	**	0 (0.0)	**	1 (0.5)
ALL AREAS					
Very often	3 (1.0)	**	1 (0.9)	**	4 (1.0)
Often	41 (13.4)	**	5 (4.6)	**	46 (11.1)
Sometimes	215 (70.5)	**	33 (30.0)	**	248 (59.8)
Never	45 (14.8)	**	70 (63.6)	**	115 (27.7)
Not applicable	1 (0.3)	**	1 (0.9)	**	2 (0.5)

Table 6.1.13 Estimate of time spent on checking patient lists

	staff function: number (%)				
SCOTLAND					
time estimate	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
0-15 mins	36 (24.0)	7 (18.4)	18 (72.0)	16 (40.0)	77 (30.4)
15-30 mins	43 (28.7)	7 (18.4)	1 (4.0)	5 (12.5)	56 (22.1)
30-60 mins	34 (22.7)	6 (15.8)	1 (4.0)	3 (7.5)	44 (17.4)
1-2 hours	16 (10.7)	7 (18.4)	1 (4.0)	2 (5.0)	26 (10.3)
> 2 hours	2 (1.3)	9 (23.7)	1 (4.0)	3 (7.5)	15 (5.9)
don't know	11 (7.3)	2 (5.3)	3 (12.0)	11 (27.5)	27 (10.7)
not applicable	8 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	8 (3.2)
ENGLAND					
0-15 mins	38 (40.4)	5 (14.3)	23 (57.5)	38 (60.3)	104 (44.8)
15-30 mins	23 (24.5)	6 (17.1)	2 (5.0)	7 (11.1)	38 (16.4)
30-60 mins	14 (14.9)	9 (25.7)	2 (5.0)	4 (6.4)	29 (12.5)
1-2 hours	6 (6.4)	6 (17.1)	4 (10.0)	2 (3.2)	18 (7.8)
> 2 hours	6 (6.4)	6 (17.1)	2 (5.0)	1 (1.6)	15 (6.5)
don't know	7 (7.5)	3 (8.6)	6 (15.0)	10 (15.9)	26 (11.2)
not applicable	0 (0.0)	0 (0.0)	1 (2.5)	1 (1.6)	2 (0.9)
ALL AREAS					
0-15 mins	74 (30.3)	12 (16.4)	41 (63.1)	54 (52.4)	181 (37.3)
15-30 mins	66 (27.0)	13 (17.8)	3 (4.6)	12 (11.7)	94 (19.4)
30-60 mins	48 (19.7)	15 (20.5)	3 (4.6)	7 (6.8)	73 (15.1)
1-2 hours	22 (9.0)	13 (17.8)	5 (7.7)	4 (3.9)	44 (9.1)
> 2 hours	8 (3.3)	15 (20.5)	3 (4.2)	4 (3.9)	30 (6.2)
don't know	18 (7.4)	5 (6.8)	9 (13.8)	21 (20.4)	53 (10.9)
not applicable	8 (3.3)	0 (0.0)	1 (1.5)	1 (1.0)	10 (2.1)

Table 6.1.14 Do you think that checking of PNL lists was a useful process?

	staff function: number (%)				
SCOTLAND					
response	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Yes	89 (63.6)	27 (71.1)	13 (52.0)	26 (61.9)	155 (63.3)
Don't know	36 (25.7)	9 (23.7)	10 (40.0)	15 (35.7)	70 (28.6)
No	15 (10.7)	2 (5.3)	0 (0.0)	1 (2.4)	18 (7.4)
Not applicable	0 (0.0)	0 (0.0)	2 (8.0)	0 (0.0)	2 (0.8)
ENGLAND					
Yes	56 (61.5)	31 (91.2)	22 (62.9)	38 (53.5)	147 (63.6)
Don't know	28 (30.8)	3 (8.8)	12 (34.3)	30 (42.3)	73 (31.6)
No	7 (7.7)	0 (0.0)	0 (0.0)	3 (4.2)	10 (4.3)
Not applicable	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (0.4)
ALL AREAS					
Yes	145 (62.8)	58 (80.6)	35 (58.3)	64 (56.6)	302 (63.4)
Don't know	64 (27.7)	12 (16.7)	22 (36.7)	45 (39.8)	143 (30.0)
No	22 (9.5)	2 (2.8)	0 (0.0)	4 (3.5)	28 (5.9)
Not applicable	0 (0.0)	0 (0.0)	3 (5.0)	0 (0.0)	3 (0.6)

WHICH OF THE FOLLOWING INFORMATION NEEDS DID YOU RESPOND TO? (Tables 6.1.15 – 6.1.21)

Table 6.1.15 Instructions on how to perform the test

	staff function: number (%)				
SCOTLAND					
frequency of enquiry	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	0 (0.0)	**	1 (4.4)	0 (0.0)	1 (1.0)
Often	6 (9.7)	**	6 (26.1)	1 (9.1)	13 (13.5)
Sometimes	56 (90.3)	**	16 (69.6)	10 (90.9)	82 (85.4)
ENGLAND					
Very often	2 (4.4)	**	3 (6.0)	3 (9.7)	8 (6.3)
Often	9 (19.6)	**	12 (24.0)	3 (9.7)	24 (18.9)
Sometimes	35 (76.1)	**	35 (70.0)	25 (80.7)	95 (74.8)
ALL AREAS					
Very often	2 (1.9)	**	4 (5.5)	3 (7.1)	9 (4.0)
Often	15 (13.9)	**	18 (24.7)	4 (9.5)	37 (16.6)
Sometimes	91 (84.3)	**	51 (69.9)	35 (83.3)	177 (79.4)

Table 6.1.16 Confusion over information provided by the pilot site

	staff function: number (%)				
SCOTLAND					
frequency of enquiry	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	1 (2.1)	**	0 (0.0)	0 (0.0)	1 (1.6)
Often	2 (4.2)	**	0 (0.0)	0 (0.0)	2 (3.2)
Sometimes	45 (93.8)	**	8 (100.0)	7 (100.0)	60 (95.2)
ENGLAND					
Very often	2 (5.9)	**	3 (15.8)	1 (7.7)	6 (9.1)
Often	7 (20.6)	**	2 (10.5)	2 (15.4)	11 (16.7)
Sometimes	25 (73.5)	**	14 (73.7)	10 (76.9)	49 (74.2)
ALL AREAS					
Very often	3 (3.7)	**	3 (11.1)	1 (5.0)	7 (5.4)
Often	9 (11.0)	**	2 (7.4)	2 (10.0)	13 (10.1)
Sometimes	70 (85.4)	**	22 (81.5)	17 (85.0)	109 (84.5)

Table 6.1.17 Advice on whether or not to participate

	staff function: number (%)				
SCOTLAND					
frequency of enquiry	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	8 (5.6)	**	2 (7.4)	0 (0.0)	10 (5.5)
Often	30 (21.1)	**	8 (29.6)	3 (23.1)	41 (22.5)
Sometimes	104 (73.2)	**	17 (63.0)	10 (76.9)	131 (72.0)
ENGLAND					
Very often	6 (6.3)	**	4 (7.6)	2 (5.6)	12 (6.5)
Often	21 (22.1)	**	11 (20.8)	6 (16.7)	38 (20.7)
Sometimes	68 (71.6)	**	38 (71.7)	28 (77.8)	134 (72.8)
ALL AREAS					
Very often	14 (5.9)	**	6 (7.5)	2 (4.1)	22 (6.0)
Often	51 (21.5)	**	19 (23.8)	9 (18.4)	79 (21.6)
Sometimes	172 (72.6)	**	55 (68.8)	38 (77.6)	265 (72.4)

Table 6.1.18 Concern/fear arising from positive results

	staff function: number (%)				
SCOTLAND					
frequency of enquiry	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	9 (6.3)	**	1 (5.6)	0 (0.0)	10 (5.9)
Often	38 (26.8)	**	6 (33.3)	0 (0.0)	44 (26.0)
Sometimes	95 (66.9)	**	11 (61.1)	9 (100.0)	115 (68.1)
ENGLAND					
Very often	6 (6.3)	**	2 (6.3)	1 (4.0)	9 (5.9)
Often	17 (17.9)	**	5 (15.6)	4 (16.0)	26 (17.1)
Sometimes	72 (75.8)	**	25 (78.1)	20 (80.0)	117 (77.0)
ALL AREAS					
Very often	15 (6.3)	**	3 (6.0)	1 (2.9)	19 (5.9)
Often	55 (23.2)	**	11 (22.0)	4 (11.8)	70 (21.8)
Sometimes	167 (70.5)	**	36 (72.0)	29 (85.3)	232 (72.3)

Table 6.1.19 Questions about bowel symptoms

	staff function: number (%)				
SCOTLAND					
frequency of enquiry	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	4 (4.7)	**	1 (9.1)	0 (0.0)	5 (5.0)
Often	23 (26.7)	**	2 (18.2)	0 (0.0)	25 (24.8)
Sometimes	59 (68.6)	**	8 (72.7)	4 (100.0)	71 (70.3)
ENGLAND					
Very often	3 (4.7)	**	3 (10.3)	2 (10.0)	8 (7.1)
Often	12 (18.8)	**	8 (27.6)	1 (5.0)	21 (18.6)
Sometimes	49 (76.6)	**	18 (62.1)	17 (85.0)	84 (74.3)
ALL AREAS					
Very often	7 (4.7)	**	4 (10.0)	2 (8.3)	13 (6.1)
Often	35 (23.3)	**	10 (25.0)	1 (4.2)	46 (21.5)
Sometimes	108 (72.0)	**	26 (65.0)	21 (87.5)	155 (72.4)

Table 6.1.20 Questions about the risks and benefits of screening

	staff function: number (%)				
SCOTLAND					
frequency of enquiry	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	2 (2.2)	**	0 (0.0)	0 (0.0)	2 (1.7)
Often	14 (15.4)	**	8 (40.0)	0 (0.0)	22 (19.0)
Sometimes	75 (82.4)	**	12 (60.0)	5 (100.0)	92 (79.3)
ENGLAND					
Very often	1 (2.1)	**	0 (0.0)	3 (15.0)	4 (4.0)
Often	8 (17.0)	**	8 (25.0)	2 (10.0)	18 (18.2)
Sometimes	38 (80.9)	**	24 (75.0)	15 (75.0)	77 (77.8)
ALL AREAS					
Very often	3 (2.2)	**	0 (0.0)	3 (12.0)	6 (2.8)
Often	22 (15.9)	**	16 (30.8)	2 (8.0)	40 (18.6)
Sometimes	113 (81.9)	**	36 (69.2)	20 (80.0)	169 (78.6)

Table 6.1.21 Explanation about the next stage

	staff function: number (%)				
SCOTLAND					
frequency of enquiry	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very often	5 (3.9)	**	1 (9.1)	0 (0.0)	6 (4.2)
Often	27 (21.3)	**	2 (18.2)	0 (0.0)	29 (20.3)
Sometimes	95 (74.8)	**	8 (72.7)	5 (100.0)	108 (75.5)
ENGLAND					
Very often	1 (1.2)	**	0 (0.0)	1 (9.1)	2 (1.7)
Often	17 (20.2)	**	2 (7.7)	2 (18.2)	21 (17.4)
Sometimes	66 (78.6)	**	24 (92.3)	8 (72.7)	98 (81.0)
ALL AREAS					
Very often	6 (2.8)	**	1 (2.7)	1 (6.3)	8 (3.0)
Often	44 (20.9)	**	4 (10.8)	2 (12.5)	50 (18.9)
Sometimes	161 (76.3)	**	32 (86.5)	13 (81.3)	206 (78.0)

MEETING BETWEEN SCREENING PILOT TEAM AND PRACTICE (Tables 6.1.22 – 6.1.23)

Table 6.1.22 Attendance at the meeting between the screening pilot team and the practice

	number (%) replying		
staff function	**YES**	**NO**	**NOT APPLICABLE**
GP	148 (48.5)	154 (50.5)	3 (1.0)
Practice Manager	70 (78.7)	19 (21.3)	0 (0.0)
Practice Nurse	42 (35.9)	75 (64.1)	0 (0.0)
Receptionist	36 (16.4)	183 (83.6)	0 (0.0)
ALL	296 (40.5)	431 (59.0)	3 (0.4)

Table 6.1.23 Preference for a feedback meeting after screening was over

	number (%) replying		
staff function	**YES**	**NO**	**NOT APPLICABLE**
GP	147 (51.6)	129 (45.3)	9 (3.2)
Practice Manager	43 (51.8)	40 (48.2)	0 (0.0)
Practice Nurse	83 (79.0)	22 (21.0)	0 (0.0)
Receptionist	56 (32.6)	114 (66.3)	2 (1.2)
ALL	329 (51.0)	305 (47.3)	11 (1.7)

AUDIT

Table 6.1.24 Audit forms: numbers returned and proportions reporting 'no enquiries' and / or 'no other activities' during the audit period.

staff function	number of forms returned (% of total)	proportion reporting no enquiries	proportion reporting no other activities
GP	87 (44.6)	33.3%	39.1%
Practice Manager	29 (14.9)	62.1%	34.5%
Practice Nurse	34 (17.4)	29.4%	41.2%
Receptionist	45 (23.1)	37.8%	33.3%
ALL	195 (100.0)	37.9%	37.4%

Table 6.1.25 Audit forms: distribution of numbers of enquiries reported and numbers of other activities reported.

number of enquiries reported	number (%) of respondents	number of other activities reported	number (%) of respondents
0	134 (68.7)	0	167 (85.6)
1	31 (15.9)	1	14 (7.2)
2	16 (8.2)	2	6 (3.1)
3	9 (4.6)	3	4 (2.1)
4	4 (2.1)	4	2 (1.0)
5	1 (0.5)	5	1 (0.5)
..	..	..	..
..	..	..	..
..	..	14	1 (0.5)

Table 6.1.26 Audit forms: categories of enquiries reported.

category of enquiry	number (%) of enquiries
telephone enquiry	14 (12.6)
enquiry during normal consultation	76 (68.5)
enquiry during consultation specifically related to CRC Pilot	6 (5.4)
other	11 (9.9)
unknown	4 (3.6)

Table 6.1.27 Audit forms: categories of other activities reported.

category of other activity	number (%) of other activities
meetings	4 (6.2)
organisational activities	2 (3.1)
discussions with other members of staff, paperwork	22 (33.8)
queries from Pilot unit	3 (4.6)
time spent with patient undergoing investigation	1 (1.5)
other	25 (38.5)
unknown	8 (12.3)

6.2 Hospital services

6.2.1 Aims

To assess the impact of the Pilot on provision of secondary care diagnostic and treatment services

6.2.2 Methods

Two principal methodologies were used to assess the impact of the CRC Screening Pilot on hospital services. Routine data were collected from each of the Scottish and English hospitals involved in the Pilot for the two year period prior to the start of the Pilot and subsequently. (In Scotland: Ninewells Hospital in Tayside, the Victoria Hospital in Fife and Aberdeen Royal Infirmary and Dr Gray's Hospital in Grampian (**Table 6.2.1**): in England: Walsgrave Hospital in Coventry, Warwick Hospital in South Warwickshire, and George Eliot Hospital in Nuneaton). Wherever possible, data on activity levels and waiting times were collected for colonoscopy, DCBE and outpatient (medical and surgical) services. These routine data were supplemented by a survey of hospital consultants (gastroenterologists, surgeons and radiologists). This was conducted by semi-structured interviews in Scotland and by a postal questionnaire survey in Warwickshire. The response rate of consultant staff was greater than 60%.

Given the generally poor quality of the quantitative data which it proved possible to collect, together with the multiple influences on activity and waiting times and resultant difficulties in interpreting the data, it was not thought appropriate (or possible) to quantify every aspect of the impact of the Pilot on hospital services. Where figures *are* given, these relate to estimated changes in workload at each of the hospitals which resulted from the screening of all eligible people within Tayside, Fife and Grampian, and Coventry and Warwickshire, during the period of the Pilot. The absolute increase in workload for any given hospital will vary according to a variety of parameters, including the population it serves, the rate at which invites are sent out (determined in part by the screening interval), screening uptake and positivity rates. Ultimately, the most important determinant of workload in hospitals is likely to be the number of colonoscopies done per month, since this is the major influence on other aspects of workload.

6.2.3 Results

Colonoscopy

1) Rate of screening

Scotland

Screening of the total population of 50 to 69 year olds in the Scottish Pilot site using FOB kits started in April 2000. The rate at which people were invited for screening (200 invites per day, 5 days per week) was based on that estimated to result in 10 colonoscopies per week for Ninewells Hospital, Tayside, 10 per week for the Victoria Hospital, Fife and 15 per week for Grampian (approximately 12 at Aberdeen Royal Infirmary and 3 at Dr Gray's Hospital, Elgin; **Table 6.2.2**). In practice, an average of around 8 Pilot colonoscopies per week have been performed in each Health Board area to date.

Despite provision of additional funding to run colonoscopy sessions exclusively for the Pilot, hospitals were unable to maintain waiting times for Pilot colonoscopies between the requisite 2 to 4 weeks, due to the high level of pressure already experienced by the service. In all Health Board areas except for Tayside, initial invitations for screening were suspended for various periods of time during the first 18 months of the Pilot (5 weeks and then 3 months in Fife, 6 months for Aberdeen Royal Infirmary and 9 months for Dr Gray's Hospital, Elgin), in order to return Pilot colonoscopy waiting times to an acceptable level.

England

In the English Pilot site, screening of 50 to 69 year olds using the FOBt kit commenced in September 2000. Invitations to screening were sent out 5 days a week at the following rates per day - Coventry and Warwick, 200; South Warwickshire 140; North Warwickshire, 100.

It was estimated that this rate would generate 11 colonoscopies per week for Walsgrave Hospital, 6 per week for Warwick Hospital, and 5 per week for George Eliot Hospital.

As in Scotland, invitation to screening was suspended in all areas on occasion, due to pressure on endoscopy services. (The initial screening timetable was based on colonoscopy clinics taking place 48 weeks of the year: in practice, because screening colonoscopy lists were mainly held on Mondays, endoscopists were only available an average of 42 weeks per year). Screening invites were suspended once in Coventry and Warwick for 8 weeks, once at the George Eliot for 8 weeks, and twice in South Warwick - first for 18 weeks, and subsequently for a 3 week period.

2) Activity levels (Figures 6.2.1 – 6.2.7)
At all seven hospitals, colonoscopy activity levels rose substantially as a result of the Pilot. Workload increased by up to 80% during some months. In addition to the expected increase from Pilot colonoscopies, the number of colonoscopies for 'symptomatic' (non-Pilot) patients also increased, although the extent to which this occurred varied between hospitals.

3) Waiting times (Figures 6.2.8 – 6.2.10)
At Ninewells, waiting times for symptomatic patients were substantially higher than for Pilot patients. In addition, waiting times for symptomatic patients increased with the start of the Pilot. In Grampian, waiting times for colonoscopy also increased slightly with the introduction of the Pilot, and there was again a wide disparity between waiting times for symptomatic and Pilot patients (varying in direction over time). In neither area is data available to distinguish between waiting times for urgent and routine colonoscopies.

Data on waiting times from English Pilot site hospitals was incomplete and is therefore not presented in this report. Where information was available, similar trends to those seen in the Scottish hospitals was observed, i.e. an increase in waiting times for symptomatic patients following the introduction of the Pilot.

4) Qualitative data
Demand for colonoscopy services (**Table6.2 3**)
Seven out of the twelve consultant staff surveyed on this issue noted an increase in the demand for colonoscopy services for symptomatic patients since the start of the Pilot. This was confirmed by the activity data collected from the Scottish Pilot sites. The following were felt to be reasons for the increase in demand for colonoscopy for symptomatic patients;

- increased awareness about bowel cancer and its symptoms, leading to increased referrals for colonoscopy in symptomatic, anxious and high risk (eg. those with a positive family history) members of the general population. This was reported by some, but not all, consultants, as an important influence on changes in activity levels. However, those who felt that it may *not* have influenced activity mentioned that publicity for the Pilot was fairly restricted and that it may become more important following greater publicity surrounding a national screening programme.
- change in threshold for performing colonoscopy, especially as expectations amongst patients and GPs increase and colonoscopists become more experienced. In one hospital, the consultant was explicit that investigations previously done by barium enema (for example for the investigation of iron deficiency anaemia) were now being performed using colonoscopy.

In addition, the following were identified as sources of increased colonoscopy activity with CRC screening in the longer term;

- colonoscopy for review of patients with adenomas. In addition to colonoscopy for FOB positive subjects, colonoscopy is used for the review of screened patients who are found to have adenomatous polyps (and some other high risk conditions). Currently the procedure for follow-up of these patients varies between hospitals. However, in general, high risk patients (those with at least one adenoma greater than 1cm diameter and/or with severe dysplasia and/or with villous histology, or those with more than three low risk adenomas) are re-scoped every 3 years, reverting to 5 yearly if found to be clear of polyps. Low risk subjects (those with only 1 to 3 adenomas of less than 1 cm diameter plus mild/moderate dysplasia only and non-villous histology) are re-scoped every 5 years. Evidence-based guidelines for the follow-up of polyps have been released (Atkin and Saunders, 2002) which should help to standardise procedures between hospitals. Since

it has been reported that up to 50% of FOB positive patients undergoing colonoscopy have polyps, the impact of adenoma follow-up on colonoscopy services is likely to be substantial. The extent of the additional work will depend on the length of time for which patients are followed-up, which at present can be until frailty or death. Once accurate figures for the amount of pathology detected at colonoscopy have been obtained from the clinical dataset and guidelines on the interval and total period of follow-up have been released, a more accurate estimation of workload can be determined.

- colonoscopy as the investigation of choice for symptomatic patients. As colonoscopy services develop, more and more investigations may be performed by colonoscopy rather than barium enema (colonoscopy is felt by many, though not all, to be the investigation of choice since it allows removal and/or biopsy of polyps and other pathology and does not expose people to ionising radiation).
- colonoscopy for review of cancer patients. Colonoscopy is also used to review patients who have already been treated for CRC. It is conceivable that in the medium term, an increased detection rate and survival from cancer as a result of screening (but before any possible reduction in cancer incidence), may result in a moderate increase in requirements for such colonoscopic review.

Quality of colonoscopy services

All consultant surgeon and physician staff who were surveyed noted an improvement in the quality of colonoscopy services that had occurred over the period of the Pilot, with one noting that it had "greatly improved". This was reflected in improved individual skills, higher completion rates, more consistency among consultants performing colonoscopies and a service that is more consultant-led than previously. The introduction of skills appraisal and increased opportunities for skills training were mentioned as reasons for some of the improvements. Three of the six consultant staff mentioned that changes in protocols or procedures had been introduced since the start of the Pilot e.g. new guidelines for colonoscopy and a greater percentage of investigations of non Pilot patients being performed by colonoscopy (rather than barium enema) than previously.

Resources for colonoscopy

All surgeons and GI physicians surveyed noted that the additional resources allocated by the Pilot were insufficient to support the Pilot activity and insufficient to lead to a sustainable service if the same level of resources were to be made available nationally for National FOB screening programme. They noted that additional support would be required for staff (endoscopy, administrative and specialist nursing) and physical expansion of patient facilities (preparation, procedure, recovery and consulting room space) for additional sessions as many units are stretched to over-capacity at present. It was noted that there are currently not enough trained endoscopy staff in the NHS to meet the needs of a national programme.

All of the surgeons surveyed noted an impact of the Pilot on inpatient surgical services due to a greater need for major bowel resections and treatment of polyp recurrences.

Other GI services

1) Quantitative data

Data collected on activity and waiting times for medical and surgical outpatients were felt to be unhelpful due to the wide range of influences on these (external to the Pilot), and changes in coding procedures over the period of introduction of the Pilot, leading to artefacts in the data.

2) Qualitative data

Outpatient services (**Table 6.2.4**)

Additional work has been noted in medical and surgical GI outpatients as a result of the Pilot. For example, in hospitals with two Pilot colonoscopy sessions per week (scoping on average 8 to 10 patients per week), approximately two to four extra patients were seen per week for review after their screening colonoscopy (those with cancer, large polyps or other pathology). The degree to which patients with non-malignant pathologies were reviewed at hospital outpatients varied between hospitals (but, if not seen by hospital consultants, these patients will create extra work for GPs). This additional work generated a related increased requirement for administrative support of these clinics.

Medical (GI) inpatient services (**Table 6.2.5**)

Only one of the consultants surveyed noted any increase in medical in-patient activity related to the Pilot.

Administrative and clerical services (**Table 6.2.5**)

All consultant staff who carried out colonoscopies noted that the increased clinical activity was associated with a substantially increased need for administrative and clerical support. This included writing letters to GPs and patients about the screening procedure and findings at colonoscopy and in outpatient clinics, obtaining information or performing investigations to determine a patient's 'fitness for colonoscopy', review of patients found to be unwell at colonoscopy and follow-up of patients who had not attended for colonoscopy despite a positive FOB test and dealing with telephone enquiries.

Surgery (**Table 6.2.5**)

All surgeons surveyed noted an impact of the Pilot on inpatient surgical services due to a greater need for major bowel resections and treatment of polyp recurrences. Initially the requirement for surgery increases as prevalent cancers are detected early. For example, during the first year of the Pilot, 53 cancers were detected in Tayside alone. Surgeons at Ninewells reported that this affected their waiting times for colorectal surgery. Theoretically, in the long-term, the requirement for surgery is unlikely to be greater than it is at present, since studies suggest that overall the number of tumours detected should not increase. Indeed, it might be expected that eventually the incidence of invasive cancer might fall as adenomas are removed. However, experience from the breast screening programme would suggest that requirements for surgery may never return to pre-screening levels.

Radiology

1) Activity levels (Figures 6.2.11 - 6.2.16)
During the first year of the Pilot, a maximum of five extra DCBEs were performed per month on screen positive patients at each of the Victoria Hospital, Ninewells and Aberdeen Royal Infirmary. This constituted, on average, between 1% and 2.5% of the overall DCBE activity at these hospitals. There was no consistent change in activity levels for symptomatic patients during this period. Although activity at ARI appeared to drop following the introduction of the Pilot, this may be at least partially explained by previously high levels of activity aimed at reducing waiting times.
In both Walsgrave and Warwick Hospitals in the English Pilot site, the number of DCBEs performed has decreased over the last 2-3 years. As in Scotland, additional activity generated by the Pilot constituted a very small proportion of the overall DCBE activity at these hospitals.

2) Waiting times (Figures 6.2.17- 6.2.22)
Waiting times for DCBE have tended to decrease during the past 2 to 3 years, primarily due to waiting list initiatives.

3) Qualitative data
There were no reports of difficulties keeping up with requirements for Pilot DCBEs using the resourced weekly sessions. However, since these procedures were done almost exclusively for incomplete colonoscopy (rather than patients unable to undergo colonoscopy), the question of whether requirements for DCBE could increase given less experienced colonoscopists arises. It is more likely perhaps that requirements for DCBE may fall in future as CT colonography replaces DCBE as the investigation of choice for failed colonoscopy. Consultants required approximately one hour per week for the administrative duties associated with the Pilot session, including writing and checking reports.

It was felt that other aspects of screening would have at most only a moderate effect on radiology workload. Radiological procedures involved in the staging of colorectal cancer include chest X-ray, abdominal ultrasound or abdominal/pelvic CT. However, with the service structured as at present and after the initial increase in cancers detected, the requirement for these procedures is unlikely to be much greater than it is at present since, theoretically, the overall number of tumours detected should not increase greatly. Requirements for radiological investigation of the liver for metasases during follow-up of patients after surgery should also remain largely unaffected, especially in the long term, for similar reasons.

Five of the six radiology staff who were surveyed noted that the resources provided by the Pilot had been adequate to cope with any small additional workload (one noted the need for additional consultant cover for radiographer sessions). It was noted however that this was largely because colonoscopy failure rates were lower than expected. This view may change if colonoscopy failure rates rise in the future. The increased workload related to the Pilot was considered minimal in relation to the overall workload of the service and related principally to increased ultrasound and CT examinations. The introduction of double reading of DCBE was the only change in procedures noted by more than one hospital. One radiologist noted that a DCBE examination on the same day as incomplete colonoscopies was more readily accepted as a result of the Pilot. The only radiologist stating that he thought that the service quality had improved since the introduction of the Pilot was at a hospital where a dedicated radiographer-led session had been introduced.

All six radiologists noted that there had been no or only minimal increased administrative / clerical burden associated with the Pilot.

Pathology

The increased workload for pathology has been substantial. Pathology activity in the three Scottish Pilot centres is shown in **Table 6.2.6**. Workload varied depending on the phase of the Pilot, but all three Scottish centres experienced sustained periods of very high screening-generated activity. For example, Aberdeen Royal Infirmary and Dr Gray's Hospital in Grampian together received an average of 98 extra 'polyps and other biopsies' per month (this figure doubled at certain times). One pathologist estimated that his workload increased by 25-30% over the duration of the Pilot, and described the personal impact as 'profound'. In England, a total of 1789 'polyps and other biopsies' were generated over the course of the Pilot (plus an additional 120 samples following resection), with a similar increase in workload for pathologists noted.

While generally supportive of the screening programme and satisfied with the quality assurance provisions built into the Pilot, it was noted by pathologists in both Scotland and England that the number of polyps expected, and therefore the resources provided to pathology services for the Pilot, was considerably underestimated. For example, it was estimated that 17-20 patients per month at each hospital would require histological investigation of 2-3 biopsies each from polyps detected at screening colonoscopy, and therefore that pathology departments would receive roughly 50 extra biopsies per month. In practice, for a substantial portion of patients removal of many more polyps has been required (up to 13 or 14 polyps in some cases), thus increasing both the length of time required for pathological diagnosis, and the amount of administrative support needed.

As detailed later in this report (Section 7.1.4.3, and Appendix C.5.3), a survey of histopathologists throughout the UK (conducted by postal questionnaire) indicated that many departments are currently working at full capacity, with difficulties being experienced nation-wide in recruitment of both pathologists and (in many cases) MLSOs. Many respondents emphasised that substantial extra resources would be required for a national programme. A report from the National Services Division of the Common Services Agency in Scotland (National Services Division Report, 2002) estimated that a national programme each District General Hospital (serving a population of 250,000) would require an additional 0.1 WTE pathologist in each DGH (this will need to be accompanied by an equivalent increase in secretarial support, and in laboratory support to undertake tissue preparation and processing).

For oncology, requirements for chemotherapy are likely to increase initially as prevalent cancers are detected, but thereafter may reduce slightly as more tumours are detected at an earlier stage, requiring less aggressive treatment.

6.3 Predicted colonoscopies from screening and adenoma follow-up

Using the estimates from Chapter 4 of the detection rates of adenomatous polyps at the prevalence screen (5.29/1000 screened) we have estimated the numbers of such people who will be in long-term

follow-up as a result of an FOBt screening programme and the effect of this follow-up alongside repeat screening on colonoscopies in a screened population.

We have modelled a prevalence and 3 incidence screening rounds (at 2-yearly intervals) for 100,000 screened individuals with the same age and sex distribution as the current pilot and made the following simplifying assumptions:

- The population does not age nor die
- The ratio of incidence: prevalence screen detection rates of adenomas is 0.33 (this follows discussions with Moss S, (personal communication) - this is likely to be a conservative assumption
- Similar ratios for cancers detected are 0.5 and for FOBt positives are 0.7
- The proportions of low-risk, medium risk and high risk adenomas are as reported in Table 4.2.9 (18% high risk, 40% medium risk and 42% low risk).
- People with cancer detected are not rescreened but those with adenomas detected are offered re-screening and accept.
- Follow-up of adenomas is as recommended in Atkin and Saunders (2002), which agree closely with the Scottish SIGN guidelines
- No-one in adenoma follow-up reverts to the 'no follow-up' group

Under these assumptions we estimate that there will be 1945 colonoscopies generated in the prevalence round of which 95% will be the direct result of screening and the remainder annual follow-up of the high risk adenomas. In the 3 incidence screening rounds there will be 4953 colonoscopies generated of which 78% will be the direct result of screening. Thus, adenoma follow-up makes an important contribution to the total number of colonoscopies generated in a screening programme (and will also lead to an increase in screening-generated pathology).

We emphasise that the assumptions applied here are simplistic and no sensitivity analyses have been applied. For example, in the Atkin and Saunders guidelines (2000) which reflect the current status of evidence and could be used as the basis of a follow-up strategy, it is indicated that it might be expected that most people would have a maximum of two follow-ups, and that one can expect a 20% non-attendance rate at each exam; this would make the process of surveillance somewhat more manageable. The model is readily available to be run using alternative assumptions (of which the most important are likely to be variations in detection rates and/or risk distribution of adenomas detected at incidence screens).

6.4 Conclusions and recommendations

During the course of the UK Colorectal Cancer Screening Pilot issues of workload and capacity have emerged as key factors in the success of a future roll-out of CRC screening. The Pilot has occurred during a time of considerable change and uncertainty within the NHS; during this period there have, for example, been protracted negotiations over new contracts for consultants and GPs. There has been a strong focus on waiting times for cancer-related appointments, investigations and treatments, and this has brought into sharp focus the additional potential burden imposed by a new screening programme. There has been a strong perception from within primary care that secondary care services are often failing to meet demand.

Against this background, it has been critical for this evaluation to provide an understanding of the workload impact and capacity issues raised by the UK Pilot.

Impact on primary care

Our surveys and audit have detected a modest impact on workload, coupled with a wide range of views on how primary care could best accommodate this new screening activity. This is reflected also in our surveys of screenees (Chapters 2 & 3) which show, for example, that a significant proportion of individuals with positive test results, and screen-detected cancers, consult their GP.

The nature of activity in primary care makes identification of the workload impact of new programmes difficult – there is an enormous array of activity in primary care, including consultations, telephone calls, home visits, administration and paperwork etc. Unlike secondary care, there are not readily-identifiable barometers of impact and activity (such as waiting lists for specific procedures) which can be measured. We have attempted, therefore, to break down the potential additional activities into their various components. Data are based on self-reports, and without a ready means of validating these reports caution must be taken in their interpretation.

Nevertheless, the data provide important insights. Almost half of respondents believe that a national FOBT screening programme will impact significantly on primary care, and a majority of GPs feel they should be remunerated for this additional workload. While our surveys and audit could only identify a modest impact on day-to-day activities, the perceptions of primary care personnel will need to be addressed in plans for roll-out. Specifically, the new contract for GMS services has a strong focus on quality performance targets, and a new range of incentives to drive activity - given the perceptions about workload impact seen in our data, care will need to be taken in rolling out screening that primary care is able and willing to accommodate the extra activity generated through FOBT screening.

There appears to be a particular sensitivity to increases in paperwork generated through new programmes such as FOBT screening; a national programme should take measures to ensure that this aspect of workload impact is kept to a minimum.

Scotland-England differences

In general, the results suggest the UK Pilot had a more discernable impact on primary care in Scotland than it did in England. There are two likely explanations: firstly, it appears that checking of prior-notification lists (PNLs) was undertaken to a greater extent in Scotland. Secondly, as detailed in Chapter 3, people screened in England were more likely to have received a leaflet and consulted a nurse prior to colonoscopy, whereas people screened in Scotland were twice as likely to have consulted their GP. Lower rates of nurse consultation in Scotland were reflected in a rate of GP consulting that was twice that of England.

In moderating the impact in primary care in a national programme, consideration should be given to the most effective model of provision of nurse appointments – clearly a great deal of information, provision and co-ordination of the screening process occurs during these consultations.

Checking of Prior-notification lists

This has emerged as a significant issue for primary care. Ideally, invitations to screening should not go to individuals in whom such an invitation is clearly inappropriate – such as patients who have had the

majority of their large bowel removed, are terminally ill or recently deceased. Screening invitations are generated from lists from the Community Health Index in Scotland, and from health authorities in England; inevitably such lists won't be completely up to date, and there is no mechanism to automatically exclude certain groups of individuals to whom screening invitations should not be sent.

Little is currently known about the adverse consequences of issuing inappropriate invitations – potentially they could cause harm and distress to individuals and their relatives. The PNL-checking process is, nevertheless, burdensome upon primary care teams – some primary care survey respondents suggested that invitations could go out to everyone on the list, and individuals could decide themselves whether or not the invitation was inappropriate. More research is required into the adverse effects of inappropriate invitations to cancer screening, and the cost-effectiveness of PNL-checking.

Impact on hospital workload

The Colorectal cancer screening Pilot has generated a considerable amount of additional work for hospital staff. This has resulted in considerable strain for services which were already hard-pressed, in particular gastroenterology, surgery and pathology. Indeed, the Pilot has only been sustained in many instances due to goodwill on the part of consultants and other staff, who are never-the-less generally supportive of CRC screening. However, staff are concerned that the service will be facing huge problems if screening is introduced without adequate resourcing. It is important that this does not only 'cover' the direct increase in requirements for colonoscopy, but also the wider workload generated as a result of screening. This will include;

- colonoscopy for adenoma follow-up and increase in demand for symptomatic colonoscopy services. A large proportion of the pathology detected at screening colonoscopy (up to 50% of colonoscopies) has been reported to be adenomas requiring repeat colonoscopy every 3 to 5 years. This, together with the associated increase in colonoscopy for symptomatic patients could result in a requirement for at least one additional colonoscopy session for every two screening colonoscopy sessions within the first 5 years of the start of screening, with requirements rising thereafter due to a cumulative effect. If, as has been predicted, there is a move away from barium enema towards colonoscopy as the investigation of choice for symptomatic patients (influenced in part by the use of colonoscopy for screened patients), the requirement for colonoscopy in the future is likely to be far greater than this. Increasing use will clearly result in increased attrition of colonoscope hardware. Increased activity may also require expanded facilities e.g. for day bed cases in some hospitals.

- outpatient review and/or correspondence for patients found to have pathology at screening colonoscopy plus administation**.** It has been estimated that between 40 and 50% of colonoscopies done for the Pilot uncovered some form of pathology which required further action to be taken. For benign pathology this ranged from sending letters to GPs for mild disease, through outpatient attendance for more severe disease to outpatient review plus referral for follow-up colonoscopy for high risk pathology, including adenomas. To deal with this increase in workload, as well as the associated administration**,** it is likely that one additional consultant session would be required for every two screening colonoscopy sessions.

- at least initial (and possibly sustained) increases in the requirement for surgery and oncology services.

Further important issues to emerge:

- there was a minimal increase in demand for DCBE services (less than 3% increase in service volume). If CT colonography replaces DCBE as the investigation of choice for failed colonoscopy this will be reduced further.

- there has been a considerable increase in workload for pathology services, at times amounting to up to 30% of workload. Substantial additional resources would be required for a national screening programme, for both clinical and non-clinical personnel.

- each NHS Board will be required to designate a screening co-ordinator for colorectal cancer should a screening programme be introduced, to provide a local lead on introduction and maintenance of screening services. A Consultant in Public Health Medicine (CPHM) usually performs this role for other current screening programmes. It is estimated that at least 0.25 WTE

CPHM, plus 0.5 WTE administrative support, will be required for each Health Board (National Services Division Report, 2002).

- central statistical support would be required by a screening programme for both production of routine quality assurance reports (for all stages of the screening process), and for evaluation of the effectiveness of the programme. Information and Statistics Division provides such support for the Breast Screening Programme in Scotland and it is estimated that to carry out similar work for a colorectal screening programme in Scotland would require an additional WTE analyst (National Services Division Report, 2002). Similar resources would be needed in England.

Evidence for an increase in demand for colonoscopy services for symptomatic patients (hospital activity data and / or consultant reports of increased service activity) gathered during the survey was found at all the Pilot hospitals. One suggestion for dealing with this increase in workload has been to have 'screening doctors' who would provide the screening colonoscopy service, review patients in outpatients, deal with the attendant correspondence and administration and possibly perform surgery. Although training of nurse endoscopists may also help, there will always be the increased workload surrounding the actual colonoscopy, including outpatient review and surgery.

Some of the administrative workload has been taken on by the 'colonoscopy specialist nurse' in each hospital. This nurse has been responsible for contacting FOB positive patients, explaining the significance of the test to them, obtaining consent for colonoscopy and arranging bowel prep, arranging appointments for colonoscopy, attending the colonoscopy sessions and helping to arrange follow-up. It was felt that one specialist nurse was insufficient for this post, and that 1.5 to 2.0 WTEs would be required in each hospital, together with 0.5 WTE secretarial support to help with sending out letters and accessing case notes etc. In at least one hospital (Ninewells), such secretarial support had been obtained, with successful results.

A number of capacity-building and quality-improvement initiatives are already underway: A major audit was recently undertaken by the Audit Committee of the British Society of Gastroenterology (Dr. MD Hellier, personal communication). The audit, which has been submitted for publication, looked in very great detail at endoscopy services within three regions and produced detailed information about 8000 colonoscopies. The Endoscopy Committee of the British Society of Gastroenterology is in the process of drawing up standards for colonoscopy stemming from this audit. The audit will provide important information in developing colonoscopy services to meet the demands of FOBT screening. Further, through the Royal College of Surgeons six endoscopy training units have been established nationally which provide excellent 'hands-on' training.

Inequity in waiting times for colonoscopy

For at least two of the hospitals participating in the Scottish CRC screening Pilot, there was a marked discrepancy between waiting times for colonoscopy for screened and symptomatic patients. For example, in Ninewells, average waiting times for Pilot patients were between 2 and 6 weeks, whereas for symptomatic patients they rose from around 10 weeks to between 16 and 18 weeks within the first year of the Pilot (**Figure 6.2.8**). We would therefore recommend that resources should be provided to a level which reduces waiting times for colonoscopy to between 2 and 4 weeks, prior to the start of screening (with further provision made for all aspects of the additional work of screening). This will prevent the inequitable situation of symptomatic patients waiting longer to be scoped than Pilot patients, but maintain the necessary short period between screening positive and having the definitive investigation, thus minimising levels of anxiety following notification of a positive FOB positive test.

Impact on quality of surgical services

All surgeons who were surveyed noted an improvement in the quality of colonoscopy services that had occurred over the period of the Pilot. This was reflected in improved individual skills and higher completion rates and the fact that the service was more consultant-led than previously. The introduction of skills appraisal and increased opportunities for skills training were mentioned as reasons for some of the improvements. Two of the four surgeons mentioned that changes in protocols or procedures had been introduced since the start of the Pilot e.g. new guidelines for colonoscopy and a greater percentage of investigations of non Pilot patients being performed by colonoscopy (rather than barium enema) than previously.

Immediate quality assurance procedures include making an assessment of the caecal intubation rate. This requires either a photograph of the ileocaecal valve or a biopsy of the terminal ileum (requiring

support for additional pathology workload). In future new colonoscopic systems which determine the exact position of the colonoscope may supersede these methods and will require capital funding for their purchase.

Monitoring of quality control over a period of years will require central flagging of medical records within the NHS to review patient outcomes (e.g. rate of colorectal cancers at 5 years among those who had a negative colonoscopy). This will require modest funding to support additional administrative workload.

Figure 6.2.1 Colonoscopy activity at Ninewells Hospital (by quarter)

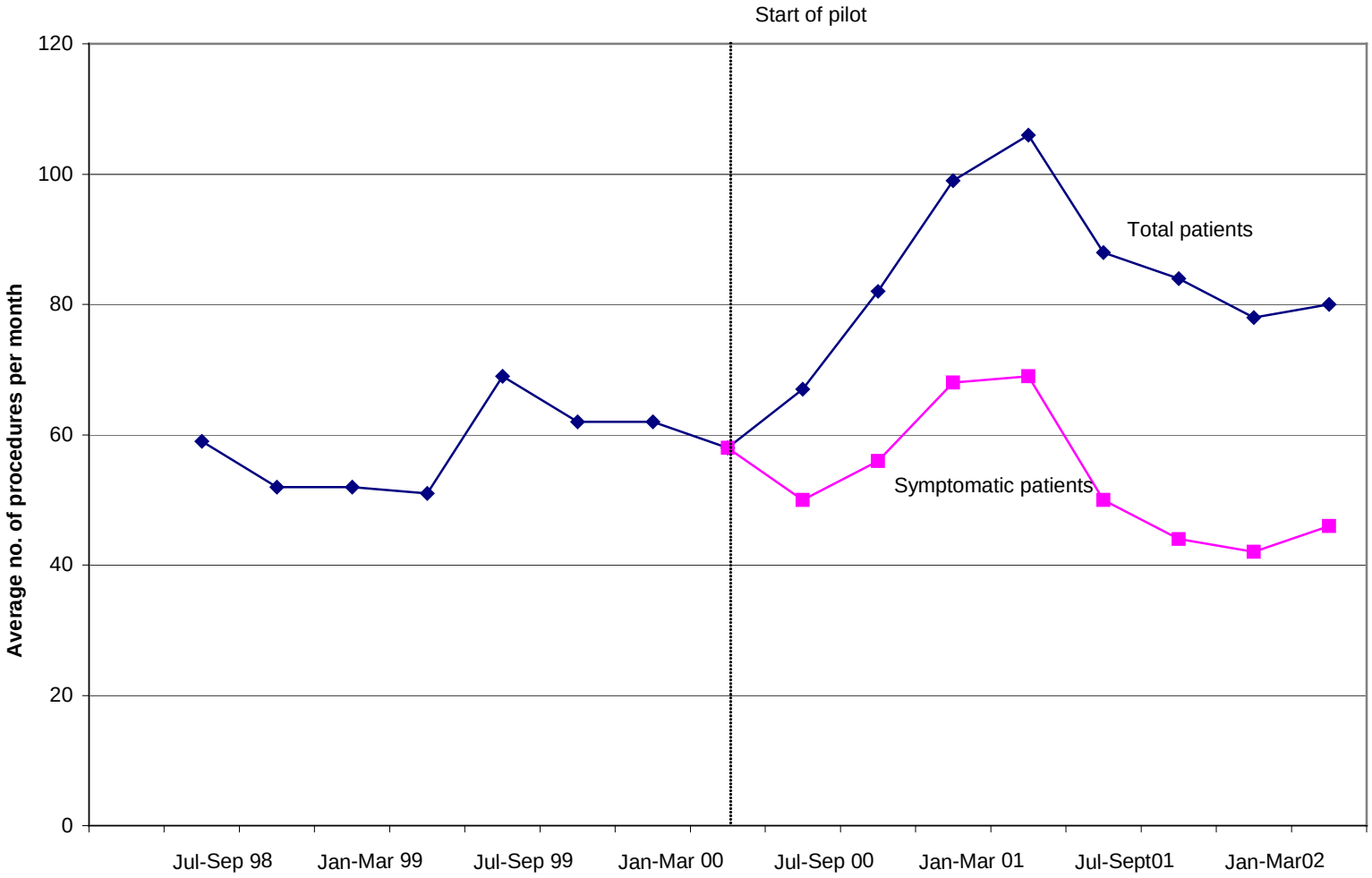


Figure 6.2.2 Colonoscopy activity at Aberdeen Royal Infirmary (by quarter)

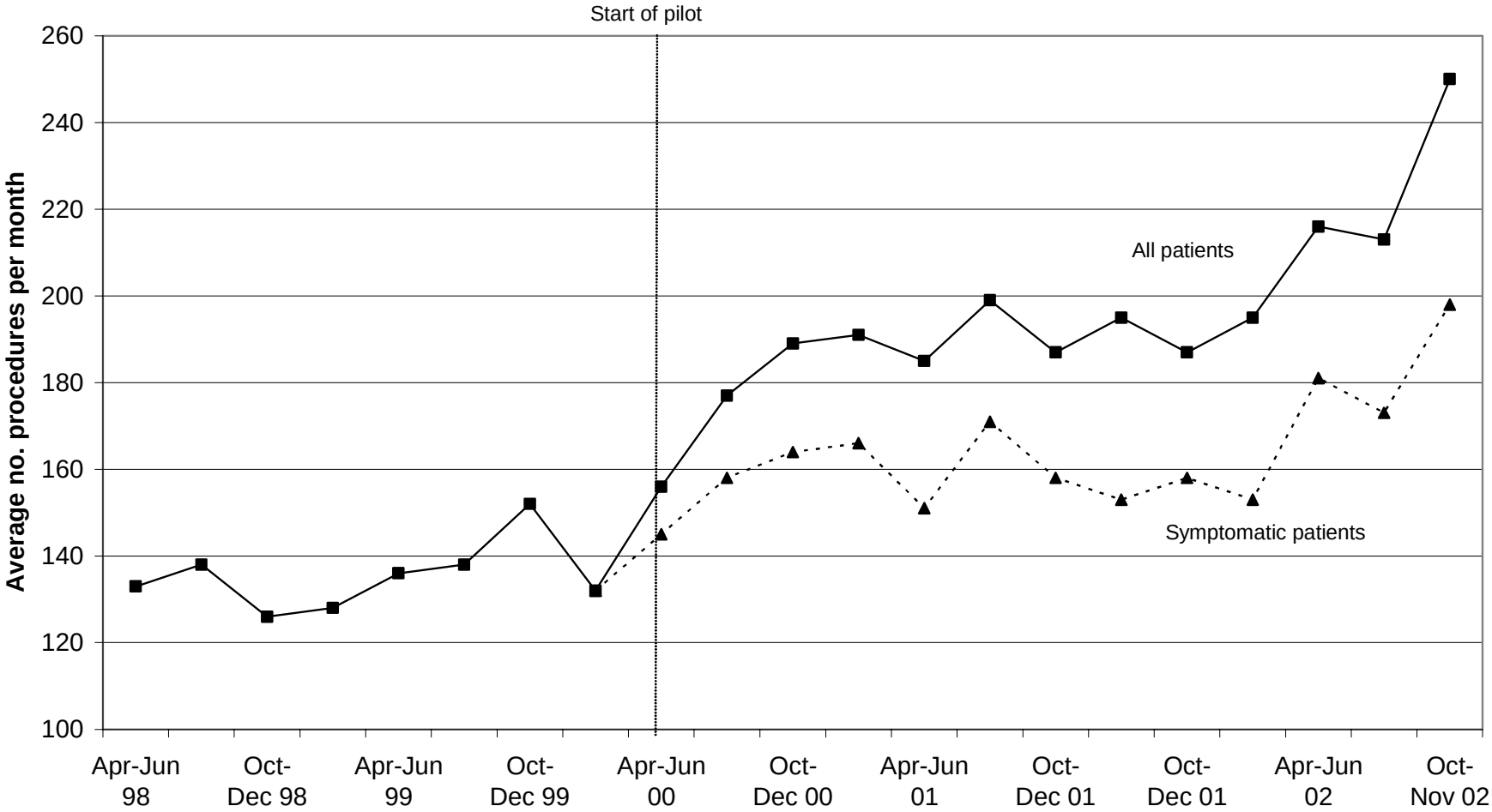


Figure 6.2.3 - Colonoscopy activity at Victoria Hospital (by quarter)

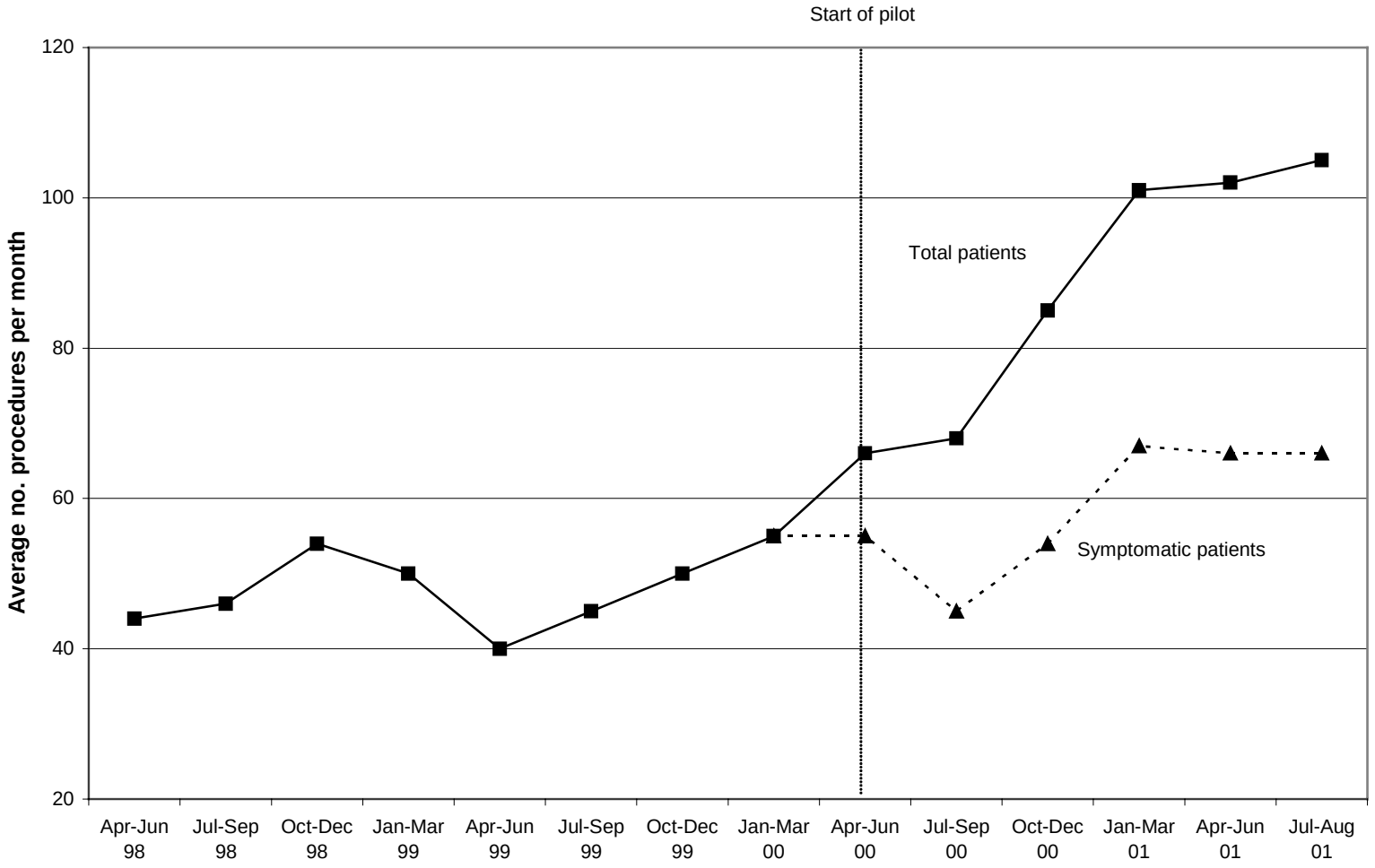


Figure 6.2.4 - Colonoscopy activity at Elgin Hospital (by quarter)

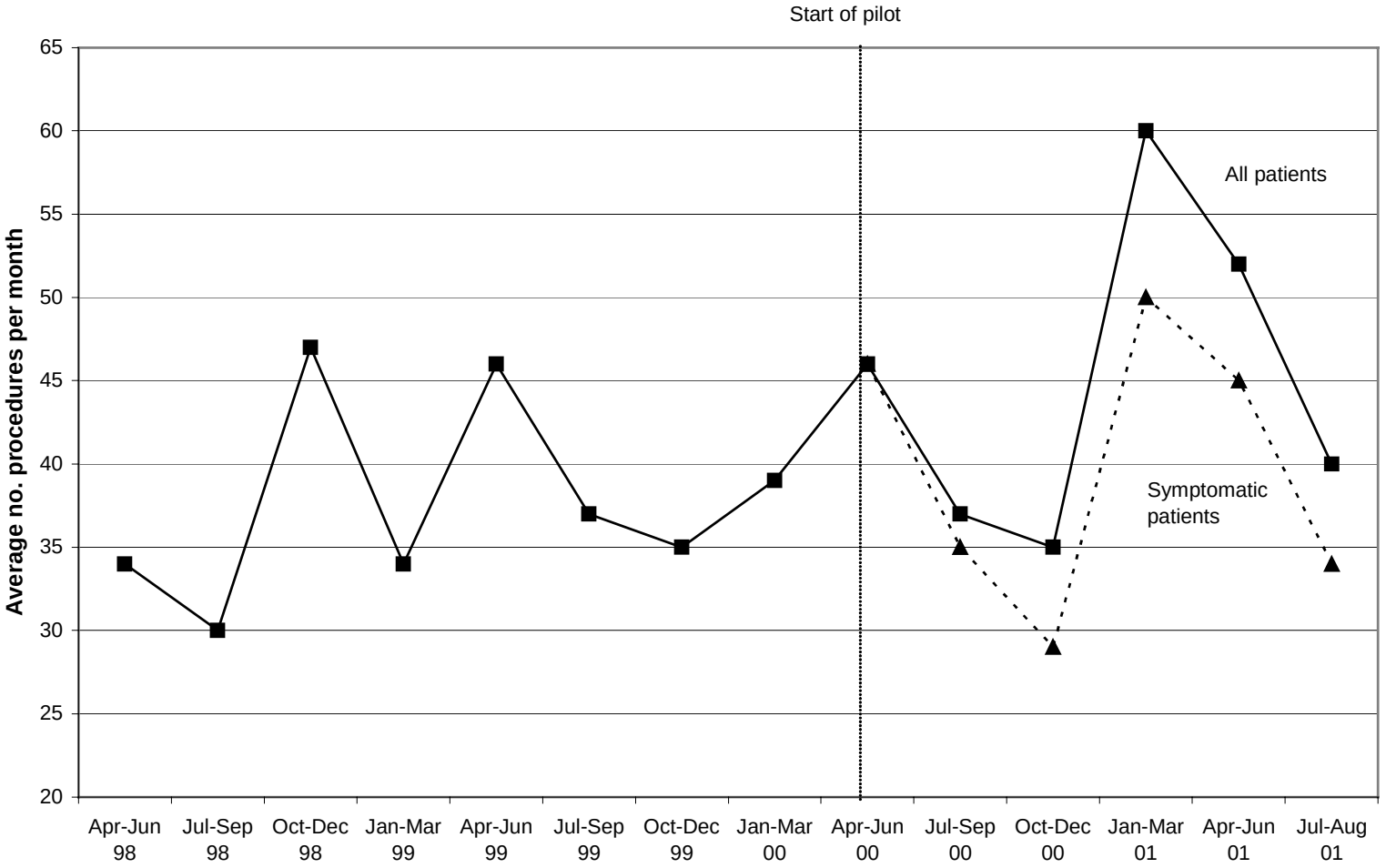


Figure 6.2.5 Colonoscopy activity, Walsgrave Hospital (by year)

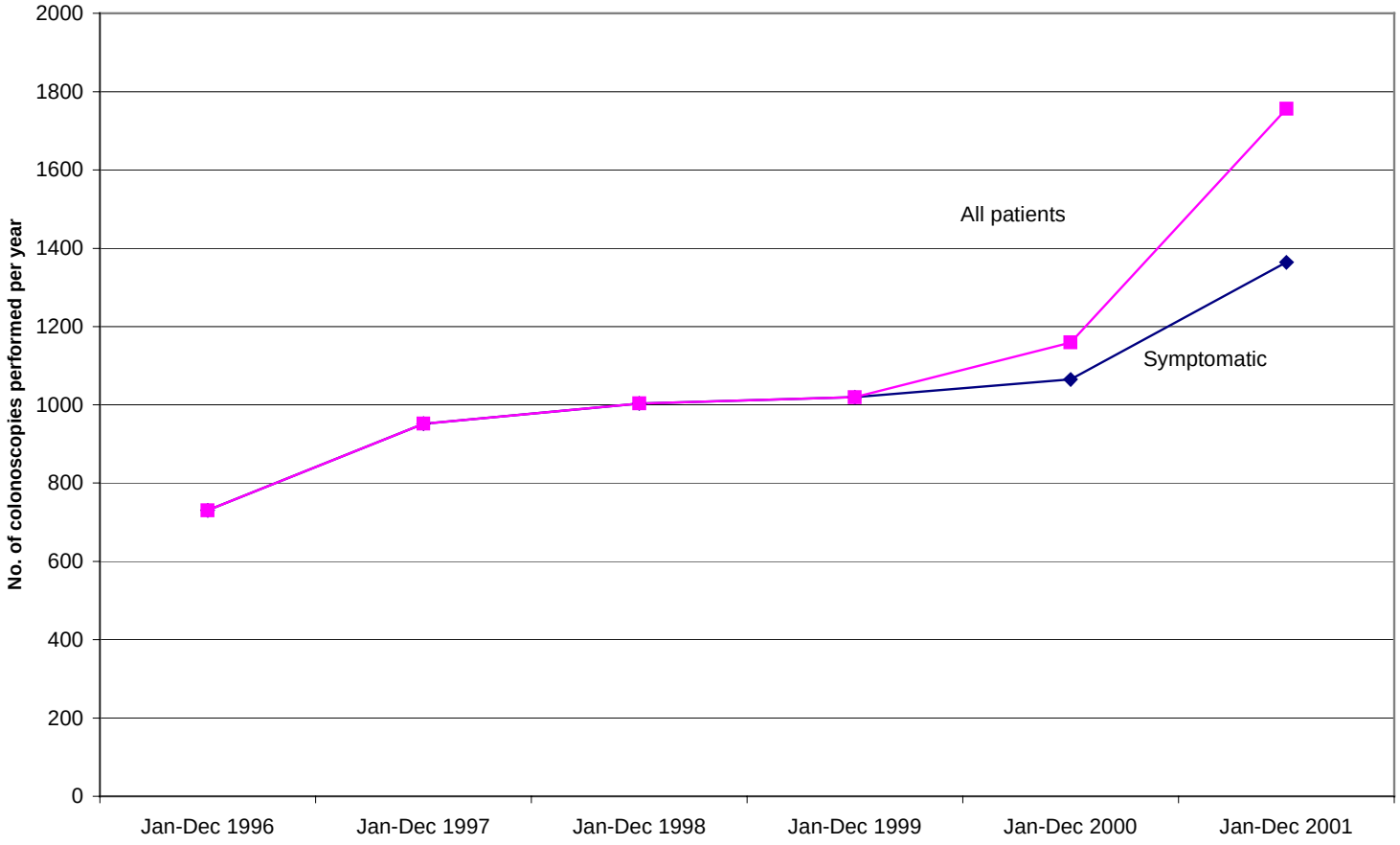


Figure 6.2.6 Colonoscopy activity, George Eliot Hospital (by Year)

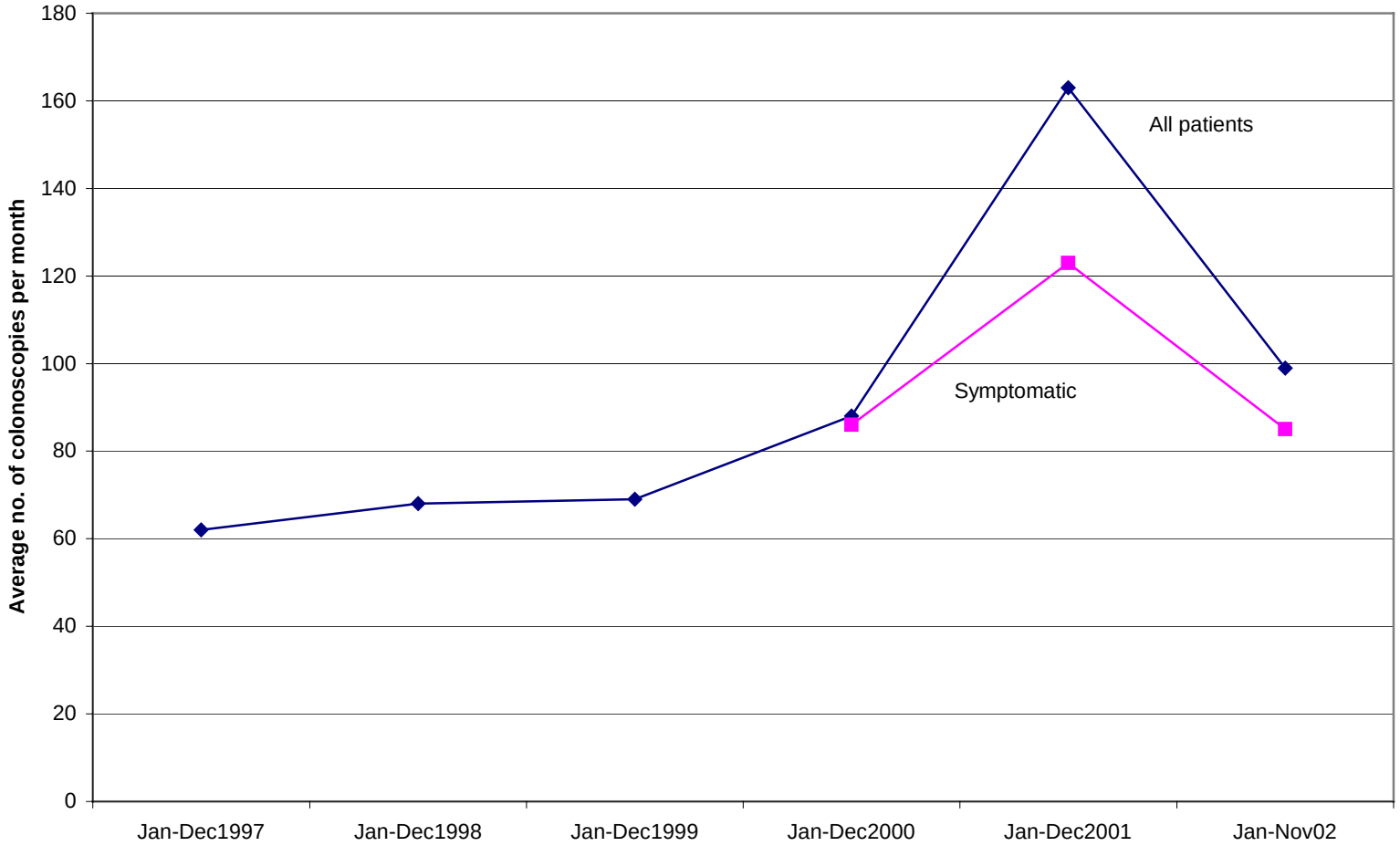


Figure 6.2.7 Colonoscopy activity at Warwick Hospital (by year)

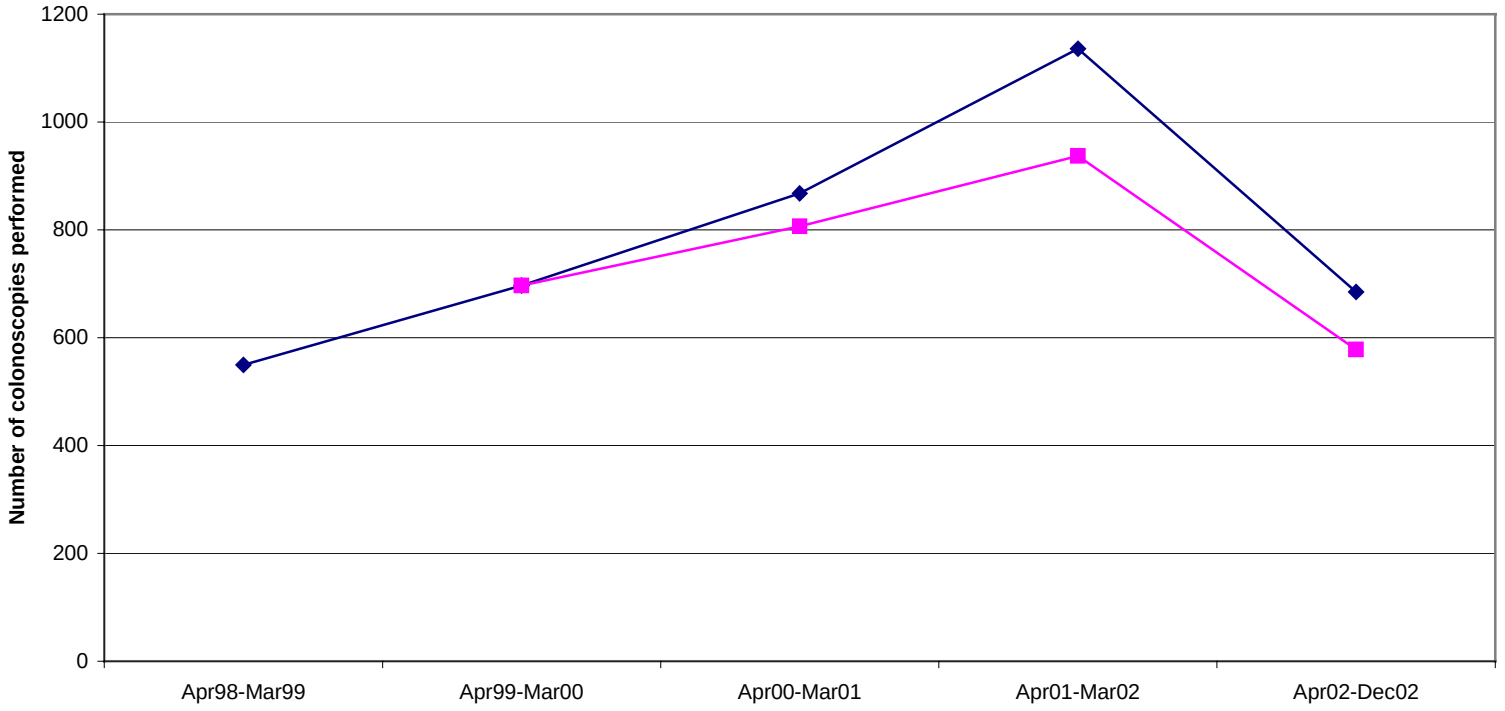


Figure 6.2.8 Waiting times for colonoscopy at Ninewells Hospital (by quarter)

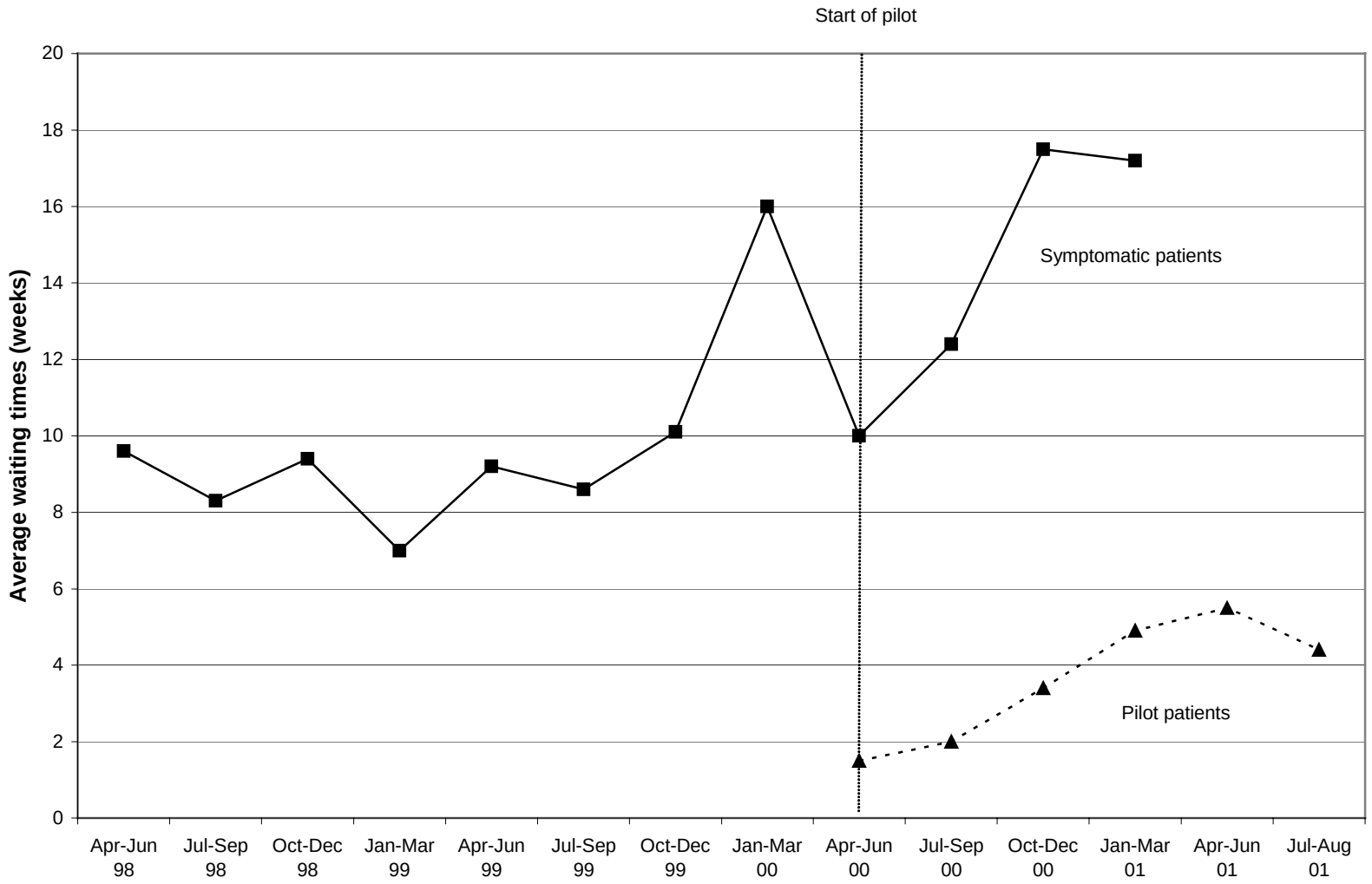


Figure 6.2.9 Waiting times for colonoscopy at Aberdeen Royal Infirmary (by quarter)

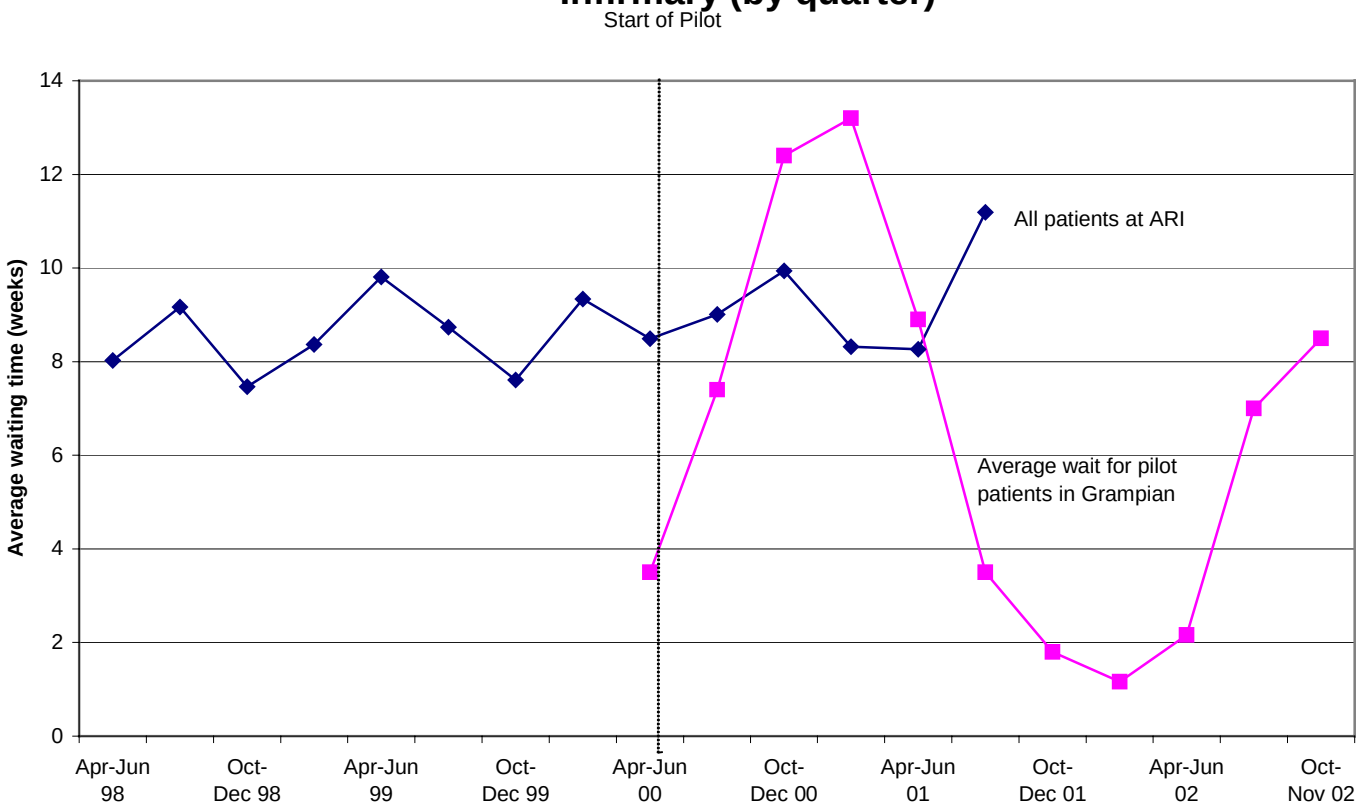


Figure 6.2.10 - Waiting times for colonoscopy at Elgin Hospital (by quarter)

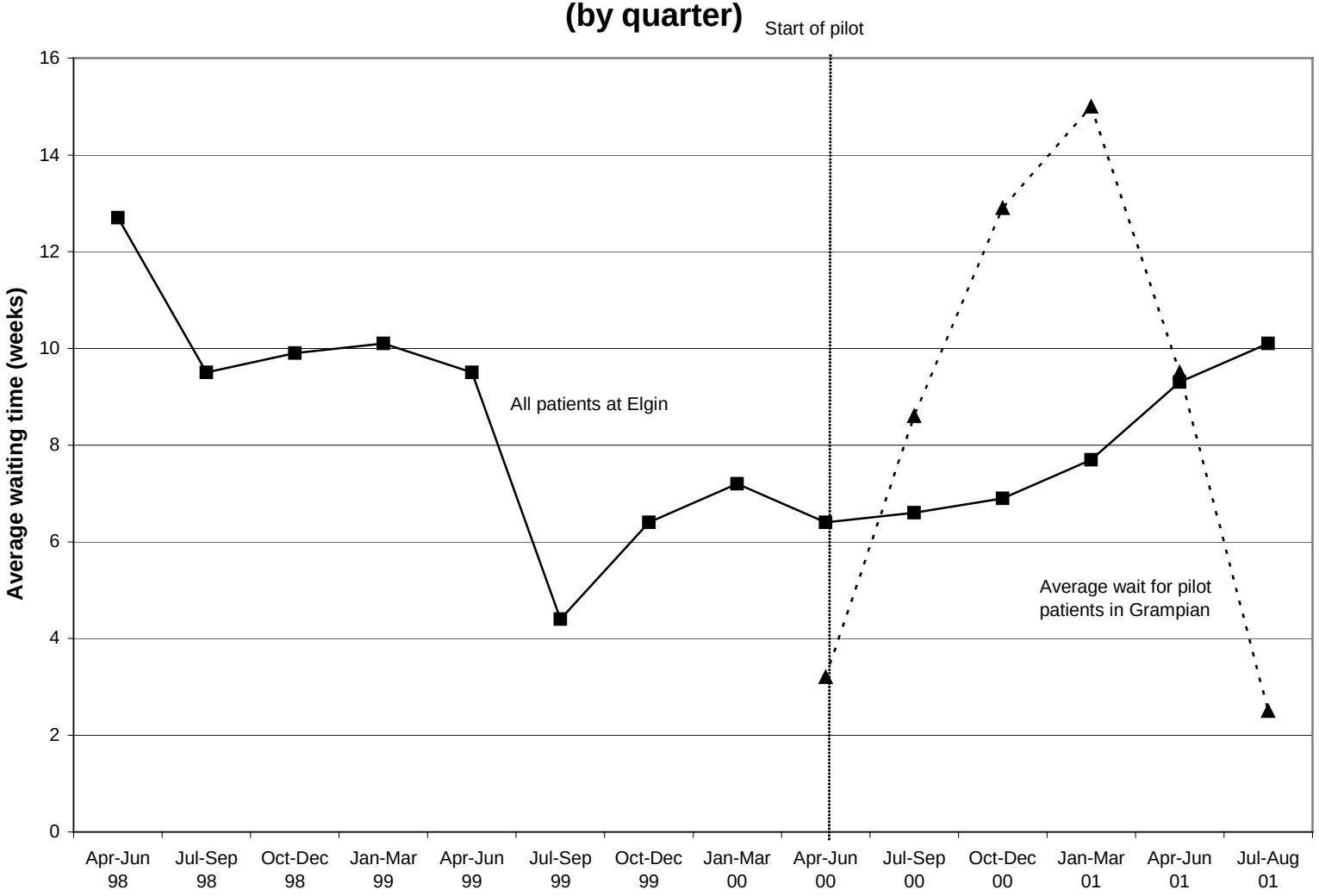


Figure 6.2.11 – DCBE activity at Ninewells Hospital (by quarter)

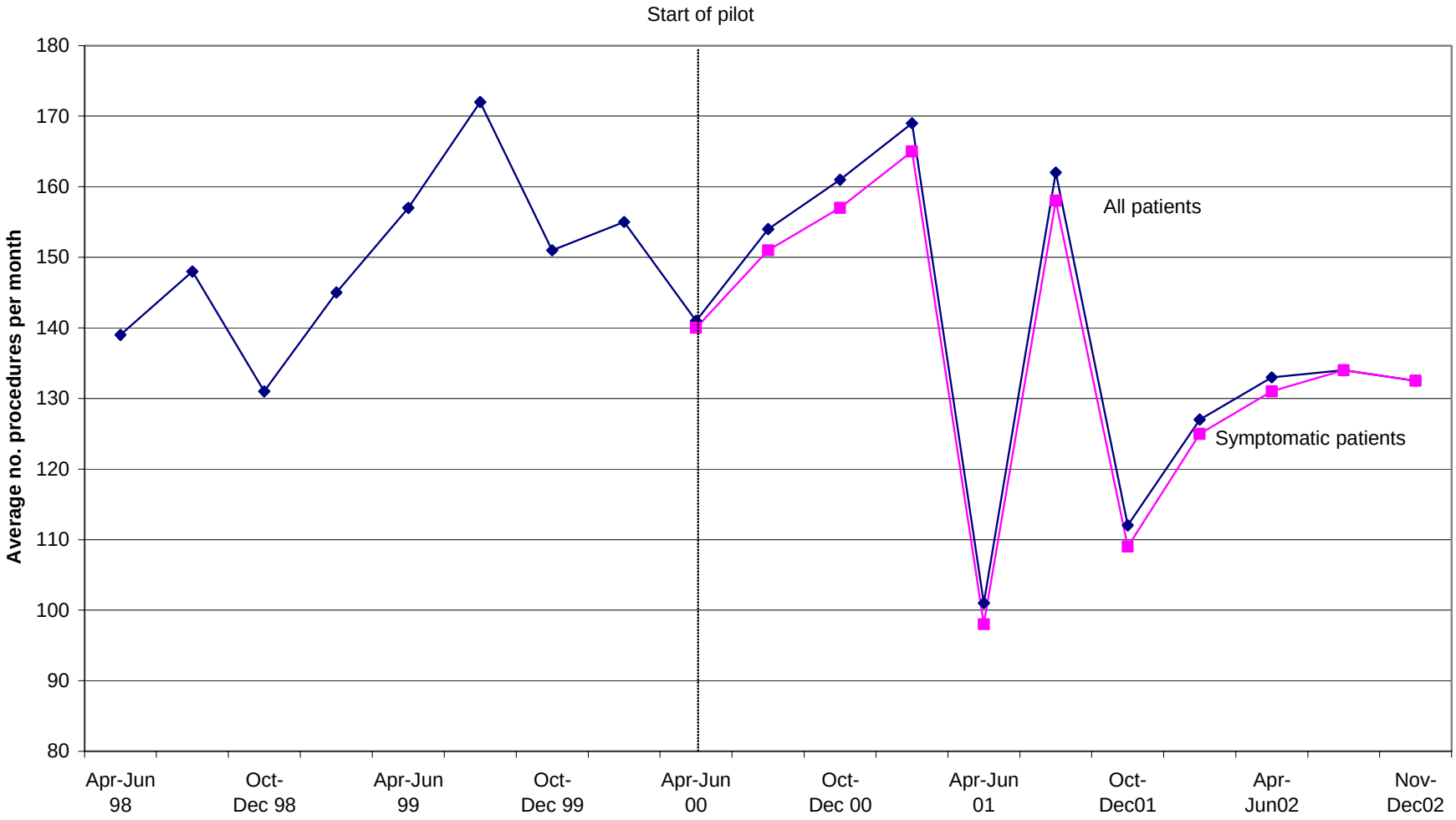


Figure 6.2.12 DCBE activity at Aberdeen Royal Infirmary (by quarter)

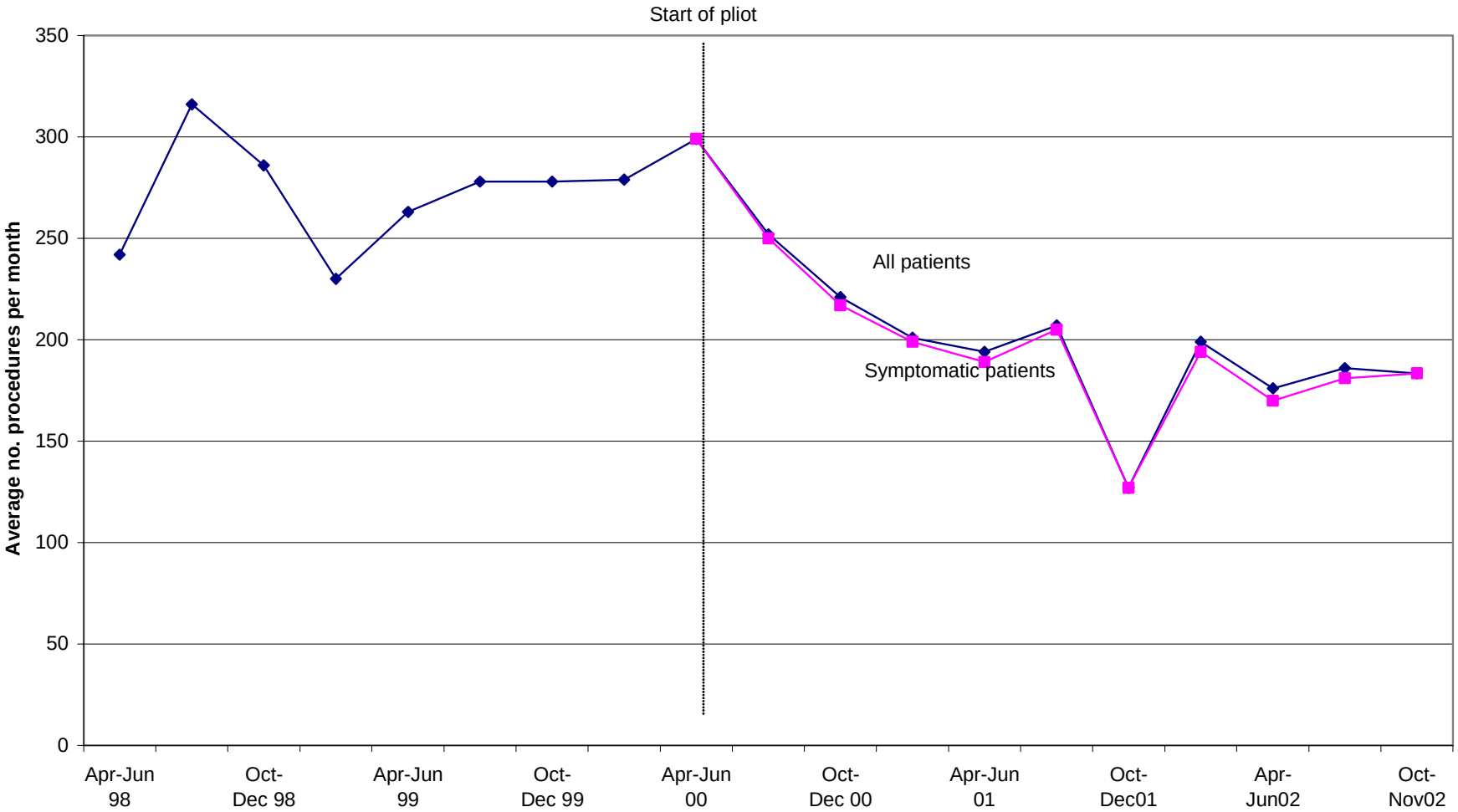


Figure 6.2.13 - DCBE activity at Victoria Hospital (by quarter)

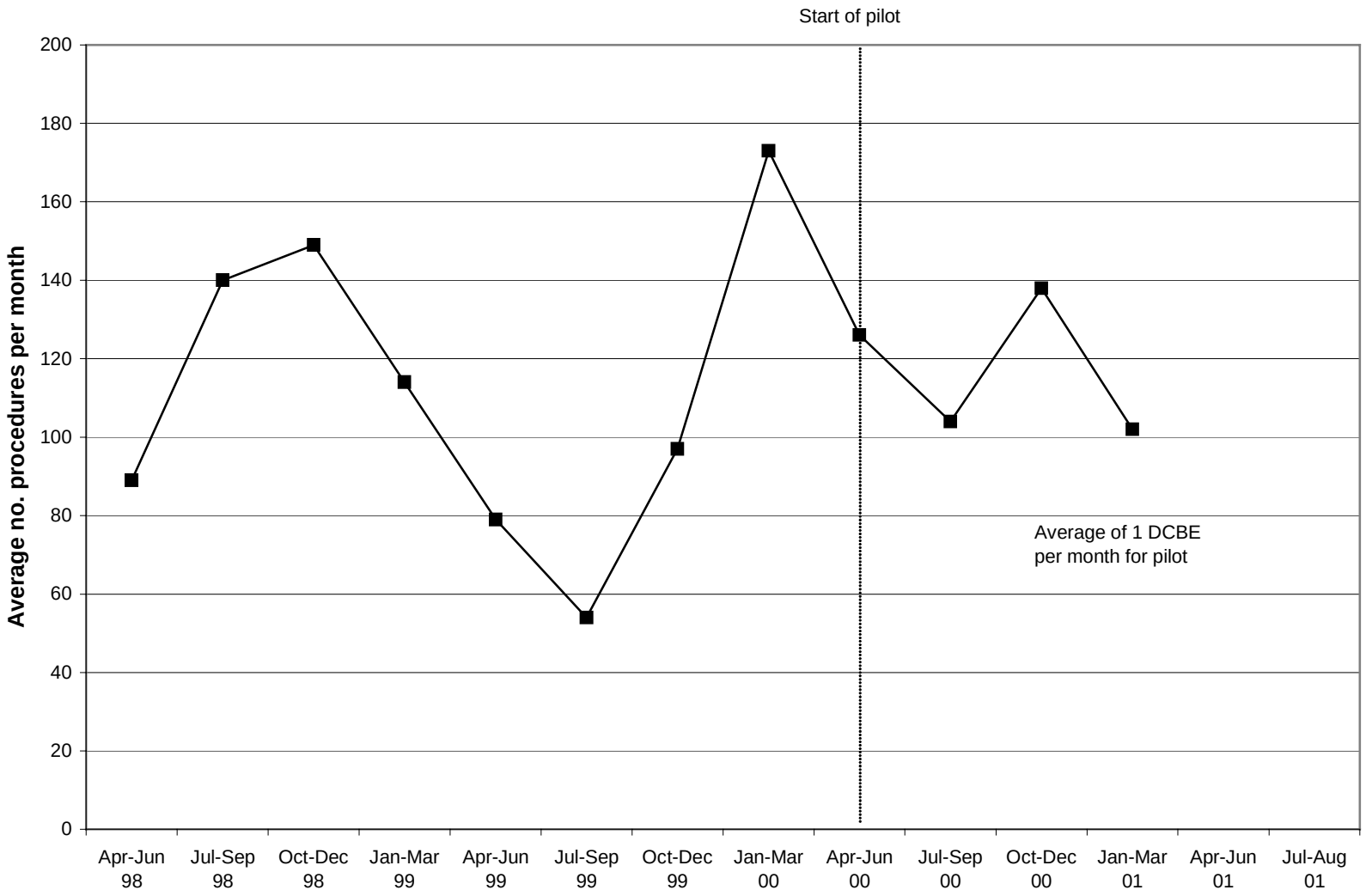


Figure 6.2.14 DCBE activity at Walsgrave Hospital (by year)

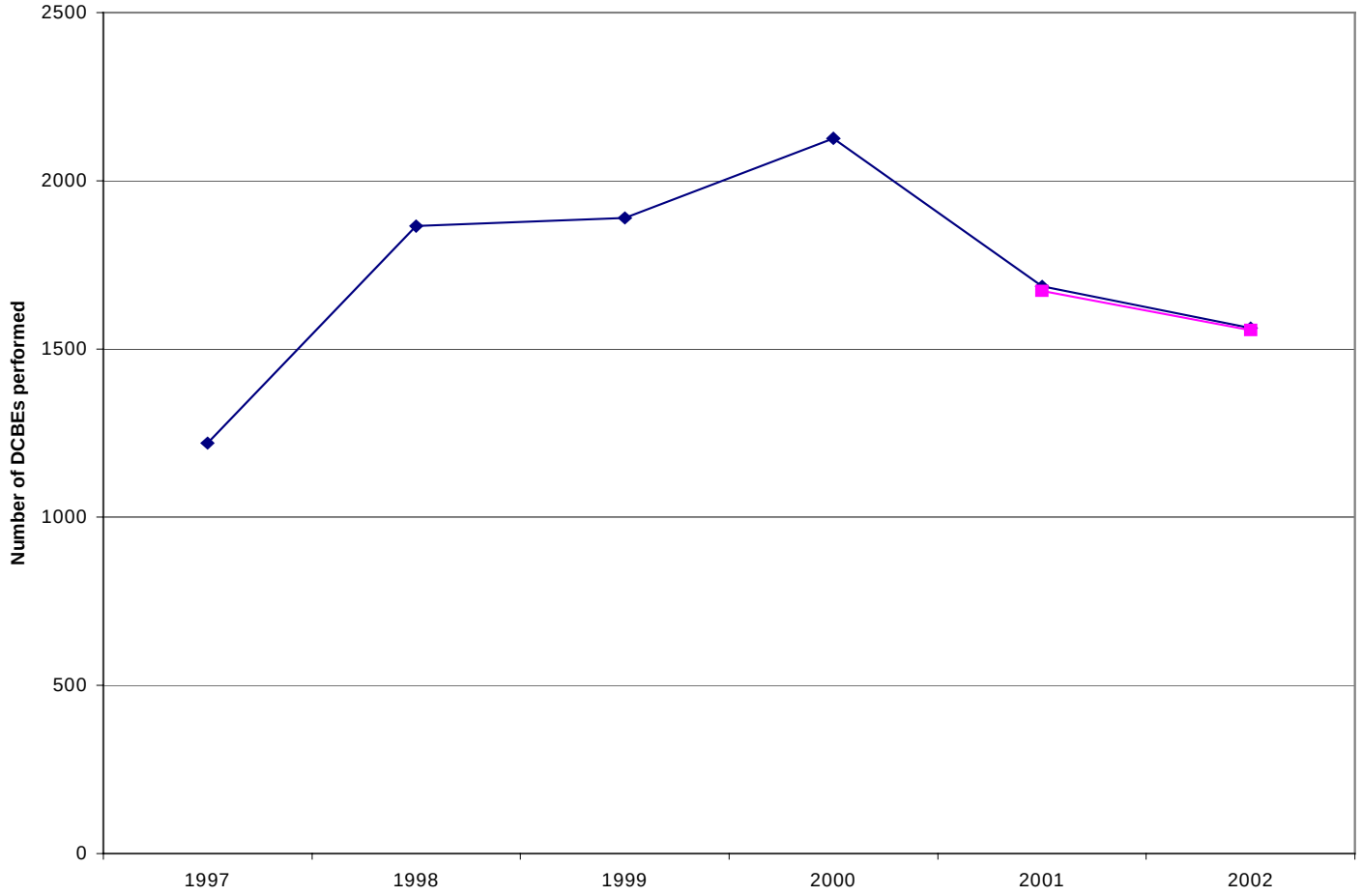


Figure 6.2.15 DCBE activity at Warwick Hospital (by year)

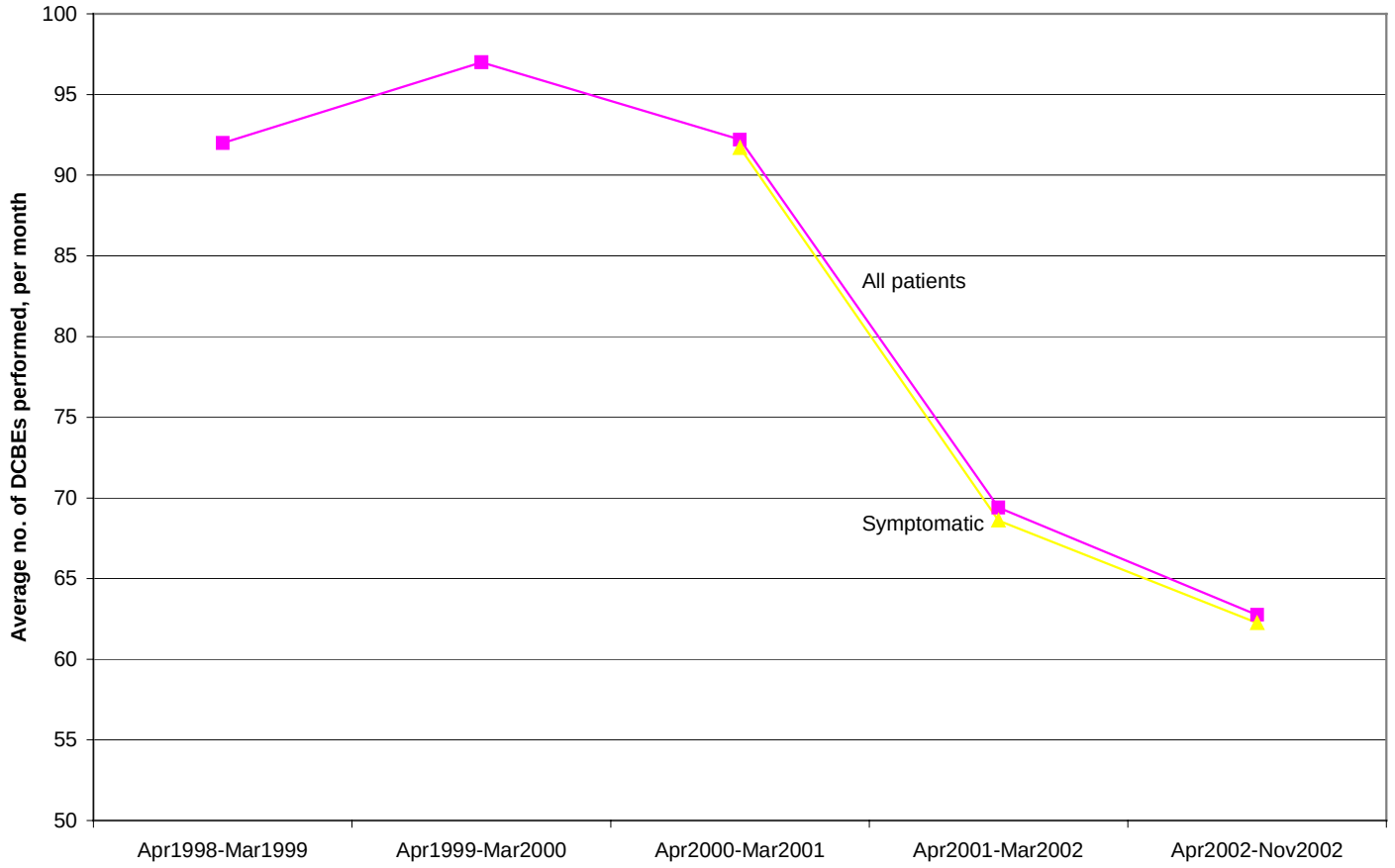


Figure 6.2.16 DCBE activity, George Eliot Hospital (by year)

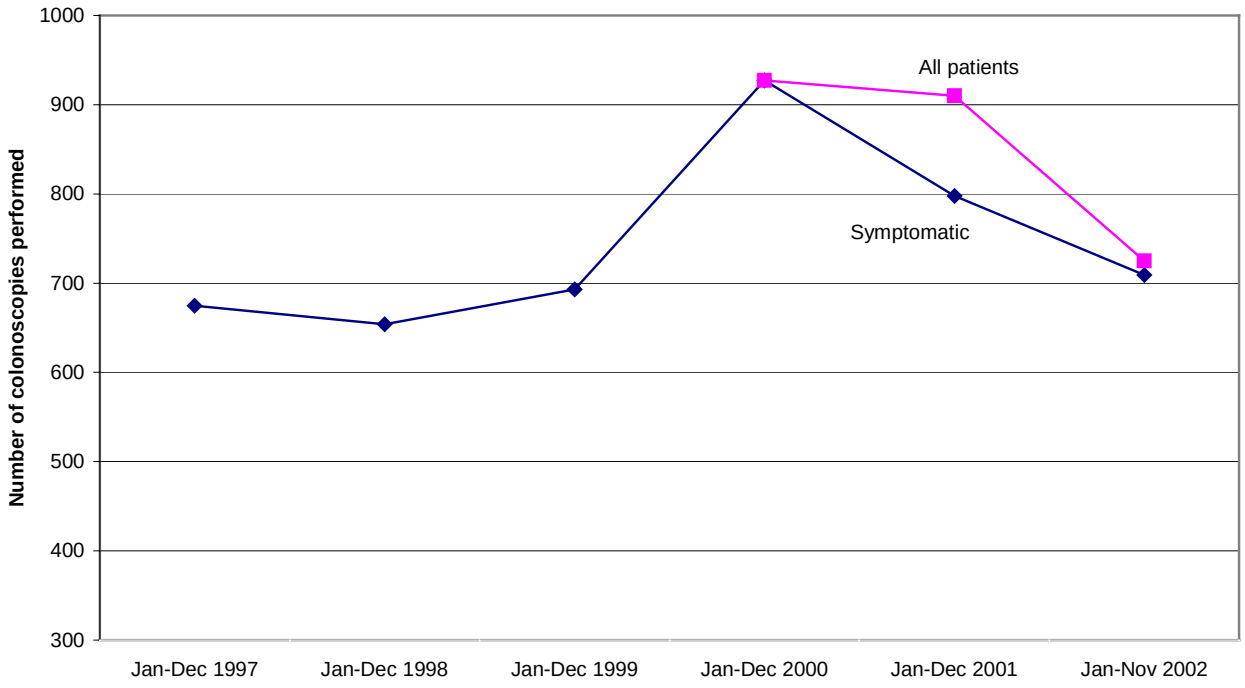


Figure 6.2.17 Waiting list size for DCBE at Ninewells Hospital (by quarter)

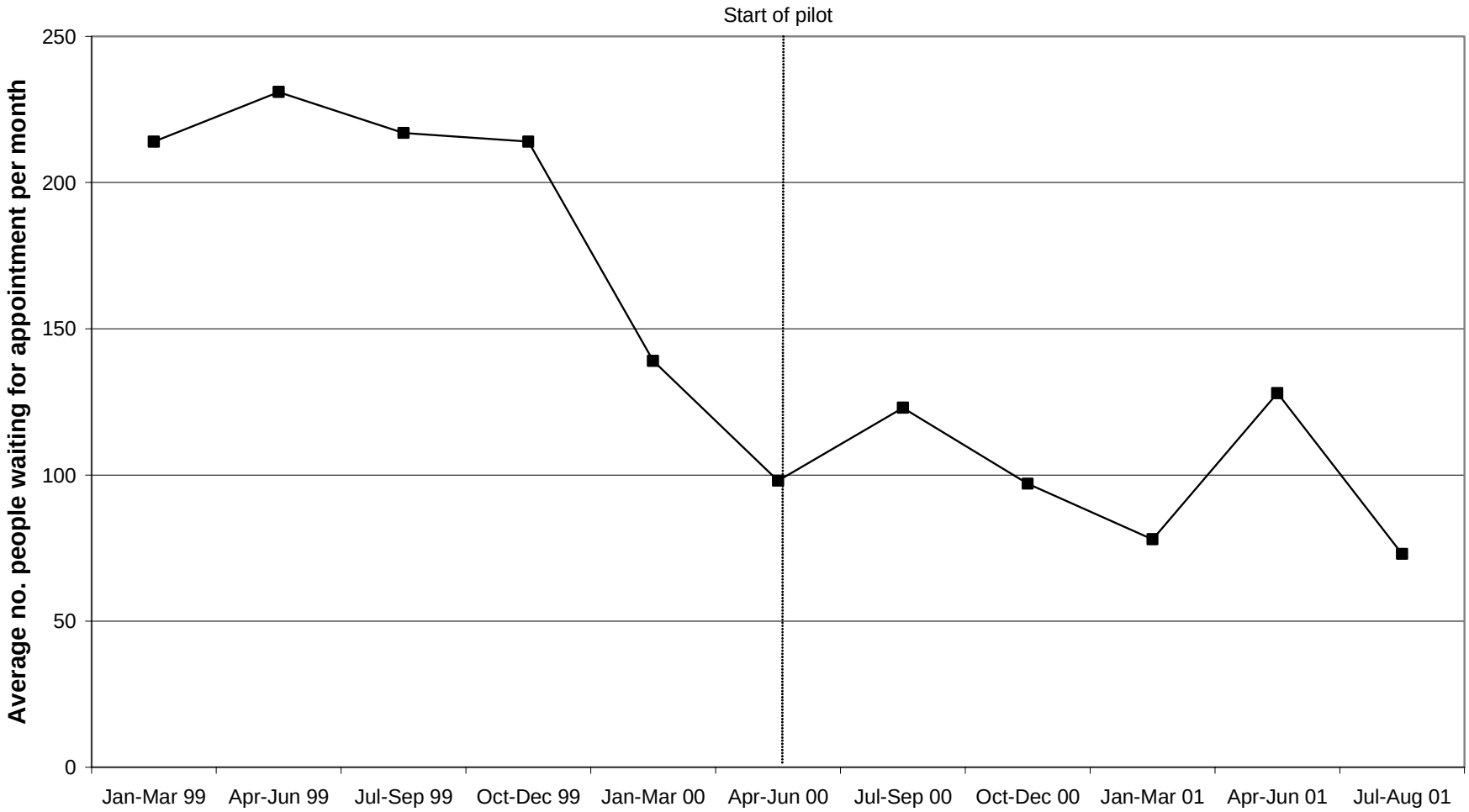


Figure 6.2.18 Waiting times for DCBE at Aberdeen Royal Infirmary (by quarter)

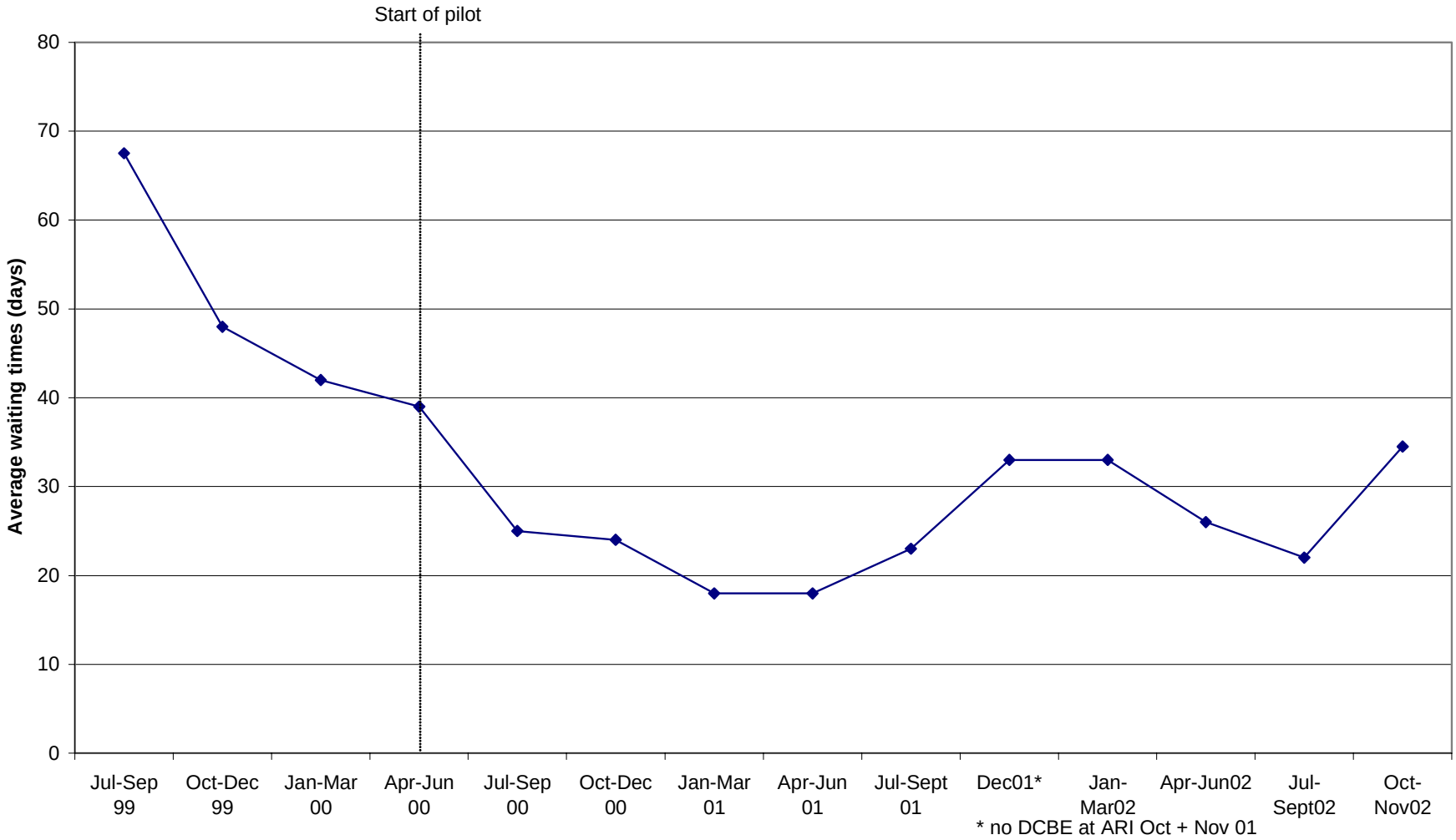


Figure 6.2.19 Waiting times for DCBE at Victoria Hospital

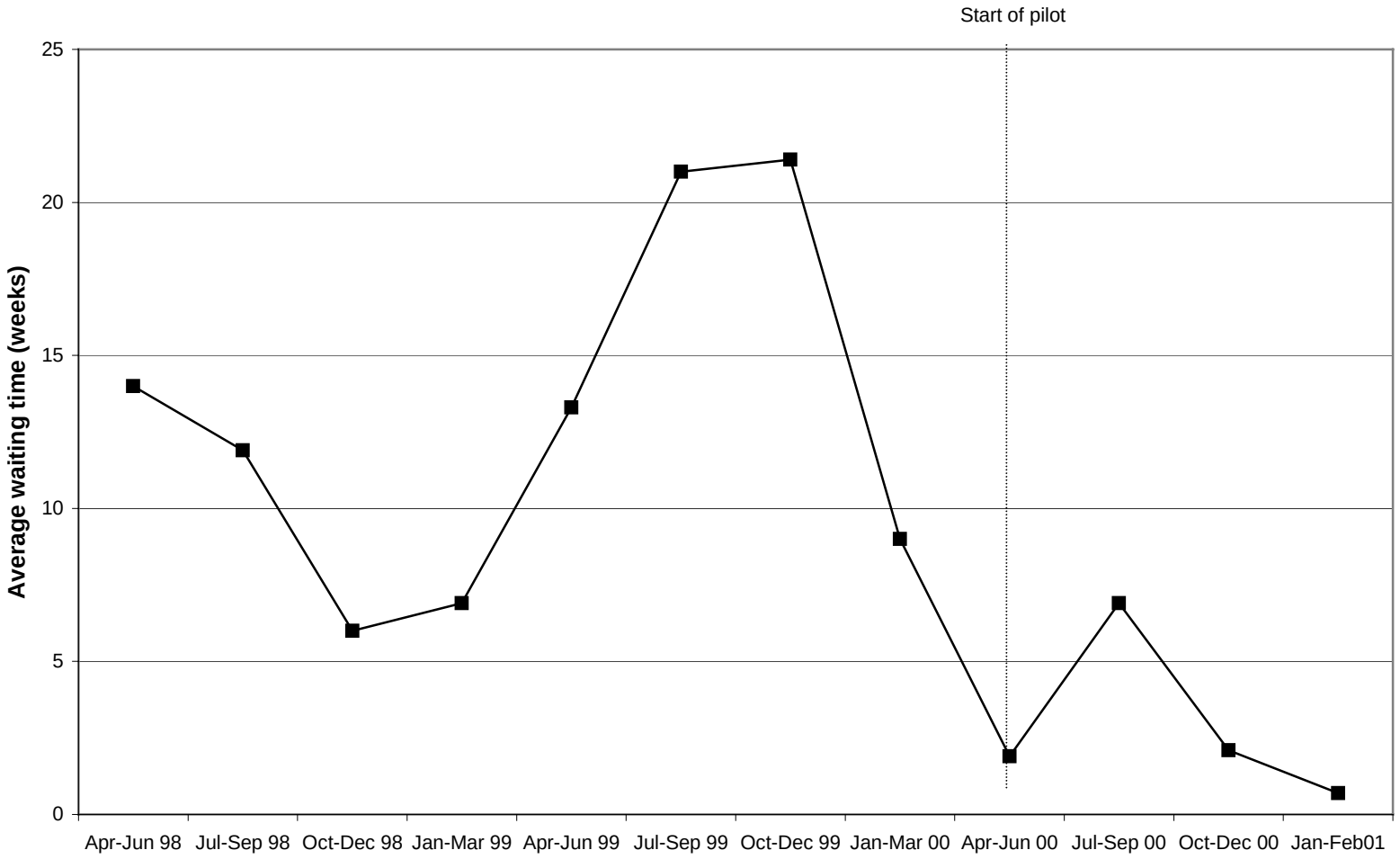


Figure 6.2.20 Average DCBE waiting time at Walsgrave Hospital (by year)

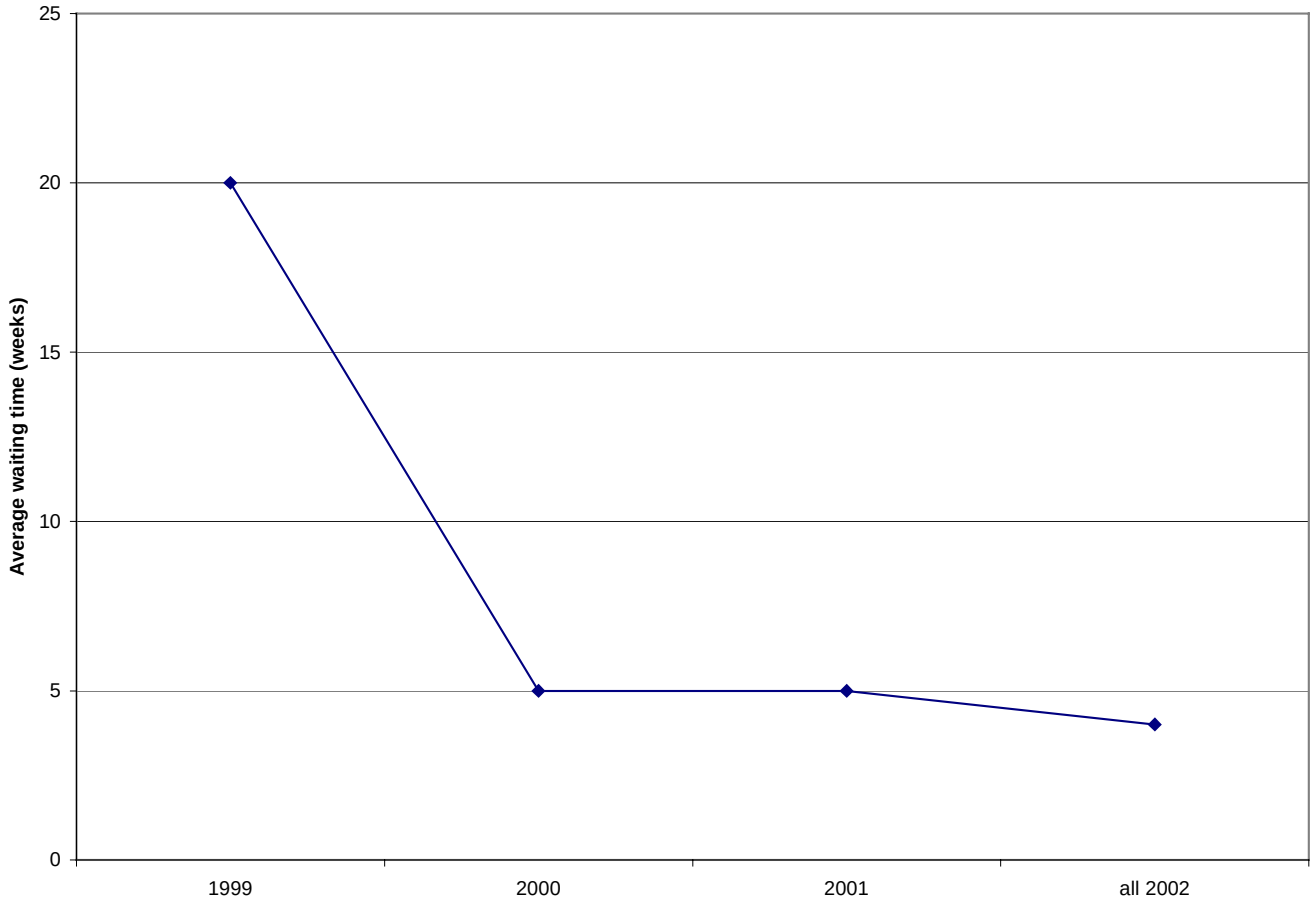


Figure 6.2.21 DCBE waiting times, Warwick Hospital (by year)

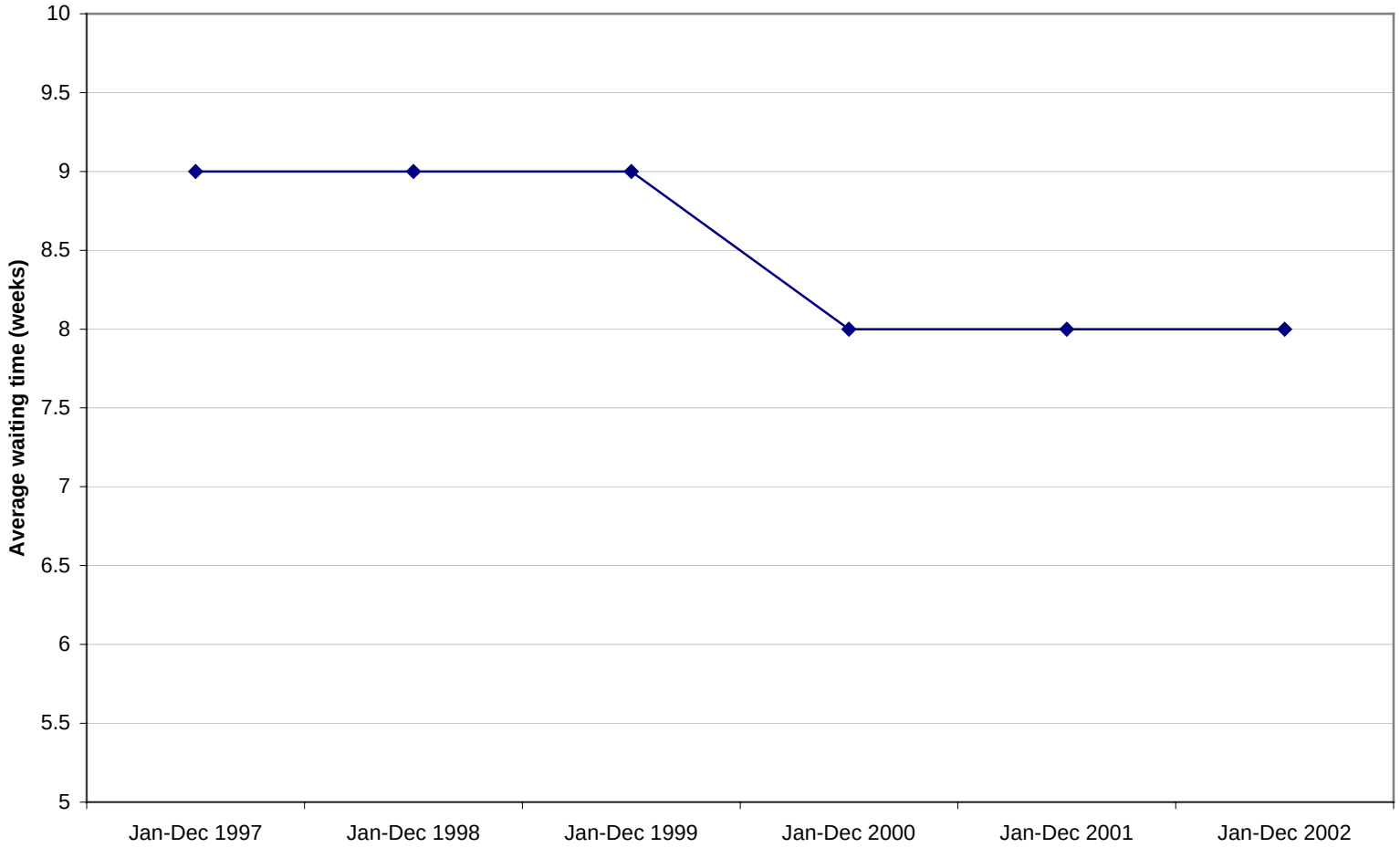


Table 6.2.1 Medical & Surgical GI Services according to Trust in Scottish Pilot site

Trust	Hospitals with Medical /GI Service	Undertaking Pilot Colonoscopy	Medical and Surgical GI Services Provided by Hospital				
			Colonoscopy	Colorectal Surgery	Out-patients	Other Services potentially affected by Pilot *	
						Medical	Surgical
Grampian NHS Trust	ARI, Aberdeen	Yes	Yes	Yes	Yes	ERCP, oesophageal Ix, endoscopic ultra-sound, pancreatic function tests, breath tests	
	Dr Gray's , Elgin	Yes	Yes	Yes	Yes	ERCP, gastrostomy	
Tayside NHS Trust	Ninewells,Dundee	Yes	Yes	Yes	Yes		
	PRI, Perth	No	Yes	Yes	Yes		
Fife NHS Trust	Victoria, Kirkcaldy	Yes	Yes	Yes	Yes		
	Queen Margaret, Dunfermline	No	Yes	Yes	Yes		

* mentioned by consultants

Table 6.2.2 Pilot colonoscopy lists by Trust in Scottish Pilot site

Trust	Target population (50-69 years) invited for screening	Period of invites (months)	Hospital	Av. No. patients undergoing colonoscopy per month	Pilot Colonoscopy				Non-Pilot endoscopy/colonoscopy
					No. lists per week scheduled[1]		Usual no. patients per list	No. Pilot patients scoped in routine lists (per month)	No. non-Pilot patients scoped in Pilot lists (per month)
					Surgeons	Medics			
Grampian	112,046	31	ARI Dr Gray's	26-27 6-7	3 (orig. 2) 1	0 0	3-4 3	0 (2) 1	1 –2 (6) 6
Tayside	90,193	24	Ninewells Perth	34 0	1 0	1 0	5 -	Occasional.[2] -	0 -
Fife Acute Hospitals NHS Trust	78,251	25	Victoria Queen Margaret	33 0	2 0	0 0	4 – 6 -	2-5 -	Very occasional. -

[1] Some lists cancelled due to unavailability of colonoscopist, including unfilled posts and holidays
[2] Including up to one routine list per month, which, if cancelled, may be used for Pilot patients

Table 6.2.3 Change in demand for &/or Provision of Colonoscopy for Symptomatic Patients Since Start of Pilot

Change in demand for &/or provision of colonoscopy for symptomatic patients					
Pilot Site	**Trust**	**Hospital**	**Subjective**	**Objective***	**Reason**
Scotland	Grampian	ARI	Yes (physician) Yes (surgeon)	Yes	"Part of long–term trend" 'Increasing trend established well before start of Pilot, probably because of fewer Ba enema lists, more gastroenterologists in post & increased awareness of greater potential (biopsies etc.) of colonoscopy vs. Ba. Enema etc.' "Awareness" "Patients and GP's aware of importance of colonic symptoms and therefore referring symptomatic patients" "Introduction of direct access"
		Dr Gray's	No	Yes	
Scotland	Tayside	Ninewells	No (physician) Yes (surgeon)	?Yes	Part of long–term trend – "General increasing acceptance that colonoscopy better than barium enema" plus" more comprehensive guidelines for the use of colonoscopy plus "increased awareness due to Pilot
		PRI	No	_	
Scotland	Fife	Victoria	Yes (physician)	Yes	"Use of colonoscopy rather than Ba enema as investigation of chance" "Possibly increased awareness but not sure whether this is due to Pilot or not"
England	Walsgrave	Walsgrave	Yes (surgeon) Yes (physician)	_	
England	Walsgrave	Warwick	Not sure (surgeon) Yes (physician)	_	For symptomatic FOB negative patients
England	George Eliot	George Eliot	No (surgeon)		

*Yes=evidence of upward trend in symptomatic colonoscopy activity since start of Pilot and/or increase in waiting times for symptomatic colonoscopy without reduction in activity

Table 6.2.4 Change in workload in out-patient Clinics

Pilot Site	Trust	Hospital	Pilot patients seen in Ops				Increased referrals for non-Pilot patients		
			MOPD/GI Y/N	MOPD/GI Reason	Y/N	Surgical Reason	MOPD/ GI	Surgical	Reason
Scotland	Grampian	ARI	No	But a few IBD patients added to MOPD lists'	No		No	Yes	"Awareness of both patients and GPs"
		Dr Gray's	Yes ~ 2/week (5mins ea.)	"Discuss results of colonoscopy, surveillance - investigate for occult anaemia"	_		No	_	
Scotland	Tayside	Ninewells	Yes ~ 2/week (10-15 mins ea.)	"Patients with CA or CA polyps or some with polyp removal seen at OP clinic to give result"	Yes 1-2/wk	'CA, including CA-polyps, and unusual histology'	No	Yes (probably)	
		Perth	-		-		-	-	
Scotland	Fife	Victoria	Yes ~2/week	"Cancer, polyps, IBD, other pathology"	_		Yes	_	'Threshold to refer has reduced as expectations rise'
England	Walsgrave	Warwick	No		No	Time set aside to discuss polyps	-	-	
England	Walsgrave	Walsgrave	No		Yes	Ca patients	No	Yes	Lower threshold for referral
England	George Eliot	George Eliot	-		Yes		No	-	Reduced number of urgent referrals from GPs

Additional comments:

"As difficult polyps & carcinomas are detected, increase in follow-up"
"No additional time given to accommodate these patients"
"GPs of patients with inflammatory bowel disease asked to refer back to OPs"
"Inflammatory bowel disease detected by surgeons referred to physicians"
'OP workload due to Pilot likely to increase with time due to follow – up of patients with polyps and surveillance of those with treated cancer, as well as cumulative affect of pathology found at colonoscopy'

Table 6.2.5 Workload in Other Services

Pilot Site	Trust	Hospital	Impact on Medical Inpatient Services		Impact on Surgical Inpatient Services		Impact on Administration Duties*			Impact on Secretarial Duties		
			Y/ N	Reason	Y/N	Reason	Medics Y/N	Surgeons Y/N	Reasons	Medics Y/N	Surgeons Y/N	Reasons
Scotland	Grampian	ARI	Y	Those with cancer need earlier (medical) assessment	Y	"Lack of operating time, facilities & surgeons" "Cancers are being dealt with at the expense of other debilitating illnesses"	Y 4-5/wk	Y 6h/wk	"Checking suitability & safety issues for a significant minority of patients" "Recurring meetings locally & nationally" "Major secretarial needs"	Y	Y	"Only half of dedic secretarial posts currently filled" "N to book, arrange… more discharge lett
		Dr Grays	N	-	-	-	Y ½ h/wk	-	-	Y	-	"Dictation"
Scotland	Tayside	Ninewells	N	-	Y	"Increased number of operations" "Beginning to increase waiting times for surgery	Y	Y (some)	"Dictation"	Y	Y	"One secretary to t colonoscopy & pol reports for Pilot" "Secretary required send letter, pull not etc."**
Scotland	Fife	Victoria	N	-	-	-	Y (++)	-	"Checking safety issues eg safe to scope & if HD, COAD etc, may have to see in clinic first, writing to GP if patient doesn't attend, letters to patients GPs, including clinic letters	Y	-	***
England	Walsgrave	Warwick	N	-	Y	"More major bowel surgery/polyp recurrences	Y	Y	Appointments, correspondence, telephone enquiries	Y	Y	-
England	Walsgrave	Walsgrave	N	-	Y	-	Y	Y	Pilot project team meetings	Y	Y	-
England	George Eliot	George Eliot	-	-	Y	More bowel surgery	Y	Y	-	-	N	-

* Increase in administration for consultant as result of Pilot, including dictating letters etc.
** One half time secretary requested & provided (to assist Screening Nurse)
*** No additional secretarial support provided by NSD

Table 6.2.6 Pathology Activity* in Colorectal Cancer Screening Pilot in Scotland

	Tayside University Hospitals NHS Trust	Fife Acute NHS Trust	Grampian University Hospitals NHS Trust
Apr-Jun2001	70	137	353
Jul-Sept2001	65	167	233
Oct-Dec2001	76	124	230
Jan-Mar2002	86	28	343
Apr-Jun2002	56	93	278
Jul-Sept2002	15	7	331

* all pathology tests (polyps and other biopsies, and following resection)

References – Chapter 6

Atkin WS, Saunders BP. Surveillance guidelines after removal of colorectal adenomatous polyps. *Gut* 2002; 51 Suppl 5:V6-9.

National Services Division, Common Services Agency. Implications and Options – Colorectal Cancer Screening. NHS Scotland; 2002.

.

7. Stakeholders, Organisation, Management and Information Systems

Chapter Summary

Context: Approach to planning and implementation of Pilot

- Both Pilot sites recommend formal approaches, for example using PRINCE type methods, for implementation of screening programmes or their Pilots. The English Pilot used these techniques successfully and, retrospectively, stakeholders in the Scottish Pilot recommended these methods for roll-out although they had used networking and informal methods for implementation in their own Pilot site.

Operational management processes (Quality Management):

- Internal audit was conducted in both Pilot sites, although not used as a planned systematic management tool in either Pilot site. We recommend audit procedures continue
- Quality assurance of colonoscopy was a persistent focus of discussion throughout the Pilot and appears to have contributed to favourable outcomes
- Quality assurance and accreditation systems for histopathology of colon samples will need further investment before any roll-out and should be driven at a UK national level.
- Capacity issues will always be present even in a fully costed service; the ability to vary rates of despatch and destinations of kits is vital.
- Protocols should be constructed so the end point of screening is clear to all service providers. In the colorectal cancer screening Pilot responsibility for the process of transition into treatment was not well defined.

General management issues

- Colonoscopy capacity issues must be addressed before roll-out; there is no spare capacity in the system that can be utilised.
- Since colonoscopy services are already stretched, colorectal cancer screening will impact on symptomatic services.
- The need for clerical functions related to patient tracking, especially through the interface between FOB testing and colonoscopy was underestimated by both Pilot sites
- Attaching nurses to screening centres where localities permit provides services with adequate cover for sick and annual leave. Centralisation improved communications both internally and externally and provided valuable informal feedback to screening centre

Human resource management issues

- Models of service for colorectal cancer screening comprising dedicated colonoscopists can be envisaged but these are likely to be staffed by colonoscopists drawn from the Nursing or Allied Health Professions as well as medically qualified colonoscopists.
- Where a centralised screening nurse service is not possible, it may be better practice to integrate the screening nurse function within local specialist (Macmillan etc.) cancer nurses' role to prevent the degree of professional isolation expressed by nurses in the Scottish Pilot.
- Both centres identified the need for a data specialist, most intensively in Scotland. This role, although absent in both Pilot sites should be filled by someone who could also be responsible for internal audit. In practice both Pilot managers undertook an audit role but it may be more efficient to have another post reporting directly to the Pilot Managers.

- Anxiety was expressed at the end of Pilot about the availability for skills training for all stages of screening including colonoscopy, and the potential for existing training facilities to provide volume of input necessary to roll-out CRCS.

Pilot - broad issues

- The end point of screening should be at the end of examination of colonoscopy specimens. In the Pilot, it was anticipated that screening would end at staging but, in practice, staging was sometimes delayed until resection. Pathologists involved with the Pilot indicated they would consider it appropriate to have a field in the IS system forcing a decision (malignant/not malignant) at the end of colonoscopy.

- Explicit and detailed Human Resource plans for the end phases of the Pilot must form part of initial Service Level Agreement between Trusts and National Screening Offices.

Information Systems

- The Information Modelling process was a worthwhile investment

- If nature of local IT contracts forces departures from the Information Model, the implications must be explored before starting to develop IS systems.

- The Information System that developed had appropriate paper-based elements. These should not be regarded as of less importance than the computer-based systems and should be included in future information quality management.

- Web based solutions were appropriate for the Pilot but where Trust servers are remote and not connected by broad band, local servers should be purchased for screening units.

- All data entry, especially by commissioned clinical services such as pathology and colonoscopy, should be via browser-based systems

UK Wide Surveys

- Although response rates placed limitations on the generalisability of results, respondents echoed the concerns of clinicians within the Pilot about capacity to extend colonoscopy.

- Rates of DCBEs within the Pilot were such that survey respondents were more confident that demand could be met.

- Concerns regarding staff vacancies were raised, echoing evidence from Royal Colleges about medium term skills shortages of both colonoscopists and pathologists

Perspectives of primary care personnel and invitees

- Screening for colorectal cancer is considered favourably by invitees and primary care teams

- Amongst all groups of invitees there are high proportions of people who indicate they would choose to undertake screening in the future

- Most primary care personnel believe FOBT screening is a very worthwhile activity and that a national programme should be given very serious consideration, provided it cam be adequately resourced

7.1 Organisation and Management

7.1.1 Aims

A key aim of this part of the evaluation has been to identify and explore organisation, planning and development of the screening programme, quality assurance mechanisms, infrastructure consequences and strategies for coping with these, and associated factors such as human resource management and training.

A secondary aim has been to assess the generalisability of these issues in other UK locations, and to develop recommendations on the conduct of UK CRC screening should evaluation of the Pilot make this appropriate. Finally, an aim which has emerged during the study, has been to examine the role of 'piloting' of a health programme prior to decisions on roll-out, and to develop recommendations for the conduct of such Pilots.

7.1.2 Methods

Three methods were used to gather relevant information.

1) *A series of interviews were held with key stakeholders (managers and clinicians) at the beginning and end of the piloting process (2000 and 2002). This enabled capture of prospective and retrospective views, and therefore the learning process in the Pilot sites.*

An initial sampling frame and list of interviewees was established following an iterative process that included widespread consultation (Strauss, 1998). This sampling frame included individuals from Trusts, the Pilot screening units and national personnel directly involved with the Pilot at both stages, although because of staff movement and changes in responsibility over the 2 year period the two samples were not identical. Interviews were conducted using a semi-structured thematic framework which was adapted slightly for the retrospective interviews. Interviews were recorded, with the consent of the interviewee. A number of mechanisms were used to limit bias and ensure validity of analyses as follows: (a) separation of textual analysis from interviews (data collection), with different researchers undertaking these tasks; (b) testing of formative and summative analyses for face validity with the data collector; (c) revisiting themes identified in the formative analysis during second interviews; (d) feedback of relevant summative findings to respondents.

2) *Document analysis: where appropriate relevant written material and documents were used to validate and inform on the issues identified in these interviews.*

Systematic collection of written materials and documents relating to meeting (eg minutes, reports) was set in place. Items were catalogued centrally. An initial extraction of themes was undertaken, and used to further validate the thematic frameworks used for interviews.

3) *A survey of key professional groups (i.e. radiologists, pathologists and colonoscopy services) was undertaken to explore the generalisability of some of the key issues that had emerged during the interviews.*

Three questionnaires were developed for key Trust staff groups and departments who might be directly involved in any roll-out; one for Radiology Departments, one for Pathology Laboratories, and one for Colonoscopy Services. The questionnaires were based on data emerging from the stakeholder interviews, particularly views on workload and impact on routine services. Where it appeared that staffing and facilities problems would be a significant constraint on roll-out, the survey questionnaires were designed to assess their likely impact. All questionnaires were piloted before use. Care was taken to ensure that the main evaluation survey questionnaires were harmonised with those used by the National Services Division in Scotland for a survey of all non-Pilot trusts to examine potential manpower/capacity and training issues associated with any potential Scottish roll-out.

Full details of the methods used for data collection (including interview sampling frames, thematic frameworks used in interviews, methods for minimising bias, UK survey samples etc) and methods used for analysis are presented in **Appendix A5.1.**

7.1.3 Results

For the prospective interviews, a total of 51/72 identified stakeholders were successfully interviewed; 8 individuals declined to be interviewed, 7 individuals referred the interviewer to others who they considered were better able to contribute, 1 person was not available after several attempts, and 5 individuals were not approached for various reasons. For the retrospective interviews towards the end of the Pilot, a total of 41/46 interviews were conducted; 5 individuals were either unavailable or refused to be interviewed for the retrospective interviews.

Full details of respondents are shown in **Appendix A5.1.**

A rich picture of the process of implementation of the Pilot, together with key organisation and management themes, emerged from the stakeholder interviews and examination of written materials and documents. This is documented in greater detail in **Supplement S5**. A formative analysis of interview material, following the initial prospective interview round, is presented in **Supplement S** The main findings of the final summative analysis are provided below, with a more comprehensive text in **Supplement S6**.

Certain planning assumptions had been made before the Pilot was initiated (Garvican et al, 1998). The two Pilot sites could use these assumptions to plan and organise the screening programmes in their localities, but they also had to introduce further developments as judged necessary.

A number of themes continued as matters of debate throughout the length of the Pilot, and remained issues that need further discussion at the end of the Pilot. Some of these relate solely to the individual localities of the Pilot itself, whereas others also have relevance for roll-out. The latter were explored in the national surveys.

7.1.3.1 Context: Approach to planning and implementation of Pilot

A key finding from both prospective and retrospective interviews was that the Pilot sites differed in the way in which the Pilot was initiated and the way in which management structures developed; this was closely related to the context in which the Pilot sites were set up. In Scotland, the health services are a close knit community, both geographically and professionally; this lends itself to informal networks and this networking is perceived by many to be an effective mechanism for development of new services. In contrast, in England the Trust chosen for piloting adopted very formal methods of project implementation for planning and implementing a service (Prince Methodology). Thus, the Scottish Pilot chose informal management methods and the English Pilot site followed the formal processes that were common practice within the Trust. Conversely, when it came to development of the information system, Scotland was bound to a formal development process, whereas the English site chose an evolutionary approach (this is discussed in greater detail under Information Systems, section 7.2). However, both sites were dependent on the enthusiasm of local clinicians in planning and implementing the screening programme.

A further feature of the internal local of the Scottish Pilot was the initial lack of involvement of senior Trust managers, with assumptions that clinical leaders were doing all that was necessary to progress the Pilot. Almost the exact opposite situation existed at the English site, where clear and very structured lines of reporting were put in place at the outset and leadership was perceived as a dual partnership between the lead clinician and Trust managers. Over the duration of the Pilot, both sites shifted somewhat towards the opposite approach. However, retrospectively there was enthusiasm for the more formal system of implementation from most interviewees. With hindsight senior managers in Scotland acknowledged that some of their more difficult issues could have been alleviated had line management been clearer and Trust management structures been stronger at the outset. In contrast, within the English site it was acknowledged that the centralised, formal approach adopted meant that there was less complete ownership of the screening Pilot by some clinicians at partner sites.

Thus, as the Pilot sites developed Scotland perceived the advantages and necessity to formalise their systems. England meanwhile, having reaped the benefits of the more formal approach, recognised that

the constraints of this system produced a rigidity which could be relaxed to progress development of systems.

7.1.3.2 Operational management processes (Quality management)
At the outset, the problems of quality assurance were perceived to be related to the testing of the kits and the subsequent diagnostic tests. Care was taken to discuss protocols for these two processes in both Pilot sites and the importance of documentation and protocols was acknowledged by both senior clinical and scientific managers and their staff. It was only after both Pilot sites had started that the implications of quality assurance for other systems began to be appreciated.
Some of the quality management issues arising from the Pilot sites were not foreseen in the planning stages. In general, many of these issues related to communications between different stakeholders. Many stakeholders referred to the usefulness of the Pilot in this respect and many shared the comment that it had been more complicated than they at first supposed. Internal audit was largely instigated as a response to a concern and was not used as a systematic management tool in either Pilot. The audits conducted during the Pilot should be continued.

In the retrospective interviews, many of the stakeholders also identified the potential importance of the Cancer Networks in supporting screening. Their role was seen as highly influential, particularly in setting and achieving quality assurance goals. Another key influence identified in the retrospective interviews was local ownership of aspirations, targets and standards.

Protocols and joint working practices
Although at the outset of the Pilot there were concerns about protocol overload, this proved to be a useful feature of the start up process. With the benefit of hindsight many of those interviewed commented on the usefulness of a shared approach to developing data sets, pathways and protocols at the outset. Meetings held for this purpose appeared to cement relationships between key personnel and also enabled the perspective of each Pilot site to broaden, although these early advantages of sharing seemed to be lost as the Pilot progressed.

- For future Pilots, setting up speciality specific staff groups can provide a useful method of inter-site learning and identifying common problems, even if by simple communication means such as teleconferencing.

Quality indicators and standards
There was universal agreement amongst stakeholders that there were too many quality indicators. However, it was also acknowledged that this was perhaps necessary for piloting, and that at the end of the Pilot a consensus would be easier to reach about reduced sets for roll-out.

- Common indicators were agreed across both sites.

Laboratory Quality Assurance (QA) processes
The screening centres had to provide a laboratory for processing and reading the completed FOB test slides. External quality assurance systems were not in place for this. Readers in the Pilot site laboratories had to become experienced in the FOB testing activity, as did the more senior staff taking clinical responsibility for reporting of results. Because there were no existing standards for quality control of large scale FOB testing in the UK context, both Pilot sites designed their systems from scratch.

Quality control methods were introduced from the start; the repetitive nature of the task of reading kits was recognised and planned for by both Pilot sites. Both laboratories recognised that enforced limitation of kit reading time was a necessary measure. There has been some debate within the Pilot about the best method of reading kits. England used two readers to assess one kit, in Scotland double reading did not take place.

Laboratory process measures, including data on throughput, profiles of results, numbers of positives etc, also formed an important part of overall quality assurance; several quality control issues, including interpretation of results, have arisen as a result.

Colonoscopy services
A key standard was the time between a positive FOBt result and colonoscopy; this was set at 2 weeks for the Pilot. However, closer examination of several issues may have suggested caution, including: current capacity and local issues eg availability of support staff at local Trusts; clinic arrangements for additional colonoscopies; speed of information flow within the system (this was unknown at the time of standard setting); and logistical issues of pace of return of FOB test kits. Other, unexpected events also adversely influenced actual colonoscopy waiting times. These included:

- the numbers of polyps disclosed for some patients, considerably lengthening time for each examination,
- the amount of paperwork required by the Pilot,
- higher than expected prevalence of positive FOBts in some areas,
- absence of some promised clinic slots,
- unexpected sickness of key personnel.

Although standards were set within the Pilot sites for time to perform colonoscopy, no similar standard was set for time to receipt of colonoscopy results. This was partly because it was recognised at the outset that pathology services were not only under pressure nationally, but also variably within the Pilot. Nurses therefore spent a considerable part of their effort chasing results and monitoring the flow of paper. Also, for patients with some pathology at colonoscopy, the speed at which a letter was despatched to their GP therefore varied.

The process for tracking colonoscopy results and despatching GP letters should be investigated as part of the revision of the QA and IT system

Completed colonoscopies
Concerns expressed during initial interviews about the demand for proof of completion were not repeated at retrospective interviews. This may be because the confidence of colonoscopists increased, and at the same time other issues absorbed reflective management time.

- The question of proof of completed colonoscopy has an impact on pathology services, as well as colonoscopy services, and needs further discussion before roll-out.

Radiology services
It was readily recognised that the standards set for DCBE were those that should have been in place anyway. None of the partner sites identified any difficulties in implementing protocols, once the difficult task of writing and negotiating them between partners sites was completed. Neither were problems of protocols anticipated for roll-out.

Radiologists' experience in general was that not as many DCBEs were undertaken as anticipated and numbers did not put pressure on the system. The pressure on radiology arose rather from the fact that those patients who presented difficulties to the colonoscopists also presented problems for radiologists. In some cases this led to these cases joining the queues for CTs and thus influencing waiting lists and total cost of screening.

Pathology services
Pathology services emerge as an important area of influence on programme quality; important factors include:

- the impact of the high number of polyps per case
- an acknowledged shortage of histopathologists
- intrinsic difficulties of classification (staging) of pathologies of which the service has less experience
- minimum data sets not yet fully adapted to the pathology that has been found in screening service (as opposed to symptomatic service).

All these factors may combine to place future services under strain. Indeed, the high number of polyps diagnosed has, in effect, increased the case load of this service by a factor of approximately five times the number of colonoscopies conducted. Pathology services can have an important area of influence on programme quality. They should be scoped as a multiple of the number of colonoscopies.

Work-flow and capacity management
A crucial part of the operations management of the Pilot sites was work-flow and capacity management. The Pilot sites were sensitive to colonoscopy waiting times within each Trust. More difficult to regulate, and therefore manage, was kit return rates. This was particularly acute over festivals and holiday periods. It can be expected that rates of despatch of kits will be better tuned in the second round of screening as knowledge of response rates on a micro level is acquired. This issue should be recognised as a regular item for process review within the FOBt service and within the information system itself.

While the screening Pilot did put additional pressure on the system, evidence from several sources suggests that some local services were suffering from completely unrelated capacity problems. In service conditions, using quality indicators at a national level alone to monitor local performance would have labelled some localities as a failing screening service. In fact, surgical and radiological services as a whole were struggling. In this situation, quality management mechanisms which include a dialogue with local commissioners become crucial, and the ability of screening to improve local quality is also important. Care was taken with the Pilot sites to involve primary care as little as possible, but it is important to include PCTs as local commissioners of these other services.

If colorectal cancer screening is to be managed and commissioned centrally, it is important that negotiation mechanisms are set up with local commissioners as part of any quality management strategy, and funding of key services such as additional capacity for colonoscopy and radiology does not become overly influenced by local priorities.

Outcome vs process measures
Initially both Pilot sites and the evaluation team considered outcome measures as important. As the Pilot progressed to the management of patients, however, their emphasis changed quite rapidly to process measures. In practice, ad hoc control processes led to a proliferation of personal systems as additional records were kept, outside the formal IT system. All reported that they would appreciate short term feedback loops inserted into the information systems. This feature was most obvious in Scotland, where the Pilot nurses developed their own paper-based systems driven by the need to manage process.

The evaluation team also identified a need for systems to ensure that all cancers are identified and recorded. The suggestion that under-recording may have taken place indicates that the Pilot site quality control process measures may be failing to identify patients with no record of a result following investigative procedures.

Assuring quality of datasets
The role of nurses in tracking data sets and local monitoring of quality issues was important. Serious consideration should be given to this in any job descriptions, but only if the clerical burden of this role is acknowledged and supported. The role of clinicians as well as clerical staff in validating data was also perceived as vital by managers of the Pilot sites, and this was a matter of team work.

Training and accreditation
The experience of both laboratories was that the variability in the returned FOBt kits and the amount of detail required within the laboratory could not have been predicted without the Pilot. At the end of the Pilot the Scottish Laboratories spend a considerable amount of time developing the Pilot protocols into a case for accreditation. This was held to have been a worthwhile exercise and of benefit in the context of colorectal cancer screening.

Another positive effect of the Pilot has been to raise awareness about the importance of training and accreditation for colonoscopy. Discussion of capacity issues relating to colonoscopists has underscored the lack of organisations able to train and accredit colonoscopists.

Links with local Trusts
Links with local Trusts also proved to be an essential component of quality management. Partially this was because IT issues crossed Pilot/ Trust boundaries. However, when problems occurred strong local links proved invaluable. These problems often revealed themselves through the quality management

framework, and when these were unravelled the solutions necessary were systems solutions that needed attention at Trust level.

7.1.3.3 General management issues

Management of capacity

Throughout the interviews there was a theme, repeated by many stakeholders within the Pilot sites themselves, that a major constraint on screening was the capacity in symptomatic services. All stakeholders had experienced the impact of pressures on colonoscopy services within the Pilot; some because they were dealing with anxious patients, others because they were negotiating with local services to find spaces or manage throughput. At the outset it was postulated that there would be an impact on radiology services and provision was made for extra DCBEs to be performed should colonoscopy be incomplete. In practice the anticipated volume of DCBEs was not reached. However, the logistics of failed colonoscopies caused concern as patients would need to undergo two bowel preparations, unless co-ordination of services was such that a same day radiology slot could be made available. In practice, it was observed that the most difficult group of patients for colonoscopy offered the most challenges for other diagnostic tests since these cases were most likely to have pathology such as diverticular disease or significant co-morbidities. A further point made about management of capacity by many interviewees from different perspectives was one of inefficient use of skill-mix, with more skilled staff carrying out less skilled tasks, a familiar situation in limited resource systems. Gaps in the information system, for example, absence of web-based data collection at points of service and failures in providing sufficient clerical support to Pilot nurses in remote locations, often resulted in highly skilled professionals spending time on routine unskilled tasks such as paper and patient chasing.

Models of Service

- FOB testing: Several interviewees speculated on the possibility of developing an industrial scale testing centre for FOB testing. For example, in Scotland, it was hypothesised that one unit could do all FOB testing supported by more local pathology and colonoscopy services.
- Colonoscopy: Many interviewees drew attention to the national shortage of qualified colonoscopists and the limited facilities currently available. Two solutions were proposed. First, there were no dissenters to the concept of increased training for nurse colonoscopists to further extend skills from flexible sigmoidoscopy, working under the supervision of a surgeon able to intervene in the case of an adverse event.
- Radiology services: Within the Pilot sites some DCBE services are provided by radiographers who managed examinations and reported jointly with radiologists. Although most discussion centred around the possibility of training nurses to perform endoscopy, respondents in these sites also raised the issue of training radiographers in endoscopy.

7.1.3.4 Human resource management (HRM) issues

Many of the human resource matters relating to the Pilot arose from the capacity issues discussed above. At the heart of these capacity issues are national shortages of key personnel; estimates by the Royal Colleges are that nationally 400 extra pathologists are needed currently and over 500 radiologists, and similarly, surgeons from most specialities are also in short supply.

Roles of professional staff

At the start of the Pilot, the majority of HRM concerns voiced in prospective interviews centred on the perceived shortage of colonoscopists and/or availability of facilities for colonoscopists (where sufficient staff were available). These concerns remained throughout the Pilot. However, as experience grew within the Pilot sites, a shift of position of many medical staff occurred towards the idea of other professions easing the burden of shortages in colonoscopists and radiologists. One of the key individuals involved in initiation of the English Pilot is a champion for nurse endoscopy and there was local experience of an extended role for allied healthcare professionals. The need for an increase in both colonoscopists and colonoscopy facilities was clearly demonstrated within the Pilot sites by lengthening of waiting lists and by a capacity survey undertaken by the Scottish Health Board. The retrospective interviews confirmed the speculation in the prospective interviews.

Support staff

At the outset of the Pilot each site specified its own staff and skills complement. In both Pilot sites this was predicated on the delivery of FOBt kits and estimates of the number of positive tests that would require colonoscopy. A minimal number of support staff were specified at clerical level. A key result of this was that as the administrative burden increased, as information systems and activity monitoring

developed, the main responsibility for maintenance of many of the systems was added to the tasks required of individual members of professional staff. The massive data collection exercise involved in the Pilot therefore placed a serious administrative burden on clinical staff. This revealed itself in two ways, firstly the amount of incomplete data reported in the data sets and secondly in the retrospective interviews, especially the interviews with the nurses who spent a substantial amount of their time chasing paperwork.

- There was a consensus across both Pilot sites that the solution was two fold. Firstly, clerical assistance should be given a higher priority for investment, especially at local trusts. Second, IT systems should be specified to minimise duplication of paperwork.

Role of nurses

In both Pilot sites the screening nurses provided a vital liaison between the service and the patient, the service and the GPs and between the screening unit and symptomatic services, particularly local colonoscopy services. The use of nursing staff however necessarily differed in the two Pilot sites, dictated by geographical considerations. Within the English Pilot, although the nurses are employed as screening nurses, their role has become well integrated within the local services to which they are attached. It was acknowledged by several interviewees in Scotland that the English model was effective and, in particular, would prevent the degree of isolation expressed by nurses in Scotland. The team working aspect of a centralised service was identified as the key to success by the nurses. As a consequence the centralised staff in the English site were able to provide support for sick leave and annual leave.

On the question of whether the liaison nurses should belong to local trusts or the screening service, mixed opinions emerged. There were advantages of belonging to the local trusts, but equally there were advantages of belonging to the screening service. It was also observed that there was a strong case to be made for integration of roles, so for example, it was envisaged that Colorectal Specialist Nurses or other cancer nurses could take on the role of screening nurses where it was not feasible to have a centralised system such as that developed at the English Pilot. All the screening Pilot nurses talked about the importance of integration into the Cancer Networks on a day to day basis.

Training

Both Pilot sites gave serious consideration to training most staff at the outset of piloting. Inevitably there was staff turn over and cover for illness, maternity leave etc, throughout the Pilot and less thought had been given to induction and training for newly recruited staff. Pilot managers, in most cases recognised this and attempted personal inductions but documentation about the Pilot was not always readily available. This is understandable as the Pilot sites were seen as a one-off project but consideration should be given to a training pack for each site for the second round of screening.

7.1.3.5 *Other general issues concerning conduct of Pilot*

Screening programme endpoints/boundaries

At the outset of the Pilot, the commissioners in both England and Scotland set specific boundaries for the screening programme. These boundaries were informally defined by specifying the end point of the programme as “the point of diagnosis”. At the time of the prospective interviews many protocols and pathways had not been finalised. The issue of pathways and end points of the programme was therefore discussed mainly in the retrospective interviews, and the views of several members of the evaluation team were also sought on this issue. Following interviews, it became clear that the information pathway is likely to be incomplete with respect to patients that have a positive colonoscopy. Commissioners of the screening programme were clear that the end of the screening programme should be after colonoscopy. However, a majority of these outcomes for the screening programme have to be collected from data held within symptomatic services, and these may not relate to the diagnostic pathway. Thus, ad hoc datasets were developed within the Pilot sites. Because the information system only recognises endpoints which have sufficient clarity, it may currently fail to identify outcomes of the screening Pilot.

Clinician issues and concerns

In both prospective and retrospective interviews clinician issues remained focused on the question of the ability of local Trusts to absorb the extra cases generated by screening. Colonoscopists especially were already dealing with full lists and a backlog of cases at the outset. Although addition resources were available, these concerns did not abate.

A constant feature, throughout the Pilot, was the tension of the effect of piloting on symptomatic services. This was experienced most acutely by the medical personnel involved with the Pilot as the screening patients were added as another set of demands. General service issues, for example the acute shortage of pathologists in some areas, also tended to become exacerbated by the screening Pilot. A key clinical issue throughout related to the impact of those who need follow-up and this remains as an important issue at the end of the Pilot.

Within the retrospective interviews concerns relating to patients centred around two issues:

- the method of information giving, especially post colonoscopy, at times depended on local practice and it was hard to set standards in this area, even though some perceived the importance of including this aspect of the service in the standards set for screening
- the problem of ensuring equity of provision, particularly in terms of waiting times for colonoscopy, for patients attending different centres. There were marked differences in waiting times and the screening Pilot sites demonstrated that they could be sensitive to this issue by varying the invitations issues, either moving to another area temporarily or changing the pace of invitations issued (call process). Formal monitoring and feedback on current waiting times at booking for colonoscopy and for receipt of pathology results would help identify areas of tension.

7.1.4 UK-wide Perspective

Many of the issues identified through interviews with Pilot sites were then tested for generalisability through national surveys. Data from the stakeholder interviews, together with information on workload and impact on routine services in the Pilot sites, were used to develop questionnaires for key staff groups who might be directly involved in any roll-out. The surveys were designed to provide evidence on specific organisational and management issues identified in the Pilot sites. In particular, where staffing and facilities problems might be a significant constraint, the survey questionnaires were designed to assess the potential impact of these on national implementation of screening, and demonstrate the feasibility of possible steps to overcome them. Three questionnaires were developed; one for Radiology Departments, one for Pathology Laboratories, and one for Colonoscopy Services.

The main findings of the final analysis are provided below, with a more comprehensive description of methods and results in **Appendix A5.2**.

7.1.4.1 Colonoscopy services

Colonoscopists were identified from the JAG database and a postal survey of 221 Consultant gastroenterologists was conducted in November 2002. The low response rate (22%) means results must be interpreted with caution. Nevertheless, only a small minority (17%) considered that they had available capacity for extra colonoscopy cases. Free text comments supported the data gathered during stakeholder interviews. In summary, findings do appear to replicate the views of the Pilot sites:

- The vast majority of respondents believe that extra resources (staff, funding, equipment and space/rooms) are essential to cope with any extra colonoscopy and DCBE investigations.
- Many departments are already working at full capacity and any increase in workload will need to be resourced. Staff shortages exist already and there is great difficulty in recruiting staff (both medical and allied healthcare professionals).
- Different departments have widely different perspectives suggesting that local consultation and capacity estimations will be essential for roll-out.

7.1.4.2 Radiology services

A postal survey of 227 clinical directors of radiology services at hospitals in the United Kingdom was despatched in July 2002 with a reminder sent to non-responders in November 2002. Fourteen respondents reported their department as not applicable for this questionnaire and 105 questionnaires (53%) were completed.

Questions were posed based on the findings of the Pilot sites i.e. in terms of the resources needed to support 1-3 extra barium enemas per week. Nearly half (forty seven or 45%) considered they could absorb 1-3 extra barium enemas per week within existing lists with difficulty. Forty eight (46%) thought they would need extra lists, 43 (41%) extra radiographers, 36 (34%) extra radiologists and 13 (12%) extra equipment or rooms. When asked what other provisions they might require 4 (4%) added that they would need extra nursing support and 3 (3%) that they would need extra administrative or clerical staff.

There was no correlation between size of current workload and estimation of barriers to extra cases. The use of radiographers for DCBEs is confirmed as widespread with 87% of services using radiographers.

However, the evidence from this survey does underline the Royal College's concerns about vacancies with 68% of this sample reporting both consultant radiologist and radiographer vacancies. The discussion within the Pilot sites of the possibility of replacing colonoscopy with Spiral CT/ virtual colonoscopy was underlined by the survey respondents reporting that 30% use Spiral CT at present and a further 28% are developing this application. Currently, a median of 5% (maximum 50%) of total examinations of colon are done using this equipment. Free text comments replicated the concerns of the radiologists interviewed in the Pilot sites.

7.1.4.3 Histopathology services

A postal survey of 264 histopathologists based in hospitals in the United Kingdom was despatched in July 2002 with a reminder sent to non-responders in November 2002. Sixteen respondents reported their practice did not include colon resections and 128 questionnaires (52%) were completed.

A minority (30%) considered that their service had the ability to absorb the anticipated 1-5 extra cases generated by a screening programme. For the remainder, a median of 1.5 (IQR 1,2) extra consultant sessions were thought necessary to cover the additional workload. Around 50% of respondents also considered that Pilot site finding that extra staff were necessary for processing of specimens would apply also to their service. Concerns regarding human resources were widely raised as around 70% of respondents' departments have current staff vacancies and are reporting difficulties in recruiting pathologists (63%) and MLSOs (82%). Scottish departments were significantly less likely to report problems recruiting MLSOs than those in England, Wales and Northern Ireland although there is no difference in difficulty in recruiting pathologists. In response to questions about accreditation and quality management, a minority considered they would need to change their QA arrangements to encompass colorectal cancer screening.

7.2 Information systems

In evaluating the information systems, the research sought to assess the efficiency of internal information flow, as well as the efficiency of external flow (particularly provision of information to patients). We sought to explore whether information systems were set up in such a way as to provide optimum programme efficiency and enable continuous measurement of quality. This component of the evaluation also sought to inform system and training requirements for roll-out to other locations should this occur.

7.2.1 Methods

A Framework Approach (Ritchie, 1993) was adopted for this component of the evaluation. As a starting place the aims of the Colorectal Cancer Screening Pilot itself were used as the aims for the IS evaluation. Five steps were then taken: familiarisation, identifying a thematic framework, indexing, charting and mapping and interpretation (Pope, 2000)

The data collected for this part of the evaluation were in the form of recorded and transcribed telephone interviews. It was originally intended that two rounds of interviews, 'before' and 'after', would be undertaken to capture initial objectives and expectations and post-piloting systems, modifications, adaptations and experiences, as with the evaluation of organisation and management. In the event one round of interviews were conducted towards the end of the piloting period when stability had been achieved within the information system. Thus, the first round of interviews for organisation and management were used as the first two steps in the Framework Approach for analysis of the information systems i.e. familiarisation and identifying thematic frameworks. It should be noted however that the process identified a thematic frameworks for Organisation and Management that differed significantly from that identified when IS issues were explored. In addition, the sampling frame for the IS evaluation was identified during analysis of the organisation and management interviews. This sampling frame was confirmed after wide consultation with all those involved in the Pilot and with the National Screening Offices. All taped interviews were transcribed and subsequently indexed and charted. This latter process was used to test the validity of the original framework for the interviews by coding any data that was outside the thematic framework identified in a prior step.

Finally, members of the research team were also present at early meetings related to Information Modelling.

7.2.2 Definition of an Information System

The term "information system" can be applied in many ways. At the most informal level it could be a grapevine or network of colleagues. What it is not is a computer and it's associated software or a computer network. One very broad definition is that "an information system is concerned with the elements and activities of human communication used in purposeful human activity"(Stowell, 1994). Thus, in this report a clear distinction is drawn between computer systems and information systems and the examination of the colorectal cancer screening information systems includes the software, paper based systems and other communication systems developed to assist communications between clinicians, between clinicians and patients, between different information systems in the healthcare environment and between the Evaluation Group and the Pilot sites. A more comprehensive description/definition (Jayaratna, 1994), which clearly defines the five functions of an information system is:

- *the most efficient and effective means of identifying the "real" needs of the users;*
- *developing information processing systems for satisfying these needs;*
- *ensuring that the resulting information processing systems continue to satisfy changing user needs by the most efficient means of acquiring, storing, processing, disseminating and presenting information;*
- *supporting operational, control and strategic organisational issues;*
- *providing facilities and a learning environment for users and information systems specialists to improve the effectiveness of their decision model.*

As can be seen from this definition, the development of the Green Book[2] (Garvican, 1998) can be viewed as an integral part of the development of the information system, as can the commissioning process for the hardware and software used to support the system. The two definitions given above, both coming from the socio-technical tradition, were used throughout the analysis to reflect upon how far the aspirational definitions had been met during the piloting process. Jayaratna's definition is used as the framework for reporting the results.

Full details of the methods used for data collection (including interview sampling frames, thematic frameworks used in interviews) and analysis are presented in **Appendix A7.1**.

7.2.3 Results

Twenty eight stakeholders were identified as interviewees for the IS evaluation. Of these three were not in post at the time of the interview and, after consultation with Pilot Managers, these people were not contacted. One stakeholder (NHS Information Authority) was not approached following a specific request from several of those consulted. Twenty three taped interviews were conducted and one face-to-face interview was conducted, at which notes were taken but no recording made; and evidence was taken from the transcripts of interviews of two stakeholders identified within the Organisation and Management framework.

Full details of respondents are shown in **Appendix A7.2**, and full details of the main findings in **Supplement S7**. The key points arising from these are summarised below.

7.2.3.1 Using the most efficient and effective means of identifying the "real" needs of the users

Developing an information system requires a complex analysis of data and information needs and processes as can be seen from the definition of an IS. The colorectal screening pilot IS development started well, led by experts with knowledge of the methods and resources necessary to achieve a successful outcome. In particular, starting the process by requirements modelling involving stakeholders from both Pilot sites and the evaluation team was seen by all stakeholders as highly efficient and effective. External consultants were used for this initial phase of the development of the Information System and high levels of satisfaction with the outcomes were reported.

[2] *The Green Book is a document produced over a long period of consultation to identify the principal components of the screening service. It includes details of the rationale, the tests to be used, quality standards etc. This book was used as a starting place for the pilot sites*

7.2.3.2 Developing information processing systems for satisfying these needs

Constraints on the development, such as infrastructure, contractual arrangements with key providers, etc., were known but the effect of one key constraint, i.e. the limited resources available to the Pilot, was not fully appreciated at the hand over of the requirements model. Thus, although a full and complete IS was needed for operation of the Pilot the resources that were necessary to produce this system were constrained. The effect of this constraint was experienced in a different way in each Pilot site.

In Scotland, contractually bound to the CHI system, all the resources were committed to a front end system which delivered a call system that sent kits out. As experience was gained, paper-based systems were bolted on based on developing need. In time the Scottish IS evolved to include both inefficient ad hoc paper-based systems and, eventually, a compromise PC-based system. Despite this compromise, the Scottish system met the majority of needs of the Pilot but at the expense of an information blank period until extra resources were made available to catch up on data entry. In England the vision was holistic, as the information model has suggested, and an appropriate solution, using web-based technology, was developed. However, the resources which could be committed to the project were insufficient to complete to the timescale set by the piloting process. The timeline for the project is illustrated in **Figure 7.2.1**.

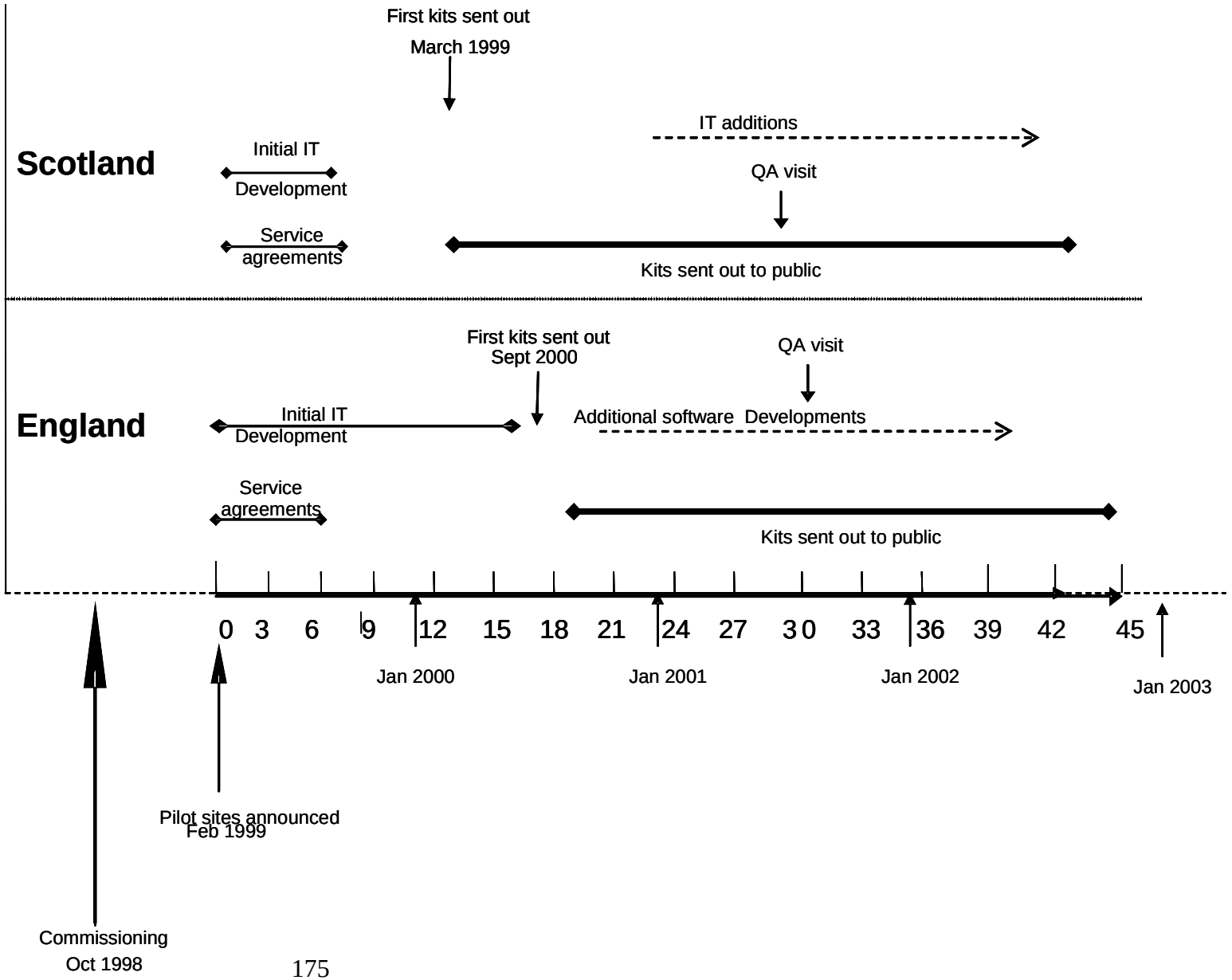
7.2.3.3 Ensuring that the resulting information processing systems continue to satisfy changing user needs by the most efficient means of acquiring, storing, processing, disseminating and presenting information

To the end of the Pilot, the English system remained constrained by two design issues, the speed of the operation of the (non-broadband) link between the server on which the software was mounted and the CRCS Unit, and increasing performance problems relating to data set size and archiving. In addition, data extraction from the English system, particularly for the evaluation team, was time consuming. The Scottish system was constrained by the non-systematic development and remained vulnerable to delays in transmission of paper-based data from source.

7.2.3.4 Supporting operational, control and strategic organisational issues

The implementation of the "front-end" of the system in Scotland, although appearing to be an IS issue driven by contractual constraints, is in fact a key issue for the screening Pilot. Both the first round of the evaluation of organisation and management and exploration of the IS issues revealed a deep division in thinking between stakeholders on the scope of a colorectal cancer screening programme. The implementation of the "front-end" only system in Scotland was made more feasible by a view held by many stakeholders that the scope of the pilot should be only concerned with FOB testing. The information modelling process clearly predicted that the screening programme extended beyond this point, and this has now been perceived to be the case, particularly for management of patients and their information, by most stakeholders concerned with the information systems.

Figure 7.2 1 Times of key events in pilot programme



In the event, a "call" system was produced but the clinical system that the information modelling process clearly defined was not produced. The need for this system rapidly became apparent but the systems then developed piecemeal, partly paper-based and partly on an unsecured software the "clinical system". The clinical system was vital to the safe operation of the screening process in risk management terms but the risk management of the software itself was bypassed. Thus, the potential for systems failure was built in at the outset because of systemic failings.

The evidence from the first round of management interviews and the IS evaluation made it difficult to continue to argue the case for a colorectal cancer screening programme with an endpoint of FOB test result. The evidence of the IS evaluation alone demonstrates that the diagnostic phase of colonoscopy is an integral part of the programme and that IS systems should be commissioned that have an endpoint at the point of receipt of pathology result following colonoscopy.

This should mark the point of episode closure for the screening programme and the opening of episode for the responsible clinician. Any additional tests or procedures performed during the wait for colonoscopy (or even preceding colonoscopy where there is a very strong clinical suspicion of malignancy) should fall within the records of standard clinical care. In addition IS systems should be commissioned which stand alone up to this point and then integrate with hospital patient administration systems. Both systems should be developed to share common clinical datasets such as Minimum Datasets for pathology, radiology etc.

7.2.3.5 Providing facilities and a learning environment for users and information systems specialists to improve the effectiveness of their decision model

The close association of the systems developers at both pilot sites enabled on-going developments, troubleshooting and continual feedback of the problems and experiences of the users. This developmental aspect of the Pilot and the continuing relationship was valued by the pilot sites.

7.3 Reflecting on the piloting process

The piloting of the colorectal cancer screening programme had several distinctive features and interviewees identified three main aspects:

- the complexity of the command and control structures required;
- the enormous amount of paperwork generated, partly because of this complexity;
- the difficulty of managing the end stages and transitional stage in the period after the last kits were despatched.

In addition, members of the evaluation team and pilot site managers have reflected on the grey areas that necessarily exist between

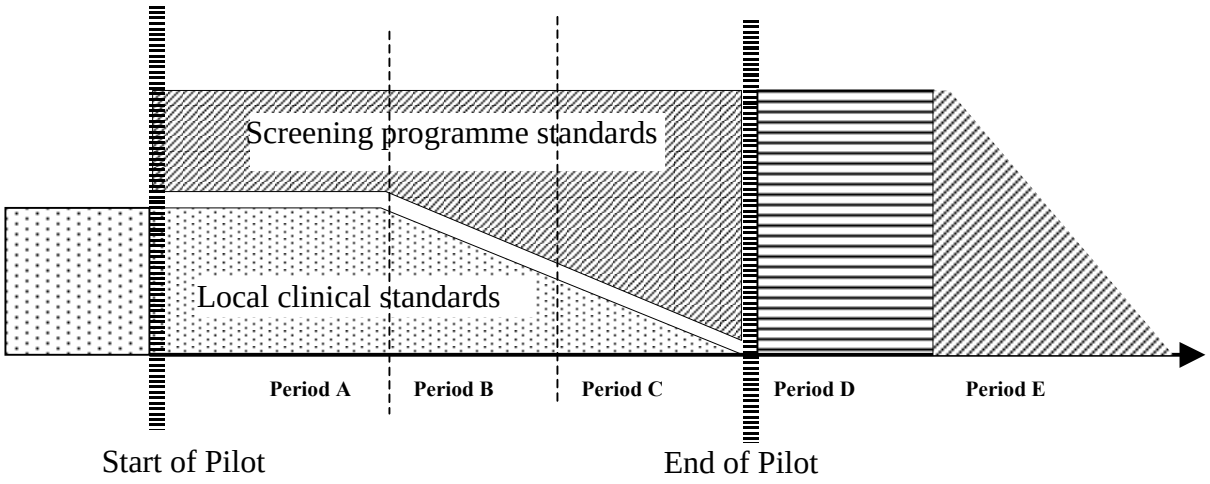
1) the pilot evaluation and its requirement for evidence
2) the Pilot itself and the data management and data collection required for the pilot process
3) National Screening Offices and the future planning that has to be undertaken by them.

These tensions, between evaluation, management of the Pilot and the future of the screening programme, were evident in the prospective interviews but were also referred to again in the retrospective interviews.

There was also some discussion over the division of responsibility for development and collation of documentation between evaluators and Pilot sites - particularly documentation relating to pathways and protocols. Although this was shared on an informal basis between the Screening Offices and within the pilot team as a whole, it was more difficult for the evaluation team to know what had been done and what papers were circulating. An approach to documentation and discussions which might be considered for future pilots is the use of Web Conference Boards. Web Conferences could be set up so users have different levels of access and explicit and transparent negotiations about access would help define the rules of engagement between evaluation and piloting. Within this approach a limited amount of data sharing may be possible and duplication would certainly be cut, as would the paper mountain.

An initial perception at the start of the Pilot was that things were rushed and there was no time for proper discussion. However, over the lifetime of the Pilot all stakeholders began to appreciate the evolutionary approach required to developing the screening programme. Clearly, the initial implementation of the pilot was stressful for all concerned and long hours were devoted to this phase. In the case of clinicians with other responsibilities, this was on top of normal duties since few got additional support for their day to day jobs. It is important that this lesson is taken from the piloting process and that for future pilots those participating understand that full operation is only expected at the *end* of the piloting phase. Management of expectations of staff within the pilot and an overt recognition of the tension between performance that is satisfactory for the first patient that enters and the evolutionary nature of the process is important. In practice the piloting process should be seen as a slow change from standards initially controlled by local clinical teams to final screening programme superimposed standards (see **Figure 7.4**). The success of the pilot initiation will be partly measured in the shortness of period A and the objective should be for smooth and rapid transfer of control until at the end of the piloting process the screening programme controls everything up to the close of a screening episode.

FIGURE 7.4 Piloting Process



Period A: Start up
Period B: Implementation of screening standards and absorption into local systems
Period C: Operational problem-solving
Period D: Evaluation, discussion, resolution of any key issues, decision
Period E: National roll-out

Period A:

This period was characterised by reliance on a small number of individuals. The initial tasks relied on strong leadership and a status in the organisations concerned that reflected both professional credibility and an ability to access resources within these organisations.

This phase was also highly dependent on excellent networks at both sites. During the start up period, high level screening standards were discussed and the objectives of the programme delineated.

Period B

During this period, both a busy and reflective time, high level standards were explored and operationalised. This process was dependent on detailed local knowledge and was undertaken by a core team of clinical managers who could each utilise resources and expertise within their own directorates. This phase was the initial troubleshooting phase when plans were turned into reality and systems brought into commission and tested. The period was characterised by the need for high quality leadership within the screening team itself and good liaison between front line staff. A good relationship with the National Screening Offices and the hands-on approach taken by the Project Officers were crucial during this period. A key function of the National Offices was to be able to stand back and take an overview.

Period C
As the teething troubles of the systems within the Pilot sites were resolved the two sites moved onto different issues during this period. The functioning of the Information System became the focus of this period as a "steady state" for test kits was reached. Certain inadequacies of both systems became clearer and solutions were identified as needed. This was also the period during which non-pilot influences on the Pilot were experienced, viz; waiting lists, capacity and staffing issues. Period C was also characterised by an increasing sense of confidence amongst the screening unit staff, coupled with a mounting sense of uncertainty about the future.

Period D
As the last test kits were dispatched the Pilot sites moved into a period of great uncertainty. There will inevitably be a gap between the ending of the pilot and the consolidation of the evidence and discussion of feasibility of national roll-out. Personnel issues dominated within the pilot sites themselves as the focus shifted away from the delivery of services and back into the policy arena of the National Screening Offices. A dilemma was left for the Trust managers involved. In the necessary gap between completion of screening and analysis, reporting and discussion of results was the team dispersed and if so how?

7.4 Perspectives of primary care personnel

7.4.1 Aims

To obtain specific views on the Pilot and a national programme from the perspective of primary care

7.4.2 Methods

Data were generated by the inclusion of questions in the Primary Care Questionnaire Survey (described in chapter 5).

7.4.3 Results

Satisfaction with information received from Screening Unit
All groups in the primary care survey were asked about their overall satisfaction with information from the Screening Pilot Centre (**Table 7.4.1**). Sixty-four percent (64%) of the respondents were very satisfied with the information they received about the pilot, and 19% were "partially satisfied". When restricted to those who actually received information from the Pilot Centre – i.e. excluding those who either did not receive information or did not read it – the proportion of 'fully satisfied' respondents rises to 76% (415 out of 545 respondents), and the proportion of 'partially satisfied' respondents becomes 22% (122 out of 545). Further, of those who rang the Pilot Centre, almost all were satisfied with the way in which their enquiries were dealt with (**Table 7.4.2**).

GPs and practice nurses were asked specifically about their satisfaction with information they received on the outcomes of their patients' participation in screening, such as test results (**Table 7.4.3**). Fifty-nine (59%) of respondents were very satisfied and 24% "partially satisfied".
There were similar responses for satisfaction with information on outcomes of patients' involvement in follow-up investigations (**Table 7.4.4**).

Views on colorectal cancer screening in general
Sixty-seven percent (67%) of GPs and practice nurses (combined) thought that a national colorectal cancer screening programme should be introduced with a further 26% wanting to wait for the results of the pilot (**Table 7.4.5**). Seventy-six percent (76%) thought that participation in the Pilot had been a valuable and positive experience for their patients (**Table 7.4.6**).

Free-text comments
As detailed in Chapter 5, there was a section for 'free-text' comments in the questionnaires for primary care personnel. The free-text comments relating to perspectives of primary care personnel are included in our Report **Supplement S4.**

A total of 59 comments were received in response to the question: 'Do you consider that a national programme of FOBT screening should be introduced?' In general, many of the comments related to the effectiveness of the programme and organisational issues. One English GP said, '*Only if effective in*

detecting cancer early and decreasing morbidity/mortality. Is it cost effective?' The other main themes emerging when asked this question related to the impact of the programme on primary and secondary care. In particular, some GPs were concerned that secondary care might not have adequate resources. One GP in Scotland commented, *'If pilot becomes a national programme then secondary investigation needs more resource to avoid a deteriorating service for symptomatic /early cancer cases.'* Several respondents particularly mentioned the time taken for colonoscopies. For example, another Scottish GP commented, *'Only if enough resource to perform colonoscopy without long delay.'*

In summary, the main themes to have emerged from these three 'free text' questions relate to resources issues, the extra time spent on administrative tasks and discussions with patients. Patient anxiety following test results was a particular concern raised by several GPs. Although some practice staff wanted remuneration in a national programme was introduced, the main issue for most staff was how to fit the extra activities into what they perceived to be an already overstretched service. Several of them also commented on the relationship between primary and secondary care and the resources issues involved (such as extra demand on colonoscopy services).

7.4.4 Discussion

There are generally positive views from practices on their experiences of participating in the Pilot, although an extensive range of suggestions on how the Pilot might have been improved emerges from the data. Most primary care personnel appear to believe that a national programme would be a worthwhile activity, provided it is adequately resourced.

7.5 Perspectives of Invitees

7.5.1 Aim

To obtain perspectives on the Pilot and FOBt screening from invitees.

7.5.2 Methods

The questionnaire survey of invitees to screening is described in detail in Chapter 2. While much of the focus of this survey was on exploring issues around uptake and acceptance, the opportunity was taken to include questions about overall impressions of FOBt screening and participation in the Pilot.

7.5.3 Results

*7.5.1.1 Views on whether FOBt screening should be widely implemented (**Table 7.5.1**)*
Across all five FOBt outcome groups (including the FOBt Non-responders) the overwhelming response to the question 'Now that you have had the opportunity to participate in the bowel cancer screening pilot do you think this type of screening should be offered regularly to all men and women your age?' was yes.

This may reflect either a) that our sample of non-responders feel that the test should be made available, but that people should have the right to choose whether to participate, or b) that our sample of non-responders have now thought about the test in more detail and wish they had participated.

*7.5.1.2 How invitees would respond to an invitation if offered again (**Table.7.5.2**)*
In order to investigate this second possibility, we examined the future intentions to participate of all FOBt outcome groups if they were sent a kit in the future. This analysis shows that although a large proportion of Phase I Non-Responders intend to do the kit if given the opportunity, there are a hard core of almost 30% who do not want to get involved in FOBt screening.

One further group, within which a notable proportion of people did not intend to participate in any future FOBt screening, was the FOBt Positive group (4.8%). Almost 100% of people in the Phase I Negatives, Phase III negatives and Cancer Positives intended to do a FOBt in the future.

Table 7.4.1 How Satisfied were you with the information from the Screening Pilot?

	staff function: number (%)				
SCOTLAND					
response	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very satisfied	129 (72.1)	36 (90.0)	20 (54.1)	29 (65.9)	214 (71.3)
Partially satisfied	45 (25.1)	3 (7.5)	8 (21.6)	6 (13.6)	62 (20.7)
Dissatisfied	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.7)
Did not receive any information	0 (0.0)	1 (2.5)	9 (24.3)	2 (4.6)	12 (4.0)
Did not read information	3 (1.7)	0 (0.0)	0 (0.0)	7 (15.9)	10 (3.3)
ENGLAND					
Very satisfied	89 (72.4)	40 (83.3)	34 (46.0)	38 (38.0)	201 (58.3)
Partially satisfied	27 (22.0)	7 (14.6)	13 (17.6)	13 (13.0)	60 (17.4)
Dissatisfied	3 (2.4)	0 (0.0)	2 (2.7)	1 (1.0)	6 (1.7)
Did not receive any information	2 (1.6)	1 (2.1)	25 (33.8)	45 (45.0)	73 (21.2)
Did not read information	2 (1.6)	0 (0.0)	0 (0.0)	3 (3.0)	5 (1.5)
ALL AREAS					
Very satisfied	218 (72.2)	76 (86.4)	54 (48.7)	67 (46.5)	415 (64.3)
Partially satisfied	72 (23.8)	10 (11.4)	21 (18.9)	19 (13.2)	122 (18.9)
Dissatisfied	5 (1.7)	0 (0.0)	2 (1.8)	1 (0.7)	8 (1.2)
Did not receive any information	2 (0.7)	2 (2.3)	34 (30.6)	47 (32.6)	85 (13.2)
Did not read information	5 (1.7)	0 (0.0)	0 (0.0)	10 (6.9)	15 (2.3)

Table 7.4.2 If you rang the Screening Pilot Centre, how well were your enquiries dealt with?

	staff function: number (%)				
SCOTLAND					
response	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very well	30 (19.1)	18 (45.0)	9 (24.3)	11 (26.2)	68 (24.6)
Acceptably	16 (10.2)	3 (7.5)	0 (0.0)	2 (4.8)	21 (7.6)
Poorly	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
Did not ring	110 (70.1)	19 (47.5)	28 (75.7)	29 (69.1)	186 (67.4)
ENGLAND					
Very well	17 (14.9)	20 (44.4)	10 (14.3)	10 (10.4)	57 (17.5)
Acceptably	7 (6.1)	4 (8.9)	1 (1.4)	2 (2.1)	14 (4.3)
Poorly	2 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.6)
Did not ring	88 (77.2)	21 (46.7)	59 (84.3)	84 (87.5)	252 (77.5)
ALL AREAS					
Very well	47 (17.3)	38 (44.7)	19 (17.8)	21 (15.2)	125 (20.8)
Acceptably	23 (8.5)	7 (8.2)	1 (0.9)	4 (2.9)	35 (5.8)
Poorly	3 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.5)
Did not ring	198 (73.1)	40 (47.1)	87 (81.3)	113 (81.9)	438 (72.9)

Table 7.4.3 How satisfied were you with the information provided on the outcomes of your patients' involvement in the initial screening (i.e. positive and negative results)?

	staff function: number (%)				
SCOTLAND					
response	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very satisfied	124 (68.5)	**	10 (27.0)	**	134 (61.5)
Partially satisfied	52 (28.7)	**	8 (21.6)	**	60 (27.5)
Dissatisfied	4 (2.2)	**	0 (0.0)	**	4 (1.8)
Did not receive any information	1 (0.6)	**	19 (51.4)	**	20 (9.2)
ENGLAND					
Very satisfied	84 (67.7)	**	28 (38.9)	**	112 (57.1)
Partially satisfied	29 (23.4)	**	12 (16.7)	**	41 (20.9)
Dissatisfied	2 (1.6)	**	2 (2.8)	**	4 (2.0)
Did not receive any information	9 (7.3)	**	30 (41.7)	**	39 (19.9)
ALL AREAS					
Very satisfied	208 (68.2)	**	38 (34.9)	**	246 (59.4)
Partially satisfied	81 (26.6)	**	20 (18.4)	**	101 (24.4)
Dissatisfied	6 (2.0)	**	2 (1.8)	**	8 (1.9)
Did not receive any information	10 (3.3)	**	49 (45.0)	**	59 (14.3)

Table 7.4.4 How satisfied were you with the information provided on the outcomes of your patients' involvement in follow-up investigations?

	staff function: number (%)				
SCOTLAND					
response	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Very satisfied	120 (66.7)	**	9 (25.0)	**	129 (59.7)
Partially satisfied	47 (26.1)	**	4 (11.1)	**	51 (23.6)
Dissatisfied	11 (6.1)	**	0 (0.0)	**	11 (5.1)
Did not receive any information	2 (1.1)	**	23 (63.9)	**	25 (11.6)
ENGLAND					
Very satisfied	84 (69.4)	**	21 (30.0)	**	105 (55.0)
Partially satisfied	24 (19.8)	**	6 (8.6)	**	30 (15.7)
Dissatisfied	1 (0.8)	**	1 (1.4)	**	2 (1.1)
Did not receive any information	12 (9.9)	**	42 (60.0)	**	54 (28.3)
ALL AREAS					
Very satisfied	204 (67.8)	**	30 (28.3)	**	234 (57.5)
Partially satisfied	71 (23.6)	**	10 (9.4)	**	81 (19.9)
Dissatisfied	12 (4.0)	**	1 (0.9)	**	13 (3.2)
Did not receive any information	14 (4.7)	**	65 (61.3)	**	79 (19.4)

Table 7.4.5 Do you think a programme of FOBt screening should be introduced?

	staff function: number (%)				
SCOTLAND					
response	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**ALL**
Yes	107 (58.5)	**	29 (69.1)	**	136 (60.4)
No	3 (1.6)	**	0 (0.0)	**	3 (1.3)
Not sure	14 (7.7)	**	2 (4.8)	**	16 (7.1)
Need to wait for Pilot results	59 (32.2)	**	11 (26.2)	**	70 (31.1)
ENGLAND					
Yes	82 (65.6)	**	66 (85.7)	**	148 (73.3)
No	0 (0.0)	**	0 (0.0)	**	0 (0.0)
Not sure	11 (8.8)	**	2 (2.6)	**	13 (6.4)
Need to wait for Pilot results	32 (25.6)	**	9 (11.7)	**	41 (20.3)
ALL AREAS					
Yes	189 (61.4)	**	95 (79.8)	**	284 (66.5)
No	3 (1.0)	**	0 (0.0)	**	3 (0.7)
Not sure	25 (8.1)	**	4 (3.4)	**	29 (6.8)
Need to wait for Pilot results	91 (29.6)	**	20 (16.8)	**	111 (26.0)

Table 7.4.6 Do you think the pilot was a valuable and positive experience for your patients?

	staff function: number (%)				
SCOTLAND					
Response	**GP**	**Practice manager**	**Practice nurse**	**Reception**	**All**
Yes	128 (70.3)	**	29 (70.7)	**	157 (70.4)
No	7 (3.9)	**	0 (0.0)	**	7 (3.1)
Not sure	47 (25.8)	**	12 (29.3)	**	59 (26.5)
ENGLAND					
Yes	100 (79.4)	**	66 (89.2)	**	166 (83.0)
No	1 (0.8)	**	0 (0.0)	**	1 (0.5)
Not sure	25 (19.8)	**	8 (10.8)	**	33 (16.5)
ALL AREAS					
Yes	228 (74.0)	**	95 (82.6)	**	323 (76.4)
No	8 (2.6)	**	0 (0.0)	**	8 (1.9)
Not sure	72 (23.4)	**	20 (17.4)	**	92 (21.8)

Table 7.5.1 Invitees overall evaluation of screening for bowel cancer.

	Yes, FOBt should be offered		No, FOBt should not be offered	
	N	**% =**	**N**	**%**
Phase I Non-Responder	431	93.7	29	6.3
Phase I Negative	670	99.3	5	0.7
Phase III Negative	408	99.3	3	0.7
FOBt Positive	492	99.2	4	0.8
Cancer Positive	193	100	0	-
Total	2,194	98.2	41	1.8

Table 7.5.2 Response to future FOBt invitation.

	If I am invited to do an FOBt in the future, I intend to do it.		If I am invited to do an FOBt in the future, I do not intend to do it.	
	N	**% =**	**N**	**%**
Phase I Non-Responder	333	72.1	129	27.9
Phase I Negative	682	98.4	11	1.6
Phase III Negative	414	99.3	3	0.7
FOBt Positive	475	95.2	24	4.8
Cancer Positive	194	100	0	-
Total	2,098	92.6	167	7.4

7.6 Conclusions and Recommendations

This chapter has examined in some depth the processes involved in establishing the Pilot sites and managing their activities. There is widespread support for the establishment of a national programme of colorectal cancer screening amongst invitees and primary care personnel.

In general, formal approaches for implementing screening programmes have been advocated by the wide range of stakeholders consulted in this chapter. A great deal of importance was placed on the establishment and maintenance of audit and quality-assurance procedures; low rates of adverse events in both Pilot sites (as demonstrated in Chapter 4) would tend to indicate that quality assurance procedures have had measurable benefits in the Pilot sites.

There needs to be clarity about the endpoints of screening; as with all screening programmes, the interface between the screening service and treatment services needs to be managed carefully.

Several models of FOBT screening programme delivery emerge; the Pilot has worked well with two sites of modest size, but consideration will need to be given in a roll-out of screening about optimal numbers of screening centres, and the degree of centralisation of service provision and coordination. This will impact on systems of quality control within a national programme. A great deal of care needs to be invested in the design and commissioning of information systems. Experiences in the two Pilot sites, which developed quite different approaches, provide important lessons for a national programme.

References – Chapter 7

Garvican L, Muir Gray JA, Holmes E, et al. A workbook for Colorectal cancer screening pilots. National Screening Committee, London; 1998.

Jayaratna N. *Understanding and evaluating methodologies.* Maidenhead, England: McGraw-Hill; 1994.

Pope N, Mays C. Qualitative Research in Health Care. BMJ Books: 2000.

Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Analysing qualitative data, Bryman A, Burgess R, eds., London: Routledge, pp. 173-194: 1993.

Stowell F, West D. Client led design. Maidenhead, England: McGraw-Hill; 1994.

Strauss A, Corbin J. Basics of qualitative research. London: Sage Publications; 1998.

8. Summary and Future Directions

There are many aspects of screening programme performance which can influence its success in moving from a pilot phase to a national programme. Our evaluation has, therefore, incorporated information on a range of issues which will be relevant in planning for potential roll-out of screening. In forming recommendations we have taken into account the context of cancer services in the UK, and current national efforts to improve diagnostic and treatment services for colorectal cancer. We have endeavoured in the report to focus on issues which will be useful both in deciding whether or not to introduce FOBt screening nationally (recognising that there is already a degree of commitment to this from the UK Department of Health), but also in 'fine-tuning' the delivery of FOBt screening, from commissioning processes to delivery of investigations.

Findings from our evaluation of the UK Colorectal Cancer Screening Pilot suggest that population-based FOBT screening is feasible. The Pilot has been able to reproduce key findings from the Nottingham trial; specifically, it has achieved uptakes rates of close to 60% amongst invitees (taken as a whole), and values for test positivity, rates of cancers detected, stage of screen-detected cancers and predictive value of positive tests do not differ substantially from those observed under the conditions of the randomised trial. Based on international comparisons, adverse effects of screening in the UK Pilot (including complications from colonoscopy) were low. This leads us to conclude that a national programme of FOBt screening, based on the model of screening used in the UK Pilot, should be able to bring about reductions in mortality which are similar to those observed in trial populations.

In this report we have made several recommendations for the implementation of a national programme of FOBt screening. They relate to all aspects of the screening process, including recruitment strategies, the targeting of low-uptake sub-groups, data recording procedures, quality assurance and audit, information systems, workforce and capacity. There is considerable effort in both England and Scotland to examine how best to respond to the experiences and outcomes of the UK Pilot. Second rounds of screening are commencing, and both health departments are already addressing the practicalities of a national programme. Given the results of this evaluation, it seems likely that such planning will continue, albeit in the context of other initiatives; the UK Department of Health has, for example, recently launched a new strategy targeting colorectal cancer, in which any FOBt screening would be part of a broader programme of initiatives targeting all stages of the cancer journey, (including early diagnosis in primary care in response to symptoms, referral strategies and surgical practice). A 'halo' effect on symptomatic services has been observed in other screening programmes, and this might well be anticipated in colorectal cancer screening.

We also conclude there are a number of areas which would benefit from further research and evaluation.

They include:

- alternative faecal occult blood tests, such as immunological tests, which may involve less complex screening histories (planning for this is already underway).
- further follow-up of individuals who have been recruited in the UK Pilot: the advent of second rounds of screening raises the prospect of examining interval cancers, and producing refined estimates of sensitivity and specificity. Further, matching with existing databases including hospital activity datasets, death registries and cancer registries would enable cross-checking of information derived from the Pilot clinical dataset, and improved information about adverse events (and other outcomes) in screening participants.
- strategies for improving uptake in population sub-groups including males, younger people, those living in deprived areas and certain ethnic minorities.
- strategies which address the psychosocial barriers to FOBt screening identified in this report
- systems of increasing the workforce capacity to meet the requirements of a national programme, at both a national and regional level.
- strategies for engaging and adequately resourcing both primary and secondary care services.

We have highlighted the capacity of the health services to respond to the new demands from FOBt screening, and conclude that the impact on primary and secondary care will need to be closely monitored. The NHS faces a constant challenge in responding to health needs, and careful consideration of funding and capacity issues will be imperative in a national programme. Issues of training, staffing and investment in quality assurance processes will be of particular importance.

In summary, the UK Pilot has demonstrated that mortality reductions demonstrated in randomised studies of FOBt screening (Towler et al, 2001) can be repeated in the models of screening used in the UK Pilot. There is presently a considerable infrastructure associated with the two Pilot sites, and it would seem desirable to maintain the sites while planning and decision making are undertaken over a national programme. Our recommendation to the Department of Health is that FOBT screening should be part of new national strategies targeting colorectal cancer. Clearly as evidence accumulates on screening using other modalities such as flexible sigmoidoscopy, consideration will need to be given as to how FOBt screening can best contribute to national efforts to reduce deaths and morbidity from colorectal cancer in the population.

Towler BP, Irwig L, Glasziou P, Weller D, Kewenter J. Screening for colorectal cancer using the faecal occult blood test, Hemoccult (Cochrane Review). In: *The Cochrane Library*, 4, 2001. Oxford: Update Software.

Appendices

List of Appendices

Appendix 1 - Glossary

ADENOMAS: All adenomas will be classified according to the following criteria:
Size: Small tumours < 1cm or tumours >= 1cm
Dysplasia: High grade dysplasia or no high grade dysplasia

For the present report:

- adenoma and non-malignant adenoma are synonymous
- recognition of a polyp as an adenoma requires histopathological confirmation

Note that when considering an individual person with adenoma(s) the classification of the 'worst' lesion among adenomas and CRC malignancies will be applied to that person.

AGE: Age at start of screening episode. This is defined by year of birth cohort [eg in 2000, 50-54s are those with yob 1946-50] and will normally be grouped into 5-year groups (50-54, etc).

CANCER: A case of primary CRC (including malignant polyps) diagnosed (or screen-detected) in the population who are or have been eligible for screening and selected. Histological confirmation is not an essential requirement. Such a case may be:

Screen-Detected Cancer: Any person with a cancer and/or malignant polyp diagnosed as a result of further investigations conducted as part of the screening process and following a screen positive result.

Interval cancer: A cancer diagnosed following completion of screening (i.e. in an individual who has a screening result available) and not more than two years later which is not screen-detected. Note that this definition includes people who had further investigations recommended but did not have them or did not complete them.

Other cancer: A cancer diagnosed in an individual who did not receive or did not complete screening in the interval from selection for screening up to two years later. This includes cancers diagnosed in the time from selection to when FOBt would have been offered and in those selected but not issued with FOBt kits.

For the present report:

- malignant polyps and 'polyp cancers' are synonymous
- histological confirmation of both malignancy and complete removal of malignancy of colonoscopy are required for these
- all other colorectal malignancies are taken to be invasive

CLINICAL PERFORMANCE DEFINITIONS (FURTHER INVESTIGATIONS):
This list will be added to and may grow so that sub-definitions are appropriate
(eg :colonoscopy, :radiology).

Complete colonoscopy: This is currently self-reported.

Method of assessment of complete colonoscopy: Discussions are currently ongoing regarding the method of assessing complete colonoscopy.

COLONOSCOPY PROCESS:
Person eligible for colonoscopy: Any person who has had a screen-positive result. *If the trial protocols change to allow unfitness to be irrevocably determined by the GP and/or the screening nurse this concept will need to be revised.* Such people can be classified into one of the following:

Colonoscopy acceptor: Any person with colonoscopy recommended who attends for colonoscopy and has the procedure performed.

Colonoscopy refuser: Refusers (at nurse consultation or later), non-attenders at either colonoscopy or nurse consultation.
Unfit for Colonoscopy: As assessed by the endoscopist. This will change if unfitness judged by the nurse specialist becomes grounds for withholding colonoscopy appointment.

Temporarily unfit for colonoscopy: Unfit but this status expected to change within a few months and subject to be invited then.

Note that for the present report we have taken as denominators for colonoscopy acceptance all those with FOBt positive result. A colonoscopy 'acceptor' is anyone in this group with evidence from colonoscopy and/or pathology datasets that a colonoscopy has been performed. Those not classified as acceptors include subjects medically unfit for colonoscopy.

DATES:
Date selected for screening: See definition of selected (below)
Date Phase I started: See definition of Phase I (below)
Date kit result available: Date test performed on an individual kit by laboratory.
Date screen result available: Date test performed by laboratory which yields screen result.
Date patient informed of CRC diagnosis & the need for treatment: The concept is the time when anxiety regarding the fact of diagnosis begins for the patient. Retrieving this from the data may not be straightforward. Data items available currently being explored by CM/KA.
Date of cancer diagnosis: This date will, in general, be earlier than the date of registration by cancer registry for screen-detected cancers but identical to the date of registration for other cancers.

Date of cancer registration: The date held by cancer registry as the 'anniversary' date (i.e. cancer registry date of diagnosis).

Date kit received: Date kit received by the Screening Unit, or the best proxy available for this date. In England this is likely to be the date the kit is logged and in Scotland the date it is read.

DCBE PROCESS (double contrast barium enema):

Person eligible for DCBE: Any person who has had a screen-positive result followed by incomplete colonoscopy, except those recommended for surgery as a result of colonoscopy. Such people can be classified into one of the following:

DCBE acceptor: Person who attends for DCBE and has the procedure performed.

DCBE refuser: Person who declines or fails to attend.

FURTHER INVESTIGATIONS: All investigations conducted as part of the screening process in evaluating individuals who are screen positive. This includes referral for nurse consultation, followed by colonoscopy/DCBE if appropriate. Normally every screen positive individual will be offered some further investigations. Investigations performed *after* definitive treatment is given and/or a diagnosis is reached are not included here. [Note that this means in particular that DCBE performed subsequent to therapy in cancers and follow-up colonoscopies in subjects with adenomas are not included]

Further investigations completed: Colonoscopy appointment attended and procedure performed. In addition, if DCBE required then appointment attended and procedure performed.

KITS SENT AND RETURNED:

Initial kit: A kit sent out as the first one to the individual concerned. [Kits sent subsequently to the same individual will not be included EVEN if it is discovered that the first one to that individual went to the wrong address]
Repeat kit: Any kit sent to an individual to whom an initial kit has already been sent. This includes dietary re-test kits and 3-month re-test kits. Repeat kits can also be sub grouped by screening phase.

Adequate Kit: A kit returned which yields a result (strongly positive, weakly positive, positive under dietary restriction, negative). This can include an expired or incomplete kit whose result is deemed acceptable (specifically, those which are positive)

Inadequate kit: Any used kit returned which does not yield a result (includes spoilt, incomplete, expired and technical failures).

Expired kit: An inadequate kit that could not be tested in the laboratory within 14 days of the first sample being given. Not to include kits that indicate a positive result despite being tested after more than 14 days.

Technical failed kit: An inadequate kit due to a technical failure in the laboratory.

Other inadequate kit: Any inadequate kit which is neither expired nor technical failed.

Unused kit: Kit returned unused. This includes kits with and without indication that screening is declined.

Kit returned at nurse consultation: Relates primarily to England where repeat kits (sent as a result of initial reminders/inadequate kits/weak positives) are taken to the nurse clinic for testing. The majority of tests will be returned to the Screening Unit by post.
See also 'REMINDER KITS'

KIT RESULT:

Negative kit: A kit returned which yields a negative result for each of the six individual spots.

Positive kit: A kit returned which yields a positive result for at least one of the six individual spots. This will include both weak positive and strong positive kits.

Weak positive kit: A kit returned which yields a positive result for >1 and <4 of the individual spots. Partially complete and partially spoilt kits can fall into this category (eg three positive and three unused spots = weak positive).

Strong positive kit: A kit returned which yields a positive result for five or six of the individual spots. This can include kits with one unused or spoilt spot.

NEOPLASIA:

Indicates a person who has a screen-detected:

- invasive cancer or
- malignant polyp or
- (non-malignant) adenoma

PARTICIPANTS:

For the purposes of clarity we use this term to describe people who make the decision to take part in surveys, focus groups etc. We never use this term to describe actions within the screening process.
(See also RESPONDER)

PHASES OF SCREENING:

Eligible: Any person 'aged 50-69' (see AGE above), registered with a responsible GP in the pilot region at the time this practice was selected for screening.

Selected for screening: An eligible individual is selected for screening and his/her ***screening episode starts*** when the GP practice (through which the individual was selected) was itself selected.

Phase I: This starts when

- the first letter about screening is sent out (England)
- the first kit is sent out (Scotland)

and continues until receipt of first adequate test (or the episode is closed). This phase may include tests done with dietary restriction for any other reason than a weak positive result.

Phase II: The ***Dietary Re-Test*** – begins with weak positive result and ends with result of a dietary re-test (or episode is closed).

Dietary restricted re-test: A dietary restricted test performed AFTER a weak positive result has been reported. This test is performed during phase II of screening and does NOT include dietary restricted tests performed following the return of a spoilt, expired etc kit.

Initial screening: embraces phases I and II

Phase III: The ***Early Recall*** phase – for people who are initial weak positives and subsequently negative on dietary restricted retest. This phase starts with the first letter in the process of re-testing and ends when the retest result is available (hence an FOBt result is available) or the episode is closed. The timing of phase III has changed during the course of the pilot. Initially, phase III began 3 months after the completion of phase II. Now it begins as soon as possible after the end of phase II.

Phase III re-test. Any FOBt test performed in phase III.

POLYPS: Polyps will be classified into two groups as follows:
Benign: See adenomas
Malignant: See cancer

REMINDER KITS:

Initial kit reminder: A kit sent out with a reminder letter to an individual who fails to return the initial kit within four to six weeks of it being issued. Reminder kits sent in response to a request for a replacement kit or as a result of an initial inadequate kit will not be included.

Dietary restricted re-test reminder kit (Scotland only): A kit sent out with a reminder letter to an individual who fails to return the dietary restricted re-test within four to six weeks of it being issued.

Phase III re-test reminder kit (Scotland only): A kit sent out with a reminder letter to an individual who fails to return the Phase III re-test within four to six weeks of it being issued.
Note:
(i) In England, any person failing to return a dietary restricted or Phase III re-test is sent a reminder letter only not an extra kit.

(ii) An examination of critical pathways by EG will help inform the definition of

(iii) further reminder kits categories as the development of evaluation outcomes continues.

RESPONDER
Any person targeted for Phase I who:

- either returns an adequate kit in Phase I
- or returns a used kit though no adequate one

This is used to identify people who (initially, at least) wish to take up the offer of screening.
(See also PARTICIPANT)

RESPONSE TO PHASE I OF SCREENING: The following are possible (see flow diagram):

- Decline (includes return of unused kit)
- No response
- Used kit returned but no adequate kit returned
- Phase I completed (adequate kit returned)

RESPONSE TO PHASE II OF SCREENING: The following are possible for subjects entering phase II (i.e. who have completed Phase I without a definite result and have not died or emigrated etc in the meantime):

- Decline/ no response/ no adequate kit returned
- Phase II completed (adequate kit returned)

RESPONSE TO PHASE III OF SCREENING: The following are possible for subjects entering phase III (i.e. who have completed phase II without a definite result and who have not died, emigrated etc in the meantime):

- Decline/ no response/ no adequate kit returned
- Phase III completed (adequate kit returned)

RESULTS OF PHASE I COMPLETED: Subjects who have completed Phase I may have one of three results:

Screen positive (see definition and flow diagram)
Screen negative (see definition and flow diagram)
Proceed to phase II

RESULTS OF PHASE II COMPLETED: Subjects who have completed phase II may have one of two results:

- Screen positive (see definition and flow diagram)
- Proceed to phase III

RESULTS OF PHASE III COMPLETED: Subjects who complete phase III may have one of two results:

- Screen positive
- Screen negative

RESULTS OF SCREENING: Subjects may complete or fail to complete any individual phase of screening.

Screening completed: means that the overall result of the FOB testing is available for the individual person and is defined as:

- Either adequate first test, result: strong positive or negative
- Or adequate first test, result: weak positive & adequate dietary restricted test, result: positive
- Or adequate first test, result: weak positive & adequate dietary restricted test, result: negative & adequate Phase III test, result: positive or negative
- Or inadequate first test & adequate dietary restricted test, result: positive or negative.
- Only two results are possible when screening is complete:

Screen negative: An individual who has screening completed but who does not meet the criteria for screen positive will be classified as screen negative. In other words, screen negative is defined as:

- Either adequate first test, result: negative
- Or adequate first test, result: weak positive & adequate dietary restricted test, result: negative & adequate Phase III test, result: negative
- Or inadequate first test & adequate dietary restricted test, result: negative.

FOBt positive: means that screening is complete and the result is positive. It is defined as:

- Either adequate first test, result: strong positive
- Or adequate first test, result: weak positive & adequate dietary restricted test, result: positive
- Or adequate first test, result: weak positive & adequate dietary restricted test, result: negative & adequate 3-month test, result: positive
- Or inadequate first test & adequate dietary restricted test, result: positive.

SCREENING: The process of FOB testing. Further investigations of screen positives are not included here (see separate definition).

STAGE OF CRC: This relates to the *person* with CRC and is the stage of the most advanced lesion identified in that person. It is required that these stages agree with the current literature and also with the usage in the RCTs of screening.

Dukes' stage: The following stages will be considered:

- Malignant polyps only:
- Other Stage A:
- **Stage B:**
- Stage C:
- Stage D: The Dukes' classification is clear but it is less clear how this stage can be identified from the minimum data-base. In particular, the role of pathological information in identifying liver and other mets needs to be clarified.
- Unstaged:
- Stage not stated:

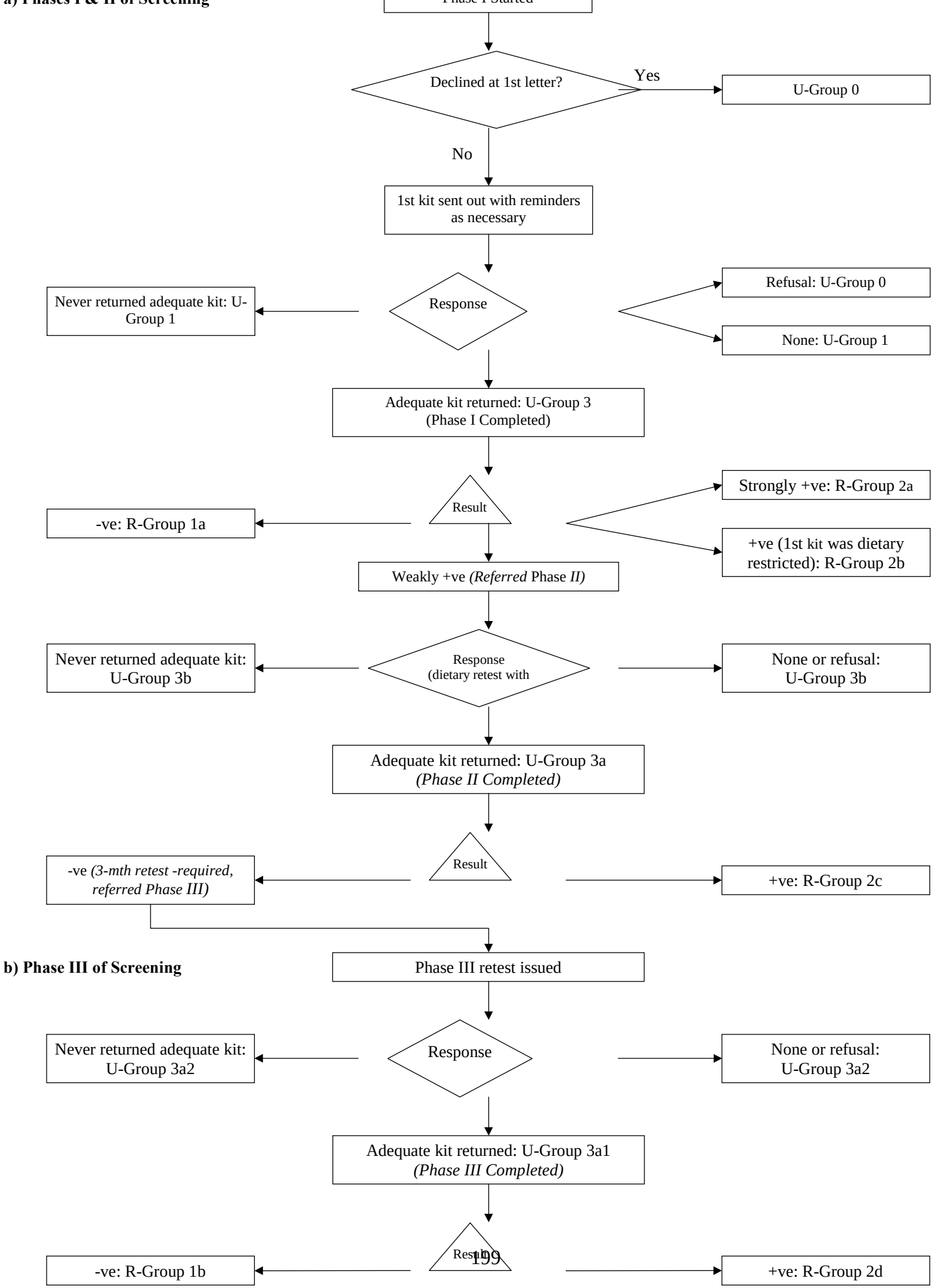
TNM: This will follow the standard clinical (cT_1-cT_4, cN_1-cN_2) and pathological (pT_1-pT_4, pN_1-pN_2) definitions and M_1-M_2. Clarification is required regarding whether cN or pN will be available.

SURVEILLANCE OF ADENOMAS: This will include all follow-up hospital visits and follow-up colonoscopies.

UPTAKE

This term describes the decision by subjects offered screening and those within the phases of screening to take up the various offers/ accept the various invitations made to them. We focus on:

- those who respond at all to the offer of screening *(of those targetted)*
- those who complete phase I of screening *(of those targetted)*
- those who achieve an FOBt result *(of those targetted)*
- those who achieve an FOBt result *(of responders)*
- those who attend for colonoscopy *(of FOBt positives)*


Phase I started
Declined at 1st letter?
Yes
U-Group 0
No
1st kit sent out with reminders as necessary
Response
Never returned adequate kit: U-Group 1
Refusal: U-Group 0
None: U-Group 1
Adequate kit returned: U-Group 3 (Phase I Completed)
Result
-ve: R-Group 1a
Strongly +ve: R-Group 2a
+ve (1st kit was dietary restricted): R-Group 2b
Weakly +ve (Referred Phase II)
Response (dietary retest with
Never returned adequate kit: U-Group 3b
None or refusal: U-Group 3b
Adequate kit returned: U-Group 3a (Phase II Completed)
Result
-ve (3-mth retest -required, referred Phase III)
+ve: R-Group 2c
b) Phase III of Screening
Phase III retest issued
Response
Never returned adequate kit: U-Group 3a2
None or refusal: U-Group 3a2
Adequate kit returned: U-Group 3a1 (Phase III Completed)
Result
-ve: R-Group 1b
+ve: R-Group 2d

Appendix 2: Interactions with Pilots: parameters of engagement between pilot sites and evaluation group, and strategies for feedback from evaluation group

1. General Principles

1.1 Introduction

The Pilots of FOBT screening provide a unique opportunity to examine the feasibility of a national programme. While mortality benefits have been demonstrated in randomised controlled trials, it is still not known whether FOBT screening will be sufficiently acceptable, affordable and effective in the context of a national programme. The pilots will have most value if they can pilot systems of screening which could be readily rolled out on a national basis. While a great deal of planning has gone into setting up the pilots, their value will be enhanced if they can modify their protocols and activities as they progress, in response to feedback on their performance.

The EG wishes to encourage appropriate and useful mechanisms of communication with the pilot sites. To do this we have established regular teleconferences with the pilot sites, and have a contact database which outlines roles and responsibilities of EG and pilot site personnel. It is in the context of these communication mechanisms that the principles outlined below guide the present proposals for EG feedback to pilot sites.

1.2. Relationship Model

An important source of such feedback is the Evaluation Group, which is conducting an independent and comprehensive evaluation of the screening pilots for the Department of Health. In Evaluating the CRC pilots there is a clear and necessary tension between the role of impartial and distant observer who comments only at the conclusion and that of active participant who comments frequently and regularly. An "Action Research" model for the EG's activities would be one which is oriented towards bringing about change. Typically, it would involve respondents (the pilots in this case) in the process of investigation, with the evaluators being aware of their influence on the programme they are examining by actually being part of the environment of the programme.

At the same time, there is the imperative of independence; many models of programme evaluation emphasise the importance of impartiality, particularly if there is a third party which is commissioning the evaluation (in this case the Department of Health). Indeed, independence is a key feature of the evaluation and, while we are required to work closely with the Pilot sites, there is a high level of awareness within the EG and other groups of the importance of maintaining independence. Roll-out of FOBT is a complex policy decision for the Department of Health, with substantial resource implications. It is therefore necessary that the information they receive from the evaluation is an impartial and accurate reflection of the experiences of the pilots.

We propose a middle course; one which allows the pilot sites to avail themselves of opportunities for feedback from the EG without compromising the evaluation's independence. In doing so, it is necessary to set parameters of engagement and to establish mechanisms for dealing with situations in which the independence of the evaluation might be perceived to be compromised.

1.3 Evaluation versus judgements on pilot performance

The sites are not perceived by the Evaluation Group as being in competition; rather we see them as collaborating in the pilot process. We do not anticipate that our conclusions will be of the form 'pilot A has performed well, pilot B has performed poorly'. Rather, we see a role in identification of successful programme elements – that is, reporting that certain procedures appear to be more useful in a CRC screening programme suitable for roll-out.

1.4. Timeliness versus robustness and validity of information

The Evaluation group recognise the need to provide information in a timely fashion to assist pilot sites in modifying their activities. We are prepared, therefore, to share data which are valid but not yet robust. We propose, however, to exercise caution: certain figures and percentages which are generated at an early stage in a screening programme (eg cancer detection rates where denominators include tests performed which have not time for early rescreens of weakly positive tests to have been completed) have the potential to be misinterpreted, and could lead to inappropriate changes in pilot site activities (we assume that pilot site staff will share this understanding of the need for caution).

1.5 EG resources

The EG's central task is to produce an evaluation for the Department of Health, and time spent on providing feedback to pilot sites and other interested parties will need to be monitored in the context of constraints on our time and resources.

1.6 Mechanisms for pilot modification of procedures

We expect that the pilots will modify their procedures with time and will, we hope, evolve a 'Workbook' protocol suitable for use nationally if roll-out occurs. Some of the modifications will arise following recommendations from us; others will be consequences of observations from the pilot site staff and others. It is our hope and intention that our evaluation will be able to comment on procedures used at any stage of the pilots and make comparisons and recommendations.

1.7. Accountability

It should be emphasised that the Evaluation is being conducted for the DH R&D Directorate. Reports will be prepared for them in the first instance and, subject to their approval, will be disseminated to pilot site staff. Other reporting will normally be through the Pilot Executive Group.

2. Interaction between EG and pilot sites: content and mechanisms

2.1. Routine information-sharing between EG and pilot sites

2.1.1 Simple counts and tables to check data transfer and interpretation

It is essential that the data held by the evaluation group are accurate and correctly interpreted. It is equally essential that the pilot site staff have confidence that this is so. Especially at the start of release of data but also at any subsequent time when a query over accuracy and interpretation of data is raised by pilot site staff we shall release sufficient simple counts and tables to conduct these checks. This will be the responsibility of Caroline Round from EG and she will work in liaison with IT staff at the pilots.

2.1.2 Mechanisms for sharing results generated by Evaluation Group.

The main results generated by the Evaluation Group will be contained in the annual reports prepared for the DH. Dr Ursula Wells has given an undertaking to the Steering Group that Copies of these reports will be available to SG, to the National Screening Committee and to the Scottish Executive. We shall be happy to discuss aspects of the reports with the pilot Executive Group and/or Steering Group. The reports are confidential and it is important that this information does not reach the public domain before the DH has given its agreement.

We shall, for some aspects of the data, provide regular tables and reports (compiled at monthly or 3-monthly intervals) directly to the Executive and Steering Groups; we expect that both these groups will influence the choice of data to be reported regularly and may make ad hoc requests; we will attempt to provide these as far as possible within the constraints of time and resource management within the evaluation and providing valid data.

2.2. EG-initiated feedback on pilot-site activities

2.2.1 Reports on the validity and integrity of pilot data

It is essential to the evaluation process that data held by the pilot sites are valid and consistent (eg that coding of location of CRC is consistent). We shall generate (for internal use) routine frequency tables and cross-tabulations whose purpose is to warn of possible violations. Where major problems are identified we shall contact the appropriate pilot site immediately (Carolyn Smith, Susan Elwell). These

and other less serious problems will be reported to the next Pilot Executive Group meeting. Further discussion of such issues will be possible at the monthly teleconference meetings with both pilot sites.

2.2.2 Routine recommendations for procedural changes.
These will be recommendations from the EG for changes which it is believed will improve the performance of the pilot. Since we shall wish to evaluate both the initial and revised procedure it is essential that changes of this type are made at one time and that this is carefully recorded; it is highly desirable that changes are made relatively infrequently. We plan that recommendations for these changes will occur at two times:

- Times planned by the pilots for modifications to certain procedures (eg literature changes, September 2000). Input would be directly from EG to the project sub-committee involved.
- The 1st year and 2nd year reports by the EG to DH. [The 2nd year report could only lead to changes in the English pilot under current plans]. Such input would be contained in the relevant reports.

2.2.3 Proposed actions if EG perceives a problem at a pilot site
Whenever, in their perusal of data or other investigations, members of the Evaluation Group note definite or possible major problems affecting the ability of one or both pilot sites to continue an effective screening programme for CRC they (ie one of the co-directors) will immediately notify the clinical director of the site involved. All such notifications will be reported to the next Pilot Executive Group meeting.

3. Pilot site-initiated requests for EG input

3.1 If one pilot site observes problems or possible problems relating to their delivery of an effective screening programme then they may wish to receive comments (and tabulations/ analyses) from the EG. We are happy to respond to this but propose that a formal procedure be followed whereby the Pilot Executive Group (or, in emergencies, the chair of the Pilot Executive Group) makes the request to EG and provides them with details and available evidence. We propose, further, that the feedback is given to the Pilot Executive Group or its chair. Further discussion will be possible at the monthly teleconference meetings with the pilot site but this should not normally be where such issues are first raised.

3.2 We consider it likely that pilot site staff will in future wish to generate results (eg peer review publications) requiring input from the Evaluation Group. This input could be comment, advice, flat files for analysis or actual statistical analysis. In principle we shall be happy to provide feedback of these kinds for this purpose. However, where conflicts arise with the conduct of the Evaluation then the latter must have priority.

4. Mechanisms for monitoring engagement between EG and pilot sites

The EG reports to its own Advisory Group. We propose to report EG-pilot interaction issues to this meeting and receive feedback from the Group on the appropriateness or otherwise of this engagement

It is also important that the commissioners of the Evaluation are satisfied that we are maintaining our independence. We suggest regular input from Dr. Ursula Wells could address this concern.

If EG members consider they are receiving requests for input/sharing of information which significantly compromise the evaluation's independence, the issue will be raised at EG management meetings, and referred to the Pilot Executive Group /lead clinicians/Dr. Ursula Wells as necessary.

Appendix 3 – Extra Tables from Chapter 2

Table A2.2.1 Overall response rate to the psychosocial questionnaire.

	No Response		Returned Complete		Returned Blank		Unavailable		Total
	N	%	N	%	N	%	N	%	
Phase I Non-Responder	2,157	61.5	473	13.5	804	22.9	74	2.1	3,508
Phase I Negative	167	16.7	697	69.7	132	13.2	4	0.4	1,000
Phase III Negative	52	9.7	421	78.4	62	11.5	2	0.4	537
FOBt Positive	280	28.0	502	50.2	204	20.4	14	1.4	1,000
Cancer Positive	64	19.1	199	59.4	65	19.4	7	2.1	335
Overall	2,819	42.7	2,360	35.8	1,311	19.9	111	1.7	6,601

Table A2.2.2 Response rate to the psychosocial questionnaire – returned blank and unavailable removed.

	No Response		Returned Complete		Total
	N	%	N	%	
Phase I Non-Responder	2,157	82.0	473	18.0	2,360
Phase I Negative	167	19.3	697	80.7	864
Phase III Negative	52	11.0	421	89.0	473
FOBt Positive	280	35.8	502	64.2	782
Cancer Positive	64	24.3	199	75.7	263
Overall	2,819	54.4	2,360	45.6	5,179

Table A2.2.3 Overall comparison of survey participants and survey non-participants.

	Survey participants		Survey Non-Participants		Chi-square
	N = 2,292		N = 2,720		
	N	%	N	%	χ^2, p
Phase 1 Non-Responder	473	20.6	2,157	79.3	1,716.51, p < .000
FOBt Responder[1]	1,819	79.4	563	20.7	
Men	1,464	53.8	1,275	55.6	1.635, ns
Women	1,256	46.2	1,017	44.4	
Age 50-54	609	26.6	883	32.5	48.792, p < .000
Age 55-59	552	24.1	751	27.6	
Age 60-64	508	22.2	530	19.5	
Age 65-69	623	27.2	556	20.4	
Depcat 1/2	583	27.8	529	19.8	74.048, p < .000
Depcat 3	485	23.2	545	20.4	
Depcat 4	473	22.6	626	23.4	
Depcat 5	327	15.6	600	22.5	
Depcat 6/7	226	10.8	370	13.9	
Depcat1/2/3	1,068	51.0	1,074	40.2	55.093, p < .000
Depcat 4/5/6/7	1,026	49.0	1,596	59.8	
Scotland	1,643	71.7	1,826	67.1	12.094, p < .001
England	649	28.3	894	32.9	

[1] Includes Phase 1 Negative, Phase III Negative, FOBT Positive, & Cancer Positive.

Appendix 4: Costs of diagnosing and managing colorectal cancer

Introduction
Screening and detection of asymptomatic cancers might have implications for subsequent treatment costs in a number of different ways:

- first, the distribution of cancers by stage might shift, changing the mix of treatments carried out - if these become simpler (eg less extensive bowel surgery) then screening might reduce treatment costs
- second, within any given stage of cancer, treatment might be simpler as a result of a smaller diameter of cancer or an asymptomatic patient with good physiological reserves
- third, through avoidance of emergency admissions and surgery which (i) reduces the need for patients to be stabilised and (ii) avoids some of the risks of obstruction or perforation of the bowel and the consequent emergency surgery.

It should be noted that there might be other implications for treatment costs such as length bias (i.e. over-diagnosis of cases that would not have caused symptoms before the patient died of unrelated causes). The MRC (Nottingham) trial also showed that the costs of treating cases presenting symptomatically in the interval between screens and in people who declined the offer of screening should be considered - the latter group in particular may have high treatment costs and poor survival. No data are available from the UK pilot study in this respect at present.

Method
The screening model developed to evaluate the UK pilot study required data on the average lifetime treatment costs for each stage of disease. Ideally, these would be obtained by prospective follow-up of the patients detected in the pilot study but since at least five years of follow-up data would be required this is not practical. Instead, an approach based on the literature plus expert judgement was used. A literature search suggested that the most recent estimates in the UK were from the Nottingham trial, but these are out-of-date in at least two respects:

- firstly, groups such as the Scottish Intercollegiate Guidelines Network (SIGN) are increasingly recommending radiotherapy and chemotherapy as part of the management of patients, but this was not common practice in the late 1980s when the Nottingham data were collected
- secondly, representative costs for all NHS trusts in England and Wales are now available through the HRG system (Department of Health 2002), allowing a more generalisable set of costs to be produced.

The approach adopted was to identify all of the possible treatments a patient could receive, assign costs to these (generally from HRGs supplemented by ad hoc sources where no HRG was available), then to estimate the proportion of patients in each stage receiving each treatment. Using these data alone would mean that the main way in which screening impacted upon treatment costs would be through the shift in staging (the first of the three ways identified at the start of this section). The only other differences between screening-detected and symptomatic cases are as follows:

- differences in the proportion of stage A cancers that can be treated endoscopically when detected on screening
- differences in the proportion of patients presenting as emergencies

The output of this stage of the exercise is thus a lifetime treatment costs for each stage for screening and for symptomatic presentation.

Categories of cost
Patients were assumed to incur costs under the following headings:

- diagnosis
- endoscopic treatment of early stage cancer
- pre-operative radiotherapy
- surgery
- post-operative radiotherapy
- primary radical radiotherapy
- post-operative chemotherapy with curative intent
- follow-up

- palliation of recurrent and terminal disease (mix of surgery, radiotherapy, chemotherapy and supportive care)

These are considered in more detail below.

Diagnosis
Two types of diagnostic pathway were considered. Firstly, elective presentation with symptoms was assumed to involve the following resource use:

- 1 GP consultation
- 2 out-patient clinic visits (one initial attendance, one follow-up) (HRG OP 100)
- 1 colonoscopy (including biopsy) (HRG F35)
- 1 ultrasound of abdomen and pelvis (HRG F18)
- CT scan in 50% of cases

Secondly, emergency presentation with symptoms was assumed to involve:

- In 50% of case: 1 A&E attendance, then direct to theatre or to the ward for surgery (the costs of which are included under "Surgery" in a later section).
- In the remaining 50% of cases: admission to stabilise the patient prior to surgery, assumed to last for seven days, assumed to be on general medical ward.

Endoscopic treatment of early stage cancer
A minority of stage A cancers can be completely excised during colonoscopy (HRG F35). This proportion was assumed to be 10% of people with stage A cancer detected on screening. A second colonoscopy to assess completeness was assumed.

Pre-operative radiotherapy
The principle literature source for treatment assumptions was the Health Care Needs Assessment (HCNA) Report on Colorectal Cancer, commissioned by the Department of Health (Sanderson et al 2000). This suggests that 50% of stage A and B rectal cancers undergo pre-operative radiotherapy. Also based on the HCNA report, the cost attached was assumed to be that for HRG W14 (complex and imaging 4-12 fractions).

Surgery
The NHS Reference Costs for England and Wales (DH 2002) report numbers of patients undergoing different types of surgery on the large intestine. It was assumed that these proportions applied to cancer patients and a weighted cost for an operation was estimated accordingly.

HRG	Surgery on large intestine	n	%	HRG cost	Weighted av. cost
	Elective				
F31	Complex Procedures	7,136	18%	£4,951	£910
F32	Very Major Procedures	11,363	29%	£4,198	£1,229
F33	Major Procedures w cc	1,606	4%	£3,564	£148
F34	Major Procedures w/o cc	4,209	11%	£2,678	£291
	Non-elective				
F31	Complex Procedures	2,127	5%	£5,087	£279
F32	Very Major Procedures	9,149	24%	£4,747	£1,119
F33	Major Procedures w cc	1,701	4%	£4,374	£192
F34	Major Procedures w/o cc	1,512	4%	£3,345	£130
		38,803			£4,298

Note that this only includes in-patient costs.

Post-operative radiotherapy
The HCNA report estimates that 20% of stage B and stage C rectal cancers receive post-operative radiotherapy. The relevant HRGs are W15 (Complex Teletherapy with Imaging, >12 <24 Fractions) and W16 (Complex Teletherapy with Imaging, >23 Fractions). The cost applied was the average of the two given in Reference Costs

Primary radical radiotherapy
The HCNA report estimates that 20% of stage C and stage D rectal cancers receive primary radical radiotherapy rather than surgery. The same HRGs as for post-operative radiotherapy above were cited.

Post-operative chemotherapy with curative intent
It was assumed that 80% of patients with stage C colorectal cancer get chemotherapy. A 5-FU based regime was assumed and the relevant HRG was taken to be X07 (colorectal cancer chemotherapy fluorouracil bolus).

Follow-up
Follow-up was assumed to involve 3 out-patient clinics per year, one ultrasound of the abdomen and pelvis, plus one colonoscopy in total. Follow-up was assumed to last for five years in patients without recurrent disease. Where recurrence or advanced disease was detected this was assumed to occur after two years on average, at which point the follow-up described above would cease.

Palliation of recurrent and terminal disease
This was defined as a mixture of surgery, radiotherapy, chemotherapy and supportive care, as follows:

- surgery - 33% chance of undergoing a second operation, which is assumed to cost the same as the initial procedure
- radiotherapy - 50% chance of undergoing palliative radiotherapy. The HCNA report cites HRGs W03 and W04, so the cost used was the average of the two.
- chemotherapy - 50% chance of undergoing palliative chemotherapy. In the HRG costs there are six colorectal cancer chemotherapy regimes and the cost used was the weighted average based on number of regimens in 2001/2.
- palliative care - 67% chance of requiring palliative care. The cost from the HCNA report was used; this was based on the need for palliative and supportive services in a population. The cost per patient was derived by dividing this estimated total cost by the projected number of cases of cancer.

Unit costs used
The following HRG costs were used (DH 2002):

HRG	Item	Cost
	General surgery out-patient clinic	£103 initial visit, £66 follow-up
F35	Colonoscopy & biopsy	£138
F18	Ultrasound	£91
W14	RT complex & imaging 4-12 fractions	£777
W15	RT complex teletherapy with imaging, 13-23 fractions	£1,014
W16	RT complex teletherapy with imaging, >23 fractions	£484
W03	Palliative radiotherapy	£229
W04	Palliative radiotherapy	£508
X07	Chemotherapy (fluorouracil bolus)	£227

Costs taken from "Scottish Health Service Costs" (Information and Statistics Division of NHS Scotland 2002) included:

- CT scan £77
- A&E attendance £48
- Day on general medical ward £247

The cost of a GP visit was assumed to be £19 (Netten et al 2002).

Difference between screening and symptomatic cancers
The two differences in assumptions used were as follows:

- 10% of stage A screening detected cancers can be treated endoscopically
- no screening-detected cancer requires an emergency admission or surgery

Otherwise, identical assumptions were used.

Stage-specific data on elective/emergency, colon/rectum and survival distributions by stage
The following data from the HCNA report (based on audit data from Wessex Region in England) were used in calculating costs:

Stage	5-year survival – colon	5-year survival – rectum	Ratio of colon / rectum for each stage
A	76%	71%	54 / 46
B	57%	58%	74 / 26
C	37%	34%	68 / 32
D	14%	8%	76 / 24

Results

The costs by stage for cancers detected through screening and through investigations of symptoms were as follows:

Stage	Screen-detected	Symptomatic
A	£6,656	£7,058
B	£7,354	£7,398
C	£7,071	£7,158
D	£6,022	£6,152

The detailed breakdown of these costs for screening detected cancers was as follows (note that these are averages for a "typical" patient detected with each stage of the disease):

Screen-detected	Stage A	Stage B	Stage C	Stage D
Diagnosis	£455	£455	£455	£455
Pre-op radiotherapy	£181	£100	£0	£0
Treated endoscopically	£28	£0	£0	£0
Surgery	£3,868	£4,298	£4,083	£2,149
Post-op radiotherapy	£0	£39	£49	£0
Post-op chemotherapy	£0	£0	£182	£0
Primary radical RT	£0	£0	£49	£37
Follow-up (cured)	£1,166	£906	£570	£198
Follow-up (not cured)	£167	£271	£405	£554
Palliation	£791	£1,285	£1,923	£2,629
Total	**£6,656**	**£7,354**	**£7,716**	**£6,022**

The following table shows the same data for patients who present with symptoms:

	Stage A	Stage B	Stage C	Stage D
Diagnosis	£455	£499	£542	£585
Pre-op radiotherapy	£181	£100	£0	£0
Treated endoscopically	£0	£0	£0	£0
Surgery	£4,298	£4,298	£4,083	£2,149
Post-op radiotherapy	£0	£39	£49	£0
Post-op chemotherapy	£0	£0	£182	£0
Primary radical RT	£0	£0	£49	£37
Follow-up (cured)	£1,166	£906	£570	£198
Follow-up (not cured)	£167	£271	£405	£554
Palliation	£791	£1,285	£1,923	£2,629
Total	**£7,058**	**£7,398**	**£7,802**	**£6,152**

Discussion

Note that while some aspects of cost do not differ between screening detected and symptomatic cases, this reflects an assumption that stage is the main determinant of cost and prognosis. In other words, a stage B cancer has the same costs and prognosis once it is treated no matter whether it was screening detected or presented symptomatically. The net impact of screening on treatment costs will be reflected by the change in the stage distribution at treatment, which is not part of this calculation but has been included in the full screening model reported in the main part of this paper.

Clearly, long-term prospective data collection has advantages over the method used above to estimate lifetime treatment costs. However, such data collection would be time-consuming and expensive.

Limited validation of model assumptions against routine NHS data is possible. The ISD of NHS Scotland supplied data on treatment rates within six months of diagnosis, as follows:

Stage	Surgery	Chemotherapy	Radiotherapy
A	93%	3%	8%
B	96%	11%	7%
C	96%	45%	11%
D	59%	30%	12%

Simple comparisons are difficult because the estimates above generally do not specify exactly when resource use occurred. With this caveat in mind, the assumptions used in the model were as follows:

Stage	Surgery	Chemotherapy	Radiotherapy
A	100%	0%	23%
B	100%	0%	13%
C	80%	80%	40%
D	50%	25%	25%

The main differences are as follows:

Scottish data shows 45% of stage Cs receive chemotherapy within 6 months whereas the model assumes 80%. The model assumption is retained because data from 1997, 1998 and 1999 show that the Scottish rate is rising by more than 5% per annum, hence 80% is assumed to be a reasonable figure for the future.

Radiotherapy was not being used as extensively in 1999 in Scotland as the model assumes. However, the model assumptions reflect the best available clinical evidence and recent increases in funding of cancer in Scotland may well increase rates in the future. Again, this was felt to be sufficient to justify the assumption.

Overall, however, the Scottish data suggest that the costs used in the model may be slight overestimates.

A recent American model of colorectal cancer screening (Frazier et al) used the following lifetime costs:

- localized cancer $22,000
- regional cancer $43,900
- distant cancer $58,300

Using simple "headline" exchange rates (£1=$1.65) suggests the American figures are far higher than those estimated for the UK, as follows:

	Frazier et al	Estimate
Localized cancer (stage A)	£13,333	£7,058
Regional cancer (stages B & C)	£26,606	£7,600
Distant cancer (stage D)	£35,333	£6,152

The American data comes from another study in that country; unfortunately neither source cites the resources used so a comparison of length-of-stay, chemotherapy rates, etc. is not possible. Some limited comparisons of costs of different types of resource use are possible, based on other cost data in the Frazier paper and HRG data for the NHS. These are shown in the following table:

HRG		HRG/UK cost	Frazier cost
N/A	FOB test	£5	$38
F06op	Colonoscopy Examination Alone	£127	$1012
F05op	Colonoscopy with Biopsy or Therapy	£138	$1519
F14op	Flexible Sigmoidoscopy Examination Alone	£119	$279
F08op	Flexible Sigmoidoscopy with Biopsy or Therapy	£121	$564
F15op	Barium Studies	£120	$296

As can be seen, the simple exchange rate cited above would not accurately convert US to UK terms – in the most extreme case (colonoscopy with biopsy or therapy) the actual exchange rate is $11=£1. This suggests that translation of crude total costs using headline rates is highly inaccurate. It would be more helpful if data on actual resource use were available; this has been requested from the American authors but was not available at the time this paper was prepared.

Reference

Frazier L., Colditz G., Fuchs C. et al. *Cost-effectiveness of screening for colorectal cancer in the general population* JAMA 2000; 284: 1954-1961.

Department of Health NHS Reference Costs 2002. Available from: URL: http://www.doh.gov.uk/nhsexec/refcosts.htm

Information and Statistics Division (ISD), NHS Scotland Scottish Health Service Costs 2001/2 Available from: URL: http://www.show.scot.nhs.uk/isd/

Netten A, Rees T, Harrison G. "Unit Costs of Health and Social Care 2001" (PSSRU, University of Kent at Canterbury). Available from: URL: http:// www.ukc.ac.uk/PSSRU/

Sanderson H, Young D, Walker A. Colorectal Cancer (Health Care Needs Assessment series, 2000)

Appendix 5: Methods (Organisation and Management)

(including interview sampling frames, thematic frameworks used in interviews, methods for minimising bias, etc)

Three methods were used to gather information for this part of the study. First a series of interviews were held with key stakeholders (managers and clinicians); these were held at the beginning and end of the piloting process (2000 and 2002) so that both prospective and retrospective views were captured. Secondly, where appropriate relevant written material and documents were used to validate and inform on issues identified in these interviews. Finally, a series of questionnaires were produced designed to be administered to key professional groups nationally i.e. radiologists, pathologists and colonoscopy services. The questionnaires sought national information on key issues that had emerged during the interviews and aimed to explore the generalisability of these and other issues identified in the Pilots.

Interviews with key stakeholders

A first series of interviews (prospective phase 1 interviews) was carried out early in the pilot implementation process during the middle of 2000. These interviews were planned to coincide with a period just before the pilot sites went live, at the start of issuing patient invitations. Interviews with the Scottish site proceeded on that basis and were concluded before October 2000. Delays with the IT system at the English pilot site meant that interviews with the English site had to be delayed. This ensured that the prospective views collected were unbiased by the adverse effects of this IT delay. Some interviewees, unaffected by the IT system delay, were conducted at the same time as the Scottish pilot site interviews.

A second series of (retrospective) interviews was conducted as the pilots approached their end in July 2002.

Sampling frame for organisation and management interviews

The interview sample consisted of individuals identified through a process of wide consultation. At each stage, recommendations on named individuals to be included in the sample was sought from evaluation team members and representatives of national bodies, producing a final interview sampling frame as shown in Table A.1. Consultation on the sampling frame for the prospective interviews was undertaken during late 1999 and for the retrospective interviews during May 2002. The sample included individuals from trusts, the pilot screening units and national personnel directly involved with the pilot at both stages, although because of staff movement and changes in responsibility over this two year period the two samples were not identical.

For both rounds of interviews, repeated attempts were made to contact all individuals in the sample.

Thematic framework used for the interviews

The first round of prospective interviews were conducted using a semi-structured thematic framework developed from pilot interviews, literature searches, and themes identified in the Green Book (Garvican 1998). The framework was designed to capture perceptions of the screening programme in its early stages and to identify issues associated with the implementation process. The content of the thematic framework underwent a round of consultation with key personnel in the pilots and members of the evaluation team, and a final version was circulated for comment prior to use. The thematic framework used for the prospective interviews is listed in Column A of Table A.2.

For the retrospective interviews a similar approach was adopted. All interviewees were given a copy of the thematic framework used in the prospective interviews as a framework for their thoughts. In addition, the interviews were structured to address three specific questions (with accompanying text);

- *What are the lessons learned about management and organisation from the pilot?*
- *What do you consider are the essential management and organisational issues to be addressed should the programme be rolled-out?*
- *What are your reflections on the piloting process?*

Conduct of interviews
Once booked, all interviews (prospective and retrospective) were confirmed by letter and a copy of the thematic framework for the interview enclosed. Interviews did not follow the order of the thematic framework rigidly, but rather questions were raised in the sequence in which topics presented themselves for discussion. However, an active checklist was maintained during the interview, and at the end interviewees were referred to the thematic framework and asked to confirm they had spoken to all the topics on which they wished to comment. To protect against missed areas in the framework, all interviewees were also encouraged, at the end of the prospective interviews, to identify and discuss any topics which had not been raised. For prospective interviews, no additional items were added to the schedule at the end of the first (5) 'pilot' interviews. These interviews lasted 45-90 minutes and were recorded with the prior consent of participants. Individuals were assured of the freedom to request that comments should be "off the record" at any point during the interview, if they so wished, and the tape recorder was stopped if this request was received.

Retrospective interviews were also recorded, with the consent of the interviewee. Interviewees were once again reminded of the confidentiality of the interview and the possibility of speaking "off the record". For retrospective interviews the three additional questions outlined above were raised in order. Following discussion of these questions, the interviewee was referred to the thematic framework and asked to comment on other topics. Prior to these interviews, the interviewer reviewed the interviewee's first interview (if undertaken). The interviewee was reminded of any particular concerns they had raised at the start of the pilot process and asked if they wished to follow up on their initial concerns.

Analysis of interview material:
A dynamic model was adopted for the analysis of all interview material (Murphy 1998). This included an initial formative analysis of the implementation based on the prospective interviews and a final summative analysis following the final interviews. The formative analysis was used to inform the retrospective interviews. It was also a requirement of the evaluation that an interim report be produced for the Pilot. A brief summary of emerging findings and themes was produced at this time.

In so far as was possible, the process of analysis was iterative with triangulation and validation of findings at several stages and by different means (7.1.3.5 following). Bias was minimised by separating the production of data (interviews and transcription) from their analysis, with different researchers undertaking these tasks, thus ensuring the most rigorous analysis possible of the interview material.

Analysis of interview data was undertaken using the inductive technique (Pope 2000) with an iterative return to the data to test the generalisability of categories formed (Ovretveit 1998). A descriptive method of reportage was also used to convey interview content analysis, with careful attention to context[3].

The researcher who analysed the prospective interview materials independently developed a thematic framework from the interview transcripts. This framework was mapped against the original thematic framework used for the interviews (**Table A5.2**). A final framework emerged from the textual analysis containing eight dimensions, as listed in **Table A5.2**. Two of these dimensions incorporated elements which represented an overlap with areas that emerged as themes in the information systems interviews.

Validation of analysis of interview material
A number of mechanisms were used to limit bias and ensure validity of analyses as follows: (a) separation of textual analysis from interviews (data collection); (b) testing of formative and summative analyses for face validity with the data collector; (c) revisiting themes identified in the formative analysis during second interviews; (d) feedback of relevant summative findings to respondents. Furthermore, on completion of the final summative analysis, the written materials collated were re-examined in relation to the key themes which had emerged from the two rounds of interviews. This enabled a further element of triangulation.

Two constraints affected the evaluation. First, the whole of the pilot process had to be observed before conclusions and recommendations could reasonably be made about organisation and management[4]. Second, there was always a possibility in the form of data capture used that information would be lost because of working from verbatim transcripts. However, this was unavoidable because resources available for the evaluation precluded analysis incorporating objective indications of the actual delivery, pace, enthusiasm, reservation or other non-verbal content underlying the recorded speech.

[3] The analysis technique was designed to reflect that there is always the possibility of an interviewee using an evaluation such as this as a platform for a covert agenda or special pleading. Presentation of the quotes is designed to protect, as far as possible, against this eventuality.

[4] The use of experiential and iterative learning techniques, often categorised as Action Research methods, were an important process in the development of the pilot itself. It was therefore not possible or appropriate to use these techniques within the evaluation. Rather the researchers took the opportunity for objective observation for the whole period of the pilot to evaluate O&M and IS.

To compensate for the latter potential short-coming any deductions and interim conclusions were fed back by the analyst to the interviewer for discussion, resolution, confirmation and conceptual ordering(Strauss 1998). This primary validation process (analyst/ data collector) also established two other facts; a) that the interview technique had not forced the respondents into an artificially constrained framework and, b) that the interview transcripts confirmed the content of the original thematic framework and allowed addition themes to be identified.

Finally, the formative findings from the prospective interviews were discussed within the Evaluation Team. No objections were raised or alterations requested. Key stakeholder groups were telephoned direct after production of an Interim Report and asked if a) they could validate their summary and, b) whether they considered that there were omissions. All assented to the summary and no omissions were identified other than issues relating to the Information Systems, which were covered in a separate part of the study. A similar process was undertaken for the Final Report.

Analysis of written materials

Collection of key written materials and documents relating to meeting (eg minutes, reports) was set in place by the Evaluation Team. All items received were catalogued centrally and lists of items copied to the researchers. An initial extraction of themes was undertaken. This exercise was used as a diagnostic tool to further validate the thematic frameworks used for interviews. The materials were also used to substantiate certain claims and arguments proffered by interviewees. In addition, documents were used to highlight aspects of screening implementation that might require further examination outwith the pilots, eg the need for national surveys.

Interviews conducted

For the prospective interviews a total of 72 stakeholders were identified who might be able to supply a valuable perspective on the Screening Pilot. In total 51 stakeholders[5], 27 conversant with the English pilot site and 24 conversant with the Scottish pilot site were interviewed as shown in **Table A5.1**. Of the remainder some declined to be interviewed (8 individuals) or referred the interviewer to others who they considered were better able to contribute (7 individuals). One person was unavailable and five individuals were not approached for various reasons.

For the retrospective interviews a total of 44 individuals were elected for interview by those consulted at this stage. Not unexpectedly this is fewer than were identified for the prospective interviews. It should be remembered that the developmental nature of the pilot after 2 years of operation had already allowed resolution and consensus to be reached on many issues. Thus, the individuals nominated for interview were considered by all to be representative of the general views of their group. In some cases the researchers also included individuals to test the assumption of consensus and thus, several people for one professional group were identified.

After the first fifteen retrospective interviews had been conducted an issue emerged that required the inclusion of two members of the Evaluation Team in the sampling frame. Thus, a total of 41 interviews were conducted at the end of the pilot, five individuals were either unavailable or refused to be interviewed for the retrospective interviews.

[5] Some interviews involved more than one person.

Table A 5.1 Sampling frame for organisation and management key stakeholder interviews

A: Prospective interviews (2000)

Name	Role	Organisation
English Screening Unit		
R Parker	Lead Clinician Director	Walsgrave Hospital
S Elwell	Programme Manager	
P Ramsell	Lead Nurse	
L McSheffrey	Office Manager	
I Girgis	MLSO, manager of FOBt lab.	
S Smith	Lead Biochemist	
E Simmonds	Unit nurses	
C Wheatley		
L Roberts		
D Froggatt		
Walsgrave Hospital (English Lead Trust)		
T Goodfellow	Radiologist	Walsgrave Hospital
D Holt[1]	*Endoscopist*	
M Newbold	Lead Histopathologist	
D Loughton	Chief Executive	
J Markman[1]	*Nursing Lead*	
S Chamberlain	Manager, Implementation and IT	
P O'Brien	**PCG Chairman**	Coventry West PCG
A Cook	SpR in Public Health	Coventry HA
K Williams	Director of Public Health	
Warwick Hospital (English partner)		
A Riley[2]	*Chief Executive*	Warwick Hospital, Warwick
M Osbourne	Surgeon	
D Clarke	Radiologist	
N Hempstead	Acting CEO	
Dr Smew	*Histopathologist*	
J Cryer[3]	*Director of Performance Develop.*	
M Graveney[4]	*Acting DPH (Cons in PHM)*	Warwickshire HA
L Griffiths	Primary Care Commissioning	
J Bonsor	South Warwickshire Community Health Council	
George Eliot Hospital, Nuneaton (English partner)		
N Carver	Chief Executive	George Eliot Hospital, Nuneaton
G Matthew	*Surgeon*	
K Vallance	Lead Radiologist	
B Ruban	Nurse Endoscopist	
D Marsden	Nurse Endoscopist	
Mr Lele[1]	*Surgeon*	
N Bajallan	*Histopathologist*	
English National Screening Office		
J Patnick	National Co-ordinator	NSO, Sheffield
K Robertshaw (ne Arundell)	Project Officer	
R Winder	Deputy National Co-ordinator	

1. Interview not requested in first round or declined to be interviewed
2. Gardening Leave prior to interviews, role taken by Nancy Hempstead
3. Transferred to new post before interviews
4. Referred to L Griffiths

Name	Role	Organisation
Scottish Screening Unit		
C Smith	Pilot Manager	Kings Cross Hospital, Dundee
A Storrs	Screening Office Manger	
J Gordon	Senior MLSO	
L Scott	Pilot Secretary	
F Jack	Pilot Nurse	Ninewells Hospital, Dundee
Tayside: Lead Trust		
R Steele	Lead Clinician Director	Ninewells Hospital, Dundee
P White[6]	*CEO*	
D Johnston	Colonoscopist	
F Carey	Lead Histopathologist	
A McCulloch	Lead Radiologist	
C Fraser	Lead Clinical Biochemist	
M Kencier	Cons in Public Health Medicine	Tayside Health Board
B Goudie	Coordinator, GP link for CRCS	West Gate Health Centre
Grampian Hospitals and Region		
A Mowat	*Surgeon*	Grampian University Hospitals NHS Trust,
A Cumming	CEO	
L Patterson	Pilot Nurse	
S Ewen	Histopathologist	
T O'Kelly	Surgeon	
P Phull	*Colonoscopist*	
T Sinclair	*Colonoscopist*	
J Hussey	*Radiologist*	
J McKinnon	*Service Manager, Gastroenterology*	
B Wilson	*Cons in PHM*	
D Williams	Colonoscopist	Dr Grays Hospital, Elgin
Fife Region		
J Wilson	Surgeon	Victoria Hospital, Kirkcaldy
J Connaghan	CEO	
K Ballantyne[5]	*Surgeon*	
G Birnie[5]	*Surgeon*	
B Adamson[5]	*Histopathologist*	
L Bradley	Nurse (peripatetic)	
A Finley[5]	*Cons in PHM, Public Health*	Fife Health Board
R Grant	GP Link	Markinch Health Centre
Scottish National Screening Office		
J Warner	National Co-ordinator	Trinity Park House
C Morton	Project Manager	

5. Screening paused in Fife and asked not to interview by Evaluation Team.
6. Suggested substitute who failed to respond to request for interview

B: Retrospective interviews (2002)

Name	Role	Organisation
English Screening Unit		
R Parker	Lead Clinician Director	Hospital St Cross, Rugby
P Ramsell	Programme Manager/ Lead Nurse	
C Beasley	Office Manager	
M Ofield	MLSO	
S Smith	Lead Biochemist	
E Simmonds	Screening Nurse	
S Dawson[1]	*Screening Nurse*	
L Roberts[1]	*Screening Nurse*	
C Wheatley[1]	*Screening Nurse*	
V Organ	Data Entry Clerk	
Walsgrave Hospital (English Lead Trust)		
T Goodfellow	Radiologist	Walsgrave Hospital
M Newbold	Lead Histopathologist	
D Loughton	Chief Executive	
K Williams	Director of Public Health	Coventry PCT
Warwick Hospital (English partner)		
C Heginbotham	Chief Executive	Warwick Hospital, Warwick
M Osbourne	Surgeon	
D Clarke	Radiologist	
J Bonsor	South Warwickshire Community Health Council	
George Eliot Hospital, Nuneaton (English partner)		
N Carver	Chief Executive	George Eliot Hospital, Nuneaton
K Vallance	Lead Radiologist	
B Ruban	Nurse Endoscopist	
English National Screening Office		
J Patnick	National Co-ordinator	NSO, Sheffield
K Robertshaw (ne Arundell)	Project Officer	
Scottish Screening Unit		
R Steele	Lead Clinician Director	Ninewells Hospital, Dundee
Linda Bradley	Pilot Manager	Kings Cross Hospital, Dundee
L Ower[1]	*Screening Office Manger*	
J Gordon	Senior MLSO	
H Hawksworth	Pilot Nurse	
J Shearer	Data Entry	
E Bennett	Pilot Nurse	
Tayside Region (Scottish Lead Trust)		
F Carey	Lead Histopathologist	Ninewells Hospital, Dundee
A McCulloch	Lead Radiologist	
F Jack	Pilot Nurse	
C Fraser	Lead Clinical Biochemist	
M Kencier	Cons in Public Health Medicine	Tayside Health Board

Grampian Hospitals and Region (Scottish Partner)		
A Mowat	*Surgeon*	Grampian University Hospitals NHS Trust
A Cumming	CEO	
L Patterson	Pilot Nurse	
S Ewen	Histopathologist	
D Williams	Colonoscopist	Dr Grays Hospital, Elgin

Fife Region (Scottish Partner)		
J Wilson	Surgeon	Victoria Hospital, Kirkcaldy
J Connaghan	CEO	

Scottish National Screening Office		
C Colquhoun	National Co-ordinator	Trinity Park House
C Morton	Project Manager	

Evaluation Team		
F Alexander	Principal Investigator	University of Edinburgh
C Round	Project Statistician	

1. Interview not requested or declined to be interviewed
2. Gardening Leave prior to interviews, role taken by Nancy Hempstead
3. Transferred to new post before interviews
4. Referred to L Griffiths
5. Screening paused in Fife and asked not to interview by Evaluation Team.
6. Suggested substitute who failed to respond to request for interview

A: thematic framework for prospective interviews

1. **Context:**
   - Key roles
   - Responsibilities
   - Systems set in place

2. **Management:**
   - Efficiency of internal processes
   - Barriers to achievement of set quality criteria
   - Compare management structures
   - Identify strengths and weaknesses

3. **Emerging management issues:**
   - Manpower
   - Quality assurance
   - Clinical governance
   - Staff delivering screening
   - Staff in symptomatic services

4. **Organisation of programme as integrated systems:**
   - Defined set of objectives
   - Agreed criteria to measure achievement of objectives
   - IS system to measure performance
   - Explicit quality standards
   - Mechanism for taking action if problems

5. **Key operational management processes:**
   - Call/recall, efficiency of processes
   - Complaints and incident procedures
   - Sample processing
   - QA systems
   - Safety standards
   - QA for help line

6. **Staffing:**
   - Structures
   - Potential shortages
   - Methods employed to overcome shortages
   - Changes to skill mix
   - Training issues

7. **Laboratory services:**
   - Efficient means of internal processing, evidence of QA systems, national standards etc.
   - Staffing issues locally
   - Opinions on potential staffing issues re UK roll-out

8. **Impact:**
   - Other services
   - Future capacity

Appendix 6 National survey: detailed methods and results

Many of the issues identified through interviews with Pilot sites were then tested for generalisability through national surveys. Data from the stakeholder interviews, together with information on workload and impact on routine services in the Pilots, were used to develop questionnaires for key staff groups who might be directly involved in any roll-out. The surveys were designed to provide evidence on specific organisational and management issues identified in the pilot sites. In particular, where staffing and facilities problems might be a significant constraint, the survey questionnaires were designed to assess the potential impact of these on national implementation of screening, and demonstrate the feasibility of possible steps to overcome them.

Three questionnaires were developed; one for Radiology Departments, one for Pathology Laboratories and one for Colonoscopy Services. All questionnaires were piloted before use.

Data were entered using Access 2002 software. SPSS version 11.0 was used for quantitative analysis, with Chi squared testing for univariate relationships. Analyses were largely restricted to respondents' views on departmental ability to cope with the anticipated extra workload.

Part way through the evaluation (October 2001), the National Services Division (NSD) in Scotland conducted a survey of all non-Pilot trusts in Scotland to examine potential manpower/ capacity and training issues for radiology, pathology and colonoscopy associated with any potential Scottish rollout. Care was taken to ensure that the content of the survey questionnaires was harmonised with the NSD exercise.

Colonoscopists' Questionnaire
Questionnaires were sent to 221 gastrointestinal endoscopists in November 2002.

The questionnaire comprised mainly closed questions asking about staffing numbers, number of colonoscopies performed, waiting lists and times, facilities, the ability to increase colonoscopies using current facilities, the ability to absorb the estimated increase in demand for colonoscopies generated by a colorectal screening programme (250 cases per 100,000 population per year) without undue deleterious affects on waiting times for other patients, quality assurance, colorectal cancer cases diagnosed, and multi-disciplinary meetings. Respondents were invited to make free text comments.

Results
Four questionnaires were returned as they could not be delivered. There were 47 (22%) completed questionnaires.

Eight (17%) respondents reported that they could increase the number of colonoscopies performed each week, using their current facilities only if other activities which could be relocated were displaced. Nineteen (40%) could, only if other activities which could not be relocated were displaced. A further 12 (25%) respondents said they would not be able to increase the number of colonoscopies using their current facilities.

Comments from 21 respondents expanding on this and 5 relevant comments from the free text space at the end of the questionnaire relating to resources were quantified as follows.

Topic	Number of comments
Shortage of space/rooms	10
Shortage of staff	9
Shortage of equipment	6
Lack of funding	6
Only *'at expense of upper GI endoscopy and colonoscopy/flex sig for other indications including other routes of potential cancer referral'*	2

When asked to indicate how difficult it would be to absorb the extra cases expected, if colorectal screening were introduced, into their lists without undue deleterious effects on waiting times for other patients, only one (2%) respondent indicated that this could be done with little or no difficulty. Seventeen (36%) said they would need extra lists, 24 (51%) extra staff, and 22 (47%) extra colonoscopists. *NB Respondents were asked to tick only one box and this may have reduced the number of responses for each option.*

Responses indicated that nurse trained endoscopists (not necessarily colonoscopists) are employed in 35 (74%) of the Trusts in which respondents work.

Discussion

- Poor response rate limits generalisability of results
- The vast majority of respondents (all but one) considered that extra resources (staff, funding, equipment and space/rooms) are essential to cope with any extra colonoscopies.

Free-text comments

Comments included

> *'An appropriate infrastructure will need to be provided and organised separate from the day to day demands of the NHS'*
>
> And
>
> *'my impression is that the programme will not cope with polyp & post op follow up in patients referred on basis of FOBt'*

Radiology Questionnaire

Questionnaires were sent to clinical directors of radiology services at 227 hospitals in the United Kingdom in July 2002 and a reminder was sent to non respondents in November 2002.

The questionnaire comprised closed questions asking about number of investigations per year, number of Double Contrast Barium Enemas (DCBEs) in previous 12 months, waiting times for urgent and routine DCBEs, dedicated DCBE lists, method of imaging large bowel, age of existing equipment, plans for purchasing new equipment, the difficulty of absorbing extra cases generated by screening programme (estimated at 2.5 per week per 1 million population) and resources required to do so, quality assurance and multi-disciplinary (MD) meetings, and the levels of staff and vacancies. Respondents were able to make free text comments as they wished.

Results

Fourteen respondents reported their department as not applicable for this questionnaire. There were 105 (49%) completed questionnaires.

Twenty five (24%) respondents said their department could absorb 1-3 extra barium enemas per week with little or no difficulty while 22 (21%) could absorb 1-3 extra barium enemas per week within existing lists with difficulty.

Forty eight (46%) thought they would need extra lists, 43 (41%) extra radiographers, 36 (34%) extra radiologists and 13 (12%) extra equipment or rooms. When asked what other provisions they might require 4 (4%) added that they would need extra nursing support and 3 (3%) that they would need extra administrative or clerical staff.

Radiographer performed DCBE lists have been introduced by 91 (87%) of the responding hospitals. The number of patients on these lists in a week ranged from 0 to 65 with a median of 18 (IQR 10,28). If these weekly totals are converted to yearly totals and expressed as a percentage of the DCBEs performed in the previous 12 months this equates to a mean of 88.5%.

There were no statistically significant correlations ($p< 0.05$) between belief that the anticipated extra workload caused by colorectal cancer screening could be absorbed without difficulty and the number of investigations per year, waiting time for DCBEs, dedicated DCBE lists, type of equipment used, frequency of attending MD meetings, or the introduction of radiographer DCBE lists. Comparison between England, Wales and Northern Ireland and Scotland was not significant either.

Seventy one (68%) of respondents had consultant radiologist vacancies. The median number of vacancies (for these 71 hospitals) was 2, (IQR 1,2)(range 0.4 – 6). Sixty seven (64%) had radiographer vacancies. Of these 67 the median number of vacancies was 4 (IQR 2,7) (Range 1,23)

In 29 (23%) hospitals staff are currently training to be radiographer practitioners.

Thirty one (30%) departments currently use Spiral CT/Virtual colonoscopy to image the large bowel and 29 (28%) report Spiral CT/Virtual colonoscopy being developed. Data from both these groups (N=50) shows that between 0 and 50% of total examinations at their hospital are performed using Spiral CT/Virtual colonoscopy equipment; median = 5% (1%, 8%).

Free-text comments
There were 43 relevant additional comments provided as follows:

Staff Shortages: The majority (15) of these were about staff shortages, both radiologists and radiographers.

'Posts are now much harder to recruit'
'Post advertised recently, but no applicants'
'Inadequate radiologist numbers'.
'We have had a rapid turnover of radiographers leaving and further training required. Shortages of radiographers will be an increasing problem in maintaining this service.'

The expansion of the radiographer's role was acknowledged as helping to keep waiting lists to a minimum (14 comments), but one respondent commented that

'shortage of radiographers is holding back advanced practice training.'

Equipment and rooms: Ten respondents commented on full capacity of existing rooms or old, unusable equipment. Using existing rooms and equipment out of normal working hours in order to keep their waiting lists acceptable was mentioned by 2 respondents, and another 2 people said they would need to do this if they had any extra workload.

Capacity: Six respondents said that their departments were currently working at full capacity.

'At the moment I cannot support the existing workload'

However another two respondents commented that they would be able to incorporate screening without difficulty.

'An extra 1 or 2 examinations per week would be NO PROBLEM'.

Audit: There was only one comment about audit: *'No facilities for audit'*.

Other comments: A concern that screening may cause delays for symptomatic patients was mentioned in 4 questionnaires.

'I believe it is critical that a colorectal screening programme should not displace other patients by transferring resources'.

Five people commented that they thought there would be more of a problem with extra colonoscopies in their hospital than with radiographic examinations.

Discussion

- The majority of respondents believed extra staff would be required and there is at present a large number of staff vacancies. This suggests that it would not be easy to supply the extra staff believed to be required.
- The majority of hospitals have already introduced radiographer DCBE lists and they appear to carry out the majority of DCBEs. Staff shortages may make it difficult to increase the number of radiographer performed DCBEs substantially.
- Equipment and space would be required by many units. Lists outside the 'usual working day' are currently used by some units to reduce waiting times and this would be a possible solution to an increased workload and no extra facilities.
- Emerging Technologies – one in three department currently use spiral CT/ Virtual colonoscopy, and a further third are developing it
- Although the majority of radiologists believed they would require more resources, nearly a quarter felt confident they could absorb the extra workload which suggests that local consultation should take place to determine local needs before introduction of a national screening programme.

Histopathologists' Questionnaire
Questionnaires were sent to 264 pathology departments in the UK in July 2002 and a reminder was sent to non respondents in November 2002.

The questionnaire consisted mainly of closed questions asking about staffing numbers, number of specimens of colorectal cancer per year, the ability to absorb the anticipated 1-5 extra cases generated by screening programme with current resources, and extra resources required to do so, quality assurance and multi-disciplinary meetings, and the levels of staff and vacancies. Respondents were able to make free text comments as they wished.

Results
Sixteen responses were excluded because the questionnaire was not applicable to them (these laboratories receive no samples of suspected colorectal cancer). There were 128 (52%) completed questionnaires.

Only 38 (30%) thought that their pathology department would have the staff resources to process specimens from colonoscopies arising from a screening programme; 87 (68%) thought not. The median number of extra consultant session that these 87 respondents thought necessary to cover the additional workload was 1.5 (IQR 1,2).
66 (52%) reported that they would require extra MLSOs to cover the additional workload. The median number of MLSO posts thought necessary was 1 (IQR 0.3, 1).
64 (50%) considered that they would need additional resources, other than staff, for the extra specimens. Comments from 57 respondents expanding on this were quantified as follows.

Topic	Number of respondents
Extra administrative or clerical support	29
Extra consumables	13
Extra equipment	8
Extra money	6
Extra IT support	3
BMS time/training	2
More space	1

88 (69%) of departments reported they have current staff vacancies. 80 (63%) reported difficulties in recruiting pathologists and 105 (82%) reported problems recruiting MLSOs. Scottish departments were significantly less likely to report problems recruiting MLSOs than those in England, Wales and Northern Ireland. (50% vs 86%, Chi Squared = 7.3, df = 1, p = 0.03). There was no difference in difficulty in recruiting pathologists (57% vs 66%).
15 (12%) departments thought they would need to change their QA arrangements if screening were implemented.

Of these, 5 said their arrangements would only need to be changed if an EQA were introduced, 5 thought that an EQA should be introduced, 5 thought that there would be increased time spent on audit, and 2 mentioned a need for increased audit support for administration, clerical or computer work.

Free-text comments

Theme	Workload specific comments (N= 63)	General comments (N=47)
Staffing	The main topic mentioned was the difficulty in recruiting staff (21 comments), BMS staff (15 comments) and consultant pathologists (6 comments). 7 respondents also mentioned that they currently had insufficient staff for their workload (7 comments, consultants (4) and BMS (2))	Most comments (19) regarded staff shortages for any increased or even current workload – even when funding was available there was difficulty recruiting staff. Administrative and clerical support should not be forgotten
'Creeping workload'	A recurring theme (11 comments) was '*creeping workload'* – the addition of small amount of work that overall had substantially increased the workload. One respondent commented that implications for diagnostic specialties, when changes in clinical practice are made, are often not understood and that it was good to see histopathologists being consulted.	There was a strong feeling that many clinical developments which each caused small increases in workload had been introduced 'by the back door' (4 comments) and that the implications of these on diagnostic services was little understood or not taken into account or sought (2 comments).
Other resources	Increased EQA work arising from extra specimens (2 comments). 'It would be the most disruptive element'.	12 respondents said more resources would be needed. Quality control (11 comments), multidisciplinary meetings (6 comments) and IT support (2) were all mentioned as activities that would need resourcing if a screening programme was introduced.
'No slack'	Four respondents said their departments were already at full stretch	12 respondents reported that their lab was already working at the limit or stretched

Level of increase in workload	Concern that the actual increase would be greater than 1-5 biopsies per week, and that the extra work in resection specimens that would follow was not being considered (3 comments).	There was a high level of scepticism that the estimated increase in workload from screening was realistic (4 comments). As well as biopsies from colonoscopy specimens, biopsies from colonic resection and surveillance would also increase. One respondent commented that less experienced colonoscopists take more biopsies and roll-out of a national screening programme may need to employ less experienced staff causing a higher number of biopsies than expected.
		A concern was raised that introduction of a screening programme raises patient expectations which pathologists will find difficult to meet. (1)
		One respondent commented that their lab would manage to meet the extra workload.

Discussion:

- Many departments are already working at full capacity and any increase in workload will need to be resourced. Staff shortages exist already and there is great difficulty in recruiting staff (both clinical and MLSO). This should be addressed.
- Different departments have widely different perspectives suggesting that local consultation would be useful in resolving problems.

Appendix 7: Methods (Information Systems)

(including interview sampling frames, thematic frameworks used in interviews, etc)

In evaluating the information system, the research team sought to assess the efficiency of internal information flow, as well as the efficiency of external flow (particularly provision of information to patients). One objective of the evaluation was to explore whether information systems were set up in such a way as to provide optimum programme efficiency and enable continuous measurement of quality. This component of the evaluation also sought to inform on system and training requirements for roll-out to other locations should this be the decision.

Research Approach

One of the features of the evaluation is that it was run alongside the pilot. This limitation, coupled with a late start to the information systems on the English site, dictated the nature of the technique used for evaluation of the information systems. A Framework Approach (Ritchie 1993) was adopted. This uses as a starting place the aims and objectives set for the evaluation. In this case the aims used were those of the pilot for the information systems. Five steps are then taken: familiarisation, identifying a thematic framework, indexing, charting and mapping and interpretation (Pope 2000). The data collected for this part of the evaluation was in the form of recorded and transcribed telephone interviews. As with the evaluation of organisation and management it was originally intended that two rounds of interviews, "before" and "after", would be undertaken to capture initial objectives and expectations and post-piloting systems, modifications, adaptations and experiences. In the event one round of interviews were conducted towards the end of the piloting period when stability had been achieved within the information system (IS). Thus, the first round of interviews for organisation and management were used as the first two steps in the Framework Approach and analysis of the information systems; familiarisation and identifying thematic frameworks. In addition the sampling frame for the IS evaluation was identified during analysis of the organisation and management interviews. The sampling frame was confirmed after wide consultation with all those involved in the pilot and with the National Screening Offices.

Sampling Frame

Twenty eight stakeholders were identified as interviewees for the IS evaluation. Of these three were not in post at the time of the interview and, after consultation with Pilot Managers, these people were not contacted. One stakeholder (NHS Information Authority) was not approached following a specific request from some of those consulted. Twenty three taped interviews were conducted and three face-to-face interviews, at which notes were taken but no recording made. In addition, researchers were present at early meetings related to Information Modelling. All taped interviews were transcribed and subsequently *indexed and charted*. This latter process was used to test the validity of the original framework for the interviews by coding any data that was outside the *thematic framework* identified in a prior step.

Thematic Framework and definitions used

All stakeholders were consulted on a thematic framework identified from the issues raised in the first round of Organisation and Management interviews (see organisation and management section). The original eight organisation and management themes were reduced to six and one theme omitted at the request of one group of the stakeholders. The original and revised Information Systems thematic frameworks are shown in **Table A7.1**.

Table A7.1: Information System thematic framework for analysis.

Identified from Organisation and Management interviews	Modified
1. Choice of approach/Implementation strategy Choice of provider and reasons Choice of implementation strategy Perceived advantages Perceived constraints 2. Systems Criteria Definition of systems criteria Setting of objectives 3. Development process Target setting and modifications Expectations and modification of expectations Project management systems Mapping to implementation strategy 4. User Involvement Commissioning process Consultation and "ownership" Compatibility with other systems 5. User support 6. Training 7. Systems evolution after commissioning 8. Quality management methods and systems	1. Systems Criteria Setting of objectives Definition of system criteria and data model Relationship to quality standards Equipment specification 2. Theoretical basis of development strategy (literature only) 3. Systems evolution after commissioning Development of datasets Compatibility with other systems User developments and interaction Needs assessment and system specification for potential systems roll-out 4. Training needs assessment 5. Post commissioning quality management Methods and systems

Table A7.2 Sampling frame for information systems key stakeholder interviews

Name	Role	Location
Information Modelling		
Pilot Consultant	Kennedy Carter Associates	
Mike Wilson,	IT Consultant,	
English Pilot		
Claire Beasley,	Office Manager	CRCS Unit
Sue Chamberlain,	Implementation & IT	Walsgrave NHS Trust
Kathryn Robershaw	Project co-ordinator	National Screening Office, England
Peter Marsh,	Manager	Walsgrave NHS Trust
Ron Parker,	Director, English CRC Pilot Unit	CRCS Unit
Julietta Patnick,	National Co-ordinator,	National Screening Office, England
Pat Ramsell,	Manager	CRCS Unit
Richard Winder,	Deputy National Co-ordinator	NSO
Mark Austin	IT Manager	Walsgrave NHS Trust
Mark Newbold	Histopathologist	Walsgrave NHS Trust
Steve Smith	Biochemist	Walsgrave NHS Trust
Pilot Nurses		CRCS Unit
Sue Elwell	Manager	CRCS Unit
Scottish Pilot		
Linda Bradley,	Manager	CRCS Unit
Carol Colquhoun,	National Screening Coordinator	National Screening Office, Scotland
Carole Morton,	Project Manager	National Screening Office, Scotland
Lorna Ower,	Office Manger	CRCS Unit
Jean Shearer,	Data Manager	CRCS Unit
Bob Steele,	Director,	CRCS Unit
Brian Thorburn,	SEMA	Paisley
Jan Warner,	Strategy lead	Scottish Health Board
Caroline Round,	Epidemiologist, Evaluation Group	Edinburgh University.
Additional evidence		
Emila Crighton	ISD	Edinburgh
Fiona Jack	Pilot Nurse	CRCS Unit, Scotland

Appendix 8: Membership of the DH Advisory Group to the Evaluation of the UK Colorectal Cancer Screening Pilot

(there were some changes during the course of the Evaluation – this is the final composition of the Group)

Dr Ursula Wells, Department of Health (Research & Development Directorate) (Chair)

Professor Clair Chilvers, Regional Director R & D, Midlands and East of England Directorate of Health & Social Care

Professor Mike Drummond, Centre of Health Economics, York

Professor Jack Hardcastle, Emeritus Professor of Surgery

Professor Theresa Marteau, GKT Medical & Dental School

Professor Nick Wald, Wolfson Institute, Royal London & St Bartholomew's School of Medicine and Dentistry

Mrs Julietta Patnick, National Screening Co-ordinator, England

Professor Bob Steele, Lead investigator, Tayside, Grampian and Fife site

Mr Ron Parker, Lead investigator, Coventry & Warwick site

Dr Rosalind Skinner, Scottish Executive

Ms Carole Morton, Project Manager, Scottish Screening Programmes

Sir Charles Nightingale, Department of Health (National Screening Policy Team)

Membership of Steering Group, UK Colorectal Cancer Screening Pilot

Prof Freda Alexander
Department of Community Health Sciences
University of Edinburgh

Professor Peter Armstrong
Academic Department of Radiology
St Bartholomew's Hospital
London

Mrs Kathryn Robertshaw
NHS Cancer Screening Programmes
Sheffield

Dr Wendy Atkin
Deputy Director
Imperial Cancer Research Fund
St Marks Hospital
Harrow

Professor Clive Bartram
St Marks Hospital
Harrow

Ms Diane Campbell
Gastroenterology Unit
Torbay Hospital
Torquay

Ms Debbie Coats
Cancer BACUP
London

Ms Carol Colquhoun
Scottish Screening Programmes
Edinburgh

Ms Lynn Faulds Wood
Beating Bowel Cancer
Twickenham

Ms Jola Gore-Booth
Colon Cancer Concern

Professor Jack Hardcastle
Nottingham

Dr Margaret Kenicer
Tayside Health Board
Dundee

Professor Chris Marks
Royal College of Surgeons
London

Ms Carole Morton
Scottish Screening Programmes
Edinburgh

Mrs Fiona Neep
Scottish Executive
Edinburgh

Sir Charles Nightingale
Health Services Directorate
Leeds

Dr Gordon Paterson (Chair)
Lumphanan, Aberdeenshire

Mrs Julietta Patnick
NHS Cancer Screening Programmes
Sheffield

Mr Ron Parker
Hospital of St Cross
Rugby

Professor John H Scholefield
University Hospital
Queens Medical Centre
Nottingham

Dr Rosalind Skinner
St Andrews House
Edinburgh

Professor Bob Steele
Ninewells Hospital & Medical School
Dundee

Professor Alastair Watson
Gastroenterology Research Group
University Clinical Department of Medicine
Liverpool

Professor David Weller
Department of Community Health Sciences
University of Edinburgh

Dr Ursula Wells
Department of Health
Research & Development Division
London

Professor G Williams
Department of Pathology
University of Wales College of medicine
Cardiff

Mr Richard Winder
NHS Cancer Screening Programmes
Sheffield