English Pilot of Bowel Cancer Screening: an evaluation of the second round.

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This evaluation was undertaken by a team of researchers based principally at the University of Edinburgh and the Cancer Screening Evaluation Unit at The Institute of Cancer Research. In order to undertake the work, the evaluation team needed to liaise closely with the Rugby Pilot site of the UK Bowel Cancer Pilot. Nevertheless, this is an independent report, and the findings and recommendations are entirely those of the evaluation team.

Acknowledgements

6
Executive Summary

Introduction

In this report we describe the screening outcome measures for the second round of the English bowel cancer screening Pilot, and the sensitivity of the screening in the first round.

We also describe the impact on health services, in particular the additional workload in colonoscopy, pathology, radiology and treatment services.

The second round of the English Pilot offered screening by FOB testing to people aged 50 to 69 at an interval of approximately two years after the first round.

In the evaluation of screening outcomes, similar methods were used to those in the evaluation of the first round of screening, and included linkage of first and second round data in order to categorise subjects in the second round according to their screening experience in the first round.

We report the outcomes of screening for 127,746 invitees; 15.9% of these were new invitees, of whom 81.0% were aged 49-51 years.

Main Findings

Screening outcomes

Of the 127,746 subjects offered a test, 52.1% (66,541) returned a screening kit. The overall rate of completion of all phases of screening was 51.7%.

Uptake, defined as the proportion of those invited who returned an adequate kit in the first phase of screening, was 51.9% (66264/127746). This compares with uptake of 58.5% in the first round.

Uptake was lower in men than women, increased with age, and fell with increasing level of deprivation.

Uptake was lower among those living in areas with a high proportion of people from the Indian Sub-Continent.

Uptake was high in those who had participated in the first round.

The report considers potential reasons for the reduced uptake in the second round; it is noted that there were different arrangements for promoting the Pilot and raising awareness in the second round – ongoing efforts will be needed to improve uptake, particularly in hard-to-reach groups.

Uptake of colonoscopy appears slightly higher in the second round than in the first round (82.8% versus 80.5% respectively). Uptake in the second round was similar in males and females, and highest in the youngest age group and in the least deprived category. There was no difference by ethnicity.
Uptake of colonoscopy was low in people who were non-responders in the previous round, and such groups may need further support to help them complete the process.

The overall rate of positive FOBT outcomes was 1.77%. This was higher than in round one, and higher than expected based on results from the Nottingham trial. Reasons for this are not clear, but re-introduction of dietary retesting did not affect the rate of positive outcomes. We examine the results of testing and re-testing, and as in the first round conclude that many invitees reach their final FOBT result after a quite prolonged process. In this report we also examine the issue of changing the number of ‘spots’ on the test to classify it as a ‘strong positive’. Reducing this threshold for immediate referral would increase colonoscopy workload, but would reduce the number of people with a protracted screening episode.

The detection rate of cancer was 0.94 per 1000; it was markedly lower than both that in the first round, and that in the equivalent population in the Nottingham trial. The detection rate of neoplasia (cancers and adenomas) was 5.67 per 1000; this was similar to that in the first round but lower than that in the Nottingham trial. The high positive rate meant that positive predictive values were comparatively low. The report discusses the implications of this reduced predictive value for the implementation of bowel cancer screening.

Linking data on bowel cancer registrations to screening data has also allowed us to report details of interval cancers and estimates of the sensitivity of screening in the first round of the Pilot. Overall the sensitivity appeared similar to that in the Nottingham trial.

Few people over age 70 requested a kit from the screening centre. Of 348 who did so, 92.8% returned an adequate kit. Consideration should be given to the information needed for this age group about continuing screening.

Impact on health services

Screening associated colonoscopy activity increased workload above the non-Pilot workload by approximately 14% at one hospital and 28% at the other. These increases are similar to those observed in the first round of the Pilot. The anticipated fall in demand for colonoscopy in the second round did not materialise.

Surveillance colonoscopies for potentially pre-malignant lesions remain a very significant issue; there is support from our findings for the concept of accommodating such surveillance under the auspices of the programme.

The more detailed colonoscopy activity data now available indicate that the trend for increased symptomatic (non-Pilot) colonoscopies, found in the first round evaluation, was probably not a result of the introduction of the Pilot, but related instead to extra endoscopy sessions operational at that time. We note that during the course of the Pilot there has been considerable activity in training for endoscopy and service modernisation – all with the potential to impact on activity and waiting times.

Personnel at all levels remained generally positive about the Pilot.

The Pilot remains influential in the improvement in endoscopy services.
The Pilot work is seen as extra work within already overstretched and understaffed pathology laboratories, but is not seen as a cause of this problem.

There has been less demand for radiology services for screening patients in the second round of the Pilot and as the level of demand was already low in the first round this has had little impact on radiology workload.

There have been fewer surgical operations for screening patients during the second round of the Pilot.

South Warwickshire General Hospitals NHS Trust made a decision not to participate in the second round of the Pilot – their priority was to concentrate on creating a sustainable, high quality endoscopic service which could integrate screening work in the future without disadvantaging non-screening patients. This highlights the need for an integrated approach for diagnostic and treatment services when introducing screening in new regions. It is also vital that management and governance arrangements in Trusts are supportive of this new service development.

In our final chapter we make a number of recommendations about implementation of FOBt screening. We comment specifically on how our findings might shape existing Department of Health guidance on the roll-out of bowel cancer screening.

**Summary of key recommendations**

- Consideration will need to be given in the roll-out process to devising ways to maintain interest and motivation in a population which is asked to participate every two years in this form of screening, which requires a relatively active role from participants.

- It is also worth noting that other forms of FOBt such as immunochemical tests are available and may be easier to use. The potential of such tests to produce higher levels of uptake, particularly in second and subsequent rounds of screening, warrants further exploration.

- The findings also reinforce the need to devise strategies which address low uptake in the subgroups which we identified. It would appear that these low levels in uptake persist in second and potentially subsequent rounds of screening in more or less the same pattern as that identified in the first round.

- Consideration should be given to the information needs for people over 70 years of age, to encourage those who may continue to benefit from screening to participate.

- FOBt positive rates should be closely monitored after roll-out, along with their effect on detection of pathology and positive predictive value.

- It is essential that the data to evaluate uptake, test performance, adverse events, pathology detected and clinical outcomes are readily available, and that cancer registries are involved in providing data.

- The process by which FOBt positive screenees are referred for colonoscopy needs to be monitored as roll-out of screening continues.
• Given the complex relationship between screening, diagnostic and surveillance colonoscopies, an organised approach will be required in the programme to the provision of endoscopy services; one which can recognise the inter-relatedness of organisational and financial aspects of these activities. This will require an appropriate administrative structure; one which taking this complexity into account can adequately plan and allocate resources.

• The recent decision by the NHS Bowel Cancer Screening Programme to bring management of screening surveillance colonoscopies into the screening programme is supported by our findings. It will reduce the administrative work in the endoscopy units and enable the impact of the surveillance workload to be more clearly determined. There is a need for more evidence to achieve national consensus on the optimal colonoscopy intervals for adenoma/polyp surveillance.

• Taking on FOBt screening requires careful planning at a local and regional level. Before taking on a screening service, hospitals need to ensure that they have sufficient capacity to provide endoscopy services, and do not have extensive waiting lists or other pre-existing resource problems. It is also critical that good management and governance arrangements are in place.

• A successful bowel cancer programme will involve progress on several fronts including early diagnosis, screening and improved treatments. It is incumbent on both trusts and policy makers at a national level to invest adequately in all these areas.

• There needs to be a detailed analysis of existing and potential future capacity, particularly in critical areas such as colonoscopy services.

• There also needs to be adequate training and awareness-raising amongst health service personnel at all levels. It is important that key groups of individuals such as surgeons, pathologists, radiologists and support staff are positive and supportive if screening is to be successful.
1. **Overview of the English Pilot of Bowel Cancer Screening: background to the evaluation of the second round**

<table>
<thead>
<tr>
<th>Chapter Summary</th>
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<tbody>
<tr>
<td>• This evaluation has been commissioned by the Department of Health to provide detailed estimates of key outcomes and an analysis of the impact on hospital services of the second round of the bowel cancer screening Pilot in England (February 2003 – April 2005).</td>
</tr>
<tr>
<td>• It builds on the evaluation of the first round of The UK Colorectal Cancer Screening Pilot which was established in 2000 to assess the feasibility of population based screening for colorectal cancer in the UK using the faecal occult blood test (FOBt).</td>
</tr>
<tr>
<td>• The English site is in the West Midlands and the second round of the Pilot involved people, aged 50 – 69 years, in Coventry Teaching Primary Care Trust (PCT), North Warwickshire PCT, Rugby PCT and South Warwickshire PCT. Acute hospital trusts involved were George Eliot Hospital NHS Trust and University Hospitals Coventry and Warwickshire NHS Trust.</td>
</tr>
<tr>
<td>• South Warwickshire General Hospitals NHS Trust participated in the first round of the Pilot, but did not accept the invitation to participate in the second round. Reasons for this are covered in this evaluation.</td>
</tr>
<tr>
<td>• The current evaluation comprises two main components: an assessment of the basic screening parameters and an assessment of the workforce and health service impact. In addition, the sensitivity of screening in the first round has been studied.</td>
</tr>
<tr>
<td>• The assessment of screening parameters used data from the Pilot site to study uptake of FOBt and of colonoscopy according to demographic characteristics and screening experience in the first round. Screening outcomes in terms of positive rates, detection rates and positive predictive values (PPVs) have been analysed.</td>
</tr>
<tr>
<td>• The assessment of the workforce and health service impact used quantitative data to indicate the levels of both overall hospital and Pilot generated colonoscopy, pathology, radiology and surgical activity and colonoscopy waiting times, and qualitative data from interviews with key staff to examine the experience of people involved. This was supplemented with timesheet and questionnaire data.</td>
</tr>
<tr>
<td>• These assessments will provide useful information for predicting uptake of screening and colonoscopy in incidence rounds of the imminent national screening programme for bowel cancer and for targeting resources to increase uptake where it is low. They will enhance the findings of the evaluation of the first round of the Pilot with respect to colonoscopy, pathology, radiology and surgical services and inform planners of the national screening programme for bowel cancer, as well as increasing understanding of the impact of an established bowel cancer screening programme on services for bowel cancer.</td>
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*Chapter 1: Overview of the English Pilot of Bowel Cancer Screening*
1.1 Introduction
Randomised controlled trials have demonstrated that colorectal cancer mortality can be reduced by screening using the faecal occult blood test (FOBt). In the light of this a Pilot was established in the UK in 2000 to examine the feasibility of population based screening for colorectal cancer. An evaluation of the first round was undertaken. This current evaluation has been funded by the Department of Health to provide detailed estimates of key outcomes and a refined analysis of the workforce and health service impact of the second round of the bowel cancer screening Pilot in England.

1.2 First (Prevalence) Round of the UK Pilot of Bowel Cancer Screening
The UK Colorectal Cancer Screening Pilot was established to assess the feasibility of population based screening for colorectal cancer in the UK using FOBt.

1.2.1 Sites
The first round of the Pilot was conducted at two sites: the West Midlands in England and Tayside, Grampian and Fife in Scotland. The following description focuses on the English Pilot site because the current evaluation of the second round only considers this site. (Data on the Pilot site in Scotland are being collected by the National Services Division of NHS Scotland.)

The West Midlands site, part of the West Midlands South Strategic Health Authority, consisted in the first round of four Primary Care Trusts (PCT) and three Acute Trusts.

Patients, aged 50-69 years inclusive, registered at general practices in Coventry Teaching PCT, North Warwickshire PCT, Rugby PCT and South Warwickshire PCT were eligible for the first round of the Pilot. Characteristics of these PCTs are shown in Table 1.1.

The Acute Trusts involved in the first round were George Eliot Hospital NHS Trust, South Warwickshire General Hospitals NHS Trust and University Hospitals Coventry and Warwickshire NHS Trust. Characteristics of these Acute Trusts are shown in Table 1.2. Secondary care services were provided at George Eliot Hospital (Nuneaton), Warwick Hospital (Warwick), and Walsgrave Hospital (Coventry).

A map showing the PCTs involved, with the hospitals marked on it, is provided on the following page.

1.2.2 Screening Unit
The English Colorectal Cancer Screening Pilot was administered from the Bowel Cancer Screening Unit (the screening unit) at the Hospital of St Cross at Rugby. Invitations were sent out from the screening unit and test kits returned to the laboratory at Hospital of St Cross. Patients who were FOBt positive were offered an appointment at the screening unit with a screening nurse who provided information and answered their questions. Bookings for screening nurse appointments and any investigations required were also arranged at the unit.

1.2.3 Dates
Screening began at the English site on 6th September 2000 and the last invitations in the first round were sent out on 26th June 2002. (At the Scottish site screening began on 31st March 2000.)
Map Showing Primary Care Trusts involved in the English Pilot

Main Screening Hospitals
1 – Warwick Hospital, Warwick
2 – Walsgrave Hospital, Coventry
3 – George Eliot Hospital, Nuneaton
4 – Hospital of St Cross, Rugby

Chapter 1: Overview of the English Pilot of Bowel Cancer Screening
1.2.4 Simplified description of first round process in England

A simplified version of the screening process is depicted in the flow charts in Figures 1.1 and 1.2. Figure 1.1 shows the first part of the screening process – up to the point when an FOBt result is available. Figure 1.2 describes the process following a positive FOBt.

There were three possible phases involved before a conclusive result from an FOB test was obtained. For a diagrammatic description of the different phases, see Appendix 2.

Phase 1: All eligible people on the local health authority database were sent an invitation letter informing them that they would be sent a test kit in a week’s time. People not wishing to take part or for whom screening was not appropriate were asked to inform the screening unit. All others were sent a test kit and information sheet one week later.

The screening process in the Pilot used the Hemascreen kit to test for blood in faeces. The test kits have six spots. On three days, participants took two samples from different parts of their stool in order to complete two spots per day. This had to be completed in time for the kit to be returned by post for testing within 14 days. An unhydrated guaiac test was used to test each spot for occult blood. Reading of an adequate kit resulted in a negative (no spots positive), weak positive (1-4 spots positive) or strong positive (5-6 spots positive) result.

Individuals with a strong positive result were invited for further investigation; participants with a weak positive result enter Phase 2 and those with a normal result have their episode closed. Inadequate kits are those that do not yield a result.

Phase 2: Participants with a weak positive test in Phase 1 entered Phase 2 and were asked to complete another test kit after omitting red meat, turnips, broccoli, horseradish, cantaloupe melon, parsnips, radishes, tomatoes or Vitamin C supplements from their diet for two days before starting to complete the kit. If this test produced a weak or strong positive result, the participant was invited for further investigation. Those with a negative test result entered Phase 3.

Phase 3: Participants with a normal result in Phase 2 entered Phase 3. This involved completing a further test kit, again under dietary restrictions. Participants who had a weak or strong positive result from this kit were invited for further investigation. Those with a normal result had their case closed.

The screening process ended with either a negative FOBt result, no response from the invitee within 13 weeks, a positive FOBt result with diagnostic investigation or a positive result with no investigation.

Further investigation: people with an FOBt positive outcome were offered an appointment with a screening nurse and, if medically fit, a colonoscopy. People unable to have a colonoscopy, but who would be fit for an operation if required, were usually offered CT colonography. If a colonoscopy could not be completed a barium enema was usually carried out on the same day.

1.2.5 Evaluation of first round of the Pilot

A comprehensive evaluation of the first round was undertaken and reported.2
In summary: the UK Pilot demonstrated that key parameters of test and programme performance observed in randomised trials of FOBt screening could be repeated in population-based pilot programmes.

The Pilot achieved uptake of screening close to the target of 60%, but subgroups with lower uptake were identified: these were men, younger people, those from more deprived areas and individuals from the Indian Sub-Continent.

Perceptions of colonoscopy experience were very positive and adverse events were low. Uptake rates for colonoscopy were influenced by deprivation and ethnicity.

Rates of detection of cancers (1.26 per 1000 screened population in England and 1.99 per 1000 screened population in Scotland) and potentially pre-malignant lesions compared favourably with trial data. There was an increased proportion of early stage screen detected cancers similar in magnitude to the Nottingham trial.\(^3\)

The results of the Pilot were considered to support the introduction of national roll-out; that is, the results of randomised controlled trials could be replicated in a national programme, and similar reductions in mortality should be achieved. Further, FOBt screening was considered the modality of choice by key stakeholders, given available evidence (although further evidence on the feasibility of screening using flexible sigmoidoscopy is needed). However it was recognised that the success of a national programme would depend on the ability to accommodate the increased health care activity generated, particularly in secondary care. Colonoscopy, pathology and radiology service provision were identified as being crucial.

1.3 Second (Incidence) Round of Bowel Cancer Screening Pilot – English site

The name of the Pilot was changed to the English Bowel Cancer Screening Pilot and will be referred to as the Pilot in this report.

The aim of the bowel cancer screening Pilot was to see if screening using FOBt as carried out under research conditions in Nottingham\(^3\) was practical, acceptable and feasible within the NHS healthcare setting. The first round (or prevalence round) took place in a population who had not been screened before. The aim of continuing the Pilot into second and subsequent rounds was to give a clearer picture of how a screening programme which invites people on a periodic basis would work. The second round (or incidence round) could determine the effects of the same process on a population who had already been invited to screening. It carried with it the advantage of being able to identify interval cancers from the first round and to calculate sensitivity of the FOBt.

1.3.1 Dates

The second round invitation process began in February 2003 with the final invitations being sent out on 9th November 2004.

1.3.2 Differences between first and second rounds

The second round was essentially the same as the first round with a few changes that are listed below.

Promotion of the Pilot: The Pilot was promoted slightly differently in the second round – although the Pilot centre had similar procedures in place (with similar workload), there was
little advertising in comparison to round one (in which it appeared, for example, on buses or the back of toilet doors). Each practice was offered a formal visit, but none accepted in the second round - generally because they already had experience of the screening Pilot. All practices were, however, sent information about the Pilot, and one of the Pilot nursing team (screening nurse) liaised with the practice nurse to ensure it was known that patients were soon going to be invited. The screening nurse visited each surgery to put up a board with sample kit, envelope and instructions in the waiting area. In addition to this the Pilot team spent considerable time in the community in the second round giving talks, going to awareness days, and meeting with ethnic groups.

Study areas: The South Warwickshire General Hospitals NHS Trust decided not to participate in the second round. The reasons for this are explained in Chapter 8. Invitations had been posted to eligible people at two of the practices before a final decision was reached and these people have been included in this evaluation. Other practices in South Warwickshire PCT were not involved in the second round.

Prior Notification List: During the first round general practitioners were sent a list of all eligible invitees and asked to check that it was appropriate to send test kits to everyone on the list. This was not done in the second round.

Exclusion from screening: The initial invitation letter was altered for two reasons: firstly in accordance with the change in policy in the second round by the NHS National Cancer Screening Programmes the letter was re-worded to indicate that bowel screening was not appropriate for anyone who had had a full bowel investigation (colonoscopy or a barium enema plus sigmoidoscopy) within the previous four years. Secondly, it came to light in the first round that certain groups of people should be advised that screening was not appropriate for them. These were people on a bowel polyp surveillance programme, those currently being treated for bowel cancer or awaiting bowel investigations arranged by their GP, and people who had had their bowel removed. The date of the last bowel examination of people suffering from an inflammatory bowel disease, such as Crohn’s disease or ulcerative colitis, is ascertained before a decision whether to screen or not is made. The invitation letter now requests that people in these categories contact the screening unit.

Opt in for 70+ years age group: In the second round, people aged 70 years or older who were registered with general practices in the Pilot area were able to request a test kit by contacting the screening unit.

Dietary restriction: During the first round, people with a weak positive FOB test and those whose initial test was not satisfactory were asked to refrain from eating specific foods for two days before all further repeat tests. For the first year of the second round, dietary restrictions were dropped. They were restarted for the second year on 1st March 2004.

Introduction of extra colonoscopy sessions: In May 2004 an extra afternoon session was introduced at Walsgrave Hospital on alternate weeks and a weekly session was introduced at the Hospital of St Cross at Rugby. Colonoscopy provision for screening patients remained unchanged at George Eliot Hospital.

Size of colonoscopy sessions: In the first round four or five colonoscopies were booked in a session depending on the colonoscopist. In the second round three colonoscopies were booked in each session for two reasons: firstly, because of concerns that some sessions had run over time in the first round; and secondly, to create some extra capacity for times when the target
waiting time for colonoscopy was under pressure. The anticipated reduction in FOB positive 
tests did not materialise and this spare capacity was therefore utilised. (Afternoon and evening 
sessions are shorter and continue to have three colonoscopies booked.)

Completion of colonoscopy: In the first round colonoscopists were expected to take a biopsy of 
the terminal ileum to check that the whole of the large bowel had been examined. In the second 
round proof of completion was checked by photographic evidence of reaching the ileo-caecal 
valve.

Post colonoscopy nurse appointments: In the first round all patients who had a colonoscopy 
were given an appointment with a nurse at an out-patient clinic after their investigation. In the 
second round this was changed, because there was very little take up of this offer in the first 
round, and those who had no significant findings at colonoscopy were given the option of an 
out-patient appointment or a phone call.

Immunological trial (ImmunoTrial): During the second round from 21st June until 9th 
November 2004, a different type of FOB test was trialled on 5122 individuals. (For more 
details see Appendix 6.) The people in the trial were excluded from the evaluation analyses. 
All these invitees and all subsequent invitees in the second round were sent an information 
sheet along with their invitation letter explaining that the trial was taking place.

1.3.3 Approach to the evaluation of the second round of screening

This evaluation comprises two main components: an assessment of the basic screening 
parameters and an assessment of the workforce and health service impact. We have also been 
able to study the sensitivity of screening in the first round.

The assessment of screening parameters used data from the Pilot site to study uptake of FOBt 
and of colonoscopy according to demographic characteristics and screening experience in the 
first round. Screening outcomes in terms of positive rates, detection rates and positive 
predictive values (PPVs) have been analysed.

The assessment of the workforce and health service impact used quantitative data to indicate 
the levels of both overall hospital and Pilot generated colonoscopy, pathology, radiology and 
surgical activity and waiting times, and qualitative data from interviews with key staff to 
examine the experience of people involved. There has been an emphasis on the services 
identified as most affected in the first round, namely colonoscopy and pathology. This was 
supplemented with timesheet and questionnaire data.

The evaluation will provide useful information

- for predicting uptake of screening and colonoscopy in incidence rounds of the proposed 
national screening programme for bowel cancer and targeting resources to increase uptake 
where it is low
- to enhance the findings of the evaluation of the first round of the Pilot with respect to 
colonoscopy, pathology, radiology and surgical services, and inform planners of the 
proposed national screening programme for bowel cancer
- to increase understanding of the impact of an established bowel cancer screening 
programme on hospital services
- to examine how roll-out takes place against a background of change and modernisation in 
the NHS: screening cannot be viewed in isolation, and the evaluation attempts to provide
some guidance and insights on incorporating a new programme such as FOBt in a dynamic service environment.

1.4 National Bowel Cancer Screening Programme

The NHS Cancer plan\(^4\) specified that if UK pilots of bowel cancer screening were successful, a national bowel cancer screening programme would be established.

Two methods of screening have been piloted. Firstly, using faecal occult blood testing (FOBt) as described above and secondly, using a ‘once-only’ flexible sigmoidoscopy. Large scale pilots of this alternative method are currently being carried out on people in their late fifties.\(^5\)

In October 2004 the Department of Health announced that a NHS Bowel Cancer Screening Programme would commence in England in April 2006. The programme will offer men and women aged 60 to 69 an FOB test every two years. People aged 70 and over will be provided with an FOB testing kit on request.

The screening programme is described in Appendix 8 and summarised here. It will be phased in gradually over a three year period, giving the NHS time to prepare and allocate resources. Five programme hubs, including testing laboratories, will be set up to invite people and analyse the test kits. It is anticipated that each hub will be responsible for up to 20 local screening centres whose responsibilities will include nurse clinics, and colonoscopy, pathology and radiology services. The screening centres will refer patients to a local hospital for treatment. Strategic Health Authorities have been invited to put forward local endoscopy services to become local screening centres. These endoscopy units will be required to fulfil several criteria (Appendix 8, Annex C) before being accepted.

The intention is that the findings of this report will be of value in informing the national programme in England.

In comparison, the NHS in Scotland plans to begin screening for bowel cancer following on from the Scottish Pilot a year later than in England, in 2007. The age range will be from 50-74 years.
Table 1.1 Primary Care Trusts profiles

<table>
<thead>
<tr>
<th></th>
<th>Coventry Teaching</th>
<th>Rugby</th>
<th>South Warwickshire</th>
<th>North Warwickshire</th>
<th>Average English PCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Population Served</td>
<td>320,361</td>
<td>84,281</td>
<td>250,717</td>
<td>174,466</td>
<td>163,803</td>
</tr>
<tr>
<td>% of population in 65+ years Age Group</td>
<td>15.2</td>
<td>16.0</td>
<td>17.2</td>
<td>14.9</td>
<td>16.0</td>
</tr>
<tr>
<td>% of SOAs in national 10% most deprived*</td>
<td>17.3</td>
<td>&lt; 0.9</td>
<td>&lt; 0.9</td>
<td>1.7</td>
<td>-</td>
</tr>
<tr>
<td>Life Expectancy at birth (Male / Female)</td>
<td>75 / 80</td>
<td>77 / 81</td>
<td>77 / 81</td>
<td>75 / 80</td>
<td>76 / 81**</td>
</tr>
</tbody>
</table>

*Index of Multiple deprivation
SOA = super output area
Source: http://www.wmpho.org.uk/
Accessed 13/09/2005
** Life expectancy at birth, 2002. Source: Department of Health

Table 1.2 Acute Trusts profiles

<table>
<thead>
<tr>
<th></th>
<th>George Eliot Hospital</th>
<th>South Warwickshire General Hospitals</th>
<th>University Hospitals Coventry and Warwickshire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approximate Population Served</td>
<td>250,000</td>
<td>270,000</td>
<td>**1,500,000</td>
</tr>
<tr>
<td>Number of Beds</td>
<td>400</td>
<td>450</td>
<td>1417</td>
</tr>
<tr>
<td>Number of Staff</td>
<td>1800</td>
<td>2500</td>
<td>6500</td>
</tr>
<tr>
<td>Sites</td>
<td>George Eliot Hospital</td>
<td>Warwick and Stratford Hospitals</td>
<td>Coventry and Warwickshire Hospital, Walsgrave Hospital and Hospital of St Cross</td>
</tr>
</tbody>
</table>

** NB. This figure is the population for ‘super-regional’ specialties e.g. cardiothoracic surgery. The base population for colorectal disease services is around 350,000.

Sources: Annual Reports
George Eliot Hospital:
South Warwickshire General Hospitals:
http://www.warwickhospital.nhs.uk/About_Us/annualreport.aspx
University Hospitals Coventry and Warwickshire:
All accessed 14/09/2005

Chapter 1: Overview of the English Pilot of Bowel Cancer Screening
Chapter 1: Overview of the UK Pilot of Bowel Cancer Screening

Figure 1.1 Screening process until test result

- **Invitée declines kit**
- **Screening office updates lists - invitation to participate and information posted out**
  - **Enter Phase 1**
- **Test kits sent to home address**
  - **Retest**
  - **Kit returned within 4 weeks**
  - **Refund and reading of used kit**
- **Kit not returned within 4 weeks; reminder sent**
- **Kit returned within 13 weeks**
- **Kit not returned in 13 weeks - case closed & letter sent to GP**

**Phase 1:** From invitation to first adequate test result. [normal -> case closed; positive -> further investigation; weak positive -> Phase 2]

**Phase 2:** From weak positive Phase 1 result until next adequate FOBT. [normal -> Phase 3; positive or weak positive -> further investigation]

**Phase 3:** From normal Phase 2 FOBT result to adequate FOBT result. [normal -> case closed; positive or weak positive -> further investigation]

**Normal Result**
- For Phase 1 and Phase 3 participants: case closed & letter sent to GP and responder
  - For Phase 2 participants: Enter Phase 3 – Retest*

**Unsatisfactory Result**
- If first Unsatisfactory Result: Retest*
  - If a further Unsatisfactory Result: advice by phone / offer of home visit

**Weak Positive (1-4 spots positive)**
- For Phase 1 invitees: Enter Phase 2 – Retest*
  - For Phase 2 or 3 participants: treat as Positive result

**Strong Positive (5-6 spots positive)**
- Further investigation
Figure 1.2 Investigation process from positive FOBt onwards

- Positive FOBt / Further Investigation
  - Letter to G.P and invitation to responder to attend Clinic
    - Nurse Clinic attended & colonoscopy discussed
    - Clinic not attended; reminder and invitation to future clinic sent to responder
      - Colonoscopy declined - letter sent to G.P and case closed
      - Colonoscopy accepted and booked
        - Polyp detected
          - Low-Risk Polyp
            - Next screening missed
          - Medium/High Risk Polyp
            - Cancer detected. Patient removed from screening programme for treatment and advice
            - Other condition detected - patient referred for further investigation or treatment.
        - Patient unsuitable for Colonoscopy - alternative investigation considered

Chapter 1: Overview of the UK Pilot of Bowel Cancer Screening
Chapter Summary

- The main aim of Chapters 2 to 6 of this evaluation is to report on the screening outcome measures for the second round of the English bowel cancer screening Pilot.

- Routine individual based data were extracted from the Pilot site database in June 2005. Additional information on the Index of Multiple Deprivation (IMD), the Carstairs index of social deprivation and on ethnicity have been linked to individuals using postcodes.

- People excluded were those not invited, those aged over 70 years, and those included in a trial of an immunological test. All but two GP practices in South Warwickshire did not participate.

- Linkage of first and second round data was performed by matching on NHS number and month/year of birth, in order to categorise people in the second round according to their screening experience in the first round.

- Analyses were conducted to compare results in the second round with those in a comparable, restricted population in the first round, and with people in the Nottingham randomised controlled trial of screening.

- Data on bowel cancers in subjects included in the first and second rounds were obtained from West Midlands Cancer Intelligence Unit, in order to identify cancers occurring in the interval between screening rounds.

- There were 127,746 people invited in the second round restricted population. The proportion of people below age 55 years was slightly lower in the second round than in the first. The distributions of IMD were similar in both rounds, but there was a slightly higher proportion of people in ethnic minorities in the second round.

- In the second round 15.9% of people were new invitees, of whom 81.0% were aged 49-51 years.

- In 107,471 people who were invited in both rounds, only 2% of invitations in the second round were sent within 27 months of the previous invitation. This was mainly due to a gap of approximately five months between the end of the first round and the start of the second round.
2.1 Aims and objectives

To evaluate screening outcome measures in the second round of the English bowel cancer screening Pilot.

1. To analyse routine data downloaded from the Pilot site in order to estimate uptake, positive rates, acceptance of colonoscopy, and rates of detection of neoplasia and cancer in the second round of the Pilot.

2. To investigate the above in relation to demographic variables, and in relation to invitation and uptake of testing in the first round of the Pilot.

3. To analyse data on interval cancers in order to estimate sensitivity of the FOBt in the first round.

2.2 Data Sources

**Screening data:** The routine second round data for the evaluation have been extracted from a download from the Pilot database, received in June 2005. The data included each person’s NHS number, gender, month/year of birth, postcode and GP practice, but did not include name or day of birth. A copy of the database for the first round of the English Pilot was obtained from the Edinburgh evaluation team. It should be noted that this contained more recent data than were available to the evaluators for the final first round report.

None of our analyses are restricted according to the date of invitation or date of positive test. In the evaluation of the first round, the analysis was restricted to individuals invited more than three months before the data download, in order to allow time for investigations following a positive FOBt outcome to have been completed. However, findings from the first round evaluation suggested that it might be necessary to allow six months for the data to be complete.

The last invitations in the second round were sent out in November 2004, and we would therefore have expected all tests to have been completed by the time we received the download in June 2005. However, the download included people undergoing repeat (phase 2 or phase 3) tests as late as March 2005. We checked with the Pilot site on 32 people with a positive episode after July 2004, for whom we had no information on colonoscopy, and as a result identified one further colonoscopy.

Some people with a positive FOBt outcome will have attended private colonoscopy. The Pilot site had information about some such people, but there would have been others that they did not know about.

**Cancer data:** Additional data were obtained from a database maintained by the Pilot site on all cancers detected by screening. These would have included any bowel (but not all) cancers diagnosed in people followed up privately. The data did not include names and were linked only by NHS number and month/year of birth.

We also obtained data from West Midlands Cancer Intelligence Unit (WMCIU) on all registered cases of bowel cancer diagnosed in people in the Pilot population (first and/or second round). The cases included cancers in people who were diagnosed before invitation with the earliest being in 1960. This was achieved by the Pilot site supplying a list of people to WMCIU for matching, in order to identify only those cases in the Pilot. Approval for this by
Incidence of bowel cancer: In order to interpret our data on interval cancers and incidence rates in non-responders in relation to regional rates, we obtained data from the Office for National Statistics (ONS) on the incidence of bowel cancer (with anal cancers identified separately – see Glossary, Appendix 1) by gender and five year age-group, for each government office region in England for the years 1990-2003.

Comparison data from the Nottingham trial: A randomised controlled trial of screening by FOBt was conducted in the Nottingham area between 1981 and 1991. Over 150,000 people were allocated equally between an intervention and control arm, and those in the intervention arm were offered two yearly screening by FOBt. The methodology of the trial is described in more detail elsewhere.3 Data from this trial are held and analysed at CSEU. One of the evaluators [SM] is a co-investigator in this trial, and we obtained permission from the principal investigator at Nottingham to use these data for comparison purposes in this evaluation.

Census geography: Data from the census are aggregated to provide small area statistics. The Central Area Statistics (CAS) wards and Super Output Areas (see Glossary, Appendix 1) were used in this report. The UKBORDERS website6 provides postcode directories that link postcode with details of these census geographies.

Deprivation: The Index of Multiple Deprivation (IMD) 2004 is a measure of multiple deprivation at the small area level. The index contains seven domains of deprivation: Income; Employment; Health and disability; Education, skills and training; Barriers to housing and services; Living environment and Crime. Each domain contains a number of indicators and an index is provided for each domain. The overall IMD is conceptualised as a weighted area level aggregation of these specific dimensions of deprivation. The IMD is provided for the lower level of the super output areas (see Glossary, Appendix 1). In a study of general practice data in England,7 patterns of health inequalities were similar whether IMD or the Townsend Index of deprivation was used.

Data on the Index of Multiple Deprivation (IMD) 2004 for England and Wales were obtained from the Office of the Deputy Prime Minister.8 The super output areas were ranked by the index, and divided into quintiles with each containing approximately 20 per cent of the population. Each person in the screening Pilot was linked by postcode to a super output area using UKBORDERS, and allocated to the quintile value of that area; Table 2.1 shows the range of values for each quintile.

Data on the Carstairs index of deprivation were obtained from the Census Dissemination Unit (MIMAS, University of Manchester)9 for each electoral ward for the 1991 census and for each Central Area Statistic (CAS) ward for the 2001 census, and each person was linked by postcode to these areas using UKBORDERS.

In the first round report the Carstairs index of deprivation from the 1991 census was used to study the effect of deprivation, since at the time of the first round evaluation only the 1991 census data were available. As the first round included areas in Scotland, the Carstairs index, which has been used in other studies in Britain was chosen for data analysis.10 In the first round report seven deprivation categories were defined using cut-off values which give the same proportion of the population within each category as the original classification chosen by McLoone.11 In this report we have used quintiles of the Carstairs index, in order to facilitate
comparison between these and the IMD. Table 2.2 shows the comparison between the 1991 and 2001 distributions. The comparison of the distributions of the people invited in Round 2 by their IMD and Carstairs quintile in Table 2.3 shows that the people were more evenly distributed across the IMD quintiles than across those for the Carstairs index.

**Ethnicity:** Data on ethnicity for the 2001 census were obtained from the Census Dissemination Unit. The numbers of people are provided for each CAS ward in the categories: White, Mixed, Asian, Black, Chinese and Other. Each category is further subdivided: Asian is subdivided into Indian, Pakistani, Bangladeshi and other. As the dominant ethnic minority in the Pilot area is Indian Sub-Continent origin, we included this variable in the analyses. The Indian Sub-Continent was defined as Indian, Pakistani, Bangladeshi, and Mixed white and Asian, but excluded ‘other Asian background’. The data were obtained by CAS ward and linked to person via postcode by the same method as deprivation. However, there is an important difference in that the quintiles are calculated for people within the Pilot area and not nationally as is the case with deprivation. People have been grouped according to quintiles for this variable (Table 2.4) and, in the data analyses, the highest quintile compared with all others.

These differ from those used in the first round evaluation due to the exclusion of the Warwick population, and due to the use of the 2001 census data as opposed to that from 1991.

### 2.3 Linkage of first and second rounds

Linkage of people in the first and second rounds was performed by matching on NHS number and month/year of birth. This linkage was performed for all people included in the two downloads.

Not all people had a new NHS number; some people had either an old NHS number or a temporary number. The NHS number for some people had changed between rounds (either from old/temporary to new or from new to old/temporary), and a total of 102 such people who were matched on gender, month/year of birth and postcode, were linked after the Pilot site confirmed that they were the same person.

A file was sent to the Pilot site of 492 potential missed linkages in people whose NHS number had changed and who were below age 68 years at date of invitation in the first round (and hence expected to be included in the second round), or over age 52 years at date of invitation in the second round, (and hence expected to have been invited in the first round) who were matched on month/year of birth and gender, but not postcode, who might have moved address between the two rounds. Very few new NHS numbers were found by the NHS Information Agency despite considerable effort. A few additional linkages were made between the first and second round (n=5) and some duplicates within the second round were identified (n=9). While it is likely that some missed linkages remain, the number of potential missed linkages is less than 500 (less than 0.5% of the Pilot population).

People in the second round have been categorised according to their screening history in the first round, as follows:-

- **Not invited**  
  - People not invited in the first round, either because they were too young, or because they moved into the catchment area between rounds.
  - 81% of people in this category are aged 49-51 years.
Non responder  People invited who did not respond in the first round.

Testing incomplete  Responded but did not complete phase 1.
Completed phase 1 but did not complete phase 2 or 3.

Negative FOBt  People with a negative overall FOBt outcome in the first round.

Positive FOBt, negative investigation  Positive FOBt outcome at first round, negative colonoscopy.

Positive FOBt, no investigation  Positive FOBt outcome at first round, no further investigation.

Positive FOBt, positive investigation  Diagnosed with cancer/adenoma at first round.

2.4 Exclusions

Most analyses have been performed on a restricted second round population (see Glossary, Appendix 1) from which a number of exclusions have been made that are detailed in this section (Figure 2.1).

People aged over 70 years: The download included 348 people aged 70 years or over at date of invitation who have been excluded from all analyses except those looking specifically at uptake and positivity in self-referrals (Section 5), since it is assumed that all such people self-referred and were not invited. We had no means of identifying self-referrals other than by age. For this reason, and because we only had data for month and year (not day) of birth, we may have included some people who were in fact invited as self referrals, and vice versa. However, the effect of this on our results will be minimal.

People not invited: The download included 470 people who were never sent an invitation to participate; some people were not sent an invitation as a result of prior notification lists, although only a few practices completed these.

Immunological trial (ImmunoTrial): A total of 5122 people in the second round were randomised to a trial in which 2595 people were offered the standard FOBt, and 2527 an alternative immunological test (See Appendix 6). The uptake and outcomes of the immunological test may differ from those of the FOBt. People in both arms were given additional information and told that they were part of this trial, and as a result uptake may also have been affected in the FOBt arm. We have therefore excluded all 5122 people from our analysis.

South Warwickshire: In South Warwickshire PCT, two GP practices were invited before the decision was made that South Warwickshire would not remain in the Pilot. In these two practices, 6243 and 4837 people were invited in Rounds 1 and 2 respectively. These two practices have been included in our analyses. A further 100 people were ‘invited’ from 27 practices in South Warwickshire. Presumably, these people invited themselves; some of these
had moved and were in the two practices invited in the first round (n=29). These 100 people have been excluded from our analyses in order to facilitate comparison with the first round.

2.5 Eligibility: denominator for uptake

Some people may never have received their invitation; the most likely reason for this is that the person had moved and the invitation was returned to the Pilot site by the Post Office. The Pilot download contained a field ‘reason screening closed’ that gave reasons why a person may not have completed the test (‘undelivered’, ‘deducted’, ‘under treatment’, ‘dead’, ‘recently screened’).

Figure 2.2 shows the numbers in these different categories. The denominator used in this report to study uptake is the number of people invited (n=127746). This definition of the denominator is close to that used for the first round report, but in the first round those not invited were included in the denominator. Including those not invited in the second round would increase the denominator by 470.

We have included in the denominator for uptake those people who declined the invitation and those classified as ‘ineligible’ defined as those recorded as ‘recently screened’, ‘deducted’, ‘under treatment’, ‘dead’, or ‘other’ (n = 3504).

People were advised to phone the screening office if they had had a colonoscopy within the previous four years, in order to confirm that it was in fact colonoscopy they had undergone. Those who did so and as a result did not complete the kit were classified as ‘recently screened’. Such colonoscopies could have been done either as a result of a positive episode in the first round or as a result of symptoms. The numbers ‘recently screened’ in the restricted populations were 2 and 1383 in the first and second round respectively. Of the 1383 in the second round, only 166 had a colonoscopy recorded in the first round, the remainder presumably being symptomatic. These 1383 people have been included in the denominator for uptake for reasons of compatibility with the first round, where such people would have been included.

The invitation letter listed several other criteria which meant it would be inappropriate for the person to be screened and asked people meeting these criteria to phone the Pilot site to discuss the issues. In many cases people who did so were then advised that they need not complete a test kit. These people have been included in the denominator, because it was not possible to identify only those who had a valid reason for not completing the test. The numbers declining their invitation in the restricted populations were 1782 and 3473 in the first and second round respectively.

2.6 Basis for comparison with the first round

We have rerun the main analyses for the first round on a comparable restricted population (see Glossary, Appendix 1). We have excluded from this population all GP practices in South Warwickshire PCT other than the two discussed above and any people who were part of the immunological trial in the second round, in order to obtain as comparable a population as possible for the two rounds. For this reason, and also because the first round evaluation was performed on an earlier download than that available to us, our numbers for the first round will differ from those in the first round evaluation report.
2.7 Basis for comparison with Nottingham trial

In the Nottingham trial, the protocol for re-invitation of people who had refused their first invitation changed during the course of the trial. For this reason, the most valid comparison that can be made between the Nottingham trial and the Pilot is to restrict both to people who responded to their first invitation and who had a second invitation. The Nottingham trial invited people between ages 45 to 74 years at entry, while the Pilot invited people between ages 49 and 69 years. The comparison is limited to people aged between 50 and 69 years at their second invitation.

The protocol for retesting initial weakly positive results in the Pilot was based on the Nottingham protocol. However, there were some differences which need to be taken into account when comparing the positive rates between the two studies.

- In the pilot phase of the Nottingham trial all people with one or more positive spots were investigated; the positive rate was therefore higher than in the main trial. The pilot phase of the Nottingham trial has therefore been excluded from our comparison.
- In publications from the Nottingham trial, people who were weakly positive at their initial test but did not respond to the retest were included amongst the positives, although they were not investigated. In our comparison, we have excluded these people from the positive rates.
- Retesting after a weak positive in the Nottingham trial was carried out over six days, compared with three days in the Pilot. The chance of finding a positive spot in these retests would therefore be greater; however we are unable to adjust for this in our comparison.

2.8 Description of second round population

2.8.1 Distribution of demographic variables

The distribution of the population included in the analyses by age and gender is shown in Table 2.5, with that for the comparable restricted first round population. The policy was to invite people who would become 50 years of age during the year and so in both rounds there are a number aged 49 years of age. In the second round, 2.8% (n=3547) of the population were 49 years of age. The distribution by gender is similar in both rounds, but there is a slightly lower proportion of people below age 55 years in the second round population.

2.8.2 Distribution by previous screening history

Table 2.6 shows the distribution according to the screening history in the first round; 15.9% are new invitees in the second round (of whom 88.6% are aged <55 years, and 81.0% aged 49-51 years). The previous non-responders in the first round tend to be younger than those previously screened negative (55.9% vs. 50.4% aged <60 years). These previous non-responders include 1255 classified as ‘ineligible’ or post office return in the first round.

2.8.3 Time interval between first and second round

The interval between invitations for the 107471 people invited in both rounds, and between dates of first test (defined as date the test was read) for the 51731 people tested in both, is summarised in Table 2.7. Data are missing on a number of people due to missing dates; in addition it is not known to what extent the outliers (e.g. intervals less than 12 months) are due to incorrect dates. There was a delay of five months before the start of the second round, which meant that only 2% of invitations in the second round were sent within 27 months of the previous invitation. The median time between invitations was 28 months, and between tests 29
months. Overall 88.1% of intervals between invitations and 76.7% of intervals between tests were 27-29 months. The majority (89%) of instances where the time between invitations was 33 months or more are in Warwick, where nearly all intervals were 33 months or more; this was the result of a longer delay in the start of the second round in this area.

2.9 Statistical analyses

Logistic regression has been used to investigate associations between the demographic and ethnic variables and measures of uptake and positivity. Results are given as odds ratios (OR) with 95% confidence intervals (CIs). Univariate analyses have been used to produce unadjusted odds ratios for each demographic factor (but reporting a term for age within each gender). Multivariate analyses including all demographic factors have been used to produce odds ratios of estimated effects adjusted for all other factors.
Table 2.1  The range of IMD 2004 values within the quintiles of super output areas for England and Wales

<table>
<thead>
<tr>
<th>IMD quintiles</th>
<th>Cut-off Values for IMD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimum</td>
</tr>
<tr>
<td>Least deprived 1</td>
<td>34.21</td>
</tr>
<tr>
<td>2</td>
<td>21.15</td>
</tr>
<tr>
<td>3</td>
<td>13.72</td>
</tr>
<tr>
<td>4</td>
<td>8.35</td>
</tr>
<tr>
<td>Most deprived 5</td>
<td>0.59</td>
</tr>
</tbody>
</table>

Table 2.2  Comparison of Carstairs Index for 1991 and 2001 by people

<table>
<thead>
<tr>
<th>Carstairs 2001 quintiles</th>
<th>Carstairs 1991</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>nk</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least deprived 1</td>
<td></td>
<td>674</td>
<td>536</td>
<td>503</td>
<td>123</td>
<td>26</td>
<td>1862</td>
<td>15.1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>561</td>
<td>928</td>
<td>560</td>
<td>830</td>
<td>90</td>
<td>2969</td>
<td>24.1</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>270</td>
<td>294</td>
<td>773</td>
<td>1210</td>
<td>417</td>
<td>2964</td>
<td>24.1</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>0</td>
<td>50</td>
<td>182</td>
<td>1056</td>
<td>1089</td>
<td>2377</td>
<td>19.3</td>
<td></td>
</tr>
<tr>
<td>Most deprived 5</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>345</td>
<td>1799</td>
<td>2144</td>
<td>17.4</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1505</td>
<td>1808</td>
<td>2018</td>
<td>3564</td>
<td>3421</td>
<td>12316</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

Table 2.3  Comparison of Carstairs Index 2001 and IMD 2004 by postcode

<table>
<thead>
<tr>
<th>Carstairs 2001 quintiles</th>
<th>Least deprived 1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Most deprived 5</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least deprived 1</td>
<td>674</td>
<td>536</td>
<td>503</td>
<td>123</td>
<td>26</td>
<td>1862</td>
<td>15.1</td>
</tr>
<tr>
<td>2</td>
<td>561</td>
<td>928</td>
<td>560</td>
<td>830</td>
<td>90</td>
<td>2969</td>
<td>24.1</td>
</tr>
<tr>
<td>3</td>
<td>270</td>
<td>294</td>
<td>773</td>
<td>1210</td>
<td>417</td>
<td>2964</td>
<td>24.1</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>50</td>
<td>182</td>
<td>1056</td>
<td>1089</td>
<td>2377</td>
<td>19.3</td>
</tr>
<tr>
<td>Most deprived 5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>345</td>
<td>1799</td>
<td>2144</td>
<td>17.4</td>
</tr>
<tr>
<td>Total</td>
<td>1505</td>
<td>1808</td>
<td>2018</td>
<td>3564</td>
<td>3421</td>
<td>12316</td>
<td>100</td>
</tr>
</tbody>
</table>

Chapter 2: Evaluation of screening outcomes: Methodology
Table 2.4  Cut off values associated with quintiles for the percentage of the population with ethnicity Indian Sub-Continent

<table>
<thead>
<tr>
<th>Percentile</th>
<th>% Indian Sub-Continent</th>
</tr>
</thead>
<tbody>
<tr>
<td>20th</td>
<td>0.95</td>
</tr>
<tr>
<td>40th</td>
<td>2.24</td>
</tr>
<tr>
<td>60th</td>
<td>4.24</td>
</tr>
<tr>
<td>80th</td>
<td>10.82</td>
</tr>
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</table>

Table 2.5  Distributions of first and second round populations by gender and age at invitation

<table>
<thead>
<tr>
<th>Second round</th>
<th>&lt;55 yrs n</th>
<th>%</th>
<th>55-59 yrs n</th>
<th>%</th>
<th>60-64 yrs n</th>
<th>%</th>
<th>65-69 yrs n</th>
<th>%</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>20016 (31.1)</td>
<td></td>
<td>18710 (29.1)</td>
<td></td>
<td>14566 (22.6)</td>
<td></td>
<td>11081 (17.2)</td>
<td></td>
<td>64373 (50.4)</td>
</tr>
<tr>
<td>Female</td>
<td>18967 (29.9)</td>
<td></td>
<td>18209 (28.7)</td>
<td></td>
<td>14520 (22.9)</td>
<td></td>
<td>11677 (18.4)</td>
<td></td>
<td>63373 (49.6)</td>
</tr>
<tr>
<td></td>
<td>38983 (30.5)</td>
<td></td>
<td>36920 (28.9)</td>
<td></td>
<td>29090 (22.8)</td>
<td></td>
<td>22762 (17.8)</td>
<td></td>
<td>127746 (100.0)</td>
</tr>
<tr>
<td>First round*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22110 (33.4)</td>
<td></td>
<td>18109 (27.4)</td>
<td></td>
<td>14684 (22.2)</td>
<td></td>
<td>11262 (17.0)</td>
<td></td>
<td>66165 (50.8)</td>
</tr>
<tr>
<td>Female</td>
<td>20770 (32.5)</td>
<td></td>
<td>17358 (27.1)</td>
<td></td>
<td>14157 (22.1)</td>
<td></td>
<td>11682 (18.3)</td>
<td></td>
<td>63967 (49.2)</td>
</tr>
<tr>
<td></td>
<td>42880 (33.0)</td>
<td></td>
<td>35467 (27.3)</td>
<td></td>
<td>28841 (22.2)</td>
<td></td>
<td>22944 (17.6)</td>
<td></td>
<td>130132 (100.0)</td>
</tr>
</tbody>
</table>

* First round population with restrictions as explained in Section 2.4

Table 2.6  Distribution of second round population by screening history

<table>
<thead>
<tr>
<th>Screening history</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>New in second round</td>
<td>20275</td>
<td>15.9</td>
</tr>
<tr>
<td><strong>Status in first round</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responder</td>
<td>42793</td>
<td>33.5</td>
</tr>
<tr>
<td>Negative test</td>
<td>63087</td>
<td>40.4</td>
</tr>
<tr>
<td>Positive test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive investigation</td>
<td>305</td>
<td>0.2</td>
</tr>
<tr>
<td>Negative investigation*</td>
<td>424</td>
<td>0.3</td>
</tr>
<tr>
<td>No further investigation**</td>
<td>176</td>
<td>0.1</td>
</tr>
<tr>
<td>Did not complete</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 1</td>
<td>416</td>
<td>0.3</td>
</tr>
<tr>
<td>Phase 2 or 3</td>
<td>270</td>
<td>0.2</td>
</tr>
</tbody>
</table>

* Includes people with incomplete colonoscopy
** Includes people who have attended for private colonoscopy

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Table 2.7  Distributions of people by time intervals between dates of invitation and dates of test in the first and second rounds

<table>
<thead>
<tr>
<th>Time interval (months)</th>
<th>Invitation</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>&lt;12</td>
<td>61</td>
<td>0.1</td>
</tr>
<tr>
<td>12 - &lt;18</td>
<td>202</td>
<td>0.2</td>
</tr>
<tr>
<td>18 - &lt;24</td>
<td>675</td>
<td>0.6</td>
</tr>
<tr>
<td>24 - &lt;27</td>
<td>1199</td>
<td>1.1</td>
</tr>
<tr>
<td>27</td>
<td>11548</td>
<td>10.7</td>
</tr>
<tr>
<td>28</td>
<td>41605</td>
<td>38.7</td>
</tr>
<tr>
<td>29</td>
<td>41610</td>
<td>38.7</td>
</tr>
<tr>
<td>30 - &lt;33</td>
<td>6060</td>
<td>5.6</td>
</tr>
<tr>
<td>33 - &lt;36</td>
<td>3984</td>
<td>3.7</td>
</tr>
<tr>
<td>≥36</td>
<td>300</td>
<td>0.3</td>
</tr>
<tr>
<td>Not known</td>
<td>227</td>
<td>0.2</td>
</tr>
<tr>
<td>Total</td>
<td>107471</td>
<td>51731</td>
</tr>
</tbody>
</table>
Figure 2.1  Flowchart showing exclusions that were used to restrict population.

Download Population
133742

Over 70?

Yes → 348*

No

Invited?

No → 470**

Yes

Participant of immunological trial?

Yes → 5078

No

South Warwickshire PCT?
(Excluding first two practices)

Yes → 100

No

Restricted Population
127746

* Includes 1 in immunological trial

** Includes 43 in immunological trial
Chapter 2: Evaluation of screening outcomes: Methodology

Figure 2.2  Flowchart showing reasons for non-completion of FOBt

- Restricted Population: 127746
- Received Invitation?
  - Yes
    - Returned Test Kit: 66541
  - No
    - Returned to Pilot Centre by post office: 2185
- "Reason Screening Closed"
  - Did not respond: 52043
  - Declined invitation: 3473
  - Recently screened: 1383
  - Deducted: 1140
  - Under treatment: 828
  - Deaded/ceased: 151
  - Other: 2
- Total: 59020
Chapter 3: Screening outcomes: uptake and acceptability of FOBt

Chapter Summary

- Of the 127,746 people in the restricted second round population offered a test, 52.1% (66,541) returned a screening kit. If those tests returned by the post office and those sent to ineligible people are excluded, the response rate is 54.5%.

- Of the 66,541 people who responded, 2.2% (1441) returned an inadequate kit; 80.8% (1164) of those subsequently returned an adequate test. Only 277 (0.4%) of those responding failed to return an adequate kit in the first phase of screening.

- Uptake, defined as the proportion of those invited who returned an adequate kit in the first phase of screening, was 51.9% (66264/127746).

- Uptake was lower in men (47.7%) than in women (56.2%), and increased with age, from 45.7% in those aged under 55 years, to 58.5% in those aged 65-69 years.

- Uptake fell with increasing level of deprivation, from 61.2% to 37.2% in IMD quintiles 1 to 5 respectively.

- Uptake was lower in those living in areas with a high proportion of people from the Indian Sub-Continent (40.4%) than in areas with a low proportion (54.0%).

- These associations remained significant in the multivariate analysis, although the effect of ethnicity was reduced.

- Uptake was lower in the second round than in the first round (51.9% vs 58.5%); this was true across all categories of the demographic variables.

- Uptake tended to be high in those who had participated in the first round, and for those with a negative result in the first round was 81.1%, whereas for those who did not respond in the first round it was 13.1%.

- In those aged 49-51 years, who were invited for the first time in the second round, uptake was 44.5%, compared with 51.9% in the same age-group in the first round.

- Uptake was also low in new invitees at older ages (41.5% in those aged 60 years and over compared with 62.1% in this age-group in the first round). Although the numbers are fairly small, this is the group most comparable to those to be invited in the planned roll-out of the screening programme.

- It is noted that there were different approaches to publicity between the second and first rounds. Increased public awareness associated with the introduction of the Pilot may have increased uptake in the first round.
3.1 Background
The evaluation of the first round of the UK Pilot reported that the uptake of the FOBt was close to its target of 60%. Uptake was higher in England than in Scotland (58.6% vs. 55.4%). Acceptability of the FOBt appeared to be lower in men, in younger people, in those from more deprived areas and in areas with the highest proportion of residents of Indian Sub-Continent origin.

In this evaluation of the second round we aimed to determine whether similar trends were observed, and how uptake in people who had been invited in the previous round varied according to their previous response.

3.2 Measures of response
We report here on:

i) response to the offer of screening
ii) completion of phase 1 (i.e. return of an adequate kit)
iii) completion of screening (availability of an overall FOBt result; i.e. people returned an adequate kit for each phase they entered)

For i), ii) and iii) the denominator is taken as those people known to have been sent an invitation.

iv) completion of screening in responders (as iii), but with the denominator restricted to responders to the offer of screening (i.e. the numerator in i)).

i) Response to the offer of screening (Figure 2.2): Of the 127,746 people offered a test, 2185 (1.7%) tests were returned to the Pilot site by the post office, 52043 (40.7 %) did not respond, and a further 3473 (2.7%) either refused or returned an unused kit. A further 3504 (2.7%) were recorded as ‘ineligible’. The response to the offer of screening including both tests returned by the post office and tests sent to ‘ineligible’ people is 52.1% (66541/127746); however, if both these two groups are excluded, then the response is 54.5% (66541/122057).

The number of people who returned a kit and completed different phases is shown in Figure 3.1.

ii) Completion of phase 1: A total of 1441 (2.2%) of the first kit issued in phase 1 returned were inadequate, of whom 1164 subsequently returned an adequate test; the completion rate of phase 1 was therefore 51.9% (66264/127746) of those invited and 99.6% (66264/66541) of those responding.

iii) Completion of screening: A total of 133 people entering phase 2 and 84 of those entering phase 3 failed to return an adequate test; the overall rate of completion of screening was therefore 51.7% (66047/127746).

iv) Completion of screening in responders was 99.3% (66047/66541)
3.3 Uptake by demographic variables

Sections 3.3 to 3.6 report on uptake, defined as the completion of phase 1 (i.e. return of an adequate test) by those who have been sent an invitation.

Uptake in the second round was 51.9%. Trends with demographic variables were similar to those observed in the first round. Uptake was significantly lower in men than women (47.7% vs. 56.1%, p < 0.0001), and increased in both genders with increasing age; from 45.7% at ages <55 years to 58.5% in the age group 65-69 years. The trend is significant for both males and females, being most marked in males where it rises from 41.3% to 56.2%, whilst that in females increases from 50.2% to 60.6% (Table 3.1 and Figure 3.2). The interaction between age and gender is significant, as in the first round.

Uptake fell with increasing level of deprivation, from 61.2% for IMD quintile 1 to 37.2% for quintile 5 (Table 3.2); the trend was significant (p < 0.0001). Use of the IMD gave a greater difference in uptake between least and most deprived categories than that observed using the Carstairs index. There was variation in uptake rate according to month/period of invitation (Table 3.3). For each round, there was a screening plan giving the order of invitation for each GP practice; these plans were the same for both rounds, although there were a few deviations. In both rounds, uptake was higher in the earlier part of the round than the latter part.

Table 3.4 shows the uptake according to percentage of population of Indian Sub-Continent origin. The uptake in the highest quintile is significantly lower than in the lower four quintiles (40.4% vs. 54.0%, p < 0.0001).

Results of the logistic regression are summarised in Table 3.5. Trends for individual variables are largely unaltered in the multivariate analysis, although the effect of invitation time becomes less marked. The odds ratio in the highest quintile for percentage Indian Sub-Continent increases but the effect is still significant. As in the first round, the model predicts lowest uptake in males in the youngest age group in the most deprived areas. Actual uptake in this group was 27.2%, compared with 69.8% in women aged 65-69 years in least deprived areas; both these are lower than in the equivalent sub-groups in the first round.

3.4 Uptake according to screening history

Table 3.6 shows uptake according to screening history in the first round. Uptake in those not included in the previous round was 43.9%. As noted in Section 2.3, 81.0% of these people were aged 49-51 years and so would have been too young to be invited in the first round; however uptake in new invitees in this age group was significantly lower than in the same age group in the first round (44.5% vs. 51.9%, p < 0.0001).

Uptake in those who completed screening with a negative test result was 81.1%, whilst in those who did not respond in the first round it was only 13.4%. In the latter group, uptake was slightly higher (21.5%) in those classified as ‘ineligible’ or post office return in the first round.

Of those with a previous false positive result 424 were invited, and 36.3% of these responded. In addition 305 people who had neoplasia detected in the first round were re-invited. In 1255 people invited but recorded as ‘ineligible’ in the first round uptake was 21.5%. Of these the main reasons for closing an episode in the first round was ‘under treatment’ (n=533, uptake=16.0%), undelivered by post office (n=496, uptake=19.4%) and ‘other’ (n=197, uptake=42.6%).
3.5 Comparison with first round

Table 3.7 shows the uptake by age and gender for the comparable restricted first round population. Overall uptake was significantly lower in the second round than the first round (51.9% vs. 58.5%, \(p< 0.0001\)). This was true across all age-groups and both genders. The decrease was most marked in the age group <55 years, but the uptake in both the older age groups (60-64 and 65-69 years) was significantly lower in the second round than in the first round. If 'ineligible' people and GPO returns are excluded from the denominators, the uptake in the second round is 54.3% (66264/122057) compared with 60.6% (76152/125648) in the first round.

3.6 Comparisons with Nottingham trial

Uptake of screening in the second round of the Nottingham trial, in responders to the first invitation who were aged 50-69 years at date of invitation to second test, was 80.5%, compared with the 79.6% observed in the Pilot in the same age-group in people who responded in the first round. Uptake in the first round of the Pilot in England had been similar to that in the first round of the Nottingham trial (58.5% vs. 57.9%).

3.7 Completion of screening in responders

Completion of screening in responders shows similar associations to uptake, although most are not significant. The completion rate increased from 99.1% in the age-group 50-54 years to 99.4% in the age-group 65-69 years, from 99.1% in males to 99.4% in females, and decreased from 99.5% to 98.5% with increasing level of deprivation. It is not lower in the highest quintile for percentage of Indian Sub-Continent origin (98.3% vs. 99.4%). Again, the adjusted odds ratios for individual factors in the multivariate analysis are similar to those in the univariate analyses.

3.8 Discussion

There are three key findings of particular relevance to a future screening programme.

Firstly, it is of concern that uptake in the second round of the Pilot (51.9%) was significantly lower than that in the first round (58.5%). Whilst this is most marked in the youngest age group, it is also true of those aged 60 years and over, where uptake is 56.8% compared with 62.1% in the first round. Uptake is higher in females than males in both rounds but the difference between males and females in the oldest age-group (65-69 years) was reduced in the second round compared to the first round.

This fall in uptake is not explained by the fact that most of Warwick was not included in the second round, since we have analysed the first round data for a comparable population. The difference remains if uptake is calculated with ‘ineligible’ people excluded from the denominator. We have presented the majority of the results including those people in the denominator, as this is likely to be most relevant to statistics from the future national screening programme.

Although there were differences between the methods used to publicise the Pilot in the first and second round, the Pilot Team spent a considerable amount of time in the community publicising the Pilot in the second round and it is not clear these differences were related to the fall in uptake. Approaches to publicity should be considered further in the national roll-out.
Secondly, the gradients in uptake by age, gender, social deprivation, and ethnicity that were found in the first round persist in the second round. The identification of subgroups with low uptake may warrant particular targeting in future screening rounds.

Thirdly, the uptake in people with different previous screening experiences is of relevance. In common with other screening programmes, uptake is high (81.1%) in those who had participated in the previous round and low (13.4%) in those who did not participate in the previous round. In those previous non-responders, uptake increases with age in males but not in females. In the NHS breast screening programme, uptake is 85% in women previously screened. (In women in the Pilot it is 82%). In the breast screening programme approximately 20% of previous non-responders attend at any given round, although the breast screening programme has now been established for some time. In order for uptake to be maintained between rounds, the number who previously responded who ‘drop out’ must be balanced by the number of previous non-responders who respond. Including invitations to previous non-responders does result in additional people responding, but it is not enough to balance the fall in uptake of previous responders.

Uptake in new invitees was low (43.9%). New invitees were mainly people reaching age 50 who would not have been invited in the first Round, and a much smaller number who moved into the area and so were invited for the first time. The uptake in those new invitees aged 49-51 years was 44.6% compared with 51.9% in the same age-group in the first round. The uptake in those new invitees over 60 years was only 41.5% (522/1257) compared with 62.1% in the same age-group in the first round. The low uptake in new invitees is of concern because non-responders tend not to respond at subsequent rounds, so that uptake will drift downwards. It is very important in the first few years of a screening programme that there is publicity to ensure that uptake in new invitees does not fall.

It is of note that the number of invitations returned by the Post Office was still high (n=2185) in the second round, whereas it might have been anticipated that this would fall as a result of the health authority database being updated. However, the majority of the Post Office returns in the second round were either new invitees (n=731) or people where invitations had not been returned by the Post Office in the first round (n=1359). Only 98 were undelivered in both rounds.
In the tables in this section, uptake of screening is defined as the proportion of those invited who complete at least phase 1 of screening.

### Table 3.1 Uptake of screening by gender and age group

<table>
<thead>
<tr>
<th>Gender</th>
<th>&lt;55 yrs</th>
<th>55-59 yrs</th>
<th>60-64 yrs</th>
<th>65-69 yrs</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Invited</td>
<td>Responded</td>
<td>Invited</td>
<td>Responded</td>
<td>Invited</td>
</tr>
<tr>
<td>Male</td>
<td>20016</td>
<td>8275</td>
<td>41.3</td>
<td>18710</td>
<td>8772</td>
</tr>
<tr>
<td>Female</td>
<td>18967</td>
<td>9528</td>
<td>50.2</td>
<td>18209</td>
<td>10239</td>
</tr>
<tr>
<td>Total</td>
<td>38983</td>
<td>17803</td>
<td>45.7</td>
<td>36919</td>
<td>19011</td>
</tr>
</tbody>
</table>

### Table 3.2 Uptake of screening by quintiles of deprivation category

<table>
<thead>
<tr>
<th>Quintiles</th>
<th>Carstairs Index 2001</th>
<th>IMD Index 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Invited</td>
<td>Responded</td>
</tr>
<tr>
<td>1 Least deprived</td>
<td>13761</td>
<td>8088</td>
</tr>
<tr>
<td>2</td>
<td>15363</td>
<td>8858</td>
</tr>
<tr>
<td>3</td>
<td>20760</td>
<td>11823</td>
</tr>
<tr>
<td>4</td>
<td>41709</td>
<td>21835</td>
</tr>
<tr>
<td>5 Most deprived</td>
<td>35424</td>
<td>15338</td>
</tr>
<tr>
<td>Not known</td>
<td>729</td>
<td>322</td>
</tr>
<tr>
<td>Total</td>
<td>127746</td>
<td>66264</td>
</tr>
</tbody>
</table>
Table 3.3  Uptake of screening by invitation time

<table>
<thead>
<tr>
<th>Invitation time</th>
<th>Invited</th>
<th>Responded</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>February 2003 – April 2003</td>
<td>15569</td>
<td>8218</td>
</tr>
<tr>
<td>May 2003 – July 2003</td>
<td>16898</td>
<td>9052</td>
</tr>
<tr>
<td>August 2003 – October 2003</td>
<td>22492</td>
<td>12642</td>
</tr>
<tr>
<td>November 2003 – February 2004</td>
<td>20730</td>
<td>11492</td>
</tr>
<tr>
<td>March 2004 – May 2004</td>
<td>21085</td>
<td>9547</td>
</tr>
<tr>
<td>June 2004 – August 2004</td>
<td>17422</td>
<td>8625</td>
</tr>
<tr>
<td>September 2004 – November 2004</td>
<td>13550</td>
<td>6688</td>
</tr>
<tr>
<td>Total</td>
<td>127746</td>
<td>66264</td>
</tr>
</tbody>
</table>

Table 3.4  Uptake of screening by quintiles of percentage Indian Sub-Continent origin

<table>
<thead>
<tr>
<th>Quintiles</th>
<th>Invited</th>
<th>Responded</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>1-4</td>
<td>105883</td>
<td>57148</td>
</tr>
<tr>
<td>5</td>
<td>19899</td>
<td>8039</td>
</tr>
<tr>
<td>Not known</td>
<td>1964</td>
<td>1077</td>
</tr>
<tr>
<td>Total</td>
<td>127746</td>
<td>66264</td>
</tr>
</tbody>
</table>
### Table 3.5  Uptake of screening by demographic factors and invitation time

<table>
<thead>
<tr>
<th>Gender</th>
<th>Male</th>
<th>1</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Female</td>
<td>1.43 (1.38 – 1.49)</td>
<td>1.42 (1.36 – 1.48)</td>
</tr>
<tr>
<td>Gender – Age (years)</td>
<td>Male: &lt; 55</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Male: 55-59</td>
<td>1.25 (1.20 - 1.30)</td>
<td>1.23 (1.18 – 1.28)</td>
</tr>
<tr>
<td></td>
<td>Male: 60-64</td>
<td>1.48 (1.42 – 1.54)</td>
<td>1.47 (1.41 – 1.54)</td>
</tr>
<tr>
<td></td>
<td>Male: 65-69</td>
<td>1.82 (1.74 – 1.91)</td>
<td>1.82 (1.74 – 1.91)</td>
</tr>
<tr>
<td></td>
<td>Female: &lt;55</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Female: 55-59</td>
<td>1.27 (1.22 – 1.33)</td>
<td>1.26 (1.20 – 1.31)</td>
</tr>
<tr>
<td></td>
<td>Female: 60-64</td>
<td>1.48 (1.42 – 1.55)</td>
<td>1.49 (1.43 – 1.56)</td>
</tr>
<tr>
<td></td>
<td>Female: 65-69</td>
<td>1.53 (1.46 – 1.60)</td>
<td>1.55 (1.48 – 1.63)</td>
</tr>
<tr>
<td>Invitation Time</td>
<td>Feb 2003 – Apr 2003</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>May 2003 – July 2003</td>
<td>1.03 (0.99 – 1.08)</td>
<td>0.99 (0.95 – 1.04)</td>
</tr>
<tr>
<td></td>
<td>Aug 2003 – Oct 2003</td>
<td>1.15 (1.10 – 1.20)</td>
<td>1.07 (1.02 – 1.11)</td>
</tr>
<tr>
<td></td>
<td>Nov 2003 – Feb 2004</td>
<td>1.11 (1.07 – 1.16)</td>
<td>0.99 (0.95 – 1.03)</td>
</tr>
<tr>
<td></td>
<td>Mar 2004 – May 2004</td>
<td>0.74 (0.71 – 0.77)</td>
<td>0.89 (0.86 – 0.93)</td>
</tr>
<tr>
<td></td>
<td>June 2004 – Aug 2004</td>
<td>0.88 (0.84 – 0.92)</td>
<td>1.03 (0.98 – 1.07)</td>
</tr>
<tr>
<td></td>
<td>Sept 2004 – Nov 2004</td>
<td>0.87 (0.83 – 0.91)</td>
<td>0.98 (0.93 – 1.02)</td>
</tr>
<tr>
<td>Deprivation Category (IMD)</td>
<td>1 Least deprived</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>0.87 (0.56 – 0.60)</td>
<td>0.86 (0.83 – 0.90)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>0.74 (0.72 – 0.77)</td>
<td>0.74 (0.72 – 0.77)</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>0.58 (0.56 – 0.60)</td>
<td>0.60 (0.57 – 0.62)</td>
</tr>
<tr>
<td></td>
<td>5 Most deprived</td>
<td>0.38 (0.36 – 0.39)</td>
<td>0.41 (0.39 – 0.43)</td>
</tr>
<tr>
<td>% Indian Sub-Continent</td>
<td>Quintiles 1-4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Quintile 5</td>
<td>0.58 (0.56 – 0.60)</td>
<td>0.89 (0.86 – 0.93)</td>
</tr>
</tbody>
</table>
Table 3.6  Uptake of screening in the second round by previous screening history

<table>
<thead>
<tr>
<th>Screening history</th>
<th>Invited</th>
<th>Responded n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>New in second round</td>
<td>20275</td>
<td>8903</td>
<td>43.9</td>
</tr>
<tr>
<td>Status in first round</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responder</td>
<td>42793</td>
<td>5732</td>
<td>13.4</td>
</tr>
<tr>
<td>Negative test</td>
<td>63087</td>
<td>51165</td>
<td>81.1</td>
</tr>
<tr>
<td>Positive test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive investigation</td>
<td>305</td>
<td>75</td>
<td>24.6</td>
</tr>
<tr>
<td>Negative investigation</td>
<td>424</td>
<td>154</td>
<td>36.3</td>
</tr>
<tr>
<td>No further investigation</td>
<td>176</td>
<td>44</td>
<td>25.0</td>
</tr>
<tr>
<td>Did not complete</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 1</td>
<td>416</td>
<td>115</td>
<td>27.6</td>
</tr>
<tr>
<td>Phase 2 or 3</td>
<td>270</td>
<td>76</td>
<td>28.1</td>
</tr>
<tr>
<td>Total</td>
<td>127746</td>
<td>66264</td>
<td>51.9</td>
</tr>
</tbody>
</table>

Table 3.7  Uptake of screening by gender and age group in the first round

<table>
<thead>
<tr>
<th>Gender</th>
<th>&lt;55 yrs</th>
<th>55-59 yrs</th>
<th>60-64 yrs</th>
<th>65-69 yrs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Invited</td>
<td>Responded n</td>
<td>Invited</td>
<td>Responded n</td>
<td>Invited</td>
</tr>
<tr>
<td>Male</td>
<td>22110</td>
<td>10842</td>
<td>49.0</td>
<td>18109</td>
<td>9525</td>
</tr>
<tr>
<td>Female</td>
<td>20770</td>
<td>12361</td>
<td>59.5</td>
<td>17358</td>
<td>11246</td>
</tr>
<tr>
<td>Total</td>
<td>42880</td>
<td>23203</td>
<td>54.1</td>
<td>35467</td>
<td>20771</td>
</tr>
</tbody>
</table>
Figure 3.1  Flowchart showing pathways through each phase

Enter Phase 1
66541

No adequate result
277

Negative
62960

Weak positive
Enter Phase 2
3105

Strong positive
115
Or Strong/Weak positive following spoilt
84

No adequate result
133

Negative
Enter Phase 3
2320

Positive
652

No adequate result
84

Negative
1916

Positive
320

Chapter 3: Screening outcomes: uptake and acceptability of FOBt
Figure 3.2 Uptake of screening (invitees completed at least phase 1) by gender and age group

[Bar chart showing uptake of screening by gender and age group]
4. Screening outcomes: uptake and acceptability of colonoscopy

Chapter Summary

- A total of 1171 people had an overall positive FOBt outcome, of whom 1074 (91.7%) attended for a nurse appointment; three were reported to be unfit for colonoscopy, and 1001 were recorded as having been referred for colonoscopy, of whom 970 attended.

- Uptake of colonoscopy appears slightly higher than in the first round. The uptake rates using number of positive FOBt outcomes as the denominator for the restricted population in the first round and second round were 80.5% and 82.8% respectively.

- Uptake of colonoscopy was similar in males and females, and there was no clear trend with age.

- Uptake of colonoscopy was highest in the least deprived quintile of the IMD but otherwise there was no clear trend with deprivation. The uptake in the quintile with the highest percentage of Indian Sub-Continent origin was not significantly lower compared with the other quintiles. These findings were largely unaltered in the multivariate analysis.

- Most positive FOBt outcomes were in people with a negative episode in the first round, and uptake was high in these people (86.8%). Uptake in people newly invited in the second round was 81.9%, and in people who did not respond to the FOBt invitation in the first round was 76.0%. Uptake in people with a positive FOBt outcome in the first round was 41.2%.

- Uptake of colonoscopy in those referred (or not referred for unknown reasons) was 95.3%.

4.1 Background

The evaluation of the first round of the Pilot reported uptake of colonoscopy in those with a positive test of 82.2%, with only 1.5% not proceeding to undergo colonoscopy because they were deemed medically unfit. However an alternative estimate of 85% was obtained after excluding people under therapy or polyp follow-up, those who had recent endoscopy, those with no colon or those intending to have private colonoscopy. The rate of non-acceptance was higher in England than in Scotland, in areas of higher deprivation and amongst ethnic minorities.

4.2 Pathways following a positive FOBt outcome

Figure 4.1 shows the pathways for those people for whom the FOBt outcome was positive (n=1171). Of those, 1074 (91.6%) attended the nurse appointment and 1001 were referred to colonoscopy. Additional information was obtained from the Pilot site about the people who
were not referred. Of these 73, 21 had had a recent colonoscopy; 20 were under treatment for bowel symptoms; 10 intended to have a private colonoscopy; 3 were unfit for colonoscopy, none of whom proceeded to have any alternative investigations; and 2 had no bowel. For the remaining 17, the Pilot site did not record a reason.

Of those attending, colonoscopy was completed satisfactorily (or polyps or suspected cancer found) in 938 (96.7%). Of the remaining 32, who were all offered double contrast barium enema, 29 proceeded.

Of 1171 people with a positive FOBt outcome, 970 (82.8%) attended for colonoscopy.

Subsequent tables report on uptake of colonoscopy using the number of people with a positive FOBt outcome as the denominator and the number of people attending colonoscopy as the numerator.

### 4.3 Uptake by demographic values

Uptake of colonoscopy was similar in males and females, and highest (86.7%) in the youngest age group <55 years (Table 4.1 and Figure 4.2). Table 4.2 shows uptake of colonoscopy by deprivation category; uptake was highest in the least deprived category and decreases between quintiles 1 and 3.

Uptake of colonoscopy is not significantly lower in the highest quintile for Indian Sub-Continent population, either with or without adjustment for deprivation. This is in contrast to the findings in the first round (Table 4.3).

Table 4.4 gives the results of the logistic regression; adjustment for other factors has little impact on odds ratios.

### 4.4 Uptake by screening history

Table 4.5 shows uptake of colonoscopy according to screening history. Uptake was highest (86.6%) in those with a previous negative test. Uptake was 81.9% in those people newly invited in the second round, but was lower (76.0%) in previous non-responders. Of those with a positive FOBt outcome in both the first and second rounds, 39% (14/36) of those who had colonoscopy in the first round and 45.5% (5/11) of those with no further investigation in the first round attended for colonoscopy in the second round.

### 4.5 Comparison with first round

The colonoscopy uptake rates for the restricted population in the first and second rounds were 80.5% and 82.8% respectively. Our estimate for the first round uptake was higher than that reported in the first round evaluation, which was restricted to people for whom more than three months elapsed between completion of FOB testing and the data download from the Pilot site. The download we received from Edinburgh after the first round evaluation would have contained more colonoscopies. With the restricted population for the first round, of the 968 colonoscopies, 59 (6.0%) took place more than three months after the nurse appointment.

In the evaluation of the first round, allowances were made for reasons such as fitness for colonoscopy, people already under treatment and those attending for private colonoscopies. The colonoscopy uptake in England was reported as 77.5% and 82.4% before and after making these allowances respectively. Using the number of people referred as the denominator is
similar to making these allowances, except that people for whom we do not have a specific reason (other or unknown in Figure 4.1) for not being referred are also excluded from the denominator. The uptake of colonoscopy in those referred is estimated as 96.9% (970/1001), and our estimate for the first round in the restricted population is 96.2% (974/1012). Uptake is slightly higher in the second round than in the first round, but the difference is not significant. If those with unknown reason for non-referral are included in the denominator, the estimated uptake for the second round is 95.3% (970/1018).

4.6 Comparison with Nottingham trial

It is not possible to compare the uptake of colonoscopy with Nottingham since although colonoscopy was the most frequent method of investigation in the Nottingham trial, barium enema and sigmoidoscopy were also used. It is possible to compare the uptake of colonoscopy in the Pilot with the uptake of investigation in Nottingham. The uptake of investigation in Nottingham was 97.7% and 97.0% in the first and second round respectively. The most comparable rate for the Pilot is the number attending out of those referred for colonoscopy which is 96.1% in the second round.

4.7 Discussion

The uptake of colonoscopy is an important measure of the performance of the screening process.

Where people with a positive FOBt outcome attend a nurse appointment but are not subsequently referred for colonoscopy the reason for this, and the alternative management, should be clearly recorded.

It is encouraging that there was no significant difference in attendance rate by gender. It might be expected that colonoscopy uptake would decrease with age, as comorbidity increases with age. However, there is no clear trend with age.

It appears that the uptake of colonoscopy in the first round in England was slightly higher than the data available at the time of the evaluation suggested, probably due to the delay between positive tests and colonoscopy in some people. It was acknowledged in the first round report that the colonoscopy uptake in England may have been higher than that reported.

There appears to have been little change in colonoscopy uptake between rounds, although it is slightly higher in the second round. In the first round in England uptake was lower in least deprived areas, which may have been due to a high rate of private colonoscopies in this group. However, in the second round uptake appears to decrease with increasing level of deprivation as measured by the IMD. Uptake in the second round did not differ between the areas grouped by quintiles of Indian Sub-Continent population, in contrast to the first round.

Uptake by screening history showed that it was lower (76.0%) in previous non-responders to screening who were screened in the second round. Further information and support may be needed among such groups to help them complete the process.
### Table 4.1  Uptake of colonoscopy in FOBt positive individuals by gender and age group

<table>
<thead>
<tr>
<th></th>
<th>&lt;55 yrs</th>
<th>55-59 yrs</th>
<th>60-64 yrs</th>
<th>65-69 yrs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive FOBt</td>
<td>Attended n</td>
<td>%</td>
<td>Positive FOBt</td>
<td>Attended n</td>
</tr>
<tr>
<td>Male</td>
<td>144</td>
<td>124</td>
<td>86.1</td>
<td>168</td>
<td>135</td>
</tr>
<tr>
<td>Female</td>
<td>105</td>
<td>92</td>
<td>87.6</td>
<td>121</td>
<td>96</td>
</tr>
<tr>
<td>Total</td>
<td>249</td>
<td>216</td>
<td>86.7</td>
<td>289</td>
<td>231</td>
</tr>
</tbody>
</table>

### Table 4.2  Uptake of colonoscopy in FOBt positive individuals by quintiles of deprivation category

<table>
<thead>
<tr>
<th>Quintiles</th>
<th>Carstairs Index 2001</th>
<th>IMD Index 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive FOBt</td>
<td>Attended n</td>
</tr>
<tr>
<td>1 Least deprived</td>
<td>120</td>
<td>103</td>
</tr>
<tr>
<td>2</td>
<td>135</td>
<td>114</td>
</tr>
<tr>
<td>3</td>
<td>163</td>
<td>135</td>
</tr>
<tr>
<td>4</td>
<td>368</td>
<td>305</td>
</tr>
<tr>
<td>5 Most deprived</td>
<td>376</td>
<td>306</td>
</tr>
<tr>
<td>Not known</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>1171</td>
<td>970</td>
</tr>
</tbody>
</table>

### Table 4.3  Uptake of colonoscopy in FOBt positive individuals by quintile of percentage Indian Sub-Continent origin

<table>
<thead>
<tr>
<th>Quintiles</th>
<th>Positive FOBt</th>
<th>Attended n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-4</td>
<td>932</td>
<td>771</td>
<td>82.7</td>
</tr>
<tr>
<td>5</td>
<td>223</td>
<td>186</td>
<td>83.4</td>
</tr>
<tr>
<td>Not known</td>
<td>16</td>
<td>13</td>
<td>81.3</td>
</tr>
<tr>
<td>Total</td>
<td>1171</td>
<td>970</td>
<td>82.8</td>
</tr>
</tbody>
</table>
Table 4.4  Uptake of colonoscopy in FOBt positive individuals by demographic factors and invitation time

<table>
<thead>
<tr>
<th>Gender - Age (years)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Female</td>
<td>1.14 (0.54 – 2.41)</td>
<td>1.09 (0.51 – 2.33)</td>
</tr>
<tr>
<td>Male: &lt; 55</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Male: 55-59</td>
<td>0.66 (0.36 – 1.21)</td>
<td>0.68 (0.37 – 1.26)</td>
</tr>
<tr>
<td>Male: 60-64</td>
<td>0.84 (0.45 – 1.56)</td>
<td>0.87 (0.47 – 1.63)</td>
</tr>
<tr>
<td>Male: 65-69</td>
<td>0.66 (0.36 – 1.21)</td>
<td>0.72 (0.39 – 1.34)</td>
</tr>
<tr>
<td>Female: &lt;55</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Female: 55-59</td>
<td>0.54 (0.26 – 1.12)</td>
<td>0.61 (0.29 – 1.29)</td>
</tr>
<tr>
<td>Female: 60-64</td>
<td>0.93 (0.44 – 1.97)</td>
<td>1.00 (0.47 – 2.13)</td>
</tr>
<tr>
<td>Female: 65-69</td>
<td>0.53 (0.26 – 1.09)</td>
<td>0.58 (0.28 – 1.21)</td>
</tr>
<tr>
<td>Invitation Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb 2003 – Apr 2003</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>May 2003 – July 2003</td>
<td>0.42 (0.20 – 0.91)</td>
<td>0.39 (0.18 – 0.83)</td>
</tr>
<tr>
<td>Aug 2003 – Oct 2003</td>
<td>0.49 (0.24 – 1.01)</td>
<td>0.49 (0.23 – 1.01)</td>
</tr>
<tr>
<td>Nov 2003 – Feb 2004</td>
<td>0.34 (0.17 – 0.68)</td>
<td>0.33 (0.16 – 0.67)</td>
</tr>
<tr>
<td>Mar 2004 – May 2004</td>
<td>0.39 (0.19 – 0.80)</td>
<td>0.40 (0.19 – 0.83)</td>
</tr>
<tr>
<td>June 2004 – Aug 2004</td>
<td>0.29 (0.14 – 0.59)</td>
<td>0.31 (0.15 – 0.63)</td>
</tr>
<tr>
<td>Sept 2004 – Nov 2004</td>
<td>0.52 (0.23 – 1.18)</td>
<td>0.56 (0.25 – 1.29)</td>
</tr>
<tr>
<td>Deprivation Category (IMD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Least deprived</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>0.59 (0.31 – 1.12)</td>
<td>0.56 (0.30 – 1.07)</td>
</tr>
<tr>
<td>3</td>
<td>0.44 (0.24 – 0.80)</td>
<td>0.42 (0.22 – 0.77)</td>
</tr>
<tr>
<td>4</td>
<td>0.57 (0.30 – 1.06)</td>
<td>0.54 (0.28 – 1.04)</td>
</tr>
<tr>
<td>5 Most deprived</td>
<td>0.44 (0.24 – 0.83)</td>
<td>0.36 (0.18 – 0.73)</td>
</tr>
<tr>
<td>% Indian Sub-Continent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quintiles 1 – 4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Quintile 5</td>
<td>1.05 (0.71 – 1.55)</td>
<td>1.37 (0.84 – 2.25)</td>
</tr>
</tbody>
</table>

Table 4.5  Uptake of colonoscopy in FOBt positive individuals by screening history

<table>
<thead>
<tr>
<th>Screening history</th>
<th>Positive FOBt</th>
<th>Attended n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>New in second round</td>
<td>127</td>
<td>104</td>
<td>81.9</td>
</tr>
<tr>
<td>Status in first round</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non responder</td>
<td>125</td>
<td>95</td>
<td>76.0</td>
</tr>
<tr>
<td>Negative test</td>
<td>853</td>
<td>740</td>
<td>86.8</td>
</tr>
<tr>
<td>Positive test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive investigation</td>
<td>4</td>
<td>2</td>
<td>50.0</td>
</tr>
<tr>
<td>Negative investigation</td>
<td>36</td>
<td>14</td>
<td>38.9</td>
</tr>
<tr>
<td>No further investigation</td>
<td>11</td>
<td>5</td>
<td>45.5</td>
</tr>
<tr>
<td>Did not complete</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 1</td>
<td>5</td>
<td>4</td>
<td>80.0</td>
</tr>
<tr>
<td>Phase 2 or 3</td>
<td>10</td>
<td>6</td>
<td>60.0</td>
</tr>
<tr>
<td>Total</td>
<td>1171</td>
<td>970</td>
<td>82.8</td>
</tr>
</tbody>
</table>
Figure 4.1 Flowchart showing investigations following a positive test outcome

Test outcome positive
1171

Attend nurse appointment

Yes

Referred for colonoscopy

No

Reason for not referring
Unfit 3
Intended to go private 10
Recent colonoscopy 21
Under treatment 20
No bowel 2
Not known 17
Total 73

Yes

Attend colonoscopy

No

31

Yes

Colonoscopy completed satisfactorily or polyps/cancer found

No

32

Yes

Attend DCBE

No

3

Yes

938
Figure 4.2 Uptake of colonoscopy in FOBt positive individuals by gender and age groups
5. Screening outcomes: test performance and neoplasia detected

Chapter Summary

- The positive rate defined as the rate of an overall positive outcome of FOBt after all the phases in those returning an adequate kit was 1.77%.

- The positive rate was significantly higher than that of 1.59% in the first round.

- As observed in the first round, the positive rate was higher in males than in females, and increased with age.

- The positive rate increased significantly with increasing level of deprivation, and was highest in the highest quintile for percentage of Indian Sub-Continent origin. These effects were reduced but remained significant in the multivariate analysis.

- The positive rate in responders to the second round was considerably higher than in the equivalent population in the Nottingham trial (1.78% vs 0.84%). (We now calculate that in the first round of the English pilot the positive rate was slightly higher than in the Nottingham trial).

- The majority of positive FOBt outcomes resulted after one or more retests.

- Re-introduction of dietary retesting did not affect the rate of positive FOBt outcomes.

- The detection rate of cancer was 0.94 per 1000; it was significantly lower than in the first round, and than in the equivalent population in the Nottingham trial. This was particularly marked for females.

- The detection rate of neoplasia (both cancers and adenomas) was 5.67 per 1000; this was similar to that in the first round but lower than that in the Nottingham trial.

- The positive predictive value of a positive FOBt outcome for cancer was 5.3%, and that for all neoplasia 32.1%. These positive predictive values were lower than in the Nottingham trial, even when the more favourable denominator (i.e. those attending for colonoscopy) was used.

- The positive predictive value for both cancer and neoplasia was significantly lower than that for the first round, but the difference is restricted to females.

- Approximately 16% of people with 3 or 4 positive spots at phase 1 eventually had neoplasia detected. Referring these people directly to colonoscopy would increase the overall positive rate to 2.1%.

- For screen-detected cancers in the Pilot with known stage, the proportions by stage are similar to those in the comparable population in the Nottingham trial.

- Few people over age 70 requested a kit from the screening centre. Of 348 who did so, 92.8% returned an adequate kit. Consideration should be given to information needed for this age group about continuing screening.
5.1 FOBt positive rate

In the evaluation of the first round of the Pilot, the proportion of overall positive episodes was reported as 1.6% in England. (This was significantly lower than that in Scotland, which was 2.1%). Positivity increased with age, was higher in men, and in more deprived areas.

Outcome of screening can be divided into the result of an individual FOBt, the overall outcome of FOBt (after all the phases), and the outcome of the episode (after further investigations in positives are complete) (see Glossary, Appendix 1). The result of a particular test is of interest both to determine at which phase an individual test made the overall result positive and secondly, to study the positive rates occurring in initial tests and in retests. In this section, we investigate all three aspects.

5.2 FOBt result by phase

As shown in Figure 5.1 there are several routes by which a positive FOBt outcome can be reached. The results of the different phases are summarized by age and gender in Table 5.1. Overall 9.8% (115/1171) of positive FOBt outcome were strong positives at phase 1, and 83.0% were positives at either phase 2 or phase 3 (55.7% at phase 2 and 27.3% at phase 3). A further 7.2% were positive at phase 1 after an initial inadequate result. The percentage of positive outcomes based on weak positive results was slightly but not significantly lower in people aged 60-69 years. The percentage of positive FOBt outcomes which were strong positives at phase 1 was slightly, but not significantly higher in men.

Of 3105 people with an initial weak positive at phase 1, 1916 (61.7%) were negative at phase 2 and phase 3, 217 (7.0%) failed to complete screening, and 972 (31.3%) resulted in a positive episode.

Table 5.2 shows the same information for different time periods. Positive rates are highest in the period March to August 2004, however this will reflect the date the invitation was sent, and not the date the test was returned.

5.3 FOBt results of initial tests and retests

In order to look in more detail at trends over time, and in particular at the effect of dietary restriction, we have studied the positive rates for first (phase 1) tests and for repeat tests, defined as either phase 1 tests following an initial spoilt result, phase 2 or phase 3 tests. In the first round, all retesting was done with dietary restriction. In the second round, retests were initially done without any dietary restriction, but this was reintroduced on 1 March 2004 due to concerns about higher than expected positive rates. Table 5.3 shows the positive (weak and strong) rates by the date of reading of the test (nearly always the day it was received) for first tests and retests. The positive rate in first tests was significantly higher in the second round than the first round (4.8% vs. 4.1%); the positive rate in retests was also higher in the second round (16.0% vs. 15.4%) but not significantly so. The effect of reintroducing dietary restriction in the second round did not decrease the positive rates in the retests significantly (16.6% to 15.4%). The positive rates for the first test varied with time, and showed an increased between March 2004 and August 2004.

Subsequent sections and tables report on positive FOBt outcome, defined as the rate of overall positive outcome of FOBt (after all phases) in those returning an adequate kit.
5.4 Positive FOBt outcome by demographic variables

Table 5.4 and Figure 5.2 show the positive rate for FOBt outcome by age and gender. Overall 1.77% (1171/66264) of people had a positive result, with the rate being significantly higher in males than in females (2.17% vs. 1.42%), and increasing with increasing age. Table 5.5 summarises the positive rates for FOBt outcome by time period, suggesting an increased positive rate between April 2004 and September 2004. Table 5.6 shows positive rates to increase significantly with increasing level of deprivation, and Table 5.7 shows positive rates to be significantly higher in the highest quintile for percentage of Indian Sub-Continent origin (2.77%).

Table 5.8 show the results of the multivariate analysis, in which the effects of deprivation category and percentage of ethnic minorities are somewhat reduced, but remain significant.

5.5 Positive rate for FOBt outcome by screening history

Table 5.9 gives the positive rates for FOBt outcome according to screening history. The rate in new invitees was not significantly different from that in all people below age 55 years. The rate in previous non-responders was significantly higher (2.18%) than that in people with a negative FOBt outcome in the first round (1.67%). The positive rate was also high in those who responded but failed to complete an adequate test (phase 1, 2 or 3) in the first round (7.9%), and in those invited but ‘ineligible’ in the first round (3.3%). In people who had a positive FOBt outcome in the first round and did not have any further investigation (and so were correctly invited in the second round), the positive rate was very high (25.0%). Those people who had a positive FOBt outcome in the first round and were investigated also had a high positive rate (23.4% and 5.3% where the investigation in the first round was negative and positive respectively).

5.6 Comparison with first round

Positive rates in the second round were significantly higher than in the comparable restricted population in the first round (1.77% vs. 1.59%, p=0.01) (Table 5.10). The increase was most marked in the youngest age-group and in females.

Table 5.11 shows the first round rates analysed by deprivation quintile, suggesting that the positive rate increased most in the most deprived quintile.

5.7 Comparison with Nottingham trial

The comparison of the positive rates for FOBt outcome with the Nottingham trial needs to take account of differences as explained in Section 2.7. The positive rate in the second round of the Pilot was significantly higher than that in the Nottingham trial (1.78% vs. 0.84%, p<0.0001). This is true even if the comparison is restricted to people with a previous negative test. In the first round of the Pilot, the positive rate was slightly higher than that in the Nottingham trial (1.61 % vs. 1.38%, p = 0.03).

The Nottingham positive rates that have appeared in publications cannot be directly compared with positive rates for the Pilot. The reasons were considered in Section 2.7 but the main one is repeated here. Nottingham positive rates use the results of the last test completed and assume that a person completes the screening protocol, which is not necessarily true, whereas rates presented for the Pilot do not count people who were weakly positive in phase 1 and did not have any further tests. The first round evaluation suggested that the positive rates in the English Pilot were lower than Nottingham (1.65% vs. 1.77%) (Table 4.1.4 in the Final Report...
of the first round evaluation). However, this is misleading, partly for the reasons described above. In addition, the numbers of positives in females for Nottingham in Table 4.1.4 were misplaced (the total figure should be 210 rather than 247). The positive rates presented in this report, which takes into account the differences between the studies, show that the positive rate in the Pilot was higher than Nottingham (1.62% vs. 1.38%), the latter being age-gender standardised to the Pilot population. (The Nottingham rate increases to 1.47% if those initial positives lost to follow up are included).

5.8 Detection of cancers or adenomas

A person has been classified as having bowel cancer if there is pathological confirmation from either a resection specimen or a biopsy/polyp removed at colonoscopy. This definition includes polyp cancers, where the cancer was confined to one or more polyps. However it excludes a few people whose cancer was advanced and only palliative treatment (either chemotherapy or radiotherapy) was given without any surgery and so no resection specimen was available to confirm the cancer. A total of 66 cancers were detected as a result of screening, which have been cross-checked with the Pilot site.

A total of 62 cancers were detected in the second round in the restricted population and are included in our analysis. Some people opted for a private colonoscopy and the Pilot site is aware of one cancer detected at a private colonoscopy. This cancer has been excluded from our analysis but is considered in Chapter 6 where we report on cancer registry data.

A person has been classified as having an adenoma where the person had a polyp(s), which on pathological confirmation was found to be an adenoma and was non-malignant. People having both adenoma and cancer are not included in the analyses of adenomas. People with adenomas can be classified according to risk:12

- Low 1-2 adenomas less than 10mm
- Intermediate either 1-2 adenomas with at least one greater than 10mm or 3-4 adenomas all less than 1mm
- High either 3-4 adenomas with at least one greater than 10mm or 5 or more adenomas.

There were 8 (out of 314) people with adenomas in the second round where a size measurement was missing that would affect the risk category. We have been advised by the Pilot site that the largest adenoma was always measured and so in these cases it was still possible to assign a risk category.

People with adenomas of low risk will not be invited to the next screening round while people with adenomas of intermediate or high risk should be put into a surveillance programme (Figure 1.2).

Detection rates and positive predictive values are presented both for cancers and neoplasia (cancers and adenomas grouped together).

Detection rates of cancer and neoplasia have been calculated using the number of people with an adequate test result (phase 1) as denominator.
5.8.1 Detection rates by demographic variables

The detection rate of bowel cancer was 0.94 per 1000 people returning an adequate test (0.53 per 1000 in females and 1.40 per 1000 in males) (Table 5.12 and Figure 5.3). The detection rate of all neoplasia was 5.67 per 1000 (3.57 per 1000 in females and 8.11 per 1000 in males), both rates increasing with increasing age (Table 5.12 and Figure 5.4).

Detection rates tended to increase with increasing deprivation category (Table 5.13); the trends for both neoplasia and for cancer are significant. The detection rate of neoplasia is significantly higher in the highest quintile for ethnic minority (Table 5.14).

Table 5.15 gives the results of the multivariate analysis for neoplasia; the effect of ethnicity disappears with adjustment for other factors.

5.8.2 Detection rates of adenomas according to risk

Table 5.16 shows the detection rates of adenomas classified according to risk. The rates of intermediate and high risk adenomas in males were 2.41 and 1.20 per 1000 respectively. The rates in females were 1.29 and 0.28 per 1000 respectively.

5.8.3 Detection rates by screening history

Table 5.17 shows the rates by screening history in the first round. The detection rate of neoplasia was notably high in those people who were invited but did not respond in the first round (7.85 per 1000). It was also high in the small numbers of people with incomplete tests at the first round (20.94 per 1000, 4/191) and in those with a previous positive not investigated (22.72 per 1000, 1/44). The rate in new invitees was slightly but not significantly higher than that in the first round in the age-group <55 years.

5.8.4 Comparison with first round

Table 5.18 gives the detection rates for the comparable population in the first round. The detection rate of neoplasia in the second round is slightly but not significantly lower (5.67 in the second round per 1000 compared with 6.17 per 1000 in the first round). However the detection of cancers is significantly lower in the second round (0.94 per 1000 vs. 1.35 per 1000) in the first round, whilst the detection rate of adenomas is similar.

5.8.5 Comparison with Nottingham trial

As described in 2.7, this comparison is restricted to people responding to invitation in the first round.

The detection rate of neoplasia was 5.67 and 5.35 per 1000 screened in the Pilot and in the Nottingham trial respectively. The detection rate of cancers was 0.91 and 1.36 per 1000 screened in the Pilot and Nottingham trial respectively. In particular, the detection rate of cancers in the Pilot in females is lower than in Nottingham (0.5 vs. 1.0 per 1000).

If the analysis is restricted to those people with a negative test in the first round, then there is very little change. The detection rates for neoplasia were 5.58 per 1000 in the Pilot and 5.29 per 1000 in Nottingham and for cancer were 0.90 per 1000 in the Pilot and 1.32 per 1000 in Nottingham.
5.9 Positive Predictive Value (PPV)

5.9.1 Positive predictive value by demographic variables

Positive predictive values (PPVs) have been calculated using all people with a positive FOBt outcome as denominator. Table 5.19 gives the PPVs for cancer and for all neoplasia by age and gender. The PPV for cancer was 5.3% and for all neoplasia 32.1%. The PPV was higher in males than females both for cancers and all neoplasia (6.5% vs. 3.8% and 37.4% vs. 25.1%) and increased with age; in people aged 60 years and over the PPV for all neoplasia was 43.9% for males and 30.4% for females.

Table 5.20 shows PPV by deprivation category, with a clear decrease in PPV for neoplasia (though not for cancer) with increasing deprivation category.

PPV was also lower in the lowest quintiles for ethnic minority (Table 5.21).

Table 5.22 gives the results of the multivariate analysis; the effect of deprivation category largely disappears when adjusted for other factors.

5.9.2 PPV by risk category of adenoma

Table 5.23 gives the PPVs for low and for intermediate/high risk adenomas, by age-group and gender. The PPVs are higher for the intermediate/high risk groups than for the low risk group in both sexes in the older age groups (over 60 years).

5.9.3 PPV by screening history

Table 5.24 shows that the PPVs for both cancer and neoplasia were slightly, though not significantly higher in previous non-responders to screening than in those previously testing negative (6.4% vs. 5.6% for cancer, and 36.0% vs. 33.5% for neoplasia).

5.9.4 Comparison with first round

Table 5.25 show the PPVs by age and gender for the comparable first round population. The PPV for both cancer and neoplasia in the second round was significantly lower than that in the first round, but this difference is restricted to females.

Table 5.26 gives the PPVs by age and gender calculated including only those people attending for colonoscopy in the denominator. The increase in the PPVs calculated in this way is 22-25%, similar to that observed in the first round.

5.9.5 Comparison with Nottingham trial

The comparison of PPVs with the Nottingham trial uses the positive FOBt outcome and so needs to take account of differences as explained in Section 2.7. The PPVs for cancer for the Nottingham trial and Pilot are 16.2% and 5.1% respectively. The PPVs for neoplasia are 63.8% and 31.8% for the Nottingham trial and Pilot respectively.

In Nottingham the PPVs increased in the second round (in the first round they were slightly higher than in the first round of the Pilot).

Table 5.27 summarises the main results in the first and second rounds of the Pilot and in the first and second rounds of the Nottingham trial.
5.10 PPV according to number of positive spots

Each test kit consists of 6 spots which when read may be positive or negative. The number of positive or negative spots was used to determine the overall positivity of the kit. A kit with 1 to 4 positive spots is recorded as 'weak positive' whereas a kit with 5 or 6 positive spots was a 'strong positive'. The classification of the sample as a weak positive led to the person being entered into phase 2 i.e. being given a further test kit, whereas positive results proceed directly to the offer of a nurse appointment.

The PPV for cancer was higher in initial strong positives (13.7%) than that for other positive tests (4.2%). The difference was most marked for males, where the PPV for cancer in initial strong positives was 18.7%, compared with 4.6% in other positive tests.

In order to establish whether altering the threshold between weak and strong positive could be used to change the referral workload strategy, the cancer and adenoma PPVs were calculated per person according to the number of positive spots per test at the end of phase 1 (Table 5.28).

Using the number of people as denominator there is a strong trend of increasing PPV for cancer with number of positive spots, rising from 0.66% with one positive spot to 18.46% with 6 positive spots. Using the number of people who actually attended a further investigation as denominator the trend is less marked, for 1-3 spots, but the PPV increases for 4 spots or more. The trend for adenomas is less clear; the PPV based on number of people is low for one or two positive spots, but in people attending further investigation the PPV is higher in initial weak positives. If all people with 3 or 4 positive spots had been referred directly, the overall positive rate would have increased from 1.77% to 2.08%; 16% of these people eventually had neoplasia detected.

5.11 Adverse events of colonoscopy

There were few adverse events of colonoscopy reported. There were no perforations; events reported were, bleeding (4), hypoxia (1), bradycardia (2) and hypotension (5). This compared favourably with the already low adverse event rates reported in the first round.

5.12 Stage of screen detected cancers

Table 5.29 gives the breakdown by Dukes’ stage of the screen-detected cancers in the second round of the Pilot, and in the second round of the Nottingham trial in attendees at the first round.

Of the 62 cancers in the Pilot, there were 11 polyp cancers, two treated only by chemotherapy and one by radiotherapy.

There was a higher percentage of cancers with unknown stage, and a higher percentage of polyp cancers than in the first round. Of those with known stage, the proportions by stage was similar to those in the comparable population in the Nottingham trial.

5.13 Self referrals in people aged 70 years and over

People aged over 70 years were not invited routinely in the second round of the Pilot, but were able to request a kit from the screening centre if they wished. The Pilot site has notified us of 378 people calling the centre helpline, with a breakdown of reasons (person may record more than one reason):
Heard about screening from GP, nurse talk, word of mouth  
Saw advertisement  
Participant in Round 1 and requested kit  
Partner in age range and received kit  
Partner screened and had positive result  

From the download we have identified 348 people (191 males and 157 females) aged between 70 and 89 requesting a kit (30 fewer than the Pilot site). The reason for the discrepancy is likely to be that 69 year old who were not invited requested a kit. We cannot identify this group. Of the 348 people, 323 (92.8%) returned an adequate kit (Table 5.30). Only 169 were aged between 70 and 72, of these 156 (92.4%) responded in the second round and 103 had been invited in the first round with 95 having a negative outcome.

Of the 323, 9 (2.8%) were positive. The detection rate of cancers was 0.3% (1/323) and of all neoplasia 1.9% (6/323).

5.14 Discussion

As observed in the first round evaluation, the majority of positive episodes result from an initial weak positive test, followed by further tests. This may result in increased anxiety as well as lengthy screening episodes through prolongation of the time taken to obtain a conclusive result. Of those people with a positive FOBt outcome, 83% completed at least two tests and 27% at least three. Of those with an initial weak positive test 96% completed at least two tests and 72% at least three. There is also the problem of ‘drop out’, with 7% of initial weak positives failing to complete the phases. Nevertheless, 31% of those with an initial weak positive test had a positive FOBt outcome and 9.3% had neoplasia detected. It would not be feasible to refer all weak positive directly to colonoscopy, since the referral rate would approximately treble. However, an option would be to refer those with 3 or 4 positive spots at phase 1, of whom approximately 19% eventually had neoplasia detected. This would have increased the positive rate by 17%, with a comparable increase in colonoscopy workload.

Trends of positive rates for FOBt outcome by age and gender and with deprivation category and ethnicity are in keeping with previous observations. The high positive rate in previous non-responders in the first round may be related to development of symptoms in this group, and highlights the benefit of re-inviting these people even though uptake was relatively low. The high positive rates in those who were positive in the first round yet refused further investigation is not surprising but perhaps they should be followed up more quickly rather than waiting two years for their next routine screen. The higher detection rate and PPVs in previous non-responders highlight the importance of continuing to reinvite these people, but there is likely to be a group who will continue not to respond and other strategies should be considered.

The higher than expected positive rate in the second round of the Pilot compared with the first round, and with the Nottingham trial is a cause for concern. The Pilot site was aware during the course of the second round of a higher positive rate, and a similar observation was made in the Pilot in Scotland. Meetings between the two centres led to dietary restriction being reintroduced only in England to enable a comparison. At the time there were concerns over the sensitivity of the active material in the FOBt; however the rates in both centres remained high. As discussed above, the positive rate of FOBt outcome is highly dependent on the further testing of the initial weak positives, which is where dietary restriction occurs. Our analysis of retests showed a small but not significant reduction after the introduction of dietary restriction.
However, the positive rate of initial tests was significantly higher in the second round, which would result in more people with weak positive tests being retested. It is perhaps not surprising therefore that reintroducing dietary restriction had little effect on the overall rate.

From the experience in the Nottingham trial the positive rate of FOBt outcome would be expected to be lower in those people being reinvited for screening. In Nottingham the rate at the second round (as opposed to all re-screening rounds) was 0.90%, or 0.84% excluding those who did not complete screening. This is the rate in those previously screened, excluding the Pilot phase in which all initial positive tests were treated as a positive FOBt outcome and led to further investigation. By contrast the positive rate in the second round of the Pilot is 1.67% in those previously screened as negative (or 1.78% in all those previously screened). In the first round of the Pilot the positive rate was 1.59% compared with 1.43% in the comparable age group in the Nottingham trial.

These rates for the Nottingham trial are lower than those taken from publications, which give figures of 2.1% for the initial screen and 1.2% for rescreens (any rescreen) occurring within 27 months of the previous screen. Exclusion of the pilot phase and of weak positives in people who did not complete the screening episode reduces the first round rate to 1.6%, and restriction to the age range 50 to 69 to 1.43%, compared with 1.61% in the Pilot. The second round rate falls due to similar restrictions, and due to including only the second round as opposed to all rescreens.

Reasons for the high positive rate are not clear. It is known that low dose (75 mg) aspirin prescribing rose rapidly in the 1990s, as fast as that for proton pump inhibitors, and this is likely to have continued into the period of the Pilot, raising the possibility that aspirin usage may be responsible for increases in positivity rates. However, the incremental rises from year to year would have been very small, particularly by the early 2000’s. Hospital admissions for gastric and peptic ulcer rose by about 10-30% in people aged 65-74 years, and 30-40% in those over age 75 years over this same period. However this is only a very rough proxy for GI bleeding detectable by FOBt; if increasing aspirin consumption had an effect on FOBt positivity between the first and second rounds this effect is likely to have been very small, and potentially insignificant compared to other factors which changed in between the first and second round. Other reasons why positive rates may change over time include change of dietary habits, and possible changes in the type of test used, or within batches of the same test kit. If the increase in positivity were due to the sensitivity of the FOBt then information on batches would enable us to look at differences between batches. It is recommended that this information is recorded on the database. In both rounds, there were time periods where the positive rate was higher.

The higher than expected positive rates in the Pilot have not resulted in higher detection rates. The detection rate of cancer in the first round was 1.35 per 1000 screened compared with 0.94 in the second round. It might be expected that the detection rate would be lower in the second round than at a prevalent screen. In the Nottingham trial, the cancer detection rate in the first round was 2.1 per 1000 compared with 1.4 per 1000 for any rescreen occurring within 27 months of the previous screen. However, restricting the age range to 50 to 69, and excluding the pilot phase, the detection rates were 1.40 and 1.36 per 1000 in the first and second round respectively. We would not therefore necessarily expect a fall in the detection rate; in fact in the second round of the Pilot the cancer detection rate in those who accepted screening in the first round was 0.91 per 1000. The detection rate of neoplasia in the first round was 6.29 per 1000 screened compared with 5.67 in the second round. The comparable figures for Nottingham were 7.93 and 5.35 for the first and second rounds respectively.
The stage distribution of screen-detected disease is an important indicator of the performance of the screening programme. Data on tumour stage need to be recorded as completely as possible in the roll-out of the National programme in both the screening offices and in cancer registries.

The effect of high positive rates and low detection rates of cancer was to reduce PPVs for cancer, which were considerably lower in the second round compared with the first round. This has considerable implications for colonoscopy workload, and also for the subsequent management or surveillance of those investigated. The lower than expected detection rates and PPVs may also have implications for estimate of effectiveness. The reason for the particularly marked reduction in females is not clear, although the numbers are small, and the increase in positive rates and decrease in --neoplasia detection rates compared with the first round is broadly consistent by gender and across all age-groups.

An alternative denominator for calculating PPV is to include only those people attending for colonoscopy. The first round report recommended the use of this denominator as being more appropriate for the purposes of quality assurance in a screening programme. Using this denominator the overall PPVs are 38.8% for neoplasia and 6.19% for cancer. These are considerably lower than those reported in the Nottingham trial.
Table 5.1  FOBt positivity by phase, gender and age group

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<td>259</td>
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<td>144</td>
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<td>168</td>
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Chapter 5: Outcome of screening: test performance and pathology detected
Table 5.2  FOBt positivity by phase and invitation time

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<td>12072</td>
<td>10953</td>
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<td>8113</td>
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<td>12401</td>
<td>11258</td>
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<td>198</td>
<td>182</td>
<td>112</td>
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Table 5.3  Positive rates at first test and retests in the first and second round populations by date when test read

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<th>First tests</th>
<th>Retests</th>
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<td></td>
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<td>% positive</td>
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<tr>
<td>Jan – Mar 2001</td>
<td>9900</td>
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<td>Apr – June 2001</td>
<td>12153</td>
<td>3.78</td>
</tr>
<tr>
<td>July – Sept 2001</td>
<td>12329</td>
<td>3.96</td>
</tr>
<tr>
<td>Jan – Mar 2002</td>
<td>6128</td>
<td>5.29</td>
</tr>
<tr>
<td>Apr – June 2002</td>
<td>12033</td>
<td>2.98</td>
</tr>
<tr>
<td>July – Nov 2002</td>
<td>2371</td>
<td>4.64</td>
</tr>
<tr>
<td>Total</td>
<td>76650</td>
<td>4.12</td>
</tr>
<tr>
<td>Second round</td>
<td></td>
<td></td>
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<tr>
<td>Mar – May 2003</td>
<td>8336</td>
<td>3.98</td>
</tr>
<tr>
<td>June – Aug 2003</td>
<td>8795</td>
<td>4.74</td>
</tr>
<tr>
<td>Sept – Nov 2003</td>
<td>12902</td>
<td>4.36</td>
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<tr>
<td>Dec 03 – Feb 04</td>
<td>7698</td>
<td>5.00</td>
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<td>Mar – May 2004</td>
<td>10109</td>
<td>4.86</td>
</tr>
<tr>
<td>June – Aug 2004</td>
<td>8736</td>
<td>6.04</td>
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<td>Sept - Jan 2005</td>
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<td>5.06</td>
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<td>Total</td>
<td>66541</td>
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Table 5.4  Positive rate for FOBt outcome by gender and age group

<table>
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<tr>
<th></th>
<th>&lt;55 yrs</th>
<th>55-59 yrs</th>
<th>60-64 yrs</th>
<th>65-69 yrs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adequate return</td>
<td>Positive outcome</td>
<td>%</td>
<td>Adequate return</td>
<td>Positive outcome</td>
</tr>
<tr>
<td>Male</td>
<td>8275</td>
<td>144</td>
<td>1.74</td>
<td>8772</td>
<td>168</td>
</tr>
<tr>
<td>Female</td>
<td>9528</td>
<td>105</td>
<td>1.10</td>
<td>10239</td>
<td>121</td>
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<td>Total</td>
<td>17803</td>
<td>249</td>
<td>1.40</td>
<td>19011</td>
<td>289</td>
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Table 5.5  Positive rate for FOBt outcome by invitation time

<table>
<thead>
<tr>
<th>Invitation time</th>
<th>Adequate return</th>
<th>Positive outcome</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2003 – April 2003</td>
<td>8218</td>
<td>137</td>
<td>1.67</td>
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<tr>
<td>May 2003 – July 2003</td>
<td>9052</td>
<td>128</td>
<td>1.41</td>
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<td>August 2003 – October 2003</td>
<td>12642</td>
<td>205</td>
<td>1.62</td>
</tr>
<tr>
<td>November 2003 – February 2004</td>
<td>11492</td>
<td>209</td>
<td>1.82</td>
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<td>March 2004 – May 2004</td>
<td>9547</td>
<td>198</td>
<td>2.07</td>
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<td>June 2004 – August 2004</td>
<td>8625</td>
<td>182</td>
<td>2.11</td>
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<td>September 2004 – November 2004</td>
<td>6688</td>
<td>112</td>
<td>1.67</td>
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<td><strong>Total</strong></td>
<td><strong>66264</strong></td>
<td><strong>1171</strong></td>
<td><strong>1.77</strong></td>
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Table 5.6  Positive rate for FOBt outcome by deprivation category

<table>
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<tr>
<th>Carstairs Index 2001</th>
<th>IMD Index 2004</th>
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<tbody>
<tr>
<td></td>
<td>Adequate return</td>
</tr>
<tr>
<td>1 Least deprived</td>
<td>8088</td>
</tr>
<tr>
<td>2</td>
<td>8858</td>
</tr>
<tr>
<td>3</td>
<td>11823</td>
</tr>
<tr>
<td>4</td>
<td>21835</td>
</tr>
<tr>
<td>5 Most deprived</td>
<td>15338</td>
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<tr>
<td>Not known</td>
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<tr>
<td><strong>Total</strong></td>
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</tr>
</tbody>
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Table 5.7  Positive rate for FOBt outcome by quintiles of percentage Indian Sub-Continent origin

<table>
<thead>
<tr>
<th>Quintiles</th>
<th>Adequate return</th>
<th>Positive outcome</th>
<th>%</th>
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<tbody>
<tr>
<td>1-4</td>
<td>57148</td>
<td>932</td>
<td>1.63</td>
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<tr>
<td>5</td>
<td>8039</td>
<td>223</td>
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</tr>
<tr>
<td>Not known</td>
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<td>16</td>
<td>1.49</td>
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<td><strong>Total</strong></td>
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<td><strong>1171</strong></td>
<td><strong>1.77</strong></td>
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### Table 5.8  Positive rate for FOBt outcome by demographic factors and invitation time

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<th>Factor</th>
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<th>Adjusted OR (95% CI)</th>
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<td>&lt; 55</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>55-59</td>
<td>1.09 (0.92 – 1.29)</td>
<td>1.10 (0.92 – 1.31)</td>
</tr>
<tr>
<td>60-64</td>
<td>1.48 (1.25 – 1.75)</td>
<td>1.49 (1.25 – 1.75)</td>
</tr>
<tr>
<td>65-69</td>
<td>1.63 (1.38 – 1.93)</td>
<td>1.62 (1.36 – 1.91)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Female</td>
<td>0.65 (0.58 – 0.73)</td>
<td>0.65 (0.58 – 0.73)</td>
</tr>
<tr>
<td><strong>Invitation Time</strong></td>
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<tr>
<td>Feb 2003 – Apr 2003</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>May 2003 – July 2003</td>
<td>0.85 (0.66 – 1.08)</td>
<td>0.85 (0.66 – 1.08)</td>
</tr>
<tr>
<td>Aug 2003 – Oct 2003</td>
<td>0.97 (0.78 – 1.21)</td>
<td>0.95 (0.77 – 1.19)</td>
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<tr>
<td>Nov 2003 – Feb 2004</td>
<td>1.09 (0.88 – 1.36)</td>
<td>1.14 (0.90 – 1.41)</td>
</tr>
<tr>
<td>Mar 2004 – May 2004</td>
<td>1.25 (1.00 – 1.56)</td>
<td>1.05 (0.84 – 1.35)</td>
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<td>June 2004 – Aug 2004</td>
<td>1.27 (1.02 – 1.59)</td>
<td>1.07 (0.85 – 1.35)</td>
</tr>
<tr>
<td>Sept 2004 – Nov 2004</td>
<td>1.00 (0.78 – 1.29)</td>
<td>0.94 (0.73 – 1.22)</td>
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<tr>
<td><strong>Deprivation Category (IMD)</strong></td>
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</tr>
<tr>
<td>1 Least deprived</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>1.13 (0.92 – 1.39)</td>
<td>1.15 (0.93 – 1.42)</td>
</tr>
<tr>
<td>3</td>
<td>1.18 (0.99 – 1.41)</td>
<td>1.19 (0.99 – 1.44)</td>
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<td>4</td>
<td>1.58 (1.29 – 1.94)</td>
<td>1.29 (1.01 – 1.63)</td>
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<tr>
<td>5 Most deprived</td>
<td>1.85 (1.53 – 2.25)</td>
<td>1.39 (1.08 – 1.80)</td>
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<td><strong>% Indian Sub-Continent</strong></td>
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<td>Quintiles 1 – 4</td>
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<td>1</td>
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<td>Quintile 5</td>
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<td>1.54 (1.27 – 1.88)</td>
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### Table 5.9  Positive rate for FOBt outcome by screening history

<table>
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<tr>
<th>Screening history</th>
<th>Adequate return</th>
<th>Positive outcome</th>
<th>%</th>
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<td><strong>Status in first round</strong></td>
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<td>Non responder</td>
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<td>125</td>
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<td>Positive test</td>
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<td>Positive investigation</td>
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<td>4</td>
<td>5.33</td>
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<tr>
<td>Negative investigation</td>
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<td>23.38</td>
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<td>No further investigation</td>
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<td>11</td>
<td>25.00</td>
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<tr>
<td>Did not complete</td>
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<tr>
<td>Phase 1</td>
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<td>5</td>
<td>4.35</td>
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<tr>
<td>Phase 2 or 3</td>
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<td>10</td>
<td>13.16</td>
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<tr>
<td><strong>Total</strong></td>
<td>66264</td>
<td>1171</td>
<td>1.77</td>
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</table>
### Table 5.10  Positive rate for FOBt outcome by gender and age group in the first round

| Adequate return | Positive outcome | %  | Adequate return | Positive outcome | %  | Adequate return | Positive outcome | %  | Adequate return | Positive outcome | %  | Adequate return | Positive outcome | %  | Adequate return | Positive outcome | %  | Adequate return | Positive outcome | %  | Total       | Adequate return | Positive outcome | %  |
|-----------------|------------------|----|-----------------|------------------|----|-----------------|------------------|----|-----------------|------------------|----|-----------------|------------------|----|-----------------|------------------|----|-----------------|------------------|----|------------|------------------|----|
| Male            | 10842            | 144| 1.33            | 9525             | 174| 1.83            | 8338             | 222| 2.66            | 6743             | 188| 2.79            | 35448            | 728| 2.05          |
| Female          | 12361            | 96 | 0.78            | 11246            | 119| 1.06            | 9359             | 138| 1.47            | 7738             | 130| 1.68            | 40704            | 483| 1.19          |
| Total           | 23203            | 240| 1.03            | 20771            | 293| 1.41            | 17697            | 360| 2.03            | 14481            | 318| 2.20            | 76152            | 1211| 1.59         |

### Table 5.11  Positive rate for FOBt outcome by deprivation category in the first round

<table>
<thead>
<tr>
<th>Carstairs Index 2001</th>
<th>IMD Index 2004</th>
<th>Adequate return</th>
<th>Positive outcome</th>
<th>%</th>
<th>Adequate return</th>
<th>Positive outcome</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Least deprived</td>
<td></td>
<td>9053</td>
<td>109</td>
<td>1.20</td>
<td>13247</td>
<td>171</td>
<td>1.29</td>
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<td>2</td>
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<td>9840</td>
<td>119</td>
<td>1.21</td>
<td>19085</td>
<td>237</td>
<td>1.24</td>
</tr>
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<td>13588</td>
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<td>1.56</td>
<td>19532</td>
<td>300</td>
<td>1.54</td>
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<td>4</td>
<td></td>
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<td>389</td>
<td>1.56</td>
<td>14290</td>
<td>272</td>
<td>1.90</td>
</tr>
<tr>
<td>5 Most deprived</td>
<td></td>
<td>17635</td>
<td>371</td>
<td>2.10</td>
<td>8963</td>
<td>220</td>
<td>2.46</td>
</tr>
<tr>
<td>Not known</td>
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<td>1035</td>
<td>11</td>
<td>1.06</td>
<td>1035</td>
<td>11</td>
<td>1.06</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>76152</td>
<td>1211</td>
<td>1.59</td>
<td>76152</td>
<td>1211</td>
<td>1.59</td>
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</table>

### Table 5.12  Detection rate (per 1000) of people with neoplasia and cancer by gender and age group

<table>
<thead>
<tr>
<th>Adequate return</th>
<th>Neoplasia</th>
<th>Cancer</th>
<th>Adequate return</th>
<th>Neoplasia</th>
<th>Cancer</th>
<th>Adequate return</th>
<th>Neoplasia</th>
<th>Cancer</th>
<th>Adequate return</th>
<th>Neoplasia</th>
<th>Cancer</th>
<th>Adequate return</th>
<th>Neoplasia</th>
<th>Cancer</th>
<th>Adequate return</th>
<th>Neoplasia</th>
<th>Cancer</th>
<th>Total</th>
<th>Adequate return</th>
<th>Neoplasia</th>
<th>Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>8275</td>
<td>37 (4.47)</td>
<td>2 (0.24)</td>
<td>8772</td>
<td>57 (6.50)</td>
<td>8 (0.91)</td>
<td>7434</td>
<td>77 (10.36)</td>
<td>15 (2.02)</td>
<td>6230</td>
<td>78 (12.52)</td>
<td>18 (2.89)</td>
<td>30711</td>
<td>249 (8.11)</td>
<td>43 (1.40)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>9528</td>
<td>18 (1.89)</td>
<td>2 (0.21)</td>
<td>10239</td>
<td>24 (2.34)</td>
<td>4 (0.39)</td>
<td>8705</td>
<td>49 (5.63)</td>
<td>7 (0.80)</td>
<td>7081</td>
<td>36 (5.08)</td>
<td>6 (0.85)</td>
<td>35553</td>
<td>127 (3.57)</td>
<td>19 (0.53)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>17803</td>
<td>55 (3.10)</td>
<td>4 (0.22)</td>
<td>19011</td>
<td>81 (4.26)</td>
<td>12 (0.63)</td>
<td>16139</td>
<td>126 (7.81)</td>
<td>22 (1.36)</td>
<td>13311</td>
<td>114 (8.56)</td>
<td>24 (1.80)</td>
<td>66264</td>
<td>376 (5.67)</td>
<td>62 (0.94)</td>
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<td></td>
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</table>
Table 5.13 Detection rate (per 1000) for people with neoplasia of cancer by deprivation category

<table>
<thead>
<tr>
<th>Carstairs Index 2001</th>
<th>IMD Index 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adequate return</td>
</tr>
<tr>
<td>1 Least deprived</td>
<td>8088</td>
</tr>
<tr>
<td>2</td>
<td>8858</td>
</tr>
<tr>
<td>3</td>
<td>11823</td>
</tr>
<tr>
<td>4</td>
<td>21835</td>
</tr>
<tr>
<td>5 Most deprived</td>
<td>15338</td>
</tr>
<tr>
<td>Not known</td>
<td>322</td>
</tr>
<tr>
<td>Total</td>
<td>66264</td>
</tr>
</tbody>
</table>

Table 5.14 Detection rate (per 1000) for people with neoplasia or cancer by quintiles of percentage of Indian Sub-Continent origin

<table>
<thead>
<tr>
<th>Quintiles</th>
<th>Adequate return</th>
<th>Neoplasia</th>
<th>Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>1-4</td>
<td>57148</td>
<td>316 (5.53)</td>
<td>53 (0.93)</td>
</tr>
<tr>
<td>5</td>
<td>8039</td>
<td>55 (6.84)</td>
<td>9 (1.12)</td>
</tr>
<tr>
<td>Not known</td>
<td>1077</td>
<td>5 (4.64)</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td>Total</td>
<td>66264</td>
<td>376 (5.67)</td>
<td>62 (0.94)</td>
</tr>
</tbody>
</table>

Table 5.15 Neoplasia detection by demographic factors and invitation time

<table>
<thead>
<tr>
<th>Factor</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 55</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>55-59</td>
<td>1.38 (0.98 – 1.95)</td>
<td>1.40 (0.99 – 1.97)</td>
</tr>
<tr>
<td>60-64</td>
<td>2.54 (1.85 – 3.49)</td>
<td>2.55 (1.85 – 3.50)</td>
</tr>
<tr>
<td>65-69</td>
<td>2.79 (2.02 – 3.85)</td>
<td>2.80 (2.02 – 3.86)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Female</td>
<td>0.42 (0.24 – 0.74)</td>
<td>0.44 (0.35 – 0.54)</td>
</tr>
<tr>
<td>Invitation Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb 2003 – Apr 2003</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>May 2003 – July 2003</td>
<td>0.85 (0.57 – 1.27)</td>
<td>0.86 (0.57 – 1.29)</td>
</tr>
<tr>
<td>Aug 2003 – Oct 2003</td>
<td>0.74 (0.51 – 1.09)</td>
<td>0.73 (0.50 – 1.08)</td>
</tr>
<tr>
<td>Nov 2003 – Feb 2004</td>
<td>1.10 (0.76 – 1.57)</td>
<td>1.14 (0.79 - 1.65)</td>
</tr>
<tr>
<td>Mar 2004 – May 2004</td>
<td>1.00 (0.68 – 1.47)</td>
<td>0.90 (0.61 – 1.34)</td>
</tr>
<tr>
<td>June 2004 – Aug 2004</td>
<td>0.95 (0.64 – 1.42)</td>
<td>0.83 (0.55 – 1.25)</td>
</tr>
<tr>
<td>Sept 2004 – Nov 2004</td>
<td>1.10 (0.73 – 1.66)</td>
<td>0.97 (0.64 - 1.48)</td>
</tr>
<tr>
<td>Deprivation Category (IMD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Least deprived</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>0.96 (0.68 – 1.36)</td>
<td>1.00 (0.70 – 1.41)</td>
</tr>
<tr>
<td>3</td>
<td>1.23 (0.89 – 1.71)</td>
<td>1.33 (0.95 – 1.86)</td>
</tr>
<tr>
<td>4</td>
<td>1.28 (0.91 – 1.81)</td>
<td>1.35 (0.94 – 1.95)</td>
</tr>
<tr>
<td>5 Most deprived</td>
<td>1.76 (1.23 – 2.52)</td>
<td>1.91 (1.27 – 2.88)</td>
</tr>
<tr>
<td>% Indian Sub-Continent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quintiles 1-4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Quintile 5</td>
<td>1.24 (0.93 – 1.66)</td>
<td>0.94 (0.67 – 1.33)</td>
</tr>
</tbody>
</table>
Table 5.16 Detection rate (per 1000) for adenomas of different risk

<table>
<thead>
<tr>
<th></th>
<th>Responded</th>
<th>Low</th>
<th>Intermediate</th>
<th>High</th>
<th>Not known</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Rate</td>
<td>n</td>
<td>Rate</td>
<td>n</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;60 yrs</td>
<td>17047</td>
<td>38</td>
<td>2.23</td>
<td>26</td>
<td>1.53</td>
</tr>
<tr>
<td>60-69 yrs</td>
<td>13664</td>
<td>47</td>
<td>3.44</td>
<td>48</td>
<td>3.51</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>30711</td>
<td>85</td>
<td>2.77</td>
<td>74</td>
<td>2.41</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;60 yrs</td>
<td>19767</td>
<td>19</td>
<td>0.96</td>
<td>13</td>
<td>0.66</td>
</tr>
<tr>
<td>60-69 yrs</td>
<td>15786</td>
<td>28</td>
<td>1.77</td>
<td>33</td>
<td>2.09</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>35553</td>
<td>47</td>
<td>1.32</td>
<td>46</td>
<td>1.29</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 60 yrs</td>
<td>36814</td>
<td>57</td>
<td>1.55</td>
<td>39</td>
<td>1.06</td>
</tr>
<tr>
<td>60-69 yrs</td>
<td>29450</td>
<td>75</td>
<td>2.55</td>
<td>81</td>
<td>2.75</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>66264</td>
<td>132</td>
<td>1.99</td>
<td>120</td>
<td>1.81</td>
</tr>
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</table>

Table 5.17 Detection rate (per 1000) for neoplasia and cancer by screening history

<table>
<thead>
<tr>
<th>Screening history</th>
<th>Adequate return</th>
<th>Neoplasia</th>
<th>Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>New in second round</td>
<td>8904</td>
<td>38 (4.27)</td>
<td>5 (0.56)</td>
</tr>
<tr>
<td><strong>Status in first round</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responder</td>
<td>5732</td>
<td>45 (7.85)</td>
<td>8 (1.40)</td>
</tr>
<tr>
<td>Negative test</td>
<td>51164</td>
<td>286 (5.59)</td>
<td>48 (0.94)</td>
</tr>
<tr>
<td>Positive test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive investigation</td>
<td>75</td>
<td>2 (26.67)</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td>Negative investigation</td>
<td>154</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td>No further investigation</td>
<td>44</td>
<td>1 (22.73)</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td><strong>Did not complete</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 1</td>
<td>115</td>
<td>2 (17.39)</td>
<td>1 (8.70)</td>
</tr>
<tr>
<td>Phase 2 or 3</td>
<td>76</td>
<td>2 (26.32)</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>66264</td>
<td>376 (5.67)</td>
<td>62 (0.94)</td>
</tr>
</tbody>
</table>

Chapter 5: Outcome of screening: test performance and pathology detected
Table 5.18 Detection rate (per 1000) for neoplasia and cancer by gender and age group in the first round

<table>
<thead>
<tr>
<th></th>
<th>&lt;55 yrs</th>
<th>55-59 yrs</th>
<th>60-64 yrs</th>
<th>65-69 yrs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate return</td>
<td>10842</td>
<td>50 (4.61)</td>
<td>10 (0.92)</td>
<td>525 (2.60)</td>
<td>6743 (13.5)</td>
</tr>
<tr>
<td>Neoplasia</td>
<td>9525</td>
<td>65 (6.82)</td>
<td>6 (0.53)</td>
<td>375 (3.75)</td>
<td>4743 (11.8)</td>
</tr>
<tr>
<td>Cancer</td>
<td>11 (1.15)</td>
<td>11 (0.22)</td>
<td>11 (1.15)</td>
<td>11 (1.15)</td>
<td>11 (1.15)</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate return</td>
<td>12361</td>
<td>27 (2.18)</td>
<td>4 (0.32)</td>
<td>11246 (8.99)</td>
<td>7738 (19.7)</td>
</tr>
<tr>
<td>Neoplasia</td>
<td>11246</td>
<td>36 (3.20)</td>
<td>6 (0.53)</td>
<td>4135 (3.65)</td>
<td>7738 (19.7)</td>
</tr>
<tr>
<td>Cancer</td>
<td>32 (2.65)</td>
<td>11 (1.15)</td>
<td>11 (1.15)</td>
<td>11 (1.15)</td>
<td>11 (1.15)</td>
</tr>
<tr>
<td>Total</td>
<td>23203</td>
<td>77 (3.32)</td>
<td>14 (0.60)</td>
<td>13697 (5.13)</td>
<td>14481 (5.62)</td>
</tr>
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Table 5.19 PPV (%) of positive FOBT outcome for cancer and neoplasia by gender and age group

<table>
<thead>
<tr>
<th></th>
<th>&lt;55 yrs</th>
<th>55-59 yrs</th>
<th>60-64 yrs</th>
<th>65-69 yrs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. Positive</td>
<td>144</td>
<td>25.69</td>
<td>1.39</td>
<td>168</td>
<td>35.83</td>
</tr>
<tr>
<td>Neoplasia</td>
<td>168</td>
<td>33.93</td>
<td>4.76</td>
<td>180</td>
<td>42.78</td>
</tr>
<tr>
<td>Cancer</td>
<td>4.76</td>
<td>4.76</td>
<td>8.33</td>
<td>173</td>
<td>45.09</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. Positive</td>
<td>105</td>
<td>17.14</td>
<td>1.90</td>
<td>121</td>
<td>37.33</td>
</tr>
<tr>
<td>Neoplasia</td>
<td>121</td>
<td>19.83</td>
<td>3.31</td>
<td>152</td>
<td>32.24</td>
</tr>
<tr>
<td>Cancer</td>
<td>3.31</td>
<td>3.31</td>
<td>4.61</td>
<td>128</td>
<td>28.13</td>
</tr>
<tr>
<td>Total</td>
<td>249</td>
<td>22.09</td>
<td>1.61</td>
<td>238</td>
<td>37.87</td>
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</table>

Table 5.20 PPV (%) of positive FOBT outcome for cancer and neoplasia by deprivation category

<table>
<thead>
<tr>
<th>Carstairs Index 2001</th>
<th>IMD Index 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Neoplasia</td>
</tr>
<tr>
<td>Least deprived</td>
<td>120</td>
</tr>
<tr>
<td>2</td>
<td>135</td>
</tr>
<tr>
<td>3</td>
<td>163</td>
</tr>
<tr>
<td>Most deprived</td>
<td>368</td>
</tr>
<tr>
<td>Not known</td>
<td>376</td>
</tr>
<tr>
<td>Total</td>
<td>1171</td>
</tr>
</tbody>
</table>

Chapter 5: Outcome of screening: test performance and pathology detected 76
Table 5.21  PPV (%) of positive test for cancer and neoplasia by quintiles of percentage Indian Sub-Continent origin

<table>
<thead>
<tr>
<th>Quintiles</th>
<th>No. Positive</th>
<th>Neoplasia</th>
<th>Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-4</td>
<td>803</td>
<td>39.35</td>
<td>6.35</td>
</tr>
<tr>
<td>5</td>
<td>276</td>
<td>19.93</td>
<td>3.26</td>
</tr>
<tr>
<td>Not known</td>
<td>92</td>
<td>5.43</td>
<td>1.09</td>
</tr>
<tr>
<td>Total</td>
<td>1171</td>
<td>32.11</td>
<td>5.21</td>
</tr>
</tbody>
</table>

Table 5.22  PPV (%) of positive test for neoplasia by demographic factors and invitation time

<table>
<thead>
<tr>
<th>Factor</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 55</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>55-59</td>
<td>1.37 (0.93 – 2.04)</td>
<td>1.35 (0.61 – 2.02)</td>
</tr>
<tr>
<td>60-64</td>
<td>2.16 (1.49 – 3.13)</td>
<td>2.25 (1.54 – 3.29)</td>
</tr>
<tr>
<td>65-69</td>
<td>2.15 (1.47 – 3.14)</td>
<td>2.22 (1.51 – 3.27)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Female</td>
<td>0.56 (0.43 – 0.72)</td>
<td>0.54 (0.41 – 0.70)</td>
</tr>
<tr>
<td>Invitation Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb 2003 – Apr 2003</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>May 2003 – July 2003</td>
<td>1.01 (0.61 – 1.67)</td>
<td>1.00 (0.59 – 1.60)</td>
</tr>
<tr>
<td>Aug 2003 – Oct 2003</td>
<td>0.67 (0.42 – 1.07)</td>
<td>0.64 (0.40 – 1.03)</td>
</tr>
<tr>
<td>Nov 2003 – Feb 2004</td>
<td>1.01 (0.64 – 1.58)</td>
<td>0.90 (0.56 – 1.43)</td>
</tr>
<tr>
<td>Mar 2004 – May 2004</td>
<td>0.73 (0.46 – 1.16)</td>
<td>0.78 (0.48 – 1.28)</td>
</tr>
<tr>
<td>June 2004 – Aug 2004</td>
<td>0.66 (0.41 – 1.07)</td>
<td>0.70 (0.42 – 1.15)</td>
</tr>
<tr>
<td>Sept 2004 – Nov 2004</td>
<td>1.16 (0.69 – 1.95)</td>
<td>1.10 (0.65 – 1.88)</td>
</tr>
<tr>
<td>Deprivation Category (IMD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Least deprived</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>0.81 (0.53 – 1.24)</td>
<td>0.79 (0.51 – 1.23)</td>
</tr>
<tr>
<td>3</td>
<td>0.82 (0.55 – 1.24)</td>
<td>0.87 (0.57 – 1.33)</td>
</tr>
<tr>
<td>4</td>
<td>0.73 (0.48 – 1.12)</td>
<td>0.80 (0.51 – 1.27)</td>
</tr>
<tr>
<td>5 Most deprived</td>
<td>0.71 (0.46 – 1.11)</td>
<td>0.90 (0.53 – 1.52)</td>
</tr>
<tr>
<td>% Indian Sub-Continent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quintiles 1 – 4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Quintile 5</td>
<td>0.64 (0.46 – 0.89)</td>
<td>0.62 (0.41 – 0.95)</td>
</tr>
</tbody>
</table>
### Table 5.23  PPV of positive FOBt outcome for Low and Intermediate/High risk adenomas by age and sex

<table>
<thead>
<tr>
<th>Age Group</th>
<th>No. Positive</th>
<th>Low</th>
<th>Int/High</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;55 years</td>
<td>Male</td>
<td>144</td>
<td>12.5 11.1</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>105</td>
<td>5.7   7.6</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>249</td>
<td>9.6   9.6</td>
</tr>
</tbody>
</table>

### Table 5.24  PPV (%) of positive FOBt outcome for cancer and neoplasia by screening history

<table>
<thead>
<tr>
<th>Screening History</th>
<th>Neoplasia</th>
<th>Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>New in Round 2</td>
<td>29.92</td>
<td>3.91</td>
</tr>
<tr>
<td>Non-responder</td>
<td>36.00</td>
<td>6.40</td>
</tr>
<tr>
<td>Negative test</td>
<td>33.53</td>
<td>5.63</td>
</tr>
<tr>
<td>Positive test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive investigation</td>
<td>50.00</td>
<td>-</td>
</tr>
<tr>
<td>Negative investigation</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>No further investigation</td>
<td>9.09</td>
<td>-</td>
</tr>
<tr>
<td>Did not complete</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 1</td>
<td>40.00</td>
<td>20.00</td>
</tr>
<tr>
<td>Phase 2 or 3</td>
<td>20.00</td>
<td>-</td>
</tr>
</tbody>
</table>
Table 5.25  PPV (%) of positive FOBt outcome for cancer and neoplasia by gender and age group in first round (using positive episodes as denominator)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>&lt;55 yrs</th>
<th>55-59 yrs</th>
<th>60-64 yrs</th>
<th>65-69 yrs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>144</td>
<td>34.72</td>
<td>6.94</td>
<td>174</td>
<td>37.36</td>
</tr>
<tr>
<td>Female</td>
<td>96</td>
<td>28.13</td>
<td>4.17</td>
<td>119</td>
<td>30.25</td>
</tr>
<tr>
<td>Total</td>
<td>240</td>
<td>32.08</td>
<td>5.83</td>
<td>293</td>
<td>34.47</td>
</tr>
</tbody>
</table>

Table 5.26  PPV (%) of positive FOBt outcome for cancer and neoplasia by gender and age group (using those attending colonoscopy as denominator)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>&lt;55 yrs</th>
<th>55-59 yrs</th>
<th>60-64 yrs</th>
<th>65-69 yrs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Attended</td>
<td>Neoplasia</td>
<td>Cancer</td>
<td>Attended</td>
<td>Neoplasia</td>
</tr>
<tr>
<td>Male</td>
<td>124</td>
<td>29.84</td>
<td>1.61</td>
<td>135</td>
<td>42.22</td>
</tr>
<tr>
<td>Female</td>
<td>92</td>
<td>19.57</td>
<td>2.17</td>
<td>96</td>
<td>25.00</td>
</tr>
<tr>
<td>Total</td>
<td>216</td>
<td>25.46</td>
<td>1.85</td>
<td>231</td>
<td>35.06</td>
</tr>
</tbody>
</table>
Table 5.27  Comparison of screening outcome measures in the first and second rounds of the Pilot with those in the Nottingham trial

<table>
<thead>
<tr>
<th>Population</th>
<th>Population</th>
<th>Uptake (%)</th>
<th>Positive outcome (%)</th>
<th>Cancer detection rate per 1000</th>
<th>Neoplasia detection rate per 1000</th>
<th>PPV Cancer (%)</th>
<th>PPV Neoplasia (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First round (ages 50-69 at invitation)</strong></td>
<td>Pilot (restricted population)</td>
<td>126527</td>
<td>58.5</td>
<td>1.61</td>
<td>1.38</td>
<td>6.29</td>
<td>8.55</td>
</tr>
<tr>
<td></td>
<td>Nottingham</td>
<td>52929</td>
<td>57.9</td>
<td>1.43</td>
<td>1.40</td>
<td>7.93</td>
<td>9.82</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(1.38)</td>
<td>(1.34)</td>
<td>(6.28)</td>
<td>(9.44)</td>
<td>(42.12)</td>
</tr>
</tbody>
</table>

| **Second round (restricted to people who responded in the first round)** | Pilot | 64677 | 79.6 | 1.78 | 0.91 | 5.67 | 5.11 | 31.77 |
|                                                                           | Nottingham | 27354 | 80.5 | 0.84 | 1.36 | 5.35 | 16.22 | 63.78 |

| **Second round (restricted to people whose test was negative in the first round)** | Pilot | 63088 | 80.8 | 1.68 | 0.90 | 5.58 | 5.37 | 33.26 |
|                                                                           | Nottingham | 27023 | 81.2 | 0.81 | 1.32 | 5.29 | 16.38 | 65.54 |
|                                                                           |            |       | (0.78) | (1.22) | (3.80) | (14.91) | (57.17) |

The numbers in brackets are age-gender standardised to acceptors in equivalent Pilot.
Table 5.28  Screening episode outcome according to number of positive spots in phase 1

<table>
<thead>
<tr>
<th>No. of spots positive in phase 1</th>
<th>No. of people</th>
<th>No. referred for further investigation</th>
<th>No. attending further investigation</th>
<th>Cancers</th>
<th>Neoplasia</th>
<th>Based on no. of people</th>
<th>Based on no. attending</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cancer PPV</td>
<td>Neoplasia PPV</td>
</tr>
<tr>
<td>1</td>
<td>1780</td>
<td>424</td>
<td>362</td>
<td>14</td>
<td>125</td>
<td>0.79%</td>
<td>7.02%</td>
</tr>
<tr>
<td>2</td>
<td>957</td>
<td>356</td>
<td>290</td>
<td>16</td>
<td>120</td>
<td>1.67%</td>
<td>12.54%</td>
</tr>
<tr>
<td>3</td>
<td>200</td>
<td>103</td>
<td>84</td>
<td>4</td>
<td>36</td>
<td>2.00%</td>
<td>18.00%</td>
</tr>
<tr>
<td>4</td>
<td>168</td>
<td>89</td>
<td>72</td>
<td>9</td>
<td>36</td>
<td>5.36%</td>
<td>21.43%</td>
</tr>
<tr>
<td>1-4 (weak)</td>
<td>3105</td>
<td>972</td>
<td>808</td>
<td>43</td>
<td>274</td>
<td>1.38%</td>
<td>8.82%</td>
</tr>
<tr>
<td>5</td>
<td>51</td>
<td>51</td>
<td>42</td>
<td>4</td>
<td>14</td>
<td>7.84%</td>
<td>27.45%</td>
</tr>
<tr>
<td>6</td>
<td>64</td>
<td>64</td>
<td>46</td>
<td>12</td>
<td>23</td>
<td>18.75%</td>
<td>35.94%</td>
</tr>
<tr>
<td>5-6 (positive)</td>
<td>115</td>
<td>115</td>
<td>88</td>
<td>16</td>
<td>37</td>
<td>13.91%</td>
<td>32.17%</td>
</tr>
<tr>
<td><strong>Spoilt</strong></td>
<td>1442</td>
<td>84</td>
<td>970</td>
<td>3</td>
<td>22</td>
<td>0.21%</td>
<td>1.53%</td>
</tr>
</tbody>
</table>

** Spoilt first result in phase 1

Table 5.29  Dukes’ stage of screen-detected cancer in the Pilot site and Nottingham trial

<table>
<thead>
<tr>
<th>Presumed stage A (polyp cancers)</th>
<th>Pilot second round</th>
<th>Nottingham</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Presumed stage A (polyp cancers)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>11</td>
<td>17.7</td>
</tr>
<tr>
<td>B</td>
<td>12</td>
<td>19.4</td>
</tr>
<tr>
<td>C</td>
<td>20</td>
<td>32.3</td>
</tr>
<tr>
<td>D</td>
<td>16</td>
<td>25.8</td>
</tr>
<tr>
<td>No stage (Chemo/radiotherapy treated)</td>
<td>0</td>
<td>4.8</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td></td>
</tr>
</tbody>
</table>
Table 5.30  Self referrals in people aged 70 years and over

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender</th>
<th>Requested kit</th>
<th>Returned adequate kit</th>
<th>No. Positive</th>
<th>No. Adenoma</th>
<th>No. Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>70</td>
<td>Male</td>
<td>42</td>
<td>39</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>26</td>
<td>23</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>71</td>
<td>Male</td>
<td>31</td>
<td>29</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>25</td>
<td>22</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>72</td>
<td>Male</td>
<td>27</td>
<td>26</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>18</td>
<td>17</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>73</td>
<td>Male</td>
<td>17</td>
<td>17</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>21</td>
<td>18</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>74</td>
<td>Male</td>
<td>19</td>
<td>16</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>19</td>
<td>19</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>75-79</td>
<td>Male</td>
<td>41</td>
<td>38</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>34</td>
<td>32</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>80-84</td>
<td>Male</td>
<td>13</td>
<td>13</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>12</td>
<td>12</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>85+</td>
<td>Male</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>348</td>
<td>323</td>
<td>9</td>
<td>6</td>
<td>1</td>
</tr>
</tbody>
</table>
Figure 5.1 Flow chart showing outcomes of screening

Did Not Respond → 57493

1st Test Kit

Did Not Respond

Strong Positive

Strong Positive

Negative

(61873)

Inadequate Test

(1449)

Subsequent Adequate Test

(1164)

Negative

(1080)

Strong/Weak Positive

No Subsequent Adequate Test

Weak Positive – START PHASE 2

(3104)

Subsequent Adequate Test

(2971)

Strong/Weak Positive

Negative

(2319)

3 Month Referral

START PHASE 3

Strong/Weak Positive

Negative

No Subsequent Adequate Test

Refuser or Unused Kits

57493

115

62953

84

285

133

652

320

1915

84

3712
Figure 5.2  Positive rates for FOBT outcome by gender and age group
Figure 5.3 Detection rates (per 1000) of people with cancer by gender and age group
Figure 5.4  Detection rates (per 1000) of people with neoplasia by gender and age group
6. Cancers according to screening history

Chapter Summary

- A total of 696 people with bowel cancer were identified in the (unrestricted) first and/or second round population after their date of first invitation, and classified according to their screening history.

- The rates for England as a whole for 2001 and for West Midlands for 1998-2000 were used as a control.

- The incidence rate in non-responders in the first round was higher than in either control population, and the expected rate in responders was adjusted accordingly.

- Interval cancers were defined as those occurring following a negative FOBt episode and before the date of any subsequent invitation. Those occurring after a positive FOBt outcome, together with anal cancers, were excluded from the estimate of sensitivity, which was restricted to interval cancers occurring within 24 months of the negative test.

- The sensitivity of the FOBt in the first round, calculated using the proportional incidence method, was estimated as 57.7% or 64.4% using England and West Midlands respectively as the control population.

- This estimate of sensitivity is similar to that observed in the Nottingham trial. However the observed difference between males and females is in the opposite direction; in the Pilot sensitivity was higher in males than in females.

6.1 Background

The occurrence of interval cancers among people previously screened negative provides an estimate of the sensitivity of the test, and provides information on the appropriateness of the screening interval. We have analysed cancers occurring in the interval between the first and second round of screening in order to estimate the sensitivity of the test in the first round, and have also analysed incidence rates in non-responders. These analyses were performed on an unrestricted population because they do not involve comparisons between the first and second round.

6.2 Methods

We obtained data from West Midlands Cancer Intelligence Unit on 672 people included in the first and/or second round diagnosed with bowel cancer, where the date of first diagnosis was after the date invited in the first round (or second round for those newly invited in this round). In 4 people with 2 cancers diagnosed after the date of invitation, only the cancer with the earlier date of diagnosis has been included. We also know from the Pilot site, of an additional 16 people with screen-detected cancer in the first round and 8 in the second round giving a total of 696 people with cancers.
Interval cancers are defined as those diagnosed following a negative FOBt episode, and before the date of any subsequent invitation. They are subdivided according to whether FOBt outcome was positive or negative. Cancers occurring following an incomplete FOBt or positive FOBt and incomplete investigation are classified separately. Those occurring in people who did not respond to a subsequent invitation are classified as lapsed responders.

Interval cancers occurring following a negative FOBt outcome in the first round have been analysed in order to estimate the sensitivity of the screening test. We excluded from this analysis cancers diagnosed in people with a positive FOBt outcome but negative or incomplete investigation in the first round, anal cancers, or those diagnosed more than 24 months from the date when the first phase 1 test was read.

The sensitivity of the FOB test has been calculated by the proportional incidence method, as \( (1 - \frac{I}{E}) \times 100\% \) where \( I \) = numbers of interval cancers and \( E \) = expected number in the absence of screening. In order to estimate the latter we have used rates by gender and age in two control populations: England for 2001 and West Midlands region for 1998-2000 (the numbers were summed to provide greater stability). The rates in the absence of screening have been adjusted to the underlying rate in the responders using the formula

\[
ra = \frac{[rc - (1-p) \cdot rn]}{p}
\]

where \( ra \) is the incidence rate in responders to screening, \( rc \) is the incidence rate in the control population, \( rn \) is the incidence rate in non-responders and \( p \) is the proportion who responded to screening.

Person-years have been calculated both for non-responders in the first round and for people whose FOBt outcome was negative in the first round. The starting date from which person-years were calculated was different for the two groups: for the non-responders it was the date of invitation for the first round, and for people with a negative outcome it was the date when the first phase 1 test for the first round was read. For both groups, the person-years were censored two years after the starting date unless bowel cancer (excluding anal cancers) is diagnosed earlier. The person-years are partitioned by gender and age at invitation in the first round (less than 60, 60 and over).

The incidence rate in the control population (\( rc \)) can be estimated with confidence; however the rate in the non-responders (\( rn \)) once partitioned by gender and five year age groups are based on relatively small numbers. Consequently, the rate in the non-responders is based on the incidence rate in the control population adjusted by the overall rate in the non-responders (see Appendix 7).

### 6.3 Results

Table 6.1 shows the screening history of the 696 cancers. Numbers for interval cancers will only be complete for the first round.

The rates of interval cancers following a negative FOBt outcome in the first round and estimated sensitivity by gender are shown in Table 6.2, and by age at invitation in Table 6.3.

The incidence rate in non-responders was 0.83 per 1000 compared with the 0.93 in the England population and 1.03 in the West Midlands population. The estimated underlying rate in the
responders is therefore higher than that in either control population (both populations being comparable for age and gender distribution).

As expected, rates of interval cancers rise in the second year following a negative FOBt. The estimated overall sensitivity was 57.7% using England as the control population, and 64.4% using West Midlands. The sensitivity was significantly higher in males than females ($\chi^2 = 4.25, p=0.04$), and higher, but not significantly, in those aged over 60 years at entry ($\chi^2 = 0.62, p=0.43$) using England as the control population.

We have not attempted to analyse interval cancers in the second round, as the data on these will not be complete.

There are a further 26 cancers (excluding 1 anal cancer) where the first round FOBt was positive but further investigation was negative or incomplete. Table 6.4 gives a breakdown of these. In 16 cases the person did not attend colonoscopy, whilst ten attended colonoscopy but no cancer was found.

The Pilot site is aware that some people had a private colonoscopy (Figure 4.1), although they do not know the result. There are 6 people whose cancer was diagnosed within 60 days of a positive FOBt outcome, and therefore may have been detected as a result of a private colonoscopy (they are marked with an asterisk in the table). One person with intermediate risk adenomas should have been put on a surveillance programme and the cancer is likely to have been diagnosed as a result. We do not know how many of the three people with adenomas of unknown risk, who were subsequently diagnosed with cancers, had been placed on surveillance, but the Pilot site informed us that one of the cancers was diagnosed as a result of surveillance.

### 6.4 Discussion

The identification of all interval cancers is critical to producing accurate estimates of sensitivity of the screening test. We were reliant on the West Midlands Cancer Intelligence Unit for the provision of cancer data. Some screen-detected cancers we learnt about only from the Pilot site, although a number of these have since been registered by the Cancer Intelligence Unit. It may be that some interval cancer data are still missing; identification of further cancers would decrease our estimates of sensitivity. In this pilot it was necessary, for reasons of data confidentiality, for matching to be carried out at the cancer registry in order to identify interval cancers.

The choice of control population influences sensitivity. The incidence rates in West Midlands are higher than the rates for England; using England as the control population gives a lower estimate of sensitivity than using West Midlands (the overall sensitivity is 57.7% vs. 64.4%). The Pilot should have made no impact on the incidence rates in West Midlands since there was minimal overlap between the years chosen (1998-2000) and the onset of the first round in September 2000. Consequently, the West Midlands estimate should be more accurate. However, data from the West Midlands Cancer Intelligence Unit suggest that, within the West Midlands region, Coventry and Warwickshire have slightly lower rates when standardised by sex and five year age group, than the region as a whole. Consequently the estimate of sensitivity using West Midlands may be slightly high.

Despite these provisos, the overall estimate of sensitivity is similar to that estimated for the first screen in Nottingham (62.7%). However the observed difference between males and

Chapter 6: Cancers according to screening history

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females is in the opposite direction; in the Nottingham trial the estimated sensitivity was significantly higher in women.
Table 6.1  Classification of bowel cancers, including anal cancers (in parenthesis) by screening history

<table>
<thead>
<tr>
<th>Round 1</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Screen detected</td>
<td>141</td>
<td></td>
</tr>
<tr>
<td>Non-responder</td>
<td>197 (4)</td>
<td></td>
</tr>
<tr>
<td>Did not complete FOBt</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Interval after negative FOBt</td>
<td>102 (4)</td>
<td>&gt; 2 years</td>
</tr>
<tr>
<td>Interval after positive FOBt</td>
<td>61 (2)</td>
<td></td>
</tr>
<tr>
<td>investigation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive FOBt, did not complete investigation</td>
<td>11 (1)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>538 (11)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Round 2</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Screen detected</td>
<td>66*</td>
<td></td>
</tr>
<tr>
<td>Non-responder</td>
<td>40 (2)</td>
<td></td>
</tr>
<tr>
<td>Lapsed responder to second round</td>
<td>20 (1)</td>
<td></td>
</tr>
<tr>
<td>Did not complete FOBt</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Interval after negative FOBt</td>
<td>25 (1)</td>
<td>all within 2 years</td>
</tr>
<tr>
<td>Interval after positive FOBt</td>
<td>2</td>
<td>negative</td>
</tr>
<tr>
<td>investigation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive FOBt, did not complete investigation</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>158 (4)</td>
<td></td>
</tr>
</tbody>
</table>

*These are cancers in the unrestricted population; the number of screen-detected cancers therefore differs from that in Chapter 5.

Table 6.2  Test sensitivity, interval cancers, and person-years of observation within the two year period following the first round, by gender

<table>
<thead>
<tr>
<th></th>
<th>England</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
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<td>Expected cancers</td>
<td>% detected by screen</td>
<td>Expected cancers</td>
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<td>46.2</td>
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Chapter 6: Cancers according to screening history
Table 6.3  Test sensitivity by age at entry, and person-years of observation within the two year period following the first round

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<tr>
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<th>Person years</th>
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<th>Expected cancers</th>
<th>% detected by screen</th>
<th>Expected cancers</th>
<th>% detected by screen</th>
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<td>0.21</td>
<td>35.4</td>
<td>63.3</td>
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<td>48.6</td>
<td>52.7</td>
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<tr>
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<td>75.2</td>
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<td>156.2</td>
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<td>183.2</td>
<td>66.2</td>
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<table>
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<tr>
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<th>Person years</th>
<th>Observed Interval cancers</th>
<th>Rate per 1000</th>
<th>Expected cancers</th>
<th>% detected by screen</th>
<th>Expected cancers</th>
<th>% detected by screen</th>
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<tr>
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<tr>
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<td>13</td>
<td>0.21</td>
<td>35.4</td>
<td>63.3</td>
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<td>39.8</td>
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<td>75.2</td>
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<td>0.46</td>
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<td>62</td>
<td>0.68</td>
<td>156.2</td>
<td>60.3</td>
<td>183.2</td>
<td>66.2</td>
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Table 6.4  Classification of cancers occurring after a positive FOBt outcome

<table>
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<th>Screening history</th>
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<tr>
<td>Did not attend nurse appointment</td>
<td>1 *</td>
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<tr>
<td>- Cancer detected within 60 days of when the last test was read</td>
<td></td>
</tr>
<tr>
<td>- Cancer detected after 365 days</td>
<td>3</td>
</tr>
<tr>
<td>Attended nurse appointment but did not attend colonoscopy</td>
<td>5 *</td>
</tr>
<tr>
<td>- Cancer detected within 60 days of nurse appointment</td>
<td></td>
</tr>
<tr>
<td>- Cancer detected between 61 and 120 days</td>
<td>1</td>
</tr>
<tr>
<td>- Cancer detected after 121 days</td>
<td>6</td>
</tr>
<tr>
<td>Outcome of colonoscopy</td>
<td></td>
</tr>
<tr>
<td>- Normal</td>
<td>1</td>
</tr>
<tr>
<td>- Detected polyp</td>
<td>2</td>
</tr>
<tr>
<td>- Detected adenoma</td>
<td></td>
</tr>
<tr>
<td>- Low risk</td>
<td>3</td>
</tr>
<tr>
<td>- Intermediate risk</td>
<td>1</td>
</tr>
<tr>
<td>- High risk</td>
<td>0</td>
</tr>
<tr>
<td>- Risk not known</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>26</td>
</tr>
</tbody>
</table>

* may have been detected as a result of private colonoscopy
Chapter 7: Impact on hospital services - colonoscopy

### Chapter Summary

- Both rounds of the Pilot have taken place against a background of considerable activity and change in endoscopy units which has made it difficult to attribute changes in trends to any one cause.

- Screening associated activity in the two Pilot hospitals increased overall workload by approximately 14% at one hospital and 28% at the other, increases that are similar to those observed in the first round of the Pilot. The anticipated fall in demand for initial screening colonoscopy in the second round did not materialise.

- The Trust where the endoscopy unit continued to manage surveillance colonoscopies alongside non-Pilot cases found it challenging to perform these in a timely manner. This supports the decision by the NHS Cancer Screening Programmes to transfer management of surveillance colonoscopies from the endoscopy units to the screening programme.

- The capacity in the endoscopy units was not always able to meet the demand for non-Pilot colonoscopies, and waiting times for routine colonoscopies were high at the time of data collection in both hospitals.

- For the introduction of screening work in an endoscopy unit to be integrated in a sustainable manner it is important that the existing demand for symptomatic colonoscopy services is met.

- The more detailed colonoscopy activity data now available suggests that the trend for increased symptomatic colonoscopies, found during the evaluation of the first round, was probably not a result of the introduction of the Pilot, but related instead to extra sessions operational at that time. However, anecdotal evidence continues to suggest that the Pilot has influenced more referrals to endoscopists.

- Screening patients have different needs compared to non-Pilot patients and the screening nurse input, at colonoscopy as well as clinics, is very valuable.

- Staff in endoscopy units continue to be very supportive of the Pilot.

### 7.1 Background

Colonoscopy is the first choice for further investigation of FOBt positive patients; the rectum and large bowel can be fully examined, and suspected abnormal tissue can be biopsied or removed for the histological testing which is required for diagnosis and to make decisions regarding further care. Colonoscopy services, provided in endoscopy units in the bowel cancer screening Pilot, are therefore key to the bowel cancer screening process. Colonoscopy service capacity is recognised as a major constraint in the roll-out of an English national bowel cancer screening programme. In the long term, the impact of a bowel cancer screening programme is expected to reduce the incidence of colorectal cancer which would reduce the requirements on endoscopy services.
The evaluation of the first round of screening found that:

- the Pilot generated considerable additional workload for colonoscopy services
- adequate resourcing of colonoscopy provision would be critical to the success of a national bowel cancer screening programme
- the Pilot led to an increased demand for symptomatic colonoscopy services
- ‘screening doctors’ and ‘nurse endoscopes’ 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
- the surveillance requirements of screening patients who have had a colonoscopy will produce a cumulative effect such that within 5 years at least one additional colonoscopy session might be required for every dedicated screening session
- screening has a potentially positive effect on the quality of delivery of colonoscopy services

7.2 Aims

The current evaluation aimed to examine the impact over time of ongoing screening on activity levels and waiting times for colonoscopy services as well as considering the organisation of screening colonoscopies within endoscopy units. It was predicted that the initial strong impact of the introduction of the Pilot would level out as the programme became established.

7.3 Methodology

Pilot activity data reported in Chapters 7, 8 and 9 (including the Pilot initial colonoscopy data described in this section) were obtained from the first and second round Pilot databases described in Chapter 2. The workload population (see Glossary, Appendix 1) that has been used in Chapters 7 and 8 consists of people aged 50-69 years who were registered with a general practitioner in Coventry Teaching, Rugby or North Warwickshire PCTs. It was assumed that people registered with a general practitioner in Coventry or Rugby Primary Care Trusts (PCTs) were investigated by UHCW NHS Trust, and those registered with a general practitioner in North Warwickshire PCT were investigated at George Eliot Hospital.

Surveillance colonoscopy information for first round patients was provided by staff at the Pilot screening centre as it was not collected routinely on the first or second round Pilot datasets. Data, from both paper-based screening unit records and hospital computer records, for patients recommended for surveillance during the first round of the Pilot were entered on to a Microsoft Excel spreadsheet for analysis. It is possible that a few colonoscopies have been captured in both the initial colonoscopy and surveillance colonoscopy numbers, but this is thought to be a very small number and will not change the general trends.

The number of colonoscopies performed in the endoscopy units (activity data) and waiting list information were requested from the two hospitals involved in the second round of the Pilot.

Eleven hospitals outside the Pilot area were invited to provide activity and waiting time data to indicate national trends in colonoscopy activity outside the areas involved with screening and use as a comparison. General information about each Trust which provided data was obtained and can be seen in Table 7.1.
Semi-structured, face-to-face interviews were held between December 2004 and August 2005 with endoscopy unit managers, colonoscopists involved with the bowel cancer screening Pilot, key nursing staff and Pilot screening unit staff. Semi structured, telephone interviews were held with the management team member identified as being most involved with the screening Pilot at each of the acute trusts and one of the colorectal cancer nurse specialists.

In June 2005, postal questionnaires (Appendix 5) were sent to all endoscopists (n=37) performing upper or lower gastrointestinal endoscopy at Walsgrave (n=18), George Eliot (n=11) or Warwick (n=8) Hospitals, who had not at that time been interviewed, to gather general opinions on issues related to the bowel cancer screening Pilot. Data from Walsgrave and George Eliot Hospital respondents are included in the results in this section. The issues included in the questionnaire were:-

- quality of endoscopy within the department
- the impact of performing screening colonoscopies on colonoscopists’ skills
- differences between screening and symptomatic colonoscopies
- referrals
- strategies for reducing waiting times
- IT systems
- nurse endoscopists
- impact of Pilot
- comparison of first and second rounds
- organisation of screening generated work

Questionnaire respondents were invited to contact the research team to discuss their experience of the Pilot.

Time sheets were completed by a convenience sample of clerical staff to record the amount of time spent on screening related work.

7.4 Activity data

7.4.1 University Hospitals Coventry and Warwickshire NHS Trust (UHCW)

In the first round two morning screening colonoscopy sessions were held each week, each of four hours duration. This continued in the second round. On occasions the waiting times for colonoscopies rose above 4 weeks (the target waiting time was within 2 weeks) and when this happened invitations were stopped temporarily. In May 2004, as a more permanent solution, extra sessions were commenced - an afternoon session at Walsgrave Hospital and another at the Hospital of St Cross, Rugby. Any unused slots could be utilised for surveillance or non-Pilot colonoscopies.

7.4.1.1 Overall (Pilot and non-Pilot) colonoscopy activity levels

Pilot colonoscopy data for the workload population (see Glossary, Appendix 1) were extracted from the Pilot database. During the second round 759 initial screening colonoscopies were performed at Walsgrave Hospital and the Hospital of St Cross, Rugby. (662 at Walsgrave Hospital and 97 at the Hospital of St Cross.) In the first round 706 initial screening colonoscopies were performed at Walsgrave Hospital and none at the Hospital of St Cross.

Surveillance colonoscopy data were obtained from screening unit records. Two hundred and sixty six people from the UHCW area were recommended for surveillance after their initial
colonoscopy in the first round of the Pilot. Overall there were 328 surveillance investigations (mainly colonoscopies and a few flexible sigmoidoscopies) between January 2001 and January 2006. More information about surveillance colonoscopies is provided below (7.4.1.3).

Data were provided by Information Services at University Hospitals Coventry and Warwickshire NHS Trust (UHCW) for 11,671 colonoscopies performed between January 1998 and January 2005 at Walsgrave Hospital and Hospital of St Cross, the two sites in the trust where colonoscopies are performed. Activity numbers matched acceptably well those from the endoscopy unit. The total annual colonoscopy numbers at UHCW from 1998 to 2004 ranged from 1235 colonoscopies in 1998 to a maximum of 1900 colonoscopies in 2001 and are shown in Table 7.2.

The graph in Figure 7.1 shows the monthly colonoscopy numbers at UHCW from 1998 until January 2005 along with the monthly number of screening colonoscopies (initial and first round surveillance) during the first and second rounds.

The number of non-Pilot colonoscopies was deduced by subtracting the number of Pilot colonoscopies (initial and first round surveillance patients) from the total colonoscopy activity. There had been an increase in non-Pilot colonoscopies prior to the introduction of the Pilot. This was maintained at the start of the Pilot and then reduced slightly before levelling off at around 1999 levels.

From November 2000 to October 2002 Pilot colonoscopies (initial and first round patient surveillance colonoscopies) increased the monthly activity (above non-Pilot figures) by 7% to 58% (average = 25%). From April 2003 to October 2004, during the second round, the corresponding figures were 10% to 41% (average = 28%). (Table 7.3) When considering these figures it should be remembered that there is a ceiling to the number of colonoscopies that can be performed which is limited by available resources, and there were more waiting list initiatives (WLIs), in which colonoscopies are performed out of normal working hours, in the first round than the second, thus reducing the proportion of Pilot work to overall workload. Waiting list initiatives started in July 1998 and sessions including colonoscopies are believed to have continued until December 2003. This illustrates the complexity of the service environment in which the Pilot was undertaken.

7.4.1.2 Waiting time information for all colonoscopies

The time from a referral request being received until date of colonoscopy was recorded on the UHCW Information Services database for 64% of cases. The average time waited by people having colonoscopies in each month has been shown in graph form in Figures 7.2 and 7.3 for routine (non-urgent) and urgent, first-appointment, out-patient colonoscopies. Breakdown into type of colonoscopy was only available from May 2000 and only 65% of out-patient cases have waiting time data so interpretation should be made with caution.

Whereas urgent colonoscopy waiting times appear to have remained fairly level, there was an increase in waiting times for routine colonoscopies performed between June 2000 and June 2002 from 40 days to 140 days, which has since levelled off at an average of 116 days. Again, there are likely to be multiple influences causing these variations.
7.4.1.3 Screening surveillance colonoscopies

The screening unit at Rugby utilised any spare capacity in the screening sessions scheduled for initial colonoscopies by filling vacant slots with surveillance colonoscopies.

As mentioned above, 266 people (approximately 39% of people having screening colonoscopies) from the UHCW area were recommended surveillance after their initial colonoscopy in the first round of the Pilot. This generated 309 surveillance investigations (mainly colonoscopy with a few flexible sigmoidoscopies) between January 2001 and January 2006.

When the data were collected in January 2006, 68 (26%) people had been removed from surveillance.

The majority (44%) of patients had a first surveillance interval of 3 years requested by the colonoscopist; for 26% it was 1 year, and for 16% it was 6 months or less (Table 7.4).

Figure 7.4 shows the number of surveillance investigations performed and the number outstanding (at January 2006) each year from 2001 to 2004. Approximately 94% of the surveillance colonoscopies requested by the clinicians were completed.

7.4.2 George Eliot Hospital

Colonoscopy provision for screening patients remained unchanged at George Eliot Hospital in the second round - two sessions were funded each week.

7.4.2.1 Overall (Pilot and non-Pilot) colonoscopy activity levels

Pilot colonoscopy data were obtained from the Pilot database. During the second round 267 people within the North Warwickshire PCT had colonoscopies as a result of the Pilot compared to 300 in the first round.

Surveillance colonoscopy data for first round patients put on to the surveillance list was obtained from screening unit and hospital records. Ninety eight people from North Warwickshire were put on surveillance after their initial colonoscopy in the first round of the Pilot. Overall there were 81 surveillance investigations for these patients between January 2001 and January 2006. More information about surveillance colonoscopies is provided below (7.4.2.3).

Colonoscopy activity data on 6586 colonoscopies from April 1999 until December 2004 were provided by the Health Informatics and Technology group at George Eliot Hospital. From May 2000 data were categorised by age and type of colonoscopy (diagnostic colonoscopy or surveillance colonoscopy).

The number of colonoscopies each month can be seen in Figure 7.5. This shows a sharp increase in symptomatic (or non-Pilot) colonoscopies after the introduction of the Pilot which dropped a year later and then remained at a steady level about 20% higher than pre-Pilot numbers. The sharp increase from October 2000 to October 2001 is most likely related to extra sessions performed out-of-hours and intended to reduce waiting lists.

From November 2000 to October 2002 Pilot related colonoscopies increased overall monthly activity figures by 3.5% to 35% above the non-Pilot workload (overall 14%). From April 2003
to December 2004, during the second round, the corresponding figures were 7% to 23% (overall 14%).

7.4.2.2 Waiting time information for all colonoscopies

The number of people waiting for routine, soon and urgent initial colonoscopies each month was provided by the endoscopy unit. The length of time patients in each category wait for an appointment could vary, but a rough guide (at April 2005) was that ‘urgent’ colonoscopies were performed within 4 weeks, ‘soon’ within 6 weeks (although this was occasionally greater) and ‘routine’ within 5 months.

The total number of people waiting for a colonoscopy each month from October 2002 until July 2005 can be seen in Figure 7.6. This is also broken down into the three types of initial colonoscopies – routine, soon, and urgent. There has been an increase in the number waiting for each type of colonoscopy over time, particularly from June 2004 to June 2005. This increase is most marked for soon and urgent colonoscopies. These figures do not include the number of people waiting for surveillance colonoscopies.

7.4.2.3 Screening surveillance colonoscopies

Screening patients were added to the hospital non-Pilot surveillance list and managed by the hospital.

As mentioned above, 98 people (approximately 35% of the people who had an initial screening colonoscopy) from North Warwickshire were recommended surveillance by the clinician after their initial colonoscopy in the first round of the Pilot. This generated 81 surveillance investigations (mainly colonoscopy, but with some flexible sigmoidoscopies for early surveillance) between January 2001 and January 2006.

When the data were collected in January 2006, 16 (16%) people had been removed from surveillance.

The majority (49%) of patients had a surveillance interval of 3 years requested by the colonoscopist and for 29% it was 6 months or less. (Table 7.4).

Figure 7.7 shows the number of surveillance investigations performed and the number outstanding (at January 2006) each year from 2001 to 2004. This appears to show a trend towards fewer requested surveillance colonoscopies being achieved each year. In 2004 the percentage achieved was 41%.

7.4.3 Initial screening colonoscopy workload for Pilot and national screening programme age groups

Table 7.5 shows the combined number of initial screening colonoscopies (from both Pilot hospitals) in each round of the Pilot for all ages and for ages 60-69 years only. Figures are also shown scaled to a screening population of 100,000. It should be noted that surveillance colonoscopy figures are not included and that these figures will be affected by the reduced uptake in the second round.

7.4.4 Non-Pilot hospitals

In order to draw comparisons with areas unaffected by screening activities, colonoscopy activity and waiting time data were requested from hospitals outwith the Pilot area.
Hospital 1:
Activity data for 2001 to 2004 from one district general hospital, (with the characteristics shown in Table 7.1) can be seen in Figure 7.8. This shows an increase in numbers each year; there was a 36% increase in 2002, a 20% increase in 2003 and a 10% increase in 2004. The average number of colonoscopies each month in 2001, 2002, 2003 and 2004 were 33, 45, 54 and 59 respectively. Correspondence with staff at the endoscopy unit revealed that the hospital had reviewed its capacity and demand and undertook a conscious exercise to reduce waiting lists. A nurse endoscopist and general practitioner now undertake the majority of diagnostic upper gastrointestinal (GI) work, freeing other endoscopists to undertake lower GI endoscopy. This has increased capacity, almost entirely cleared the upper GI waiting list, and substantially reduced the lower GI waiting list, although there is ‘still a long way to go’.

Hospital 2:
Activity data from 1997 to 2005 from a hospital whose characteristics are shown in Table 7.1 can be seen in Figure 7.9. There is a general upward trend with the peak in 2003/4. Other data provided by the hospital show that the number of un-booked and the number of overdue colonoscopies dropped between May 2003 and September 2004, but then rose again to just below the previous levels.

Hence, data from these two non-Pilot hospitals illustrate the important changes which were occurring at a national level during the period of the Pilot; the period was characterised by a general upward trend in colonoscopy activity, the establishment of training centres and a considerable focus on service modernisation.

7.5 Questionnaire and Qualitative data

In this section we provide a summarised report of the information obtained from semi-structured interviews with key staff in the endoscopy units, staff at the screening unit in Rugby, and colorectal cancer nurse specialists and managers at the hospitals; the timesheets given to clerical staff; and the questionnaire survey.

The full analysis of the qualitative data is provided in Appendix 3 and of the questionnaire survey from respondents at the three hospitals involved in the first round of the Pilot in Appendix 4. Results from the two hospitals in the second round are included in this section. Responses were received from 13 (45%) endoscopists at these two hospitals.

Analysis of the semi-structured interviews categorised the main topics into four sections; three relating to the impact of the Pilot on the colonoscopy services - additional workload, improved quality of colonoscopy and staff satisfaction - and the other relating to organisational choices for endoscopy units.

7.5.1 Additional workload

The most obvious impact on endoscopy services was that the Pilot created additional work for departments that were already busy. The introduction of Pilot colonoscopies, over and above the non-Pilot work, inevitably increased the departments’ workloads.

Another source of additional workload related to the Pilot is surveillance of patients found to have polyps at their initial colonoscopy. When the screening unit has taken over the management of surveillance colonoscopies and schedules them on commissioned sessions...
there will be a reduction in the administrative and clinical non-Pilot workload for endoscopy units. Likewise, the changes in surveillance protocols will also reduce anticipated workload. One unit commented that meeting the demand for surveillance colonoscopies was already a problem even before screening was introduced.

There was also some anecdotal evidence that the introduction of the Pilot increased demand for non-Pilot colonoscopy. Questionnaire respondents were, however, more likely to attribute the increase in GP referrals to the introduction of the two-week standard for referrals, a change in GP referral thresholds or media influence. There was also a suggestion that there was increased use of FOBt by GPs in a population where there is an increased use of anticoagulants. These extra demands were taking place alongside an existing high demand for non-Pilot colonoscopies. Keeping non-Pilot waiting times within target levels appeared to be increasingly difficult, particularly in one of the hospitals.

' the capacity just doesn’t meet that demand.’ (ID 12)

It was thought, however, that meeting demand for colonoscopy was a problem nationally and that the impact of the Pilot had not been huge.

Pilot colonoscopies also increased workload in other ways:

- some interviewees thought screening colonoscopies took longer than symptomatic colonoscopies because screening colonoscopies were more likely to find polyps in the course of the examination, although questionnaire respondents had divided opinions regarding this.
- completing Pilot data requirements was time consuming.
- extra clerical work was required to add Pilot patients to the hospital computer systems, to send out colonoscopy information and bowel preparation medication, and to liaise with screening unit staff. At Walsgrave Hospital this extra clerical work was estimated to be four hours each week.

This increased demand for services and the introduction of targets to ensure minimal waits for diagnostic services for patients with suspected cancer has put considerable pressures on endoscopy units and forced them to implement innovative ways of organising work to improve capacity. In general, the impact of the Pilot was not thought to be as great as that of national influences. An audit in one hospital found that about one third of endoscopy time in normal working hours was unused because of staff annual leave or study days and patients failing to attend. Measures that have been considered or implemented to address this include phoning patients prior to their appointment to check that the endoscopy is still appropriate, pooling of lists, validation of lists, and increased use of nurse endoscopists to use spare session capacity when another endoscopist is unable to take the session. Other initiatives to reduce waiting times include out-of-hours (OOH) (or extended day) working which might also be preferred by some patients and staff, and partial booking as well as waiting list initiatives. Waiting list initiatives (WLIs) were recognised as being expensive for the hospitals and hard work for the colonoscopists if they have 8 or 9 procedures in a day.

Questionnaire respondents were very much in favour of more accommodation (rooms); more nursing staff, colonoscopists, and endoscopists; improved IT systems and WLIs as strategies for reducing waiting lists. There was less support for validation of waiting lists; more nurse endoscopists; more clerical support; more colonoscopes; and pooling of lists; and very little support for partial booking systems at Walsgrave Hospital where they had recently been introduced. One interviewee was concerned that the additional colonoscopies will mean that
the best, and therefore most used, colonoscopes will need replacing at an earlier date and it can be difficult to get funds to do this.

Another example given of a way to improve an endoscopy unit’s efficiency was to create a better administrative structure within the department by, for example, employing an administrator to free the nursing sister to carry out other skilled tasks. Also the introduction in many endoscopy units nationally of endoscopy users’ groups or multi-disciplinary teams running the department has led to change and improvements in the service. Traditionally surgeons and gastroenterologists put their own cases on their own waiting lists; these often have different waiting times and the multi-disciplinary approach to running a department can be useful in balancing out these waiting times and utilising unused capacity. The impact changes like this can make is demonstrated by a recent reduction in waiting times for routine endoscopies in one of the hospitals from approximately 12 months to 3 months.

The suggestion that a response to long waits for colonoscopy might be for a greater proportion of non-Pilot (symptomatic) patients to have a barium enema and/or flexible sigmoidoscopy as an alternative investigation had a mixed response from questionnaire respondents. Five endoscopists thought this was the case, three disagreed that this was happening and four did not know. Waiting times for barium enema differ at each hospital, but because of the low number of respondents it was not possible to determine if this was the cause of the variation in responses.

However, it was also recognised that the Pilot had benefited at least one of the endoscopy units by enabling the unit to reduce routine waiting times by utilising unfilled colonoscopy slots in screening sessions.

7.5.2 Improved quality of colonoscopy

There was general agreement among interviewees that an improvement in the quality of colonoscopy services within the departments was at least partly related to the introduction of the bowel cancer screening Pilot, although questionnaire respondents were more divided in their opinions on both whether services had improved and the role of the Pilot in this.

Several reasons for there being an improvement in quality of colonoscopy services were given by the interviewees. The Pilot had raised the profile of the endoscopy department within the hospital and there was increased managerial support for modernising endoscopy. The Pilot had paid for top quality colonoscopy training and extra equipment, and the skill level of screening colonoscopists had also improved because of the large amount of therapeutic work required in screening colonoscopies. Questionnaire responses from endoscopists performing screening colonoscopies did not show such agreement; one of the three respondents believed their skills had improved because they had participated in the Pilot, one disagreed and one was unsure. Improved accommodation and more consultants, nurse practitioners and nurse endoscopists were also mentioned as factors that helped to improve quality although not necessarily directly attributable to the Pilot.

The high level of service provided for screening patients, necessitated because screening patients had been invited to participate in screening and had not approached the health services themselves, was also felt desirable for non-Pilot patients and aiming to achieve this has also helped raise standards for non-Pilot patients.
7.5.3 Staff satisfaction

For several reasons relating to the introduction of the Pilot there appeared to be a positive effect on in staff satisfaction. Staff could see the benefits of screening both for patients and for the hospital, and screening added another dimension to the endoscopy unit work. Participating in the Pilot was seen to raise the status of the hospital. It also presented research opportunities: a new population of asymptomatic people who have tested positive for FOB and been found to have polyps at colonoscopy now exist and disease progression in them may be different to previously studied populations; the detection of many more early stage cancers has led to new and interesting discussions at the multi-disciplinary team meetings on the best way to manage these early cancers; and an environment has been established where new screening technologies (tests) can be assessed.

However, screening also caused stressful situations for staff. The pressure of long waiting lists on one colonoscopist was evident.

‘there’s no slack for us to take [annual leave]’ (ID 19)

Also, the risk of causing damage to someone who was invited to screening, someone who had not sought healthcare, was mentioned as a concern by one interviewee.

7.5.4 Issues relevant to future organisation of screening colonoscopies within endoscopy units

Many issues discussed with interviewees related to organisational factors. Those relevant to colonoscopy and the future national screening programme for bowel cancer are described in this section.

It was evident that there will be a lot of decisions to be made and plans to put in place for prospective screening centres. It was felt important that plans were well thought through, based on the best possible estimation of screening workload, and that decision making should include all staff who are likely to be affected, to allow them to have some input into and control over the introduction of the new service and solving the problems that would arise. The Pilot had been well organised and it would be efficient for new screening centres and units to follow the methodologies used in the Pilot, rather than developing their own systems.

The most important factor mentioned was managing existing, non-Pilot patients in a timely manner before embarking on a screening programme to ensure that the waits for non-Pilot patients are not considerably longer than the waiting time for the screening patients. The waiting time for a Pilot colonoscopy can be kept within the standards set by adjusting the level of invitations sent out, and commissioning extra sessions if the demand exceeds that expected. This is not so for the non-Pilot service and this can lead to ‘an obvious two-tiered element’ to the service with longer waits for symptomatic patients unless capacity for non-Pilot demand can be met.

To provide sufficient colonoscopists to meet the increased workload, extra consultant sessions would probably be required with screening work included in consultants’ job descriptions. For consultants to be only providing screening colonoscopy work was thought to be a waste of their skills as well as tedious for them. The use of nurse endoscopists or endoscopy technicians could help to increase the supply of colonoscopists, either by performing upper gastrointestinal work to free colonoscopists for colonoscopies or by performing colonoscopies under the supervision of a consultant. Questionnaire respondents mainly agreed that nurse endoscopists
or endoscopy technicians were a good idea and could free medically trained personnel to perform more colonoscopies, but were evenly divided in their opinions on nurse endoscopists or endoscopy technicians performing colonoscopies under the supervision of a medical colonoscopist. One respondent believed a long training would be required.

Currently, it was thought, consultants do not have sufficient time to train these non-medical staff as colonoscopists.

One interviewee wondered how extra colonoscopists might be employed in the future if other technologies such as more specific screening tests or colonography are developed and implemented thus reducing the need for colonoscopy.

Some comments highlighted that the invasive nature of colonoscopy, with its inherent risk, requires quality of service, which currently is not measured within the NHS system, and that screening colonoscopists should be validated regularly with respect to completion rates, patient satisfaction, and competence.

The importance of screening work being an integrated part of the work of the endoscopy was raised by at least two people.

‘……… it should be part and parcel, another referral source into that unit, rather than it being something special’ (ID 20)

However, another interviewee indicated that they thought it would be better if the screening unit managed all the screening work, while the unit provided the staff and usual support services for these colonoscopies.

The use of dedicated screening sessions, rather than mixing screening and non-screening colonoscopies in one session, was felt to have several benefits. Screening lists have a different ethos because in non-Pilot colonoscopies the cause of symptoms is being investigated, while in Pilot patients the colonoscopies are specifically to determine whether or not the person has cancer. It is also logistically easier to plan separate sessions when different booking administrators (screening unit or endoscopy unit) are involved. Dedicated lists also allow screening nurses, who know the patients well, to attend screening colonoscopies and give the patients the extra support they need. This has been recognised as very valuable by patients, colonoscopists and screening nurses. On the other hand, sessions with a mixture of endoscopies were thought to be less arduous and more interesting.

The majority of questionnaire respondents who answered the question relating to organisation of screening colonoscopies were also of the opinion that dedicated screening lists were preferable, citing as reasons the use of experienced colonoscopists, the extra time required for screening colonoscopies, not affecting the symptomatic waiting lists, and this being an easier way to track patients through the screening process.

Suggestions of how to reduce work for the endoscopy unit included management of surveillance for screen detected polyps by the screening unit; using screening sessions for these surveillance colonoscopies; and for screening nurses to give patients their bowel preparation products and colonoscopy information.

As improved information technology (IT) facilities are introduced throughout the NHS one interviewee was hopeful that electronic transfer of data could reduce the extra work required to
complete the screening database. This is mainly a paper-based system at present which as well as increasing workload also increases the risk of errors. However, it does mean that there is a consistency in the interpretation of data entry that might be difficult to achieve if data were entered on to the computer by people at different sites. An ideal situation would be for data to be transferred directly from, for example, the endoscopy reporting system to the screening database.

Questionnaire respondents indicated general agreement that the department computer systems were good for reporting endoscopies and audit, but less so for booking appointments and managing waiting lists.

It was thought that a benefit of participating in the Pilot would be an easier transition to becoming part of the national programme.

**7.6 National Capacity Building and Quality Assurance**

It is important to emphasise that, during the course of the UK Bowel Screening Pilot, a great deal of effort has been invested in service improvements for bowel cancer. Much of this effort is of direct relevance to establishing a bowel cancer screening programme.

Much has been achieved since the NHS National Endoscopy Programme began in April 2000 to support endoscopy units modernise their systems in order to improve the service to patients by ensuring quality of service and sufficient capacity. The Diagnostics National Leadership Group (DNLG) was set-up by the Department of Health in 2004 and now has the remit to provide national support for diagnostic services. The National Endoscopy Leadership Group, which leads the endoscopy programme, reports directly to the DNLG. This group contains representatives from key stakeholder groups and three other groups report to it – the service delivery group, the workforce and training group and the quality assurance group.

**7.6.1 Background**

Two main factors provided the incentive for this modernisation programme. The NHS Cancer Plan (September 2000) contained several targets, including a maximum 31 day wait from diagnosis to treatment and a maximum 62 day wait from urgent GP referral to treatment for all cancers by 2005. For gastrointestinal cancers, efficient and timely endoscopy services are key to achieving these targets. In addition the introduction of a Bowel Cancer Screening Programme (BCSP) was on the horizon. The BCSP will increase demand for colonoscopy services and will also require the highest standards of colonoscopy to ensure that the benefits of screening outweigh the risks.

As well as these motives other targets and reports in the intervening years have also added to the desire for modernisation. The NHS Improvement Plan (June 2004) set a new overall goal for the NHS – that by 2008 all patients will be treated within 18 weeks from GP referral, and in particular all scans and diagnostic procedures will take place within 13 weeks. Endoscopy is recognised as a constraint in achieving these targets and the Department of Health will be investing in diagnostic services in 2006. The Government policy that up to 15% of diagnostic care should be provided by the independent sector by 2008 has implications for the NHS. To preserve NHS endoscopy services, hospital trusts will need to provide adequate resources to withstand competition. Additionally, the National Confidential Enquiry into Patient Outcome and Death highlighted risk areas and a colonoscopy audit identified weaknesses in the provision of colonoscopy services and these created a focus for improvement.
7.6.2 Modernisation process

Modernisation of endoscopy services to meet the growing demand and expectations has been spearheaded by the National Endoscopy Programme which has worked with other organisations including the Joint Advisory Group on Gastrointestinal Endoscopy (JAG),21 the British Society of Gastroenterology (BSG) and BCSP. Modernisation has been focused around training and service redesign, and the approach has been patient centred, emphasising both quality and safety.

7.6.2.1 Training Initiatives

For the past 15 years the JAG has developed endoscopy training courses, appraised colonoscopists, and accredited endoscopy units for training endoscopists. The colonoscopists who participate in the BCSP will in addition need to meet levels of competence and performance agreed by the BCSP.

The National Endoscopy Training Programme was introduced in April 2004 to increase the number of endoscopists and ensure high standards. Three national and seven regional training centres began delivering JAG approved endoscopy courses which address the clinical and managerial aspects of delivering endoscopy services. Outreach training work has increased the geographical coverage. In the first year of operation, 278 colonoscopy training places were commissioned. These places were available to a wide range of medical professions (including GPs and nurse endoscopists) in order to increase the quantity of service available as well as to improve quality. New courses continue to be developed including training for trainers. As well as the training needs of endoscopists, thought has been given to identifying an ideal skill mix for the endoscopy team and considering the training needs of all team members. The Workforce Development Directorate at North East London SHA is the lead body for the commissioning of education and training to support the cancer workforce in delivering the NHS Cancer Plan.

To measure the competence of colonoscopists in training two approaches have been used. Firstly, there is a paper assessment based on a competence framework created by Skills for Health. Secondly, there is also DOPS – direct observation of procedural skills. Standards for competence have been defined by the JAG.

For endoscopists who were established before there was a requirement to assess endoscopists’ competence there is a re-accreditation process (aka the advanced colonoscopy driving test) which is a requirement to be allowed to perform BCSP colonoscopies. The BCSP aims to recruit up to 200 expert colonoscopists over the 3 year implementation period of the screening programme. To apply for the advanced colonoscopy driving test colonoscopists are required to record satisfactory completion rates in the preceding year and preference will be given to applicants carrying out greater numbers of colonoscopies (with a minimum of 150 per annum).

Ongoing monitoring of colonoscopist performance is being introduced and the standards of performance relate directly to the quality and safety indicators in the Global Rating Scale (see below).

7.6.2.2 Service modernisation

Service redesign for endoscopy units includes both capacity building and quality assurance initiatives. The National Endoscopy Programme initially identified what was required to
modernise the service and then developed a document and CD entitled “Modernising Endoscopy Services - A Practical Guide to Redesign” which was published and distributed to the 10 endoscopy training centres. Its advice focused on ensuring that endoscopy services had clear ownership and managerial responsibility and engaged in identifying bottle-necks by analysing their patients’ progress through the system. To help facilitate this, the CD contained a set of Excel workbooks (the endoscopy toolkit) which was designed to simplify the process of collecting robust and standardised data on service delivery at all stages. The first wave trial led to improvements and further developments in the process of modernisation, and the ensuing tools (including the revised endoscopy toolkit), which provided more information on possible ways to improve efficiency and ways of working, were piloted by 26 endoscopy centres in the second wave pilot. These tools are available on-line for all endoscopy units who wish to use them.\textsuperscript{22}

Pilot work showed that strong clinical leadership, backed by Trust Board support and good operational management, were necessary to improve services and between May 2003 and March 2004 Strategic Health Authority based endoscopy clinical leads were appointed to promote the modernisation process.

The National Endoscopy Team, along with the JAG, the BCSP and the British Society of Gastroenterology (BSG) has worked since September 2004 to create a quality assurance framework to assess standards of both individuals and endoscopy units.

The Global Rating Scale (GRS), a self-reported assessment for endoscopy units, was introduced, piloted and revised. The GRS has evolved into a quality improvement tool - a guide of what is required to achieve high standards of care in endoscopy. It consists of 12 items which describe aspects of the patient experience (divided into customer care, and quality and safety). There are 4 levels of achievement (A-D) for each item which are now underpinned by a number of measures. All English endoscopy units are now requested to submit scores on-line twice yearly, and in autumn 2005 90% of Acute Trust Endoscopy Units participated.

The Endoscopy Team continues to provide practical support. A Knowledge Management System (KMS) is in its early stages and is intended to support units improve their GRS by collating solutions that have worked in units around the country. An action planning template and traffic light functionality have also been added to the system to aid service improvement, and evaluation of both progress and the level of support still required.

The GRS is backed up by a JAG accreditation visit to endoscopy units. The National Endoscopy Programme and the BCSP have provided the means for introducing JAG visits to verify items covered by both JAG questionnaires for accrediting endoscopy units as training units for JAG approved training courses and global rating scales.\textsuperscript{21} The accreditation of units for training was previously largely paper based and not verified by formal inspection mainly because of lack of resources. This accreditation process now encompasses the accreditation needed for participation in the BCSP and a trial of it was due for completion in December 2005.

As mentioned above, to be accredited as a screening centre for the BCSP, endoscopy units must achieve certain standards of care measured on the GRS. In 2005 these levels were agreed by the NHS Cancer Screening Programmes and the NHS National Endoscopy Team Quality Assurance group. For example, one item on the GRS is ‘timeliness’ and units are required to achieve Level A, and to sustain this for three months, before being accepted as a screening centre.\textsuperscript{23} Level A requires waits for endoscopies to be less than 2 weeks for urgent procedures.
and less than 6 weeks for routine procedures; waits for surveillance procedures to be less than 6 weeks beyond the planned date; and that capacity can be flexed according to demand to ensure waits are within the above limits. Endoscopy units therefore need to be able to provide the capacity to meet the demand for their services, both symptomatic and screening.

7.6.3 National Initiatives - summary
To improve the efficiency of and standards within endoscopy units a process of identifying needs, developing tools to aid robust data collection, providing possible solutions to meet the challenges met by units intent on modernising their services, and promoting the political and managerial will to resource the change process has been ongoing for the past six years. This has been accompanied by the development of defined standards, and assessment procedures for both individuals and organisations to show that they have met the standards. Achieving defined standards will be necessary to participate in the Bowel Cancer Screening Programme. Initial standards are set out in Appendix 8, annexes A, B and C.

7.6.4 Effect of national capacity building initiatives on Pilot hospitals
Ongoing measures to increase capacity and quality existed at both Pilot hospitals, and as at national level these involved two main areas – training and service improvement.

7.6.4.1 Training
Both hospitals have JAG accreditation for training endoscopists but neither are national or regional endoscopy training centres. One of them is keen to become a training centre and was working towards providing facilities to support that. To ensure everyone was working to the same standards a competency booklet had been written for new endoscopy staff who are then assessed before performing endoscopies without supervision. Performance monitoring for endoscopists exists at both hospitals.

7.6.4.2 Service improvement
The only capacity increasing measure acknowledged to be a direct consequence of the introduction of the Pilot was, at one of the hospitals, the addition of an extra room and provision of the nursing staff and equipment required to run it. Another room is expected to ready for use in the near future.

Both hospitals were part of the second wave pilot of the modernisation programme and thus tested the revised endoscopy toolkit to assess their existing services, identify areas for improvement and put their plans into practice. Examples of new ways of working at both hospitals include partial booking which has reduced non-attendance rates, and pooling, as far as possible, of endoscopy waiting lists to ensure a more equitable service for patients. Validation of lists has been completed at one hospital, but there has not been time to do this since the latest guidelines were introduced at the other hospital. However, all patients who have had a polyp removed are seen by a nurse specialist who arranges surveillance according to the guidelines unless the clinician judges that a different surveillance interval is clinically necessary. This helps to ensure consistency.

At one hospital the number of colonoscopists increased when two further gastroenterologists were employed to expand gastrointestinal services. At the other hospital two nurse endoscopists are training as colonoscopists. It is hoped that this will increase capacity and bring down waiting times by the nurse endoscopists ‘filling in’ for other colonoscopists when they are not available to perform their regular sessions.
Scope washers and support worker porters have been introduced at one hospital and this allows endoscopy nurses to concentrate on work within the endoscopy room and increases the throughput of patients. This initiative is also helpful as it can be difficult to recruit nursing staff.

The Global Rating Scale was seen by one interviewee as burdensome but was recognised in both departments as providing a focus for improvement in several areas. This included updating patient information and initiating a ‘patient comfort audit.’ Annual updating of the patient information was expected to be onerous.

'We just do it [GRS] as an extra burden, to be honest, because it’s asking for a hell of lot really, which you almost don’t have time to do really. The amount of audit that’s involved in it and things like that is just absolutely phenomenal really' (ID 10)

It was thought that integrated and improved IT systems would facilitate data collection for the GRS.

An innovation at one hospital which began in the third round of the Pilot is to have a screening session in the early evening. This frees up the sessions during the day for non-Pilot work and thus restores capacity. Outside the Pilot work the potential for out-of-hours sessions is limited by a lack of nursing and clerical staff.

As mentioned above, most of these modernisation changes were not thought related to participation in the Pilot, but to a need to improve the service to meet government targets. In the future the hospitals will also need to meet the requirements for participating in the bowel cancer screening programme.

7.7 Discussion

It is important to understand the impact of the Pilot on endoscopy services in order to aid management of the current Pilot and future bowel cancer screening work. The need to adequately address the resourcing of colonoscopy provision was highlighted as being a critical determinant of the success of roll-out of a national screening programme in the evaluation report of the first round of screening. We have examined the ongoing impact of the second round of screening on the endoscopy units of the two hospitals that provided colonoscopy services to the second round of the Pilot.

From the available data it appears that, at the time of data collection at in the first half of 2005, non-Pilot colonoscopy activity had remained at a steady level at both hospitals since waiting list initiatives ended around the middle of the first round of the Pilot. However, at one hospital waiting times up to December 2004, although not increasing, were above the desired level, and at the other hospital, until July 2005, the number of patients waiting for colonoscopy was gradually increasing. This demonstrates the challenges facing the units in providing the capacity to meet demand.

The activity and waiting time figures are backed up by data from the qualitative interviews where staff expressed concerns about having sufficient capacity to meet the demand. Further evidence that waiting times for colonoscopy were longer than desired came from questionnaire responses indicating that barium enemas are occasionally used as an alternative to colonoscopy.
for some non-Pilot (symptomatic) patients. Considerable efforts are being made in both hospitals to provide sufficient capacity to meet the demand for colonoscopies and the situation may now be improving. However, we are aware of several reasons for interpreting the quantitative data with a degree of caution.

- Overall hospital activity data accuracy is dependent on the accuracy of the data held by the information services departments in the hospital. It is unclear how accurate these data are, although a comparison of the figures from UHCW with some figures provided by the endoscopy unit at Walsgrave Hospital suggested that the data were reasonably accurate. Further confidence in the data is provided by the similarity in the percentage increases in workload compared to non-Pilot workload for both colonoscopy and pathology (large bowel biopsy and polyp specimens) data.
- The UHCW data only had waiting time information for 65% of out-patients. There was no similar comparison measure available for the George Eliot Hospital data.
- Surveillance colonoscopy data for patients entered on to surveillance during the second round of the Pilot are not included in the Pilot workload and have not been removed from the non-Pilot workload. Their impact on hospital workload in the second round is likely to be small but their omission could lead to an underestimate of the increase in overall workload in the second round.
- It is possible that there might be some repeat colonoscopies recorded in the Pilot database that are also included in the surveillance colonoscopies and this might inflate Pilot colonoscopy activity slightly, but have an opposite effect than the point above. Also, some ‘short-term’ surveillance work was carried out using flexible sigmoidoscopies which would add less to the workload than colonoscopies.
- UHCW data for both the Pilot and non-Pilot work includes colonoscopies performed at both Walsgrave Hospital and Hospital of St Cross in Rugby. The proportion of work at each hospital has not been obtained.
- The hospital where patients had their colonoscopy has been assumed by mapping the Primary Care Trust of the patient’s GP to the hospital most likely associated with that Trust. (Coventry Teaching PCT and Rugby PCT with Walsgrave Hospital or Hospital of St Cross Hospital; and North Warwickshire PCT with George Eliot Hospital). This might not always have been the case, but was felt to be a reasonable assumption to make and the small number of cross boundary cases are not expected to make any difference to the report findings.

The Pilot clearly increased the number of colonoscopies in each hospital with data from one hospital suggesting that Pilot related work increased workload by 28% (14% at the other) in the second round, very similar to first round figures (Table 7.3). However, the impact of the Pilot on non-Pilot waiting times is difficult to judge with many factors involved and staff, in general, did not feel that the Pilot contributed much to the challenges they faced in meeting demand. The general trends observed are probably a combination of many factors; hospital, Pilot and national events. Any improvement in the reduced uptake noted in the second round will increase numbers of screening colonoscopies.

It has been unfortunate that colonoscopy data from more non-Pilot hospitals has not been forthcoming to help determine whether the trends seen at the Pilot hospitals are a consequence of the impact of the Pilot or whether they are caused by forces affecting other English hospitals. This probably reflects the time-consuming nature of collating the data and concerns about making comparisons meaningful without publishing sufficient data about the Trust so as to identify it. Waiting time/list data are sensitive issues for hospitals preparing to be considered.
Data from the two hospitals outside the Pilot area show a greater increase in colonoscopy activity than at either of the Pilot hospitals reported on in this chapter. There could be several explanations for this:

- The impact of the Pilot has reduced the number of symptomatic colonoscopies.
- Participating in the Pilot could have reduced the ability of the units to increase colonoscopy numbers in line with demand.
- Other local factors may influence the figures. For example, a change in the proportion of upper and lower gastrointestinal endoscopies, local staff shortages or changes in GP referral patterns to local hospitals.

It was intended that initial screening colonoscopies would be carried out over and above non-Pilot work and resources were calculated on this basis. Each hospital used its resources differently to best suit their local circumstances and this has provided useful information on the impact of the Pilot in different contexts.

At Walsgrave Hospital (a large hospital with regional as well as local responsibilities) an extra room and support staff were provided for screening sessions and one of the screening approved colonoscopists was partially retired allowing for more flexible work patterns. It was difficult at times to provide the capacity for the initial screening colonoscopy work and so extra sessions were initiated – one at Walsgrave and one at Hospital of St Cross as there was not, at that time, spare capacity at Walsgrave Hospital. Surveillance colonoscopies were performed on these lists when there was spare capacity in order to avoid wastage.

At George Eliot Hospital (a smaller, district general hospital) the same resources were provided. These were used in a different way and screening sessions were scheduled in the existing accommodation during usual working hours. This appeared to reduce the capacity for non-Pilot work and was a cause of concern for some staff. Surveillance work was added to the normal surveillance pathways and our data suggest it was not always performed in a timely manner.

The decision by the National Screening Programmes to bring surveillance of patients remaining in the screening programme (but not those who required treatment) under the management of the screening programme is supported by these findings. Further analysis of the outcomes of first and second round surveillance colonoscopies could be carried out to improve estimates of workload generated by screening surveillance to enable the screening programme to plan for this level of work. One unexpected finding was that a considerable proportion of surveillance investigations occurred within 6 months of the initial screening colonoscopy. This produces an increase in workload earlier in the screening round than would be predicted if it was assumed that all surveillance fell within the national guidelines. Further consideration of this phenomenon could be useful for estimating future workload patterns.

As described in this chapter, hospitals have had several reasons to modernise and streamline endoscopy services in recent years. These have included ensuring that government targets for the provision of diagnostic services in a timely manner and the requirements of the Bowel Cancer Screening Programme are met. These are both focused on maintaining acceptably short waiting times. With regard to becoming a screening centre, the Endoscopy Quality Assurance group have agreed that endoscopy units should achieve Level A for the Timeliness item on the
Global Rating Scale, and that this should be sustained for three months.\textsuperscript{23} Level A requires waits for endoscopies to be less than 2 weeks for urgent procedures and less than 6 weeks for routine procedures; waits for surveillance procedures to be less than 6 weeks beyond the planned date; and that capacity can be flexed according to demand to ensure waits are within the above limits. Both Pilot hospitals are currently employing strategies advocated in national guidance to reduce their waiting lists and, although being part of the Pilot will make it easier to transfer to the National Programme after the third round of the Pilot, the challenge of acceptable waiting times remains. The requirement that the existing capacity is sufficiently flexible to ensure waits are within the defined limits is particularly important in the context of screening as variation in demand for screening colonoscopies exists. Non-Pilot patients have benefited from utilising spare Pilot capacity in both rounds of the Pilot, and flexibility in both directions might be necessary. If so, transparency such that all staff are aware of this will be important to avoid misunderstandings that might lead to resentment of the national programme.

Staff involved in the Pilot advised that units aiming to become screening centres should plan carefully how to provide, in a sustainable manner, the increased capacity required for the extra Pilot work whilst preventing inequities of service arising between symptomatic and screening patients. The plans will depend on local circumstances and are likely to include ways of maximising session capacity (such as pooling of lists, partial booking, validation of lists, the use of nurse endoscopists or colonoscopy technicians, and flexible working hours); or provision of sufficient consultant colonoscopy sessions, accommodation, equipment, support staff or an improved IT infrastructure. Estimates for the level of demand for screening colonoscopies for individual units should be well developed, based on population figures and screening Pilot data. Planning should involve discussions with all staff who will be affected - the importance of this should not be underestimated.

While the current organisation of screening and non-screening work within the endoscopy units is acceptable for a Pilot, the integration of screening work within an endoscopy unit needs to be worked through and sustainable systems developed to meet local needs and provide a cost effective service. Consultants involved in screening will need to have the screening element of their work included in their job descriptions. Hospital staff of all disciplines were positive about the benefits of the Pilot and this no doubt helped to make the process run smoothly. It could be argued that the special circumstances of being a Pilot site might influence their commitment, however the resounding reasoning behind their support appeared to be the belief that screening benefited the patients. The plan to roll-out bowel cancer screening nationally in a competitive means should ensure that there is high morale and enthusiasm amongst at least the senior staff. Including representatives from all staff in the planning stages has been suggested as being essential for the smooth introduction of bowel cancer screening and this will also encourage ownership by everyone.

The quality of screening colonoscopies remained high with 96.7\% of the Pilot colonoscopies being satisfactorily completed and/or having polyps or suspected cancer found (see Chapter 4, 4.2), and few adverse events occurring (see Chapter 5, 5.11). Pilot colonoscopy work continued to be beneficial to colonoscopists in maintaining or developing their skills and thus maintaining or improving the quality of colonoscopy within the department.

Screened patients who receive a diagnosis of cancer following colonoscopy have different support needs from those whose cancer was detected following a diagnosis based on symptoms. This, together with the acknowledgement that these ostensibly healthy individuals have had a potentially life-threatening illness diagnosed through the direct intervention of a screening programme means that it is especially important that the care they receive within the
service must be of the highest standard. This will have resource implications. Ultimately, such a culture should improve the experience of care for all patients, irrespective of their path to diagnosis.

The second round benefited from the lessons learnt in the first round. The simplification of data reporting requirements for the Pilot database in the second round was appreciated by staff in the endoscopy units, as was the attendance of screening nurses at screening colonoscopies: it is recommended that both of these developments are incorporated into the practices of future screening units.

The qualitative data along with the more detailed data available at the time of this evaluation suggests that the trend for increased symptomatic colonoscopies found during the first round was related to waiting list initiatives operational at that time and was probably not a result of the introduction of the Pilot. There is, however, anecdotal evidence that the Pilot influenced some people to seek their GPs’ advice, but it is not known by how much this has increased referral rates. Many factors affect population behaviour, referral rates and hospital colonoscopy numbers and it is difficult to judge the size of any impact the Pilot has had on increasing demand for colonoscopy services.

In summary, the Pilot has taken place in a time of great change for endoscopy units throughout the country. There has been continued development of symptomatic services with initiatives to improve referral practice and speed up that process; implementation of important and demanding targets for the timely throughput of patients; and measures to improve the capacity and quality of endoscopy services. It is therefore difficult to attribute trends and changes to any one cause. Despite the challenges, staff remain committed to screening and are hopeful that the benefits of screening will be reflected in lower workload levels in the future, as well as immediate benefits for patients. Management can support endoscopy staff with good planning and provision of the resources necessary to provide a timely, high quality service for non-Pilot patients.
Table 7.1  Non-Pilot hospital acute Trust profile

<table>
<thead>
<tr>
<th></th>
<th>Hospital 1</th>
<th>Hospital 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population Served:</td>
<td>&lt;250,000</td>
<td>250,000 - 500,000</td>
</tr>
<tr>
<td>Number of Beds:</td>
<td>Not known</td>
<td>1000 - 1500</td>
</tr>
<tr>
<td>Staff:</td>
<td>1500 - 2000</td>
<td>5000 - 7500</td>
</tr>
<tr>
<td>Sites:</td>
<td>One district general hospital</td>
<td>Two district general hospitals</td>
</tr>
</tbody>
</table>

Source: Annual Reports: for further information please contact the authors
Accessed 13/09/2005

Table 7.2  Annual colonoscopy figures

<table>
<thead>
<tr>
<th>Year</th>
<th>Walsgrave Hospital + Hospital of St Cross</th>
<th>George Eliot Hospital</th>
<th>Non-Pilot Hospital 1</th>
<th>Non-Pilot Hospital 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All</td>
<td>Pilot</td>
<td>Pilot (first round) surveillance</td>
<td>All</td>
</tr>
<tr>
<td>1998</td>
<td>1235</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>1999</td>
<td>1466</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2000</td>
<td>1610</td>
<td>27</td>
<td>1015 11</td>
<td>-</td>
</tr>
<tr>
<td>2001</td>
<td>1900</td>
<td>304</td>
<td>1495 138 15*</td>
<td>399</td>
</tr>
<tr>
<td>2002</td>
<td>1883</td>
<td>372</td>
<td>1160 150 37*</td>
<td>538</td>
</tr>
<tr>
<td>2003</td>
<td>1620</td>
<td>219</td>
<td>1055 91 6</td>
<td>645</td>
</tr>
<tr>
<td>2004</td>
<td>1819</td>
<td>375</td>
<td>1265 146 13</td>
<td>707</td>
</tr>
</tbody>
</table>

*includes a proportion (data not currently available) of flexible sigmoidoscopies
** Year from April – March
Second round patients’ surveillance figures currently not available.

Table 7.3  Colonoscopy workload (Pilot and non-Pilot) in the period when Pilot activity was most stable

<table>
<thead>
<tr>
<th></th>
<th>First Round</th>
<th>Second Round</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colonoscopies</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pilot</td>
<td>Non-Pilot</td>
</tr>
<tr>
<td>UHCW</td>
<td>690</td>
<td>79</td>
</tr>
<tr>
<td>George Eliot</td>
<td>294</td>
<td>49</td>
</tr>
</tbody>
</table>
Table 7.4  Surveillance intervals following initial screening colonoscopies

<table>
<thead>
<tr>
<th>Surveillance Interval</th>
<th>UHCW number</th>
<th>UHCW percentage</th>
<th>George Eliot number</th>
<th>George Eliot percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 6 months</td>
<td>44</td>
<td>16%</td>
<td>29</td>
<td>29%</td>
</tr>
<tr>
<td>1 year</td>
<td>71</td>
<td>27%</td>
<td>4</td>
<td>4%</td>
</tr>
<tr>
<td>2 years</td>
<td>1</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>3 years</td>
<td>117</td>
<td>44%</td>
<td>49</td>
<td>49%</td>
</tr>
<tr>
<td>5 years</td>
<td>1</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Unknown</td>
<td>15</td>
<td>6%</td>
<td>15</td>
<td>15%</td>
</tr>
<tr>
<td>Removed from list</td>
<td>17</td>
<td>6%</td>
<td>1</td>
<td>1%</td>
</tr>
<tr>
<td>Total</td>
<td>266</td>
<td>6%</td>
<td>98</td>
<td>1%</td>
</tr>
</tbody>
</table>

Table 7.5  Summary of initial screening colonoscopy workload for ages 50-69 years and 60-69 years

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Workload population</th>
<th>Number of initial screening colonoscopies</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Round</td>
<td>Actual</td>
<td>124586</td>
</tr>
<tr>
<td></td>
<td>Scaled</td>
<td>100000</td>
</tr>
<tr>
<td>Age 50 - 69</td>
<td>Actual</td>
<td>50815</td>
</tr>
<tr>
<td></td>
<td>% of 50-69</td>
<td>41</td>
</tr>
<tr>
<td></td>
<td>Scaled</td>
<td>100000</td>
</tr>
<tr>
<td>Age 60 - 69</td>
<td>Actual</td>
<td>124477</td>
</tr>
<tr>
<td></td>
<td>Scaled</td>
<td>100000</td>
</tr>
<tr>
<td>Second Round</td>
<td>Actual</td>
<td>52099</td>
</tr>
<tr>
<td></td>
<td>% of 50-69</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td>Scaled</td>
<td>100000</td>
</tr>
</tbody>
</table>
Figure 7.1

UHCW: Number of Colonoscopies Per Month

- Pre Pilot: Average no. of Non-Pilot colonoscopies = 118/month
- Pilot - 1st Round: Non-Pilot = 125/month
- Pilot - 2nd Round: Non-Pilot = 113/month

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Figure 7.2

UHCW: Average Waiting Times (days) for First Non-Urgent OP Colonoscopies

Graph of average waiting times for OP, 1st appointment, routine colonoscopies with waiting time data each month since May 2000. (3552 cases in this category with 3014 = 85% having waiting time data)

Chapter 7: Impact on Hospital Services: Colonoscopy
Figure 7.3

UHCW: Average Waiting Times (days) for First Urgent OP Colonoscopies

Graph of average waiting time in days of OP urgent first appointments of colonoscopies each month for cases after May 2000. Waiting time data available in 865 (74%) of 1174 cases since May 2000.

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Figure 7.4

UHCW: Surveillance colonoscopies for first Round surveillance patients

- Number of colonoscopies performed:
  - 2001: 1
  - 2002: 2
  - 2003: 64
  - 2004: 61
- Number of colonoscopies not yet performed:
  - 2001: 20
  - 2002: 71
  - 2003: 4
  - 2004: 6

Legend:
- □ Surveillance colonoscopies performed
- □ Surveillance colonoscopies not yet performed
Figure 7.5

George Eliot Hospital: Number of Colonoscopies Each Month

Pre Pilot
Average number of Non-Pilot colonoscopies = 71/month

Pilot - 1st Round
Non-Pilot average number of colonoscopies:
During first year (Oct 00 - Sep 01 Inc) = 116/month
During remainder of Round (Oct 01 - Feb 03 Inc) = 84/month

Pilot - 2nd round
Average number of Non-Pilot colonoscopies = 85/month

Average number of Non-Pilot colonoscopies: During first year (Oct 00 - Sep 01 Inc) = 116/month
During remainder of Round (Oct 01 - Feb 03 Inc) = 84/month
Figure 7.7

GEH: Surveillance colonoscopies for first Round surveillance patients

![Graph showing the number of surveillance colonoscopies performed and not yet performed for each year from 2001 to 2004.](image-url)
Figure 7.8

Non-Pilot Hospital 1: Number of Colonoscopies Each Month

Year / Month

Number of Colonoscopies

Monthly average = 33

Monthly average = 45 (35% increase)

Monthly average = 54 (20% increase)

Monthly average = 59 (9% increase)
Figure 7.9

Non-Pilot Hospital 2 - Number of Colonoscopies per year
8. Impact on hospital services: pathology, radiology, surgery

Chapter Summary

- This chapter reports on the impact of the second round of the Pilot on pathology, radiology and surgical services. Data were collected using both quantitative and qualitative methods.

- There has been a reduction in resection specimens sent to pathology for investigation in the second round compared to the first round, from 66 to 40 at Walsgrave Hospital and 27 to 16 at George Eliot Hospital.

- Pilot resection workload decreased from approximately 13% to 4% of non-Pilot workload between rounds at Walsgrave Hospital during the time period when Pilot workload was steady, and the respective figures at George Eliot Hospital were 12% to 4%.

- Biopsy and polyp specimen numbers from initial Pilot colonoscopies unexpectedly increased at Walsgrave Hospital from 799 in the first round to 1024 in the second round, but reduced at George Eliot Hospital from 351 to 247. At Walsgrave Hospital a smaller proportion of patients had polyp and biopsy specimens sent to the pathology laboratory in the second round than the first round, but these patients had more specimens per person than in the first round.

- Surveillance colonoscopy biopsy and polyp numbers currently make up a very small proportion of workload, but this will increase as surveillance becomes established.

- The Pilot work is seen as extra work within already overstretched and understaffed pathology laboratories, but is not seen as the cause of this problem.

- There are likely to be quality assurance and efficiency benefits from creating larger centres to report on polyp and biopsy specimens. However, effective input to multi-disciplinary team meetings would need to be ensured.

- Effective IT links are key to reporting screening specimens efficiently.

- Pathologist staff shortages would likely be exacerbated by the introduction of a national screening programme for bowel cancer and it is worth investigating the potential of an extended role for biomedical scientists.

- There has been less demand for radiology services for screening patients in the second round of the Pilot and as the level of demand was already low in the first round this has had little impact on radiology workload.

- There have been fewer surgical operations for screening patients during the second round of the Pilot. However, hospital surgical-related staff were aware of screening patients increasing their workload and the costs in terms of increased waiting times for non-urgent patients and the provision of extra operating and staging services.
8.1 Pathology

8.1.1 Background

Work is generated for pathology departments if patients who have been screened for colorectal cancer have a biopsy taken or polyp removed during colonoscopy or if they require surgery to remove suspected malignant tissue. The tissue samples are analysed by the pathology departments to determine their histology.

Most patients who have cancer are likely to require pathological examination of tissue specimens at some time. The effect of a screening Pilot is to have the work presented at an earlier date which causes an increase in workload for a short time. Once a screening programme is established it is hoped that the amount of pathology will level off, but initially, in the prevalence round, there will be a higher workload. It could be argued that in the long term screen detected cancers will reduce the pathology workload because cancers will be detected at an earlier stage with smaller tumours on which to report. However, lower mortality rates in screen detected cancer patients might increase the number of surveillance colonoscopies performed on these patients over time which could increase the number of biopsies requiring analysis.

FOBt positive patients who do not have cancer but are investigated by colonoscopy will add to the pathology workload if any biopsies or polyps are removed at colonoscopy and if they require surveillance for adenomas detected at colonoscopy. It is possible that polypectomy in these cases will reduce the need for more complex pathology at a later date by preventing the formation of cancerous cells.

Given the complexities described above it was difficult to predict, and therefore plan for, the impact of introducing the Pilot on pathology workload. Funding was provided for each hospital to cover the costs of one medical laboratory scientific officer (MLSO), one consultant pathologist session per week, and the extra consumables required.

During the first round, completion of colonoscopy was determined by biopsy of the terminal ileum. This also increased pathology workload, although not all colonoscopists routinely followed this protocol. In the second round photographic evidence, which does not involve pathology input, was used to verify completion of colonoscopy.

Another feature specific to the first round of the Pilot and the English site was that, for staff relocation reasons, biopsies and removed polyps from Pilot related colonoscopies at one hospital (Warwick) were reported at another (Walsgrave).

The impact on pathology workload at both sites was considered in the evaluation of the first round of the Pilot but recognised to be poorly documented. The impact was found to be substantial. Pathologists reported that the number of polyps expected from the Pilot had been considerably underestimated, and indeed the number of polyps removed at colonoscopy was higher than expected. A national shortage of pathologists was also noted.

8.1.2 Aims

The aims of the current evaluation of the impact of the second round of the Pilot on the pathology services were to quantify the trends in workload generated by the Pilot as a proportion of total workload and to discover how this change in workload had been experienced by the staff involved.
8.1.3 Methodology

As in Chapter 7, the workload population (see Glossary, Appendix 1) from the first and second round Pilot databases has been used for all Pilot data in this Chapter unless specified otherwise.

Two principal methods were used to assess the impact of the second round of the Pilot on pathology services.

Firstly, the two histopathology departments involved provided monthly activity data from 1998 until January 2005 for biopsies and polyps sourced from colonoscopies, and for colorectal resection specimens. Work was split into these two categories because resections require considerably more work than biopsies and polyps. The number of screening generated specimens was obtained from the Pilot data sets for screening colonoscopies and from the screening unit for surveillance colonoscopy specimens.

Secondly, semi-structured interviews were conducted with the key pathologist and the laboratory manager at each hospital to explore issues related to the Pilot. The interviews took place towards the end of the second round of the Pilot. The broad subject headings were: role within the pathology department; impact of the second round of the Pilot on workload and quality standards; staffing levels and roles; benefits of participating in the Pilot; drawbacks of participating in the Pilot; adequacy of resources provided; changes recommended if starting again/advice to other hospitals starting screening work; any problems foreseen as screening continues. The interviews were recorded and transcribed and the content allocated to themes which were summarised. The interview summary was sent to the interviewee who could then clarify points or make additional comments as they wished.

In addition to this quantitative and qualitative approach, time sheets were given to a few suggested clerical or administrative staff to estimate screening work as a proportion of their working time.

8.1.4 Activity data

Endoscopic biopsy and polyp specimens (from initial and surveillance colonoscopies) and surgical resection specimens are reported below for both hospitals involved in the second round of the Pilot. Workload requirements for the total population screened are presented later in this Chapter (8.4).

8.1.4.1 Walsgrave hospital

The histopathology laboratory manager provided overall numbers of pathology requests and blocks received by the laboratory since 1998 (Figure 8.1). It can be seen that there has been an increase in the number of requests and blocks over the years. The increase in the complexity of the work is demonstrated by the difference in the average increase in number of requests over the past 6 years which was 3.4% per annum and the average increase in the number of blocks which was 5.8% per annum. The Pilot work would not account for all of the increase in 2000 as the Pilot started in September 2000.
Biopsies and polyps:

Pilot biopsy and polyp specimens generated at endoscopy come from several sources:

- Initial screening colonoscopies (see Glossary, Appendix 1)
- Terminal ileum biopsies used as proof of completion of colonoscopy in the first round
- Surveillance colonoscopies.

Pathology from initial screening colonoscopies:

During the second round of the Pilot 1024 biopsies or polyps from initial screening colonoscopies were sent to the pathology laboratory for examination. In contrast, during the first round, 799 from Walsgrave Hospital and 655 from Warwick Hospital (total 1454) were reported at Walsgrave Hospital. (Table 8.1) Although there were more biopsies, fewer people who had a colonoscopy had polyps or biopsies sent to pathology (406; 56% of people having a colonoscopy) compared to the first round (496; 72% of people having a colonoscopy); the average number of specimens per person was higher in the second round.

Surveillance biopsies:

As a proxy for pathology specimens generated from surveillance colonoscopies for first round patients the number of polyps reported at colonoscopy has been used. There were 98 in the first round time period (September 2000 – January 2003) and 189 from February 2003 to April 2005. Figures for surveillance colonoscopies will be slightly greater in the second round people when people entered on to the surveillance programme during the second round are included.

Terminal Ileum (TI) biopsies:

In the first round biopsies of the terminal ileum were reported to confirm that the whole of the large bowel had been examined. Two hundred and thirty two biopsies from Walsgrave colonoscopies and 241 from Warwick colonoscopies were recorded in the Pilot database and reported at Walsgrave Hospital. This number was considerably reduced in the second round (when photographic evidence was used to confirm completion of colonoscopies) with 51 terminal ileum biopsies at Walsgrave Hospital on the database (and none at Warwick).

Monthly numbers of biopsy and polyp specimens collected at all large bowel endoscopies from September 1998 until November 2004 were received from the pathology laboratory and the TI biopsies and Warwick specimens which would not normally be part of screening workload have been subtracted to give total overall workload. Non-Pilot specimen numbers were then calculated by subtracting the Pilot specimens (initial colonoscopy and first round patients’ surveillance colonoscopy specimens, but not second round surveillance colonoscopy specimens) from the total specimens. Figure 8.2 shows UHCW Pilot specimens and overall specimens as average monthly figures each quarter. Non-Pilot workload appears to have reduced since the introduction of the Pilot which might in part be related to the ending of waiting list initiatives.

During the first round, from November 2000 to October 2002, the proportion of biopsies and polyps generated from the screening Pilot compared to non-Pilot work ranged from 7% to 76% giving an average increase in total workload of 20.2%. In the second round, from April 2003 until October 2004, the comparative figures are 13% to 77% and 31.4% (Table 8.3). Overall...
workload, although variable, has not increased since before the Pilot started. Again, waiting list initiatives prevalent around the start of the Pilot might mask the impact of the Pilot.

Resections:

There were 40 large bowel resections from Pilot patients in the second round compared to 66 during the first round (Table 8.2).

Figure 8.3 shows the average monthly number of large bowel resections (for all causes, not just colorectal cancer) each quarter from September 1998 until December 2004 at Walsgrave Hospital along with the Pilot generated resection specimens. During the first round of the Pilot between November 2000 and October 2002 the monthly increase in colorectal resections generated by the screening Pilot ranged from 0% to 38.9% of the non-Pilot activity with an overall increase of 12.8%. However, there does not appear to have been an overall increase compared to the previous two years. In the second round of the Pilot between April 2003 and October 2004 the monthly increase in colorectal resections as a consequence of the Pilot was much less because there were fewer Pilot detected cancers and more non-Pilot resections. The monthly increase ranged from 0 to 19%, with an overall increase of 4.2% (Table 8.3). The lower overall numbers at the end of the first round and the rise in resection specimens after April 2004 is likely to be related to the appointment of an additional consultant colorectal surgeon at the hospital.

8.1.4.2 George Eliot Hospital

Data collection at George Eliot Hospital was not straightforward. The number of cases (not specimens) of colorectal histopathology was recorded in a database until May 2004. After this the number of specimens was collected on a different database which had not been fully updated at the time of data collection. Figures from this database have not been collated for this report as it would not be possible to get a meaningful comparison using this different measure and incomplete data. There are therefore only data for the first year of the second round of the Pilot.

The cases of colorectal histopathology each month were categorised into resections or not by the researcher, on the basis of a coding entry in the database. The accuracy of all entries could not be verified, therefore we are aware of the potential for some error in this component of the data.

Biopsy and specimen data from the Pilot database were converted to the number of people with a biopsy or polyp specimen or with a resection specimen to allow direct comparison of data.

Biopsies and polyps:

Pathology from initial screening colonoscopies: During the second round 247 biopsy or polyp specimens were generated by the Pilot compared to 351 in the first round (Table 8.1). These biopsies/polyps were from 133 patients in the second round and 172 in the first round.

Surveillance biopsies and polyps:

As for Walsgrave Hospital pathology data, the number of polyps found at surveillance colonoscopies has been used as a proxy for specimens sent for examination. There were 35 in the first round time period and 28 in the second round. These were removed from 20 people in
the first round and 21 in the second round. The low figures reflect the large number of overdue colonoscopies at this hospital (see Chapter 7) and would undoubtedly be higher when surveillance work is able to be performed in a timely manner.

Terminal Ileum biopsies:

Very few terminal ileum biopsies are recorded on the Pilot database for George Eliot Hospital patients. There were 4 in the first round and 1 in the second round. These have not been included in Figure 8.4.

The relationship between Pilot workload and non-Pilot workload can be seen in Figure 8.4 which shows the Pilot generated work (in cases) compared to the overall numbers of cases with biopsy or polyp specimens.

In the second round (from April 2003 to April 2004) Pilot related biopsy and polyp cases increased workload by 7.8% (monthly range 2.2-15.4%) compared to 9.3% (monthly range 1.3–18.8%) in the first round (November 2000 to October 2002). (See Table 8.3).

Resections:

In the second round there were 16 resection specimens (and cases) from George Eliot Hospital Pilot patients. In the first round there were 27 specimens (26 cases). Figure 8.5 shows resections compared to the average monthly cases each quarter.

During the first year of the second round (April 2003 – April 2004 inclusive), Pilot resections increased resection workload by approximately 4% compared to 11.7% in the first round (November 2000 to October 2002). However there has been no obvious increase in overall workload since the start of the bowel cancer screening Pilot

8.1.5 Qualitative data

8.1.5.1 Attitudes towards Pilot

The pathology departments involved in the second round of the screening Pilot differ considerably in size. At the time of the interviews one had three consultant pathologists who shared all the work (apart from screening generated work) between them. The other had nine consultant pathologists who ‘sub-specialised’.

Neither of the pathologists interviewed had a problem with the introduction of the Pilot, nor the extra work it generated for the departments they worked in. Reporting of specimens within the guideline timeframe had not suffered as a consequence of the introduction of the bowel cancer screening Pilot.

One pathologist commented that it had been interesting to be part of the Pilot because it had generated a higher number of early stage cancers – with a rate of curable colorectal cancers at about 20% compared to about 12% at most centres in the country.

"It adds to the colorectal [pathology] work to have the screening element.'

(ID 6)

One of the laboratory managers commented that in general programmes to detect disease at an earlier stage than normal are a good idea but they need to be properly resourced.
8.1.5.2 Workload implications

One pathologist expressed the opinion that in general the impact of screening on pathology laboratory workload is not large. It was thought most of the impact of the increased number of specimens was felt by the laboratory staff. Because of a shortage of staff the laboratory was already 'struggling to do the routine work, and the colorectal cancer screening Pilot work was an added pressure.' (ID 4)

The screening work in the second (incidence) round was thought to be less than the first (prevalence) round and not a huge amount of work. There has been a steady increase in endoscopic biopsies over the last 10 years, which may have masked the specific impact of the Pilot, and one interviewee commented that they might never have noticed the Pilot starting if they had not been told and added that they were not usually told about extra endoscopy sessions.

At Walsgrave hospital the increase in the number of large bowel resections in 2004 (as shown in Figure 8.3) was probably because a new surgeon was employed. Referrals patterns might have changed (to another hospital) when waiting times were rising before the consultant’s appointment which would explain the decrease in resections in the years prior to that. Only a small proportion of the resection work comes from screening patients and the pathologist is not usually aware whether the resections have come through the screening route or not as they are not always identified as such at that stage, unlike the endoscopic biopsies.

It was recognised that screening actually ‘puts more people through the system’ but that a lot of curable cancers are detected which will bring forward resection operations or prevent them (through polypectomies), so the complexity and workload should reduce over time, and this is a benefit to the patients too.

Both laboratory managers indicated that the workload has increased in the past few years – at one laboratory it was 5-10% a year, and at the other the number of specimens had increased by about 10% in the past few years and the rise in complexity of the work had increased the number of slides by about 25% over 3 or 4 years. They both thought it difficult to comment on the impact of the introduction of the Pilot on workload because there are so many other factors at play (e.g. an increase in breast and prostate biopsies, the number of surgeons) and workload fluctuates greatly. When processing the specimens/slides the staff are not aware whether they are generated from the Pilot or not. An increase in the number of resections from colorectal surgery would be more noticeable than a change in the number of endoscopic biopsies. Staff were not aware of any difference in screening workload in the two rounds.

Both pathologists commented on the extra time needed to report the information required by the bowel cancer screening Pilot. It was thought to be important to create practical pro-formas. If it is not carefully planned, data entry for the screening database can take as long as writing the report and be a waste of medical time. One pathologist structured his report so that the screening unit nurses could use it to complete the database themselves which saved time.

One pathologist thought that secretarial or clerical input for screening work was proportional to the increase in total workload that the screening generated cases produced. The staff would probably not be aware whether the work they deal with was screening work or not and would
treat all work similarly. Secretarial staff at one hospital completed a timesheet for two weeks in December 2004. Screening related work during this two week period consisted of typing five reports which took a total of 66 minutes. It was estimated that this was the amount of screening generated work they normally experienced during the second round of the bowel cancer screening Pilot. They were not aware of any phone calls relating to screening patients during this time period.

It was recognised at the Pilot screening unit that there was an increased pressure on pathology departments and that this needs attention when planning for the national programme.

8.1.5.3 Staff issues

Advice to other departments embarking on screening work included ensuring that both laboratory and consultant staffing levels reach the Royal College guidelines before starting.

‘If you had the people to do the work it wouldn’t be a problem.’ (ID 4)

There were acknowledged difficulties in providing the exact number of staff the extra work required.

‘We’re looking at a fraction of a lab person and a fraction of a pathologist……….. The problem for labs is that if you bring a little bit of extra work you can always absorb it up to a point, but if you always absorb it and never make any incremental increases in staffing then you do get behind eventually. And then the next little bit of extra work, you find yourself saying, “I need a whole member of staff for that”, and then they say "well that’s ridiculous".’ (ID 6)

It was suggested that well trained, sub-specialised pathologists able to classify polyps (which requires considerable skill) were necessary. However, there was an awareness that there were insufficient pathologists in the country and, although training greater numbers is being addressed, other ways of coping with the increased volume of work generated by a bowel cancer screening programme need to be considered. The training of biomedical scientists to perform extended rolls could relieve pathologists of some of their more routine work and there was general agreement that this was worthy of consideration. Several points were raised:

- Trained biomedical scientists could prepare the specimens, but a shortage of consultants has meant that it has not been possible to train laboratory staff to triage or do some of the more routine work that could free up consultant time.
- At one hospital some biomedical scientists do dissect large specimens but none do microscope work.
- Extended role biomedical scientists working in colorectal pathology could report normal cases, and a trial of this would be useful.
- Straightforward specimens are very easy and do not take a lot of time so there may be little gain in employing biomedical scientists for this.
- Pathologists like the variety of easy and less straightforward specimens in one session - it would be difficult to have a whole session of complex work. The importance of polyp specimens should not be underestimated, because if cancerous cells are found the patient might require major surgery.
- Without the experience of a wider range of specimens a biomedical scientist might not pick up when something is a bit odd and look further into it.
- An extended role would be beneficial for career pathways for biomedical scientists.
• It can be difficult to recruit biomedical scientists because a) it is difficult to get the funding for a post; b) there is a shortage of trained staff due to under investment in biomedical scientist training over the years, and c) it is difficult to attract people to the area from a limited workforce.

In the smaller district general hospital where pathologists were not specialised, the requirement of the screening Pilot that one pathologist report all screening work could interfere with the rota that the staff worked.

Both pathologists found it rewarding to carry out the Pilot work. In the first round, 26% of cancers (31% of resected cancers) were Dukes’ Stage A compared to 11% nationally which added interest to the work.

8.1.5.4 Quality assurance

Neither pathologists nor laboratory managers thought that the Pilot had had an effect on the quality assurance measures in their department although the pathologist in the larger centre thought that quality assurance would be made easier if large centres with sub-specialisation were used for the screening work.

Sub-specialisation enables work to be done more quickly and much more consistently reducing the need for spending a lot of time on quality assurance measures. In smaller hospitals sub-specialisation is not feasible and this supports the idea of having fewer, bigger laboratories for a screening programme. Lessons could be learnt from the cervical screening programme, and pathology services for screening biopsies in each area could be centralised to amalgamate work from about three hospitals at one site - and resources put into that rather than trying to resource a percentage of a member of staff.

One reason why this is important is that there are more ‘borderline malignancies’ in screening patients because the disease is found at an earlier stage. These need to be reported consistently so that if (as has been the case) different centres use different treatment approaches (polypectomy or colectomy) the results of these different methods can be compared. Otherwise 'you don't know whether you're seeing an artefact of an inconsistent approach or whether it's a genuine difference'. (ID 6)

In the first round there was a different rate of colonic resections in the two sites, and between hospitals within the same site. Because of the uniformity in pathology reporting this indicates a different approach to disease management.

Although screening biopsies and polyps were thought to be better served centrally it was thought important to examine resections locally because they go through the multi-disciplinary team meeting and there is a national reporting standard for all resections.

8.1.5.5 Resources

One pathologist was unaware of the resources the department had received for the extra screening Pilot work. The other thought that extra resources should reflect the extra work and their funding had been put towards appointing an extra consultant.
The laboratory managers both expressed that pathology departments had absorbed increases in workload for a long time without extra funding, but that this was no longer acceptable and they need to account for their budgets.

‘In the past we’ve been our own worst enemies - we just picked up the extra work, “well we’ll do it,” it just adds to the overspend, but they seem to be the norm throughout the NHS in general - you’ve probably noticed this – the need to manage overspends means that people are more reluctant to take on extra work without it being funded now.’ (ID 7)

It was recognised that it can be difficult to estimate costs when the complexity of specimens is not known beforehand. The majority of the costs in cellular pathology laboratories are staffing costs.

Funding from the screening unit was not evident, at least in one laboratory, and making limited resources fit an expanding service was problematic.

‘You’re expected to provide a service within a budget but without control of the workload. Inevitably with increasing demands on the service, you overspend and then the accountants/senior managers say you must find the money to pay for your overspend - there’s a bit of logic missing in there somewhere I think. You know, someone’s sending you the work, they should pay for it.’ (ID 7)

With an inadequate budget and staff shortages, direct patient care (i.e. reporting specimens sent to the laboratory) takes priority over other managerial activities. This creates a tremendous amount of stress for departmental managers torn between their managerial responsibilities and the need to issue reports in a timely manner. Screening work is seen as only a small part of this problem.

8.1.6 Discussion

At Walsgrave Hospital there were more Pilot generated biopsy and polyp specimens in the second round than the first, and there was a reduction at George Eliot Hospital. The data collected also suggest that the proportion of Pilot generated biopsy and polyp specimens compared to non-Pilot workload at Walsgrave Hospital was considerably higher than at George Eliot Hospital. Possible explanations for this include measuring the George Eliot Hospital workload by case rather than per specimen (which would not reflect the increased numbers of polyps found in screening patients compared to non-Pilot patients); a reduction in non-Pilot specimens at Walsgrave Hospital; or anomalies in the data.

There was a fall in Pilot resection specimens at both hospitals in the second round of the Pilot, which was anticipated for the incidence round compared to the first (or prevalence) round.

For pathology laboratories the workload generated by screening was just part of the ongoing gradual increase in workload they have experienced over the past 10 years, in both the number of specimens and the complexity of the work. However, laboratory staff were not consciously aware which specimens were generated from the Pilot and at one hospital may have been surprised to know that the data suggest that Pilot activity increased colorectal specimens by around 30%.
The pathologists did not find it difficult to fit the screening specimens into their workload. However, neither pathologist interviewed had been in post for a great length of time before the Pilot was introduced, with one appointed towards the end of the first round. Consequently, the Pilot generated workload did not come as an addition to their usual workload and their perceptions of the increased workload might be different from a pathologist who had been established in a department before screening was introduced.

These findings contrast with those in the first round which mainly reflected the impact on pathologists in Scotland who felt overburdened with the extra workload. Also, the postal survey of histopathologists (both Scottish and English) in the evaluation of the first round of the Pilot found considerable difference in the perspectives of different pathologists. This evaluation of the second round in England has not found the Pilot workload to be a burden for the pathologists involved, but it is difficult to predict whether the experience of the two pathology departments at the Pilot hospitals will be replicated in other hospitals when bowel cancer screening is rolled out nationally.

The reporting of Pilot specimens interfered with rotation systems used by the pathologists in the smaller hospital and local solutions to problems like this need to be created if local laboratories are used to examine screening colonoscopy polyps and biopsies. It is important that pathology reporting is well integrated into clinical discussions involving resection of specimens, and this applies equally in colorectal cancer screening. If central facilities are used for the specimens generated by a bowel cancer screening programme, careful consideration needs to be given to the method of reporting malignant specimens to the local multi-disciplinary team meetings and to facilitating any ensuing communications.

Efficient data reporting methods are important for minimising the impact on workload, and entry of data on the Pilot database evolved over time to minimise time consuming clerical work for one of the pathologists. Improving integration between IT systems is recommended to reduce double entry of data.

All staff were keen to undertake the Pilot work providing it was fully resourced. Laboratories need to be adequately staffed and resourced before screening work is introduced. Shortages nationally of both pathologists and biomedical scientists remain a problem. Whether an extended role for biomedical scientists could be helpful in the context of a bowel cancer screening programme is worth consideration, as it has the potential to reduce costs and improve job satisfaction by utilising experienced biomedical scientists (BMSs) in specimen reporting. It is not clear however if it would solve the existing qualified staff shortages, but in the longer term extra BMSs could be trained more quickly than pathologists.

Using large centres to report pathology from screening endoscopies could be advantageous in maintaining quality assurance and overcoming the difficulty of employing small percentages of staff to cover the increased workload. It would also enable more efficient systems. However, it would be important to develop standardised protocols for the removal and reporting of lesions across all centres, not only to aid the correct diagnostic reporting of, for example borderline malignancies, but also to allow accurate comparison between centres of rates of malignancy and other pathologies. Efficient methods for liaising with multi-disciplinary teams would also need to be developed.
8.2 Radiology

8.2.1 Background

Radiology services are required for screening invitees if an FOBt positive screening participant has an incomplete colonoscopy or is unable to tolerate colonoscopy. When cancer is diagnosed radiological services are used for staging investigations.

When a colonoscopy cannot be completed the aim is generally to perform a double contrast barium enema (DCBE) on the same day to prevent the patient requiring bowel preparation for a second time. In the evaluation of the first round of the Pilot it was found that this was a rare occurrence with a maximum of five extra DCBEs being performed per month at hospitals in the Scottish site. In both Scotland and England the additional activity generated by the Pilot constituted a very small proportion of the overall DCBE activity. It was commented that this level of activity might increase if less experienced colonoscopists performed screening colonoscopies.

Patients who are unfit for colonoscopy, perhaps because of mobility or bowel conditions, are usually also unable to tolerate a DCBE and will instead be referred for CT colonography. When patients are unfit in general for a colonoscopy consideration of whether they could tolerate treatment in the event of an abnormality being found at investigation is considered.

Radiology techniques used for staging investigations for people with cancer include ultrasound, CT and MRI scans.

8.2.2 Aims

The aim of this section was to measure radiology activity related to both screening and symptomatic services, and to elicit the views of radiologists and service managers on the impact of the Pilot on radiology services.

8.2.3 Methodology

Activity and waiting time data were requested from the radiology departments at both hospitals. Email contact was made with lead colorectal radiologists to gather their perspectives on the impact of the screening related activity on radiology services. Enquiries were made of clerical and administrative staff through timesheets and direct communication to elicit the increase in their workload related to the bowel cancer screening Pilot.

8.2.4 General impact

Radiology services were only used very occasionally during the screening process and where they were it was usually organised so that the barium enema was performed on the same day as the failed colonoscopy, thus only requiring the patient to have bowel preparation medication once.

8.2.5 Impact at Walsgrave Hospital

Pilot data were obtained from the first and second round Pilot databases for the workload population. In the second round there were 24 DCBEs recorded compared to 26 in the first round. A radiologist involved with colorectal work did not notice any difference in demand from Pilot patients between the first and second rounds. He thought that the impact of the Pilot on radiology services had been small and that the cancers would have been investigated and staged in the department eventually anyway.
The Radiology Services Manager provided activity and waiting time data and explained how the screening work had been organised within the department.

In UHCW trust DCBEs are carried out at Walsgrave Hospital and the Hospital of St Cross at Rugby. There were 116 DCBEs in the year July 2003 – June 2004. Monthly activity and waiting time data for that year can be seen for both Walsgrave (Coventry) and Hospital of St Cross in Figure 8.6. At Walsgrave Hospital, where all the screening DCBEs were carried out, activity levels have remained fairly constant over this time period and annual activity was slightly lower than previous years. Waiting times have fallen to 2 weeks which is felt to be the optimum time to wait, allowing patients time to prepare for their procedures, and is less than during the first round of screening. This suggests that the DCBE screening work in the second round has been easily assimilated into radiology services.

The DCBE radiographer reported that failed colonoscopies requiring a ‘same-day’ DCBE in the second round were very infrequent and estimated that they had occurred at most once in 6 months.

MRI and CT body scan figures for the year July 2003 to June 2004 were 536 for MRI body scans and 6177 for CT body scans. Activity generated by Pilot FOBt positive patients unable to withstand colonoscopy or barium enema is a very small proportion of this total workload. Waiting times for these investigations at Walsgrave Hospital are quite short and this might account for few barium enemas being requested for screening patients as the consultants can get these more complex imaging techniques done in a reasonable time frame.

There was an indication from the endoscopist questionnaires that because of long waiting times for colonoscopy the use of DCBEs and flexible sigmoidoscopies as alternative investigations for non-Pilot (symptomatic) patients might increase. However this is unlikely to be directly related to the introduction of the Pilot.

8.2.6 Impact at George Eliot Hospital

Again, Pilot data for the first and second rounds were obtained from the Pilot databases. In the second round there were 14 DCBEs recorded compared to 35 in the first round. This is consistent with a radiologist’s report that there were much reduced numbers of DCBEs from the screening Pilot in the second round compared to the first. A corresponding reduction in administrative work was noted. A timesheet completed by a member of clerical staff in the radiology department for a two week period in December 2004 indicated that none of her workload in that time period was related to Pilot patients.

Annual activity data for DCBEs from April 2001 to March 2005 was provided by the radiology department and can be seen in Table 8.4.

Waiting times for DCBEs from 2002 onwards are shown in Figure 8.8. The waiting times are unlikely to be related to the Pilot with the small number of investigations involved, but it was acknowledged that screening patients add to the waits for barium enemas. Unlike in the first round, most Pilot DCBEs in the second round were booked rather than being on the same day as an incomplete colonoscopy. The same-day DCBEs are fitted in as extras and do not impact DCBE waiting times for symptomatic patients, however the booked Pilot cases are given priority appointments over routine non-Pilot patients and therefore might lengthen maximum waiting times.
8.2.7 Resources

Funding from the Pilot was provided to employ a radiographer and one session a week for a consultant radiologist at both hospitals. Because fewer radiological investigations than anticipated were required this level of funding is being reviewed.

Both radiologists declared little knowledge of the resources actually allocated, but felt that radiology services in general should be better resourced and in particular this should happen before a national bowel cancer screening programme is introduced.

It was commented that there was a problem filling vacant radiology and radiography posts at George Eliot Hospital.

8.2.8 Discussion

There has been less demand for radiology services from screening patients in the second round of the Pilot and, as the level of demand was already low in the first round, this has had little impact on radiology workload.

8.3 Surgery

8.3.1 Background

Hospital surgical services are affected when screening participants are found to require surgical treatment. The evaluation of the first round of the Pilot recognised that there were at least initial (and possibly sustained) increases in the requirement for surgical services.

8.3.2 Aims

The aim of this section was to consider the number of surgical cases generated by the screening Pilot in the first and second rounds compared to the number of non-Pilot cases, and to discover how the impact of the Pilot was perceived by staff involved with surgical care.

8.3.3 Methodology

The West Midlands Cancer Registry provided data on the number of colorectal cancer cases that were treated with surgery at Walsgrave and George Eliot Hospitals from 1998 to 2003. The number of Pilot patients who had surgery was obtained from the Pilot database. Non-Pilot workload was estimated by subtracting Pilot work from overall work. Semi-structured interviews were undertaken with colorectal surgeons and a colorectal nurse specialist at each hospital.

8.3.4 Activity data

Second round database figures indicated that 41 Pilot patients from Coventry Teaching and Rugby PCTs required colorectal surgery and this is assumed to have taken place at Walsgrave Hospital. Similarly, 14 patients from North Warwickshire PCT required colorectal surgery, and this is assumed to have happened at George Eliot Hospital. These data were more recently revised to give an overall total of 57 colorectal operations required for second round patients. Of these, 49 had a diagnosis of colorectal cancer.

In the first round of the Pilot there were 68 operations at Walsgrave Hospital and 28 at George Eliot Hospital. West Midlands Cancer Registry data has been used as a comparative overall figure although this will underestimate the number of comparable operations, as non-cancer...
operations are not included. The first round operations represented an approximate increase of 20% and 18% above the non-Pilot cases at each hospital. A similar percentage for the second round cannot be calculated without further data from the West Midlands Cancer Registry.

The number of operations, both Pilot and non-Pilot cases, at Walsgrave and George Eliot Hospitals can be seen in Figures 8.9 and 8.10. The impact of the Pilot in 2000 was very small, with only one operation being performed at Walsgrave and none at George Eliot Hospital. A limited comparison can be made of the number of operations in the years 1998 – 2000 with 2001 and 2002 when the Pilot was active, and it does not appear that the overall number of operations for colorectal cancer was greater in these years than in previous years at either Walsgrave or George Eliot Hospitals.

### 8.3.5 Qualitative data

It was thought by all interviewees that the hospitals have had to treat a larger number of colorectal cancers because of the introduction of the Pilot. The costs associated with this (staging investigations, surgery, in-patient care) have been absorbed by the Acute Trusts and although most cases would need to be treated eventually it was thought there would be some people who would never have become symptomatic or required treatment before they died of other causes.

One surgeon thought that on average an extra operating list per week was required at his hospital because of the screen detected colorectal cancer cases. Another surgeon commented that although the Pilot had generated extra workload this was shared between several surgeons and it was not a problem.

One interviewee thought that on average about one new screening patient a fortnight was presented at the multi-disciplinary team meeting. The extra work had not caused a noticeable increase in pressure of work.

> ‘I do think whatever impact it has on our workload now it’s going to be worth it to try and catch as many early ones as we can. That’s our philosophy.’ (ID 11)

The number of cases of colorectal cancer diagnosed is expected to eventually return to close to earlier levels. How to manage the changes within the surgical workload was thought difficult to determine currently because there are other background changes such as the number of colorectal surgeons employed at any time and changes in treatment protocols for other diseases – for example haemorrhoids being treated as day cases – that would need to be considered.

One impact of diagnosing screening cancers was thought to be that non-urgent, non-cancer operations were delayed longer and these patients also had to wait longer for consultations and diagnostic tests as well as treatment.

> ‘I guess it impacts on patients because people with benign disease tend to get pushed further back I believe, and it is more difficult because surgeons are filling their lists with the cancers which have to have the priority, other cases do have to wait.’ (ID 11)

Another impact mentioned was the extra out-patient clinic work generated for surgeons.
All the interviewees were positive about screening for colorectal cancer and staff have accommodated the extra work knowing that they are dealing with earlier stage cancers which is of benefit to their patients.

‘it would be a very funny surgeon that wouldn’t want to be presented with early cancers.’ (ID 17)

8.3.6 Discussion

Data from the West Midlands Cancer Intelligence Unit did not show a marked increase in surgically treated cases of cancer at either hospital during the first round of the Pilot compared to previous years. However, it has been difficult to obtain detailed information regarding overall surgery figures and those used are only a proxy and their accuracy uncertain. Hospital staff perceived an increased workload which is to be expected and without more accurate data it would be inadvisable to assume otherwise. Staff also noted increased waiting times for non-urgent operations patients and the need for the provision of extra operating and tumour staging services.

There have been fewer surgical operations required for screening patients during the second round as would be expected in an incidence round compared to the prevalence round.

Despite their perceived increase in workload staff were very positive about the benefits of the screening Pilot. This enthusiasm should not be misused and local resourcing issues might need to be addressed at individual hospitals to cope with an increase in, for example, out patient, clerical or clinical workload, but this would depend on current resourcing levels of these services.

There are important training implications in a national trend towards earlier stage diagnosis; surgery on the ‘early’ cancers is often performed with different aims and outcomes to later stage presentations.

8.4 Pathology, radiology and surgical workload for Pilot and national bowel cancer screening programme age groups

Table 8.5 shows the number of biopsy and polyp specimens, resections, operations and DCBEs (from both hospitals) generated in each round of the Pilot for ages 50-69 years and ages 60-69 years only. These figures differ slightly from those reported in the pathology resection sections in this chapter as these figures were updated recently. Figures are also shown scaled to a screening population of 100,000. It should be noted that surveillance colonoscopy specimen figures are not included, and that any change in uptake or test sensitivity will have an impact on the figures.
Table 8.1  Biopsies/polyps sent to pathology from Pilot colonoscopies

<table>
<thead>
<tr>
<th></th>
<th>George Eliot</th>
<th>Walsgrave</th>
<th>Warwick</th>
<th>Walsgrave + Warwick</th>
</tr>
</thead>
<tbody>
<tr>
<td>First round</td>
<td>351</td>
<td>799</td>
<td>655</td>
<td>1454</td>
</tr>
<tr>
<td>Second round</td>
<td>247</td>
<td>1024</td>
<td>56</td>
<td></td>
</tr>
</tbody>
</table>

Table 8.2  Number of Pilot resections

<table>
<thead>
<tr>
<th></th>
<th>George Eliot</th>
<th>Walsgrave</th>
<th>Warwick</th>
</tr>
</thead>
<tbody>
<tr>
<td>First round</td>
<td>27</td>
<td>66</td>
<td>27</td>
</tr>
<tr>
<td>Second round</td>
<td>16</td>
<td>40</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 8.3  Pathology workload (Pilot and non-Pilot) in the period when Pilot activity was most stable

<table>
<thead>
<tr>
<th></th>
<th>Biopsies and Polyps</th>
<th>Resections</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pilot – initial cols</td>
<td>Pilot – initial cols</td>
</tr>
<tr>
<td></td>
<td>Pilot Surv-ence</td>
<td>Non-Pilot cols</td>
</tr>
<tr>
<td>UHCW</td>
<td>748</td>
<td>74</td>
</tr>
<tr>
<td>George Eliot</td>
<td>168</td>
<td>19</td>
</tr>
</tbody>
</table>

Table 8.4  George Eliot Hospital overall DCBE activity

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Examinations</th>
<th>Pilot Examinations</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2001 - March 2002</td>
<td>846</td>
<td>14</td>
</tr>
<tr>
<td>April 2002 - March 2003</td>
<td>762</td>
<td>18</td>
</tr>
<tr>
<td>April 2003 - March 2004</td>
<td>1389</td>
<td>6</td>
</tr>
<tr>
<td>April 2004 - March 2005</td>
<td>585</td>
<td>8</td>
</tr>
</tbody>
</table>
Table 8.5 Summary of Pilot workload figures

<table>
<thead>
<tr>
<th></th>
<th>Workload population</th>
<th>Biopsy or polyp specimens</th>
<th>Resections specimens</th>
<th>Operations</th>
<th>DCBEs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Round</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age 50 - 69</td>
<td>Actual</td>
<td>124586</td>
<td>1150</td>
<td>93</td>
<td>96</td>
</tr>
<tr>
<td></td>
<td>Scaled</td>
<td>100000</td>
<td>923</td>
<td>75</td>
<td>77</td>
</tr>
<tr>
<td>Age 60 - 69</td>
<td>Actual</td>
<td>50815</td>
<td>654</td>
<td>63</td>
<td>63</td>
</tr>
<tr>
<td></td>
<td>% of 50-69</td>
<td>41</td>
<td>57</td>
<td>68</td>
<td>66</td>
</tr>
<tr>
<td></td>
<td>Scaled</td>
<td>100000</td>
<td>1287</td>
<td>124</td>
<td>124</td>
</tr>
<tr>
<td><strong>Second Round</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age 50 - 69</td>
<td>Actual</td>
<td>124477</td>
<td>1271</td>
<td>59</td>
<td>59</td>
</tr>
<tr>
<td></td>
<td>Scaled</td>
<td>100000</td>
<td>1021</td>
<td>47</td>
<td>47</td>
</tr>
<tr>
<td>Age 60 - 69</td>
<td>Actual</td>
<td>52099</td>
<td>772</td>
<td>45</td>
<td>45</td>
</tr>
<tr>
<td></td>
<td>% of 50-69</td>
<td>42</td>
<td>61</td>
<td>76</td>
<td>76</td>
</tr>
<tr>
<td></td>
<td>Scaled</td>
<td>100000</td>
<td>1482</td>
<td>86</td>
<td>86</td>
</tr>
</tbody>
</table>
Chapter 8: Impact on Hospital Services: Pathology, Radiology, Surgery

Figure 8.1

Walsgrave Hospital: Total Histology Workload

<table>
<thead>
<tr>
<th>Year</th>
<th>Pre-Pilot</th>
<th>Pilot - 1st Round</th>
<th>Pilot - 2nd Round</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Increase:</td>
<td>1999  6.97%</td>
<td>2001  2.78%</td>
<td>2004  5.82%</td>
</tr>
<tr>
<td>Blocks:</td>
<td>4.66%</td>
<td>3.72%</td>
<td>5.12%</td>
</tr>
<tr>
<td>Requests:</td>
<td>0.94%</td>
<td>4.84%</td>
<td>3.40%</td>
</tr>
</tbody>
</table>

Number of Requests

Number of Blocks

Chapter 8: Impact on Hospital Services: Pathology, Radiology, Surgery

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Figure 8.2

Walsgrave Hospital - Average number of monthly biopsies by quarter

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Average number of Non-Pilot biopsies by month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre Pilot</td>
<td>196/month</td>
</tr>
<tr>
<td>Pilot - 1st Round</td>
<td>170/month</td>
</tr>
<tr>
<td>Pilot - 2nd Round</td>
<td>145/month</td>
</tr>
</tbody>
</table>

NB. The figures here exclude terminal ileum biopsies and Warwick biopsies examined at Walsgrave.

Chapter 8: Impact on Hospital Services: Pathology, Radiology, Surgery
Figure 8.3

Walsgrave Hospital: Average number of monthly resections per quarter

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Pre Pilot</th>
<th>Pilot - 1st Round</th>
<th>Pilot - 2nd Round</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average non-pilot cases</td>
<td>= 26 / month</td>
<td>= 22 / month</td>
<td>= 26 / month</td>
</tr>
</tbody>
</table>

Chapter 8: Impact on Hospital Services: Pathology, Radiology, Surgery
Figure 8.4

George Eliot Hospital: Average number of monthly biopsies by quarter

Pre Pilot
Average number of Non-Pilot biopsies = 77/month

Pilot - 1st Round
Non-Pilot ave. = 84/month

Pilot - 2nd Round
Non-Pilot ave. = 81/month

Chapter 8: Impact on Hospital Services: Pathology, Radiology, Surgery
Figure 8.5

George Eliot Hospital: Average number of monthly resections per quarter

- Pre Pilot
  - Average non-pilot cases = 9.1 / month

- Pilot - 1st Round
  - Average non-pilot cases = 8.0 / month

- Pilot - 2nd Round
  - Average non-pilot cases = 7.9 / month

Chapter 8: Impact on Hospital Services: Pathology, Radiology, Surgery
Figure 8.6

UHCW: DCBE Activity

- Coventry Activity
- Rugby Activity
- Pilot Activity

Chapter 8: Impact on Hospital Services: Pathology, Radiology, Surgery

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Figure 8.7

UHCW: DCBE Waiting Time

Pilot - 2nd Round

Chapter 8: Impact on Hospital Services: Pathology, Radiology, Surgery
Figure 8.8

George Eliot Hospital: Barium Enema waiting times

Year / Month

Waiting Times (weeks)

Urgent  Routine

Pilot - 1st Round  Pilot - 2nd Round
Figure 8.9

Walsgrave Hospital: Overall colorectal cancer surgery and Pilot surgery

Chapter 8: Impact on Hospital Services: Pathology, Radiology, Surgery
Figure 8.10

George Eliot Hospital: Overall colorectal cancer surgery and Pilot surgery

![Graph showing colorectal cancer surgery and Pilot surgery](image-url)
9. Warwick Case Study

Chapter Summary

- The decision by South Warwickshire General Hospitals NHS Trust not to participate in the second or third rounds of the Pilot was based on concerns about their ability to provide sufficient colonoscopy capacity for their overall colonoscopy demand, both at that time and in the future, without sufficient planning and time to implement measures to improve colonoscopy provision within the endoscopy unit.

- A decision was made to concentrate on creating a sustainable, high quality endoscopic service which could integrate screening work in the future without disadvantaging non-screening patients.

- The issues around colonoscopy at Warwick are similar to those at the other hospitals involved with the Pilot. The main problem was keeping the waiting time for both non-Pilot and Pilot colonoscopies within acceptable levels.

- The experience of Warwick Hospital emphasises the importance of existing colonoscopy/endoscopy services being efficient and coping with demand before a screening element is added to the workload.

- The introduction of a colorectal cancer screening service requires managerial commitment and support, both financial and organisational, to ensure existing services are protected and staff morale undiminished.

- Important factors indicated for improving the capacity of the department included sufficient colonoscopists, good equipment, a skilled department administrator, central booking and pooled lists, and a commitment from endoscopists to minimise all waiting lists.

- The issue raised regarding waiting time targets for surveillance colonoscopies is important. Unless there are national waiting time targets for all colonoscopies (including surveillance colonoscopies) those without targets risk being given a lower priority when demand is greater than capacity.

9.1 Introduction

The South Warwickshire General Hospitals NHS Trust participated in the first round of the Pilot, but declined the invitation to participate in the second round. Understanding the reasons behind this decision has the potential to provide useful information about the impact of the Pilot on hospital services and inform planners of the national programme for bowel cancer screening.

9.2 Aims

To determine the reasons for South Warwickshire General Hospitals NHS Trust deciding not to participate in the second round of the Pilot.
9.3 Methods

Semi-structured interviews (face-to-face or by telephone) were held between March and August 2005 with the endoscopy unit manager, the colorectal surgeon with a dedicated screening session in the first round of screening, the regional clinical lead for endoscopy and a director in the Trust. These data are supplemented by the opinions of three other endoscopists who completed postal questionnaires.

Unit colonoscopy numbers and information about extra endoscopy sessions were obtained from the Endoscopy Unit Manager. Pilot colonoscopy and surgery numbers were obtained from the first round Pilot database using the workload population (Warwick) (see Glossary, Appendix 1). The total number of operations at Warwick Hospital for colorectal cancer was obtained from the West Midlands Cancer Intelligence Unit.

A telephone interview was held with the Director of the Pilot and further background information obtained from a Warwick Hospital document describing the outcomes of the Pilot.27

9.4 Background information

The Clinical Effectiveness Department at South Warwickshire General Hospitals NHS Trust summarised the local findings of the Pilot at Warwick Hospital.27 Despite problems of more surveillance work being generated than anticipated and non-Pilot colonoscopies being displaced for screening colonoscopies, the benefits of detecting earlier stage colorectal cancers were thought to outweigh this and continuing with screening for colorectal cancer was recommended.

It had been estimated that six colonoscopies a week would be required for the Pilot and funding was provided to resource two consultant colonoscopy sessions. The hospital chose to provide for these screening colonoscopies by running one dedicated colonoscopy session, of four colonoscopies, for the Pilot each week, and spreading the other two colonoscopy slots for the Pilot within the sessions of two of the four other Pilot colonoscopists (two surgeons and two physicians) each week. In practice these colonoscopies were unevenly distributed and one consultant carried out 38 colonoscopies, the equivalent of about 10 sessions which would otherwise have been available for his non-Pilot patients, in the 27 month period. A new consultant post was created and the dedicated session built into its job description.

The surveillance requirements resulted in a significant number of booked colonoscopies for the new consultant from 2004 onwards leaving little space for non-Pilot work.

Two issues arose with the sessions. Firstly, the loss of Monday sessions because of Bank Holidays was substantial, and secondly, the sessions ran over time on 22 occasions which had an impact on the afternoon sessions as well as the consultant’s afternoon commitments.

Seventy one bed days were utilised as a consequence of the screening colonoscopies. It was reported that the original business case underestimated nursing and administrative requirements.

Two changes that were taking place in the hospital at the time of the Pilot were the appointment of a new Chief Executive and the introduction of an upgraded endoscopy unit.
9.5 Activity data

9.5.1 Colonoscopy

During the first round 422 Pilot colonoscopies took place at Warwick Hospital.

The total number of colonoscopies performed annually for selected years from 1996 is shown in Table 9.1. These range from 549 in 1998/9 to 1139 in 2001/2, and although there is not a linear progression the general trend is upwards.

Extra sessions to reduce non-Pilot waiting times occurred in 2000/1 (15 extra sessions), 2001/2 (31 extra sessions), 2002/3 (15 extra sessions) and 2003/4 (9 extra sessions). This contributed to the large increase in colonoscopy numbers in 2001/2002 along with the addition of the Pilot work.

More detailed monthly figures incorporating the Pilot figures can be seen in Figure 9.1.

From November 2000 to January 2003, when the screening colonoscopy numbers were fairly consistent Pilot colonoscopies increased the non-Pilot monthly activity by 3% to 46% (average 24%).

Data on waiting times were not available.

9.5.2 Surgery

There were 34 operations at Warwick Hospital between October 2000 and December 2002 for cancers detected by screening. Annual surgery activity data for 1998 to 2003 can be seen in Figure 9.2 and ranged from 95 to 119 operations. It can be seen that the additional surgical cases in the first two full years of the bowel cancer screening Pilot, 2001 and 2002, increased the number of colorectal cancer operations to a level greater than in the three previous years.

9.6 Qualitative data

All the colonoscopies in the South Warwick Hospitals NHS Trust are performed at Warwick Hospital.

The resources provided by the Pilot were used to partially fund a new consultant surgeon post which included one session a week dedicated to Pilot colonoscopies in the job description. The hospital agreed to carry out six screening colonoscopies each week which was the number estimated for the size of the screening population. Four slots were available in the 4 hour dedicated session and two other slots for screening colonoscopies were provided each week, distributed between the four other colonoscopists (2 surgeons and 2 physicians) in the unit. As well as the dedicated screening session there were nine other GI sessions (which included flexible sigmoidoscopies and upper GI work) each week, so screening was a small part of the overall department workload.

All five colonoscopists were funded by the Pilot to attend the training course at St Mark’s Hospital, Harrow. It was believed that integrating screening into the work of the endoscopy unit by sharing the workload of screening generated colonoscopies was important in order to:

• ensure the continuity of the screening programme if one colonoscopist left or was absent for a protracted period, for example on sick leave
• improve the quality of colonoscopies across the unit
• generate a sustainable programme

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'Our feeling as clinicians is that we are committed to screening, but we’re committed to doing screening in a way that makes us comfortable in terms of the quality assurance but, moreover, is sustainable on an organisational footing.'  (ID 1)

Another overriding principle was that the service for symptomatic patients should be equal to that of the screening patients.

In practice Warwick Hospital had a mixed experience of the first round of the bowel cancer screening Pilot.

9.6.1 Benefits of participating in the bowel cancer screening Pilot

There were several positive experiences from participating in the first round of the Pilot.

Firstly, the colonoscopists felt their skills had improved because of the volume of work and the two day training course at St Mark’s’s Hospital where a lot was learnt about colonoscopy and colonoscopy techniques. Subsequently, completion rates improved.

The whole team in the endoscopy unit benefited from being involved with the screening Pilot and became better at managing and dealing with big polyps, bleeding polyps, snaring, tattooing, etc. The increased rates of pathology also made the work more interesting for the nursing staff as well as increasing the skills of the operator.

'And I noticed, over the very short period of time, how skills improved and things became slicker and teams worked together better. I mean, the nurses enjoy this as well because it brought a whole new dimension to the work that we did. We were, you know, a lot more involved with the procedures; there were far more interesting, different bits and pieces. As equipment became available I was bringing in new pieces of equipment as well, like the clipping devices and the endo-loops, so we were extending our skills as the doctors were expanding theirs - so from a personal perspective it was actually very interesting to get involved with and I know the nurses enjoyed working on those lists as well.'  (ID 2)

The experienced surgeon excised cancers endoscopically and although this could take longer than by resection, the recovery time was much shorter, not requiring an overnight stay in hospital.

Secondly, the quality of screening colonoscopies was thought to be high.

It was recognised that screening colonoscopies were different from symptomatic ones and more time had to be allocated to each examination. Screening colonoscopies were often longer because:

- there was a higher incidence of abnormality;
- the patient required reassurance that all their bowel had been examined and they did not have cancer;
- the work was more closely audited and completion rates were monitored;
- a good view of the whole bowel was needed because the lesions might be small and there were no symptoms to indicate their position or a different diagnosis;
• the patient was younger and could tolerate more. An older person’s bowel might be more susceptible to damage;

Screening colonoscopies changed professionals’ views of quality assurance from the patients' perspective. It was felt that because the screening patient had not sought medical help but had instead been brought into the hospital following a screening invitation, their experience should 'be acceptable' and 'patients should not be put through unnecessary discomfort'.

It was thought that patients were supportive of the Pilot because there were very few times when patients did not attend for their colonoscopy and they were appreciative of the good quality service.

Thirdly, these high quality colonoscopies led to an awareness of what was needed to give all patients a good experience and outcome from colonoscopy.

The staff believe that standards for the screening patients should be rolled out to everybody. Colonoscopies for functional bowel symptoms can also be challenging because of the sensitivity and irregularity of the colon. Since screening began 'the whole face of colonoscopy in England has changed quite significantly' (ID 1) through the Modernisation Agenda.

'I think one thing that’s changed in this country in the last five years is the recognition that a reasonable endoscopy list [of 4 hours duration] would comprise four or five colons and not more than that.' (ID 1)

Another benefit of the Pilot was that it raised awareness about the importance of colorectal cancer services among other staff in the hospital and created a drive to reform working practices by giving:

'some power to those of us .......... who wanted to change the way things were being done. Colleagues sat and looked and said ‘mmm, yes, maybe it is a good idea’. So I think it did actually help us progress.' (ID 1)

9.6.2 Disadvantages of participating in the bowel cancer screening Pilot

The main disadvantage was that it was found to be impossible to keep the waiting time for screening colonoscopies within the prescribed timeframe without disadvantaging symptomatic patients.

To keep the waiting time for screening colonoscopies within the prescribed timeframe, the endoscopy unit would have had, at times, to perform more screening colonoscopies than they had agreed to do. There was pressure from the screening unit to do this, but this would have meant increased waiting times for symptomatic patients and so was decided against. When the waiting time for screening colonoscopies became too long, screening invitations had to be suspended for a period of time.

'We were being pushed continuously to do more screening colonoscopies at the expense of anything else because it needed to be done to keep up with everybody else' (ID 3)

As well as the screening colonoscopies building up, there was also a problem with symptomatic colonoscopies. One questionnaire respondent commented that the main impact of the Pilot was a detrimental effect on the service provided for symptomatic patients because
there was insufficient capacity. An interviewee said that incorporating two screening colonoscopies into the regular sessions already meant the loss of two symptomatic patient slots each week.

'That’s 80 procedures a year that we were losing for NHS work that had been taken up for the Pilot and that’s a lot.' (ID 2)

Also, one consequence of the Pilot appeared to be an increase in referrals. Three interviewees and two questionnaire respondents thought that there had been an increase in the number of referrals after the Pilot had started. One person said a significant number of people, aged 50-69 years, who had a negative FOB test, sought medical advice from their GP because they had bowel symptoms and possibly also a family history. Many screened patients do have symptoms, although screening is designed to detect asymptomatic disease. It was also suggested that the increase was because people outside the screening age group had heard about the Pilot and decided to visit their GP as they were concerned about bowel symptoms they had. A majority of questionnaire respondents also indicated that the Pilot was in part responsible for the perceived rise in referrals.

This increase in referrals was considered both good and bad:

One interviewee expressed the opinion that meeting the health needs of the local population is the prime purpose of the NHS and changes in capacity need to be addressed to meet the demand (not the other way around). To accommodate people concerned about their bowel symptoms after reading the screening information leaflets, either GPs need to be trained to assess and filter patients or more staff should be made available in clinics.

'I think the heightening of awareness is a very good thing.' (ID 1)

Another interviewee was not so certain that this was a good thing.

'I don’t think that necessarily the population as a whole benefit from increased awareness of bowel cancer particularly, that’s my personal opinion, screening can save lives but people being generally more aware of it doesn’t necessarily save lives'. (ID 3)

In a more deprived area it would be a distinct advantage, but

'round here I’m not so sure it was, all it did was produce even more worried well people who pitched up wanting investigations even though they’re fine.' (ID 3)

It was acknowledged that the introduction of the two week standard also affected referral patterns and awareness so it was not easy to determine the exact impact of screening on referral rates.

There was also an increase in colonoscopies because of the growing number of surveillance colonoscopies added to the waiting list. Considering how this would increase over time caused concern about how screening colonoscopies could be sustained.

It was thought that surveillance colonoscopies for screened patients would cause an exponential rise in the number of colonoscopies over time. Polyps were found at about 75% of colonoscopies and these patients needed further scoping - occasionally 3 months later for large
polyps; some needing surveillance in a year; and most in 3 years. Also, any resections for malignancies that were detected needed surveillance. Many patients remain well until they are 90 years old and surveillance might be necessary until then.

’All you are doing is increasing your workload year on year on year and it never goes away.’ (ID 3)

The waiting time for a surveillance colonoscopy in April 2005, for the surgeon with the dedicated screening session, was about a year beyond the optimum date.

It was recognised that guidelines for surveillance colonoscopy have changed in the last 2 years and now less surveillance is recommended which would lessen this problem. The increased workload had been timetabled into the consultant’s job, but there was also an increase in administrative paperwork, phone calls about results, letters, etc. for the secretarial and support staff.

It was thought unlikely that the benefits of a screening programme (in reducing colorectal deaths) will produce a balance in workload within 10 years, and by then screening technology will probably have changed.

Screening patients also required more time to have the situation explained to them because screening work tends to generate more anxiety than in the symptomatic population who know they are unwell.

’somebody who comes to you with symptoms, especially if they are not very nice symptoms, which you then diagnose with serious disease quite often after that, are actually relieved that you’ve identified a problem and you’re going to do something about it. When you take somebody who was completely normal, still is completely normal, but has been told potentially they’ve got something seriously wrong with them by the nurse, then they have a colonoscopy and are told they’ve got cancer, it’s actually quite crushing and they get very much more uptight about the whole business and much more worried about it. Therefore screening patients generate a lot more phone calls etc. than people who are more relieved.’ (ID 3)

The Trust now employs two colorectal nurse specialists (there was only one during the first round of the Pilot) who work with patients who have cancer. This should help with the increased workload.

The pressure of audit on time to treatment was also an issue. It was difficult to fit the screen detected cancer patients into the normal pathway for cancer patients. In general the aim is to put patients through the system as sensibly and quickly as possible, giving the patients time to ‘get to grips with what is going on’. It was more difficult to do this with the screening patients - there was pressure for the hospital to get the patients’ CT scans and treatments started soon after the initial diagnosis because this was being audited. Ideally however, these patients should fit into the same pattern and timescales as non-screening cancer patients.

It was found that screening colonoscopies were more expensive than their symptomatic counterparts. Three new colonoscopes, which were needed because of the increase in

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colonoscopies, were funded through the Pilot. Also, one nurse session per week was funded, as well as consumables. However;

'as time went on we realised we were going to do more and more therapeutic work, with the knock on effect being the cost of all these accessories impacting on to budgets.' (ID 2)

As well as increasing the overall workload in an already busy department and increasing future workload because of the number of surveillance colonoscopies generated, another disadvantage of the Pilot was that the funding did not cover the extra costs incurred when a cancer was found (staging investigations and operations etc.). It is an additional surgical capacity pressure and changes might be necessary to ensure meeting targets. Also the funding did not cover the surveillance work and that is something that should be taken in to account when the screening programme is rolled out.

9.6.3 Decision to decline participating further in the bowel cancer screening Pilot.

The principal reasons that Warwick Hospital chose not to participate in further rounds (both second and third) of the Pilot were concerns about coping with surveillance colonoscopies and providing an equal service for screening and symptomatic patients.

'Our reservations were basically around the impact of imposing screening on a hard pressed department that was relatively under resourced, in terms of the negative impact that would have on the symptomatic workload.' (ID 1)

Instead, participating in the Pilot had made it apparent to the endoscopy unit what was required to be part of a screening programme, and currently time and resources are being put into providing these things.

'I think we have a greater responsibility to the local population to organise our service so that we can actually consider tendering a bid for the roll-out of the screening, and that if we took part in the Pilot that’s not necessarily going to facilitate us preparing our service to accommodate a sustainable screening programme long term'. (ID 1)

It was thought that concentrating on developing the colonoscopy service was a much more valuable thing to do for the community and the Trust rather than to take part in another round (second or third) of screening which would

'just ruin everything and wouldn’t tell us anything new.’ (ID 3)

They saw the aim of the Pilot being to determine uptake, costs and whether hospitals could provide the services. Since they found they were unable to maintain acceptable waiting times for colonoscopy for both symptomatic patients and screening patients they believed this demonstrated that they were not in a position to provide screening services, and if they continued to do so

- it would be thought that they could do it
- their whole service could fall apart
- the government would be getting screening ‘on the cheap’
- other units embarking on screening would be misled

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'We're not carrying on because all we're doing is basically ruining our normal service.' (ID 3)

'I think we categorically proved we couldn't do it.' (ID 3)

'The government would just say “well, they’ve done it so everybody else can do it; we only gave them 10p a patient, you can do it for 10p a patient”. So we said "no, we need to be absolutely sure about this - we can’t do it, we’ve tried and are gradually falling more and more behind, our other service is gradually getting more and more cramped so if we carry on doing it we’re just going to get worse and worse and worse".' (ID 3)

'We weren’t going to demonstrate anything different from what we demonstrated before by doing the third round. Apart from keeping up the screening it wasn’t going to tell us anything we didn’t know already. And secondly, we thought it was much more important we tried desperately to get ourselves in a position of having enough facilities and enough organisation within the whole Trust to cope with screening when it came in …… so that when we started doing it we had enough endoscopists, we had an endoscopy unit that was sufficiently good in training to do it, and that we had the facilities to manage the surveillance colonoscopies that were going to be generated afterwards'. (ID 3)

Clinicians were concerned that

'Involvement in the third round might amount to nothing more than a distraction.' (ID 1)

It was thought that the financial recompense offered for participating in the second round ‘wasn’t a big carrot’ and that it was important that the resources that are put in are sustainable. There was believed to be a short term-ism in what was offered to enable the hospital to continue with the Pilot and this was not acceptable because of the concern that the longer term implications (of the large numbers of surveillance colonoscopies) would not be met, and this would be detrimental to other services.

'That was our biggest worry because we’ve got a problem now with the surveillance colonoscopies already, and we only did it for two years, and so we said that unless there’s a sustainable, proper system put in place to manage the workload that is generated by screening over the years then there is no point in doing it because you just get more and more in a mess'. (ID 3)

The amount of money required to fund the screening service would be difficult to calculate, but it would be reassuring for the people involved in screening to know that it was being funded properly, but the way the resources were calculated or used by the Trust was never clear to the endoscopy staff.

Having had the time and Trust support to modernise the endoscopy services, as has been done since declining to participate in the second round, has made at least one staff member who originally thought that the hospital should continue in the Pilot, think that the decision not to
participate was the correct one. The endoscopy department believe they are now in a good position to tender for roll-out.

‘So we feel that, yes, the number of colonoscopies engendered by a screening programme could be taken on board, plus the potential knock-on effects of picking up polyps and putting patients on to surveillance programmes.’ (ID 16)

There are sufficient colonoscopists, the challenge is seen to be fitting them into appropriate sessions to get adequate through-put of patients per session and maximising session utility.

9.6.4 Moving towards an integrated screening and symptomatic endoscopy service

The decision was made at Warwick Hospital to put resources into colorectal services as this was believed to be a realistic area in which a district general hospital could excel. Less common, more specialised work is better provided at a larger hospital, serving a larger population, but the more common diagnostic services and treatments needed for bowel cancer are viable at a district general hospital and can provide a local service for their population. Several changes have already been made to modernise the endoscopy unit.

9.6.4.1 Accommodation:

The endoscopy unit moved into a newly equipped, well laid out unit just over 2 years ago and this is a great improvement on the old unsatisfactory accommodation. The working environment is believed to be very important for both the quality of work and staff morale. A comment was made that small hospitals may not have sufficiently spacious and modern accommodation for endoscopies. The new area includes a private room to talk to patients and a decontamination area with a full electronic patient/equipment/procedure/staff tracking system. Nurses found that screening patients have different requirements to symptomatic patients because it was a shock to patients, who had assumed they were healthy, to discover they had a positive screening test. Nurses had to spend more time with them.

‘Talking to these patients was quite different to patients that actually came to us through the normal system. They’ve actually had quite a shock and they needed a little bit more time and explanations, and the discussions and the questions that they were asking were a little different as well ..... it’s having a private area that you can actually talk to your patients in - that should be for anybody at any time. That really brought it home to us at how inappropriate it was where we were.’ (ID 2)

9.6.4.2 Sufficient endoscopists:

The hospital has increased the number of skilled colonoscopists who can remove polyps.

'We are very fortunate here, we’ve got three gastroentologists and five surgeons who all can colonoscope and that’s a huge number of consultants. In some hospitals of a similar size there are only two people who can colonoscope'. (ID 3)

9.6.4.3 Endoscopy equipment:

Improved endoscopy equipment has been installed. Twin channelled endoscopes were found to be invaluable because of the large amount of therapeutic work the Pilot generated.

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9.6.4.4 General medical equipment:

Good quality procedure trolleys, patient monitoring and emergency equipment, and reporting equipment - the endoscope processor and monitor should be of good quality – are now in place. Endoscribe software is used, although it is not ideal as it does not help with audit and appointments. A very good quality printer is required too, along with recording equipment.

'very occasionally patients can be lying on these trolleys for longer than two hours, and you need a good trolley that you can actually manoeuvre and is comfortable for a patient to be lying on for any length of time ...... we've got trolleys with nice thick comfy mattresses - it might not seem much, but for patient quality and support it's something that's important.' (ID 2)

9.6.4.5 Administration equipment:

A fax machine, an answering machine and computer are all necessary for communicating with the central screening unit and for general administration.

9.6.4.6 Department administrator:

An administrative lead has been appointed, and responsibility for the booking and scheduling along with the running of the department is moving towards being centralised.

To integrate a sustainable screening programme the following things are still thought to be required.

9.6.4.7 More qualified nursing staff:

9.6.4.8 Greater organisational back-up:

This includes IT and managerial support within the department to enable managing their own waiting lists. The Pilot had considerable audit requirements above the usual which require IT and clerical support. It would also be useful to be able to monitor the number of patients requiring extra care because of medical (e.g. diabetes) or social (e.g. no carer at home) circumstances.

'As a department we are under-resourced in terms of both staff and IT support for actually managing the workload.' (ID 1)

Once information was received from the screening unit in Rugby the appointments were written manually into a diary, and the appointment letter, patient information and bowel preparation medication sent to the patient.

9.6.4.9 Waiting list management:

Central booking, pooled lists, planned activity – setting up sessions in advance – are all thought to be necessary to improve the efficiency of the workload throughput. These are quite major changes to which there is some resistance and they are taking time to achieve.

Issues relating to waiting lists were highlighted.

a) It is often difficult to get the information required to manage a busy department.

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'Again I think unless you know how many people are on your waiting list you don’t know what your service requirements are and sometimes trying to get that sort of information out of the hospital IT system - and it’s not just for this hospital, but I think the waits set up generally - it’s very difficult and sometimes you’re hitting your head against a brick wall.’ (ID 2)

b) pooling of lists

Historically, the endoscopy unit was a place where individual consultants did their work and then went away again, but there is a move now to see the output of the department as a greater priority than the output of any one individual consultant. There are six or seven waiting lists and times at present (for different consultants), and the short-term aim is to get it down to just a medical and a surgical waiting list.

Each surgeon having their own waiting list makes it difficult to know how long the waiting times are. Pooling of lists would be a move towards equality of care and is believed to be critical in creating the desired structure of the department and to incorporate the screening colonoscopies in all the sessions. This will require consistency in the session structure (numbers in sessions) and performance of colonoscopists (completion rates, levels of sedation, and possibly in the future levels of disease detection (number of polyps in particular groups of patients etc.)).

Another advantage or consequence of pooling is to improve quality. This happens because endoscopists are aware that their performance is being monitored which naturally makes people perform at their highest level.

Putting screening patients into the proposed pooled colonoscopy system might be possible if the audit and reports required for screening could still be produced easily. This will require improved IT systems.

Questionnaire respondents were in favour of pooling of lists although one commented that having all patients on a pooled list might causes clashes between clinical need and screening targets.

c) There are no figures for surveillance waiting times – ‘there are no 'targets' for seeing surveillance/recall patients and it is difficult to establish how many patients are on the surveillance/recall lists’ - and these colonoscopies are delayed so that the waiting times that have government targets can be kept within the targets.

‘That concerns me in so much as these are patients who have got proven pathology, they’re on a surveillance programme for a particular reason - they’ve had a colon cancer, they’ve had a large polyp that was about to turn into something, they’ve got a Barrett’s oesophagus that again may develop into something - it may not but the possibility is there - but the targets, the pressure is on to get the patients in ..........and those [the surveillance colonoscopies] are the ones that can be pushed to one side and left and I don’t think that’s right.’ (ID 2)

d) Alternative management of surveillance colonoscopies was mentioned: one suggestion was that GPs could be responsible for their patients’ surveillance and could assess whether a
surveillance colonoscopy was appropriate given the patient's health and preference when their surveillance is due, rather than the endoscopy unit sending out an appointment etc. at the time.

'I think there needs to be some way of making sure that when they send for them again it's still the right procedure for that patient at that time and there needs to be a system in place to be able to make sure that that part of it is correct.' (ID 2)

e) Planned activity: setting up sessions in advance (even 3 years) so that you know you can cope with the workload generated. The government is keen on 'planned activity' and this is sensible.

'If the patient's got a date then they are actually more comfortable with that and can plan their life around it.' (ID 3)

f) The consultants’ surveillance waiting lists have been validated. This has involved updating individual patients’ surveillance requirements according to the most recent BSG guidance, checking against the deceased register and whether the patient still fit enough for a colonoscopy.

There was a mixed response to validation of waiting lists being a good idea or helping reduce waiting times from the three questionnaire respondents.

g) Centralised booking:
The booking of surveillance colonoscopies is now managed centrally and the colonoscopies are performed by any of the nine colonoscopists. This prevents staff who have been at the hospital a long time from having a much longer waiting list than more recent appointees.

h) Questionnaire respondents (n=3) were in general favourable of the following for reducing waiting times: pooling of lists, partial booking, validation of lists, more colonoscopies, more colonoscopists, more nurse endoscopists, more nursing staff, more rooms for endoscopy and improved IT systems. The following were not fully supported: waiting list initiatives, more endoscopists and more clerical support staff. One suggested that instead of extra rooms and colonoscopies, evening or weekend sessions could be introduced. One respondent commented that WLIs are probably not sustainable and could distort capacity and demand figures which would lead to poor planning. It was also thought that a consequence of WLIs might be an increase in staff sick leave.

9.6.4.10 More non-consultant grade endoscopists:
Nurse endoscopists, trainee registrars, technicians, or GP endoscopists could fill this role, and the questionnaire respondents agreed that nurse endoscopists or endoscopy technicians were a good idea. There is however, debate on how best to utilise non-consultant endoscopists. The decision to perform a colonoscopy and the expertise to deal with pathology that is found require medical knowledge, and one way forward might be for three technicians/nurses to be performing colonoscopies that have a low probability of pathology (e.g. surveillance), with one consultant covering them all to help out when and if necessary. They could also perform diagnostic gastroscopy and diagnostic flexible sigmoidoscopy freeing consultants to perform more colonoscopies.

There was however general agreement that nurse endoscopists could best fill this role because they have several other advantages. They could also train endoscopy nursing staff and
potentially improve recruitment and QA. They are thought to be proportionally more important to a smaller hospital

\[\text{‘because the added value that they bring to the department is that much more critical and I think every department should really aim to try and provide in-house training for a nurse endoscopist.’ (ID 1)}\]

A comment was made that organisations need to understand that endoscopy nurses are very specialised and it's not advisable to transfer their skills between day surgery units and endoscopy suites.

Trainees (SPRs and registrars) need to be trained in colonoscopy and as they are training they cannot be expected to put through a large volume of diagnostic service work.

GP endoscopists are very experienced in South Warwickshire, but do not have the flexibility to utilise the hidden capacity (vacant sessions when consultants are on call, study leave or annual leave) in the way that a nurse endoscopist within the department would do. The flexible work patterns of nurses would allow optimisation of the physical and professional resources. A questionnaire respondent commented that at Warwick the recent appointment of extra colorectal surgeons enables the surgeons to work more flexibly and back-fill some lists.

It was recognised that reorganisation of the unit, to improve performance, needs to have problems resolved and sorted from an endoscopy perspective, not by having solutions from other areas expected to work for them (e.g. partial booking).

\[\text{‘There are individual challenges and individual problems that need to be addressed within each department.’ (ID 1)}\]

9.6.5 Advantages and disadvantages of dedicated and mixed sessions

It had been estimated that there would be on average 6 screening colonoscopies a week; 4 would be on the dedicated session and the other 2 would be shared between the other 4 colonoscopists. Having a dedicated session worked well in general, but it overran quite often causing delays for the afternoon session. It was on a Monday and could not be utilised on Public Holidays. Also, the plan to have 2 screening colonoscopies in general sessions did not always work, so backlogs would occur and invitations to screening stopped while the unit caught up.

Most of the time the dedicated screening session was fully booked. A system was arranged with the screening unit whereby they would let the endoscopy unit know one week ahead if there were any vacant slots which were then 'back-filled' by the secretaries.

At Warwick, screening patients needed a different administration system - they were not put on the hospital PAS (Patient Administration System) system (believed to be because of coding and costing reasons) unless they were found to require treatment - and they had their own paperwork which was kept separately and required office space. A form was designed for each patient and the information collated into a report. IT support would have been appreciated to help set up processes.

From a managerial point of view it is easier to have a dedicated screening session as this makes monitoring and auditing the screening programme easier. It might be feasible to work with the IT department to build screening patients into the system in a way that would make it easy to
integrate the symptomatic and screening colonoscopies. At the moment, while the screening patients are not on the hospital PAS system, in a mixed session the staff can waste time and appear inefficient if they look for patient details on the system when they are not there.

One questionnaire respondent thought that keeping screening colonoscopies separate from symptomatic colonoscopies was preferable because they take longer and have a higher proportion of polypectomies. Patients also need extra support which can be given by the screening nurses. It is also easier to track patients through the screening system if there are dedicated sessions.

It would be possible to have separate screening staff and symptomatic staff, but in a small unit covering annual leave, study leave, sick leave, maternity leave etc. becomes difficult.

’If you’re running it as part of a much bigger unit where all are getting involved with doing it, then you can keep up the service even if there are glitches in the supply of staff. That’s what we’re trying to do at the moment - we’re trying to pool all the colonoscopy; we’re trying to pool the workload such that we continue to provide a regular number of colonoscopy lists every week even though the members of staff that are doing them are not always there every week.’ (ID 3)

This is much more flexible and

’it keeps the whole unit doing everything so the expertise levels are still high throughout the whole unit and you don’t have one set of nurses who can do difficult therapeutic endoscopies and the other set of nurses that are only used to doing upper GI endoscopies that are easy’. (ID 3)

9.6.6 Other suggestions and issues

Productive dialogue with the PCT could be useful in order to improve consistency and appropriateness of GP referrals (both within and outside the 2 week standard) and to examine the appropriate use of diagnostic FOB testing in primary care.

Another suggestion is to have a meeting of local endoscopy units, both those involved in screening and those not, to focus on the hurdles to integration. This could also benefit the screening unit.

One questionnaire respondent suggested that consideration of reducing existing services (such as diagnostic OGDs or flexible sigmoidoscopies) might be worthwhile in order to liberate capacity to accommodate the extra screening workload. The main reason for this would be to retain expertise, set local standards and ensure local quality control, as well as providing opportunities for training from within the local endoscopy unit.

Before applying to start in the screening programme it was thought that the most important thing to do is plan it very carefully to ensure that it is sustainable:

- Get the systems working well
- Validate waiting lists
- Have a centralised booking system
- Have an agreement that the work is distributed between several colonoscopists so that no one person is burdened with it

Chapter 9: Warwick Case Study
It is uncertain with the new commissioning system whether the PCTs will actually commission the surveillance colonoscopies from the hospital that is doing the screening colonoscopies.

‘In future, we will not decide in the hospital service what we will do. The commissioners will decide what they pay for. I think this is an issue that needs to be very carefully looked at ...’ (ID 16)

The standards that need to be achieved to be a screening centre or screening colonoscopist could be seen as being overly bureaucratic, and not worth the bother if there is a risk that the contract might be moved to another unit. On the other hand this future market could improve standards.

As well as changes in commissioning and the uncertainty that surrounds that for future planning, there may well be technological advances, such as high quality images produced by CT colonography, that reduce the need for colonoscopies. This has impacts on managerial decisions which need to be debated.

‘there may be advantages in investing in software and high-quality CT scanners .............. rather than employ 2 or 3 extra colonoscopists who may not be necessary.’ (ID 16)

9.7 Discussion

The staff at Warwick Hospital were very positive about the benefits of bowel cancer screening, both for the patients and for improving staff skill levels. The decision not to participate in the second or third rounds of the Pilot after their experience in the first round was based on concerns about their ability to provide sufficient colonoscopy capacity for their overall colonoscopy demand, both at that time and in the future. The demand for non-Pilot colonoscopies and Pilot surveillance colonoscopies was growing and the unit was already struggling to provide a timely service to keep waiting times acceptable. Despite new management appointments and a newly situated and upgraded endoscopy unit several staff believed that by continuing in the Pilot the situation would get worse and time was needed to consider the options available for increasing capacity and to implement the changes they thought would best achieve this in their unit. They wanted to be able to provide a sustainable, high quality endoscopic service which integrated screening work and did not disadvantage non-screening patients. With hindsight, one dissenter came to believe that this was probably the correct decision.

Several points can be highlighted from Warwick’s experience:

- Colonoscopy/endoscopy services need to be able to cope with existing demand before a screening element is added to the workload.
- The existing endoscopy service should be of a high standard, similar or equivalent to that required by the screening programme.
- Screening colonoscopy work should not impinge on the existing non-screening capacity.
- Spreading screening colonoscopies among several colonoscopists, and not to depend on a small number, is desirable to provide a sustainable service.
- The introduction of a bowel cancer screening service requires managerial commitment and support, both financial and organisational, to ensure existing services are protected and staff morale undiminished.
- The ‘knock on’ effects of screening (for example surgery or surveillance colonoscopies) need to be well estimated and the resources required for these secured.
Several of these issues are very similar to those discussed in Chapter 7. The main problem in all hospitals has been keeping the waiting time for both non-Pilot and Pilot colonoscopies within acceptable levels. After considerable discussion, management and staff at Warwick chose to withdraw from the Pilot as they felt that this was the best way to address the problem and to improve the systems within their endoscopy unit. There was a determination to manage the situation so that non-Pilot patients have a service comparable to the high standards provided for the Pilot patients. The other Pilot hospitals have found other ways to cope with the problem. As mentioned in Chapter 7 one hospital has now moved a screening colonoscopy session to early evening, and at the other hospital two extra screening sessions were commenced, one at another hospital within the Trust.

The expertise or knowledge of endoscopy units with experience of the Pilot is a rich source of useful information for other units considering participating in national roll-out. Providing a forum, such as a conference, for this to take place could be beneficial to endoscopy units interested in becoming screening centres.

Important factors indicated for improving the capacity of the department included sufficient colonoscopists, good equipment, a skilled department administrator, central booking and pooled lists, and a commitment from endoscopists to minimise all waiting lists.

Although not unique to screening work, issues raised regarding the use of IT systems for integrating administration and reporting of colonoscopies, and the sharing of information about available computer support systems between endoscopy units being helpful to smaller units are worthy of consideration in planning future services.

The suggested introduction of waiting time targets for surveillance colonoscopies is important. Unless there are national waiting time targets for all colonoscopies (including surveillance colonoscopies) those without targets are likely to wait longer if the demand for colonoscopies is greater than available capacity.

Including screening patients in pooled lists would require protocols to be put in place to decide how to prioritise patients with evident clinical needs along with asymptomatic screening patients.

Bowel cancer screening does increase workload – in particular, both colonoscopy and surgical – and the decision by South Warwickshire General Hospitals NHS Trust to decline the invitations to participate in further rounds of the Pilot has highlighted the importance of the extra resources, capacity and efficient systems required to meet the increased demand. It is preferable that this increased demand generated by screening is met whilst maintaining or creating an equal standard of service for non-screening patients.
Table 9.1. Yearly colonoscopy numbers at Warwick Hospital

<table>
<thead>
<tr>
<th>Year</th>
<th>Total number of colonoscopies</th>
<th>Pilot colonoscopies</th>
<th>Number of extra sessions - Waiting list initiatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1996 – March 1997</td>
<td>627</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>April 1998 – March 1999</td>
<td>549</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>April 2000 – March 2001</td>
<td>769</td>
<td>67</td>
<td>15</td>
</tr>
<tr>
<td>April 2001 – March 2002</td>
<td>1139</td>
<td>225</td>
<td>31</td>
</tr>
<tr>
<td>April 2002 – March 2003</td>
<td>898</td>
<td>129</td>
<td>15</td>
</tr>
<tr>
<td>April 2003 – March 2004</td>
<td>992</td>
<td>-</td>
<td>9</td>
</tr>
<tr>
<td>April 2004 – March 2005</td>
<td>898</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

NB First round screening Pilot activity began in November 2000 and stopped in February 2003. There were 4 screening sessions in 2003/4 that have not been included in the first round figures.
Chapter 9: Warwick Case Study

Figure 9.1

Warwick: Number of Colonoscopies Each Month

- **1998/1999**
  - Monthly average of Non-Pilot c'oscopies = 59

- **2000 Before Pilot**
  - Non-Pilot c'oscopies = 59/mnth

- **Pilot - 1st Round**
  - Non-Pilot c'oscopies = 63/mnth

- **Non-Pilot c'oscopies**
  - Non-Pilot c'oscopies = 76/mnth

- **Non-Pilot c'oscopies**
  - Non-Pilot c'oscopies = 60/mnth
Figure 9.2 Surgical cases at Warwick Hospital

Warwick: Surgically treated colorectal cancer cases per year

Chapter 9: Warwick Case Study
10. Conclusions and recommendations

Chapter Summary

- In this report we have highlighted important differences between the first and second rounds of screening.
- Low uptake is a very significant issue; FOBt screening appears to require on-going recruitment/awareness-raising efforts to maintain adequate levels of participation.
- Population sub-groups with low uptake are consistent in first and subsequent rounds of screening – particular efforts are needed in order to achieve satisfactory uptake in these groups.
- Positive rates and detection rates need careful monitoring to ensure adequate performance of screening.
- A careful analysis of existing services is critical for acute trusts embarking upon the programme. An integrated approach to the planning of incorporating screening work within the existing services is required, whilst dedicated funds are required for screening activity.

This evaluation of the second round of screening in the English Pilot has provided the opportunity of examining how screening could potentially operate beyond the first round once the programme is established in the UK. The evaluation has identified a number of issues which were not evident in the first round evaluation; this is not unexpected, since the dynamics of ongoing/periodic screening are different to those of a one-off prevalence type screen.

The screening centre and trusts involved remained the same with the exception of South Warwickshire General Hospitals NHS Trust which we have treated separately in the report. Screening continued with similar processes and test kits (HemaScreen). We have outlined in Chapter 1 some minor differences between the first and second rounds (e.g. those around dietary restriction and the fact that a small trial of an immunochemical test was performed in the second round).

Methods were essentially similar to those of the first round evaluation, and for the various uptake and outcome measures involved downloads of information from the pilot sites to the evaluators. We were able to link previous screening history to uptake and outcomes in the second round and this provided important new insights; in the second round, 15.9% of subjects were new invitees, mostly in the 49-51 year old age group. As most of South Warwickshire did not participate in the second round of screening, we needed to compare results on uptake and screening outcome with those for the first round once similar exclusions had been made.

10.1 Uptake

Clearly one of the key findings of this second round report has been the low overall uptake (51.9% versus 58.5% in the first round). This is not explained by differences in denominators, or by demographic differences, since comparable populations have been analysed in both rounds. Further, similar ‘low uptake’ groups were identified in both rounds; uptake was lower in men, younger invitees, those with higher levels of deprivation and those who belonged to...
areas with high proportions of people from the Indian Sub-Continent. A previous screening history of acceptance was a strong predictor of uptake in the second round (a common feature of cancer screening programmes); it was only 13.1% in previous non-responders. Low uptake was not confined to those being invited for a second time; uptake in new invitees was only 43.9%.

As we have indicated in Chapter 3, it is possible that this low uptake was due to differences between methods of promotion in the first and second rounds. When the UK Pilot was first established, there was a degree of promotion in local newspapers and other local media. However, this publicity was arguably not very intense and it is difficult to say with certainty that lower uptake was attributable to differences in publicity. It does, nevertheless, highlight the need for ongoing efforts to promote uptake in this form of screening; unlike cervical and breast screening, FOBt screening requires a relatively ‘active’ role in participants. They must complete a test kit and return it to a central laboratory. Further, as we have demonstrated in both the first round and second round evaluations, screening episodes are often prolonged, requiring re-testing in the case of equivocal results or spoilt test kits. The dynamics of ongoing participation and periodic screening where such an active role is required are possibly different to cervical and breast screening.

Consideration will need to be given in the roll-out process to devising ways of maintaining interest and motivation in a population which is asked to participate in this form of screening every two years. It is also worth noting that other forms of FOBt such as immunochemical tests are available and may be easier to use. The potential of such tests to produce higher levels of uptake, particularly in second and subsequent rounds of screening, warrants further exploration. The findings also reinforce the need to devise strategies which address low uptake in the subgroups which we identified. It would appear that these low levels in uptake persist in second and potentially subsequent rounds of screening in more or less the same pattern as that identified in the first round.

10.2 Continuation of screening in older people

Although people over 70 years of age were able to request an FOB test in the second round, few actually did so. It is known that many women above the upper age limit for invitation in the NHS breast screening programme wrongly assume that they are no longer at increasing risk of the disease. Consideration should be given to the information needs for this high risk age group to encourage those who may continue to benefit from screening to participate.

10.3 Uptake of colonoscopy

The process of referral to a nurse-led appointment following a positive FOBt continued in the second round. Amongst those who attended this appointment and were referred for colonoscopy, uptake of colonoscopy was 96.9% (compared to overall uptake of 82.8% in those with a positive FOBt outcome). We identified slightly higher levels of uptake of colonoscopy in FOBt positive individuals than we did in the first round. This may reflect better or more streamlined processes once positive individuals have been identified, although the results need to be treated with some caution because the mechanisms for recording reasons for non referral to colonoscopy were slightly different in the second round compared to the first. The process by which FOBt positive screenees are referred for colonoscopy needs to be monitored as roll-out of screening continues. Similar rates of successful colonoscopy were achieved and the predictors of uptake were similar to the first round, although in the second round there was no clear trend by deprivation.


Chapter 10: Conclusions and recommendations

10.4 Positive rates

The higher than expected overall positive FOBt outcome rate in the second round is a cause for some concern. Clearly the FOBt positive rate is the main driver for the rates of colonoscopy and this is one of the key workforce/capacity issues in FOBt screening. As we have discussed, there seemed to be little effect on the positive rate from the reintroduction of dietary restrictions. In considering possible causes for this increased positivity rate, increased rates of aspirin usage did not seem to be a likely cause. If an increase in positivity is due to differences in test characteristics (e.g. between batches) then this should be closely monitored and recorded.

One of the important findings of the first round evaluation was the high level of positive results which arose from initial weak positive tests. The potential for long and complex screening histories remains a factor in the second round and subsequent rounds of screening. We have looked at altering the threshold between ‘weak positive’ (1 to 4 spots positive) and ‘positive’ (5 or 6 spots positive). Changing this threshold (for example, by referring all patients with 3 to 4 spots for investigation) would lead to more investigations, and further reduce the predictive value of the test, but would reduce the length of the screening episode in around 15% of people referred, and potentially reduce the number lost to follow-up.

10.5 Detection of neoplasia

In conjunction with the high positive rates, we have also noted lower than expected detection rates of cancer and positive predictive values of a positive test for both cancer and adenoma. There was a drop-off in cancers detected in the second round (0.91 per 1000) which is not unexpected in an ‘incidence’ versus ‘prevalence’ round of screening. The detection rate for all neoplasia (both cancers and adenomas) remained stable. A similar pattern is likely in centres involved in roll-out of screening. Increasing positive rates coupled with falling cancer detection rates inevitably means that the predictive value for cancer of a positive test result is lower than in the first round. This needs to be considered when introducing screening in new regions. Positive predictive value is one of the most important markers in screening programmes; high rates of false positives lead to large numbers of investigations being undertaken on individuals on whom no pathology will be found. Ultimately this has an effect on cost effectiveness of screening. It will be important to monitor closely trends in positive rates over time as the programme rolls out; we have demonstrated that rates can vary considerably.

The second round data has allowed us to calculate the sensitivity of the FOBt used in the Pilot (Hemascreen). It was very similar to that observed in the Nottingham trial (it ranged from 57.7% to 64.4% depending on the reference population used). As always, there is a trade-off between sensitivity and specificity. FOBt screening using Hemascreen has the added dimension of needing to repeat many tests; this is an additional burden for invitees, and results in prolonged screening episodes for many. This underlines our previous recommendation to continue to look at the possibility of using different types of FOB tests which do not lead to such high rates of re-testing.

10.6 Impact of screening on health services

One of our key aims in this report has been to look at the impact of ongoing screening on key diagnostic and treatment services.

One of our major findings from the first round report centred on the impact of the screening Pilot on colonoscopy activity, and we noted increases in non screening activity as well as in
colonoscopy directly related to screening. This increase has not continued into the second round but maintaining acceptable waiting times has been challenging for the endoscopy units. Although we speculated that demand for initial screening colonoscopy might level off in the second round, this did not materialise.

In this second round report we emphasise the difficulty of ‘teasing out’ the influence of screening-generated colonoscopy activity on the prevailing trends. Much activity has been brought about by efforts such as service modernisation and training initiatives and there have also been other associated factors such as waiting list initiatives, and new clinics being started which have clearly had an important effect on parameters of impact such as waiting lists and activity.

As both the activity data and qualitative/questionnaire data have indicated, there is sometimes a complex relationship between screening, diagnostic and surveillance colonoscopies and many of these inter-relationships are described in the report. An organised approach will be required, one which can take account of these inter-relationships and recognise the inter-relatedness of organisational and financial aspects of these activities. National targets have been set for roll-out of the screening programme. While the possibility always exists for such targets to be temporarily suspended to accommodate local implementation issues, there is nothing in our report to support such an approach (indeed, stakeholders we have interviewed are generally in favour of a clearly-specified roll-out timetable, and there was strong commitment to the roll-out process). Equally, it is important that services for symptomatic patients are not compromised and the suspension of national targets for this group of patients is not indicated. Appropriate administrative structures are vital; ones which can adequately plan and allocate resources, taking this complexity into account.

10.7 Surveillance of individuals with potentially premalignant, screen-detected lesions

We have highlighted the importance of planning for surveillance colonoscopies. Colonoscopy services are frequently struggling to meet demand for symptomatic referrals. The recent decision by the NHS Bowel Cancer Screening Programme to bring management of screening surveillance colonoscopies into the screening programme will not reduce the number of colonoscopies required, but will reduce the administrative work in the endoscopy units and enable the impact of the surveillance workload to be more clearly determined. We note there is on-going uncertainty over optimal colonoscopy intervals for adenoma/polyp surveillance; there is a need for more evidence to achieve national consensus on this issue if screening-generated surveillance post roll-out is to be well planned, and incorporated into existing services.

10.8 Accommodating screening within existing services

Our report has highlighted the problems which arise when there are major discrepancies in waiting times between symptomatic and screening colonoscopy services. The conclusions that we can draw from both our activity and qualitative data are that before taking on a screening service, hospitals need to ensure that their capacity to provide endoscopy services is sufficient and that there are no pre-existing problems with extensive waiting lists, or other resource problems. It is also critical that good management and governance arrangements are in place; taking on FOBt screening requires careful planning at a local and regional level. Further, there are ‘market’ and other forces operating within health services which may work against the implementation of new screening programmes at a local level. Successful roll-out will be predicated upon co-operation and collaboration at local, regional and national levels. Local
service issues, and competition by providers and consumers of health services, can put constraints on this process.

It is likely that the Pilot is having a very positive effect on the quality of colonoscopy services and this is in keeping with the experiences from other screening programmes such as the breast screening programme. There is a similar although less important message for pathology in terms of ensuring that capacity is adequate prior to taking on further screening activity. Existing staff at all levels are keen to accommodate screening activity. In terms of radiology services, there has not been any difficulty in managing the small amount of work that screening investigations generated. It should be recognised that hospitals have absorbed the costs of staging and treating screen detected cancers.

There are important lessons to emerge from the experience in Warwick. Perhaps most important when it comes to colorectal services is that a bowel cancer programme needs to progress on several fronts which include early diagnosis, screening and improved treatments. It is incumbent on trusts and policy makers at a national level to invest adequately in all these areas. Clearly given a number of local factors at Warwick a decision was made to focus more on symptomatic/treatment services and for the time being forego screening. It is possible to see other hospitals and trusts reacting in similar ways if the appropriate organisational arrangements are not put in place prior to screening.

Whilst there are a number of generic lessons to be learnt about implementation of screening in various regions of the country, our findings highlight the importance of taking local factors into account. There needs to be a detailed analysis of existing and potential future capacity, particularly in critical areas such as colonoscopy services. There also needs to be adequate training and awareness-raising amongst health service personnel at all levels. It is important that key groups of individuals such as surgeons, pathologists, radiologists and support staff are on side if screening is to be successful.

It is important to note that some variation in practice was observed between the two hospitals involved in the Pilot: for example, in the proportion of people having biopsies taken at colonoscopy, and in the number of specimens collected from each colonoscopy. Such variation has implications for workload and for detection rates at these hospitals; we anticipate such variation will also be a feature of roll-out and should be monitored, and the potential impact on quality of service provision assessed regularly.

10.9 Plans for roll-out: relevance of our evaluation findings

As indicated in our report, there is now Department of Health guidance on implementation of the Bowel Cancer Screening Programme (see Appendix 8). Our findings have relevance to several elements of this guidance:

1. The model of programme hubs and local screening centres appears to be one which can accommodate the various recommendations we have made about implementation. Strategic Health Authorities are being instructed to consider endoscopy capacity, and to ensure that accreditation and quality criteria are met.

2. Engagement of PCTs – this will be vital in assessing local context. As our report illustrates, local factors such as management arrangements, equipment, and training and modernisation initiatives all profoundly affect the ability of a hospital and/or region to accommodate a new service such as bowel cancer screening. Participating PCTs are being encouraged to make such
assessments, and to ensure adequate public health input. They are also being encouraged to examine issues of uptake, particularly in ensuring equity of access to the programme.

3. The plans highlight the need for high standards of data monitoring through clinical and health indicators. It will be vital as the programme becomes established that the data necessary to evaluate uptake, test performance, adverse events, pathology detected and clinical outcomes are readily available. These should include where possible data from private practice. Our evaluation has highlighted considerable variation in important screening parameters such as uptake and positive rates – these have profound effects on the ability of a screening programme to reduce mortality, and close on-going monitoring will be needed. The involvement of cancer registries in providing data is also essential. In particular, liaison between the screening programme and cancer registries is essential for complete identification of interval cancers, and the most appropriate mechanism for this in the roll out needs further consideration.

4. Careful planning is being employed in establishing call and recall processes within the programme hubs. Our evaluation has highlighted the need for consistent and well-implemented policies and protocols, and this consistency is being encouraged in roll-out.

5. The role of programme hubs as ‘focal points’ for the programme, and as catalysts for research is also being encouraged. Our experience of conducting this evaluation with the Rugby Pilot site has highlighted the benefits of having a ‘research-friendly’ culture in these sites. A great many questions have been raised, and answered, during the course of the Pilot as a result of this attitude to research. The role of NHS Cancer Screening Programmes in developing appropriate research ideas (such as trialling of immunochemical tests and looking at invitation procedures) has also been important.

6. The role of local screening centres in promoting screening at a community level is also being advocated in the guidance. This will be critical, particularly in view of our findings of falling uptake rates between the first and second rounds of screening.

7. The guidance refers to a ‘local surveillance programme’ for individuals with potentially pre-malignant lesions, requiring on-going monitoring. This has been superseded by plans for the programme hubs to schedule surveillance colonoscopies on screening commissioned lists when they are due, and this change in management is supported by our findings that more detail and specification may be required here: surveillance colonoscopies require dedicated resources and planning.

8. Finally, we note that considerable effort is being invested in developing information materials, in conjunction with the CRUK Primary Care Education Research Group. This will likely require on-going effort, and there will be a need to develop tailored materials for individuals in low-uptake groups.

Hence, we consider the findings in this evaluation report to be of great relevance to the process of roll-out in the Bowel Cancer Screening Programme. Our intention has been to present our findings in a way which will facilitate their usefulness and uptake.
References


Appendix 1: Glossary of terms

Adenoma:
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.

Anal cancer:
Anal cancer refers to cancers of the anus and anal canal (ICD-10 code C21).

Bowel cancer:
Cancer registrations include cancers of the colon (ICD-10 code C18), rectosigmoid junction (C19) and rectum (C20). Anal cancers are excluded unless specifically mentioned.

See anal cancer.

Cancer:
A case of primary bowel cancer (including malignant polyps) identified by the screening unit in the population who are or have been eligible for screening and selected. Histological confirmation is not an essential requirement.

Census Area Statistics (CAS) Wards:
Census Area Statistics (CAS) wards were introduced at the 2001 Census to avoid the confidentiality risks of releasing data for very small areas. Unlike actual electoral wards they are required to meet certain minimum size. There are a total of 7969 CAS wards in England.

Further details can be found at:

Colonoscopy categories:
• Initial Screening colonoscopies:
Colonoscopies performed after a positive FOBT plus any repeat colonoscopies required as a result of these – for example, if there is poor bowel preparation.

• Surveillance colonoscopies:
Colonoscopies performed after a clinical decision is made, following the initial colonoscopy, that a patient would benefit from surveillance. Surveillance is usually recommended when adenomas have been removed at the initial colonoscopy and the patient is therefore at an increased risk of developing colorectal cancer.

Eligible/ineligible non-responders:
These terms were used to distinguish between two groups of non-responders. Ineligible were people for whom there was a reason recorded for why they did not respond (e.g. moved away, under treatment).

Further details can be found in Chapter 2 (2.5).
Episode:
An episode starts when an invitation is sent out and finishes when the FOBt is complete and any investigation following a positive FOBt outcome is complete. It may be ended prematurely by the patient not responding to a FOBt or not attending the investigation.

See FOBt outcome.

FOBt kit result:
The screening process in the Pilot used the Hemascreen kit to test for blood in faeces. The test kits have six spots. Two samples from different parts of the stool are put on the kit on three different days in order to complete the six spots on the kit. An unhydrated guaiac test is used to test each spot for occult blood.
- Negative result: no spots positive
- Weak positive result: 1-4 spots positive
- Positive result: 5-6 spots positive

FOBt outcome:
This term is used to describe the final result of the FOB tests carried out. The outcome may be positive, negative or incomplete when a person does not respond to a test. It encompasses the three phases of testing.

See Episode.

Initial Screening colonoscopies:
See Colonoscopy categories.

Interval cancer:
A cancer diagnosed following completion of screening (i.e. in an individual who has a screening result available) and before the date of next invitation which is not screen-detected. Note that this definition includes people who had further investigations recommended following a positive FOBt result but did not have them or did not complete them.

Neoplasia:
Includes:
- Invasive cancer or
- Malignant polyp or
- (Non-malignant) adenoma

Phases of Screening:
There are three phases of screening. The majority of people have screening completed in Phase 1.

- Phase 1: This starts when the first letter about screening is sent out and continues until receipt of first adequate test (or the episode is closed because of non-response). This phase may include tests done with dietary restriction for any other reason than a weak positive result.

A person with a negative FOBt result has their screening episode closed; someone with a positive FOBt result is invited for further investigation; and someone with a weak positive FOBt result progresses to Phase 2.
Appendix 1: Glossary of terms

- **Phase 2**: Phase 2 begins with a weak positive result and ends with a negative or positive result (or episode is closed because of non-response).

A person with a negative FOBt result progresses to Phase 3; and someone with a positive or weak positive FOBt result is invited for further investigation;

- **Initial screening**: embraces phases 1 and 2

- **Phase 3**: People who are initial weak positives and subsequently test FOB negative progress to Phase 3. 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.

A person with a negative FOBt result in Phase 3 has their screening episode closed; and someone with a positive or weak positive FOBt result is invited for further investigation.

The timing of Phase 3 changed during the course of the first round of the Pilot. Initially, Phase 3 began 3 months after the completion of Phase 2. Now it begins as soon as possible after the end of phase 2.

Any FOBt test performed in Phase 3 is called a Phase 3 re-test. Phase 3 is sometimes referred to as the *Early Recall* phase.

N.B. these three phases of screening are presented as a flow-chart in Appendix 2

**Polyp**
Polyps will be classified into three groups as follows:

- **Low**: 1-2 adenomas less than 10mm
- **Intermediate**: either 1-2 adenomas with at least one greater than 10mm or 3-4 adenomas all less than 1mm
- **High**: either 3-4 adenomas with at least one greater than 10mm or 5 or more adenomas.

**Restricted population**
In order to facilitate comparisons between rounds, a population was defined with certain exclusions (people in the immunological trial, people in South Warwickshire PCT) that were applied to the population for each round. The resulting populations are referred to as the restricted populations.

Further details can be found in Chapter 2 (2.4)

**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 positive FOBt outcome.

**Super Output Areas (SOA)**
Super Output Areas are a geographic hierarchy designed to improve the reporting of small area statistics in England and Wales that were developed for the Index of Multiple Deprivation. Three layers have been created to allow disclosure at different scales depending on the nature.
of the data. Each layer approximates to a minimum population size. The population size for
the lower, middle and upper layer are 1000, 5000 and 25000 respectively.

Further details can be found at www.statistics.gov.uk/geography/soa.asp.

**Surveillance colonoscopies:**
See Colonoscopy categories.

**Workload population:**
The number of people, aged 50 – 69 years, known to be registered with a general practitioner
in Coventry, Rugby or North Warwickshire Primary Care Trust and who were invited for
screening. The workload population is the basis of the Pilot data provided in Chapters 7 and 8
and differs from the restricted population used in Chapters 2 to 6 as it includes people who
were in the ImmunoTrial and it excludes people who were 49 years at time of invitation and
people registered with a general practitioner in South Warwickshire Primary Care Trust.

**Workload population (Warwick):**
The number of people, aged 50 – 69 years, known to be registered with a general practitioner
in South Warwickshire Primary Care Trust and who were invited for screening in the first
round. This workload population is the basis of the Pilot data provided in Chapter 9.
Appendix 2: Invitees’ progression through screening phases

- Normal Result
- Unsatisfactory Result
  - Sent and return another kit
  - Unsatisfactory Result
  - Investigation Begins
- Weak Positive (1-4 spots positive)
  - Enter Phase 2
  - Return kit
  - Unsatisfactory Result
  - Investigation Begins
  - Negative
  - Positive
- Strong Positive (5-6 spots positive)
  - Investigation Begins
- Normal Result
- Unsatisfactory Result
- Weak Positive (1-4 spots positive)
  - Enter Phase 2
  - Return kit
  - Unsatisfactory Result
  - Investigation Begins
  - Negative
  - Positive
- Strong Positive (5-6 spots positive)
  - Investigation Begins
Appendix 3: Colonoscopy Qualitative Data - Full Analysis

In this appendix we provide an analysis of the qualitative interviews with key staff in the endoscopy units, staff at the screening unit and managers at the hospitals; the timesheets given to clerical staff; and analysis from the questionnaire survey.

The findings have been categorised into four main topics of which three are related to the impact of the Pilot - additional workload, improved quality of colonoscopies and staff satisfaction- and one reports on issues relevant to the future organisation of screening colonoscopies within endoscopy units.

Additional Workload

The most obvious impact on endoscopy services was that the Pilot created additional work for departments that were already busy. The workload increased in several ways and for several reasons.

a) Screening colonoscopies
The most obvious impact on endoscopy services was that the Pilot created additional work for departments that were already busy. The introduction of Pilot colonoscopies, over and above the non-Pilot work, inevitably increased the departments’ workloads. One interviewee expressed the hope that the anticipated reduction in colorectal cancer incidence resulting from the removal of potentially cancerous polyps at screening would reduce the overall number of colonoscopies in the future.

Colonoscopies for the Pilot were commissioned and funded over and above the symptomatic work. However, not all staff were aware of this and there was some concern that symptomatic work was being displaced by the screening colonoscopies. One person commented that it was difficult to measure the hidden costs of the Pilot because patients who were displaced might be scoped on (more expensive) extra waiting list initiatives.

Colonoscopists performed the screening colonoscopies on top of their agreed work commitments and were remunerated for it. This was not the case for the support staff and so their perception of screening colonoscopies displacing symptomatic colonoscopies could stem from this.

There was agreement in general that screening colonoscopies take longer than symptomatic colonoscopies because of the amount of therapeutic work required to remove the polyps found, and the need to examine the whole bowel thoroughly. In the second round FOBt positivity unexpectedly remained at the same level as in the first round, but the amount of pathology at colonoscopy was less.

‘So we’re finding less polyps and less cancer, which makes the lists easier and makes us feel we’ve had an impact.’ (ID 17)

The reason for FOBt positivity remaining at the same level when it was expected to halve is not known. It is thought that fewer polyps are detected in an incidence round because there are fewer people taking part in screening for the first time.

Completion of forms for the screening database is extra work. This has been simplified and screening nurses can be helpful in filling in the forms.
However, it was also recognised that the Pilot had benefited at least one of the endoscopy units by enabling the unit to reduce routine waiting times by utilising unfilled colonoscopy slots in screening sessions.

b) Surveillance work
The adenomas found at screening colonoscopies require surveillance for an unknown length of time and were added to the list of people waiting for surveillance. This is a major issue - staff were concerned about the large increase in work generated by the surveillance colonoscopies.

One person commented that because people are being investigated before they have symptoms they may require surveillance for a longer period of time than they might otherwise.

At one hospital the colonoscopists thought it prudent to re-scope patients who had large polyps excised about 6 months after the initial colonoscopy. This had an impact on workload.

A few screening patients (estimated to be between 10 and 15) have contacted the screening unit as they have not been called for surveillance as promised.

One interviewee expressed the preference that surveillance colonoscopies for screening patients were managed by the screening unit and that their commissioned sessions were used to accommodate these colonoscopies. This has since happened and is thought to be a good thing.

Another interviewee commented that even without the Pilot there was a problem with fitting in non-Pilot surveillance colonoscopies because of lack of capacity.

‘it’s a problem now, rather than it’s a problem that is going to be caused by screening’ (ID 14)

The alterations to the length of time before surveillance in the most recent guidelines, introduced after the Pilot began, will mean that the additional workload will probably not be as great as initially anticipated.

It was also acknowledged by the colonoscopy related staff that the large number of polyps found at colonoscopy (both initial and surveillance) increased the workload for the pathology services.

‘The pathology work there is just enormous compared to a symptomatic population.’ (ID 8)

c) Increased demand for non-Pilot (symptomatic) colonoscopies

Anecdotal evidence suggested that the publicity about and introduction of the Pilot raised public awareness of colorectal cancer and its symptoms which led to an increase in people consulting their GPs and being referred to secondary care. It was suggested that there are parallels with breast cancer screening where, several years after its introduction, women talked more openly and without embarrassment about breast cancer.

Also, people who had tested FOB negative, but who had symptoms or a family history of colorectal cancer were also believed to be consulting their GPs. General increased coverage of bowel cancer, diets and bowel cancer symptoms in the media, and a change in dietary habits...
within the population that is more likely to lead to increased bowel problems was also believed to have caused an increase in referrals and need for colonoscopy services.

Other reasons given for an increase in symptomatic colonoscopies were the introduction of the two week standard and the increased use of the FOBt by GPs in a population where more and more people are using anticoagulants, thus increasing the rate of false positives.

Questionnaire respondents were more likely to attribute the increase in GP referrals to the introduction of the two-week standard for referrals, a change in GP referral thresholds or media influence than increased patient awareness of symptoms from the introduction of the Pilot.

This increased demand for services and the introduction of government targets to ensure minimal waits for diagnostic services for patients with suspected cancer has led to a move towards innovative ways of organising work within endoscopy services to improve capacity. The level of impact of the Pilot is debatable. One interviewee suggested that screening had little impact compared to national initiatives like the modernisation agency and the government priorities laid down in the cancer plan which have highlighted issues in endoscopy and radiology. However, the involvement of management in discussions about the Pilot raised the priority of the unit within management circles along with all the other things that have been going on.

‘I think that screening came along at the same time as very many things and probably has had some influence, but with screening it has not been as... if you miss a target for your cancer then you have to account for that - if you miss your target for screening then it’s not as accountable at the moment as it may be in the future. So although yes, it has an impact, it’s not one of the major ones I don’t think.’ ID 14

An audit in one hospital found that about one third of endoscopy potentially useable time in normal working hours was unused because of staff annual leave or study days and the failure of patients to attend appointments. Measures that have been considered or implemented to address this include phoning patients prior to their appointment to check that the endoscopy is still appropriate, pooling of lists, validation of lists, and increased use of nurse endoscopists to use spare session capacity when a colonoscopist is unable to take the session. Other initiatives include out-of-hours (OOH) working, partial booking, as well as waiting list initiatives. Waiting list initiatives are recognised as being expensive for the hospitals and hard work for the colonoscopists if they have 8 or 9 procedures in a day. Staff at one hospital saw the advantages of partial booking as being a) a reduction in the number of people who do not attend and b) the validation of waiting lists – people are removed if they do not respond to a second letter. Disadvantages included the use of a central call centre rather than unit clerical staff which has on occasions led to having sessions with no endoscopist or unfilled clinics. Endoscopists also find it inconvenient to give 6 weeks notice of annual leave, study leave etc..

Another example given or a way to improve an endoscopy unit’s efficiency was to create a better administrative structure in the department, for example, by employing an administrator to free up the nursing sister from administrative duties. Also the introduction in many endoscopy units of endoscopy users’ groups or multi-disciplinary teams running the department has led to change and improvements in the service. Traditionally surgeons and gastroenterologists put their own cases on their own waiting lists; these often have different waiting times and the multi-disciplinary approach to running a department can be useful in balancing out these waiting times and addressing the problem of unused capacity.
d) Increased waiting times for non-Pilot patients
The influence of the Pilot on non-Pilot workload is unclear.

One interviewee thought there was no noticeable impact on colonoscopy numbers during the second round of the Pilot. Another said that patients with less serious conditions have to wait longer for consultations, diagnostic tests and treatment.

At one hospital there has been a gradual increase in the number of people waiting for an initial endoscopy (including colonoscopy) over the past four years: in 2001 the number was approximately 500 people, in April 2005 it stood at over 700.

'which is a phenomenal amount and the capacity just doesn’t meet that demand. If we do a screening list a week as well I lose the capacity to do that so it puts it back again.' (ID 12)

It was thought, however, that meeting demand for colonoscopy was a problem nationally and that the impact of the Pilot had not been huge. One interviewee commented that the Pilot has added work to a very busy unit - 'it’s just extra work' (ID 12) -and thought it wrong that screening compromises the ordinary waiting list work as it has done.

Another reason given for the increase in the number of people waiting for colonoscopy was a lower number of colonoscopists available at certain time periods – either because of retirement or annual leave. When waiting times are long colonoscopists feel under pressure and there can be problems when they take annual leave.

‘there’s no slack for us to take [annual leave]’ (ID 19)

The length of time to wait for a Pilot colonoscopy can be kept within the standards set by adjusting the level of invitations sent out, and commissioning extra sessions if the demand exceeds that expected. This is not so for the symptomatic service and so it leads to ‘an obvious two-tiered element’ (ID 17) to the service with longer waits for symptomatic patients.

e) Clerical work
Clerical workload has increased for two reasons: firstly, because of the increase in demand for colonoscopy, and secondly, because once a person is booked for a screening colonoscopy the clerical staff add their details to the hospital computer system and post information and bowel preparation medicines to them.

The timesheets completed by clerical staff at one hospital suggested that this takes about half a day each week for first colonoscopies (not including surveillance colonoscopies) and unit staff agreed that this was a reasonable estimate of extra resources required. The impact on clerical workload was perceived to have been the same in both rounds.

f) Alternative investigations
Data from the questionnaires suggested that because of the long waits for colonoscopy more non-Pilot patients are being investigated by barium enema and flexible sigmoidoscopy at Walsgrave Hospital. Opinion about this was more divided in the other hospital possibly because of long waiting lists for Barium enemas. It was also suggested that in the future colonography might reduce the need for as many colonoscopies.
**Improved quality of colonoscopy service**

There was general agreement that an improvement in the quality of colonoscopy services within the departments was at least partially related to the introduction of the bowel cancer screening Pilot. Reasons for this improvement in quality stemmed from several things.

a) Raised profile
The Pilot raised the profile of the endoscopy department within the hospital enabling modernisation of endoscopy units to move forward.

At a national level the likelihood of a national bowel cancer screening programme has also heightened the profile of endoscopy services and the need to invest in a service, that it was felt, had not been sufficiently resourced and supported over the years.

> ‘Endoscopy services as a whole were really a Cinderella service which had been developed at each Trust, usually by an enthusiast, and usually with resources that ran behind the demand – as soon as it was set up the demand began to escalate and the resources never kept track.’ (ID 17)

As well as increased investment nationally another consequence of this heightened profile is that three national and six regional endoscopy training centres have been set up.

b) Extra resources
The funding for the Pilot was considered to be adequate and had paid for top quality colonoscopy training and extra equipment. Improved accommodation and more consultants, nurse practitioners and nurse endoscopists were also mentioned although not necessarily directly attributable to the Pilot.

c) Increased staff skills
The level of therapeutic work required in the screening colonoscopies along with the training provided increased the skill level of screening colonoscopists, which improved the quality of colonoscopy services throughout the unit as well as for the screening patients. The need to examine the bowel thoroughly and provide proof of completion ensured that staff consistently performed at their best.

d) Differing needs of screening patients
Because screening patients had been invited to participate in screening and had not approached the health services themselves it was felt to be imperative to provide a high quality service. It was also recognised that their need for colonoscopy came as a greater shock and required greater explanation than patients who already knew that they needed medical help because of their symptoms.

Screening patients differ from symptomatic patients because of the shock of discovering they have cancer when they thought they were healthy.

> ‘Sometimes it’s a little bit more of a shock simply because they feel so well. They’ve had no symptoms and they’ve done the test because they think it’s the right thing to do and then they’re quite shocked when actually something is found.’ (ID 11)
Screening patients were described as being well motivated and having a good understanding of what to expect after discussion with the screening nurse. The input of the screening nurses in this is very valuable. Also the patients are younger and in general have good bowel preparation.

A desire to maintain equity of service between non-Pilot and Pilot patients has helped to raise standards for non-Pilot patients.

**Staff satisfaction**

For several reasons relating to the introduction of the Pilot there was an increase in staff satisfaction.

a) The improvement in quality of service

b) Screening work has added another dimension to the endoscopy unit work
Nurses found that being involved in the Pilot gave them the opportunity to learn more and increase their job satisfaction. Close working relationships with the screening nurses was felt to be very valuable.

c) Staff could see the benefits of screening for patients and the hospital. Staff rated benefits to patients highly.

> 'They're not having to go down the lines of cancer treatment and big operations - it's a snare and a take off the polyp' (ID 10)

> 'We've certainly had a number of very early ones and that's wonderful because you do feel that you're making a difference.' (ID 11)

> 'It's giving the people of this city a great opportunity to be screened' (ID 11)

> 'The business of picking up cancers early is tremendous, it's very exciting after a lifetime of picking up cancers of the bowel late, quite often' (ID 17)

After the initial shock patients are relieved that the cancer has been detected and they have been treated whilst they are fit and able to cope with any surgery. Patients are keen to encourage other people to participate in screening. However, a concern was raised that people who have had a negative test think that they don't have cancer.

In addition it was thought that GPs were also positive about the benefits of the Pilot.

As well as benefits to patients, savings were realised for the hospital by detecting and treating cancers at an early stage when less expensive treatments were required. There was anecdotal evidence that there was a reduction in the emergency surgery for bowel obstructions and it is anticipated that there will be a reduction in the number of cancers diagnosed as a result of the removal of adenomas.

The Pilot was seen to raise the kudos of the hospital participating.
d) Research opportunities
The Pilot has uncovered a population of asymptomatic people who have tested positive for FOB and have been found to have polyps at colonoscopy. It is possible that in these people disease progression is different to previously studied populations and this can be studied. Anecdotal evidence was conflicting but one interviewee perceived that screened patients were more likely to have polyps at surveillance compared to symptomatic patients.

The detection of many more early stage cancers has, according to one interviewee, led to new and interesting discussions at the multi-disciplinary team meetings on what the best way is to manage these early cancers.

The Pilot does, and the National Programme when it is established will, provide an environment where new screening technologies (tests) can be assessed.

For the reasons given above, staff reported satisfaction with many aspects of the Pilot. However, a number of issues were a cause of anxiety for colonoscopy staff.

a) Concerns
Screening colonoscopies raise problems for colonoscopists when people known to have Crohn’s disease are sent for colonoscopy. Also the risk of causing damage to someone who was invited to screening, someone who had not sought healthcare, is a concern, and it is a problem to find a cancer and then tell someone they are not fit enough for treatment.

“That is one of the biggest problems, having unfit patients coming to your door who are FOB positive.’ (ID 19)

b) Lack of information
Problems could arise when staff were not fully informed about the introduction of the Pilot and how it worked or would affect existing work. One example of this is that there is a widespread belief that the Pilot reduces the number of slots for symptomatic patients. If this is so, it is because the local management have reduced the number of symptomatic slots – the Pilot was funded to be in addition to the existing workload. The introduction of screening sessions in the early evening instead of the normal working day is seen to be a solution to losing daytime capacity.

Where staff are expected to do more work without being involved in the planning there is potential for resentment which can make it more difficult to iron out the inevitable teething problems.

Issues relevant to future organisation of screening colonoscopies within endoscopy units

Many issues discussed by interviewees related to organisational factors. Those relevant to colonoscopy have been described in this section and considered in relation to the future national screening programme for bowel cancer.

- General
  It was thought that there will be a lot of decisions and plans to put in place for prospective screening centres. It was felt important that plans were well thought through, based on the best possible estimation of screening workload. As well as organising colonoscopy services for the screening programme, it will be important to ensure that the whole ‘corporate culture’ around
screening is attractive to people. The nurse-led clinics, as well as the endoscopy services, need to project an attractive image. At the Pilot clinic people are greeted and treated as individuals and plenty of time is allowed for a very sympathetically led interview. This is very necessary because people have been invited to participate and it is not fair to do that and then not provide an efficient service which minimises the anxiety created. People are often surprised by the individualistic way they are treated by the Pilot staff and do appreciate the thoughtful and timely service.

It was thought important to have one person in a unit who coordinates the screening services and that it might be preferable that the person is not medical - a nurse, manager or clerical person with knowledge of the finer details of organising the day-to-day work within the unit would be ideal. As time goes by this does not take up much time although it may take a considerable amount of time when screening is being implemented. Their responsibility would be to make sure that the screening is running smoothly and to be a contact person if the screening unit has any problems.

It was felt important that the decision making should include all staff who are likely to be affected, to allow them to have some input into and control over the introduction of the new service and in identifying and resolving problems that might arise.

- Learning from the Pilot experience
  It was strongly recommended that endoscopy units that become screening centres in the national screening programme for bowel cancer should learn from the experience of the Pilot. It was thought that the Pilot had been well organised and it would be efficient for new screening centres and units to follow the methodologies used in the Pilot, rather than developing their own systems.

The Pilot team, based in Rugby, are willing to explain what is involved in the screening process to people involved in the introduction of the screening programme in new areas, and hope that people will do this. An ‘Operations Manual’ is being prepared to facilitate this and workshops and other forum are intended in order to help with the planning of roll-out.

  ‘We [the Pilot screening unit] know what problems we faced – it would be like trying to reinvent the wheel if others don’t learn from what we’ve learnt.’ (ID18)

The transition for the Pilot hospitals to the national bowel cancer screening programme should be easier having had the experience of the Pilot which led to a more streamlined service in the second round. One interviewee thought that the two main issues for the transition at their hospital would be sufficient capacity for screening and non-screening work, and bringing screening within the consultants’ job descriptions.

  The only other problem I can see is building this other session in to the consultants’ workload, and obviously trying to fit it in with endoscopy capacity in the future. (ID 14)

- Integration of screening work within the endoscopy unit
  The importance of screening work being an integrated part of the work of the endoscopy unit was raised by at least two people.
‘……… it should be part and parcel, another referral source into that unit, rather than it being something special’ (ID 20)

However, another interviewee indicated that they thought it would be better if the screening unit managed all the screening work, while the unit provided the staff and usual support services for these colonoscopies.

These two opinions are not necessarily mutually exclusive and integration within the department will mean different things in different departments.

• Sustainable funding of colonoscopy for screening
In the Pilot colonoscopic work is done over and above consultants’ contracted work. Consultants therefore receive a higher rate of pay for screening work. This can be funded for a Pilot (and has been necessary in getting the Pilot off the ground) but is not considered sustainable or a good use of resources for a long term programme and it was thought preferable to employ extra staff and include screening work within the consultants’ job descriptions. This would facilitate integration of screening work within the endoscopy units.

Employing consultants to only perform screening work was considered by one interviewee to be a waste of their skills as well as being boring for them.

• Sufficient capacity to manage symptomatic service
The hospitals need to be able to manage the investigation of symptomatic patients in a timely manner before embarking on a screening programme so that the waits for non-Pilot patients are not considerably longer than the waiting time for the screening patients.

‘In terms of priority, symptomatic patients should take priority, they’ve got symptoms.’ (ID 8)

However, inviting people to be screened makes it very different from a symptomatic service.

Patients do not come to the NHS and ask for help with symptoms. A screening service asks them to take part. It is therefore imperative that the service deals with those people who do take up the offer to be screened, quickly. (ID 18)

Therefore it was felt important that robust quality controls are put in place to ensure that long waiting times for screening colonoscopies never become accepted as the norm because it is not thought acceptable for someone who has a positive screening FOBt to be asked to wait 6 weeks for a colonoscopy.

To achieve both of the objectives mentioned here it would seem that the endoscopy units have to provide a timely service that reduces anxiety in screening patients and doesn’t disadvantage symptomatic patients.

‘We need to bring the symptomatic service up to ….. Pilot standards because I think that’s where the problems are at the moment, it takes too long to get people through their investigations or get their results.’ (ID 18)

• Dedicated screening sessions:
The advantages or disadvantages of dedicated screening sessions were often raised in interviews.

Dedicated screening sessions rather than mixing screening and non-screening colonoscopies in one session, were thought preferable by some people because the colonoscopies are different and each type of session has a different ethos. This is because in symptomatic patients’ colonoscopies the cause of symptoms is sought, while in screening patients the colonoscopy is specifically to determine whether the person has cancer or not. The degree of suspicion is higher in a screening colonoscopy, and finding smaller polyps in younger people is more significant than in older people who have symptoms which are indicative of other diseases. It is also logistically easier to plan separate sessions. The screening unit have complete control over dedicated sessions, and work closely with the endoscopy units offering slots for symptomatic patients when they are not full. They also allow dedicated screening nurses who know the patients to attend screening colonoscopies and this has been recognised as very valuable by patients, colonoscopists and screening nurses.

Having mixed sessions would mean screening colonoscopies would more likely be done in working hours which one colonoscopist thought an advantage. Sessions with a mixture of endoscopies were also thought to be less arduous and more interesting.

- Screening nurses
  One difference between the first and second rounds was that in the second round nurses from the screening unit could attend screening colonoscopies. There was strong support for this from both staff and patients, and it was thought to improve working practices e.g. recording of data.

  ‘The support this provides is invaluable to patients.’ (ID 18)

To do this dedicated screening sessions are needed.

During the first two rounds of the Pilot the screening nurses have been based at the screening unit, not at the hospitals. As this will not be possible given the scale of distances in the national programme the nurses are going to spend time based primarily in the hospitals in order to gain an understanding of the issues involved. There is concern that the decrease in ease of giving mutual support that this is likely to mean will have a negative impact. It was thought vital that the screening nurses can work closely with the screening unit or future hubs, and regular ‘get-togethers’ are highly recommended. The current interaction between hospital and screening nurses was recognised as being beneficial to staff development and this could develop further if screening nurses were based in hospitals.

Dedicated screening nurses were believed to be essential as dealing with symptomatic and screening patients was perceived to require a different approach and data collection for the two sets of patients is different.

Space is required in hospitals for the screening nurses to hold their clinics and this needs to be in a central location, accessible for patients.

- Monitoring quality of colonoscopy
  The invasive nature of colonoscopy, with its inherent risk, requires a high quality of service and this is poorly measured at present.
‘There are very few quality indicators when it comes to performance of endoscopy in the NHS.’ (ID 8)

It was recommended that screening colonoscopists should be validated regularly with respect to completion rates, patient satisfaction, and competence.

- Greater number of endoscopists:
  It was thought that there may be a need for extra endoscopists, but certainly extra consultant endoscopy sessions are very likely to be necessary. This does not mean there need to be more consultants, but that they work in different ways – perhaps overseeing other staff.

Nurse endoscopists are considered by some to be a potential solution to the shortage of endoscopists.

Nurses perform fewer endoscopies in a session because they take longer with each patient giving more detailed explanations to the patients. However, they are more likely to start their sessions on time because they have fewer commitments than the doctors – patients on wards, clinics, teaching, Grand Round meetings.

‘You tend to get better value for money from the nurse endoscopists.’ (ID 10)

They can also step in and replace another endoscopist who is unable to undertake their session because of annual leave or other commitments. This will maintain capacity rather than losing it.

It is difficult to find the time to train nurses to be colonoscopists because training time is already used for specialist registrars.

If the national screening programme moves away from FOBt to sigmoidoscopy, using nurse endoscopists will probably be the way forward to cope with the increased number of sigmoidoscopies.

As well as nurse endoscopists, other people could train to become endoscopy technicians.

- Flexible working:
  To provide the level of service required, especially where there is limited accommodation or equipment, screening sessions could be in evenings or at weekends, but this would require extra staff to be employed and more flexible work patterns. There may well be people who would like to work in a more flexible way as this might suit their family life.

  ‘if you can’t fit in the colorectal screening, then you have to work at nights, evenings, and possibly Saturdays.’ (ID 9)

Although this is recognised to provide a better use of resources another interviewee cautioned that patients’ opinions of out-of hours screening colonoscopies were as yet unknown.

- Surveillance colonoscopy management:
  It was suggested that surveillance for screen detected polyps should be managed by the screening unit and fitted into the screening colonoscopy sessions commissioned by the screening unit. This would avoid extra work for the endoscopy unit staff in managing the waiting list and getting involved with partial booking which is time consuming.

Appendix 3: Colonoscopy Qualitative Data Full Analysis
• Reducing clerical workload:
It was suggested that the screening nurses give the bowel preparation products and colonoscopy information sheets when the screening colonoscopy patients decide to accept the invitation to have a colonoscopy and are added to the screening list. This would reduce the extra work that the endoscopy unit clerical staff incur.

‘I think this would have been part of the agreed policy if we were to start it again.’ (ID 10)

• Computer facilities:
It was commented that a computer link between the screening nurses who book colonoscopies and the clerical staff who post out the bowel preparation would be helpful. This might not be such an issue when screening nurses are based in the hospitals rather than the screening unit which is likely to happen in the future.

As improved information technology (IT) facilities are introduced throughout the NHS one interviewee was hopeful that electronic transfer of data could reduce the extra work required to complete the screening database. This is mainly a paper-based system at present which as well as increasing workload also increases the risk of errors. However, it does mean that there is a consistency in the interpretation of data entry that might be difficult to achieve if data entry was more widespread. An ideal situation would be for data to be transferred directly from, for example, the endoscopy reporting system to the screening database.

• Funding of endoscopy units
Comments were made that increased funding was required for endoscopy units in general (not just because of the Pilot) because an increased number of referrals is likely in the future – both because of a more educated, aware public and the poor diet many people have which will cause more bowel disease. One interviewee was concerned that additional colonoscopies will mean that the best, and therefore most used, colonoscopes will need replacing at an earlier date and it can be difficult to get funds to do this.
Appendix 4: Endoscopists’ Questionnaire Results

All endoscopists performing upper or lower GI endoscopies were identified by the endoscopy unit managers. Questionnaires were posted to 29 endoscopists at Walsgrave and George Eliot Hospital and a modified version was sent to 8 endoscopists at Warwick Hospital. Two endoscopists at Warwick Hospital were not included because they had already been interviewed. One endoscopist at Walsgrave Hospital subsequently gave an interview which is reported in the qualitative analysis.

There were 13 (45%) responses from Walsgrave and George Eliot Hospitals and 3 (38%) from Warwick Hospital.

Respondents included 2 colorectal surgeons, 9 gastroenterologists, a nurse endoscopist and a colorectal cancer nurse specialist, a cardiothoracic surgeon, and an associate specialist and a staff/trust grade endoscopist who did not disclose their specialties.

Nine (56%) of the respondents were working in the endoscopy unit when the Pilot commenced. Eleven of the respondents had their own endoscopy waiting lists, three did not, and 2 did not answer that question.

Twelve (75%) of the respondents performed colonoscopies, flexible sigmoidoscopies, and upper GI endoscopies. Neither nurse performed colonoscopies; one performed both FSs and upper GI endoscopy while the other carried out FSs only. The cardiothoracic surgeon only carried out upper GI work in relation to his interest in oesophageal cancer, and one gastroenterologist only indicated that s/he carried out colonoscopies without answering the questions on FS or upper GI endoscopy.

Eleven of the respondents performed colonoscopies on patients referred with symptoms and 4 of them (one surgeon and 3 gastroenterologists) performed screening colonoscopies.

**Screening colonoscopies:**
Of the four screening colonoscopists, two agreed that screening colonoscopies took longer than symptomatic colonoscopies and one disagreed (the other did not answer). Both thought that more pathology was the reason for the screening colonoscopies taking longer (and one added that the need for intervention e.g. polypectomy increased the time taken). One thought that screening colonoscopy examinations were more thorough while the other disagreed with this. One colonoscopist agreed that his/her colonoscopy skills had improved through participating in the Pilot, two disagreed and one did not know.

**Endoscopy quality:**
There was little agreement on whether the quality of endoscopy in the departments had improved since the Pilot started with 4, 5 and 6 of the 15 respondents to that question replying ‘Yes’, ‘No’, and ‘Don’t Know’ respectively. The answers did not appear to be related to hospital or screening experience although none of the screening colonoscopists answered ‘No’. Of the four endoscopists who thought the quality of endoscopy in the department had improved since the Pilot started, one thought this was related to the introduction of the Pilot and the improved colonoscopy technique because of the extra training provided; two were not sure if it was related to the Pilot introduction; and one thought it was partly related to the introduction of the Pilot.
Alternative investigations:
Again there was little agreement on whether, since the Pilot began, more patients were having barium enemas because of longer waiting times for colonoscopy. Five endoscopists thought so, three thought not and seven did not know. Because of the low number of respondents it is difficult to know if the answers varied by hospital, but the figures did seem to accord with what would be expected given that one hospital had a much longer waiting time for barium enemas.

GP referrals
Nine respondents believed there had been an increase in the number of referrals from GPs (since October 2000) of patients with bowel symptoms, 4 thought not and 2 didn’t know. Of those who thought there had been an increase, the introduction of the two-week standard in July 2000 and a change in GP thresholds for referral were the most common reasons. The introduction of the Pilot and increased media coverage were also thought to be reasons (see Table) although 2 endoscopists disagreed that the Pilot had had any effect on referrals. One endoscopist reported seeing more patients whose GPs had ordered FOBts because of vague symptoms, while another thought that more patients were presenting themselves to their GPs with bowel symptoms.

<table>
<thead>
<tr>
<th>There has been an increase in the number of referrals from GPs of patients with bowel symptoms because …</th>
<th>Agree</th>
<th>Disagree</th>
<th>Don’t Know</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)…. people are more aware of the symptoms of colorectal cancer because of the screening Pilot</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>b)…. people are more aware of the symptoms of colorectal cancer because of increased media <strong>coverage</strong></td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>c)…. of the introduction of the 2 week standard for referrals</td>
<td>6</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>d)…. of a change in GP referral thresholds</td>
<td>6</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Initiatives to reduce waiting time:
Endoscopists were asked whether they thought the items listed in the table below would be good ideas in their unit to help reduce waiting times. The overall results are influenced by opinions at Walsgrave Hospital, in particular the dislike of pooling of lists and a partial booking system, and desire for more clerical support staff which are at odds with answers from staff at the other two hospitals. The low numbers and response rate and further possible confounding by differences in roles and experience of the Pilot limit substantial conclusions. It did appear, however, that screening colonoscopists looked on WLIs less favourably but were more in agreement about having more colonoscopes; and that surgeons did not favour more clerical support staff.
Ratio of staff thinking initiative is good idea to bad idea.

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Overall</th>
<th>Walsgrave Hospital</th>
<th>George Eliot Hospital</th>
<th>Warwick Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>more nursing staff</td>
<td>14:2</td>
<td>7:1</td>
<td>4:1</td>
<td>3:0</td>
</tr>
<tr>
<td>more rooms for endoscopy</td>
<td>14:2</td>
<td>7:1</td>
<td>5:0</td>
<td>2:1</td>
</tr>
<tr>
<td>more colonoscopists</td>
<td>13:3</td>
<td>7:1</td>
<td>4:1</td>
<td>2:1</td>
</tr>
<tr>
<td>improved IT systems</td>
<td>12:3</td>
<td>6:1</td>
<td>4:1</td>
<td>2:1</td>
</tr>
<tr>
<td>waiting list initiatives</td>
<td>11:4</td>
<td>6:1</td>
<td>4:1</td>
<td>1:2</td>
</tr>
<tr>
<td>validation of waiting lists</td>
<td>11:5</td>
<td>5:3</td>
<td>4:1</td>
<td>2:1</td>
</tr>
<tr>
<td>more endoscopists</td>
<td>10:5</td>
<td>5:2</td>
<td>4:1</td>
<td>2:1</td>
</tr>
<tr>
<td>more nurse endoscopists</td>
<td>10:5</td>
<td>5:2</td>
<td>3:2</td>
<td>2:1</td>
</tr>
<tr>
<td>more colonoscopes</td>
<td>10:6</td>
<td>6:2</td>
<td>2:3</td>
<td>2:1</td>
</tr>
<tr>
<td>pooling of lists</td>
<td>9:5</td>
<td>3:4</td>
<td>3:1</td>
<td>3:0</td>
</tr>
<tr>
<td>more clerical support staff</td>
<td>9:6</td>
<td>6:1</td>
<td>2:3</td>
<td>1:2</td>
</tr>
<tr>
<td>partial booking system</td>
<td>8:8</td>
<td>2:6</td>
<td>3:2</td>
<td>3:0</td>
</tr>
</tbody>
</table>

One person suggested that more colonoscopy training centres were required across the UK. Another suggested that an alternative to more accommodation and equipment would be to use them in evenings and at weekends.

Respondents indicating that they were willing to provide further information were contacted by email and asked to expand or clarify some of their answers.

One respondent who did not think waiting list initiatives were a good idea to reduce waiting times explained that differential rates of pay and unforeseen sick leave for staff were problem areas. It was thought that WLIs and other ‘ad-hoc’ sessions, which are a result of the current target-driven culture, were probably not sustainable and could also distort the demand figures and lead to poor planning.

On the topic of nurse endoscopists, they were thought to be more flexible than medical staff and able to back-fill sessions. However, recent appointments of extra colorectal surgeons at one hospital has enabled them (surgeons) to work more flexibly and back-fill some lists.

**IT systems:**

There was general agreement that the department computer systems were good for reporting endoscopies and audit, but less so for booking appointments and managing waiting lists. See table below. One person commented that they used Endoscribe which was ‘virtually defunct’.

<table>
<thead>
<tr>
<th>The department has a computer system which…</th>
<th>Agree</th>
<th>Disagree</th>
<th>Don’t Know</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)....is good for reporting endoscopies</td>
<td>12</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>b)....is good for booking appointments</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>c)....is good for audit purposes</td>
<td>11</td>
<td>4</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>d)....is good for managing waiting lists</td>
<td>6</td>
<td>6</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>e)....integrates the functions above</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>
**Non medical endoscopists:**
There was considerable support for nurse endoscopists or endoscopy technicians, but people were less certain about them performing colonoscopies.

<table>
<thead>
<tr>
<th>Nurse endoscopists or endoscopy technicians….</th>
<th>Agree</th>
<th>Disagree</th>
<th>Don’t Know</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)….are a good idea</td>
<td>13</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>b)….could free up medically trained personnel to perform more colonoscopies</td>
<td>13</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>c)….could perform colonoscopies under the supervision of a medical colonoscopist</td>
<td>9</td>
<td>6</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

One person commented that they could need a long training. Another said that if there were more nurse endoscopists lists could be ‘backfilled’ more easily.

No clear trends by hospital or staff role were discernable because of the small number of respondents.

**Main impacts of the Pilot:**
Topics raised in answer to the following question, ‘What do you think have been the main impacts (if any) in the endoscopy department of the introduction of the screening Pilot (in Autumn 2000)?’ were:

- **Hospital 1**
  - Increased workload for screening colonoscopists and nursing staff
  - Increased workload from surveillance of large number of people found to have polyps when screened

- **Hospital 2**
  - Increased workload
  - Detrimental impact on service for symptomatic patients because of insufficient capacity

- **Hospital 3**
  - Longer waiting times
  - More FOBt pos referrals (non-Pilot)
  - Increased GP referrals

**Differences between rounds of Pilot:**
Of the 13 endoscopists at the two hospitals which continued participating in the second round of the Pilot only two thought that there had been a noticeable difference between the first and second rounds. One cited organisation and staffing and the other reported less pathology in the second round. Five said there was no difference and 6 did not answer the question.

Of the three respondents from Warwick Hospital, two answered the question regarding a noticeable difference in workload after the Pilot finished at the end of the first round and they had opposing views.

**Organisation of screening work within departments:**
There was no common consensus on how screening work should be integrated into the department workload.
Hospital 1
- Both respondents preferred the option where screening colonoscopies were completely separate from the usual symptomatic workload. Reasons given were that the best colonoscopists had to be used for the screening patients as they are asymptomatic and complications have to be avoided. Also, it was felt that the alternative option given in the question would increase waiting times for symptomatic patients and result in increased workload for unit staff.

Hospital 2
- One respondent preferred screening colonoscopies to be separate from the usual workload because 1) colonoscopies can take longer, as there are a higher proportion of polypectomies; 2) screening nurses are needed to support these patients, they are often shocked to find they have disease as they usually feel “well”; and 3) it is much easier to track patients through the screening system if there are dedicated lists. It was commented that it would be ideal to scope all patients within a tight timescale but in reality, at present, there would be a clash between clinical need and screening targets.
- The other respondent preferred a system that was as integrated with the existing service as possible and suggested contemplating a reduction in existing services (such as diagnostic OGDs or flexi sigmoidoscopies) to free capacity to accommodate the extra workload. The main reason for this would be to retain expertise, set local standards and ensure local quality control as well as providing opportunities for training within the unit.

Hospital 3
- Three of the 4 people who answered this question preferred the separatist approach. One respondent gave 2 reasons: this option will not have any impact on regular endoscopy lists and if a screening colonoscopy patient is in the middle of regular list there might not be adequate time for a thorough examination.
Appendix 5: Questionnaire for endoscopists: the impact of the bowel cancer screening Pilot on endoscopy services

Understanding your experience of and opinions on managing colonoscopies for screen detected FOBt positive patients is important in order to provide information that will be useful for planning the introduction of a national colorectal cancer screening programme.

If you would like to give more detailed explanations or raise issues not covered here we encourage you to do this either in writing or by speaking to the researcher (Roma Robertson: 0131 650 9459; roma.robertson@ed.ac.uk)

All information will be reported anonymously.
This questionnaire includes both tick boxes and requests for comments on the issues raised.

Section A.

A1 Do you perform:-
- Colonoscopies
- Flexible sigmoidoscopies
- Upper GI tract endoscopies

If the answer to ALL of these is no, please return this questionnaire unanswered

A2 Who are you?
- Role: Colorectal surgeon
- Grade: Consultant
- General surgeon
- Registrar
- Gastroenterologist
- Specialist registrar
- Nurse endoscopist
- Staff grade or Trust grade
- Nurse endoscopist
- Other (please specify)

A3 When did you start working in the endoscopy unit at the hospital you currently work in?
Date (month and year)

A4 Do you perform colonoscopies on:-
- a) patients with bowel symptoms referred to secondary care? (symptomatic patients)
- b) patients identified as FOBt positive in the bowel cancer screening Pilot? (screening patients)

*If you do not perform colonoscopies for screening patients omit section B and go to section C.

Section B. Your experience of screening colonoscopies. (If you do not perform colonoscopies for screening patients go to Section C).

Please tick whether you agree or disagree with the following statements

B1 Colonoscopies for screening patients usually take longer than for symptomatic patients ..........
- If you agree please answer B2, otherwise go to B3

B2 a)..................because there is more pathology ...........................
- b)..................because the patient needs more explanation ..............
- c)..............because the whole bowel is examined ...........................
- d).............because the examination is more thorough .......................
- e)................for other reasons (please specify)

B3 My colonoscopy skills have improved because I have participated in the screening Pilot

Any comments
Section C. General questions

Please tick to answer the following questions.

Since October 2000 (when the colorectal cancer screening Pilot was introduced) do you think …..

C1 ....the quality of endoscopy in the department has improved?  
Yes No Don’t Know

If yes, do you think this is related to the introduction of the Pilot and why?  

C2 ....a greater proportion of symptomatic patients are having a barium enema and/or flexible sigmoidoscopy because of longer waiting times for colonoscopy  

C3 ....there has been an increase in the number of referrals from GPs of patients with bowel symptoms …….  

If yes please answer C4, otherwise go to C5

C4 I think there has been an increase in the number of referrals from GPs of patients with bowel symptoms because …  
a)…. people are more aware of the symptoms of colorectal cancer because of the screening Pilot ………………………………  
b)…. people are more aware of the symptoms of colorectal cancer because of increased media coverage ………………………  
c)…. of the introduction of the 2 week standard for referrals ……  
d)…. of a change in GP referral thresholds ………………………  
e)…. of other reasons (please specify)

C5 Which of the following do you agree is a good idea to help reduce waiting times in your endoscopy unit. (Please tick to indicate if you think it is a good idea or not).

<table>
<thead>
<tr>
<th>Good idea</th>
<th>Not good idea</th>
</tr>
</thead>
<tbody>
<tr>
<td>waiting list initiatives ..........................</td>
<td></td>
</tr>
<tr>
<td>pooling of lists .................................</td>
<td></td>
</tr>
<tr>
<td>partial booking system ..........................</td>
<td></td>
</tr>
<tr>
<td>validation of waiting lists ....................</td>
<td></td>
</tr>
<tr>
<td>more colonoscopes ...............................</td>
<td></td>
</tr>
<tr>
<td>more endoscopists ...............................</td>
<td></td>
</tr>
<tr>
<td>more colonoscopists .............................</td>
<td></td>
</tr>
<tr>
<td>more nurse endoscopists ........................</td>
<td></td>
</tr>
<tr>
<td>more nursing staff ..............................</td>
<td></td>
</tr>
<tr>
<td>more clerical support staff ....................</td>
<td></td>
</tr>
<tr>
<td>more rooms for endoscopy ......................</td>
<td></td>
</tr>
<tr>
<td>improved IT systems ............................</td>
<td></td>
</tr>
<tr>
<td>other (please specify) .........................</td>
<td></td>
</tr>
</tbody>
</table>

Comments:
Please tick whether you agree or disagree with the following statements

<table>
<thead>
<tr>
<th></th>
<th>Agree</th>
<th>Disagree</th>
<th>Don’t Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>C6</td>
<td>The department has a computer system which…</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>a)…is good for reporting endoscopies …………………</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>b)….is good for booking appointments …………………</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>c)….is good for audit purposes ………………………</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>d)….is good for managing waiting lists ………………</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>e)….integrates the functions above ……………………</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>C7</td>
<td>Nurse endoscopists or endoscopy technicians….</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>a)….are a good idea ………………………………………..</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>b)….could free up medically trained personnel to perform more colonoscopies …………………</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>c)….could perform colonoscopies under the supervision of a medical colonoscopist ………………………</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Comments:

C8 What do you think have been the main impacts (if any) in the endoscopy department of the introduction of the screening Pilot (in Autumn 2000)?

C9 Has there been a noticeable difference between the first and second rounds of the screening Pilot? (The second round started in March 2003)  If so, please explain

Yes ☐ No ☐

C10 Do you have a list of patients waiting for an endoscopy?

Yes ☐ No ☐

If Yes:
We would like to gather data on trends of waiting times or numbers of patients on waiting lists from before the colorectal cancer screening started until the present time. If you have waiting time data available which we could have please could you provide contact details of the person who could provide this.

Name:
Email or phone number:

Appendix 5: Questionnaire for endoscopists: 207
Section D. Organisation of screening generated work

The colonoscopies generated in a bowel cancer screening programme could be organised in several ways. Below are two options at the extremities of many possible models.

Please comment on the merits or otherwise of each of them.

1. Screening colonoscopies are fully integrated within the endoscopy department’s workload. The endoscopy unit coordinates with the screening unit to book the initial screening colonoscopies and then manages the ensuing surveillance colonoscopies. Nursing staff at the endoscopy unit provide explanations and support to the patients. Patient information and bowel preparation medication is dispatched from the endoscopy unit. The endoscopy lists are mixed with both screening and symptomatic patients on lists. There is also a mix of endoscopy types on each list. List pooling exists and all colonoscopists take a share of the screening colonoscopies.

2. Screening colonoscopies are completely separate from the usual symptomatic workload. The screening unit books screening patients on to dedicated screening lists for initial and surveillance colonoscopies. Patient information and bowel preparation medication is dispatched from the central screening unit. Provision of the lists is negotiated with the endoscopy unit. Screening colonoscopists are employed to cover the lists. Screening nurses are employed to support the screening patients.

Comments on the merits or otherwise of 1 and 2

If you are agreeable to being contacted to clarify or expand your answers please provide contact details:

Name .........................................................................................................................................................
Phone Number ................................................   Email ...........................................................................

Thank you for completing this questionnaire. Please return it in the envelope provided to:

Roma Robertson
School of Clinical Sciences and Community Health: General Practice Section
University of Edinburgh
20 West Richmond Street
Edinburgh, EH8 9DX
Appendix 6: A summary of the results of the ‘ImmunoTrial’

During a six-month period during the second round of the Pilot, a randomised comparison of an immunological FOBt kit (Inform® by Enterix) versus the Hemascreen kit routinely used in the Bowel Cancer Screening Pilot was carried out. The Immuno kit does not require the handling of stool as a brush-sampling method is used. 5122 individuals aged 50-69 were randomised by household to receive either an Immuno kit or a control standard kit. The kits and full instructions were mailed out from the Screening Centre in Rugby as per usual practice: kits were returned in the envelopes provided to the Screening Centre and analysed there. Repeat testing with dietary restriction was not required with the Immuno test: if the test was positive, a person was invited to meet a screening nurse to discuss colonoscopy. All subsequent stages in the screening process were identical for participants in the two arms of the study.

The Table below shows summary statistics from the study Report1. Uptake of screening (return of a completed kit) was compared between the Immuno and control kit.

<table>
<thead>
<tr>
<th></th>
<th>Immuno kit</th>
<th>Standard kit</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>All invitees</td>
<td>1168/2527 (46.2%)</td>
<td>1274/2595 (49.1%)</td>
<td></td>
</tr>
<tr>
<td>Previous uptake?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>889/1195 (74.4%)</td>
<td>1013/1275 (79.5%)</td>
<td>-8.4, -1.6 **</td>
</tr>
<tr>
<td>No</td>
<td>129/985 (13.1%)</td>
<td>124/973 (12.7%)</td>
<td>-2.6, +3.4</td>
</tr>
<tr>
<td>New invitees Round 2</td>
<td>150/347 (43.2%)</td>
<td>137/347 (39.5%)</td>
<td>-3.7, +11.1</td>
</tr>
</tbody>
</table>

*Confidence limits are shown for the percentage difference in return rate between the Immuno and Standard groups as estimated from the multilevel model. Significance is shown as ** = p<0.01.

Associations between uptake and demographic variables were investigated: Sub-group analyses suggest that younger men from areas of greater deprivation were significantly more likely to complete and return the Immuno kit than the standard kit.

The Local Research Ethics Committee determined that an additional letter must be sent to everybody being screened in the Pilot from the onset of the Immuno trial onwards (i.e. not just those in the trial), describing the trial. We do not know the effect of the inclusion of this additional letter on people’s screening behaviour. Variation in uptake rates is seen throughout the course of the 2nd round of screening; rates are lower in the last six months of the screening round, but it is not possible to attribute this directly to the inclusion of the trial letter as uptake rates in the last six months of Round 1 in the 1st round of screening also show lower levels compared to the overall average.
Appendix 7: Proportional incidence method of calculating sensitivity

The sensitivity of the FOB test has been calculated by the proportional incidence method, as \((1 - I/E) \times 100\%\) where \(I\) = numbers of interval cancers and \(E\) = expected number in the absence of screening. The rates in the absence of screening have been adjusted to the underlying rate in the responders using the formula

\[
ra = \frac{[rc - (1-p) \; rn]}{p}
\]

Where:
- \(ra\) is the incidence rate in responders to screening,
- \(rc\) is the incidence rate in the control population,
- \(rn\) is the incidence rate in non-responders,
- \(p\) is the proportion who responded to screening.

The results are presented by age at invitation (<60 and 60+ years of age) while the internal calculations use current age in five year age groups.

The rates in the control population (\(rc\)) are based on the population of either England or West Midlands and can be estimated with confidence. Table 1 show the control rates by gender and age.

The proportion responding (\(p\)) by gender and age at invitation can be estimated with reasonable confidence since they are both based on reasonably large numbers. Age at invitation was used rather than current age. Table 2 shows the proportion responding.

The rate in the non-responders (\(rn\)) however is based on relatively small numbers so cannot be estimated directly from the Pilot data. The remainder of this Appendix is devoted to estimating this rate, \(rn\).

The sensitivity is estimated for two periods (0-12 months and 12-24 months following a negative FOBt outcome). However, the non-responder rate, \(rn\) use the whole of this period and the same estimate is used for both periods.

The rate in the control population by gender and age is used to provide a base estimate that is adjusted by the non-responder population by gender and age at invitation according to the formula

\[
rn_{ij} = rc_{ij} \left( \frac{\sum_{k} o_{ik} \; py_{ik} \; * \; rc_{ij}}{\sum_{k} py_{ik} \; * \; rc_{ij}} \right)
\]

Where:
- \(i\) is gender,
- \(j\) is age in five year age groups,
- \(k\) is age at invitation (<60, 60+ years),
- \(o\) is observed number of cancers in the non-responders
- \(py\) is person years in non-responders.
Table 3 shows the observed and expected number of cancers in the non-responders censored at two years following the date of invitation by gender and age at invitation.

### Table 1  Incidence rates by gender and age for England 2001 and West Midlands 1998-2000

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>45-49</td>
<td>19.71</td>
<td>21.1</td>
</tr>
<tr>
<td></td>
<td>50-54</td>
<td>45.32</td>
<td>46.81</td>
</tr>
<tr>
<td></td>
<td>55-59</td>
<td>84.09</td>
<td>89.52</td>
</tr>
<tr>
<td></td>
<td>60-64</td>
<td>139.08</td>
<td>158.74</td>
</tr>
<tr>
<td></td>
<td>65-69</td>
<td>215.33</td>
<td>247.37</td>
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<tr>
<td></td>
<td>70-74</td>
<td>303.54</td>
<td>349.13</td>
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<tr>
<td>Female</td>
<td>45-49</td>
<td>18.91</td>
<td>22.09</td>
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<tr>
<td></td>
<td>50-54</td>
<td>33.06</td>
<td>40.13</td>
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<td></td>
<td>55-59</td>
<td>56.10</td>
<td>64.62</td>
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<td></td>
<td>60-64</td>
<td>87.11</td>
<td>93.49</td>
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<tr>
<td></td>
<td>65-69</td>
<td>127.31</td>
<td>132.85</td>
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<tr>
<td></td>
<td>70-74</td>
<td>180.08</td>
<td>192.03</td>
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</table>

### Table 2  Proportion responding to invitation by gender and age at invitation

<table>
<thead>
<tr>
<th>Gender</th>
<th>Age at invitation</th>
<th>Proportion responding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>&lt;60</td>
<td>0.440</td>
</tr>
<tr>
<td></td>
<td>60-70</td>
<td>0.533</td>
</tr>
<tr>
<td>Female</td>
<td>&lt;60</td>
<td>0.532</td>
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<tr>
<td></td>
<td>60-70</td>
<td>0.603</td>
</tr>
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</table>

### Table 3  Observed and expected number of cancers in the non-responders censored at two years following the date of invitation by gender and age at invitation

<table>
<thead>
<tr>
<th>Gender</th>
<th>Age at invitation</th>
<th>Observed</th>
<th>Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>&lt;60</td>
<td>41</td>
<td>43.0</td>
</tr>
<tr>
<td></td>
<td>60-70</td>
<td>41</td>
<td>64.4</td>
</tr>
<tr>
<td>Female</td>
<td>&lt;60</td>
<td>20</td>
<td>23.3</td>
</tr>
<tr>
<td></td>
<td>60-70</td>
<td>26</td>
<td>29.4</td>
</tr>
</tbody>
</table>
Appendix 8: NHS Bowel Cancer Screening Program: Advice to the NHS

Author: Department of Health. Published: July 2005 (Restricted – Policy)

1. Introduction

Positioning the NHS Bowel Cancer Screening Programme

1.1 The Public Service Agreement (PSA) 2002 stated that the target for cancer was to reduce the mortality rate by at least 20% in people under 75 by 2010.

1.2 Research undertaken in Nottingham and Funen in the 1980s showed that screening men and women aged 45 to 74 for bowel cancer using the Faecal Occult Blood test (FOBt) could reduce the mortality rate from bowel cancer by 15% in those screened. An independently evaluated pilot in Warwickshire and Scotland showed that this research can be replicated in an NHS setting. The NHS Cancer Plan in September 2000 stated that a national bowel cancer screening programme would be introduced subject to evidence of effectiveness of the pilot.

1.3 Based on the final evaluation report of the pilot and a formal Options Appraisal, the Secretary of State for Health announced in October 2004 that the NHS Bowel Cancer Screening Programme would begin in April 2006. The programme will begin screening men and women aged 60 to 69, in order to achieve full national coverage with available and expanding capacity. Once national coverage has been achieved, the programme can be expanded to offer FOB testing in a wider age group, or by implementing new technologies.

1.4 The screening programme forms part of the NHS Bowel Cancer Programme, published in February 2003. Other elements of the programme include: improving treatment; streamlining the patient pathway; expansion and modernisation of endoscopy; and a communications strategy.

Scope

1.5 The NHS BSCP will offer men and women aged 60 to 69 a guaiac based FOBt every two years. People aged 70 or over will be provided with a FOBt kit on request. Those testing positive will be offered colonoscopy as the investigation of choice. Where cancer is found, the individual will be referred for treatment as needed. Where an intermediate/high risk polyp is found, the individual will transfer from biennial FOBt to a three yearly colonoscopy surveillance programme within the programme.

4 UK Colorectal Cancer Screening Pilot Group Results of the first round of a demonstration pilot of screening for colorectal cancer in the United Kingdom BMJ 2004:329:133-5
5 Colorectal cancer screening options appraisal: Cost-effectiveness, cost-utility and resource impact of alternative screening options for colorectal cancer (School of Health and Related Research, University of Sheffield: report to the Department of Health, September 2004) www.cancerscreening.nhs.uk
1.6 The NHS BCSP is to commence in April 2006. It is expected that there will be 5 Programme hubs, one in each Local Service Provider cluster, and approximately 90 to 100 local screening centres serving populations of at least 500,000 to 2 million people each.

2. Delivery Strategy

Strategic Health Authority Role

2.1 SHAs are now invited to put forward local endoscopy services to become Local Screening Centres and begin screening in the first wave of the programme, 2006/7. A similar exercise will take place in summer 2006 for SHAs wishing to nominate local endoscopy services to begin screening in the second wave, 2007/8. SHA endoscopy leads are now in post to assist with this process.

2.2 The planning line (PSA03c) for Bowel Cancer Screening was deferred from the initial year of the current planning process and discussions are taking place around how this area should be included in the remaining two years of the planning cycle, ie 2006/7 and 2007/8. Further guidance will be issued in the autumn.

2.3 Endoscopy units proposed by SHAs will be expected to meet a number of criteria before funding can be released and operations commence. Firstly, they must receive a satisfactory report after undergoing an accreditation visit from JAG (the Joint Advisory Group on Gastrointestinal Endoscopy). They must also achieve a high score on the Global Ratings Scale. Finally, they must have sufficient accredited colonoscopists. These standards should be met at least 3 months before centres become operational. For those units who wish to be in the first wave (2006/7), this will mean September 2006 at the latest.

2.4 For ongoing monitoring, the British Society of Gastroenterology (BSG), together with NHS Cancer Screening Programmes, have developed the Quality Assurance standards for the programme. These can be found at Annex A.

2.5 A key element for SHAs to consider will be to assess the capacity of the proposed endoscopy unit. Funding will not be released to units to provide screening services where capacity is not sufficient to ensure there is no detrimental effect on services for symptomatic patients and that current symptomatic waits are within acceptable limits.

2.6 The environment of healthcare provision is undergoing a period of rapid change. With the concept of the 5 Programme Hubs performing the call/recall and FOB testing, different parts of the service will need to be committed to joint working. SHAs are well placed to ensure this joint working takes place.

PCT Role

2.7 The PCT will be responsible in due course for commissioning the services of the local screening centre for its own responsible population, as happens with breast cancer screening and cervical screening. Therefore PCTs need to be engaged with the programme from the outset. Commissioning will be best carried out by PCTs acting in

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6 www.thejag.org.uk
7 www.grs.nhs.uk
clusters to a joint and agreed specification, with coordination being taken on as a lead function by one PCT. The PCTs will be responsible from the outset for ensuring that there was a local infrastructure in place of knowledgeable professionals who are in a position to support informed choice about participation in the screening programme and ensure equity of access to the service. Public health advice and input is an integral part of all elements of the programme.

2.8 The pilot schemes demonstrate variable take up, both of invitation to participate and of follow up of abnormal test findings. Primary care trusts will need to assess:
- the likely impact of introducing the bowel screening programme within their local population
- how to ensure the target population is invited to participate by the screening centres
- appropriate action to counteract any potential, or actual, inequalities in programme provision or outcome

2.9 Commissioning teams should incorporate appropriate clinical and health indicators within the contract monitoring process. It will be particularly important to monitor coverage and uptake in “hard to reach” groups of the population and in areas of high deprivation. The proposed screening programme includes several distinct elements, involving a number of providers across the pathway, from inside and outside the NHS. Each element should be considered within the context of the programme as a whole and all necessary and relevant communication/information flows should be defined and included within the service level agreements and contracts.

2.10 Clinical governance arrangements should be explicit and consistent across all providers. As a minimum any service agreement or contract should specify:
- responsibility and accountability for the outcome of care
- responsibility and accountability for clinical audit, including provision of accurate and timely data
- key indicators of quality of care and expected performance against these
- process for escalation of concerns about the quality of care
- arrangements for investigating any concerns of the quality of care, whether arising from patients, clinicians or provider organisations
- employment arrangements and organisational responsibilities for any staff involved
- responsibility for reporting of untoward incidents

2.11 It will be important to ensure that issues around the ownership or accessibility of relevant clinical records cannot impede the investigation of untoward incidents or other concerns over the quality of care.

Public Health Role

2.12 Whilst not the sole responsibility of public health, there is an important role for public health in maintaining the programme perspective across the population and ensuring all parties are engaged in relevant fora. This is likely to include primary care teams, endoscopists in primary and secondary care, community pharmacists, health promotion specialists and community workers, surgeons and pathologists.

2.13 Promoting screening for bowel cancer is one aspect of supporting individuals to choose a healthy lifestyle. Public health teams need to ensure that this programme is included within, and supported by, complementary public health initiatives. Strong partnership
arrangements with community leaders and other programme leaders working within local and regional government offices are encouraged.

2.14 Local screening centres will be commissioned to provide services, including colonoscopy of FOBt positive individuals, to a population of at least half a million to 2 million people. This will require robust collaborative arrangements to commission services at local level, which should be sensitive to the needs of the local population.

Public health teams have a role in providing a needs assessment to support this process which would be expected to include:

- assessment of local demography in comparison with that elsewhere
- population trends
- user preferences for health care
- key health indicators (mortality and morbidity associated with bowel cancer and its determinants)

2.15 Continuous evaluation of the contribution the programme is making will be necessary and this will be done at national level. However, in order to be most meaningful it will be supported by detailed knowledge of the situation in local communities and amongst certain groups of the population. Specialists with a public health background would be expected to make a major contribution to this.

**Programme Hub**

2.16 Call and recall for the screening programme and despatch and processing of FOBt kits will be most effectively carried out for very large populations of around ten million people. These two activities are intimately interlinked due to the entirely postal nature of this initial stage of the screening programme. For 98% of the population, this is all the contact that there will be with the screening programme.

2.17 Five Programme Hubs will be sufficient for England, each covering one LSP cluster but working together as a national network. Each hub will thus link with its own LSP provider, as will all the screening centres it serves. This will facilitate good electronic communications that are essential for this service. In addition having few centres will facilitate adherence to common policies and protocols, it will make quality control of both call and recall and kit handling easier and obviate the need for massive investment in a quality assurance mechanism and infrastructure. The mass operation will permit automation, which is both more reliable than human handling of kits and reduces the risk of RSI in operators.

2.18 Furthermore with a large centre, staff can be dedicated solely to bowel cancer screening and can be well trained and monitored in this task. Specialised services can be developed to serve small disparate communities which would generally not be possible in smaller offices (e.g. a multilingual helpline). Finally it will be more cost effective to run large centralised centres rather than smaller facilities and there can be effective stock control of kits, reagents, leaflets etc which is difficult in smaller quantities where there is less margin for safety.

2.19 The hubs would also provide a cluster wide focal point for the programme. Multi centre activities could take place at the hub and a home could be provided for the entire programme, bridging the programme hub and local screening centres and undertaking quality assurance and training activities. They would also be able to oversee research and trials over large populations as new screening tests are investigated. There is major
research activity currently looking at markers in stool for bowel cancer and these centres would facilitate such trials and evaluations.

2.20 The five Programme Hubs will be commissioned centrally by NHS Cancer Screening Programmes, and funded by the Department of Health. The Hubs could be provided by NHS or Independent Sector providers. A procurement exercise will take place later in the summer. As this is a new service, the Hubs will allow for local NHS services not to be burdened by the FOB testing element of the programme.

2.21 The staffing of the Hub will include a manager for the call and recall facilities and a lead clinical biochemist. Links to a local clinical biochemistry laboratory will facilitate this. There will also be an individual identified as the Director of the Hub and who might, or might not, also fulfil one of the aforementioned roles.

2.22 The tasks to be undertaken by the Programme Hub will follow national policies, procedures and standards (except as part of an agreed trial). These will include nationally produced literature and promotional materials. The specific tasks and selection criteria for the Programme Hubs are at Annex B.

Local Screening Centres

2.23 The local face of the NHS Bowel Cancer Screening Programme will be the screening centre. This will act as the local management point for the programme and provide endoscopy and nurse clinics for follow up of FOBt positive individuals. They will also act as the major source of information for the local health community and will be expected to take an active role in leading the promotion of the new service to the general public. This will be supported by nationally provided guidance and materials, but should be appropriate to the local community and fit in with other local initiatives.

2.24 Those testing positive will require colonoscopy. However, if this is unsuccessful, or if the individual is unfit for colonoscopy, imaging may be used. The experience of the pilot was that this was not a frequent occurrence\(^8\). Approximately 2% of those tested will test positive and it is the experience of the pilot site that very few will be unfit for colonoscopy. FOBt screening will require one to two sessions per week of colonoscopy to follow up positive FOB tests for a population as described above of at least half a million people, and possibly up to 2 million people. This team may deliver its service on a number of different sites but should maintain common protocols and a single clinical lead and single MDT at which screening patients and the programme can be discussed regularly.

2.25 Since there will be not have been any direct contact between a health professional and an individual with a positive FOB test, every positive FOBt result will be accompanied by the offer of a local appointment with a nurse to discuss the implications and to have colonoscopy offered and explained. The nurse will also assess the patient for fitness. If there is any doubt, the implications and options will be discussed with the patient and, if necessary, their medical team, while maintaining required timescales.

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\(^8\) Evaluation of the UK Colorectal Cancer Screening Pilot Final Report (February 2003, revised May 2003). The UK CRC Screening Pilot Evaluation Team [www.cancerscreening.nhs.uk](http://www.cancerscreening.nhs.uk) (supplementary report and report on ethnicity can also be found on this site)
2.26 Where cancer is found, patients will need referral according to usual local treatment protocols. Where intermediate/high risk polyps are found patients will be recalled through the Programme for surveillance colonoscopy. In time this will double the amount of colonoscopy needed by the Programme. This will build up in years three to six after local programmes start up and then reach a steady state. Where a low risk polyp is found, patients will not be entered into surveillance but will be offered a FOBt again after four years if still within the target age range. Incidental non malignant findings (eg IBD) should be managed according to local protocols.

2.27 Screening centres will be responsible for managing patients through the offer of colonoscopy through all necessary and appropriate investigations for cancers of the colon or rectum, to the point where the patient can be discharged back to the screening programme, discharged to a local surveillance programme, discharged to the care of their general practitioner or referred for treatment.

2.28 There should be a screening centre clinical director and identified leads for colonoscopy, nursing, pathology and radiology together with appropriate management arrangements for both the programme overall and the screening centre.

2.29 These centres would also be expected to participate in multicentre research trials of new development and technologies.

2.30 The specific tasks and the selection criteria for the local screening centres are at Annex C.

Quality Assurance

2.31 QA in the NHSBCSP will be on two levels: programme hubs and local screening centres. All the activity in the programme hubs will be quality assured to designated standards at a national level by NHS Cancer Screening Programmes with reports to the Department of Health and RDsPH as required.

2.32 Local screening centres will be quality assured to designated standards. SHAs should be responsible for quality assurance of the local screening centres in their areas, probably through their SHA Endoscopy Leads.

Training

2.33 The current DH funded endoscopy training initiative will continue until March 2006. It is then intended that the scheme will be devolved to the NHS with SHAs funding endoscopy training. The National and Regional training centres will be the first to be accredited for bowel cancer screening, and will be considered alongside other endoscopy units to be amongst the first wave of the screening programme in 2006/7. The training centres will be able to support other endoscopy units in their area. The provisional plan is to have a centre of excellence placed strategically in each SHA with 3 to 5 of these being able to develop particular expertise in colonoscopy as part of the national bowel cancer screening programme and who could be commissioned by the Programme to provide specialist training and development in the long term.
Roll-out Timing and Funding

2.34 Roll-out will begin on 1st April 2006. It is envisaged that around 25% of England will be covered by the end of 2006/7. A further 25% will begin in 2007/8, with the final 50% beginning in 2008/9.

2.35 A central budget has been announced of £12.5 million for 2006/7 and £25 million for 2007/8. Provision beyond 2007/8 will be subject to the SR2006 exercise. SHAs who wish to nominate one or more of their endoscopy centres to become a Local Screening Centre in the First Wave (ie 2006/7) will be provided with cost estimates based on the pilot. All planning documents will be available on an NHS net only website.

Information for Invitees and Primary Care

2.36 National invitation leaflets for the bowel screening programme will be mandatory for legal reasons, as are those for breast and cervical screening. They are being developed by the CRUK Primary Care Education Research Group, and will follow the informed choice principles of the breast and cervical leaflets.

2.37 The Group is also developing a bowel cancer screening information pack for primary care and leaflets about colonoscopy.

2.38 Both the leaflets and the GP packs will be centrally funded and provided free to the service. The leaflets will be translated into a number of languages and formats and supplementary resources will also, over time, be developed nationally for local use.

IT Support

2.39 Connecting for Health are developing an IT system to support the NHS Bowel Cancer Screening Programme. This will support the Programme Hubs and follow patients through the diagnostic process including cancer characteristics where a cancer is diagnosed. Local screening centres will need to send information about colonoscopy and, where appropriate, pathology, radiology and the cancer dataset, to the system either over a confidential web server link or on a download from the existing system. Further IT specs for screening centres will be provided on the NHS net Bowel Cancer Screening Programme website (www.bcsp.nhs.uk).
3. Leadership and Performance Management

SHA Role

3.1 On an ongoing basis, the SHA would be expected to maintain the SHA endoscopy lead to quality assure the screening centres in the SHA and to act as clinical guardian. Where the independent sector is providing a major part of the service, the guardian would have the responsibility of ensuring that there were good and functioning links with this provider and the NHS units responsible for other parts of the screening programme and for treatment of individuals identified through the programme. Inter-ShA cooperation should take place to ensure QA of the endoscopy lead’s own unit.

3.2 It will be important to maintain a programme perspective with an appropriate balance of quality assurance across all elements, including input from those who do not take up the invitation to participate. The responsibility for ensuring the comprehensive approach to quality assurance should reside within public health teams and SHAs, who are appropriate organisations to take this forward for local screening centres in their area.

3.3 SHAs have clear responsibilities for performance monitoring across the NHS and are playing an important role in performance monitoring the new public health agenda. The bowel cancer screening programme should be included within the arrangements for performance monitoring at SHA level and public health teams should expect to contribute to this. The overall strategy having been set by the SHA, the PCTs and hospital trusts or independent sector providers would then work closely together to develop the local screening centres.
4. Next Steps

4.1 SHAs are invited, in collaboration with their PCTs and local endoscopy services, to express an interest in those services being included in the First Wave of the NHS Bowel Cancer Screening Programme (ie during 2006/7). SHAs should take note of the current capacity of those services, particularly in regard to having no detrimental effect on symptomatic services and implications for the National Cancer Waits Project. SHAs will need to demonstrate that the required standards will be achieved by 3 months in advance of the anticipated start date.

4.2 SHAs should put their initial expressions of interest in writing stating likely start dates, potential screening centres and approximate population size to:

Mrs Julietta Patnick CBE
Director
NHS Cancer Screening Programmes
The Manor House
260 Ecclesall Road South
Sheffield S11 9PS
e-mail: Julietta.Patnick@sheffield-ha.nhs.uk

4.3 A bid format will be sent out in response to those expressing interest, which should be returned electronically by the 30th of October 2005.

4.4 NHS Cancer Screening Programmes will begin the procurement exercises for the five Programme Hubs and the first year’s supply of FOBt later in the summer.

4.5 For further information, please contact:

NHS Cancer Screening Programmes (0114 2711060)

Tim Elliott, Department of Health (0207 972 4194)
e-mail: Tim.Elliott@doh.gsi.gov.uk
1. **Investigation After Positive Guaiac FOBt: Age 60 - 69**

**OBJECTIVE**

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>MINIMUM STANDARD</th>
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<tbody>
<tr>
<td>1. Investigate individuals with positive FOB test results</td>
<td>Acceptance rate of colonoscopy after positive FOBt ≥ 85% undergo colonoscopy</td>
</tr>
<tr>
<td>2. Entire colon examined</td>
<td>Completion rate with photographic evidence of i/c valve 90% completion (on intention to treat basis)</td>
</tr>
<tr>
<td>3. Identification of adenoma/cancer present in the population</td>
<td>Adenoma detection rate 6 per 1000 people screened Cancer detection rate 2 per 1000 screened</td>
</tr>
<tr>
<td>Polyp recovery</td>
<td>&gt;90% polyps excised</td>
</tr>
<tr>
<td>5. Planning of surgery</td>
<td>(i) Identification of tumour position in correct segment of colon &gt;95% cancers</td>
</tr>
<tr>
<td>6. Minimising harms to the population</td>
<td>(i) Colonoscopies per year undertaken or supervised by accredited operator &gt;200</td>
</tr>
<tr>
<td>(ii) Perforation rate</td>
<td>&lt;1:1000 colonoscopies</td>
</tr>
<tr>
<td>(iii) Post polypectomy bleeding requiring transfusion</td>
<td>&lt;1:100 colonoscopies</td>
</tr>
<tr>
<td>(iv) Post polypectomy perforation rate</td>
<td>&lt;1:500 colonoscopies</td>
</tr>
<tr>
<td>(v) Rate of serious colonoscopic complications requiring admission</td>
<td>≤3 per 1000 colonoscopies</td>
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### Specific Tasks for the Programme Hubs

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<thead>
<tr>
<th></th>
<th>Specific Tasks for the Programme Hubs</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Link to Exeter systems or PDS for call and recall according to national protocols</td>
</tr>
<tr>
<td>2</td>
<td>Selection of the population for invitation</td>
</tr>
<tr>
<td>3</td>
<td>Assembly and despatch of kits to selected population</td>
</tr>
<tr>
<td>4</td>
<td>Receipt and development of kits</td>
</tr>
<tr>
<td>5</td>
<td>Recording of results on to the national database/national spine</td>
</tr>
<tr>
<td>6</td>
<td>Despatch of repeat kits for spoilt kits and weak positives</td>
</tr>
<tr>
<td>7</td>
<td>Despatch of results to participants and their GPs (electronically when available) within 48 hours of receipt</td>
</tr>
<tr>
<td>8</td>
<td>Booking nurse clinics in local screening centres for FOBT positive patients</td>
</tr>
<tr>
<td>9</td>
<td>Provision of helpline (multilingual) for enquiries/instruction on kit completion</td>
</tr>
<tr>
<td>10</td>
<td>Liaison with “client” local screening centres and adjustment of invitation and clinic booking rate as necessary</td>
</tr>
<tr>
<td>11</td>
<td>Participation in the national laboratory and call and recall quality assurance and audit network activities. This will include sharing data on a named basis</td>
</tr>
<tr>
<td>12</td>
<td>CPA accreditation must be maintained for the biochemistry laboratory on a stand alone basis or through an associated Clinical Biochemistry laboratory</td>
</tr>
<tr>
<td>13</td>
<td>Adherence to NHS Cancer Screening Programmes confidentiality and information security policies</td>
</tr>
<tr>
<td>14</td>
<td>Stock control of materials from national purchase</td>
</tr>
<tr>
<td>15</td>
<td>Liaison with LSP</td>
</tr>
<tr>
<td>16</td>
<td>Liaison with PCTs, SHAs and commissioners</td>
</tr>
<tr>
<td>17</td>
<td>Liaison with GPs where necessary (eg enquiries on behalf of a patient)</td>
</tr>
<tr>
<td>18</td>
<td>Provision of appropriate input into the selection of kits for the national programme through a national purchase</td>
</tr>
<tr>
<td>19</td>
<td>Participation in the evaluation of new kits or processes</td>
</tr>
<tr>
<td>20</td>
<td>Facilitating cluster wide QA activities</td>
</tr>
<tr>
<td>21</td>
<td>Ensuring “client” local screening centres adhere to national protocols</td>
</tr>
</tbody>
</table>
### Selection Criteria for the Programme Hubs

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Experience in despatch of kits and receipt of specimens</td>
</tr>
<tr>
<td>2</td>
<td>Experience in developing and interpreting of guaiac FOBt kits</td>
</tr>
<tr>
<td>3</td>
<td>Experience in running screening call and recall systems</td>
</tr>
<tr>
<td>4</td>
<td>Experience in dealing with members of the public</td>
</tr>
<tr>
<td>5</td>
<td>Experience in provision of (multilingual) helplines</td>
</tr>
<tr>
<td>6</td>
<td>CPA status of associated Clinical Biochemistry laboratory</td>
</tr>
<tr>
<td>7</td>
<td>Sufficient dedicated and trained staff to cover all functions</td>
</tr>
<tr>
<td>8</td>
<td>Supervision from a consultant clinical biochemist</td>
</tr>
<tr>
<td>9</td>
<td>Research interest and capability</td>
</tr>
<tr>
<td>10</td>
<td>Ability to train hub staff</td>
</tr>
<tr>
<td>11</td>
<td>Ability to contribute to training in colorectal cancer management and bowel cancer screening</td>
</tr>
<tr>
<td>12</td>
<td>Office space for outlines functions</td>
</tr>
<tr>
<td>13</td>
<td>Laboratory space for receipt and development of kits including that required for associated computer entry</td>
</tr>
<tr>
<td>14</td>
<td>Sufficient space to allow for running trials of alternative kits and processes alongside standard operations</td>
</tr>
<tr>
<td>15</td>
<td>To comply with NHS Connecting for Health, printer drivers will needs to support PDFs (format in which letters, reports etc will be in)</td>
</tr>
<tr>
<td>16</td>
<td>Likely start date</td>
</tr>
</tbody>
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### SPECIFIC TASKS AND SELECTION CRITERIA OF THE LOCAL SCREENING CENTRES

#### Specific Tasks:

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Set up clinics (both nurse and endoscopy)</td>
</tr>
<tr>
<td>2.</td>
<td>Communication directly with patients regarding appointments and results clinics/letters</td>
</tr>
<tr>
<td>3.</td>
<td>Deal with telephone queries (bowel history and endoscopy)</td>
</tr>
<tr>
<td>4.</td>
<td>Education of and liaison with local primary care and public health</td>
</tr>
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<td>5.</td>
<td>Coordination of/liaison with local health promotion activities to improve access to screening by all sections of society</td>
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<tr>
<td>6.</td>
<td>Liaison with Programme Hub including communication of results in a timely manner</td>
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<td>7.</td>
<td>Monitor work flow and liaise with Programme Hub in order to adjust invitations, referrals where necessary</td>
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<tr>
<td>8.</td>
<td>Liaison with patients’ GPs</td>
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<td>9.</td>
<td>Provide written confirmation of results of colonoscopy to the patient and their GP within one week of the examination</td>
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<td>10.</td>
<td>Offer an appointment to discuss the results within two weeks for patients with high risk polyps or cancer</td>
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<td>11.</td>
<td>Referral of individual patients for investigation and treatment according to local pre-agreed patterns (including barium enema and management of incidental findings)</td>
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<td>12.</td>
<td>Liaison with MDTs and treatment services including pathology to ensure appropriate follow up of results and facilitate audit</td>
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<tr>
<td>13.</td>
<td>Liaison with QA activity at Programme Hub</td>
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<td>14.</td>
<td>Coordination of sites in which the team operate</td>
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<tr>
<td>15.</td>
<td>Monitoring and data collection including of treatment and histology outcomes and of adverse events</td>
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#### Selection Criteria

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<tr>
<th>Criteria</th>
<th>Description</th>
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<tr>
<td>1.</td>
<td>Global rating scale score with particular emphasis on symptomatic waiting times and patient experience</td>
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<td>2.</td>
<td>A satisfactory peer-review visit conducted under the auspices of the JAG, and the local training and SHA clinical leads.</td>
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<td>3.</td>
<td>Have an IT system able to meet national requirements and download data to national screening database OR ability to enter data directly and promptly onto national database via a web link</td>
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<td>4.</td>
<td>Ability to undertake and provide endoscopy unit audit data on key quality indicators for all colonoscopy performed in the unit, within which the screening patients will be identified, on a continuous basis to the programme hub screening QA office</td>
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<td>5.</td>
<td>Sufficient colonoscopists to provide timely colonoscopy for screen positive patients. The colonoscopists must be accredited and plan to perform or...</td>
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supervise 250 colonoscopies per year per practitioner with at least one PA per week\(^9\)

| 6. | Sufficient trained and competent nurses and administrative staff to perform necessary functions |
| 7. | Identification of a centre director and professional leads with identified time |
| 8. | Ability to see all patients with a positive FOB test an appointment with a nurse within one week of the date of the result letter. |
| 9. | Ability to offer all patients with a positive FOB test an urgent appointment colonoscopy within two weeks of their appointment with the nurse since the suspicion of colorectal cancer is high. |
| 10. | At least 70% of patients should be seen on segmented lists. Segmentation in this context refers to patients on segmented lists having similar clinical characteristics and follow-up needs (in this case patients referred with a positive FOB test), i.e at least 70% of patients will be seen on special lists for FOBt positive patients. |
| 11. | Experience of dealing with FOBt positive patients |
| 12. | Experience of dealing with screening population |
| 13. | Experience of health promotion activities |
| 14. | Ability to deliver training to medical and non-medical trainees |
| 15. | Research interest and capability |
| 16. | Likely start date |

\(^9\) Resources for Coloproctology, Association of Coloproctology of Great Britain and Ireland 2001

*Appendix 8: NHS Bowel Cancer Screening Program: Advice to the NHS*