

## Results of the first round of a demonstration pilot of screening for colorectal cancer in the United Kingdom

UK Colorectal Cancer Screening Pilot Group

### Abstract

**Objectives** To assess the feasibility of introducing into the United Kingdom's NHS a national screening programme for colorectal cancer based on faecal occult blood testing.

**Design** Demonstration pilot.

**Setting** Two English health authorities and three Scottish health boards.

**Participants** People aged 50-69 years.

**Results** 478 250 residents of the pilot areas were invited to take part in the screening programme. Uptake (the proportion for whom a final faecal occult blood test result was available) was 56.8% (n = 271 646). The overall rate of a positive test result was 1.9% and the rate for detecting cancer was 1.62 per 1000 people screened. Both these values were higher in Scotland than in England, were higher in men than in women, and increased with age. The positive predictive value was 10.9% for cancer and 35.0% for adenoma. 552 cancers were detected by screening; 92 (16.6%) were polyp cancers. 48% of all screen detected cancers were Duke's stage A, and 1% had metastasised at the time of diagnosis.

**Conclusions** Screening for colorectal cancer by testing for faecal occult blood is feasible within the context of the United Kingdom's NHS. Screening should lead to a reduction in deaths from colorectal cancer in the population offered screening.

### Introduction

In colorectal cancer, guaiac based testing of faecal occult blood is the only screening modality that has been shown to reduce disease specific mortality by means of population based randomised trials.<sup>1-3</sup> Studies of most relevance for the United Kingdom were those carried out in Nottingham, England, and in Funen, Denmark.<sup>2,3</sup>

On the advice of the National Screening Committee, the UK health departments carried out a demonstration pilot to test the feasibility of a national screening programme for colorectal cancer. We report on the uptake, outcomes, and consequences of the project.

### Methods

The pilot was carried out in two areas: Coventry and Warwickshire (two English health authorities, popula-

tion around 800 000), and Grampian, Tayside, and Fife (three Scottish health boards, population around 1.2m). Guaiac based faecal occult blood tests were carried out over a two year period.

The faecal occult blood test used in the pilot (Hema-screen; Immunostics, USA) had identical biochemical characteristics to that of the test used in the Nottingham and Funen trials. Faecal material was assessed from two samples taken from each of three stools, with repeat testing for weak positive results. People who had a positive test result and therefore needed further investigation were defined as test positive.

All residents of the pilot areas aged 50-69 were invited to participate. They were sent a test kit, which included information on screening and instructions on performing the test and returning it to a laboratory.

Colonoscopy was carried out by endoscopists who attended evaluation sessions and who agreed to submit their results to a database and quality assurance programme. Patients who had an incomplete colonoscopy were offered a double contrast barium enema. Histopathological examination of specimens was carried out by specialist gastrointestinal pathologists.

The pilot was evaluated independently by a multidisciplinary group that examined performance against central benchmarks derived from the Nottingham trial. We set out the key findings of the pilot in this context. The group also examined several other issues; details are in its final report ([www.cancerscreening.nhs.uk/colorectal/finalreport.pdf](http://www.cancerscreening.nhs.uk/colorectal/finalreport.pdf)).

### Results

Screening started on 29 March 2000 with the despatch of the first test kits. The prevalence (first) round was completed on 19 May 2003 with the last colonoscopy. The results presented here pertain to uptake, the rate of positive test results (positivity), colonoscopy, positive predictive value, and distribution of stage of cancer.

#### Uptake and positivity

Overall, 478 250 residents (England 185 267, Scotland 292 983) were invited to participate; testing was

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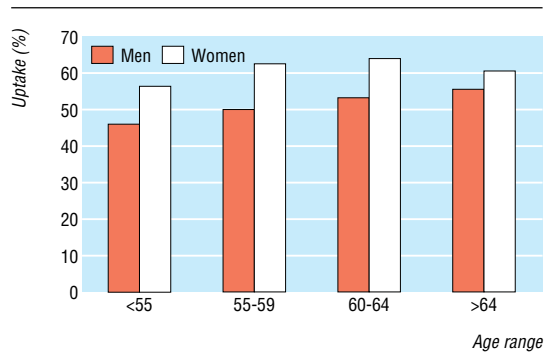
BMJ 2004;329:133-5



Details of the pilot group are on [bmj.com](http://bmj.com)



This is the abridged version of an article that was posted on [bmj.com](http://bmj.com) on 5 July 2004: <http://bmj.com/cgi/doi/10.1136/bmj.38153.491887.7C>



Variations in uptake of faecal occult blood test by age and sex

completed for 271 646 (56.8%). This uptake was higher for England than for Scotland (see *bmj.com*), was higher in women than in men, and increased with age (figure). Of 276 819 responders, 98.1% (n = 271 646) completed the test. The overall uptake (56.8%) was comparable to that in the Nottingham study (57% in the prevalence round).<sup>2</sup>

Although the positivity rate in the Nottingham study was 2.1%, this trial embraced a wider age range (50-74) than the pilot; the rate was 1.8% for the 50-69 age range (J H Scholefield, personal communication, 2003).<sup>2</sup> Thus, although the results for England were similar to those for Nottingham, the positivity rate for Scotland was higher. Men had a higher rate than women, and positivity increased with age.

**Colonoscopy and positive predictive values**

Overall, 3700 of 4116 people had a complete colonoscopy (completion rate 89.9%). The uptake of colonoscopy among people with a positive test result was 81.5% (4116 of 5050), but 278 (5.5%) were either medically unfit or had other good reasons for not undergoing the examination.

The positive predictive values of a positive test result were 10.9% for invasive cancer and 35.0% for adenoma. The values for cancer were higher for Scotland and in men. All values compared favourably to those of the Nottingham study in the 50-69 age range (table 1).

**Cancer detection rates**

Overall, 552 cancers detected by screening were diagnosed, of which 92 (16.6%) were invasive polyp cancers, removed at colonoscopy. The proportions of screen detected cancers presenting at Dukes's stages A or B were similar for England and Scotland. Both were comparable to the Nottingham values at the first invitation to participate (table 2).

The cancer detection rate for the pilot was 1.62 per 1000 people screened, and 6.91 for all neoplasia (cancers and adenomas). The cancer detection rate in England was comparable to the 50-69 age range in the prevalence round of the Nottingham trial whereas it was higher in Scotland (table 3). The overall detection rate for neoplasia was higher in Scotland than in England, particularly for men.

**Discussion**

Screening for colorectal cancer by testing for faecal occult blood is feasible within the context of the United Kingdom's NHS, as shown by this demonstration pilot conducted in two health authorities in England and three health boards in Scotland. Randomised trials of screening by faecal occult blood testing have shown reduced disease specific mortality.<sup>1-3</sup> The most important question was whether the short term outcomes of the randomised trials could be achieved by a comprehensive screening programme covering large, representative areas of Britain; if this was possible, then a national programme could reasonably be expected to bring about a comparable reduction in mortality from colorectal cancer. The results of the trial from Notting-

**Table 1** Positive predictive values of colonoscopies conducted in screening pilot and Nottingham trial

Variable	Men			Women			Both		
	England	Scotland	Nottingham	England	Scotland	Nottingham	England	Scotland	Nottingham
Cancer*	11.6	12.7	10.1	9.9	10.3	8.5	10.2	11.8	9.5
Neoplasia†	53.7	53.6	—	36.1	37.3	—	46.9	47.3	—

Nottingham values are for prevalence round and age corrected for 50-69 years but do not include all polyp cancers (age corrected values for total neoplasia not available).

\*Includes polyp cancers.

†Includes all invasive cancers and adenomas.

**Table 2** Dukes's stage of colorectal cancer in pilot and in Nottingham trial at first invitation to participate. Values are numbers (percentages)

Dukes's stage	England	Scotland	Nottingham
Not available	7 (5.3)	28 (9.4)	0
Available:	124 (95.3)	270 (90.6)	83 (100.0)
A or B	89 (71.8)	197 (73.0)	59 (71.1)
C or D	35 (28.2)	73 (27.0)	24 (28.9)

Polyp cancers included in category A when nodal status is unknown.

**Table 3** Detection rates for cancer and neoplasia per 1000 people screened (faecal occult blood testing complete) for pilot and prevalence screen of Nottingham trial

Variable	Men			Women			Both		
	England	Scotland	Nottingham	England	Scotland	Nottingham	England	Scotland	Nottingham
Cancer	1.8	2.9	1.7	0.8	1.2	1.1	1.3	2.0	1.6
Neoplasia	8.3	12.4	—	3.7	4.4	—	5.8	8.0	—

Values are standardised for age or age and sex to age range in pilot (50-69 years).

ham were used as benchmarks as this was the largest population based trial of screening for colorectal cancer and was carried out in the United Kingdom.

The overall uptake, number of positive test results, positive predictive value of the faecal occult blood tests, and distribution of stage of screen detected cancers were comparable to the Nottingham trial. There are, however, some other important considerations of the pilot.

Firstly, only those aged 50-69 years were offered screening on the basis of the fall off in uptake in people over 70 in the Nottingham study.<sup>2</sup> However, data from the Funen trial indicate that if the age at entry to the study had been raised from 50 to 55 then this would have missed 3% of the screen detected cancers whereas lowering the age at completing the study from 74 to 69 would have missed 25%.<sup>4</sup> Before implementing national screening, therefore, consideration should be given to the appropriate age range to be invited to participate.

Secondly, around 40% of the population declined to take part in the pilot. Uptake tended to increase with age, and women were more likely to comply than men. In addition, over 10% of participants with a positive result for faecal occult blood testing did not take up the offer of colonoscopy despite the implications of the result being explained by the pilot nurses. This may reflect a lack of understanding of the screening process.

The completion rate for colonoscopy of around 90% was better than the UK average,<sup>5</sup> but the pilot areas were chosen on the basis of being able to provide colonoscopy to the required standard. National programmes will require a high quality colonoscopy service. It is therefore timely that endoscopy training centres have been established in England, and that guidelines for surveillance by colonoscopy of patients with adenomas have recently been issued.<sup>6-8</sup>

One of the concerns at the beginning of the pilot was the involvement of general practitioners at the invitation stage. Previous research by the Nottingham group had shown that screening invitations signed by a general practitioner were more likely to be accepted than those issued by an unfamiliar individual or organisation.<sup>9</sup> To minimise the impact on primary care, however, it was decided that the invitation letters should be signed by the lead clinicians and this did not seem to impact greatly on uptake.

Interval data on cancer from the Nottingham study have indicated that the guaiac based faecal occult blood test may be only about 50% sensitive in a screening context, and that about half of all colonoscopies carried out on the basis of a positive test result show no evidence of neoplasia.<sup>2</sup> Endoscopy of the lower gastrointestinal tract is widely used for screening, and both colonoscopy and flexible sigmoidoscopy have their proponents.<sup>10-11</sup> Colonoscopy has the advantage of high sensitivity and specificity, but it is expensive and associated with morbidity, and in the absence of randomised trials, the cost and benefit ratio for population screening is difficult to determine.

Flexible sigmoidoscopy is the subject of an ongoing randomised trial, and preliminary results are encouraging.<sup>11</sup> However, mortality data from the flexible sigmoidoscopy trial are not yet available, but only people expressing an interest in screening were recruited and randomised so that compliance is impossible to estimate for the population.

## What is already known on this topic

Population based randomised controlled trials have shown that screening by faecal occult blood testing for colorectal cancer can reduce mortality

## What this study adds

A screening programme for colorectal cancer using faecal occult blood testing is feasible in the United Kingdom

Such a programme should lead to a reduction in mortality from colorectal cancer

Screening by faecal occult blood testing costs about £5900 (\$10 800; €9000) per life year saved,<sup>12</sup> which is well below the threshold most European countries are willing to pay.<sup>13</sup> In the United Kingdom, however, there is little doubt that a screening programme would put further pressure on an already overstretched endoscopy service, and the introduction of screening must go hand in hand with improvements in provision of services.<sup>14</sup>

This study forms part of the independent evaluation of the UK colorectal cancer screening pilot commissioned by the policy research programme at the Department of Health, England. The views expressed are those of the authors and not necessarily those of the Department of Health. We thank J H Scholefield, Queen's Medical Centre, Nottingham, for providing unpublished data from the Nottingham trial.

Contributors: See [bmj.com](http://bmj.com)

Funding: Health departments in England and Scotland.

Competing interests: None declared.

Ethical approval: Ethical approval was not sought for the pilot. This was a decision made by the National Screening Committee, and endorsed by the health departments, on the grounds that faecal occult blood screening for colorectal cancer is a technology of proved efficacy, and that the study was not research based but rather evaluated the feasibility of introducing a screening programme into the NHS.

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(Accepted 6 May 2004)

doi: 10.1136/bmj.38153.491887.7C