

PRACTICE OBSERVED

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Randomised trial of compliance with screening for colorectal cancer

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Abstract

A randomised trial of compliance with screening for colorectal cancer by means of the haemocult test was conducted in Farnborough and Basingstoke districts. In each of the 14 participating practices (41 general practitioners) 25 852 men and women aged 40 and 70 years were randomly allocated by household to one of six groups. The group determined the method of invitation to screening: a letter and the test were sent to the patient, or a letter with an appointment to attend the surgery was sent, or during a routine consultation the general practitioner invited patients to participate, and some patients received an educational booklet about bowel disorders and screening.

Of the 17 824 people who were offered screening, 7545 (42%) complied. Compliance was significantly affected by the method of invitation, but not by whether an educational booklet was received, and was highest (57%) in the group that was offered

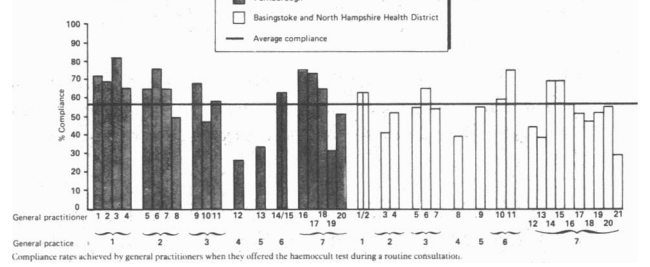
the haemocult test during a routine consultation (the "opportunistic" approach). In this group the compliance rate achieved by individual general practitioners ranged from 26% to 82%.

Compliance was significantly higher in Farnborough, in the older (55-70) age group, in women, and in households in which two or more people were offered screening. The higher compliance in Farnborough may be explained by the higher proportion of older people and by the higher proportion of people living in households of two or more in the population that was offered screening. The fact that the screening programme in Farnborough was offered to the whole community and that the researcher may have acted as a facilitator were probably also important.

One per cent of the patients screened had a positive test, and 24 (38%) of the 63 patients who were positive and were investigated in hospital had neoplastic disease. The yield was 1.2 cancers and 1.2 benign adenomas (1 cm or larger in size) per 1000 people screened. This low yield is likely to be a consequence of the relatively young age group screened.

Introduction

Colorectal cancer is the second most common cause of death from cancer; nearly 19 000 deaths in 1983. Survival after treatment is directly related to the stage of the disease. Over 90% of patients with Duke's type A disease, limited to the mucosal surface of the colon, were compared with 27% of patients with advanced tumours. Less than 10% of patients present with symptomatic type A disease.¹ Those who are at a high risk of developing colorectal cancer are over 40 and have a history of benign adenomatous polyps. It is estimated that nearly half of adenomas over 2 cm in size become malignant.² Thus screening for colorectal cancer aims at detecting



effect of the district, compliance was significantly higher in the older age group ($p < 0.001$), in women ($p < 0.001$), and in households where two or more people were offered screening ($p < 0.001$). Thus, compliance was highest (48%) in older women in households in which two or more people were offered screening and lowest (33%) in younger men in households where they were the only person offered screening.

POSITIVE RESULTS

Of the 7545 haemocult tests returned, 31 (0.4%) were incorrectly completed. Seventy five (1%) of the 7514 correctly completed tests were positive—that is, one or more of the six stool samples showed a blue coloration. Thirty six (48%) of the patients with positive results were aged between 60 and 70, and 14 (39%) were under 50; 41 (55%) were men, and 34 (45%) were women. Of those who complied with screening, there was a significantly higher proportion of positive tests in the older age group (55.7%) than in the younger age group ($40.54; \chi^2 13.2; df 1; p < 0.001$ and, allowing for age group, among men than among women ($\chi^2 4.1; df 1; p < 0.04$).

Ten (18%) of the 75 patients with a positive test were not referred to hospital for further investigation, one died before investigation, and one did not attend the outpatient appointment. Therefore, 63 (84%) of the patients who were positive were investigated. At Farnley Park Hospital 27 (66%) of the 41 positive patients had colonoscopy only, 54% of colonoscopy and double contrast barium enema (28%). At Basingstoke District Hospital, eight (16%) of the 22 positive patients had colonoscopy, and half of those had a barium enema as well. Ten (16%) of the patients had neither colonoscopy nor barium enema because an obvious cause for the bleeding was found. Of the 63 positive patients who were investigated in hospital, 24 (38%) had neoplastic disease, 28 (44%) had non-neoplastic colorectal conditions, 3 (5%) had benign adenoma, and the remaining eight (13%) had no abnormality. Six of the 24 patients with neoplastic disease had cancer (four Duke's type B, two Duke's type C), three had an adenoma with malignant change (one over 10 cm in size, one 2 cm, and one 1 cm), the remaining 15 patients had benign adenomas, nine of which were 1 cm or larger. One (3%) of the 40-49-year-old patients who were positive had neoplastic disease compared with nine (41% and 14 (48%) of those aged 50-59 and 60-70 respectively).

Thirty seven (49%) of the 75 positive patients had only one out of six positive stool samples. For the 24 patients with neoplastic disease, the number of positive samples ranged from one to six, with seven (29%) patients having only one positive sample. When seen in the outpatients department 40 (66%) of the positive patients said that they had recently noticed one or more symptoms of colorectal disease. Twenty four (60%) had noticed one symptom, rectal bleeding being the most common (60%), followed by a change in bowel habit (30%), abdominal pain (25%), weight loss (10%), and other symptoms (2%). Rectal bleeding had been noticed by 11 (75%) of the patients with neoplastic disease compared with 11 (58%) of those with non-neoplastic colorectal conditions, whereas abdominal pain and change in bowel habit were more common among the latter. The yield of cancers, including adenoma or papilloma with malignant

change was 1.2 per 1000 people screened. The yield of benign adenomas per 1000 people screened was 2.0 for all sizes and 1.2 for adenomas of 1 cm or larger.
Of the 7514 people who returned a correctly completed haemocult test, 39 had a positive result, but no neoplastic disease, giving a false positive rate of 0.5%.

Discussion

In previous studies of screening for colorectal cancer low compliance rates have been reported, although higher rates have been shown when methods other than posting an invitation have been tried.³⁻⁷ In none of the studies, however, was a randomised trial of compliance carried out in which the sample of patients in each general practice was randomly allocated to different methods of invitation to screening.

The results of our randomised trial of compliance show that the uptake of screening for colorectal cancer by the public can be appreciably increased if invitations are issued personally. The most effective method was clearly the one in which general practitioners offered the haemocult test during a routine consultation; this is sometimes referred to as the "opportunistic" approach but should not be confused with an "unplanned" approach. For the planned "opportunistic" approach to screening, the general practitioner identifies a group of people—for example, a particular age group—and offers screening the next time each person presents at the surgery. In this trial, 67% of the selected "routine consultation" group had at least one consultation with their general practitioner over 12 months. If such an approach to screening was adopted the people who had not consulted the doctor after a specified period could be contacted by letter.

The overall compliance rate achieved by offering the test during a routine consultation was nearly 60%. Individual general practices and practitioners, however, achieved much higher rates—seven of the 41 doctors had a compliance rate of over 70%; the highest rate being 82%. Factors such as the number of patients and the workload might influence the compliance rates of individual doctors, but high rates may indicate the general practitioners' motivation and interest, a positive attitude to screening, and good communication skills.

Sending a letter with a specific appointment to invite patients to colorectal screening resulted in a lower compliance rate than the "opportunistic" approach, but a higher rate than sending the haemocult test by post. Such a method may be considered unsatisfactory by some general practitioners because of the inevitable increase in workload, but appointments can be taken by

asymptomatic, type A tumours and benign adenomatous polyps to reduce premature mortality from the disease.

The results of studies of screening for colorectal cancer that have been carried out in the United Kingdom have been summarised. The screening test (usually haemocult) detects occult blood in the faeces. It requires smearing a small sample from two parts of the stool onto three slides of guaiac-impregnated filter paper over three consecutive days, providing six stool specimens for analysis. When the slides are developed with hydrogen peroxide the haemoglobin that is present in the faeces splits off the oxygen, which is shown as a blue coloration. A positive (blue) result indicates the presence of blood in the faeces, and further investigation is required. The most recent study reported that 2% of patients screened had a positive result. Half of these had neoplastic disease, and three quarters of the invasive carcinomas were Duke's type A.⁸

A major problem in these studies has been the low uptake of screening by the public. In most studies a haemocult "patient pack" was sent to people aged over 40 or 45, accompanied by a letter from their general practitioner. The compliance rate has ranged from 27% to 43%. There is evidence, however, that education may improve compliance. For example, compliance increased from 37% to 47% and 52%, respectively, when subjects were sent an educational letter or were interviewed at home before being sent the test.⁹ Compliance might also improve if general practitioners personally distributed the test to patients who consult them.

A randomised trial was conducted to evaluate whether compliance with screening for colorectal cancer using the haemocult test could be improved, and several methods of invitation were offered. General practitioners were closely concerned in this, and subjects were provided with information about bowel diseases and screening.

Method

Twenty general practitioners from the seven practices in Farnborough and 21 general practitioners from five practices and two health centres in the Basingstoke and North Hampshire Health District participated in the trial. Altogether 25 852 people aged between 40 and 70 years, who were registered with these 41 doctors in January 1982, were randomly allocated by household to one of six groups in each general practice. The group determined the method of invitation to participate in screening for colorectal cancer and whether or not the person would receive an educational booklet about bowel diseases and screening for bowel cancer and polyps (table 1).

TABLE 1—Six groups for trial of screening for colorectal cancer

Group	Method of invitation to screening	
	Booklet	No booklet
Letter by post	Refused from the general practitioner with a booklet	Accepted from the general practitioner with a booklet
Letter by post	Refused from the general practitioner with a booklet	Accepted from the general practitioner with a booklet
Letter by post	Accepted from the general practitioner with a booklet	Accepted from the general practitioner with a booklet
Letter by post	Accepted from the general practitioner with a booklet	Accepted from the general practitioner with a booklet
Letter by post	Accepted from the general practitioner with a booklet	Accepted from the general practitioner with a booklet
Letter by post	Accepted from the general practitioner with a booklet	Accepted from the general practitioner with a booklet
Letter by post	Accepted from the general practitioner with a booklet	Accepted from the general practitioner with a booklet
Letter by post	Accepted from the general practitioner with a booklet	Accepted from the general practitioner with a booklet
Letter by post	Accepted from the general practitioner with a booklet	Accepted from the general practitioner with a booklet
Letter by post	Accepted from the general practitioner with a booklet	Accepted from the general practitioner with a booklet
Letter by post	Accepted from the general practitioner with a booklet	Accepted from the general practitioner with a booklet

The letters from general practitioners (groups 1-4), which explained the test and emphasised prevention and early detection, were sent out over an 18 month period. The medical notes of people who were to be offered the test during a routine consultation (groups 5 and 6) were flagged for one year. The test was accompanied by a specially prepared sheet of "helpful hints" on how to collect stool samples and a pre-paid envelope in which to return the test. The general practitioners kept a record of appointments and consultations that related to the screening programme.

Completed haemocult tests were developed by EK (Farnborough) or SN (Basingstoke), without refrigeration, by adding two drops of hydrogen peroxide solution and reading after 30 seconds. The general practitioner was informed immediately of a positive result. The management of these patients

was the general practitioner's responsibility, but referral to hospital for further investigation was strongly recommended. Most of the patients with positive results were seen by RCL and RJH. The consultant surgeon arranged the investigation, colonoscopy or double contrast barium enema, or both, after an outpatient appointment.

Results

A total of 2507 people were excluded from the trial for various reasons, including 1358 (54%) who had left the practice, 251 (10%) who were considered unsuitable for screening by the general practitioner (because of mental or emotional problems, too many other medical problems, known rectal bleeding, or colonic disease already under investigation or treatment), 170 (7%) who had died, and 670 (27%) who were not contacted owing to the limited time allocated for the trial. Thus the sample size was 23 345 people. The compliance rate for each of the six groups is shown in table 2. The compliance rate (No. of patients who returned a completed test/No. of people who were offered test) > 100 .

For the statistical analysis, GELM was used to determine whether there were significant differences in the compliance rates between the six groups in the trial. Similar analyses were carried out to determine the effect of age, sex, and size of household on compliance rates.

COMPLIANCE

Effect of method of invitation to screening and educational booklet—Overall, 7545 (42%) out of 17 824 people completed the haemocult test. Compliance was highest (58%) in the group that was offered the haemocult test but no educational booklet during a consultation. The method of invitation had a significant effect on compliance ($p < 0.001$), which was highest (57%) in the consultation group, intermediate (49%) in the group that was offered a specific appointment, and lowest (38%) in the group that was sent the test by post. Allowing for method of invitation, the educational booklet had no significant effect on compliance rates ($p < 0.17$, table III). Similar patterns of

TABLE 2—Summary of compliance with screening by method of invitation and receipt of educational booklet. Figures are numbers who completed or number offered screening, percentages in parentheses

Method of invitation	Education booklet	
	No booklet	Booklet
Letter by post	1572 (41%)	1546 (40%)
Letter by post	1017 (26%)	1076 (27%)
Letter by post	411 (11%)	411 (10%)
Letter by post	411 (11%)	411 (10%)
Letter by post	411 (11%)	411 (10%)
Letter by post	411 (11%)	411 (10%)
Letter by post	411 (11%)	411 (10%)
Letter by post	411 (11%)	411 (10%)
Letter by post	411 (11%)	411 (10%)
Letter by post	411 (11%)	411 (10%)
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Letter by post	411 (11%)	411 (10%)
Letter by post	411 (11%)	411 (10%)
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Letter by post	411 (11%)	411 (10%)
Letter by post	411 (11%)	411 (10%)
Letter by post	411 (11%)	411 (10%)
Letter by post	411 (11%)	411 (10%)
Letter by post	411 (11%)	411 (10%)

compliance were found in the Farnborough and Basingstoke districts—that is the method of invitation, but not the educational booklet. had a significant effect on compliance rates. Allowing for the method of invitation, however, there was a significant difference ($p < 0.001$) between the two districts, with compliance higher in Farnborough than in Basingstoke. There was also a significant interaction ($p < 0.001$) between district and method of invitation, with compliance higher in Farnborough in the appointment and consultation groups, but similar in the groups sent the test. Five hundred and ninety eight (9%) of the patients who completed the test enclosed a stamped addressed envelope for the result, 1218 (12% of the non-compliers returned the test unused in the prepaid envelope, most (8%) anonymously.

Effect of "opportunistic" appointments in Farnborough—Appointments at two of the seven Farnborough practices were with a health visitor or surgery nurse rather than with the general practitioner. The status of the "instructor" had a significant effect on compliance ($p < 0.001$): 1206 (53%) patients complied when the "instructor" was a doctor compared with 440 (35%) for the health visitor or nurse.

Effect of general practitioner at routine consultation—The compliance rate achieved by the 41 general practitioners when the haemocult test was offered during routine consultations ranged from 26% to 82% in Farnborough, and from 29% to 75% in the Basingstoke district (figure).

Effect of age, sex, and size of household of people offered screening—The age group (40-54/55-70), sex, and size of household (one two or more for the age group) offered screening affected the compliance rate. Allowing for the

another member of the primary care team. Our results, however, suggested that compliance will be lower if the "instructor" is a health visitor or practice nurse rather than the general practitioner. When the method of invitation required the patient to make an appointment or to collect the test from a reception compliance was lower than when the test was sent by post.

The results did not suggest that education—in this case a booklet about bowel disorders and screening—is likely to increase the uptake of screening. The reason for this is not clear, because over 90% of respondents to a follow up postal survey said that they had read the booklet and had increased their knowledge of bowel disorders (S. Nichols, unpublished observations). Nevertheless, greater knowledge may not lead to a more positive attitude to preventive health practices or to an increase in the individual's perceived need for screening, both of which may be important motivating factors.¹⁰ The lack of effect of the educational booklet on compliance rates does not necessarily imply that education is ineffective. When offering screening by appointment and during routine consultations the general practitioners were taking on an educational role.

For the appointment and consultation groups compliance rates were higher in Farnborough than in the Basingstoke district. This may partly be explained by the significantly higher proportion of older (55-70) people and households of more than one person in the group offered screening in Farnborough. Compliance was similar in the two districts, however, for the groups that were sent the haemocult test by post. The screening programme in Farnborough was a community programme in which all the general practitioners participated, and this may have had a motivating or competitive influence on the doctors and a motivating effect on the population offered screening. Furthermore, EK was in regular contact with the Farnborough practices and may have acted as a facilitator. Her influence would have been greatest on the appointment and consultation groups.

Compliance rates were generally higher among the older age group (55-70), among women, and among those from a household in which two or more members were offered screening. Previous studies have consistently found compliance to be lower in men than women and among the very elderly (70 and over).⁸

Ten per cent of the sample of nearly 26 000 registered was not included in the trial. Inaccuracies in age-sex registers accounted for 1521 (61%) of the exclusions.

The rate of 1% positive tests and the yield of cancers and benign adenomas were lower than those reported in many previous studies of asymptomatic persons.⁸⁻¹⁰ It was also disappointing that the cancers detected were not at an early stage. The positive rate and yield are likely to be related to the age group screened, since the incidence of colorectal cancer increases with age. Thus, the relatively young minimum age of the population screened and the cut point of 70 years may account for the lower positive rate and yield of neoplastic disease. Furthermore, 54% of the positive patients who were investigated by repeat colonoscopy, 43% had a double contrast barium enema, and 16% had neither. Colonoscopy is a more reliable investigation for the detection of colorectal tumours than double contrast barium enema.¹¹ The false positive

rate of 0.5%, lower than reported elsewhere,⁸⁻¹⁰ is likely to be related to the low positive rate. It is not known whether this low false positive rate will be matched by a high false negative rate, but it seems likely.

Undoubtedly, the uptake of screening for colorectal cancer would be greatly improved if general practitioners offered the haemocult test in the consultation. The motivation and enthusiasm of individual doctors might also affect the compliance rate.

The results of a recent survey indicate that most general practitioners are not in favour of screening for colorectal cancer.¹² We suggest that the success of screening for asymptomatic colorectal cancer lies with general practitioners in the role of health promoters. There is no firm evidence that premature mortality from colorectal cancer can be reduced by screening for the disease. More general practitioners are likely to favour screening when evidence is available from the follow up of the Nottingham controlled trial.¹³

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