THE EARLY DETECTION OF COLORECTAL CANCER AND ITS

PREVENTION.

A dissertation submitted for the degree of Doctor of Medicine

at the University of Leicester

by

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This work is dedicated to my mother and father

Summary of colorectal cancer screening and an outline of the thesis.

A national screening programme for colorectal cancer is needed to reduce the high mortality from this disease. The programme must detect asymptomatic pre-malignant adenomatous polyps and early colorectal cancers. There are two methods of screening, faecal occult blood testing and sigmoidoscopy, but their value in reducing mortality is unclear. The success of screening depends on achieving a high compliance, although in studies from British general practices it is often below 50%. To address this problem, other modes of delivery need to be considered and interventions for raising compliance investigated. This thesis explores the value of inviting people to participate at their place of work, an opportunistic method and the development of effective health education.

The first half of the thesis assesses methods for the delivery of screening. Residents of Market Harborough were offered free faecal occult blood tests through postal invitations from general practitioners. Uptake was recorded according to age and sex. Compliance in two work based approaches in private and public industries was compared with that in Market Harborough in men and women aged 51 to 65 years. The two workplaces studied were Brush Engineering, Loughborough and Leicester General NHS Trust Hospital. An opportunistic method of delivering screening was investigated in Leicestershire blood donors when they came to give blood.

Secondly, effective health education about screening was developed and assessed. A leaflet was written explaining screening, faecal occult blood tests, the high frequency of colorectal cancer and addressing reasons for non-compliance. Reasons for non-participation were identified by interviewing those declining screening in Market Harborough. The leaflet's effectiveness was first piloted on one hundred subjects before testing in a large randomised controlled trial.

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Abstract. The Early Detection of Colorectal Cancer and its Prevention

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Three cross-sectional surveys of acceptance of faecal occult blood testing for colorectal cancer screening, one survey of non-acceptors and one randomised controlled trial of an information leaflet were conducted. These were workplace based schemes in the private and public sectors and opportunistic screening using blood donors as a model. Simple educational leaflets explaining the high frequency of colorectal cancer and screening which addressed reasons for non-compliance were investigated.

Subjects completed faecal occult blood tests at home and those with positive results underwent colonoscopy. Completion of tests in general practice in those aged 51 to 70 years was 33% (665/2029) in men and 42% (900/2147) in women. In private industry in subjects aged 41 to 65 years, compliance in men was 25% (425/1703) and in women 32% (40/125). In public industry in subjects aged 41 to 65 years compliance was 32% (53/165) in men and 46% (376/820) in women. With opportunistic screening at the blood donor centre compliance in those offered screening aged 51 to 65 years was 66% (75/114) in men and in women 59% (41/70).

The health educational leaflets increased awareness of cancer and screening and raised intention to participate in a 100 subjects accompanying patients to hospital clinics. Reasons for non-compliance addressed in the leaflet, were identified from an interview survey of 81 non-compliers in Market Harborough. Common reasons were the unpleasantness of stool collection, lack of appreciation that healthy subjects should participate, fear of further tests and surgery and intercurrent illness. After piloting the leaflet it was tested in a randomised community controlled trial in general practice in subjects aged 61 to 70 years. The leaflet increased compliance in men from 25% (91/360) to 38% (143/381) ($X^2=12.9$, $p < 0.001$), but was ineffective in women (33%, 134/405, vs 34%, 145/425, $X^2=0.1$,ns).

Organisers of screening should consider opportunistic approaches and health education leaflets to increase participation. As compliance in this study was lower than in some other programmes, more work is needed to identify other reasons for non-compliance.

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Statement.

The accompanying thesis submitted for the degree of Doctor of Medicine entitled "The early detection of colorectal cancer and its prevention" is based on work conducted by the author at Leicester General Hospital during the period 1st August 1991 to 30 September 1994. All the recorded work is original unless otherwise acknowledged in the text or by references. None of the work has been submitted for another degree in this or any other university. Some of the work is published or is accepted for publication:

1. Hart AR, Wicks ACB, Mayberry JF. A survey of industries and colorectal cancer screening of employees in the East Midlands of England. Journal of the Royal Society of Medicine 1993;86:571-572.

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Acknowledgements

Chapter One.

Review of the Literature.

An Introduction to Screening.

Screening is defined by the World Health Organisation and The United States Commission on Chronic Illness as "the presumptive identification of unrecognised disease or defect by the application of tests, examinations, or other procedures which can be applied rapidly"(1,2). Morrison defined screening as "the examination of asymptomatic people in order to classify them as likely or unlikely, to have the disease that is the object of screening. People who appear likely to have the disease are investigated further to arrive at a final diagnosis" (3).

The aim of screening is to detect occult disease which is potentially curable. The realisation of the extent of occult disease in Britain dates back to the Boer War, where there was a high rejection rate of volunteers for army service on medical grounds (4). This experience was repeated during the two world wars in both the military and civilian populations (5). One of the first studies to quantify occult and undiagnosed disease in Britain was conducted by Pearse in the London Borough of Peckham starting in 1926 (6). A staggering amount of previously undetected disease was discovered and the phrase "the iceberg of disease" was coined. In 4 000 people living in a thousand families in Peckham, two-thirds had some form of pathology ranging from mild infections and vitamin deficiencies to undiagnosed renal disease and cancers (7). In the early 1960's a further attempt was made to quantify this iceberg (8,9), where one author hypothesised that only a half of all cases of diabetes and pulmonary tuberculosis and two-thirds of those with hypertension were being diagnosed (8).

With the inception of the National Health Service in 1948, one might have expected screening and services to detect undiagnosed disease to proliferate. However, because the emphasis of the newly formed service was on treating symptomatic patients, research on the

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identification of undetected disease was conducted in a patchy and ad hoc way. One classic early study was by Dr Exton-Smith who visited 215 of his elderly patients in their homes in St Pancras in 1952 (10). He found two-thirds were confined to bed and a third were suffering from such illnesses as cerebrovascular disease, heart failure and bronchitis. In 1972, the results of an extensive screening of a 1 000 geriatric patients in south-east Scotland were reported (11). Randomly selected subjects aged over 65 years were visited in their homes by health visitors who explained they had been chosen for survey. Subsequently subjects were seen in their homes by a doctor who took a medical history and invited subjects to come to the medical centre for a complete examination. The commonest unreported medical conditions diagnosed were anaemia and cardiac failure. Partial blindness, deafness and urinary symptoms were also frequently discovered. A proportion of this discovered disease was treatable. Half of the subjects with incontinence had a urinary tract infection and a third of those with deafness were cured by removing ear wax with syringing. Screening services for cancer were not offered to large populations until the late 1980's. For example in cervical cancer screening, although the Papanicolaou smear was described in 1943 (12) and screening has been offered since the 1960's, it is only recently that family practitioner committees have begun computer assisted call and recall of women for smear testing. Similarly in breast cancer screening, although the efficacy of mammography was reported in 1977 (13), it was only following the Forrest Report (14) in 1986, that a national programme was implemented.

In colorectal cancer screening there is no national programme for early detection and prevention, as currently there is insufficient evidence of the benefit of screening. This introductory chapter will present current research in colorectal cancer screening and discuss some of the associated problems.

The Principles of Screening.

The aim of screening is simple i.e. to save lives by detecting early disease, although there are many problems which make this goal difficult to achieve. For example, great demands are placed on screening tests which must be sensitive enough to detect cancer but exclude those without disease. The ability of tests to detect pathology before symptoms does not imply efficacy in reducing mortality. This was shown in studies of mass chest radiography for bronchial carcinoma, where asymptomatic detection of pathology did not increase survival (15,16,17). The efficacy of screening tests must be proven and this requires large and expensive clinical randomised controlled trials. Once efficacy is shown, then the test has to be made acceptable to the public who will benefit from screening. If a screening test satisfies all these vigourous demands then finally it must also be economically viable. The long-term economic aim is to prevent or treat disease early so the productive life of the population is prolonged benefiting the national economy. Health economists must scrutinise the costs and benefits to determine whether the investment is justified. The World Health Organisation has established several criteria (18) by which to assess screening programmes. These are shown in table 1.1. However, even within these broad concepts there can be problems with interpretation. For example, for a disease to be considered an important problem it does not need a high prevalence. Phenylketonuria is extremely rare but warrants screening in view of the serious consequences if not discovered early. Conversely, maturity onset diabetes mellitus is common and can be screened for, although it is often of a mild degree.

The ability of a screening test to identify people with preclinical disease is referred to as the sensitivity of the test. Sensitivity is usually defined as the proportion of cases with a positive screening test which is among all cases of preclinical disease, as identified by a

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Table 1.1 World Health Organisation Screening Criteria.

The Disease

An important problem

Recognised latent or early symptomatic stage

Natural history must be understood

The Screen

Suitable test or examination (of reasonable sensitivity & specificity)

Test acceptable by population being screened

Screening must be a continuous process

Follow-up

Facilities must exist for assessment and treatment

Accepted form of effective treatment

Agreed policy on whom to treat

Economy

Cost must be economically balanced in relation to possible expenditure on medical

care as a whole.

Wilson JMG, Junger G. 1968. Principles and practice of screening for disease.

Public Health Papers No 34. World Health Organisation, Geneva.

positive diagnostic test. The definition is problematic, as it is impossible to apply a diagnostic gold standard test, which is often a surgical procedure, to asymptomatic people to determine if they have pre-clinical disease. To overcome this problem sensitivity can be assessed by comparing the efficacy of different screening tests. The specificity of a test is defined as its ability to designate as negative people who do not have the disease. Test specificity determines whether the frequency of false positives will be low enough for a screening programme to be feasible (3). Sensitivity and specificity measure the ability of a test to correctly identify diseased and non-diseased people. In contrast, reliability of a test is its capacity to give the same result on more than one occasion, whether positive or negative.

For a screening programme to be successful, the disease must be caught early before onset of symptoms. Lead-time is defined as the interval between detection of the disease by screening and the time at which the diagnosis would have been made due to symptoms. If the lead-time is short, then the disease is close to presenting with symptoms. The establishment of a screening programme may increase the population's awareness of symptoms, thereby reducing lead-time and any subsequent health gains of screening. Ideally, there must be enough lead-time in a sufficient number of cases to make screening worthwhile. If lead-time is short, cases will not be diagnosed and treated in time to stop their ultimate clinical progression. If few cases are detected, then early treatment no matter how effective will not have an important impact on the disease burden. The lead-time interval in an individual with screen detected disease cannot be measured as screen detected disease is treated. However, an estimation of lead-times created by a screening programme can be evaluated by comparing the frequency of diagnosed cases by time between a screened and a control group. Randomised trials are vital to measure effectiveness and eliminate biases in interpreting results of screening procedures. In lead-time bias, although disease is detected

earlier in its natural history, this may not imply increased survival. A further bias is length-biased sampling where screen detected disease may be more benign and progress at a slower rate than disease diagnosed through symptoms (3). Where length-bias exists, say in early cancer detection, then a non-randomised uncontrolled trial would give a false impression of the benefits of screening. Length-biased sampling is likely to be greatest for cases detected at the initial screen, where the prevalent pool of pre-clinical disease is weighted by those with long pre-clinical phases.

In this review chapter, I will discuss whether colorectal cancer screening meets the criteria that are required for a successful screening programme. Experience with breast and cervical cancer screening programmes is discussed where it is relevant to colorectal cancer.

Colorectal cancer is a significant public health problem.

There are 25 000 annual colorectal cancer registrations in England and Wales (19) and a further 3 000 in Scotland (20). Over 19 000 people die from the disease each year in Britain making it the second commonest cause of death from malignancy after lung cancer in men and breast cancer in women. Similarly in the United States there are 152 000 new registrations and 57 000 deaths (21) from the disease. The tumour is uncommon in people under 40 years of age but increases in incidence thereafter. Five year survival is related to tumour staging and despite advances in surgery and chemotherapy it is still poor at 30% to 57% (22,23,24,25). Those patients with a lesion confined to the bowel wall (Dukes' A) have a survival of 82% to 87%, compared to only 7% to 13% for patients with metastatic disease (22,24). In the north-east of Scotland, which has the highest recorded rate of the disease in Britain, half the patients were found to be potentially curable at laparotomy and

half were alive without recurrence seven years later (26,27). As most tumours are advanced at the time of presentation, screening must detect early asymptomatic lesions.

Treating patients with colorectal cancer is expensive. Each year the National Health Service spends at least £100 million treating in-patients with the disease (28) at a cost of £4 500 per patient. A cost-effective national colorectal cancer screening programme is urgently required to detect asymptomatic lesions and reduce the significant mortality and morbidity of colorectal cancer.

Natural history of colorectal cancer: the adenoma-carcinoma sequence.

Colorectal cancer is ideally suited to a screening programme as malignant neoplasms are thought to arise from benign adenomatous polyps. Any colorectal cancer screening programme must detect these adenomatous polyps as well as early cancers.

Large series of polyps removed endoscopically and at surgery (29,30,31,32,33) have shown that approximately two-thirds of patients have a single adenoma and these are usually in the rectosigmoid region. Between 27% and 71% are larger than 1cm and a quarter to one third had either tubulovillous or villous histology. Five to eleven per cent of polyps contained invasive carcinoma and an even higher proportion had carcinoma in situ.

The evidence that adenomas undergo malignant transformation comes from histological (31,34,35), radiological (36) and genetic studies (37,38,39). Polyps often contain foci of neoplastic cells and it would seem reasonable to assume malignant spread occurs. In 2 500 polyps reported from St Mark's Hospital, London, (31,34) the frequency with which malignant tissue occurred depended on size, histology and degree of dysplasia. Only 1% of polyps less than 1cm in diameter contained malignant cells but this

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increased to 46% for those greater than 2cm. Polyps containing villous adenomatous tissue and severe dysplasia are more likely to harbour malignant cells. The American National Polyp Study (32,33,40) analysed polyp characteristics in patients referred for colonoscopy. In total 2362 patients had 5066 polyps, 66.5% of which were adenomas, 11.2% hyperplastic and the rest were classified as "other" eg juvenile polyps. Of the adenomas removed 86% showed mild dysplasia, 7.7% moderate dysplasia and 6.2% either severe dysplasia or carcinoma in situ. Just over a quarter of polyps were larger than 1cm and two thirds were distal to the splenic flexure. The number of adenomas containing malignant tissue also increased with increasing size and villous histology. The American National Polyp Study (32,33,40) also demonstrated a reduction in the expected incidence of colorectal cancer through the practice of polypectomy and follow-up colonoscopy (41). The incidence of colorectal cancer was compared with that in two cohorts (36,42) in which polyps were not removed and one general population registry (43). Only 5 asymptomatic early colorectal cancers (malignant polyps) were detected by follow-up colonoscopy compared to an expected number of 48, 43 and 21 polyps in the three reference groups, representing a reduction in incidence of at least 76%. Although the American Polyp Study is not a randomised trial of polypectomy, and its results have been compared with those of other studies, it is the best available evidence that polypectomy is beneficial. Clearly a randomised trial would be both impracticable and unethical.

The adenoma-carcinoma sequence is supported by genetic studies demonstrating in vitro transformation of benign cell lines to malignant cells (37,38). This occurs when exogenous carcinogens such as nitrosoguanidines are applied (37) and is accompanied by a decreased response to inhibitory growth factors (38). Abnormalities in multiple tumour

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suppressor genes in chromosome 18 are partly responsible for malignant transformation and progression of colorectal cancer (39). Radiological data (36) showed 8% of polyps became malignant over 10 years and 24% at 20 years. Finally, in a small study of 4 patients with rectal polyps who refused polypectomy, 3 developed malignancies (34).

Interrupting the adenoma-carcinoma sequence fulfils the screening criteria that early asymptomatic disease can be diagnosed and easily treated. This concept also exists in screening for cervical carcinoma where early asymptomatic benign lesions are sought. The natural history of cervical carcinoma shows that like colonic cancer, both pre-symptomatic dysplastic cervical lesions and carcinoma-in-situ become malignant (44,45,46). As colonic polyps take many years to turn malignant, so does cervical carcinoma-in-situ with an average of 10 to 12 years for lesions to become invasive (47,48,49,50,51,52,53,54). In mammographic screening for breast cancer, although no pre-cancerous lesions are detected, cancers diagnosed by screening are at an earlier stage of development than in controls (13,55,56).

The evidence that pre-malignant lesions of colorectal and cervical cancer become malignant is convincing but not supported by controlled clinical trials. Clearly such a study would have major ethical limitations. However, both these cancer screening programmes aim to detect such pre-malignant lesions.

Nature of faecal occult blood tests.

Detection of asymptomatic colorectal cancer by faecal occult blood testing was developed by Greegor in 1967 (57,58). Guaiac impregnated cardboard slides on which small stool samples are smeared is the most frequently used technique. This method specifically identifies blood from the colon whereas blood from upper gastrointestinal

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sources has a minimal effect (59,60). Hydrogen peroxide developer solution is added to stool samples and if positive, a blue colour appears on their surface. Hydrogen peroxide activates pseudo-peroxidase in haem and converts the phenol guaiaconic acid in the slide to a quinone, guaiacum blue (figures 1.1 and 1.2). The reaction may be falsely positive in the presence of animal haemoglobin from red meat or vegetable peroxidases, but high fibre has no effect (61). The positive rate may be reduced by three-quarters in healthy volunteers who avoid red meat (62). Similarly when foods with a high peroxidase content, such as cauliflower, cucumber, grapefruit and carrot were omitted from the diet the positive rate fell by 85%. In screening programmes, dietary re-testing of positive individuals on a modified diet more than halved the initial rate and reduced the number of those needing colonoscopy (63). When individuals with an initial positive test, but a repeat negative one on dietary restrictions were re-tested at 3 months, a cancer was diagnosed in one in every eighty such people.

Drugs can influence the results and Vitamin C preparations, aspirin and non-steroidals should be avoided. Although iron is probably acceptable, the staining of stools makes smears more difficult to read (64). Vitamin C causes false negatives in vivo and in vitro by inhibiting the peroxidase reaction (65). Although aspirin and non-steroidals cause upper digestive tract bleeding as blood passes through the gut, pseudo-peroxidase activity of haem is decreased, reducing the chances of a positive test (59,60). In practice, the blood loss due to non-steroidals is similar to controls (66).

The proportion of guaiac tests that are positive is related to the quantity of gastrointestinal blood loss. Normal gastrointestinal loss is between 0.5 and 2 ml/day (67,68,69,70) and this itself can cause guaiac tests to be positive. Stroehlein observed that for a blood loss of 10-20ml/day, 61% of slides were positive, but this increased to 93%

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Figure 1.1. Faecal occult blood test kit (Haemoccult).
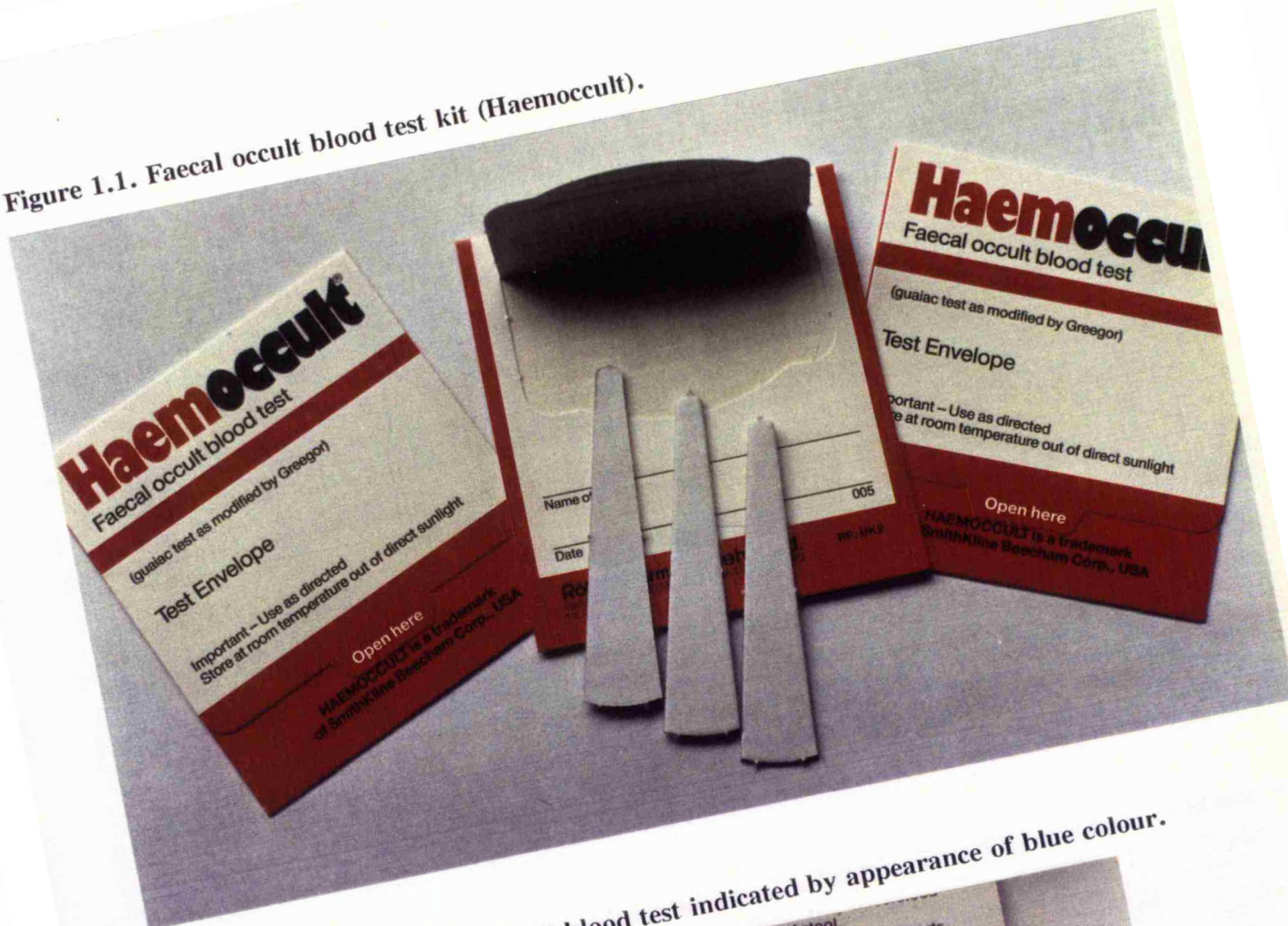
Figure 1.2. Positive faecal occult blood test indicated by appearance of blue colour.

Instructions for use and applicators for taking samples of stool.

2. On three consecutive days the patient takes a pea size sample from two parts of the stool and spreads them onto the two red-framed openings inside the test envelope. If the patient does not have a bowel movement on one day he should take a sample from his next stool.

The three test envelopes are given to the physician at the end of the test.

for the laboratory

The analyst opens the back of the test envelope – no contact with the stool – and applies at least two drops of developer solution to each of the two stool specimens covered by the reagent paper.

Evaluation

Positive test
Blue colour within 30 seconds

Negative test
No blue colour

Read the test exactly 30 seconds after applying the developer solution, at which time the blue colouration is most intense and both an earlier and later evaluation may lead to false-negative classifications. Any blue around the specimen – irrespective of its intensity – is positive. Even one positive test from the six taken is a "positive" result.

Any positive result should be followed by usual diagnostic procedures, i.e. digital examination, proctoscopy, sigmoidoscopy, double contrast barium enema, colonoscopy.

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for 30 ml/day (71). For screening to work, the kit must have a high sensitivity for occult blood. As tumours bleed intermittently and in variable amounts, collection over three days is recommended (72). In patients with colorectal carcinoma sensitivity from three stool collections ranged from 53% to 82% (72,73,74,75). Increasing the testing period from 3 to 6 days reduced the false negative rate from 28% to 10% (74) but would probably reduce compliance. Sensitivity for polyps is lower at 19% to 45% (67,76,77,78), although increased with multiple adenomas, larger polyps (76) and left sided lesions (67). People with false negative tests will present with "interval cancers" ie tumours diagnosed between a negative slide and a rescreen one or two years later.

Test sensitivity is improved by slide rehydration prior to addition of developer solution. The possible need for slide rehydration arose from concern that drying of slides during storage may cause false negative results (79,80,81). Although rehydration increases sensitivity, specificity decreases. In a study of 205 cancers, adding a drop of water to slides raised sensitivity from 81% to 93%, but specificity fell from 98% to 90% (82). This was accompanied by a fall in the positive predictive value for carcinoma from 6% to 2%. Rehydration unfortunately increases the number of false positives tests and leads to many unnecessary colonoscopies.

Guaiac stool tests are ideal for a screening programme as they are safe and inexpensive. Ultimately their usefulness may be limited by lack of sensitivity for polyps and their inability to exclude everyone without disease. To improve diagnostic accuracy new faecal occult blood test are under development. These include immunological tests which use antibodies directed against the globin of human haemoglobin and haem-porphyrin tests which measure stool haemoglobin and its degradation products. New tests will require full evaluation in controlled trials.

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Lack of sensitivity and specificity are not unique to colorectal cancer screening. In the United Kingdom, initial mammographic breast screening had a specificity of 94%, although only 1% of women required a biopsy to establish the lesion was not malignant (83). Referral rates are usually highest in the first screening round and fall throughout the programme (84). Unfortunately, interval breast cancers do occur at a rate of 1.4 per 1 000 screened in Britain (85). This is comparable to the British colorectal cancer screening programme where approximately one in every eight hundred subjects with a negative test presented with an interval carcinoma (86). Test sensitivity is a problem in cervical screening and is related to how often smears should be taken. A screening frequency of 1 year will reduce the calculated cumulative rate of invasive cervical cancer by 93%, whereas a screening frequency of 5 years gives a reduction of 84% (87). Paterson et al addressed the question of the sensitivity of smear testing by examining the screening history of 300 women in Yorkshire who had a diagnosis of invasive cervical carcinoma (88). They showed that 19% of women with cancer had a negative smear within 5 years of their diagnosis. With cervical cancer there is the additional problem of a borderline smear. Such a smear shows only minor nuclear abnormalities and could reflect inflammation or potential for neoplastic change. The number of such smears can be as high as 4% with 22% of these patients developing true positive smears over a 9 year period (89).

No screening test can have total sensitivity and specificity, a concept which\ should be emphasised to the public through health education. Also they must be made aware that a negative screening test does not prevent the development of cancer in the future.

Cancers detected by faecal occult blood tests.

There have been five large controlled trials of faecal occult blood testing in Europe (90,91,92) and the United States (93,94, table 1.2, table 1.3). These have measured detection rates and effects on mortality. Compliance was highest in Minnesota (93) and New York (95) where volunteers and those already participating in health prevention schemes were enrolled. Although uptake was lower in the Nottingham trial, acceptance rose to over 60% during the study (90). The variation in test positive rates between trials is related to slide preparation, with centres rehydrating slides having the highest figures (92,93). All trials showed favourable staging of tumours in those screened compared to patients with symptoms. In Nottingham (86,90) there were 4 times as many Dukes' A cancers in the screened group (52% vs 13%, $p<0.001$) with a similar ratio in Sweden (92) (50% vs 12%, $p<0.01$). This favourable difference was still maintained when the whole test or "intention to screen" group (non-responders and interval cancers) was compared with controls. In Nottingham the proportion of Stage D cancers was lower in those screened (5% vs 22%, $p<0.001$) but this difference did not exist for the whole test group. The Danish study in Funen confirmed this earlier staging of tumours detected during screening (91,96,97). The Minnesota project reported that the cumulative incidence of Dukes' A lesions was higher in those screened annually than controls (6.9 cases/10^4 vs 5.5/10^4) and the incidence of metastatic disease was nearly halved (93). The New York study, was a trial of rigid sigmoidoscopy versus rigid sigmoidoscopy plus faecal occult blood testing in 21 756 people enrolled in a preventive medicine programme (77,94,95). Those attending were divided into patients who came annually for a check-up and those who presented because of health worries. Compliance was initially high at 75%

Table 1.2. Results of controlled trials of faecal occult blood testing.

Centre	Trial size	% tests positive	compliance %	Dukes' A cancers test group	control group
Nottingham, England	142 690	2.1	53.8	30%	13%
Minnesota, USA	46 551	9.8	75.2	30%	22%
Goteborg, Sweden	51 325	6.0	65.0	30%	12%
Funen, Denmark	30 970	1.0	67.0	27%	9%
New York, USA	22 000	3.7	74.0	65%	33%

The test group is composed of those completing kits, patients presenting with interval cancers and non-responders. If the latter two groups are excluded the proportion of Dukes' A cancers is higher.

but declined over a five year period. The positive test rate was 1.7% and the predictive value for neoplasia 30%. Approximately six times as many cancers were detected due to investigations following a positive stool test than were found on rigid sigmoidoscopy. In those having their first health check, the cancer prevalence was 4.5 per 1 000, compared to 1.5 per 1 000 in people who came annually. There was a difference in tumour staging in those undergoing their first investigation, where 18 of 26 cases (69%) were Dukes'A or B or a malignant adenoma compared to only 6 of 17 (35%) in the control group not offered stool testing. Ten of these 26 study patients actually had symptoms on presentation but were included in the analysis. The study is limited by its recruitment of health conscious individuals enroling for medical checks and large differences in population size and characteristics between study and control groups.

The trials showed screen detected cancers are more amenable to treatment by endoscopic polypectomy, fewer emergency procedures are needed (86) and patients spend less time in hospital with fewer post-operative complications (91).

Other colorectal cancer screening programmes include a controlled trial of 94 000 people in Burgundy, France (98) and a case control evaluation in former West Germany (99,100). Provisional results from the French trial show a compliance of 52% with a cancer diagnosed in one in every thousand subjects completing the test, half of which were Dukes'A lesions. In Germany, the faecal occult blood test is offered as a component of the statutory health insurance system in 1977. The results from this German study have been analysed in the form of a case-control evaluation (100) and are discussed in the next section.

Table 1.3. Polyps detected by screening.

Centre	patients with adenomas/10^4		polyps >1cm (%)	villous or tubulovillous histology (% polyps)
	screened group	control group		
Nottingham	8.3	1.1	64	38
Denmark	4.2	1.2	79	17
Sweden	9.5	1.6	55	-

The polyp incidence shown for all 3 centres is that detected at the initial screen. For Denmark and Sweden, the polyp characteristics are those found at the first screen. The polyp characteristics for Nottingham represent those found at screening and rescreening.

Does faecal occult blood testing reduce mortality?

The crucial question in screening is whether early detection of disease reduces mortality. Screening may just detect cancer earlier in those who are going to succumb to the disease anyway (lead-time bias) or detect slow growing, well differentiated tumours with a good prognosis (length bias). This length bias has been reported (86) where more screen detected cancers (90%) were well or moderately differentiated compared to controls (70%). Fortunately, controlled trials of colorectal cancer screening will give an answer on mortality. The Minnesota study is the first to report a significant reduction in mortality with annual faecal occult blood testing (93), but not in those tested once every two years. In the annually screened group the 13 year cumulative mortality fell by 33%. This result must be interpreted cautiously as nearly 10% of slides were positive and 38% of participants had at least one colonoscopy. Reduction in deaths may be due to cancers and polyps detected by colonoscopy rather than as a benefit of stool testing. The New York (95) study reported a 43% reduction in mortality from colorectal cancer, although this just failed to reach statistical significance (P=0.053). Provisional results from the first 5 years of the Danish programme did not demonstrate a reduction in mortality with screening every 2 years (101). The full results of the European trials of faecal occult blood testing should be available within a few years.

A case-control study from population based screening in Germany showed a protective benefit from faecal occult blood testing in females but not in males (100). Faecal occult blood testing is offered as an optional component of the insurance system in Germany. In order to investigate its effectiveness, a case-control study was conducted in Saarland, a southwestern state of the country. For 3 years prior to diagnosis 13% of male cases and 14% of male controls had completed a faecal occult blood test. For females

16% of cases had been screened and 29% of controls. The protective effect of screening was shown for females but not for males where uptake was much lower. Clearly many selection biases existed and these results must be interpreted as supportive but not conclusive evidence of the benefit of screening.

Despite the need for clinical trials to show the benefit of screening, this only exists for breast cancer. Here two large randomised controlled trials of mammography showed a reduction in mortality of 30% (13,55), although the benefit was confined to women over the age of 50 years. Results from the non-randomised United Kingdom trial have shown a reduction in mortality of 20%, although this just failed to reach significance (85). There is no randomised trial of cervical screening, but supportive evidence comes from a comparison of screened and unscreened groups and correlations between mortality reduction and intensity of screening (102,103). For example, in British Columbia the incidence of invasive cervical carcinoma during 1961 to 1975 ranged from 30 to 45 per 100 000 in unscreened women, whilst in those screened it was 3.5 to 6 per 100 000 (102). Furthermore, over the period 1955 to 1985, the incidence of clinically invasive carcinoma of the cervix fell by 78% and mortality by 72% (102).

The problem of "missed" cancers.

Missed cancers give screening programmes a bad reputation. The interval cancer rate is defined as those presenting between a negative test and rescreening, divided by the total number of cancers diagnosed. This rate assumes that missed tumours were present at the time of testing, although this may not be so. Theoretically it can be reduced by more frequent and sensitive tests. In Nottingham and Denmark between rescreening there was an interval cancer rate of 28% and 48% respectively (90,96). The positive rate of faecal

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occult blood tests in Britain was double that of Denmark and this contributed to fewer interval cancers. In Sweden, approximately a third of cancers were missed with a screening interval of 15 to 20 months (92). The interval cancer rate in the Swedish trial was lowest in the largest cohort whose slides were rehydrated.

Unfortunately, missed cancers occur in other programmes such as mammographic screening. The number of interval cancers is related to the age of women participating. For example, the ratio of screen-detected to interval cancers was about 1:1 for women younger than 50 years and 3:1 for older women during a 2 year screening interval (104). A quarter of these cancers were missed on previous mammograms, due to observer or technical error. The problem of interval cancers with smear testing was discussed earlier, where nearly one in five women with cervical cancer had a negative smear within 5 years (88). To reduce the interval cancer rate, all screening programmes must include vigourous quality control procedures.

In summary, faecal occult blood testing meets several screening criteria, in that the disease is identified earlier in its natural history, diagnosing more lesions with a better prognosis. The current available evidence gives conflicting opinions on whether mortality is reduced, although the European trials have yet to report their mortality figures.

The role of sigmoidoscopy in screening.

Sigmoidoscopy is more sensitive than faecal occult blood testing for distal tumours and polyps as they can be directly visualised. However, there is no controlled clinical trial showing a benefit from either rigid or flexible sigmoidoscopy in preventing cancer or improving prognosis. Despite this, The American Cancer Society suggests annual faecal occult blood testing and flexible sigmoidoscopy every 3 to 5 years from the

age of 50 (105). This recommendation is based on a mathematical model (106) derived from clinicians' opinions on the disease's history and treatment outcomes. The model analyses efficacy and costs of sigmoidoscopy, colonoscopy, faecal occult blood tests and barium enemas. A yearly faecal occult blood test and a flexible sigmoidoscopy once every three years reduced the probability of a male aged 50 to 75 years dying from colorectal cancer by 36% (106,107). Although organisations such as the American Gastroenterological Association (108) and the World Health Organisation Collaborating Center for the Prevention of Colorectal Cancer (109) promote screening sigmoidoscopy in conjunction with occult blood testing, neither the Canadian Task Force on Periodic Health Examinations (110) nor The United States Preventive Services Task Force (111) recommend it in individuals at average risk.

Much of sigmoidoscopy's value is thought due to the protective effect of the first sigmoidoscopy which removes polyps (112). The first sigmoidoscopy diagnoses asymptomatic cancers and identifies polyp formers, who should enter a colonic surveillance programme. Atkin et al (112) argued that such a programme could prevent 5 500 colorectal cancer cases and 3 500 deaths in the UK each year, but this is dependent on a compliance of 65%.

Uncontrolled trials of sigmoidoscopy.

In an uncontrolled study in 21 000 people, 113 800 rigid sigmoidoscopies were performed, together with polypectomy where indicated (113). Twenty-seven cancers were found on initial examination i.e one in every 800 people screened. The follow-up period was of over 100 000 patient years experience. Only 13 rectal cancers developed compared with an expected 90. The authors concluded that proctosigmoidoscopy with

polyp removal led to an 85% reduction in incidence of rectal cancer. The 5 year survival rate of 64% was twice that reported for people who present with colonic symptoms. There were 27 cancers detected at the initial screening examination. If these were added to the 13 detected by follow-up examination, the preventive effect was 55% of those expected. Supportive evidence for screening sigmoidoscopy came from a follow-up study of 1600 patients who had adenomas removed at rigid sigmoidoscopy (42). Patients were observed for an average of 14 years and only 0.9% developed rectal cancer compared with an estimated 5 to 10%. At least 80% of rectal tumours were prevented and three quarters of those who developed cancer had incomplete polyp excision.

In 1964, the Kaiser Permanente Health Care Program began a randomised trial of rigid sigmoidoscopy in California (114). 5 156 members were offered annual sigmoidoscopy and mortality from colorectal cancer compared with 5 557 controls not offered screening. Over a 16 year period, the number of colorectal cancer deaths in the control group was more than twice that in the study population. However, the authors subsequently questioned the value of the programme, as 30% in the study group had had at least one sigmoidoscopy and 25% in controls, with a similar removal rate for polyps (115). The observed reduction in mortality in this small trial may have been due to a lower than expected incidence and improved staging of cancer in those screened. Selby et al (116) used Kaiser Permanente data for a retrospective case control study. The use of rigid proctosigmoidoscopy 10 years before death in 261 cases of colorectal cancer was compared with 868 control subjects. Only 9% of cancer patients had undergone proctosigmoidoscopy and polypectomy compared to 25% of controls, suggesting a 70% reduction in risk because of the procedure. There was no difference in cancer mortality in those with lesions beyond the instrument's reach. In a smaller case-control analysis,

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exposure to predominantly flexible sigmoidoscopy was associated with a reduction in incidence of 80% (117). Hertz (118) reported the results of rigid examination in 26 000 patients, nearly half of whom had some colonic symptoms. Carcinoma was diagnosed in 58 cases with an overall detection rate of 0.22% or one in 450 examinees. 81% of the cancers were Dukes' A or B and data available on 50 of these patients at 5 years revealed a survival rate of 88%. In this study only 60% of tumours were actually seen at proctosigmoidoscopy, the others were found on barium enemas requested because of bleeding or other symptoms.

The available evidence shows that flexible sigmoidoscopy is an acceptable investigation. In an Irish study compliance was 68% (119) and in a programme in Norway total attendance was 81% (120). The detection rate for adenomatous polyps ranged from 6% to 35% and a carcinoma is found in one in every two hundred individuals screened (119,120,121,122,123,124).

Acceptance of screening.

In the published trials, compliance has been highest in the USA (table 1.2) where volunteers from the American Cancer Society (93) and those in private health schemes were recruited (94). European studies are community based programmes and in Scandinavia (91,92) compliance reached 65%. In Nottingham compliance rose from an initial 45% (125) to 60% in the most recently recruited practices (90). Generally compliance is better in women aged 50 to 60 years.

Smaller studies from general practice confirm this sex and age difference. In Frome, Somerset, overall compliance was only 27% (126) and in both sexes, compliance was lowest in those over 70 years old. Similarly in Salford, Manchester, (127) overall

participation was 28% with more 40 to 49 year olds completing kits (31%) than those over 70 (17%). In Surrey (128), the compliance rate was 42% with again more young women participating. The data from these practices and experience in Nottingham show that initially compliance is low but increases once the process is established. However, there is still a long way to go to achieve comparable uptake to the 60% seen in British trials of mammography (56,85).

The effect of social class on the uptake of stool testing is uncertain. Farrands et al (129) found acceptance lowest in social classes 3 and 4. However, Dent and Goulston (130) reported blue collar workers as saying that they were more likely to participate (78%) than white collar staff (65%). More work is required to analyse uptake of colorectal cancer screening according to social class, although in mammography (131,132) and smear testing (133,134) it is least in lower social classes.

Methods of delivering and promoting screening.

The method of delivering screening affects compliance. A letter of invitation from the family doctor was more effective than a similar letter from a university department of community medicine (135). Hobbs et al (136) offered people a haemoccult test at routine general practice consultations. Although 56% of those offered a test completed it, only 26% of the target population were screened within 2 years. Similarly, in Farnborough and Basingstoke, when kits were offered directly to patients at routine consultations uptake was 57% (137). Mant et al (138) offered faecal occult blood testing with a free health check but found this did not raise compliance. Elwood et al (139) reported that group meetings away from a hospital or clinic were more effective in recruitment. These meetings consisted of American Cancer Society volunteers explaining

to retirement groups the purpose of the test and distributing slides to those who requested them.

Remailing of non-responders can raise overall compliance by a further 5 to 10% (90, 140). A telephone reminder call to non-compliers 30 days later significantly raised compliance from 27% to 48% (141). Furthermore, a second telephone call at 7 days giving test instructions increased uptake to 48%. In cervical cancer screening, telephoning non-responders also raises compliance. In one study (142) a third of women overdue for a smear who were contacted by telephone subsequently attended for screening.

Reminders to physicians on their patient's screening status at a routine consultation are effective (143,144,145,146). In one study supplying doctors with computer generated lists of overdue screening tests increased compliance with faecal occult blood testing by 19% (143). Turner et al (145) found that a combination of a computerised reminder and a questionnaire delivered to patients on their screening status raised compliance with stool testing from 30% to 46%. Methods which have been shown to increase compliance are shown in table 1.4.

Media advertising has been used to publicise screening programmes. In Chicago, promotion on the television's evening news was reinforced by radio and newspaper features (147). Over 54 000 kits were distributed, but only 14 000 (26%) were completed. In 1986 and 1987 an educational series on colorectal cancer was delivered in Lancaster, Pennsylvania nightly by a local television station (148). A total of 130 000 kits were delivered as a result of the programmes with an average compliance of 53%. In Chicago, subjects had to provide a self addressed stamped envelope and a third were charged for kits. In contrast Pennsylvania subjects could collect free kits directly from

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Table 1.4. Approaches which increase compliance in colorectal cancer screening.

Approach	compliance		
	control	test	ref
Letter from G.P rather than from community health department	26%	38%	135
Pre-invitation educational letter.	38%	47%	135
Pre-invitation interview	38%	52%	135
Test offered at consultation	42%	57%	136
Telephone reminder	27%	48%	141
Postal reminder	36%	44%	90,140
Group meetings	15%	29%	144-6
Physician reminders	34%	50%	120-123

local pharmacies. In neither study was the size of the target population known, so it is impossible to accurately assess the level of compliance.

The delivery of screening is logistically difficult. Administrative problems encountered in cervical screening provide lessons for colorectal cancer programmes (149,150,151). Beardow et al (149) found half the invitations for smear testing mailed by a district health authority were sent to the wrong address. A fifth of these invitations were to women who were ineligible. Elkind et al (151) noted invitations to women in inner city areas were least likely to be correctly delivered. These women were more likely to attend another clinic for screening than the one specified in the invitation. Such administrative problems are due to a combination of patients changing addresses and failing to notify their practitioners (152), practices not informing family practitioner committees (153) and these organisations failing to alter their records. Similarly in a study of non-attendance at mammography, MacLean et al (131) found 21 of a sample of alleged 150 non-compliers had actually attended for screening. Sending a specific appointment time for a cervical smear increased compliance by 24% compared with just a letter of invitation asking the patient to make an appointment (154). Such an approach could be applied to flexible sigmoidoscopy programmes. Supplying women with educational pamphlets at routine consultations caused 50% to participate in cervical screening (155). The value of tagging non-compliers' case notes is effective in cervical (145,156) and breast cancer screening programmes (144,146) and may have a place in colorectal screening.

Occupational based screening programmes.

The interest of British firms in employee colorectal cancer screening programmes is unknown and there is only one reported programme (157). In this study workers over

40 years of age in 2 industrial organisations were offered a free Haemoccult kit and asked to complete a symptom questionnaire. The service was well publicised with lectures, leaflets and small group discussions. The overall compliance was 51% with women participating significantly more than men (61% vs 47%). However, compliance according to age and occupation was not reported.

Offering retired workers cancer screening has successfully recruited participants in a gastric cancer screening programme amongst coal miners (158). Several studies reported coal miners are at increased risk of gastric cancer (159,160,161) which in Britain is approximately one and a half times greater than for non-miners (161). This excess was greatest in South Wales, intermediate in the north of England and least in south England (161). The increased risk in miners may be due to a direct carcinogenic effect of coal dust (162) or possibly the conversion of aromatic coal derivatives to mutagenic nitroso-compounds in the stomach (163). The role of Helicobacter pylori in gastric cancer had not been readily recognised at the time of these studies. Harrison et al (158) sent a dyspepsia questionnaire to 2 099 retired coal miners in Nottinghamshire. The response rate was 82% of whom a third had dyspeptic symptoms. Those with symptoms were seen at a special dyspepsia clinic and half were investigated with gastroscopy. Of those endoscoped 88% had gastritis and 41% mild oesophagitis. In the 229 miners endoscoped, seven had a gastric polyp, but no carcinomas were diagnosed. More miners had histological evidence of gastritis and intestinal metaplasia than a control group of 192 non-miners who were also endoscoped. The high response rate to the questionnaire may be because many had symptoms and wanted investigation and the letter was signed by the President of the Union of Democratic Mineworkers with whom workers could identify. Finally, as many retired miners live around Mansfield there would have been much

localised publicity which generated interest. In another study conducted in the Rhondda Fach in South Wales (164), Cochrane et al offered mass chest X-ray screening to the adult population of 19 000, where the majority of men were miners. The purpose of the screening was to detect evidence of early tuberculosis and pneumoconiosis with fibrosis. The screening was performed at the pithead, although there was intensive publicity at local social and political clubs and non-compliers were actively followed up by contacting them at home. Compliance in miners was at least 95% in each age group and higher than in non-miners. This study illustrated that workplace screening is successful in an occupational group aware they are at high risk of disease and where screening publicity and follow-up procedures are intense.

In America, the interest of companies in cancer screening is well documented (165,166). A survey of businesses in Colorado found 25% offered colorectal cancer screening, although many more had a hypertension and pre-employment screening service (165). Over 80% of firms that offered screening perceived the major benefit as improved employee morale. Several studies documented compliance with colorectal cancer screening using a combination of flexible sigmoidoscopy and faecal occult blood testing. Uptake ranged from 31% to 68% (167,168,169,170,171,172). For example, following the discovery of an excess number of colonic cancers at a Texan polypropylene factory, past and present employees over 40 years of age were offered screening (167). Overall participation was 52% although amongst current employees it was 68%. Attendance at a promotional briefing was associated with increased participation. The relatively high participation was partly due to an intensive educational campaign. Workers were invited to attend discussion seminars, a telephone information line was available and four reminders were sent to non-participants. The American Pennzoil Company offered

screening to employees over 40 years old and with a family history of colonic carcinoma (169). Compliance was 20% with faecal occult blood testing and 31% with sigmoidoscopy. The low uptake was probably related to the complex recruitment procedure. Employees had to complete a risk assessment questionnaire which determined their suitability to undergo screening. Subsequently a letter was mailed asking them to attend a consultation with a nurse educator or screener to complete a further risk-assessment questionnaire. Scrutiny of the second questionnaire determined whether the employee was referred for flexible sigmoidoscopy.

In Japan, 2 440 workers from 2 plants were enrolled in a mass screening programme for colorectal cancer using a single immunological faecal occult blood test (173). Compliance was high at 72% and 73% of those with positive tests consented for either colonoscopy or a barium enema. Five cancers were detected (one in every 360 individuals tested), four of which were localised cancer contained within a polyp. Speculation as to the reason for this high compliance would suggest the Japanese workforce are already aware of the principles and benefits of screening through programmes for gastric cancer screening. The success of Japanese worksite screening programmes was demonstrated in another study in Kitakyushu City (174). Amongst those who had gastric cancer screening, middle aged men were mainly endoscoped through workplace programmes. Older men over 60 years tended to wait till they developed abdominal symptoms and were then investigated at hospital clinics.

Educating employees about colorectal cancer risk can be done effectively at the workplace. Lee (175) et al investigated this approach in 278 federal employees in Washington State, USA, using the Cancer Risk Appraisal system. This system calculated an employee's risk of developing colorectal cancer from information including age, family

history of colorectal cancer and dietary habits. Twice as many employees sent information about their colorectal cancer risk stated an intention to have a screening test in the next year compared to a control group without this intervention.

The value of workplace based breast cancer screening and heart disease prevention has been investigated. An American company recommended mammography to 212 women at a worksite periodic health examination (176). After 4 months 26% had complied, although a telephone reminder raised compliance to 36%. In the Belgian Heart Disease Prevention Project (177) over 19 000 men aged 40 to 59 years employed in 30 industries were involved in a coronary risk assessment. 83% of employees participated and factors assessed included smoking habits, diet, cholesterol, blood pressure and electrocardiography.

Screening for hypertension is one of the commonest worksite screening programmes that has been developed and compliance ranges from 22% to 84% (178,179,180,181,182,183,184). In New York City all employees at a large department store were offered blood pressure measurement and treatment and follow-up (181). Part of the programme's success in recruiting 84% of employees was pre-programme education. In addition to employees receiving a personal invitation they were briefed by physicians at union meetings. Shop stewards then scheduled employees to be screened during working time. The costs of the programme and drugs were paid for by the company. In this programme nearly all employees who needed treatment were being reviewed at the workplace within one year. Other hypertension screening programmes, where employees were less well educated about the benefits, recruited fewer participants (180). The precise site where workplace screening is performed is important (185). In an American programme (185), compliance was only 20% when offered at a trade union hall

away from the worksite, but rose to 80% in two other industries where measurements were performed on site. One role of occupational programmes may be to interest and educate employees on aspects of health maintenance, following which employees can decide where to seek their screening. Hopefully, compliance in colorectal cancer screening similar to hypertension programmes could be achieved if British workplace programmes were adopted. Physicians may be more ready to screen for hypertension, as there is evidence of the benefit of reducing blood pressure (186,187,188,189). Currently there is only one study which has shown a reduction in mortality by screening with faecal occult blood tests (93).

Workers in particular industries are at greater risk of colorectal cancer. There are reports of an increased incidence of colorectal cancer amongst workers in the polypropylene industry who have contact with petroleum (190), in coke by-product workers in the steel industry (191), in pattern-makers in car factories (192) and in employees exposed to synthetic fibres in the carpet industry (193,194). For example, in a Canadian carpet factory (193,194), the incidence of colorectal cancer was 11 times higher in employees.

Screening programmes organised by British industry will never be a complete alternative to a nationally organised programme. Not all 50 to 65 year olds are in employment and not all companies would develop a screening service. However, if compliance with workplace screening is much higher than with invitations from general practitioners, then a national programme should liaise with companies to develop screening programmes. Companies could advertise screening at the workplace and supply lists of employees to the national programme who could send out invitations on company notepaper. Employees receiving an invitation from the workplace would not receive a

second one from their general practitioner. This combined approach may recruit more participants and ultimately save more lives. Such a partnership would have benefits for both the government and industry if screening is shown to be cost-effective in health and economic terms. The early detection and prevention of cancer would be a health benefit to employees and employers and may reduce health costs to the country of treating those with colorectal cancer. Industries associated with a higher risk of developing colorectal cancer should be particularly encouraged to develop screening services. Experience with workplace based schemes from outside the United Kingdom showed a high acceptance can be achieved if there is effective health education and active follow-up of non-compliers (167). In Britain, the value of workplace screening is unknown. This thesis will determine whether industry would finance and support screening and measure the compliance with faecal occult blood testing according to age, sex and occupation in the private and public sectors.

Models predicting compliance with health care and screening.

There are several theoretical models which attempt to predict factors related to both non-participation and participation in health care and screening programmes. During the 1950's a group of social psychologists working at the United States Public Health Service developed a theoretical framework for explaining the likelihood of individuals participating in preventive health action (195) which became known as the Health Belief Model (196). Criteria include an individual's perceived susceptibility to disease and the severity of its consequences. The model investigates participation in terms of susceptibility or severity and barriers such as physical, psychological and financial ones. The Health Belief Model stipulates that cues to action in enrolment in screening

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programmes must occur. These cues may be internal such as perception of symptoms or external through mass media campaigns. Studies applying the Health Belief Model to participation in colorectal cancer screening show parts of the model predict compliance. For example, in a study by Macrae et al (197) nearly 600 people attending doctors' surgeries in Melbourne, Australia, completed a questionnaire on health beliefs and were offered a free faecal occult blood test. Eighty-six per cent accepted, although only half completed the kit. Only perceived barriers to taking the test, such as embarrassment and perceived susceptibility to colorectal cancer were significantly related to compliance. The New York group (198) which utilised faecal occult blood testing and rigid sigmoidoscopy applied the Health Belief Model to their population. Here perceived susceptibility was similar in responders and non-responders. This result is not surprising, as the study population enrolled at a private general health check of their own volition. The main findings were that non-compliers considered colorectal cancer a more severe illness and were less confident of treatment. They were less likely to visit their doctor when well and had fewer health checks. Conversely, in a Dutch study, perceived seriousness of the illness was a factor which encouraged compliance (199). These results suggest compliance may be increased by raising awareness of colorectal cancer, the benefits of early detection and improving acceptability of tests. However, whether portraying colorectal cancer as a severe illness increases compliance is unclear. The Health Belief Model was also used to investigate reasons for non-attendance at mammography (200). Attenders were more likely to feel vulnerable and be concerned about breast cancer. This study found attenders rated their health as better than non-attenders. Increased vulnerability in acceptors may be due to personal knowledge of someone who had breast cancer or a breast lump (201).

The Health Belief Model does not fully predict behaviour in screening activities, so other hypotheses affecting compliance have been developed. These include the cognitive model, social determinants of compliance and the Health Action Model. The cognitive model states compliance correlates with understanding, memory and satisfaction in health prevention programmes (202). Understanding will have direct effects on memory, satisfaction and compliance, and through its effect on satisfaction, an additional indirect effect on compliance. Several studies showed associations between these variables (203,204). For example in a general practice in Liverpool, patients were interviewed after a consultation with their doctor and compliance with recommended treatment assessed through measurement of patient satisfaction and understanding. Compliance was measured by use of prescribed medication and if advice regarding diet, smoking and exercise was heeded (204). Patients' comprehension and satisfaction with advice were also recorded. Compliance was dependent on satisfaction and higher comprehension related to higher compliance, although the result was not quite significant. Although this was a study of verbal information given to patients, it is likely results would be similar for written material. In an American study, patients' knowledge of their illness and compliance was investigated in sufferers of arthritis, diabetes, cancer and hypertension (203). Patients' knowledge was assessed according to awareness of symptoms and complications of the disease and whether they had experience of caring for someone with the condition. Compliance was measured by patients' attendance at monitoring visits and adherence to treatment or advice. The study showed a statistically significant relationship between knowledge and attendance behaviour, and patients with low knowledge scores were more likely to terminate follow-up monitoring. Evidence also exists for a correlation between satisfaction variables and retention of medical information (205,206,207). Bertakis and

Brody (205,206) found the amount recalled by patients correlated with degree of satisfaction with the physician's communications. Furthermore, a procedure successfully used to increase recall also increased satisfaction providing evidence of the relationship (205). The cognitive model shows that participation in treatment regimes is related to understanding and knowledge of illness and recall of information. In screening involving asymptomatic people, health education literature must comply with the model's aims. Such literature must be understandable and satisfy participants by imparting knowledge about screening and answering their questions. Written material has an advantage over a verbal consultation in that memory and retention of information is less important as participants can re-read educational leaflets. To effectively increase knowledge, measures for assessing the comprehensibility of health education literature have been developed. The formula most often used for written health related information is the Flesch Formula (208) derived from a regression equation for predicting difficulty in reading a text. The Flesch formula measures reading ease by determining the average number of syllables per hundred words and the average number of words per sentence. Assumptions of the model and other readability scores are that polysyllabic words and longer sentences are harder to understand. Reading ease is calculated for each passage and an average score calculated. This score is correlated with a qualitative assessment ranging from "very hard" to "very easy", referenced to an appropriate reading age, the type of literary material e.g. comic, scientific document and an estimate made of the population who would be able to understand it (table 1.5). The higher the score, the easier the material is to understand. A score of 90 to 100 is classed as "very easy" appropriate to a 6 year old and typical of the text of a comic. A score of 0 to 30 is "very hard" appropriate to an 18 year old attending college and equivalent to a scientific text. There is evidence showing reading scores give

Table 1.5 Flesch Reading Scores and their interpretation.

Reading ease score	verbal description	typical text	grade level	% population aged 25 years+ understanding
91-100	very easy	comics	4	97
81-90	easy	pulp magazine level	5	95
71-80	fairly easy	Time magazine level	6	90
61-70	standard	Readers' Digests level	7-8	90
51-60	fairly difficult	literary level	some high school	77
31-50	difficult level	scholarly /some college	high school	31
16-30	very difficult	scientific	college	7
0-15	ultra difficult	scientific	college	7

accurate assessments (209,210). Such reading scores correlate with standard reading texts for defined age groups, comprehension and retention of material, and texts with higher scores are preferred by readers (210). Although a poor score indicates that the document requires simplification, good readability scores can be seen in documents written with bad style and poor content. Readability of material can also be assessed with the Flesch Human Interest Score (208) and a negativity score (211). Human interest is evaluated according to the Flesch index of reader interest. The score is dependent on the percentage of personal words and personal sentences. Personal words include first, second and third person pronouns and pleural pronouns referring to people. Personal sentences contain one or more personal words or are delineated by quotes, exclamations, question marks etc. Such personal sentences are designed to be directly addressed to the reader. A score ranges from zero to a hundred and is allocated a qualitative description ranging from "dull" to "very interesting" (table 1.6). A sentence such as "Does your son need a new bicycle?" would be allocated a higher human interest score than "Most children could use a new bicycle". Finally negativity is evaluated by counting negative words and sentences and comparing them to a standard table. Negative words include "no", "can't", "don't" ,etc. The scale again ranges from zero to a hundred and a qualitative assessment is assigned (table 1.7). For example, a higher positivity score will be achieved by a sentence such as "Take the ball outside to play with" rather than "don't play with the ball in the house".

Social factors influence participation in preventive health programmes and are also determinants of health. Several prospective studies reported a decreased mortality rate associated with a higher level of social relations and activities (212,213). Compliance with decisions regarding health-related advice are more successful if taken by a group

Table 1.6. Flesch Human Interest Scores.

Flesch Score	Assessment
0-10	Dull
11-20	mildly interesting
21-40	Interesting
41-60	very interesting
61-100	dramatic

Table 1.7 Negativity Scores.

Score	Assessment
55-100	Affirmative
33-54	Mildly affirmative
21-32	Neutral
12-20	Mildly negative
0-11	Negative

than individuals. For example, new mothers were more likely to follow dietary advice about vitamin supplementation when a dietician saw a group of six patients than if women were seen separately (214). Discussion and peer pressure may have led to increased acceptance. Social class also affects participation, with women from semi-skilled occupations less likely to request mammography or cervical smear testing (131,132,133,134). In colorectal cancer screening any relationship between participation and social class is less clear cut (129,130). Farrands et al (129) found acceptance lowest in social classes 3 and 4. In contrast Dent and Goulston (130) reported blue collar workers were more likely to participate than white collar staff. Sociodemographic data are important for they allow specific and intensive targeting of poorly compliant groups.

A further model for explaining health behaviour is the Health Action Model (215). This consists of two parts: factors contributing to an individual's intention to act and secondly factors determining whether intention is translated into action. Individual factors determining compliance are intellectual skills, motivational state and the influence of social pressure. The factors determining actual compliance are those concerned with post-decisional support. In screening, such factors include time of work and ease of appointments for screening. Social factors and support are again involved. The Health Action Model recognises the importance of emotions which may influence health behaviour. For example, the alcoholic knows the damage he is causing his family but is influenced by the addiction to alcohol. Motivational forces, a component of the Health Action Model are themselves dependent on several factors related to experience and individual perceptions. A woman who has had an unpleasant experience with one screening procedure may be reluctant to participate in other screening programmes. People may be poorly motivated because they perceive cancer as a single disease which is

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difficult to cure (216). Currently no study has specifically analysed participation in colorectal cancer screening programmes according to the criteria of the Health Action Model. Components of different models attempting to analyse health behaviour overlap. For example, cues to participate described by the Health Belief Model are similar to motivational factors described in the Health Action Model. The cognitive theory and the Health Action Model both emphasise educational and intellectual influences. Although the models are theoretical, they provide a framework for explaining non-compliance and designing effective health education.

A thorough understanding of why people fail to participate is essential if high compliance is to be achieved. If mortality is to be reduced then publicity and education about screening must be more widespread. Education is needed to promote the concept of asymptomatic illness. Identification of tests that patients find more acceptable is critical to the success of any screening programme.

Health Education Literature.

There is little and conflicting work on the value of health education literature in colorectal cancer screening. Hardcastle et al (217) found an educational letter sent two weeks before the test invitation raised compliance by nearly 9%. An explanation of screening at an interview prior to the invitation raised compliance by 13%. Another study showed no benefit from educational booklets (137) and in one report uptake fell by 9% when a leaflet was included (218). The content and precise wording of such material is likely to be critical and may be more successful if cancer prevention is emphasised and reasons for non-compliance addressed. Problems have occurred with other screening programmes because of their educational material. In a survey of 174 authorities, 25%

reported difficulties with the design of letters and leaflets about cervical cancer (219). Only 65% included an educational leaflet with the invitation and in many cases the letter was not signed by the patient's doctor but by the head of the screening institution. Health education must explain the results of tests and what is meant by pre-cancer. This concept is poorly understood by the lay public, and women who have had notification of dysplasia on smears often assume they have cancer (220). A comparable problem could arise in colorectal cancer screening when explaining the nature and consequences of polyps.

Experience from the Queensland melanoma early detection programme in Australia showed health education programmes could have an impact (221). Queensland has the highest worldwide incidence of melanoma, yet survival is twice that in other areas. This success is due to diagnosing the disease at an early stage through intense local publicity about melanoma. Children are taught about skin cancer at school and the message is re-enforced in health centres and in public places such as libraries. Local television stations and the press devote regular features to the campaign. The more difficult message to convey in colorectal cancer screening is that asymptomatic rather than symptomatic people are investigated.

In colorectal cancer screening there is a need for effective health education literature which can be shown to raise compliance. A simple leaflet explaining the high incidence of the disease, its asymptomatic nature and which addresses reasons for non-compliance could fulfil this need and will be investigated in this thesis.

Acceptability of stool testing.

Non-compliance studies are difficult because people who decline screening are reluctant to be interviewed (222) and it can be hard to elicit precise reasons and be

confident they are valid. In Denmark where 1 000 non-compliers were questioned, 37%
did not give a specific reason (223) and in a British group of 360 non-compliers (129)
40% were "too busy" and "didn't get round to it". In an Australian study of hospital
employees, reasons given were "too lazy, couldn't be bothered, kept putting it off, forgot
or mislaid slides" (224). Such apparent lethargy and lack of time may mask real fears
about screening and cancer. In a questionnaire study of 581 people offered a free faecal
occult blood test (197) Macrae et al found refusers were more likely to rate tests as
embarrassing, distasteful, worrisome, discomforting or inconvenient than acceptors. For
those who requested a kit but did not return it "embarrassment" and "worry" were the
only concerns. In a review of 330 non-compliers, Farrands et al (129) found 22%
thought faecal testing unacceptable, although this was not investigated further. In an
occupationally based screening programme (225) a third of those who received a kit
described it as unpleasant and 17% said the specimen was too difficult to collect. As less
than 50% of people returned a questionnaire the number holding this view was probably
higher. Finally, in a general practice based study, non-completers were seven times more
likely to rate faecal occult blood testing as "disgusting" than completers (226). Distaste of
faecal occult blood tests is clearly a major reason for refusal of colorectal cancer
screening. Designing a more acceptable kit may increase compliance but is a difficult
task. One system under evaluation involves dropping a card into the toilet and looking for
a colour change (226). This relies on blood on the surface of the stool forming a film
with which the test card reacts. Patients prefer this test to Haemoccult because samples do
not have to be collected (227). Unfortunately it is less sensitive than Haemoccult and
problems may occur when patients read their own tests. In another test, participants wipe

their anus after defecation with a special tissue pad and then develop the pad with a guaiac/peroxide spray (226).

The immediate barriers to completing a screening test seem to outweigh the possible long-term benefits of screening in some non-compliers. This is true in cervical cancer screening where there is concern that taking the smear will be painful and embarrassing (133,150,151). Similarly in breast cancer screening many women are concerned about the clinic experience (131) where over a third of women expressed negative feelings and a dislike of doctors, physical examination and the presence of other women at the clinic.

The concept of asymptomatic illness.

To increase compliance, concepts of asymptomatic illness and screening need to be promoted as the public are unaware of such concepts (129,223,225). Farrands et al found acceptors were more aware that cancer could be present before causing symptoms and could be diagnosed by medical tests (129). Acceptors were more likely to believe asymptomatic cancer was curable. Similarly Silman et al found 64% of those who declined screening did so because of lack of symptoms (225). In a non-compliance study from Denmark (223) 13% refused because they felt well. This lack of awareness of the concepts of screening is seen in other screening programmes. In cervical screening, attenders are more likely than non-attenders to believe smears can reveal disease prior to symptoms and that early detection is beneficial (133). King (133) reported many women assumed they could detect the symptoms of cervical carcinoma themselves and that if they had not noticed any discharge, then their health must be satisfactory. In mammography, 38% of non-attenders felt well and thought screening unnecessary (131). The same study

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found that over 20% of women were concerned that screening was tempting fate and that one should "not seek trouble". Similarly Hunt et al (132) reported that women who declined screening perceived themselves to be in good health. Healthy women felt they were wasting valuable professional time (228). Others commented that screening "clinics" were for unhealthy people and that the term "centre" should be adopted. People in working class groups are more likely to feel that factors such as poor housing, pollution, unemployment and income are more important to health (229). Public education about asymptomatic illness and the value of its early detection is urgently needed especially for people who find this difficult because of work or home commitments (201).

Other reported reasons for non-participation include intercurrent illness, advancing age (223) and fear of cancer (129,225). Klaaborg et al (223) found 32% of rejectors cited another illness or current medical treatment and 4% felt they were too old to benefit. In two British studies (129,225) surprisingly few people directly voiced concerns about fear of cancer, although denial is probably important.

The cost of screening from controlled trials.

A national screening programme will not be developed until there is a reliable estimate of its cost benefits. Currently this is difficult as a reduction in mortality due to screening has not yet been demonstrated. However, several studies have calculated the costs of a screening programme (230,231,232) and compared this with the resources used to treat patients presenting with symptoms (233). In Nottingham (230), £5 was spent per person screened and the cost per screen detected cancer was £2 700. This costing included staff and administration as well as faecal occult blood tests and colonoscopies. There would then be the extra cost of treating patients identified by screening, although

ultimately some would become symptomatic and require treatment. A similar sum was spent on investigations and treatment following a positive stool test as for a symptomatic patient (233), with the majority of the cost being on in-patient care rather than investigations or surgery. Although it is more expensive than a barium enema, colonoscopy is the investigation of choice (234) as it has a greater sensitivity for polyps.

The cheapest method of screening is to mail kits from a hospital unit rather than asking individuals to collect them (231) as this produces higher compliance. Screening older asymptomatic people is more cost-effective as the incidence of disease is increased (232).

Costs calculated from a mathematical model and polyp removal.

The mathematical model of screening constructed by Eddy (106) has been used to cost colorectal cancer screening programmes. An annual faecal occult blood test and three yearly flexible sigmoidoscopy costs four times that of a yearly faecal occult blood test but is one and a half times better at reducing the risk of death. The most effective way to reduce mortality is a yearly occult blood test and full colonoscopy but this was 8 times more expensive than a three yearly sigmoidoscopy.

Screening should reduce the amount spent on treating colorectal cancer because of earlier diagnosis and polyp removal. Allison and Feldman (235) compared the resources spent over 5 years on treating 12 patients with screen detected carcinoma with the cost had they presented symptomatically with more advanced disease. Diagnosing patients earlier cost 15% less over this period. Whynes et al (236) calculated 53 cancers would have been prevented by polypectomy in the Nottingham study and that this saving covered 20% of the costs of the programme. In a proposed trial of flexible

sigmoidoscopy, Atkin et al (112) suggested the cost of preventing a cancer is similar to that spent treating a symptomatic patient. Assuming 70% compliance, the cost of screening and surveillance in the UK would be £30 million annually. This translates to £5 500 per cancer prevented or £ 8 500 per cancer death prevented. These figures need to be compared with the £100 million spent on in-patient care (£4 500 per patient) for colorectal cancer in England and Wales (28).

Although faecal occult blood tests are relatively cheap (£1.20 in 1994), the work up of a patient with a positive test is 200 times that of the stool kits (237). Therefore screening must minimise false positives and avoid investigating healthy people. In the USA, Eddy calculated (237) that for every 1% increase in the false positive rate 570 000 more people would need to be investigated if there was a national screening programme in a population of 57 million aged over 50 years.

The economics of colorectal screening can be compared with breast screening. The United Kingdom Breast Cancer Screening Programme was evaluated using QALY techniques (quality adjusted life year gained) and a figure of £3304/QALY calculated at 1983-84 prices (14). This compares with a cost of £2 700 to detect one colorectal neoplasm by stool testing (230) and £8 500 to prevent a death by flexible sigmoidoscopy (112).

When mortality data are available, a more accurate cost-benefit analysis can be calculated. Meanwhile, governments must decide whether it is appropriate to allocate money to colorectal cancer screening research. Provisional cost estimates suggest the beneficial effects of finding earlier tumours and polyps may pay for a third of the service. Costs for screening and treatment seem of a similar order fulfilling an important screening principle.

Guide to the thesis.

The first half of this thesis compares compliance with faecal occult blood screening between a general practice based approach, workplace schemes in private and public industries and an opportunistic method. The general practice approach (chapter 2) was studied in Market Harborough, Leicestershire because of the large community served by a single practice, the interest of the partners in screening and the close proximity of the town to Leicester. The results of the uptake of screening from the town served as a "standard" against which workplace and opportunistic programmes were compared. The private sector company studied was Brush Engineering Loughborough (chapter 3) and Leicester General Hospital was chosen as a public sector industry (chapter 4). In chapter 5, an opportunistic system of delivering screening was investigated at Leicester blood donor centre.

In the second part of the thesis, I investigated if simple health education leaflets could raise compliance in colorectal cancer screening programmes. The leaflets explained the high frequency of bowel cancer, the principles of screening and addressed reasons for non-compliance. These reasons were identified by interviewing non-compliers from the general practice programme in Market Harborough (chapter 6). Before the leaflet was tested in a randomised controlled trial, its effectiveness in increasing intention to participate in screening was piloted on a sample of a 100 relatives of patients (chapter 7). Finally the leaflet's effect on compliance in a general practice based community screening programme was studied (chapter 8).

In the final chapter, I summarise my results and make recommendations for the future.

Chapter Two.

Colorectal Cancer Screening in General Practice.

Summary.

An invitation to receive a free faecal occult blood test (Haemoccult) was sent from general practitioners to 4 176 people aged 51 to 70 years living in Market Harborough, Leicestershire. The kits were completed on three separate days and returned to Leicester General Hospital for testing. Subjects with positive tests were invited to undergo colonoscopy.

Compliance is defined as the number completing faecal occult blood tests. The total compliance was 38% with women participating more than men (42% vs 33%, $p < 0.0001$). This difference was due to younger women aged 51 to 60 years participating more than men of similar age (47% vs 32%, $p < 0.0001$). Two patients with carcinoma and a further four with adenomatous polyps were found, a detection rate of one patient with a significant lesion per 260 screened.

The study found that compliance with general practice based screening was low especially in men and older women.

Theoretical justification for this work.

This work measured uptake of faecal occult blood testing in a community invited to participate by local general practitioners. This uptake was compared with alternative approaches of delivery, namely workplace based and opportunistic ones. Non-compliers were interviewed to determine reasons for declining the offer of screening. From these responses a health education leaflet was written and tested in a subsequent randomised community controlled trial of screening.

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Introduction.

Compliance with faecal occult blood testing in general practice is usually less than 50% (125, 126,127,128,135,137,138) with most studies showing acceptance as highest in women, particularly those aged 51 to 65 years. When colorectal cancer screening is offered directly to patients at routine consultations uptake is higher (136,137), although only a small proportion of the total target population is screened. Combining the offer of a faecal occult blood test with a general health check does not increase acceptance (138). In the largest British screening trial in Nottingham where tests were offered to over 71 000 participants, compliance was raised to over 60% in the most recently recruited practices (90).

The area chosen for screening in my study was Market Harborough (Fig 2.1) a town in south-east Leicestershire with a population of 23 000. The community has a stable population with most people working in local industries or the surrounding country. Some people commute daily to work in the City of Leicester and a small number take the one hour train journey to London. A single large group practice of 10 general practitioners serves the majority of the community from this mixed suburban and rural population. Faecal occult blood testing was offered to a target population of over 4 000 people aged 51 to 70 years registered with the practice. Interest was raised by articles in the local press and radio.

Figure 2.1 Market Harborough, Leicestershire.

Method.

4 176 people aged 51 to 70 years identified from the current practice register were sent a letter from their general practitioner explaining the rationale of faecal occult blood testing (appendix 2.1) and containing an invitation to participate. The study and availability of the kits were publicised in the local newspaper and on radio. Through these it was emphasised that doctors would discuss screening in surgery and that a telephone number was available to supply information. Those who accepted were sent a free faecal occult blood test (Haemoccult) which included instructions on how to perform the test (appendix 2.2). Initially no dietary restrictions were imposed but subjects were asked to refrain from taking vitamin C preparations which cause false negative tests (65). Fresh stool was collected and applied to cardboard slides from the kit. Two slides were completed on three separate days by the patient and returned to Leicester General Hospital for analysis. A test was considered positive if a blue colour appeared on the addition of hydrogen peroxide and denatured alcohol to the stool sample. All the tests were analysed by myself and a trained research nurse colleague.

People with positive results were asked to repeat the investigation on dietary restrictions avoiding red meat, cauliflower, cabbage, spinach, broccoli and bananas. This approach reduces the number of false positives by 60% (63) while not decreasing the initial compliance rate. If one or more of the slides tested on this second occasion were positive, patients were informed of the results and invited to attend for colonoscopy. The length of time between the first positive result and a decision by patients to undergo colonoscopy was noted.

With the colonoscopy invitation, patients received a description of the procedure and the standard bowel preparation. Prior to colonoscopy a history was taken and patients

underwent a complete physical examination. The investigation was arranged as a day case procedure on a routine endoscopy list and was performed by one of a team of four experienced colonoscopists. As the colonoscopies were requested over a period of a year the extra workload was easily absorbed into these lists. If the colonoscopy was incomplete a barium enema was obtained.

Individuals whose repeat test was negative were sent a third kit to complete four months after the negative slides on dietary restrictions. Patients who had either a normal colonoscopy or negative repeat slides were told to contact their doctor if in the future they developed a change in bowel habit or related symptoms.

The number of people completing kits was analysed by age and sex and tested for statistically significant differences using a chi square statistic. All statistical tests in the thesis were performed by myself using standard computer packages.

Results.

a. Uptake of screening.

In Market Harborough, of the 4 176 people offered screening 1565 (38%) returned completed Haemoccult test kits. There were an additional 533 (13%) people who requested a kit but did not return it. As a result of the screening invitations fifteen subjects or their relatives informed the hospital that the addressees were deceased or had colorectal cancer.

Compliance in men was 33% (665/2029) and was similar for those aged 51 to 60 years and 61 to 70 years (32% vs 34%, $X^2=1.9$, ns). Compliance in women was 42% (900/2147) with younger women aged 51 to 60 years participating more than those aged 61 to 70 years (47% vs 37%, $X^2=21.7$, $p<0$ .0001). Overall, women participated more

than men (42% vs 33%, X^2=37.2, p<0.0001). This difference was due to younger women aged 51 to 60 years participating more than their male counterparts (47% vs 32%, X^2=54.7, p<0.0001). Completion of faecal occult blood tests was similar in men and women aged 61 to 70 years (34% vs 37%, X^2=1.0 ns). Compliance according to age and sex is shown in table 2.1 and figure 2.2.

b. Test positivity and pathology detected.

The kits were analysed by myself (75% of testing) and a research nurse colleague (25% of testing). There was found to be no inter-observer variation in a set of 42 test kits analysed by both investigators. In all the other studies all the kits were tested by myself.

A hundred and six (6.8%) of the initial screening tests and 48 (3.1%) on retesting with dietary restrictions were positive. After the first six months 300 kits had been tested and the remaining 1265 were analysed in the second half of the year. Our ability to interpret slides was reviewed after six months and following this the number of positives fell and accuracy increased. One patient declined to repeat the slides after their first set was positive. One patient who was positive on repeat testing declined colonoscopy and a further patient with Christmas disease was investigated first with a barium enema. Of the 57 subjects who had an initial positive test, but a negative repeat on dietary restrictions, 39 (68%) completed a further kit four months later, all of which were negative.

Of the 47 patients investigated an abnormality was detected in 13, of which 6 had a malignant tumour or pre-malignant polyp (table 2.2). A carcinoma was detected in two patients (0.13% of tested people). The first patient had a Dukes' C carcinoma in the ascending colon (and a sigmoid tubulovillous adenoma) and the second patient a rectal

Dukes' D carcinoma. A further four patients (0.26% tested people) had a total of 7 adenomatous polyps, 6 of which were tubular adenomas. One patient had two adenomas and one had three adenomas. Three polyps were less than 1cm in diameter, 2 were between 1 and 2 cm and 2 were greater than 2cm in diameter. Two polyps were moderately dysplastic and 5 showed minimal dysplasia.

The mean delay by patients after notification of their first positive result to return the second test kit on dietary restrictions was 16 days (range 7-37 days). Subjects took a mean of 13 days (range 4-69 days) to decide to undergo colonoscopy after notification of a repeat positive test. This delay of a month must be added to the month spent on the waiting list for the procedure.

Table 2.1.Compliance with faecal occult blood testing in a screening programme for colorectal cancer in Market Harborough.

Age (years)	Male (total, %)	Female (total,%)
51 - 55	209/702 (30%)	284/614 (46%)
56 - 60	152/444 (34%)	245/521 (47%)
61 - 65	146/428 (34%)	185/513 (36%)
66 -70	158/455 (35%)	186/499 (37%)
TOTAL	665/2029 (33%)	900/2147 (42%)

Women completed more kits than men ($X^2=37.2$, $p<0.0001$), the difference due to younger females aged 51 to 60 years accepting more than such men ($X^2=54.7$, $p<0.0001$).

Fig.2:2 Compliance with screening
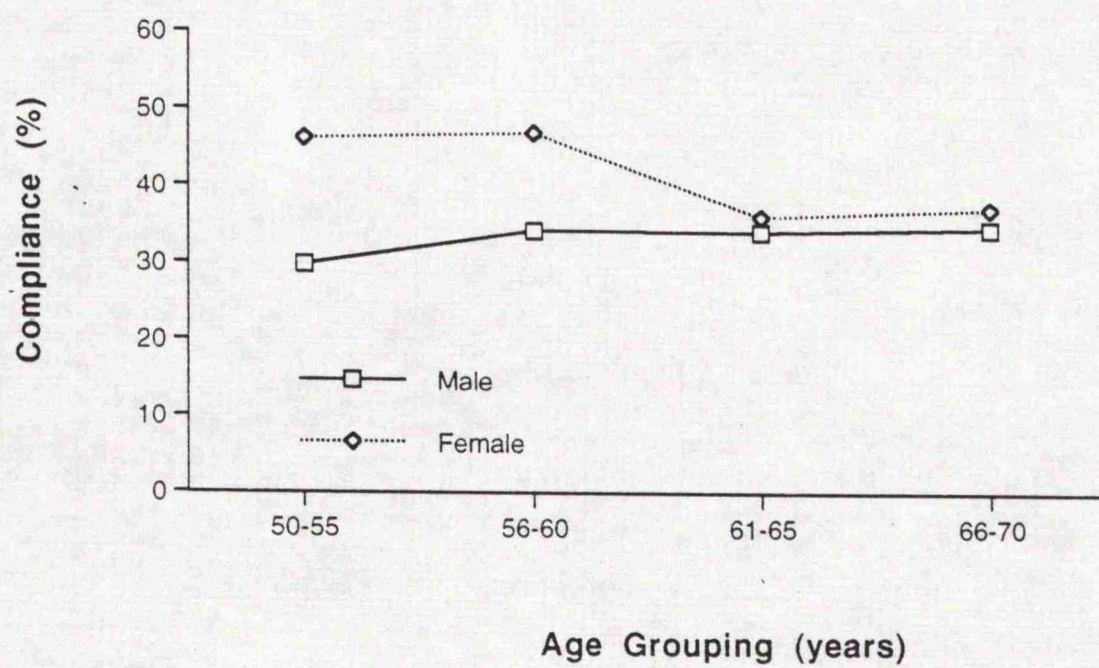
Table 2.2. Pathology detected by screening.

Pathology	Number diagnosed
ADENOCARCINOMA	2
TUBULOVILLOUS ADENOMA	2
TUBULAR ADENOMA	6
METAPLASTIC POLYP	4
COLITIS	1
ANGIODYSPLASIA	2

Abnormalities were detected in 13 people. The carcinomas were Dukes' stages C and D. One patient had both a tubular and tubulovillous adenoma and another patient had a carcinoma and tubulovillous adenoma. A further patient had 3 tubular adenomas.

Discussion.

In this study 38% of subjects participated in a community based colorectal cancer screening programme in general practice in which compliance was highest in women aged 51 to 60 years. I had hoped acceptance of screening would be higher because of local publicity and availability of advice from family and hospital practitioners. The low uptake illustrates the need for a thorough understanding of reasons for non-compliance, effective health education to promote uptake and alternative methods of delivering screening. If acceptance cannot be raised, then screening will be ineffective in both health and economic terms. To address this problem, subjects who declined screening were interviewed (Chapter 6) so that effective health educational leaflets could be developed (Chapters 7 & 8). Also workplace based (Chapters 3 & 4) and opportunistic methods of delivery (Chapter 5) were investigated.

Compliance in this study was similar to many other community based programmes in general practice (125,126,127,128,137,138,217), all of which had acceptance rates of less than 50%. However, the largest British faecal occult blood screening trial in Nottinghamshire reported a compliance of 60% in the most recently recruited practices (90). Two studies which reported compliance according to age and sex (126,128) confirmed our finding of highest acceptance amongst women aged 51 to 60 years. In Nottinghamshire, acceptance was greatest in females aged 55 to 64 years (86). Younger women may participate more as they are aware of screening and the detection of asymptomatic illness through exposure to breast and cervical cancer screening programmes. All groups need to be targeted in future programmes, although this is particularly true for men and older women.

Compliance may have been increased by directly sending subjects a faecal occult blood kit rather than an invitation to receive one. This approach would remove any apprehension about the size and nature of the testing kits. Remailing of non-responders has raised compliance by 5% to 10% (90,140) and telephone reminders are also effective (141). In this study, kits were not mailed and reminders not used, to avoid undue harassment. An alternative to the postal approach is to offer screening tests at routine medical consultations. With this method 56% (136,137) of patients completed tests but only a quarter of the target population was reached within 2 years (136). Linking opportunistic screening with a free health check did not improve compliance (138).

Large trials of faecal occult blood testing show that approximately 500 people need to be screened to detect one cancer and one to two hundred screened to find a polyp (90,91,92). In my smaller study in Market Harborough a cancer was found in every 800 people screened and a polyp in every four hundred tested. If the population had been bigger, our detection rate would probably have approached that of larger trials. As in other studies we found more patients with polyps than carcinomas. Removal of these polyps at colonoscopy is a direct benefit to the patient in preventing progression to malignant lesions (31,36,37). A methodological limitation of this study was the high number of initial Haemoccult tests diagnosed positive. However, with experience gained throughout the trial and with retesting on dietary restrictions this fell to an acceptable level of 3%. A positive Haemoccult test depends on the appearance of a blue colour when test reagent is added to the stool sample (figure 1.2). As more kits were tested we were better able to recognise true blue results. This emphasises the need for adequate training and reassessment of staff processing kits to achieve acceptable positivity.

All screening programmes must provide rapid diagnosis and exclude those without disease following a positive result. In this study, two months elapsed between an initial positive stool test and diagnostic colonoscopy. This period consisted of the time for patients to complete repeat kits, decide to undergo colonoscopy and the waiting time for the procedure. Completing a repeat kit on dietary restrictions is essential to reduce unnecessary investigations. However, an immediate rectal examination and rigid sigmoidoscopy performed by the general practitioner would identify many patients with distal lesions. Colonoscopy was performed on average one month after the repeat test. This delay consisted of obtaining the colonoscopy referral from the general practitioner, the waiting time for the procedure and the five days on bowel preparation. To reduce this delay, direct referral to colonoscopy clinics specifically for investigation of screened patients would be needed.

In the following chapters, uptake of colorectal cancer screening with workplace based and opportunistic schemes are compared with the compliance reported in this general practice approach. Reasons for not participating in non-compliers were used to write educational leaflets which were piloted before testing in a randomised community controlled trial (Chapters 6,7 & 8).

Chapter Three.

Colorectal cancer screening in an industry employing largely men. A study of compliance in the independent sector.

Summary.

Compliance with a workplace based colorectal cancer screening programme in private sector industry was investigated. 1828 employees aged 41 to 65 years at a large industrial company in the East Midlands received an invitation to receive a free faecal occult blood test. Completion of kits was measured by age, sex and occupational groups and compared with acceptance in the community based programme (Chapter 2).

Total compliance was 25.4% with similar participation in men (25.0%) and women (32.0%, X^2=3.0, ns). Men aged 51 to 60 years complied more than men in their forties (30.5% vs 21.9%, X^2=15.1, p<0.001) and sixties (16.6%, X^2=11.6, p<0.001). Participation by women of different ages was similar (X^2=1.5, ns). More managers participated than employees with clerical or blue collar jobs (28.6% vs 23.5%, X^2=5.6, p<0.02). 1% of tests were positive and one patient with a tubular adenoma was detected.

Compliance with workplace based screening was compared with that in general practice for men and women aged 51 to 65 years. In men aged 51 to 60 years and 61 to 65 years and women aged 51 to 60 years uptake was similar (X^2<0.7, ns). The general practice approach was more successful in men aged 61 to 65 years (34% vs 17%, X^2=16.0, p<0.000).

A workplace based colorectal cancer screening programme in this independent company achieved a similar uptake in middle aged people to that in a general practice study in Market Harborough. Therefore workplace based approaches do not offer any major advantage over community schemes in recruiting participants.

Theoretical justification for this work.

Compliance with faecal occult blood testing in general practice based programmes is low (125,126,127,128,135,137,138) so alternative methods of delivering screening should be investigated. Workplace schemes could be successful in recruiting more participants through publicity displayed in factories and offices, the availability of occupational doctors and nurses to answer enquiries and discussion about screening amongst employees at a single industrial site. However, workplace based screening has not been fully evaluated in British industry. This study will measure compliance with such screening which will then be compared with uptake in general practice in Market Harborough (Chapter 2).

If uptake of workplace screening is much higher than community schemes, any future national screening programme could liaise with large local industries in innovative partnership schemes to raise acceptance. Those who had received an invitation from the workplace would then not receive one from their general practitioner. Such schemes would benefit the government by more people participating and companies would gain by improving employee health. However, as only a proportion of the total population eligible for screening is employed in private industry, workplace schemes will never be a complete alternative to a nationally organised programme delivered through local health authorities and general practitioners.

Introduction.

Workplace based colorectal cancer screening programmes have been successful in the United States (167,168,172) and Japan (173,174), but this method of delivering screening needs to be investigated in Britain. Therefore free faecal occult blood tests were offered to employees aged 41 to 65 years at a large industrial company and compliance

was measured according to age, sex and occupation. The company chosen, Brush Engineering, is a heavy engineering firm in Loughborough, Leicestershire (Figure 3.1). The company consists of four subsidiary firms which employ over 4 000 people on a single industrial site. Locomotives for British Rail and the Channel Tunnel project are manufactured at the site. There is an on-site medical centre staffed by three fulltime nurses and a part-time occupational physician. Brush Engineering was chosen for study because it employed a large workforce, had a medical centre to help co-ordinate screening and its personnel departments assisted with administration. The company was based outside the City of Leicester (Figure 3.2) and although Loughborough has three times the population of Market Harborough, the two towns have certain similarities. Both border neighbouring health authorities, have local cottage hospitals and general practitioners refer their patients with acute medical and surgical conditions to hospitals in Leicester.

The rational for offering workplace screening was that on-site education and discussion about screening amongst employees and the availability of advice from firm's medical centres might encourage uptake. The purpose of this study was to investigate whether participation is greater than in community based programmes. If so there may be a place for work-based screening. This may consist of a future national colorectal cancer screening service liaising with companies to develop programmes which recruit many participants. Also if workplace schemes are successful then employees working in industries with an increased risk of colorectal cancer (190,191,192,193,194) could offer a screening service to their employees.

Figure 3.1. Brush Engineering, Leicestershire.

Figure 3.2. Map of Leicestershire showing the locations of Leicester, Market Harborough and Loughborough
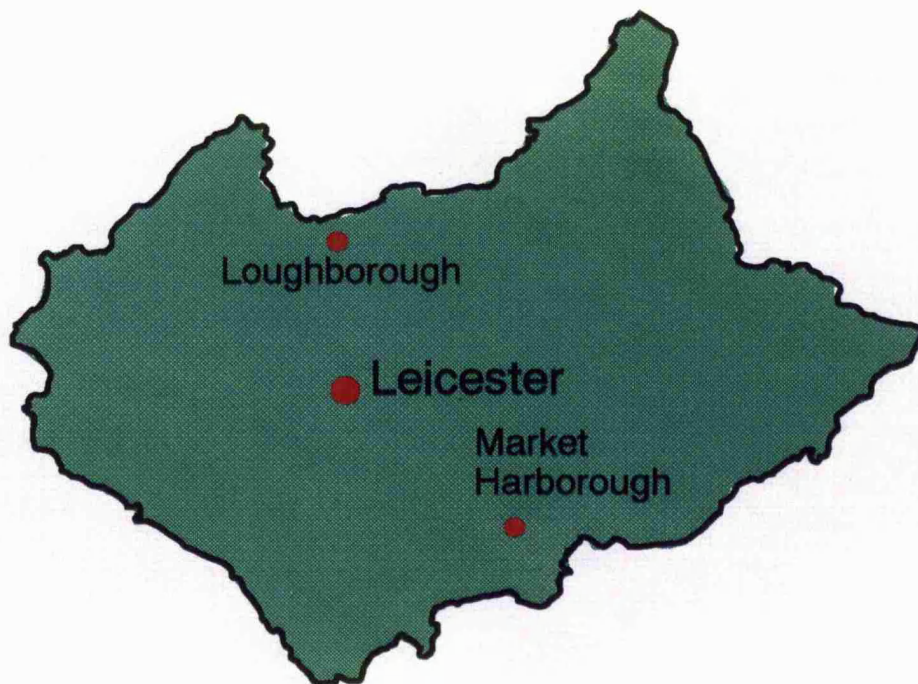
Method.

To select a company for study, the Leicestershire Chamber of Commerce and Industry provided a list of 128 companies in the East Midlands of England who were members. A standard questionnaire (appendix 3.1) was sent to the head of personnel of each company informing them of the rationale of colorectal cancer screening and requesting if their company could be studied. The questionnaire emphasised the costs would be met by research funds and that there was no suggestion their employees were at any greater risk of developing colorectal cancer. Companies were asked to give the number of employees over the age of 40 years so that a large firm could be studied. Firms unwilling to enrol were asked to give their reasons from a list of options (appendix 3.1).

Senior managers of the Brush Group of companies in the East Midlands gave permission for their employees aged 41 to 65 years to receive an invitation to participate in a colorectal cancer screening project. The personnel departments of the engineering company sent a letter to employees explaining the purpose of bowel cancer screening and in this they were offered a free Haemoccult test pack. This letter of invitation was identical to the one used in general practice in Market Harborough (Appendix 2.1). The screening programme was advertised with posters displayed in factories and offices (appendix 3.2) and staff in the work's medical department answered enquiries. Employees who accepted the offer were sent a Haemoccult pack which included instructions on how to perform the test (appendix 2.2). Small amounts of stool were collected and applied to cardboard slides from the kit. These were completed by employees who were not on dietary restrictions on three separate days and subsequently returned to Leicester General Hospital. Here they were all analysed by myself.

A test was positive if a blue colour appeared on addition of a solution of hydrogen peroxide and denatured alcohol to the stool sample. Employees with positive results were asked to repeat the test on dietary restrictions, avoiding red meat, black pudding, cauliflower, cabbage, spinach, radishes, parsnip, broccoli and bananas. This method reduced the number of false positives by 60% (63) while not decreasing the initial compliance rate. If any one of the slides tested on this second occasion was positive, employees and their general practitioners were informed and offered colonoscopy. Family doctors were given clinical freedom to refer patients to hospitals of their choice for colonoscopy, although in practice all were completed at Leicester General Hospital.

With the invitation to colonoscopy, employees received a description of the procedure and standard bowel preparation. Bowel preparation consisted of a low residue diet for five days before the procedure and two sachets of "Klean-Prep" an iso-osmotic bowel clearance solution the day before. Prior to endoscopy a history was taken and employees underwent complete physical examination. Individuals whose repeat tests were negative were sent a third kit to complete four months after the negative slides on dietary restrictions. Patients who had a normal colonoscopy or negative repeat slides were told to contact their doctor if they later developed a change in bowel habit or related symptoms.

The numbers of employees completing kits were analysed by age, sex and occupational group. Two distinct occupational groups were identified, namely managers and non-managers (clerical staff and blue collar workers). Differences in completion rates between groups were compared with a X^2 statistic.

Results.

a. Number of Companies willing to participate.

Brush Engineering was chosen from thirty-five companies who were prepared to participate in the research (27% of the total mailed). A further 28 (22%), were unwilling to participate and their reasons are shown in table 3.4.

b. Uptake of screening.

The overall compliance in employees aged 41 to 65 years with workplace based screening was 25.4% (465/1828, table 3.1). An additional 20.7% (378) employees requested a pack but did not return it completed.

The compliance in men of all ages was 25.0%. Significantly more men aged 51 to 60 years participated than both men aged 41 to 50 years (30.5% vs 21.9%, X^2=15.1, p<0.001) and 61 to 65 years (30.5% vs 16.6%, X^2=11.6, p<0.001). Compliance in men aged 41 to 50 years and 61 to 65 years was similar (21.9% vs 16.6%, X^2=2.1, ns). Compliance in women in the three age ranges was statistically similar (Yates corrected chi square<2.8, ns). Men and women aged 41 to 50 years complied at a similar rate (21.9% vs 29.6%, X^2=2.2, ns) as did those aged 51 to 60 years (30.5% vs 40.4%, X^2=2.0, ns) and 61 to 65 years (16.6% vs 0%, Yates-corrected chi square=0.4, ns).

Compliance was measured according to occupation (table 3.2). From data supplied by the company the occupations of 1803 of 1828 (98.6%) employees were recorded. Of the 25 employees for whom occupation was unknown, 11 returned kits and this small sub-group was excluded from the analysis. Managers complied more than those with non-managerial jobs i.e. clerical and blue collar workers, (28.6% vs 23.5%, X^2=5.6, p<0.02). This difference was due to male managers aged 41 to 50 years

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complying significantly more than male non-managers of the same age, (26.6% vs 19.4%, $X^2=5.7$, $p<0.02$). For men of other ages there were no significant differences in compliance between occupational groups. Compliance between female managers and non-managers was not statistically different in each of the three age groups ($X^2<3.1$, ns).

c. Comparison of compliance in general practice & workplace based screening programmes.

Compliance with screening was compared between approaches in those aged 51 to 65 years (table 3.3). In men aged 51 to 60 years uptake was similar (32% vs 31%, $X^2=0.2$,ns) but significantly more men aged 61 to 65 years complied with an invitation from their general practitioner (34% vs 17%, $X^2=16.0$, $p<0.0001$). In women compliance was similar for those aged 51 to 60 years (47% vs 40%, $X^2=0.7$,ns) and 61 to 65 years (36% vs 0%, Yates corrected X^2 test$=2.5$, ns).

d. Test positivity and pathology detected.

Four of the 434 kits were positive but only one of these four was again positive on re-testing with dietary restrictions. The patient with a repeat positive test was informed and his general practitioner referred him for colonoscopy at Leicester General Hospital. At colonoscopy the patient had a 1cm pedunculated polyp at the splenic flexure which was removed through the colonoscope. Histology showed a tubular adenoma with mild dysplasia and complete excision margins. The three subjects who had repeat negative tests on dietary restrictions completed a further test four months later all of which were negative.

Table 3.1 Compliance with workplace based screening at Brush Engineering, Loughborough.

AGE (YEARS)	MALE	FEMALE
41-50	188/860 (22%)	21/71 (30%)
51-60	213/698 (31%)	19/47 (40%)
61-65	24/145 (17%)	0/7 (0%)

Overall compliance for men (25.0%) and women (32.0%) was similar ($X^2=3.0$, ns).

Table 3.2. Compliance with occupation based colorectal cancer screening at Brush, Loughborough.

AGE (YEARS)	MANAGERIAL	NON-MANAGERIAL
MEN		
41-50	76/286 (27%)	110/566 (19%)
51-60	76/223 (34%)	128/461 (28%)
61-65	14/65 (22%)	10/80 (13%)
WOMEN		
41-50	4/13 (31%)	17/56 (30%)
51-60	0/6 (0%)	19/40 (48%)
61-65	0/1 (0%)	0/6 (0%)

Compliance in managers was greater than in employees with non-managerial jobs (28.6% vs 23.5%, $X^2=5.6$, $p<0.02$).

Table 3.3. Comparison of compliance with a colorectal cancer
screening programme between a general practice in Market
Harborough and an industrial based approach at Brush,
Loughborough.

Age (years)	General Practice	Industry	Significance
Men.			
51-60	361/1146 (32%)	213/698 (31%)	p=0.7,ns
61-65	146/428 (34%)	24/145 (17%)	p<0.0001
Women.			
51-60	529/1135 (47%)	19/47 (40%)	p=0.4, ns
61- 65	185/513 (36%)	0/7 (0%)	p=0.1, ns

Compliance with workplace screening was similar to that in general practice
for women and men in their fifties.

Table 3.4. Companies reasons for rejecting screening.

Reason	companies rejecting screening (n=28) no (%)
Logistically difficult to run screening at company	9 (32%)
Management stating workforce would not be interested	8 (29%)
Unsuitable economic climate	3 (11%)
Not the company's responsibility to look after employee's health	2 (7%)
Employee representatives disinterested	2 (7%)
Embarrassment to employees	1 (4%)
Medical advisor disinterested	1 (4%)
A similar screening programme is already operated by the company	1 (4%)

Of 28 companies who rejected screening, 24 gave 27 reasons for

not participating.

Discussion.

This study found the overall uptake of faecal occult blood testing was low despite publicity with posters in factory sites, offices and the medical department answering enquiries. Compliance may have been increased by promotional lectures, although disruption to working practices prevented this. Use of a reminder if employees failed to request may also have increased compliance, but these were not sent to avoid undue harassment. In community studies remailing did raise uptake by 5 to 10% (90,140) and telephone reminder calls have also proved effective (141). In men, compliance was lowest in those aged 41 to 50 years and 61 to 65 years. Younger employees in their forties may feel at low risk of colorectal cancer and therefore did not participate. Offering screening to this group is probably not worthwhile as the incidence of cancer is low and the uptake of screening poor. This workplace approach was ineffective in targeting male employees aged 61 to 65 years. A possible reason was that older men still at work may perceive themselves as healthy and not in need of screening. Alternatively, male employees in their sixties may feel too old to benefit from screening. The similar uptake of screening in men and women of all ages with the workplace approach is encouraging, as compliance is less amongst men in general practice based studies (86,126,128,135,137,138). Discussion about screening at the workplace may have educated men about its value and encouraged participation. Intensive education of employees seems essential if compliance is to be increased in workplace screening, although this may be difficult because of interference with routine work. Managers at the Brush plant were keen that the screening service would not involve any lost working hours. The only previous British study of workplace screening achieved a participation rate of 51% through a programme of education with leaflets, lectures and small group discussions as well as the formal invitation letter (157).

In this study from London, workers over 40 years in two industrial organisations received a haemoccult kit and completed a symptom questionnaire. Here significantly more women than men participated (61% vs 47%). Similarly in a Texan polypropylene plant where there was an intensive educational campaign, discussion seminars and a telephone advice line, uptake was 68% (167). Past and present workers were offered a faecal occult blood test and flexible sigmoidoscopy following the discovery of excess numbers of colorectal cancers at the plant. Overall participation was 52% although amongst current employees it reached 68%. As in my study, compliance was highest in men in their fifties. Process workers, mechanics, administrators, engineers and chemists were more likely to participate than laboratory staff. In workplace studies where education was less intense or recruitment procedures complicated, uptake was less (168,169,170). For example, the American Pennzoil Company offered colorectal cancer screening to employees over 40 years of age and with a family history of colonic carcinoma (169). Compliance was 20% with faecal occult blood testing and 31% with sigmoidoscopy. This relatively low compliance may be due to the laborious recruitment procedure. Employees first attended an educational seminar on the early detection of all major cancers and then filled out a risk assessment questionnaire. Employees were subsequently invited for a discussion and asked to complete a further risk assessment. At the interviews, faecal occult blood tests were analysed and a proportion of employees referred for sigmoidoscopy. Age did not affect participation, although in men a family history of colorectal disease increased uptake. An analysis of uptake according to occupation was not reported.

Compliance in workplace screening seems to be high if workers are aware of the concepts of screening or have symptoms (158,173). In Japan where the population is exposed to a gastric cancer screening service, participation in a work based colorectal

cancer screening service with an immunological faecal occult blood test was high at 72%

(173). In another Japanese study, more men actually received their gastric cancer

screening through a workbased rather than a community programme (174). The presence

of symptoms encouraged coal miners to participate in a "screening" programme in

Nottinghamshire using a dyspepsia questionnaire. Here 82% of miners returned the

questionnaire of which a third had symptoms. The overall low participation rate in my

study emphasised the need for a thorough understanding of reasons for non-compliance

and for effective health education. If adequate health education cannot be delivered to

employees prior to the commencement of workplace screening then uptake will often be

low. In this thesis another approach to raising uptake will be assessed by interviewing

non-compliers (Chapter 6) to determine reasons for non-compliance and then these will be

addressed in health educational leaflets (Chapters 7 & 8). Other industrial companies have

used various incentives to encourage participation. In an attempt to reduce smoking, an

industrial company in Michigan paid workers $75 if they successfully completed the

programme (238). Employees also had to pay $25 if they failed to comply throughout the

scheme. The company organised employees into teams and the one with the best record at

the end received a further financial bonus. If an employee was caught smoking, then that

team was subjected to a financial deduction. Although the trial was uncontrolled, half the

employees had continued to stop smoking for seven months. The combination of financial

incentives and the team approach appeared effective. A similar team approach was

adopted by an American company in a work sponsored weight reduction programme

(239). Here, team competitions to loose weight were more effective in encouraging

participation than when individuals were approached on their own. As an "incentive"

employees were weighed during the lunch hour in the staff canteen. At the Brush plant,

offering financial incentives to participate was not possible, although offering a team prize

to the occupational group that participated most may have encouraged a larger response.

The low participation rate at Brush may have been due to the relatively large size of the

company, as previous work has shown uptake tends to be higher in smaller firms

(240,241). Presumably discussions which may encourage participation are easier amongst

a relatively smaller group of workers. Paradoxically though, smaller businesses are less

likely to consider introducing health promotion schemes at the workplace

(166,242,243,244). Hollander et al (242), conducted a questionnaire survey of the largest

500 American firms. Two-thirds of the companies that returned the questionnaire offered

worksite screening and health promotion, the commonest programmes were for

hypertension and advice on smoking and alcohol reduction. Sixty-two per cent of

companies with less than a thousand employees had such schemes compared to 75% of

businesses that employed more than ten thousand people. Larger firms were more likely

to be actively considering the expansion of their health promotion services. Industries

concerned with printing, mining, office equipment, oil refining and cosmetics showed

greatest interest in employee health and those involved with transportation, textiles and

metal products the least.

One hypothesis under investigation in this thesis was whether compliance with

workplace screening programmes would be higher than in community schemes. The

rationale was that participation would be increased through on-site advertising and

discussion about screening amongst employees on a single site. If compliance was much

higher, then future national programmes could liaise with industry in an attempt to

encourage participation. Screening could be advertised at the workplace and invitations

mailed on company note paper. Those invited from their place of work would not receive

a similar invitation from their general practitioner. However, as uptake for different age groups was either similar or lower at the Brush plant than in Market Harborough this approach is inappropriate. This finding is disappointing and other methods for delivery of screening need to be considered.

A major omission in publications on colorectal cancer screening is a failure to report the effects of occupation or social class. If this were known, screening could be more specifically targeted. In the study reported here, completion of faecal occult blood tests was related to occupation with managers participating more often. One community study, found highest uptake in social classes I and II, but the expected trend of falling compliance in less skilled classes was not seen (129). In a hospital based screening programme "participation was higher in the middle ranks than for upper or lower prestige occupations, although this did not attain statistical significance" (224). As to which occupations were of high and low prestige was unclear. Data from my workplace screening study at the Brush plant showed participation was low in both managers and non-managers and that both groups need encouragement. Other workers have shown participation was lower in blue collar than white collar workers (239,245). In a weight reduction programme white collar workers were twice as likely to participate as blue collar workers (239). In addition, salaried employees were more prepared to complete a health appraisal questionnaire than their hourly paid colleagues (245).

A major limitation of this study was the predominance of men who comprised 93% of the workforce. In the next chapter where screening in the public sector industry is investigated, the majority of the workforce were women. At the Brush plant there were only 7 female employees aged 61 to 65 years, none of whom completed a faecal occult blood test. Statistical comparison of compliance in women aged 61 to 65 years between

the two approaches is appropriate using a Yates-correction to the chi square test. However, this comparison must be interpreted cautiously due to the small number of women. Locating an industry employing more women in their sixties would be difficult as until recently the recommended female retirement age was 60 years. A further limitation was in the comparison of compliance, no correction could be made for social class differences in the structure of the two populations. Other work has shown uptake across social classes can vary by 13% (129).

The positive rate for stool testing was 1% and a lesion was detected for every 465 employees screened. This low positivity and detection rate is due to the large number of employees younger than 50 years old. The four employees with positive tests were all over 55 years old and the patient with the adenomatous polyp was 58 years. The detection rate in this trial of one person with a polyp amongst 250 screened in the 51 to 60 years age group was similar to other work (86,91,92).

Workplace based initiatives in private sector industry do not recruit more participants than general practice based programmes. Industry could be involved in a future national screening programme by advertising the service, rather than actually delivering or developing screening programmes. Occupational physicians and nurses at large companies could inform workers of the benefits of screening. The findings in this study need to be confirmed in other workplace programmes in other industries such as the public sector and where compliance can be more fully assessed in women. In the next chapter, compliance was measured in a large National Health Service teaching hospital where 83% of the workforce were women.

Chapter Four.

Colorectal Cancer Screening in the Public Sector. An example from a hospital study with a largely female population and an assessment of the effect of remailing.

Summary.

Free faecal occult blood tests (Haemoccult) were offered to 985 employees (820 women, 165 men) aged 41 to 65 years in a large NHS teaching hospital. Compliance was measured according to age, sex and occupation. Staff were classified into the following occupational groups: clinical support staff (45 employees such as pharmacists, radiographers, physiotherapists and occupational therapists), nurses (408), clerical workers (201), non-clinical ancillary staff (265), doctors (35) and managers (31). Total compliance was 44% with women participating more than men (46% vs 32%, $p < 0.002$). This difference in uptake was due to women aged 41 to 50 years returning more kits than their male counterparts (46% vs 24%, $p < 0.0005$). Participation was highest in clinical support staff (56%), nurses (50%) and clerical workers (44%, $p < 0.05$). Participation by non-clinical ancillary staff was 37%, doctors 26% and managers 23%. Four employees (1%) had positive faecal occult blood tests but three were negative on repeat testing with dietary restrictions. The fourth patient had a colonoscopy and proctitis was diagnosed. Uptake was statistically similar ($X^2 < 1.6$) in general practice and at this workplace in the following four groups: men aged 51 to 60 years (32% vs 39%), men aged 61 to 65 years (34% vs 41%), women aged 51 to 60 years (47% vs 48%) and women aged 61 to 65 years (36% vs 33%). Workplace based screening in the public sector does not lead to greater uptake than in general practice schemes.

Theoretical Justification for this work.

For a screening service to be successful, many subjects must participate. As compliance with faecal occult blood testing in general practice based programmes is low, other methods by which screening can be delivered should be considered. One approach

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is to offer faecal occult blood tests to asymptomatic employees working in the public sector, a method not previously investigated in Britain. This programme could recruit more participants through publicity displayed at the workplace and because of the availability of an occupational health department to answer enquiries.

A second workplace was investigated to give a more comprehensive assessment of the value of such programmes. A hospital was chosen for study because the National Health Service is the largest employer in Britain and if uptake was high, then screening delivered to health service employees would benefit a large section of society. Another reason was a majority of employees were women, which contrasted with the workforce at Brush. Data from the Department of Employment show three times more men are employed in private companies but that public services employ similar numbers of men and women (249). As funding of public and private sector screening would come from different sources i.e the government and individual companies it is important for these organisations to know what response is likely.

Introduction.

In the previous study, workplace screening in a private sector industry which employed mainly men, recruitment was no better than in general practice. This chapter reports a similar scheme offered in public sector industry where most employees were women. If successful, such programmes could reduce cancer mortality because of the large number of people employed in the public sector. Such industries could liaise with any future national programme by advertising screening, advising employees through occupational health departments and mailing invitations. The largest public sector employer in Britain is the National Health Service with over a million people.

Leicester General Hospital (figure 4.1) was chosen for this study because of the interest of senior doctors and managers in developing employee health programmes, the willingness of the occupational health department to be involved and the convenience of an endoscopy unit on site. This hospital is a large university teaching hospital with 900 beds offering acute and elective medical and surgical services. Two thousand people work in the hospital, with approximately half in the age range eligible to participate in a colorectal cancer screening programme. The Human Resources and Occupational Health Departments agreed to remail non-responders after two months. The response to remailing has not previously been studied in a British workplace programme.

Workplace based colorectal cancer screening programmes in the public sector for asymptomatic employees have not been investigated in the United Kingdom. In my study, free faecal occult blood tests were offered to hospital employees aged 41 to 65 years and compliance measured according to age, sex and occupation. The rationale behind such a programme was on-site publicity and discussion amongst employees might encourage a high uptake, similar to that achieved in American and Japanese workplace studies (167,172,173). If participation is greater or comparable to that in community based programmes then there may be a place for such work based schemes in the public sector.

Figure 4.1 Leicester General Hospital.

Method.

A total of 985 employees aged 41 to 65 years were offered colorectal cancer screening using faecal occult blood tests (Haemoccult). The letter of invitation was sent jointly from the Departments of Gastroenterology, Human Resources and Occupational Health at the Leicester General Hospital and was similar to one used in general practice (Appendix 2.1). The letter contained an invitation to participate in the programme which took place over the period March 1993 to July 1993. The project was advertised in the hospital newspaper (Figure 4.2) and with posters displayed throughout the hospital (appendix 3.2). Additional information and advice were available in the Department of Occupational Health (appendix 4.1). The project had the support of all members of the Joint Staff Consultative Committee. This is a staff committee composed of representatives from each hospital department which meets monthly to discuss employment and staffing issues. Those employees who accepted were sent a free Haemoccult pack which included instructions on how to perform the test. Fresh stool was collected and applied to the cardboard slides from the kit. These were collected on three separate days by the employee and returned to the research unit at Leicester General Hospital where they were analysed by myself. Slides were not rehydrated and were considered positive if a blue colour appeared on the addition of a solution of hydrogen peroxide and denatured alcohol to the sample.

Employees with positive faecal occult blood tests were asked to repeat the stool samples avoiding red meat, cauliflower, cabbage, spinach, broccoli and bananas. In a study from Nottingham, dietary retesting reduced the number of false positives by 60% (63). If any repeat slides were positive, patients and their general practitioners were informed and the patient invited to attend for colonoscopy. With the invitation to

FIGURE 4.2 HOSPITAL NEWSPAPER ADVERTISING SCREENING

● **Trust**

   Board

   Members

   Announced

   See inside

● **New**

   Junior

   Doctors

   See inside

● **OT**

   Staff

   Work In

   Romania

   See inside

CANCER PREVENTION

Campaign to protect staff

An innovative health promotion campaign at LGH aims to protect staff against bowel cancer, which kills 20,000 people a year in Britain. Many of these deaths could be prevented by early detection.

Free tests designed to detect early signs of bowel cancer at a stage when it can be cured are being offered to all employees on a voluntary basis. In March employees aged between 40 and 65 years of age will be sent a personal and confidential letter offering tests.

Simple Test Pack

Those who take part will receive a small, simple test pack which can detect microscopic traces of blood produced by the cancers.

This scheme is the first of its kind offered to hospital employees in the country. It is being run as a joint promotion by Occupational Health, the Department of Gastroenterology and the Human Resources Directorate and has the full backing from the staff side of the JSCC.

Project manager is Dr Andy Hart, Registrar in Gastroenterology.

colonoscopy, patients received a description of the procedure and the standard bowel preparation. Prior to endoscopy a history was taken and physical examination completed. The investigation was arranged as a day case procedure on a routine endoscopy list.

Patients who had repeat negative slides were told to contact their doctor if in the future they developed a change in bowel habit or related symptoms. A further test was offered to these employees 4 months later.

The numbers of employees completing kits were analysed by age, sex and occupation and tested for differences with a X^2 test. A comparison of compliance with this workplace approach, after the first invitation, was made with that in general practice and in the private sector industry programme at the Brush plant.

To investigate the effect of remailing, non-compliers were sent a repeat invitation two months after the initial one. The second letter was identical to the original invitation except it informed the that employee they were being re-mailed in case they had changed their mind. The effect of re-mailing was tested for statistical significance in men and women with a X^2 test.

Results.

a. Uptake of screening.

The overall compliance was 44% (429/985). A further 148 employees (15%) people requested kits but did not return them (table 4.1).

In men, uptake was similar for those in their forties (24%), fifties (39%) and sixties (41%, $X^2 < 3.7$, ns). Women aged 41 to 50 years complied at a similar rate to women in their fifties (46% vs 48%, $X^2 = 0.4$, ns) and to those in their sixties (46% vs

33%, X^2=2.8, ns). More women aged 51 to 60 years participated than those in their sixties (48% vs 33%, X^2=3.8, p<0.05).

More women participated than men (46% vs 32%, X^2=10.5, p<0.002). This difference was due to young women aged 41 to 50 complying more than their male colleagues (46% vs 24%, X^2=12.7, p<0.0005). Uptake in men and women was similar in those aged 51 to 60 (39% vs 48%, X^2=1.7, ns) and 61 to 65 years (41% vs 33%, X^2=0.4, ns).

Compliance was similar in clinical support staff (56%), nurses (50%) and clerical workers (44%) (X^2<1.9,ns, table 4.2). These three groups all participated more than doctors (26%), managers (23%) and non-clinical ancillary staff (37%, X^2>4.2, p<0.05), the only exception being a similar uptake in clerical and non-clinical ancillary staff (44% vs 37%, X^2=2.8, ns). Compliance was similar in doctors (26%), managers (23%), and non-clinical ancillary staff (37%, X^2<2.4, ns). Within an occupational group, men and women participated at a similar rate (Yates-corrected X^2<0.8, ns) except in clerical workers where more women participated (47% vs 21%, X^2=4.6, p<0.05).

Following the reminder letter, a further 27 people participated (2.7%) and completed a test kit, although this did not significantly raise the response rate (44%, 429/985 vs 46%, 456/985, X^2=1.5, ns). Reinvitation increased uptake in men by only 1.8% (3/165, X^2=0.1, ns) and in women by 2.9% (24/820, X^2=1.4, ns). There was no significant difference in the effects of remailing between men and women (1.8% vs 2.9%, Yates-corrected X^2=0.3, ns).

Table 4.1 Participation with a colorectal cancer

screening programme in a university teaching hospital.

AGE (YEARS)	MEN (n=165)	WOMEN (n=820)
41-50	19/79 (24%)	194/425 (46%)
51-60	25/64 (39%)	165/344 (48%)
61-65	9/22 (41%)	17/51 (33%)
TOTAL	53/165 (32%)	376/820 (46%)

Younger women aged 41 to 50 years complied more than their male colleagues (X^2=12.7, p<0.0005). Compliance in men and women aged 51 to 65 years was the same (X^2=1.2, ns).

Table 4.2. Compliance with occupational based screening for colorectal cancer in a university hospital.

OCCUPATIONAL GROUP	MEN (n=165)		WOMEN (n=820)	
Clinical support Staff	4/7	(57%)	21/38	(55%)
Nurses	4/11	(36%)	198/397	(50%)
Clerical	4/19	(21%)	85/182	(47%)
Non-Clinical Ancillary staff	29/84	(35%)	68/181	(38%)
Doctors	8/33	(24%)	1/2	(50%)
Managers	4/11	(36%)	3/20	(15%)

Compliance was highest in clinical support staff, nurses and clerical workers ($X^2 > 4.2$, $p < 0.05$).

b. Comparison of compliance between general practice and public sector industry.

Compliance with screening was compared between approaches (table 4.3) in those aged 51 to 65 years. Uptake was similar in general practice and at the workplace in men aged 51 to 60 years (32% vs 39%, $X^2=1.6$, ns) and 61 to 65 years (34% vs 41%, $X^2=0.4$, ns). Compliance in women aged 51 to 60 years was similar in the two approaches (47% vs 48%, $X^2=0.2$, ns) and in those aged 61 to 65 years (36% vs 33%, $X^2=0.2$, ns).

c. Comparison of compliance between private and public sector industries.

In men, compliance was highest in the public sector programme in the hospital (32% vs 25%, $X^2=4.1$, $p<0.05$, table 4.4). This difference was due to older men aged 61 to 65 years participating more (41% vs 17%, Yates-corrected $X^2=5.7$, $p<0.02$). There were similar participation rates for men in their forties (24% vs 22%, $X^2=0.2$, ns) and fifties (39% vs 31%, $X^2=2.0$, ns).

In women, compliance was also higher in the hospital based programme (46% vs 32%, $X^2=8.4$, $p<0.01$). This difference was due to more younger women in their forties participating (46% vs 30%, $X^2=6.4$, $p<0.02$). There were similar participation rates for women in their fifties (48% vs 40%, $X^2=0.9$, ns) and sixties (33% vs 0%, Yates-corrected $X^2=1.9$, ns).

d. Test positivity and pathology detected.

1% of faecal occult blood kits tested were positive. Of the four people who had an initial positive test, 3 were negative on dietary re-testing. The fourth patient, who was symptomatic but had not consulted her general practitioner had severe proctitis to 10cm at colonoscopy. Treatment with steroid enemas was commenced.

Table 4.3 Comparison of compliance in a general practice and public

sector approach to delivering screening.

Age	General Practice (n, %)	Public Sector (n, %)	Significance
Men			
51-60 years	361/1146 (32%)	25/64 (39%)	p=0.21, ns.
61-65 years	146/428 (34%)	9/22 (41%)	p=0.51, ns
Women.			
51-60 years	529/1135 (47%)	165/344 (48%)	p=0.66, ns
61-65 years	185/513 (36%)	17/51 (33%)	p=0.70, ns

For each age group in both men and women, workplace screening

achieved a similar compliance to that in general practice ($X^2=1.6$, ns).

Table 4.4. Comparison of compliance between private sector industry at the Brush Plant, Loughborough and public sector industry at Leicester General Hospital.

Age (years)	Private Sector (n, %)	Public Sector (n, %)	Significance
Men			
41-50	188/860 (22%)	19/79 (24%)	p=0.70, ns
51-60	213/698 (31%)	25/64 (39%)	p=0.16, ns
61-65	24/145 (17%)	9/22 (41%)	p<0.02
Women			
41-50	21/71 (30%)	194/425 (46%)	p<0.02
51-60	19/47 (40%)	165/344 (48%)	p=0.33, ns
61-65	0/7 (0%)	17/51 (33%)	p=0.17, ns

Overall, compliance was greater in the hospital programme than at Brush Engineering (44% vs 25%, X^2=96.9, p<0.0001).

Discussion.

The aim of this thesis was to determine if compliance could be increased by novel methods in the delivery of screening, including work-based programmes in the public and private sectors. Although any future screening programme would probably be co-ordinated regionally through general practitioners, liaison between industry and health authorities could be developed in an effort to increase participation, if workplace programmes were successful. However, this study found completion of faecal occult blood tests was similar in men and women aged 51 to 65 years in general practice and the public sector programme. Therefore, workplace based programmes did not offer any advantage in terms of increased uptake and such programmes should probably not be developed. Although public sector industries could advertise screening at the workplace they should not be concerned with its delivery. Other ways to increase compliance through general practice based schemes should be considered such as more effective health education. This will be explored later in the thesis.

This screening programme was compatible with the aims of the government's document "Health at work in the NHS" (246). This provides advice for NHS staff on aspects of health including smoking, diet, alcohol intake and exercise but also states that management should "provide opportunities for all staff to have health checks and attend screenings and appropriate follow-up". The document identifies the need for "management agreement to provide work time for checks and any treatment and ensure confidentiality." The Department of Health suggests that the way forward with the healthy workplace initiative is to appoint a co-ordinator to bring together a wide range of expertise to run a successful scheme. Results from this study suggested screening studies will not meet the aims of this document, as compliance was less than 50%. Uptake may have been higher if

there had been more intense publicity with explanatory lectures and seminars. Unfortunately, working practices within the hospital did not allow for this. Other work where education was intense, including discussion groups, a telephone enquiry service and multiple reminders gave a high compliance of 83% (167). If the government wishes to promote such health schemes in the NHS, adequate time must be allocated for staff education.

Amongst male hospital employees, compliance was lowest in those in their forties, although this difference did not quite reach statistical significance. This finding was confirmed in the previous study of younger men working in a private industry (chapter 3). Men of this age may feel at little risk of the disease. Low compliance and low incidence of colorectal cancer at this age means screening them is not worthwhile. Younger women in their forties did participate, which may be because they are aware of the concept of screening through other cancer prevention programmes such as cervical screening. The major limitation of this study was the relatively small number of male employees which constituted only 17% of the hospital's workforce. For example, there were only 22 men aged 61 to 65 years, although this number was statistically adequate to allow a comparison with similar aged men in Market Harborough. However, in the previous study at Brush Engineering, large numbers of men were offered faecal occult blood testing. In women hospital employees, compliance was lower in those in their sixties than fifties, a finding confirmed in general practices in Market Harborough (Chapter 2) and other areas (125,126,128). This may reflect a view that older women feel too old to benefit from screening, a finding reported in a study of non-compliance (223). Employees who initially declined screening were reinvited and this raised compliance by 5% and 10% in two community based approaches (90,140). In the hospital, remailing had

only limited effect. The time and financial resources spent identifying non-compliers and re-inviting them cannot easily be justified. This failure of remailing confirmed the need to achieve a high compliance at the first invitation. Although more intense publicity might raise compliance, the cost and time required may be prohibitive. Alternatively, test kits could be directly mailed to employees together with appropriate educational leaflets.

Compliance was highest in clinical support staff, nurses and clerical workers and lowest in doctors, managers and non-clinical ancillary staff. In all six occupational groups, compliance in men and women was similar except for clerical workers. However, a limitation of the study was that the numbers of men or women in some occupational groups were small and here comparisons must be interpreted with caution. Participation by doctors and managers was disappointing and whether these groups are unconvinced of the benefits of screening or are indifferent to their own health is unclear. Alternatively, doctors and managers may prefer health care away from hospitals at which they work. Certainly such reasons need to be addressed if medical staff are to encourage others to participate in screening programmes. As uptake amongst nurses was greater than doctors they may be the better group to publicise and discuss the value of screening to the public. Studies on patient education in inflammatory bowel disease confirmed that individuals other than doctors can provide information on aspects of health care. For example, in Nottinghamshire, trained lay counsellors discussed medical and social problems that patients experienced with their disease, many of whom felt they could not do this with their doctors (247). In a screening programme in an Australian hospital "participation was higher in the middle ranks than for upper or lower prestige occupations", although this did not reach statistical significance (224). Those occupational groups which constituted these "prestige" groups were not defined. This curvilinear relationship with occupational

rank was broadly similar to the finding in my British hospital study. The poor response by doctors and managers is contrary to the findings in a community based programme where individuals belonging to social classes 1 and 2 participated most (129). However, in this study, uptake of screening was higher in those in social class 5, than either 3 and 4. It is important to know how compliance varies according to social class, so screening can be better targeted. In colorectal cancer screening, no study has examined whether reasons for non-compliance differ across social classes. However, data from Oxford did show variations for factors important to general health, which may be relevant to screening (229). In Oxford, a questionnaire was mailed to 8 107 subjects which investigated attitudes to factors influencing health. Subjects in social classes 1 and 2 were more likely to stress the importance of smoking, diet and exercise, while those in classes 4 and 5 were more likely to emphasise socioeconomic influences such as unemployment, income, pollution and housing. In mammographic screening MacLean et al reported acceptance was lowest in the lower social classes, primarily due to increased anxiety about screening and cancer (131). Another study on mammography from Manchester showed that self-referral for screening was associated with higher social class and higher educational achievement (248). In cervical cancer screening, incidence of the disease is highest in social classes 4 and 5, where uptake of smear testing is the lowest (133).

Overall compliance with screening in the public sector was higher than at the Brush plant in both men and women. There was similar advertising at both workplaces and both occupational health departments answered employees' questions on screening. Speculation would suggest hospital employees may be more aware of medical matters than those in the private sector. Hospitals are a legitimate place to study public sector industry

as the NHS is the largest UK employer, although other public sector companies may be more representative.

This is the first reported colorectal cancer screening programme for British hospital employees. In a similar scheme in Australia, 728 employees of a Sydney teaching hospital were offered a free faecal occult blood test. Overall compliance was 41% with women participating more than men (35% vs 46%, 224). Participation was unrelated to age, but positively associated with Australian or British origin, single status and those with a personal knowledge of someone who had colorectal cancer. In Sydney, reasons cited for failure to participate were lack of time, feeling well and a preference to see their own doctor. This latter point illustrates a difficulty in workplace programmes in that workers may not expect to receive health promotion and screening from their employer.

Screening asymptomatic employees for cancer in public sector industry has not been fully investigated in Britain. However, in the early fifties, a radiographic screening programme for pulmonary tuberculosis and pneumoconiosis was offered to the community of the Rhondda Fach, Wales (164). The compliance in miners was high at 95% which was partly related to screening facilities being made available at the pithead. There was intense publicity and follow-up of non-compliers outside the workplace with lectures in local social and political clubs and publicity in the press and television. Non-compliers were actively pursued with some receiving six home visits to persuade them to participate. In the United States more data are available on workplace screening. Lee et al conducted a randomised trial of assessing colorectal cancer risk in federal employees in Washington State (175). Risk of the disease was calculated from age, family history of colorectal cancer and dietary habits. The largest effect of the intervention was on employees' intention to get a faecal occult blood test within the next year (63% in the

intervention group vs 36% in the control group). However, intentions and actions did not match-up and after a three month period, there was only a 4% higher compliance with testing in the intervention group. In a workplace hypertension screening programme in Michigan, 80% of sanitation and postal workers had their blood pressure measured on site (185). Although this scheme was highly successful, it is clearly easier to raise acceptance of a procedure such as blood pressure measurement than to get employees to complete faecal occult blood tests.

The positive rate of stool testing in this study was 1% which is lower than in many larger trials (90,92,93). This was for two reasons, namely slides were not rehydrated prior to testing, as this decreases specificity (82) and people in their forties have less pathology. Only one patient of the 450 screened was colonoscoped and a proctitis to 10 cm found. In larger studies, one neoplastic lesion is diagnosed for every one hundred to one hundred and seventy people screened over 50 years (86,91,92). In this project 233 such people participated so at most I might have found two neoplastic lesions.

The studies in this thesis demonstrate workplace schemes are not an effective alternative to community schemes delivered through general practice. Workplace schemes are limited, as not all the population are employed and so a proportion would not be invited. If workplace schemes were developed then screening must occur in both public and private sectors as they have different employee structures. Data from the Department of Employment show a similar proportion of women work in both public and private sectors, but three times more men are employed by private companies (249). If a screening service was only developed in the public sector then relatively few men would be invited. In view of the lack of success of workplace screening, I investigated an

opportunistic method of delivery and then the role of health education in raising

compliance.

Chapter Five.

Screening volunteers at blood donor centres: an opportunistic approach

to screening.

Summary.

To investigate opportunistic screening, faecal occult blood tests were offered to blood donors aged 51 to 65 years when they came to give blood. A doctor was available at the donor centre to explain screening and to distribute kits.

Over a three month period 556 registered donors (309 men and 247 women) aged 51 to 65 years were invited to give blood at the Leicester blood donor centre. 63% of subjects who accepted a faecal occult blood test kit completed the investigation with a similar compliance in men and women (66% vs 59%, $X^2=1.0$, ns). Compliance was higher in donors aged 61 to 65 years than those of 51 to 60 years in both men (90% vs 60%, $X^2=7.0$, $p<0.01$) and women (51% vs 87%, $X^2=6.2$, $p<0.02$). The proportion of the target population screened, which included donors invited to give blood but who did not attend, was 21%. In this opportunistic approach more male and female recalled donors completed kits than subjects in the community study in general practice (men 66% vs 32%, $p<0.0001$ and women 59% vs 43%, $p<0.02$). As the uptake of screening was high in those who came to give blood, centres should display cancer screening and health promotion literature. Doctors supervising sessions could provide further information and advice to donors.

Theoretical justification for this study.

The previous chapters suggested that any future national screening programme for colorectal cancer will probably be community based with invitations coming from general practitioners. However, within this system complementary methods of delivering screening could exist. Opportunistic approaches, where screening is offered to individuals at routine consultations with family doctors or other health professionals could be

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successful. Medical staff would explain the purpose and benefits of screening and answer questions or concerns. In Britain, opportunistic colorectal cancer screening has been investigated to only a limited extent, even within general practice (136,137). This study addressed this deficiency by assessing an original mode of delivery in which blood donors attending donation sessions were offered faecal occult blood testing. If compliance was high, then the value of direct contact with potential screenees is emphasised. The blood donor service could work with the organisers of national screening programmes to publicise the availability of such services and even offer or arrange appointments for screening.

Introduction.

Opportunistic approaches to colorectal cancer screening, where subjects are directly educated by a doctor and offered faecal occult blood testing, may increase compliance rates. This form of opportunistic screening was assessed in two British general practice based studies (136,137) where uptake was 56% and 57% in those over 40 years old. However, opportunistic screening has not been investigated in settings outside general practice, although clearly such approaches may be effective.

One method which has not been studied is the uptake of faecal occult blood testing by blood donors. Colorectal cancer screening could be publicised at donor centres and doctors supervising such sessions could explain the test and offer screening to donors. This direct approach should lead to a high uptake in a motivated group of people who could then encourage friends and relatives to participate. Furthermore, free cancer screening may be an incentive to donors to attend sessions. Such a scheme could operate

within the frame work of a national screening programme as a complementary method of raising compliance.

A programme for screening donors was evaluated at the Leicester branch of the Trent Regional Blood Transfusion Service (Figure 5.1). The Trent Regional Service is the largest in the country and the Leicester branch is located in the city centre. Prior to attending, donors received a letter about screening (appendix 5.1) which stated a doctor would be present to offer faecal occult blood testing. Previous work showed blood donors are more likely to be male, white, married, have college or technical training and earn greater than the average national wage (250,251). Although more women are first-time donors than men, the proportions are reversed on subsequent donations (252,253). In a study of 15 United States blood donor centres it was found that frequent donors had incomes approximately 30 per cent higher than non-donors (254). The same study showed that these donors were better educated than non-donors. In a Canadian sample of 1784 randomly selected donors 60% had some higher education compared with 20% in Toronto as a whole (255). The initial decision to donate is influenced by peers, a sense of community responsibility and a personal moral obligation (256). Other work showed donors tend to be more vigorous, energetic and active, join organisations and are more concerned with personal and family health (257,258). Most donor recruitment initiatives attempt to cultivate a commitment to donate regularly. Individuals begin to define themselves as regular donors after their third or fourth donation (259). A variety of methods is used to recruit donors. These include advertising delivered through the mass media, incentive based recruitment strategies, where donors are given certificates after a standard number of donations and social strategies, for example where a mobile unit visits the workplace (260). Although Piliavin and Callero found material rewards encouraged

Figure 5.1. Leicester Blood Donor Centre.

donation by new donors, long-term donors are less likely to donate when material rewards are offered (261). A possible reason for this is that repeat donors may identify themselves as altruistic people who donate to help others. Receiving material rewards removes this sense of providing a service for others (260).

In this study, blood donors are classified into two groups: recalled donors and attending donors. Recalled donors are those invited by postal invitation to give blood and include a proportion who will not attend. As such, recalled donors represent "the intention to treat groups". Attending donors are those who both come and donate. The uptake of faecal occult blood testing in both groups is reported.

Method.

All blood donors aged 51 to 65 years were sent a letter which explained screening, together with the request to donate blood at the Leicester Centre (Appendix 5.1). The letter explained the frequency of colorectal cancer, benefits of early detection and that a free faecal occult blood test would be offered by a doctor when they came to donate blood. This letter was similar to the one used in general practice in Market Harborough and in screening programmes in industry and at Leicester General Hospital (Appendix 2.1). The invitation explained that donors could obtain further information from a doctor on arrival.

At the centre, a doctor (myself) explained the nature of colorectal cancer screening and faecal occult blood tests to eligible donors. Those wishing to participate received a free faecal occult blood test kit to complete at home. The age and sex of donors taking kits were recorded. Faecal occult blood tests (Haemoccult) were completed on a normal diet and returned to Leicester General Hospital for analysis. Donors with a

positive test were asked to repeat the procedure on dietary restrictions, which reduces the number of false positive tests (63). Donors with repeat positive tests were referred for colonoscopy. Those donors with a negative test were informed and told to contact their general practitioner if they had or developed symptoms (Appendix 5.2). Donors' general practitioners were also informed of their patient's results (Appendix 5.3) .

The number of recalled and attending donors who completed kits was recorded. Differences in completion according to age and sex were tested with a X^2 statistic. The completion of faecal occult blood tests in attending donors aged 51 to 65 years was compared with the response in subjects in the general practice and industry based studies (chapters 2, 3 & 4) again using a X^2 statistic.

Results.

The screening service was offered at 24 two hour sessions over a three month period. During this time 556 donors aged 51 to 65 years received an invitation to donate blood and to participate in the screening programme.

a. Results for attending donors.

63% (116/184) of attending donors i.e.those who actually came to give blood and took a faecal occult blood kit completed the test (table 5.1). Male attending donors aged 61 to 65 years completed kits more often than those aged 51 to 60 years (90% vs 60%, $X^2=7.0$, $p<0.01$). Similarly, older female attending donors aged 61 to 65 years completed more kits than those aged 51 to 60 years (87% vs 51%, $X^2=6.2$, $p<0.02$). There was no statistical difference in completion rates between male and female attending donors (66% vs 59%, $X^2=1.0$, ns).

b. Results for recalled donors.

21% of all recalled donors i.e. those who received an invitation to give blood, completed screening.

Male recalled donors aged 61 to 65 years completed more kits than those aged 51 to 60 years (33% vs 22%, $X^2=4.8$, $p<0.05$). Similarly female donors aged 61 to 65 years complied more than those aged 51 to 60 years (29% vs 14%, $X^2=6.4$, $p<0.02$).

Significantly more recalled male donors completed kits than female recalled donors (24% vs 17%, $X^2=4.9$, $p<0.05$). This difference was due to more male recalled donors aged 51 to 60 years completing kits than females of this age (22% vs 14%, $X^2=5.2$, $p<0.05$). In recalled donors aged 61 to 65 years there was no difference in compliance between men and women (33% vs 29%, $X^2=0.2$, ns).

The number of recalled donors aged 51 to 65 years attending during the three month study period (33%) was similar to attendance in all donors for an eight month period after the study finished (23%).

c. Comparison of compliance in general practice and an opportunistic approach.

More male recalled donors completed kits than men in the general practice community based approach in both age groups 51 to 60 years (51% vs 32%, $X^2=9.0$, $p<0.01$) and 61 to 65 years (90% vs 34%, $X^2=27.4$, $p<0.0001$). In women, the opportunistic approach recruited more women aged 61 to 65 years (87% vs 36%, $X^2=15.9$, $p<0.0001$) but a similar number of women aged 51 to 60 years (47% vs 51%, $X^2=0.4$, ns, see table 5.2).

d. Comparison of compliance between an opportunistic approach and that in public and private sector industry.

i. Private industry.

Compliance was greater in male recalled donors in the opportunistic approach for those aged 51 to 60 years (60% vs 31%, $X^2=32.3$, $p<0.0001$) and 61 to 65 years (90% vs 17%, $X^2=52.2$, $p<0.0001$). Women aged 51 to 60 years participated at a similar rate (51% vs 40%, $X^2=1.1$, ns) but the opportunistic approach was more successful in women 61 to 65 years (87% vs 0%, Yates-corrected $X^2=11.5$, $p<0.001$, see table 5.3).

ii. Public Sector Industry

Compliance was greater in male recalled donors aged 51 to 60 years (60% vs 42%, $X^2=4.9$, $p<0.05$) and 61 to 65 years (90% vs 45%, $X^2=9.9$, $p<0.01$). Women aged 51 to 60 years participated at a similar rate (51% vs 51%, $X^2=1.1$, ns) but more female recalled donors aged 61 to 65 years complied than women at the hospital (87% vs 37%, $X^2=11.3$, $p<0.001$, see table 5.3).

e. Positive testing rate.

A total of 116 faecal occult blood tests were completed all of which were negative.

Table 5.1. Acceptance of faecal occult blood tests by blood donors.

Age	Men	Women
Attending donors		
51-60 years	56/93 (60%)	28/55 (51%)
61-65 years	19/21 (90%)	13/15 (87%)
Recalled donors		
51-60 years	56/252 (22%)	28/202 (14%)
61-65 years	19/57 (33%)	13/45 (29%)

Overall compliance in recalled donors was 21% and in attending donors 63%.

Table 5.2. Comparison of compliance between the general practice and opportunistic approach at the blood transfusion service.

Age	General practice	Blood donors (attending)	Significance
Men			
51 - 60 years	361/1146 (32%)	28/55 (51%)	$X^2=9.0$, $p<0.01$
61 - 65 years	146/428 (34%)	19/21 (90%)	$X^2=27.4$, $p<0.0001$
Women			
51 - 60 years	529/1135 (47%)	28/55 (51%)	$X^2=0.4$, $p=0.5$, ns
61 - 65 years	185/513 (36%)	13/15 (87%)	$X^2=15.9$, $p<0.0001$

The opportunistic approach was more successful in recruiting men ($X^2>9.0$, $p<0.01$) and women aged 61 to 65 years ($X^2=15.9$, $p<0.0001$).

Table 5.3. Comparison of compliance between opportunistic screening at the blood donor centre and industry in the public and private sectors.

Age (years)	Opportunistic Screening	Private Sector	Public Sector
Men			
51-60	60%	31%	42%
61-65	90%	17%	45%
Women			
51-60	51%	40%	51%
61-65	87%	0%	37%

Opportunistic screening produced a higher compliance in men and women aged 61 to 65 years ($X^2 > 4.9$, $p < 0.05$). Compliance between the approaches was similar in women aged 51 to 60 years ($X^2 < 1.1$, ns).

Discussion.

In this study, opportunistic screening was more effective in men and older women than in the general practice programme and the two industrial studies. A personal approach on a one to one basis to inform people about colorectal cancer screening and answer enquiries is an effective approach. Only in women in their fifties was compliance similar to general practice or workplace studies. This may be because women are often the best compliers (126,128) and attempts to increase their uptake further will be difficult. Other approaches to raising uptake in this group are needed, perhaps by addressing specific reasons for non-compliance and this will be investigated in subsequent chapters.

One may speculate that certain characteristics of donors, namely a high educational level (254,255) and concern about their health contributed to the high participation in attending donors. Those with a higher educational level may have understood the screening information better and consequently this increased compliance. There is evidence that donors are more health conscious and healthier than non-donors. For example in a questionnaire survey, donors were often men who expressed an interest in their health, whereas non-donors were more likely to be women without such concerns (258). In a survey of blood donors in East Anglia, a third of non-donors stated medical reasons for not attending (262). In a study of American donors 20% felt donation helped maintain good health and a third of non-donors did not participate because of medical reasons (263). The last two studies did not directly compare medical records of donors and non-donors so it is impossible to assess if overall non-donors are less healthy. In Leicestershire, blood donors did not appear to be especially health conscious as only a third attended the centre when free screening was offered. This number was similar to the total percentage of donors who attended when screening was not offered. If most were

health conscious, one would have expected a higher attendance to take advantage of screening. The study from East Anglia, where a third of donors did not attend because of illness, suggests they may not be a particularly healthy group (262). Common reasons for medical non-attendance were taking medication, hypertension, anaemia and advice from their doctor not to donate.

The success of this approach in encouraging those who attended to participate in screening, suggests opportunistic screening methods should be developed. To improve compliance in national screening services, doctors could discuss screening at routine consultations and in other clinical situations outside the surgery. At the very least, donor centres could supply the public with screening information, if the time of doctors supervising such sessions is limited. The role of the blood transfusion service in encouraging compliance in national screening programmes would be valid but small. Only 5% of the population are donors and the cut off age is usually 64 years.

Two studies from British general practice confirm the value of opportunistic screening (136,137). Patients attending an inner city or a suburban general practice in Birmingham were offered free colorectal cancer screening with faecal occult blood tests. Patients were given a short explanatory sheet and at an appropriate point during the consultation, a doctor or nurse provided further information on screening and instructions on sample collection. In the age group 51 to 69 years, completion of the test was 62%, an uptake substantially higher than non-opportunistic screening programmes in general practice (126,127,128,138,217) including Market Harborough. In a general practice study in Farnborough and Basingstoke, a randomised trial of opportunistic screening was conducted (137). In the group offered screening, compliance was 58% compared to 38%

in those sent a postal invitation. In both studies compliance was higher in women than men.

In opportunistic screening programmes only a small proportion of the target population is actually screened (136). In the blood donor programme, although many who took a kit completed it, only 21% of the target population was screened. In Leicestershire, only a third of invited donors actually attended to give blood, although two-thirds of these completed a kit. Compliance in the target population was slightly higher in men than women. This may be because more invited males attended (36% men vs 28% women) and were informed about screening by myself. In the general practice opportunistic study in Birmingham, only 26% of the target population had been screened within two years (136). Patients attending the suburban practice were twice as likely to be offered screening as those in the inner city. A similar proportion of men and women were offered screening, although women were more likely to return a kit. In the Farnborough and Basingstoke study, the proportion of the target population screened was not reported (137). Although opportunistic screening is effective in encouraging people to comply, it is a haphazard process which will limit coverage of at-risk populations. The overall low level of the target population screened in this and general practice based studies means such programmes can only be an adjunct to mass community screening programmes. Reasons for non-compliance in general practice probably also apply to donors e.g. lack of understanding of asymptomatic illness and screening, dislike of testing kits and fear of hospital investigations and treatment (129,224,225, see thesis chapters 6 & 7).

Compliance in male and female donors who took a test home was similar and highest in donors in their sixties, although absolute numbers were relatively small. This contrasts with most general practice studies where compliance is less in men

(86,126,128,138,217) and often higher in younger women. Opportunistic screening may be of particular value in encouraging groups who participate less. A likely reason is the availability of a motivated doctor to explain screening, the nature of faecal occult blood testing, to answer questions and to motivate participation. The availability of a doctor is a likely reason for raising compliance as the written information about screening supplied was similar to that in previous programmes and did not address reasons for non-compliance. A limitation of the study was the small numbers of donors who attended. For example, 45 women in their sixties were recalled, although only 15 arrived to donate. However, the numbers were sufficiently large to allow statistical comparisons.

In this study, none of the 116 kits tested were positive and consequently no pathology was detected. Usually only one or two in every hundred tests is positive, of which half show significant pathology at colonoscopy (86,91). Therefore, as the sample size of donors who completed kits was relatively small it was not surprising that no lesions were found. In addition, one large study of 37 795 blood donors showed they had lower general cancer rates than the general population (264). At a median follow-up time of nine years, a total of 1152 cancer cases were diagnosed compared to an expected number from an age matched population of 1459, giving a relative risk of 0.79. The number of cases of colorectal cancer was similar in the two groups (observed/expected ratio = 0.8, 95% confidence limits 0.6-1.1).

This is the first study where cancer screening was offered to blood donors. If colorectal cancer screening does reduce mortality, then the transfusion service could display cancer screening literature and doctors supervising sessions should publicise its value. If such screening is a representative model of uptake, then other forms of health education and cancer screening literature could be successfully targeted at donors. This

study of opportunistic screening, and similar ones in general practice, showed such approaches successfully recruited participants directly informed about screening. However, only a small proportion of the target population is reached. The role of opportunistic screening is as an aid to recruitment and could complement any national programme delivered in the community through general practitioners. However, doctors in both primary care and other disciplines need to be aware of the value of this form of delivery for screening.

Chapter Six.

Reasons people refuse colorectal cancer screening. A study of non-compliance with faecal occult blood testing in general practice.

Summary.

A random sample of 100 subjects who declined colorectal cancer screening programme in a general practice in Market Harborough (Chapter 2) were approached to ascertain reasons for non-compliance. All standard interviews were conducted by a research nurse in subjects' homes using a questionnaire. Eighty-one of the hundred subjects approached consented to interview.

Non-compliers were divided into those who declined screening and those who, following initial acceptance, returned an unused faecal occult blood test kit. Amongst the former, the commonest reasons given were intercurrent illness (39% of subjects), fear of further tests and surgery (24%), feeling well (22%) and the unpleasantness of stool collection (10%). In subjects returning unused kits, the commonest reasons were unpleasantness of the stool collection procedure (65%), feeling well (30%), intercurrent illness (23%) and fear of further tests and surgery (20%). The only significant difference between the two groups was that more non-compliers who returned an unused kit considered stool collection unpleasant than those who declined screening (65% vs 10% of subjects, $X^2=26.5$, $p<0.0001$). In both groups non-compliers were more afraid of further diagnostic tests and surgery than at the lack of effective treatment for colorectal cancer.

To increase compliance, health education and publicity must encourage apparently healthy people to participate and allay fears of hospital investigations and treatment. The benefits of screening should be emphasised to help encourage acceptance of the stool testing procedure. People with intercurrent illness should be advised to consult their doctor to see if they are suitable to undergo screening.

Theoretical Justification for this work.

To design effective health education to increase participation in colorectal cancer screening programmes, reasons for non-compliance must be understood. To document these reasons, a sample of subjects who declined screening in Market Harborough (Chapter Two) were interviewed. Subjects' responses were used to design a health education leaflet about screening which specifically addressed reasons for non-participation. This health educational material was validated (Chapter 7) and tested in a randomised clinical controlled trial (Chapter 8).

Introduction.

Compliance with faecal occult blood testing in general practice in Market Harborough was low at 38% (Chapter 2). In most other studies in general practice compliance is also poor (125,126,127,128,135,137) and has been as low as 26% (138). If screening programmes are to reduce mortality and be economically viable, then more of the target population must participate. Effective health education about screening and faecal occult blood testing must address concerns about colorectal cancer and inform people of the benefits of early detection. The aim of the research described in this chapter was to identify reasons people failed to complete tests so they could be dealt with in health educational material.

Several British studies identified reasons for not completing faecal occult blood testing in screening programmes (129,140,226). Reasons cited included lack of time and procrastination, feeling well with no colonic symptoms, fear of cancer, medical reasons, unpleasantness of the test procedure and lack of effective treatment for bowel cancer. Although these studies provided useful information, they had limitations including a

choice of few non-specific reasons for declining (129,225,226) such as "didn't get round to it" or "the whole idea put me off", postal questionnaires (225,226), small interview samples (140) and a poor response rate to the questionnaires (225,226). None of the studies appeared to utilise their information to develop interventions to increase uptake. The advantages of my study were a comprehensive list of reasons for non-compliance, personal interviews and insistence on achieving a high response rate. Importantly, the data were then used to design educational material to promote screening.

The success of this study depended on the structure of the questionnaire and the skill of the interviewer. A good questionnaire has been defined as "one that works" (265). Ultimately, this questionnaire's success in identifying valid reasons will be determined by whether the resulting educational leaflet increased participation. The questionnaire met criteria necessary for a successful study (265). The questions asked were intelligible and brief, unambiguous and avoided medical jargon. They were precise and confined to a single idea.

Method.

Faecal occult blood testing was offered to residents of Market Harborough aged 51 to 70 years by their general practitioner (Chapter 2). A random sample of a 100 subjects, who either returned the invitation slip but declined screening or returned an unused kit, were approached for interview. These subjects were contacted by telephone and a convenient time for interview arranged. All interviews were conducted by a clinical research nurse. Subjects unwilling to be seen at home were asked if they would answer a structured questionnaire by telephone. Interviewees were told that the purpose of the study was to understand reasons for declining screening so that more effective

programmes could be designed. An assurance was given that answers were strictly confidential.

A structured questionnaire (appendix 6.1) which contained 11 possible reasons for rejecting screening was used as the basis for the interview. The questionnaire was compiled by a discussion group composed of two hospital doctors, a general practitioner and a research nurse. No standard questionnaire exists for interviewing those who decline faecal occult blood tests, so validation with other work was impossible. Answers were recorded as "yes" or "no". Subjects were asked to indicate one or more reasons which best described why they declined. After the first five interviews the design of the questionnaire and the method of approaching subjects was assessed. Subjects who decided to participate after an interview were sent a testing kit.

Non-compliers were divided into two sub-groups i.e. those who returned the invitation slip but declined screening and those who returned an unused kit. The frequency of stated reasons was analysed in the group as a whole and assessed for differences between the two sub-groups with a X^2 statistic. Differences in responses between men and women were also tested with a X^2 test.

Results.

a. Structure of the sample interviewed.

In Market Harborough 2611 people from the original 4 176 (63%) approached failed to take up the offer of screening. In this group of non-compliers, 218 subjects returned the invitation slip and declined screening and another 133 wrote back enclosing their unused kit. Approximately two-thirds of these 351 subjects were women. The remaining 2260 non-compliers did not return their invitation slip or did not return a

requested test kit. One hundred subjects from the 351 who wrote back declining or returning an unused kit were randomly chosen to be interviewed and 81 consented (58 women and 23 men). The mean age of men interviewed was 64.5 years (range 55-70 years) and in women the mean age was 61.5 years (range 51-70 years). Fifty-four interviews were conducted at home and the remaining 27 by telephone. Of those interviewed 41 declined screening (9 men and 32 women) and 40 requested a kit but returned it unused (14 men and 26 women). After the first five interviews, the questionnaire was re-assessed but no changes were made.

b. Reasons for non-compliance.

The commonest reasons given by the 81 subjects for non-compliance were: stool collection unpleasant (37% subjects), intercurrent illness (31%), felt well (26%) and frightened by the prospects of more tests and surgery (22%). Only four subjects (5%) did not participate because of "lack of no known treatment", "no family history of bowel cancer" or "bowel cancer is so rare I am unlikely to have it". No one failed to comply because of religious beliefs or because they had been advised not to by another individual. All but one of those interviewed understood the test was to detect colorectal cancer. Everyone realised testing kits were free and the cost of postage was covered. Of the twenty-five non-compliers with an intercurrent illness five had cancer at a site other than the bowel, five had undergone surgical operations, a total of ten had either a medical, gynaecological or psychological illnesses and 5 would not state their illness. Thirteen subjects gave 11 reasons not specifically listed on the questionnaire (see table 6.2).

The reasons for non-compliance in the two sub-groups are shown in table 6.1. In both sub-groups subjects were more concerned about further tests and surgery than they were at lack of effective treatment for colorectal cancer. More non-compliers who

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Table 6.1. Reasons for declining colorectal cancer screening.

Reason for non-compliance	Kit not requested (n=41)	Uncompleted kit returned (n=40).
Intercurrent illness	16 (39%)	9 (23%)
Afraid of further tests & surgery	10 (24%)	8 (20%)
Felt well	9 (22%)	12 (30%)
Stool collection unpleasant	4 (10%)	26 (65%)
No treatment	1 (3%)	1 (3%)
Bowel cancer rare	0 (0%)	1 (3%)
No family history	0 (0%)	1 (3%)

More non-compliers who returned an unused kit thought stool collection was unpleasant than non-compliers who did not request a kit (65% vs 10%, $X^2=26.5, p<0.0001$).

Table 6.2 Reasons for non-compliance not on the questionnaire (excluding subjects who declined as they felt well).

Reason	Number of subjects
"Could not be bothered"	2
Cervical smear was clear	1
Did not want to stop vitamin pills	1
Going away on holiday	1
Similar test 7 years ago	1
Under stress	2
Mother died of bowel cancer & felt care was unsatisfactory	1
Caring for ill relative	2
Test done privately	1
Recent bereavement	1
Recent barium enema	1

requested and returned an unused kit thought "stool collection unpleasant" than non-compliers who did not request a test (65% vs 10%, X2=26.5, p<0.0001). There were no other significant differences between sub-groups (X2<2.6, ns). The number of men and women giving the four commonest reasons for non-compliance were similar (X^2<2.7, ns).

Discussion.

The four main reasons identified for non-participation were unpleasantness of the stool collection procedure, intercurrent illness, feeling well and fear of further tests and surgery. It is important to decide if these are true reasons and not merely excuses for non-compliance and if they are potentially reversible so that uptake can be increased in future. The most frequently reported reason for non-participation was the unacceptability of the stool collection procedure. Collecting a sample of motion will be physically difficult for some and many more find it revolting. Not surprisingly, subjects who requested a kit and then declined to complete it were more likely to say stool testing was "repellent" than subjects not requesting a test. Other studies have reported this problem (129,197,225,226). In Oxfordshire, non-participants were five times more likely to describe the collection procedure as disgusting (226). In an attempt to solve this problem other stool screening tests have been designed which include "Coloscreen Self Test" and "Early Detector" (226) With the Coloscreen Self-Test, patients float a tissue pad on the toilet water after passing a motion and look for an orange red colour on the surface of the reagent paper. The test is completed on three separate days and a colour change indicates a positive result which is notified to the doctor. A second alternative is the Early Detector Test where participants wipe the anus after defecation with a tissue pad. The pad is

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developed by spraying a guaiac/peroxide solution onto the surface. A blue discolouration around the faeces indicates a positive test. A questionnaire survey of those completing three different tests (Haemoccult, Coloscreen Self-test and Early Detector) found subjects reported the last two tests easier to perform and less messy (226). One approach to solving the problem of non-compliance in the group who return unused kits may be to mail a second more acceptable testing kit such as Coloscreen. This could encourage participation in those deterred by Haemoccult tests and the process of collecting stool samples. Such an approach may also be successful in residents of Market Harborough who requested a kit but neither completed it nor returned one unused to the hospital. A problem with these alternative tests is that their efficacy has not been tested in large controlled trials. Subjects themselves have to interpret the tests, a process in which they have no experience. If standard faecal occult blood tests cannot be made more acceptable, then people's reluctance to use them may be overcome by emphasising the long-term benefits, including the early detection of cancer and pre-malignant polyps. The only trial to show a reduction in mortality with screening found that subjects had to complete kits annually for 13 years (93). Continually encouraging participation year after year may be a major problem. A screening test such as flexible sigmoidoscopy, where most subjects only need the examination once would overcome this problem (112). A limitation of the interview survey reported here, was that this concern about stool collection was not explored further. Interviews could have been developed to assess whether kits were physically difficult or embarrassing to use and precisely which component was distasteful. This area has not been fully explored in British studies of non-compliance (129,226) although one reported 17% of non-compliers thought samples difficult to collect (225). Many subjects felt well and therefore had not appreciated the concepts of screening. In

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Market Harborough, the number of subjects declining screening for this reason is probably accurate. Subjects would not give this response if they understood screening and asymptomatic illness for fear of looking ignorant. In the questionnaire, feeling well was not listed as a response and was volunteered by subjects. If specifically included, more may have decided it was applicable to themselves. If future programmes are to be successful, then the public must be educated about asymptomatic illness, emphasising that healthy people should participate. Other studies showed a lack of understanding of the principles of screening (129,140,223,225). In a community programme of faecal occult blood testing, more non-acceptors than acceptors did not appreciate asymptomatic disease and were less convinced that detected cancers were curable (129). Box et al found 30% of non-compliers did not participate because they felt well, with half the subjects commenting they would have complied if they had symptoms (140). An occupational study found 56% of non-compliers had not appreciated the value of screening and 6% reported they had slight bowel symptoms about which they had not sought medical advice (225). In a non-compliance study from Denmark, 13% refused to participate because they felt well (223). Similarly, in cervical cancer screening, attenders were more likely than non-attenders to believe smears could reveal disease prior to symptoms and that early detection was beneficial (133). In mammography, many non-attenders thought screening unnecessary as they were well and that they should not waste professionals' time (131).

An important finding was the greater fear of further hospital tests and surgery than of a lack of effective treatment for colorectal cancer. Twenty-two per cent of subjects mentioned this as a reason for not participating, compared to only 3% who replied there was no effective treatment. Subjects were not asked about the investigations which they thought would follow a positive test, although such information might have

helped dispel fears. Many studies of non-compliance have failed to assess whether fear of investigations is a barrier to participation (129,197,198,222,223,226,266). Future work into non-compliance should include aspects of pain, embarrassment and lack of dignity. Colonoscopies and barium enemas should be performed in relaxed, private and dignified environments to minimise distress to patients. Concerns about pain can be allayed by emphasising availability of sedation and analgesia and that investigations will be stopped at patients' request.

Nearly a third of non-compliers did not participate because of intercurrent illness. Half had undergone surgery or developed cancer and several had chronic medical illnesses such as diabetes. Illness may be a barrier to participation because of failure to cope with more than one condition at a time or previous unpleasant experiences associated with medical services. However, Farrands et al reported that having an illness in the six months prior to screening encouraged participation (129). Other work showed that having a family member who is unwell is also a barrier to participation (140). In some non-compliers, intercurrent illness may be an excuse and mask other concerns about cancer and screening.

Only a few subjects reported other reasons for non-compliance including lack of treatment for bowel cancer, perceived rarity of the disease and no family history of the condition. Only two people were concerned there was no effective treatment for bowel cancer, although this could be an unrealistically low figure. Subjects may be unwilling to admit to ignorance about treatment or give other reasons for non-compliance which hide fears about cancer therapy. Not all British studies investigated whether lack of effective treatment was a barrier to participation (225,226) although some suggested it was unlikely (129,140). In Market Harborough, only one subject did not participate because bowel

cancer is rare. This may be an under-estimate as subjects may not wish to appear ignorant about the incidence of colorectal cancer. The limited literature on awareness of colorectal cancer (129) showed only a third of compliers and a quarter of non-compliers were able to correctly name the three commonest cancers, although specific knowledge of the frequency of bowel cancer was not investigated. One approach to raising compliance may be to increase public awareness, an approach investigated later. Certainly, the Health Belief Model (196) which assesses reasons for participation suggests compliance with faecal occult blood testing will be higher if people feel susceptible to cancer (197). Only one subject did not participate because of a lack of family history of the illness. In this study, subjects were not asked if they had a family history of colorectal cancer, although this may increase participation. Other work showed a higher acceptance of screening in families with a history of the disease (267). Conversely, in an Australian study, knowing a friend with colorectal cancer did not increase participation (197). The initial invitation letter was satisfactory as everyone realised the tests were to diagnose bowel cancer and they were free. The study also showed that no one was discouraged from participating by others or religious beliefs.

Reasons not listed on the questionnaire were mentioned by many subjects. Broadly they fell into two categories i.e. those experiencing major life events or those who felt at low risk of colorectal cancer. Two subjects were caring for ill relatives, one was recently bereaved and another felt "under stress". They may have complied with a reminder invitation at a later period when these events resolved. Several subjects gave reasons which suggested they felt protected against cancer through completing previous investigations. Two subjects replied they had previously completed a faecal occult blood test and another had undergone colonic investigations. Clearly participants in screening

programmes must be told that a negative result does not confer immunity against cancer. Screening test results must clearly state the specific site under investigation, as one lady perceived a negative cervical smear test to have a universal protective effect. Four people did not comply because either they "could not be bothered", would not stop their vitamin tablets or were away on holiday. These reasons suggest they did not perceive a benefit, or wished to mask concerns about cancer.

As a result of the screening invitations ten subjects or their relatives informed the hospital that the addressees were deceased or had colorectal cancer. As there may be other such individuals who had not written to give this information, only residents who returned the invitation slip were selected for interview. This selection method avoided causing distress, but as a consequence the sample may not be totally representative of non-compliers and is the major limitation of this study. There were 2611 non-compliers in Market Harborough, but only 351 (13%) replied and declined. Of this latter group, a hundred were randomly selected for interview. A further bias was more women than men were interviewed, although more women participated in screening. This occurred because women were more likely to return the invitation slip or kit. However, this bias had little significance as the responses of men and women were similar. The sample selection method may have biased some responses e.g. it was surprising to find 30% of interviewees suffered with an intercurrent illnesses. This figure seems inappropriately high and suggested those willing to be interviewed were more unhealthy or had been exposed to hospital investigations. Therefore, concomitant illness and fear of tests and surgery may be over-represented in this study.

In all non-compliance studies, some people refuse to be interviewed. This introduces a self-selection bias, as reasons given by those co-operating may not be

representative of the whole group. Fortunately, in this study 81% of those contacted were interviewed, minimising this bias. Other studies of non-compliance in colorectal cancer screening experienced this problem of self-selection bias. In a general practice study in Oxfordshire, only 26% of subjects returned a non-compliance questionnaire (226) although in Nottingham 91% of non-compliers were interviewed (129). In an occupationally based programme 46% of non-compliers did not return questionnaires (225). In two general practices in the South West Thames Region, there were administration problems as 37% of alleged non-compliers denied receiving a test kit and 8% claimed to have returned a completed kit (140).

The questionnaire used in this study met many of the criteria essential for success (265). These included appropriate, intelligible, unambiguous, brief and precise questions avoiding medical jargon. The purpose of the questionnaire was explained to subjects by a preliminary telephone call and on the day of the interview they were thanked for their assistance. The questionnaire was read to subjects to avoid embarrassment and distress caused by illiteracy. To relax subjects, questions on age and availability of a pre-paid envelope were asked before sensitive issues such as fears about cancer and its treatment. The questionnaire had several possible limitations. For example, questions were not omnicompetent i.e. capable of dealing with all possible responses. Subjects could only reply "yes" or "no" and a "don't know" or "possible" option perhaps should have been included. The questionnaire could have been expanded and more specifically worded for some questions. For example question 6 which asked if patients were concerned about "more tests and a possible operation" should have been two separate questions.

Pilot studies are important to identify problems with questionnaires so corrective action can be taken by investigators. After the first five interviews the questionnaire was

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discussed and no modifications were introduced. A pilot study allows an assessment of validity and reliability. Validity is the extent to which the questionnaire measures responses and is most commonly determined by a comparison with a "gold standard". Unfortunately in colorectal cancer screening, no standard questionnaire exists and questionnaires are not published (129,140,225,226). The validity of my questionnaire could therefore not be formally assessed. Pilot studies also determine reliability i.e. the extent to which it gives consistent results. To measure reliability, subjects should be re-interviewed after an interval. Reliability was not measured in this study because subjects' general practitioners felt re-interviewing constituted undue harassment.

This study identified reasons why people chose **not** to participate in colorectal cancer screening programmes with faecal occult blood tests. In summary, the principle reasons were fear of hospital investigations and treatment, intercurrent illness, unpleasantness of the stool collection procedure and lack of appreciation of the reason for completing screening tests. Few subjects were concerned about lack of effective treatment for colorectal cancer. To increase compliance in future studies, an educational leaflet was written which explained screening, faecal occult blood testing and aimed to overcome reasons for non-compliance. To ensure the leaflet was understandable its educational effect was tested on a hundred subjects (Chapter 7) before it was tested in a randomised controlled clinical trial (Chapter 8). In future programmes it would be interesting and perhaps useful to identify reasons people complied. These benefits could then also be used in the development of effective educational material.

Chapter Seven.

The Development of Effective Health Education Literature in

Colorectal Cancer Screening.

Summary.

The ability of a health educational leaflet to raise awareness of colorectal cancer and its asymptomatic nature and increase participation in screening was investigated. The leaflet explained the high frequency of colorectal cancer and polyps, defined screening and addressed reasons for non-compliance identified previously. One hundred subjects were interviewed before and after reading the leaflet. Before reading the leaflet only 20% of men and 30% of women thought the tumour was "very common" although 64% of men and 58% of women knew it could be asymptomatic. After reading the leaflet 60% of men stated bowel cancer was "very common" ($X^2=16.7$, $p<0.0001$) and 92% knew it could be asymptomatic ($X^2=11.4$, $p<0.001$). 70% of women commented bowel cancer was "very common" after reading the leaflet ($X^2=16.0$, $p<0.0001$) and 94% understood it could be asymptomatic ($X^2=17.8$, $p<0.0001$). After reading the leaflet, 55% of men and 50% of women who initially declined screening changed their minds (men $X^2=16.5$, $p<0.0001$, women $X^2=17.3$, $p<0.0001$). The commonest reasons given for declining screening before reading the leaflet were feeling well (77% of subjects declining), concern about further tests (38%), unpleasantness of faecal occult blood testing (13%) and intercurrent illness (6%). This leaflet successfully educated people about colorectal cancer and increased intention to participate. The leaflet was then tested in a randomised controlled trial in the community (Chapter eight).

Theoretical Justification for this work.

Simple health educational leaflets which explain screening and discuss reasons for non-participation are a potential means of raising compliance in colorectal cancer screening programmes. In this study such a leaflet was developed. It emphasised the high

frequency of the disease and its asymptomatic nature. The last section of the leaflet encouraged participation by addressing reasons for non-compliance identified in the previous study (chapter 6). Such a leaflet should be piloted to ensure it is effective before formal testing in an expensive randomised community controlled trial.

Introduction.

The acceptance of faecal occult blood testing in the colorectal cancer screening programme in Market Harborough was low (Chapter 2) and reasons for this were identified (Chapter 6). If screening is to reduce mortality from the disease and be economically viable more people must participate. One approach to raising compliance is to include simple health educational leaflets with the screening invitation. Such leaflets must identify misconceptions and concerns people have about screening and cancer detection and allay them. Although previous groups have looked at the value of health education they have found it of little benefit (137,218). Possible reasons are that the leaflets were too complicated and did not discuss issues which concern people. Surprisingly no educational material has been specifically designed from a study of reasons for non-compliance.

In this study a health educational leaflet about colorectal cancer screening was developed. The leaflet explained bowel cancer was a common illness and emphasised it could be present before symptoms. The concept of screening and the nature of faecal occult blood testing were discussed as well as the benefits of participating. The concerns which led to non-acceptance in Chapter 6 were discussed. To ensure the leaflet was effective and would increase intention to participate it was assessed in this interview based study.

Method.

The design of the educational leaflet.

It was a short educational leaflet about colorectal cancer and screening. (Appendix 7.1). "Detecting Bowel Cancer Early" was written by myself and a consultant gastroenterologist (Dr John Mayberry). It dealt with:

i. The high frequency of the disease. (paragraph 1).

ii. The concepts of asymptomatic illness and screening (Paragraphs 2 & 4). The benefit of screening was emphasised by stating early cancers were easier to cure.

iii. The nature of polyps. Paragraphs 1 & 4 stressed their frequency and the benefits of their removal.

iv. Faecal occult blood testing including the process of collection (paragraphs 5 & 6).

v. Reasons for non-compliance were addressed as follows:

a. the unpleasant nature of stool testing was addressed in paragraphs 6 and 10.

b. fear of further tests in paragraph 7.

c. concept of asymptomatic illness in paragraphs 2 and 8.

d. encouraging those with intercurrent illnesses to participate (paragraph 9).

The leaflet also explained the symptoms of colorectal cancer. Readability, negativity and human interest of the leaflet were assessed from the Flesch Reading Score (208,211).

Study Subjects.

The leaflet's ability to raise awareness of colorectal cancer and asymptomatic illness, to encourage intention to participate in screening and to reverse reasons for non-compliance were measured. Subjects aged 51 to 70 years were chosen from accompanied relatives or friends of patients who attended medical and surgical out-patient departments at Leicester General Hospital (Figure 7.1). The interviews were conducted by one of two interviewers and inter-observer variation tested for by analysing responses to a standard question (Appendix 7.2, section 3, question 2). I conducted two-thirds of the interviews and Dr T L Barone, clinical anthropologist the remaining third. A pilot study of 20 subjects was first conducted before the main study of a hundred subjects (50 men and 50 women).

Design of the questionnaire to assess the health educational leaflet (Appendix 7.2).

The study was explained to subjects who were told it was to assess health education in colorectal cancer screening. Initially, demographic data on age and sex were collected.

Subjects' responses to questions about the frequency of colorectal cancer and if it could be asymptomatic were recorded. They then read a section of the leaflet which said it was the second commonest cancer and could be asymptomatic (appendix 7.1, paragraphs 1 & 2). The interviewer then repeated the two original questions. The change in knowledge about colorectal cancer was tested with a X^2 statistic. Subjects then rated the leaflet's explanations of screening, the screening tests, the symptoms of colorectal cancer and whether they had heard of faecal occult blood tests (paragraphs 3,4 & 5 of the leaflet). After reading the leaflet subjects were asked if they would accept a screening faecal occult blood test kit (Appendix 7.2, section 3, paragraph 2). Replies were recorded

Figure 7.1. Out-patients' Department, Leicester General Hospital.

as "definitely", "probably", "no" or "don't know". Those who replied definitely were thanked for their help and not interviewed further. Those who answered "probably", "no" or "don't know" were asked for their reasons from a list of 5 possible causes for non-compliance. Subjects who gave a particular reason were asked to read the relevant section in the leaflet e.g. individuals who declined because they felt well, then read paragraph 8 which explained early cancers and polyps do not give symptoms. Subjects were then asked whether this would alter their decision. The leaflet was considered to have reversed the decision if subjects replied "definitely yes" or "possibly" and the effect on intention to participate tested with a X^2 statistic.

Results.

The Flesch Reading Score of the leaflet was 69.0 (208). On a readability scale of "very easy" to "very hard" this is classed as "standard" equivalent to material such as Readers' Digest. The reading age was of a 13 year old and 90% of the population over 25 years of age would understand it. The negativity score was 93 which is classed as "optimistic" on a scale from "cynical" to "optimistic". The human interest score was low at 19 which is classed as "mildly interesting" on a scale "dull" to "dramatic" (211).

In the pilot study only 2 out of 10 subjects changed from "yes" to "no" in response to the question "Do you think bowel cancer can be present before giving rise to symptoms?" As a result, this section was altered to emphasise this point and then successfully piloted on a further 10 subjects. No other changes were made to the leaflet or questionnaire following the pilot study. Inter-observer variation was tested by analysing replies to the question "Would you request a testing kit ?" and no significant difference

found ($X^2=0.1$, ns). The mean age of men interviewed in the main study was 63 years (range 51 to 70 years) and in women it was also 63 years (mean age 50 to 70 years).

a. The effect of the leaflet on knowledge of colorectal cancer and its asymptomatic stage.

Subjects were asked how common they thought bowel cancer was both before and after reading the leaflet. The leaflet's effectiveness was judged by the increase in those stating bowel cancer was "very common" and the decrease in those replying "don't know". In men, the leaflet increased the number stating bowel cancer was "very common" from 20% to 60% ($X^2=16.7$, $p<0.0001$) and decreased those replying "don't know" from 24% to 0% ($X^2=13.7$, $p<0.001$). In women the leaflet increased the number stating bowel cancer was "very common" from 30% to 70% ($X^2=16.0$, $p<0.0001$) and decreased the number replying "don't know" from 16% to 4% ($X^2=4.0$, $p<0.05$).

The leaflet increased the "yes" response to the question "Can bowel cancer be present before giving symptoms?" from 64% to 92% in men ($X^2=11.4$, $p<0.001$) and from 58% to 94% in women ($X^2=17.8$, $p<0.001$).

b. Subjects' opinions on the leaflet's explanations.

Subjects were asked to comment on the leaflet's explanation of screening, screening tests and the description of a change in bowel habit. For men at least 84% thought the explanation was "very well" or "well" written for each category and for women, the figure was 94% (Table 7.1).

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c. Reasons for non-participation.

After reading the section of the leaflet dealing with colorectal cancer and its detection by screening, 56% of men and 48% of women said they would "definitely" accept any offer of a faecal occult blood test. The remainder who replied "probably", "no" or "do not know" were asked to give reasons. The 22 men who would not comply gave a total of 34 reasons and the 26 women gave 37 reasons (table 7.2). There were no differences between men and women in the frequency with which the common reasons for non-compliance were given ($X^2 < 2.0$, $p > 0.16$). In both sexes, the commonest reason for not requesting a test was that subjects felt well (86% men and 69% women). Three men gave 4 "other" reasons for not participating that were not listed in the leaflet. These included: concern about completing the kit correctly, a view that tests should be done in hospital rather than at home, an unwell wife and concern over unnecessary investigations. Three women gave three other reasons which were: the test was unnecessary as she had no family history of cancer, recent investigations for anaemia were negative and the stool test was inserted into the rectum.

d. Increasing intention to participate.

12 of 22 men (55%) ($X^2 = 16.5$, $p < 0.0001$) and 13 of 26 (50%) women ($X^2 = 17.3$, $p < 0.0001$) decided they would participate in colorectal cancer screening as a result of reading the leaflet.

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Table 7.1. Opinions on the leaflet's explanations.

	Concepts of screening (%)		Screening tests (%)		Change in bowel habit (%)	
	M	F	M	F	M	F
			(Males n=50, females n=50)			
very well or well explained	90	96	96	100	84	94
poor or poorly explained	10	4	4	0	16	6

Most subjects thought the explanations were understandable.

Table 7.2. Reasons why subjects declined screening and whether the leaflet altered this decision.

Reasons for declining screening	subjects who gave reason No. (%)	subjects who changed their mind after reading leaflet. No. (%)
Men. (n=22)		
feel well	19 (86%)	12 (63%)
concern about more tests	7 (32%)	4 (57%)
no time	0	0
testing sounds unpleasant	3 (14%)	3 (100%)
another illness	1 (5%)	1 (100%)
Women. (n=26)		
feel well	18 (69%)	11 (61%)
concern about more tests	11 (42%)	10 (91%)
no time	0	0
testing sounds unpleasant	3 (12%)	2 (67%)
another illness	2 (8%)	0 (0%)

Overall the book changed the minds of 55% of men ($X^2=16.5$, $p<0.0001$) and 50% of women ($X^2=17.3$, $p<0.0001$).

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Discussion.

This study showed the leaflet was readable, informative and increased knowledge of bowel cancer and its asymptomatic nature. The commonest reasons for not participating were that subjects felt well and were concerned about further investigations following a positive stool test. However, the leaflet effectively addressed these concerns and reversed decisions not to participate in 50% of subjects.

The leaflet was acceptable to those on whom it was tested. Most subjects thought explanations of screening, faecal occult blood testing and change in bowel habit were either "well" or "very well" written. This acceptability may have been linked to the leaflet's readability, equivalent to that of a 13 year old. Applying readability scores to texts is appropriate as they correlate with comprehension and retention of material and ease of reading (210). The measurement of reading level of health educational material with objective scores is essential to check they are understandable. This appears not to have been done in previous colorectal cancer screening programmes (135,137,218). The leaflet had a positivity score rated as "optimistic" on the qualitative scale. This was achieved by avoiding negative words such as "don't", "can't" etc, and is important in a fearfully emotive subject such as cancer.

The sample interviewed was representative of those who would be offered screening. Equal proportions of men and women were questioned over the age range of 50 to 70 years. Relatives or friends of patients were approached rather than patients to avoid the bias of ill health. The study also emphasised the importance of interviewing a pilot sample. Following the first pilot study of 10 interviews, only 2 subjects changed their opinion from "yes" to "no" when asked "Do you think bowel cancer can be present before giving rise symptoms?". Consequently, the structure of the appropriate paragraph

in the leaflet was altered to emphasise the asymptomatic nature of the disease. Other studies in colorectal cancer screening showed no benefit from health educational material (137) or even an adverse response (218) but they failed to report any pilot studies.

The questionnaire met many criteria for a successful study (265). Firstly, demographic data were collected to put subjects at ease before moving to more sensitive subjects such as knowledge of cancer and reasons for non-compliance. All questions were brief, intelligible, avoided medical jargon and each addressed just one issue. Finally, a range of answers was available to most questions including a "don't know" option. Validity of questionnaires depends on the extent to which they accurately measure responses. As no gold standard exists for measuring non-compliance in colorectal cancer screening, validity could not be assessed. Reliability i.e. the extent to which a questionnaire gives consistent results, would have required subjects to be re-interviewed later and was impractical, because of the opportunistic way subjects were identified.

The population interviewed was unaware of the high frequency of colorectal cancer, as only a quarter of subjects considered the disease "very common". Many people who were unsure about the disease's frequency replied it was "common". After reading the leaflet most changed to "very common". Other studies support this lack of awareness of colorectal cancer. Farrands et al (129) found only a third of people who accepted faecal occult blood tests were able to correctly name the three commonest cancers and that for non-acceptors this fell to 25%. Macrae et al found non-compliance was associated with a perceived decreased susceptibility to colorectal cancer (197). If screening reduces mortality from colorectal cancer, then the public will need to be educated about the high frequency of the disease. Simple health educational leaflets such as the one piloted in this chapter are effective in conveying this information.

Raising awareness of asymptomatic illness may increase compliance in screening programmes. In this study, only 61% of subjects appreciated this concept before reading the leaflet. However, education increased awareness to 93%. Farrands et al (129) found participants in colorectal cancer screening programmes were more aware than non-compliers of asymptomatic illness and believed that such illnesses could be detected early. In addition acceptors thought asymptomatic disease was curable. In an occupational based programme 64% declined because they had no symptoms (225) and in a Danish study 13% declined because they were well (223). My results showed that as well as raising awareness of colorectal cancer, a simple leaflet can also convey the idea of asymptomatic bowel cancer.

In this study, subjects who declined faecal occult blood testing were asked their reasons and a leaflet's ability to reverse them tested. The commonest reason was that subjects felt well. However, the section which specifically addressed this reason for non-compliance i.e "Do I do the Home Test if I am feeling well and have no bowel problems" reversed the decision not to comply in two-thirds of subjects. A similar misunderstanding of screening is seen in cervical and breast cancer programmes. Attenders are more likely to believe smears can reveal disease prior to symptoms and that early detection is beneficial (133). In breast cancer screening, 38% of non-attenders felt well and thought screening unnecessary (131). Clearly public health education needs to emphasise the value to healthy people of participating in screening programmes.

The second commonest reason for non-compliance was concern about further investigations. Fear of more tests seemed to act as a major deterrent and out-weigh long term gains of early cancer or polyp detection, but most studies have not investigated this aspect (129,140,197,198,223,225,226,266). However, Box et al (140) found 7% of non-

compliers were put off by earlier hospital experiences. A questionnaire study of patients attending clinics in New Mexico found non-compliers were more likely to object to procedures performed in diagnostic evaluation (238).

Only 13% of non-compliers were put off by the testing procedure and most reversed this decision after reading the leaflet. Faecal occult blood testing was presented as a simple test, performed at home, that could be done quickly and hygienically, was accompanied by instructions and could save a participant's life. Many studies show that the unpleasantness of the stool testing procedure is a major barrier to successful screening (129,140,225,226) so such approaches are vital.

Reasons for non-compliance identified in this study may be more representative of the general population than those in the previous interviews in Market Harborough (Chapter 6). This study in out-patients included a cross section of subjects who would probably decline screening, whereas the sample from Market Harborough (Chapter 6) was chosen from those **who wrote back** and declined.

The main limitation of this work was that the intention to participate rather than the actual completion of kits was measured. In the interviews, subjects read the leaflet and were asked "would you request a testing kit if offered". Some subjects may have answered "yes" to please the interviewer. However, the response from women was similar to those who completed tests in Market Harborough (42%, Chapter 2). However, more men (56%) said they would comply than did so in general practice (33%). Perhaps men understood the concepts and benefits of screening less well, but still wanted to please the interviewer. The limitations of the leaflet and questionnaire included a failure to define polyps. Most people probably do not know what a polyp is and this may have introduced confusion. As the detection and removal of polyps is essential to understanding

of colorectal screening, a definition was introduced into the leaflet used in the screening study described in chapter eight. Discussion of symptoms of colorectal cancer in a leaflet about screening was probably inappropriate. This approach emphasised the symptomatic rather than the asymptomatic nature of the disease. Consequently in the leaflet used in the randomised trial the symptoms of colorectal cancer were omitted. A further limitation was only a selected list of reasons for non-compliance was given, although there was a section on the questionnaire for "other" responses. If a more comprehensive list had been given subjects may have chosen these. Such a list was not offered in order to ensure interviews were brief and it was the leaflet's ability to reverse reasons for non-compliance that was being assessed.

Reasons identified for non-compliance in this and the previous chapter are compatible with components of the Health Belief Model (195,196), Cognitive Theory (202) and Health Action Model (215). The Health Belief Model states compliance is related to perceived susceptibility and severity of the disease and benefits, cues and barriers to participating (195,196). In this study, many people did not participate as they felt well and so perceived themselves not to be susceptible to colorectal cancer. When the frequency of colorectal cancer was explained, nearly two-thirds of non-compliers changed their minds. Clearly a major task of health educators is to increase awareness of the illness which may raise participation. Barrier factors to compliance were recorded which the Health Belief Model states are an important influence on compliance. Major barrier factors identified were the unpleasant nature of stool collection and fear of further investigations following a positive stool test. Barrier factors were more important than perceived disease severity, with only two people declining because they thought there was no known treatment. The findings in this thesis are similar to those in an Australian study

using the Health Belief Model where only perceived susceptibility and barriers to participation were related to compliance (197). In a study from New York, perceived susceptibility to cancer was not related to compliance (198). However, the population interviewed was a select one i.e. those presenting for a private health screen and not representative of the attitudes of the total population. Other criteria of the Health Belief Model were fulfilled in that non-compliers perceived colorectal cancer to be a more severe illness and were less confident about the benefits of treatment. Other aspects of the model, namely cues and benefits to participation, were not investigated in this thesis as compliers were not interviewed. Another model of health behaviour i.e. the cognitive model emphasises the importance of patient understanding, memory and satisfaction (202). To increase understanding, the Flesch Reading Index was applied to the leaflet and a high score indicated it was an easy read. As data from other studies showed compliance is related understanding (203,204), the educational leaflet's ability to reverse decisions not to comply may be related to its high readability score. Patients' memory and retention of information was not assessed as they were allowed to study the leaflet for as long as required. Finally, the Health Action Model states compliance is related to an individual's intention to act, and secondly, factors that determine if this is translated into action (215). Individual factors include intellectual skills, motivational state and if that individual is influenced by social pressure. In this thesis these factors were not assessed, although measures to increase the social range of people who could understand the leaflet were taken by using the Flesch Reading Scale and ensuring it was acceptable to those with a low reading age. Factors determining whether intention to act is actually translated into action are those concerned with providing post-decisional support. Part of the success of opportunistic screening at the blood donor centre, and this interview survey where

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intention to participate was high, may be due to the attending doctor providing such support by answering concerns about screening. Many of the components of the different theoretical models of health behaviour overlap. However, they provide an important framework on which to base attempts to raise compliance. Results from this thesis applied to the different models suggest that increasing perceived susceptibility to colorectal cancer with simple health education and removing barriers and fears about participating are important.

This leaflet reversed decisions not to comply with screening and was suitable for testing in a randomised community controlled trial. The ability of the educational leaflet to improve compliance is assessed in the following chapter.

Chapter Eight.

The Effect on Compliance of a Health Education Leaflet in

a Community Based Colorectal Cancer Screening Programme.

Summary.

The ability of a health educational leaflet about colorectal cancer screening to increase compliance with faecal occult blood testing was assessed in a randomised controlled trial. 1571 residents of Market Harborough aged 61 to 70 years were sent an invitation to participate in screening, half of whom were randomised to receive the health educational leaflet. Faecal occult blood tests were analysed and colonoscopies performed at Leicester General Hospital. The overall compliance was 33%, with a similar uptake in men and women (32% vs 34%, $X^2=0.7$, ns). More men who received the health education leaflet completed kits than those who did not (38% vs 25%, $X^2=12.9$, p<0.001), although in women the leaflet had no effect (34% vs 33%, $X^2=0.1$, ns). The positive rate for stool testing was 3.7% (19/513) but after re-testing on dietary restrictions it fell to 1.6%. Two patients had carcinoma (Dukes' A and B) and another five patients had a total of 5 adenomatous polyps. The educational leaflet had a valuable effect in increasing compliance in men but not in women.

Theoretical justification for this work.

Compliance with faecal occult blood testing must be raised to ensure colorectal cancer screening programmes are effective in both health and economic terms. One method is to enclose simple health educational leaflets with the screening invitation. Such a leaflet was developed in my thesis by identifying reasons for non-compliance (Chapter 6) and piloting it on a sample of a hundred subjects (Chapter 7). The effectiveness of the material was then tested in a randomised community trial described in this chapter.

Introduction.

Simple interventions to increase compliance in colorectal cancer screening programmes are required, as participation in community studies is low (125,126,127,128,138). One such intervention is a simple health education leaflet explaining the high frequency of the disease, its asymptomatic nature and addressing reasons for non-compliance. Previous studies gave conflicting results of the benefit of such leaflets (137,217,218), with one reducing levels of participation (218). The design and wording of the literature is vital and should address reasons for non-compliance. None of these three studies tested their educational material in pilot studies or reported on its readability. Several scales have been devised by Flesch (208,211) which measure readability, human interest and positive aspects of written material. These scales give objective assessments of a leaflet's content. Only one study published their pamphlet and none addressed concerns about cancer detection and screening.

In this study, the effect of a simple health educational leaflet on compliance was tested in a randomised community controlled trial in Market Harborough, Leicestershire. Such a study is essential if the effect of educational material on compliance is to be assessed. The leaflet used (appendix 8.1) was similar to the one piloted in out-patients (appendix 7.1) although several improvements were made. Firstly, the nature of a polyp was defined as a "harmless growth tag arising from the bowel wall". Secondly, to emphasise that asymptomatic people should participate, a description of the symptoms of colorectal cancer was omitted. To improve impact, several sentences were shortened giving a slight increase in readability and key words were highlighted in bold print. The numbering system for paragraphs was removed. Finally to emphasise few would need

further investigation, the second leaflet contained the statement "Only one in every hundred people will need further tests".

Method.

An invitation to receive a free faecal occult blood test was sent to 1571 residents of Market Harborough (Figure 8.1) aged 61 to 70 years, registered at a single large general practice. This second study was conducted two and a half years after the screening programme described in chapter two. The invitation was sent on practice note paper and was identical to the one used in the initial study (Appendix 2.1). Half the subjects were randomly allocated to receive the screening leaflet. The leaflet sent was entitled "How I can help myself avoid the second commonest cancer in Britain" and contained the footnote "Health in Harborough" (figure 8.2). The Flesch Reading Scale was used to measure the reading level of the leaflet and the Flesch Human Interest Scale to assess positivity and human interest (208,211).

Households with two eligible members both received the same intervention i.e leaflet or no leaflet to avoid any contaminating effect. To eliminate the bias of one member of the household influencing the other, only the first member was included in the analysis. Eligible members of each household were listed alphabetically on the register. The leaflet explained bowel cancer was the second commonest cancer in Britain, affecting 28 000 individuals annually or 1 in 26 of the population over the age of 50 years. The purpose of this section was to increase awareness of the frequency of the disease, as previous work showed that those who feel at risk of developing cancer are more likely to comply (197). Next, the asymptomatic nature of the illness was described and screening defined because these concepts are poorly understood (129,223,225). The leaflet explained

Figure 8.1. Market Harborough, Leicestershire.

Figure 8.2. Title page of the screening booklet.

**How I can help myself avoid
the Second Commonest Cancer
in Britain**

HEALTH IN HARBOROUGH
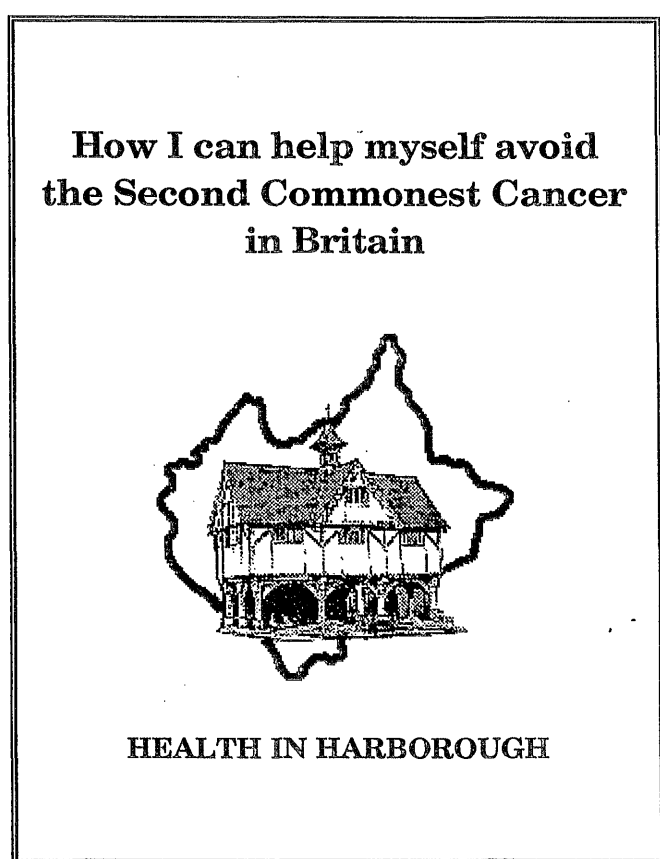
bowel cancers can arise from polyps which screening tests detect as well as cancers. Faecal occult blood tests were described and it was emphasised they were completed at home, but returned to the hospital for testing. Finally, the leaflet addressed reasons for non-compliance, identified in chapter six, namely unpleasantness of the stool collection procedure, fear of further investigations and the role of intercurrent illness. The screening programme was not advertised in the local press or on radio to avoid contamination. A pre-paid envelope was included with which to return the requests for kits.

Subjects who accepted screening were sent a free faecal occult blood test (Haemoccult) which included instructions on how to complete the test. Kits were completed over three days and returned to the Leicester General Hospital for testing. Initially no dietary restrictions were imposed but subjects were asked to refrain from taking vitamin C preparations which can cause false negative results (65). A test was considered positive if a blue colour appeared on adding hydrogen peroxide and denatured alcohol to the sample. Subjects with positive tests were asked to repeat them on dietary restrictions avoiding red meat and various vegetables which decreases the number of false positives (63). Subjects with repeat positive tests were informed and their general practitioner asked to refer the patient for colonoscopy at Leicester General Hospital. With the colonoscopy invitation patients received a description of the procedure and the standard bowel preparation. Bowel preparation consisted of a low residue diet for five days and two sachets of "Klean-Prep", an iso-osmotic bowel clearance solution the day before the procedure. Prior to colonoscopy, a history was taken and patients underwent a complete physical examination. The colonoscopies were arranged as day case procedures on routine endoscopy lists.

All subjects who had a negative faecal occult blood test were informed of the result with a standard letter (Appendix 8.2). This told them to contact their doctor if they had or developed symptoms and that the test could not prevent cancer in the future. Subjects who had an initial positive test, but a repeat second negative one, were sent a third test four months later.

The number of subjects completing kits was recorded according to age, sex and whether they received the leaflet. Differences in compliance between these groups were tested for statistical significance using a X^2 statistic. The size, location and histology of cancers and polyps were recorded and the detection rate pathology per 100 subjects screened calculated.

Results.

a. Readability of the leaflet.

The Flesch Reading Score was 73.7 (range 0 to 100). On a scale of "very easy" to "very hard" 73.7 is classed as "fairly easy", equivalent to a simple fictional novel. The reading level was that of a 12 year old and 90% of the population over 25 years would be able to comprehend it. The leaflet had a negativity score of 94 (range 0 to 100) which is classed as "optimistic" and a personal human interest score of 12 (range 0 to 100) which is rated "mildly interesting".

b. The uptake of screening (table 8.1).

The overall compliance with screening was 33% (513/1571). More men complied who received the screening leaflet than those who did not (38% vs 25%, $X^2=12.9$, p<0.001). The leaflet raised compliance significantly in men aged 61 to 65 years (36%

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vs 27%, $X^2=4.0$, p<0.05) and 66 to 70 years (39% vs 23%, $X^2=9.7$, p<0.01). In

women, the leaflet did not affect compliance (34% vs 33%, $X^2=0.1$, ns) and this was

true regardless of age (61 to 65 years 38% vs 36%, $X^2=0.1$ ns, and aged 66 to 70 years

(31% vs 31%, $X^2=0.0$, ns).

Compliance in men and women who received the screening leaflet was similar

(38% vs 34%, $X^2=1.0$, ns). More women who did not receive the leaflet complied than

men not receiving it (33% vs 25%, $X^2=5.6$, p<0.02).

c. Pathology detected by faecal occult blood screening.

Nineteen subjects had initial positive faecal occult blood tests (4% of those

tested) but only eight were again positive on repeat testing (2% of those tested). The

positive rate was significantly lower in this second Market Harborough study than the first

(4% vs 7%, $X^2=6.4$, p<0.02). Two patients had a carcinoma detected (0.4% of people

screened). One of these patients had a Dukes' B sigmoid carcinoma and the second

patient a large 3.5cm sigmoid polyp on a thick stalk which contained carcinoma within a

severely dysplastic tubulovillous adenoma (Dukes' A lesion). Five patients had a total of

five adenomatous polyps (1.0% of people screened, see table 8.2). One of these patients

had a further small rectal metaplastic polyp. Another patient had endoscopic colitis to 30

cm confirmed on histology and two sigmoid polyps showing chronic inflammation.

Although this patient was symptomatic he had not sought medical advice.

Table 8.1 Compliance with faecal occult blood testing.

Age	Booklet	No Booklet
Men		
61-65 years	72/199 (36%)	52/194 (27%)
66-70 years	71/182 (39%)	39/166 (23%)
Total men	143/381 (38%)	91/360 (25%)
Women		
61-65 years	79/209 (38%)	67/186 (36%)
66-70 years	66/216 (31%)	67/219 (31%)
Total	145/425 (34%)	134/405 (33%)

The leaflet raised compliance in men but not in women.

Table 8.2. Polyps detected at screening.

Patient size	polyp	location	Histology
One	1.5 cm	sigmoid	tubulovillous adenoma moderate dysplasia
Two	2 x 1 cm	sigmoid	chronic inflammatory polyps
Three	1.2 cm	sigmoid	tubular adenoma moderate dysplasia
Four	3 cm	sigmoid	tubulovillous adenoma moderate dysplasia
Five	0.8 cm	sigmoid	tubulovillous adenoma moderate dysplasia
Six	1 cm	sigmoid	tubulovillous adenoma severe dysplasia
	0.5 cm	rectal	metaplastic polyp

An adenomatous polyp was detected in 1.0% of people screened.

One patient with initial positive tests, but repeat negative ones, contacted the screening unit to explain she had a two year history of constipation. This lady was seen and examined in clinic and a barium enema requested. This showed an apple core stricture in the ascending colon suggestive of a carcinoma. However, at laparotomy a fibrous stricture was found with no evidence of cancer.

Discussion.

The main finding of this study was that a health educational leaflet significantly increased compliance in men but not women. The leaflet raised men completing faecal occult blood tests by 52% from 25% to 38%. The positive effect of the leaflet in men is encouraging, especially as the intervention is cheap and can be included with screening invitations. Based on population figures from the 1991 Census (268), if there were a national screening programme for colorectal cancer then the leaflet would recruit an extra 373 893 men leading to the detection of 748 asymptomatic tumours. This positive effect is most likely due to the leaflet explaining why screening tests should be completed and by addressing reasons for non-compliance.

Speculation would suggest several reasons for the leaflet working in men but not women. Women through exposure to breast and cervical cancer screening programmes may be more aware of the concepts of asymptomatic illness and the benefits of early detection. Conversely, men are less aware of screening as there is no national programme for early detection of male cancers and are more likely to be influenced by the leaflet which explained its benefits. A second possible reason is that many women have had unpleasant experiences associated with mammography (131) and smear tests (133,150,151). These include painful investigations, embarrassment and loss of dignity

when attending screening centres. Consequently, women may be unconvinced by a leaflet which portrayed investigations as acceptable. Future research into compliance should explore the effect of unpleasant experiences in one screening programme on participation in others. Health education material sent to men and women may have to differ in emphasis. In men, the principles of screening should be highlighted, and in women reservations about the screening test overcome. Alternatively, other forms of health education may be more effective in women. More women than men aged 40 to 70 years accepted faecal occult blood testing when offered at routine consultations (136) and a more personal approach from general practitioners may be required. Women are familiar with this approach in cervical screening, where the practitioner recommends smear testing and is involved in the procedure. Some other health promotion programmes, particularly smoking cessation schemes, are more successful in men (269). In such a programme in Pennsylvania, subjects were given an introductory lecture and provided with information and support to continue stopping smoking over the next month (269). Although the initial success rates of 70% were similar in men and women, three years after the programme, twice as many men had stopped smoking. In a British study, advice on smoking cessation from a chest physician, consolidated by a psychologist, reduced smoking in 39% of patients, with a greater success in men (270).

Although the leaflet raised compliance, overall uptake was disappointing at 33%. A possible reason is that there was no advance publicity in the local press or radio. Advance publicity and prior knowledge of a colorectal cancer screening programme can themselves raise compliance by 10% and direct interview of potential participants by 15% (217). Television advertisements encourage participation (147,148), although it increases cost. Another reason for the low overall acceptance may be that this was the second

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programme in two and a half years. Several residents replied they had participated previously and thought a further test unnecessary. It is likely there were many similar instances where people did not write. These people may feel a previous test offered protection against cancer and so further testing was unnecessary. This possibility needs to be explored to ensure subjects who develop symptoms are not falsely reassured by a negative screening test. Although the leaflet was effective in men, other interventions to raise compliance are clearly needed as overall compliance was low. Interventions of proven value include remailing, telephoning non-responders and tagging notes of participants eligible for screening (90,140,141,143).

Compliance in men and women who received the leaflet was similar, although in most programmes acceptance is less in males (86,128,136,138). In those who did not receive the leaflet, acceptance was less in men than women. The major effect of the leaflet was to raise male acceptance of screening to a level comparable to women. In both men and women, compliance in those receiving the leaflet was less than that expected from the pilot study on a hundred subjects described in the previous chapter.

This is the first British study where an educational leaflet about colorectal cancer screening was assessed for readability, addressed reasons for non-compliance and piloted in a preliminary study. Readability was measured with the Flesch Reading Score (208). This counts syllables and words per sentence and allocates a score and reading age. The higher the score, the more readable the material and the lower the reading age. Objective scales are invaluable tools for writing and simplifying educational material and they correlate with understanding and retention of information (210). The cognitive model of health behaviour states both are determinants of compliance (202). The high readability score, may have contributed to the leaflet's effect on men. The leaflet was also assessed

with the Flesch Human Interest Reading Scale (208,211) which determined how positively and personally the leaflet was written. The leaflet had a high positivity score of 94, regarded as "optimistic" which may be important in educational material about prevention. Leaflets with a positive approach are more likely to be successful than those written negatively. Unfortunately, the leaflet scored only 12 on the personal human interest score which is classed as "mildly interesting" on a scale from "dull to dramatic". The leaflet contained only 11 personal words such as "you" or "your" and 8 personal sentences. This aspect of the leaflet could have been improved by changing a sentence such as "Screening is where people have tests to find cancer before it gives symptoms to "Screening is where **you** have a test to find cancer". Readability scores have their limitations in that no measurement of content or style is made. However, material with consistently low scores is likely to be complicated with little personal interest (210). Reasons for the lack of effectiveness of other educational material in colorectal cancer screening may have been that readability, positivity and human interest were not assessed (137,218). Only the Nottingham group published their educational leaflet which had a negative effect on compliance (218). I analysed the scores of the Nottingham leaflet and found readability was similar to my own, the number of personal words and sentences was higher, but the leaflet was less positively written. Negative aspects were mentioned such as "late" presentation, "lack" of treatment for symptomatic cancer and "unwillingness" to discuss cancer. Readability and positivity were not mentioned by this group and the educational material was not piloted to highlight deficiencies.

Only one previous study in British general practice reported a positive effect of educational material on compliance (217). Here, education consisted of a preliminary letter "about colorectal cancer and the purpose of the test 2 weeks before being sent the

invitation". The content of this letter was not published and did not appear to address reasons for non-compliance. The letter raised acceptance of screening by 24% from 38% to 47%, although its effects according to age and sex were not reported. An interview of potential subjects to discuss colorectal cancer and screening two weeks before the invitation raised compliance to 52%. Another community based study in Nottinghamshire found an educational leaflet dropped compliance from 55% to 46% (218). Mailing the leaflet two weeks before the invitation also had a detrimental effect. There are several reasons why this leaflet was ineffective. Firstly its purpose was not explained, although the fact that the illness often presents late, when treatment is ineffective, was reported. Such an approach is unlikely to interest healthy people in the benefits of screening and cause fear in others. Similarly, if the leaflet is an advertisement for screening it is confusing to mention symptoms. In contrast, my leaflet encouraged interest by stating health benefits. In the Nottinghamshire study (218), reasons for non-participation were not addressed. The leaflet did not explain the nature of faecal occult blood tests and would only be appropriate to use if kits were enclosed with it. Finally, it is unclear whether the leaflet was piloted before use. This group also found a bowel symptom questionnaire sent with invitations decreased compliance. Such an approach is probably inappropriate, as those without symptoms should be encouraged to participate and those with symptoms should seek medical advice. In Farnborough and Basingstoke, compliance was similar in those receiving educational material to controls (137). The leaflet was unpublished, although the authors stated it was about "bowel diseases and screening for bowel cancer and polyps". Neither readability nor a preliminary pilot study were reported. This study assessed the leaflet on several methods of recruitment including mailing kits, offering it at a routine consultation and giving patients specific appointment

times to collect tests. Of these three methods the offer of screening at a routine consultation was most effective. However, within each group the educational booklet had no significant impact.

The value of health education was extensively investigated in "screening" for the early detection of malignant melanoma. In Glasgow and the West of Scotland, general practitioners were updated on melanoma and a public education programme of leaflets and posters displayed in health centres, citizen's advice bureaus and at workplaces (271). Referrals to dermatology clinics rose three fold and one in 22 patients had melanoma. The programme was successful and resulted in a rise in the detection of early lesions from 38% to 54%. Such an improvement in tumour staging was not seen in Eastern Scotland where there was no education. In Leicestershire, an intensive campaign encouraged patients with new or changing lesions to seek medical advice and was conducted on local television, radio, the press and with leaflets and posters (272). The programme was initially successful with a significant rise in early melanomas diagnosed, although subsequent campaigns were less productive. A similar study was organised in Nottinghamshire and a third more early melanomas were diagnosed, although the results were not significant due to small numbers of patients (273). As a consequence of the health education programme, referrals to a pigmented lesion clinic increased by five times. Although more early lesions were diagnosed, the total number of melanomas per patient fell. Knowledge of the sun's effect in inducing melanoma can be imparted at an early age. Hughes et al (274) designed an educational leaflet called "Sun Cool" for 12 to 16 year olds. It was successful in raising awareness and the use of sunscreens. One of the most successful health education campaigns for early cancer detection was the Queensland Melanoma Project, Australia (221). Although this state has the highest incidence of

melanoma in the world, the 5 year survival is twice the average rate at 80%. This success was due to early detection of melanoma through intensive public awareness of the disease. Children are taught about skin cancer at school and the message is reinforced with leaflets in clinics, health centres, libraries and other public places. Also television and the press give regular coverage to the topic. These studies showed that leaflets can be successful in promoting awareness of cancer. The message in colorectal cancer screening is different to melanoma, detection as asymptomatic, rather than symptomatic people should undergo screening. To encourage participation in colorectal cancer screening, a comprehensive educational package will be needed, a component of which should be leaflets such as the one assessed in this study.

Health education has been used with varying success in conditions other than colorectal cancer screening. Sackett et al (275) assessed the value of an audio-cassette and information booklet on improving compliance with anti-hypertension medication. The educational material explained the effects of hypertension on life expectancy, the benefits of treatment and the need for compliance with medication. Although the tape and booklet significantly raised patient's knowledge about high blood pressure, unfortunately drug compliance and systolic blood pressures were similar to controls. Similarly, in patient education in asthma, an information booklet explaining the condition and its drug treatment, raised patient awareness but had no effect on compliance, inhaler technique or the self-management of attacks (276). Both studies emphasised the importance of changing disease outcomes rather than changes in knowledge. Another study on educational material in asthma found both cassette tapes and a glossy 27 page booklet raised awareness of drugs and decreased patient's perceived disability as measured through time off work and missed social functions (277). However, rates of consultation for asthma

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and other conditions were similar in test and control groups. A study monitoring the outcome of an intensive diabetic health education programme showed an improvement in clinical variables (278). In this controlled study, patients in the test group attended a weekly two hour seminar on basic disease self-management including self monitoring, drug usage, footcare and late complications. At one year, patients in the intervention group had significant decreases in body weight, plasma triglycerides and required less sulphonylurea medication. Another randomised controlled trial of health education in diabetes confirmed this beneficial effect, with an intensive eight week instruction course producing changes in blood glucose, glycosylated haemoglobin, weight and blood pressure (279). The most successful effect was where both patients and doctors received the health education package. In a study in general practice, the value of a booklet explaining common childhood symptoms on the rate of patient-initiated consultations was investigated (280). This booklet gave advice on six common symptoms including sore throat and vomiting. It explained how these symptoms could be managed at home and when medical advice should be sought. At one year, although the number of requests for home visits had decreased in the study group, consultation rates at the surgery were similar. In a general practice based initiative to reduce smoking, an educational leaflet plus advice from the doctor and a warning of follow-up, reduced the number of smokers by 5.1% at one year compared to 0.3% in a control group (281). Although this effect was relatively small, the authors commented that if applied nationally, such a leaflet would reduce the number of smokers by half a million. Mazzuca et al (282), in a review of health educational material in several chronic illnesses, found education was most successful where serious attempts were made to change behaviour rather than just increase knowledge. Although the leaflet developed in this thesis raised compliance in men, studies

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in other illnesses showed leaflets were most successful when part of an overall educational package. In colorectal cancer screening this could take the form of mass media advertising, seminars, cassette tapes and a commitment to follow-up non-compliers.

My study emphasised the importance of informing patients of their test results and asking them to seek medical advice if they have symptoms. One lady complaining of constipation for several months had initial positive tests but repeat negative ones on dietary restrictions. On receipt of her test result letter she contacted the screening unit and was investigated with a barium enema. This showed a stricture in the caecum and she was referred for surgery. Fortunately, the stricture was found to be of a benign fibrous nature at laparotomy.

The positive rate for stool testing of 1.6% was similar to that in many other large programmes where slides were not rehydrated (86,91). Although test sensitivity is improved by slide rehydration, specificity falls resulting in many unnecessary colonoscopies (82). The positive rate of stool testing was lower in this second Market Harborough study than the one two years previously. This was due to my increased experience in recognising a real colour change on slide testing. To ensure false positives are minimal, it is essential those testing kits are adequately trained. The detection rate of one carcinoma per five hundred subjects screened was similar to other European studies (86,91,92). However, the detection rate for polyps in Market Harborough (one in every 100 subjects screened) was higher than Nottingham (1 in 120, reference 90) and Denmark (1 in 240 screened, reference 91). Although our sample size was relatively small, four of the five patients had polyps with tubullovillous histology, which is the form most likely to become malignant. The large number of subjects with polyps of a potentially high

malignant nature suggests the Market Harborough community would benefit from regular screening.

This chapter showed educational leaflets which are simple, positive and address reasons for non-participation can increase compliance. Such leaflets are cheap to print and their development and use in future colorectal cancer screening programmes in general practice should be encouraged.

Chapter Nine.

Summary, Discussion and Recommendations.

An effective national screening programme for colorectal cancer is urgently needed, as the disease is a significant public health problem with both high mortality and morbidity. Faecal occult blood testing and flexible sigmoidoscopy can detect early cancers and potentially pre-malignant adenomas. However, there is still some uncertainty as to whether this can reduce mortality. A high compliance with screening in any national programme will be critical to its success. Unfortunately, most general practice studies which have used faecal occult blood tests to screen their populations have achieved compliance rates less than 50%. The results were confirmed in Market Harborough where compliance was only 38% with invitations again coming from general practitioners. Participation by women was high because more younger women completed kits. These findings from Market Harborough underlined the problem of compliance. This must be addressed in both men and women right across all ages. Such poor responses in general practice are disappointing, and if mirrored nationally, large scale screening could not be justified either in health or economic terms. One aspect of this thesis was the investigation of alternative methods for delivering screening, including the role of health education. Alternative methods of delivery included workplace based programmes in the private and public sectors as well as an opportunistic approach in blood donor centres. In the second half of this thesis, health education leaflets were designed to address reasons for non-compliance and increase awareness of colorectal cancer. If their use was successful, organisers of a national programme could utilise such approaches.

Two workplace screening programmes were conducted: one in a heavy engineering firm and the other in a large NHS teaching hospital. Neither programme recruited more participants than the community scheme when results were age and sex matched. In Britain, workplace based colorectal cancer screening programmes do not

seem to offer any advantage in recruitment and may miss vulnerable sections of society. This is disappointing, as many people could be enrolled in programmes and if companies sponsored them, as a service to such employees, the savings to the national economy would be large. An alternative role for industry could be the advertisement of screening services available in the local community. This would help raise awareness.

Compliance at both worksites was low, with just under half the hospital staff participating and only a quarter of those at Brush Engineering. These figures illustrate the magnitude of the compliance problem. The results from these occupational studies are unhelpful in identifying any particular group which needs to be targeted. At Brush Engineering, uptake was slightly higher in managers, but in hospital compliance amongst managers and doctors was poor. Compliance needs to be raised in all groups and techniques other than workplace screening should be explored. Approaches I studied were opportunistic screening at blood donor centres and the role of simple health educational leaflets.

Opportunistic screening can be an effective method of recruitment, but unfortunately only a small cross-section of the population is reached. In colorectal cancer screening, opportunistic screening has only been investigated to a limited extent in general practice. Such an approach at Blood Donor Centres was successful and recruited two-thirds of actual donors. The presence of a doctor who was able to explain screening and answer questions contributed to this high rate of compliance. I would recommend that because uptake was high, blood donor centre managers publicise all screening services, so donors can be made aware of their value. If faecal occult blood testing leads to a reduction in mortality, then kits could be offered at such centres. Such an approach could supplement a general practice or community based national programme. On a broader

front, these results emphasise the value of direct contact in encouraging participation, a finding confirmed in general practice. Organisers of national programmes should regularly encourage doctors to personally publicise screening at routine consultations. However, the small proportion of the target population reached means opportunistic approaches can only be an adjunct to community delivered screening.

Educational leaflets which raised awareness of colorectal cancer, explained screening and addressed reasons for non-compliance had a significant effect. The commonest reasons for non-compliance were a failure to understand the principles of screening, unpleasantness of stool collection, concern about investigations following a positive test and intercurrent illness. The principles of screening can be explained through health education campaigns in the media and at a personal level. A major challenge to the medical profession is the education of at-risk people about screening and pre-symptomatic disease. Many declined testing because of their concern about further investigations following a positive result. Screening units need to be aware of these anxieties and should be as private, personal, dignified and unthreatening as possible. Distaste for the collection of faeces is understandable but could be overcome by emphasising the benefits of the test. Because of the reluctance of people with intercurrent illness to participate, general practitioners need to be aware of this problem so they can encourage them. Surprisingly, lack of effective treatment for established colorectal cancer was not a major anxiety and people were more fearful of the immediate consequences of a positive test, such as further investigations.

Few people thought bowel cancer was very common before reading the leaflet, and for any screening programme to be successful, people must believe it could affect them. Awareness could be raised through the media and health education campaigns once

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an effective screening modality has a significant effect on mortality. Such campaigns would need to tell people that colorectal cancer can be asymptomatic, as a third of those interviewed in my study were initially unconvinced. Awareness of this concept and the commonness of the disease must be increased in men and women and would be achieved through simple leaflets such as the one I developed.

When interventions to raise compliance rates are developed, their effectiveness should be tested in randomised controlled trials. My leaflet significantly raised compliance in men but had no effect in women. However, the leaflet's effect in the trial was less than expected from the pilot study conducted in a hospital out-patient department where the intention to participate was raised by 50%. Although awareness and knowledge can be increased, this does not alter the behaviour of some people. However, amongst men I would recommend an explanatory leaflet should be included in screening invitations, as it increased compliance by 50% compared to a control group in Market Harborough. Which aspect of the leaflet was responsible for the positive effect on compliance I could not determine from my work. Leaflets are cheap and simple to produce and could easily be included in the initial invitation.

Although leaflets had a positive effect in men, overall compliance remained low and other interventions must be adequately researched. A possible reason for this low uptake may have been that residents from the first programme in Market Harborough felt protected and were falsely reassured by a negative test in that study. Health education leaflets should include a short paragraph explaining that screening is a continuous process. The response in women and the lack of effect of a leaflet were disappointing. The low response may have been for similar reasons. Although awareness of cancer and screening were increased and reasons for non-compliance addressed in the leaflet, behaviour was

not altered. This could have been due to unpleasant experiences associated with breast and cervical cancer screening. Perhaps more emphasis should have been placed on the non-invasive aspects of the tests.

Any future national screening programme for colorectal cancer should be run regionally through invitations from general practitioners, as alternative methods of delivery such as workplace schemes are unsuccessful. However, opportunistic screening can be a useful supplement, as high national compliance rates would be crucial to the success of such a programme. Health educational leaflets certainly increase knowledge of colorectal cancer and the purpose of screening and can increase compliance amongst men. However, such leaflets must be used in conjunction with other measures if more deaths from colorectal cancer are to be prevented.

Appendices.

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Appendix 2.1

<div align="right">
Market Harborough Medical Centre,
67 Coventry Road,
Market Harborough,
Leics.
</div>

Dear

      As your family doctor I would be very pleased if you would participate in a new and simple screening test to make sure that the lining of your bowel is healthy. I am offering this test to patients of your age, who like yourself, have no particular bowel symptoms.

      In the whole of Leicestershire there are over 300 new cases of bowel cancer each year. Detection in the early stages greatly increases the chances of a complete cure.

      These tests can detect small amounts of blood in the stool that would normally go unnoticed. Often the cause is not serious, but it may indicate the earliest stage of bowel cancer, when treatment can result in complete cure.

      If you would like to receive one of the test kits with an instruction leaflet, please complete and return the slip below in the enclosed envelope. If you require any further information please telephone Leicester 490490 extension 4352.

      Yours sincerely,

      Dr M F Biggin & Partners.

- -

Name   _

Address   _

         _

         _

I would / would not like to receive a stool test kit (please delete)

Appendix 2.2.

Helpful Hints on the Haemoccult Test.

Thank you for requesting a testing kit.

A few ideas on collecting samples from people who have already done it.

1. Float several sheets of strong toilet paper or sheets of newspaper in the toilet.

2. Pass a stool into a potty.

3. Pass a stool onto a foil freezer container or paper plate.

4. Place a cling film over the top of the toilet.

Finally,

1. Please try and avoid taking vitamin pills whilst doing the test, but you can eat food

containing vitamins.

2. Please do not forget to put your name on the back of each test.

3. Please complete the address slip below and return it with your samples.

                    Thank you

— —

Name   _

Address   _

            _

            _

Date of Birth   _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

G.P's name   _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Appendix 3.1. Questionnaire sent to local companies to recruit a study company.

Section A.

1. Would your company be willing to supply us with a list of your employees over the age of 40 years so that we may invite them to participate in a scheme for the early detection of bowel cancer?

Please tick the appropriate box below,

YES___   NO ___

Section B.

1. Name of Company   _____

2. Total number of employees of all ages   _____

3. Number of employees over 40 years old   _____

Section C.

      If you would NOT consider offering screening, please tick any number of the

reasons below, which best describe your reasons for not wanting to participate.

1.   Not the firm's responsibility to look after the

      medical care of its employees.

2.   I do not think the workforce would be interested.

3.   Discussed project with the firm's medical officer who

      does not think the scheme is worthwhile.

4.   Discussed project with the trade union who do not think the scheme is worthwhile.

5.   A similar project for the detection of bowel cancer is already operated by our

        firm.

6.   The scheme would be logistically difficult to run.

7.   Unsuitable economic climate.

8.   Other reasons (please state).

        Thank you for your time and effort in completing this questionnaire. Please return it in the pre-paid envelope.

Appendix 3.2 Posters displayed in the hospital and at Brush Industries.

The Early Detection of Bowel Cancer

Leicester General Hospital would like to offer employees aged 41 to 65 years the opportunity to receive a free kit which helps detect early signs of bowel cancer. This involves collecting a tiny sample of stool with the aid of the kit at home which is then tested in the laboratory for traces of blood produced by the cancer. The kits consist of three small cardboard slides each three inches square and can be returned in the post. If you would like to see one of the kits before requesting one, please contact the occupational health department.

Appendix 4.1 Information available in the Department of Occupational Health.

How big are the kits?

The Haemoccult kits are approximately 10 cm square and are thin enough to be returned through the post.

How do I collect the samples?

An instruction sheet is supplied giving advice on several easy methods to collect the samples. The samples are collected on three different days on no special diet.

What happens if a test is positive?

Certain foods can cause a positive test. These are red meat, black pudding, cauliflower, broccoli, parsnip, swede, cabbage, radishes and bananas. People whose first tests are positive are asked to repeat them avoiding the above foods whilst doing the samples. If the test is again positive then we recommend a colonoscopy.

What is a colonoscopy?

This is a telescopic examination of the bowel done as an out-patient. A general anaesthetic is not required but patients are given a sedative and drugs to relax the bowel.

What are the chances of me having a cancer discovered?

About one in every five hundred people completing the kits will have a cancer diagnosed. Cancers discovered through screening are usually at an earlier and more treatable stage than by the time symptoms develop.

Will my G.P. be informed?

The programme is being run by the hospital but your family doctor will be informed of the results of the stool test and colonoscopy if needed.

Appendix 5.1. Letter of invitation for screening sent to blood donors.

Department of Gastroenterology,
Leicester General Hospital,
Gwendolen Road,
Leicester, LE5 4PW.

Dear Donor,

Each year in Leicestershire there are over 300 cases of bowel cancer and detection in the early stages increases the chance of a complete cure. If you are aged **50 to 65 years** The Blood Transfusion Service and Leicester General Hospital would like to offer you the opportunity of receiving a simple screening test which can detect early signs of bowel cancer.

We are offering this test to people who like yourself have no particular bowel problems and come to donate. The test pack consists of 3 small cardboard slides each 3 cm square which can be completed at home and returned in an envelope. These can detect very small amounts of blood in your motion that would normally go unnoticed.

The tests will be offered to you the next time you come to give blood. If you are aged 50 to 65 years please let the receptionist know on arrival if you would like to take part. We hope that you will feel able to help, naturally there is no obligation. As this is a pilot scheme a member of staff from the hospital will be present to answer your questions and to explain the procedure. Everybody who completes a test will be informed quickly within 3 weeks of the result. The vast majority will have a negative test and only about one in a hundred people will have a positive result. If the first test is positive we would ask you to repeat it but this time avoiding certain foods which can sometimes also cause it to be positive. The first test is done with no dietary restrictions so as many people as possible can participate. If the second test is positive we would recommend a telescopic examination of the bowel called a colonoscopy. This is done as a hospital out-patient under sedation to relax both yourself and the bowel. Again the very small number of donors who need more tests will be informed quickly and their general practitioners notified.

Thank you for reading this letter. Any further questions you may have we will be happy to answer when you come to the donor centre.

Yours sincerely,

Mrs. B. Jestico	Miss C. Antill	Dr. Andrew Hart
Donor Services	Leicester Transfusion	Medical Registrar
Manager	Centre Manager	

Appendix 5.2 Letter to donors with a negative test result.

Dear Donor,

Thank you for returning the stool kit which I am pleased to report is clear. I have also let your doctor know the test is negative. If in the future you develop a change in your bowel habit such as new diarrhoea, constipation or bleeding please consult your doctor.

Thank you again for taking part.

Yours sincerely,

Dr. A.R. Hart	Dr. J.F. Mayberry	Dr. A.C.B. Wicks
Registrar	Consultant	Consultant
	Physician	Physician

Appendix 5.3. Letter to donor's general practitioners.

Department of Gastroenterology,
Leicester General Hospital,
Gwendolen Road,
Leicester,
LE5 4PW.

Dear Doctor,

re _____

Address _____

_____

_____

Date of birth_____

The above patient who is a blood donor was recently offered a free faecal occult blood test for screening for colorectal cancer when they came to donate blood. I am pleased to report that their test is clear and we need not take any further action. We have also informed the patient of the result. As you are aware only half of all cancers bleed so a negative test does not exclude the condition if they present with symptoms in the future.

Yours sincerely,

Dr A Hart   Dr J F Mayberry

Registrar   Consultant Physician

Appendix 6.1 Questionnaire used to assess reasons for non-compliance.

We would be interested to know why you chose not to receive a test kit so that we may plan better tests and screening in the future. Please could you tell us which of the following reasons made you decide not to receive a test kit. Your answers are strictly confidential.

1. There was no stamped addressed envelope in which to return my reply.

2. The thought of collecting motions repelled me.

3. I have another illness and do not wish to undergo further tests.

4. I did not realise the test was to diagnose bowel cancer.

5. I would be afraid of having bowel cancer diagnosed as I thought there was no known
   treatment.

6. I would be frightened by the thought of more tests and a possible operation.

7. There is no history of bowel cancer in my family so I do not need a test.

8. I was told by another person not to complete the test.

9. I did not complete the test as bowel cancer is so rare that I am unlikely to have it.

10. Religious beliefs prevented me completing the test.

11. I did not realise the test was free.

12. Other reasons.

Thank you for your time and help.

Appendix 7.1.

DETECTING BOWEL CANCER EARLY.

This leaflet explains how bowel cancer may be diagnosed before it gives rise to symptoms. This is called screening. The following information should answer any questions or concerns you may have about screening.

1. How common is bowel cancer?

Bowel cancer is the second commonest cancer in Britain which affects 28 000 people each year. About one in every 26 people will develop the illness at some time. Many more people have polyps in the bowel. About 1 in 10 of these will turn into cancer. Removal of the polyps should stop cancer developing.

2. Can bowel cancer be present without causing symptoms?

Yes. Bowel cancer may be present for many months before giving rise to any symptoms at all. When symptoms do occur there may be bleeding or a change in bowel habit. Polyps or pre-cancers rarely give symptoms.

3. What is meant by a change in bowel habit?

This means any change from normal which lasts more than three weeks. This could be diarrhoea, constipation or a mixture of both.

4. What is screening?

Screening is where people undergo tests to detect cancer before it gives rise to symptoms. Bowel cancers found by screening are easier to cure than when they later give

rise to symptoms. Doctors are keen to diagnose bowel polyps as removing them may prevent cancer developing.

5. What are the screening tests for bowel cancer?

The simplest screening test is done at home and looks for microscopic traces of blood in the motions. This Home Test consists of three small cardboard slides. Tiny samples of motion are smeared on the slides using the applicator from the kit. The kit is then tested in a hospital for microscopic traces of blood produced by cancers and polyps.

6. How easy is the Home Test to do?

The test is very easy. It may sound unpleasant but can be done quickly and hygienically. A leaflet is sent with the Home Test to explain how to do the test. Several minutes spent completing this test may save your life by cancer being detected early.

7. What happens if the Home Test is positive?

You will need an examination of the bowel using a flexible camera. This is called a colonoscopy and is done as a day-case. Through the camera cancers can be diagnosed and polyps removed. Only one in every hundred people who do the home test will need a colonoscopy. Patients are given medicines to relax the bowel and you can also be given sedation to make the test easier if you wish. Many patients remember very little of the colonoscopy.

8. Do I do the Home Test if I am feeling well and have no bowel problems?

Yes. You may still have an early cancer or polyp which has not yet given rise to symptoms. The cancers detected at this stage are easier to treat and removal of polyps may actually stop cancer developing.

9. Will other illness interfere with the Home Test?

No. If you are feeling unwell or suffering from another illness you should still complete a home test. You should however discuss this first with your doctor.

10. I don't have time to do the Home Test.

The test will only take several minutes of your time but could well save your life by finding cancer at an early stage.

Appendix 7.2. Questionnaire to assess health educational leaflet.

<u>Introductory comment to subject.</u> "We are conducting a research project into what people know about bowel cancer. We would like your opinion of a leaflet we have designed about bowel cancer and screening".

Section 1. Patients' knowledge of bowel cancer and screening, prior to reading the

leaflet,

1. Enrol patient's relatives aged 50 to 70 years.

    Age ____   sex ____

2. Ask the following questions,

a,   How common do you think bowel cancer is ?

   i   very common,   ____   iii. uncommon   ____

   ii common,   ____   iv.   very rare   ____

        v. Don't know. ____

b. Do you think bowel cancer can be present before giving rise to symptoms?

   i yes   ____   iii no   ____

   ii.no   ____   iv Don't know.   ____

   iii possibly   ____

Section 2. Does the leaflet educate about the frequency of bowel cancer & screening?

Ask subject to read questions 1 to 4 in the booklet, then ask,

"Having read the booklet"

1. How common do you think bowel cancer is?

   i   very common ____   iii. uncommon   ____

   ii   common   ____   iv.   rare   ____

         v don't know   ____

2. Do you think bowel cancer can be present before giving rise to symptoms?

i   yes   ___   iii. no   ___

iii no   ___   iv. rare   ___

v. don't know   ___

3. How well did the booklet explain what is meant by a change in bowel habit.

i   very well   ___

ii   well   ___

iii poorly   ___

iv   very poorly   ___

4. How well did the booklet explain what is meant by screening.

i   very well   ___

ii   well   ___

iii poorly   ___

iv   very poorly   ___

Section 3. How well did the leaflet explain the screening tests for bowel cancer?

Ask subject to read paragraphs 5 and 6.

1. How well did the booklet explain the screening tests for bowel cancer?

i   very well ___   iii poorly   ___

ii well   ___   iv very poorly   ___

2. Having read paragraphs 5 and 6 would you request a testing kit if offered ?

i   definitely ___

ii probably ___

iii no   ___

iv don't know ___

Section 4. Does the booklet help reverse the reasons for non-compliance?

If the answer to the question above is not "definitely" ask "have any of the following reasons made you decide not to definitely request a test?". If replies to any of the reasons below is "definitely yes" or "possibly" present the appropriate section of the book and ask "has the book changed your mind?".

1. I would not do the Home Test as I feel well and have no bowel symptoms (paragraph 8).

	pre-book	post-book
definitely yes	___	___
possibly	___	___
definitely no	___	___

2. I would not do the Home Test as I would be concerned about further hospital tests if the home kit was positive (paragraph 7).

	pre-book	post-book
definitely yes	___	___
possibly	___	___
definitely no	___	___

3. I would not do the Home Test as I do not have time (para 10)

	pre-book	post-book
1 definitely yes	___	___
possibly	___	___
definitely no	___	___

4. I would not do the Home Test as it sounds unpleasant (paragraph 6)

	pre-book	post-book
definitely yes	___	___
possibly	___	___
definitely no	___	___

5. I would not do the Home Test as I have another illness (paragraph 9)

	pre-book	post-book
definitely yes	___	___
possibly	___	___
definitely no	___	___

6 Other reasons please state _____

Appendix 8.1. How I can help myself avoid the second commonest cancer in Britain-

Health in Harborough.

This leaflet is about how bowel cancer may be found before symptoms appear. This is called **screening.** This leaflet answers questions about screening.

How common is bowel cancer?

Bowel cancer is the second commonest cancer in Britain, affecting **28 000** people each year. About **one in every 26 people** will have the illness at some time. Many more people have polyps in the bowel. A polyp is a harmless growth tag, arising from the bowel wall. About 1 in 10 polyps turn into cancers after many years. Removal of these polyps should prevent cancer.

Can bowel cancer be present before causing symptoms?

YES. Bowel cancer may be present for many months before giving any symptoms. Polyps or pre-cancers rarely give symptoms.

What is screening?

Screening is where people have tests to find cancer before it gives symptoms. Bowel cancers found by screening are easier to cure. Screening also finds bowel polyps. Removing these polyps should **prevent** cancer.

What are the screening tests for bowel cancer?

The simplest screening test is done **at home.** This Home Test consists of three small cardboard slides. Tiny samples of motion are smeared on the slides. The slides are then tested at the hospital for invisible traces of blood from cancers and polyps.

How easy is the Home Test to do?

The test is **very easy.** It may not sound nice, but it can be done quickly and cleanly. A leaflet in the Home Test explains how to do the slides. A few minutes spent doing this test may save your life.

Will I need more tests after the Home Test?

<u>Only one in every hundred people will need further tests.</u>

The recommended test uses a flexible camera to look at the bowel. This is done as an out-patient. Through the camera cancers may be found and polyps removed. Medicines are given to relax the bowel and make you sleepy. This makes the test easier.

Can the Home Test help me if I feel well and have no bowel symptoms?

Yes. You may still have an early cancer or polyp which has not yet given symptoms. Early cancers are easier to treat and removal of any polyps may **prevent** cancer developing.

Will other illnesses interfere with the Home Test?

No. If you are unwell or have another illness you may still do a Home Test after talking with your family doctor.

What if I don't have time to do the Home Test?

The test only takes several minutes but **may save your life** by finding cancer early.

Appendix 8.2. Letter to subjects with a negative faecal occult blood test.

Dr M F Biggin	A T Johnston	Market Harborough Medical Centre,
A P Bennett	R A Lloyd-Williams	67 Coventry Road,
A Inglis	N T Leach	Market Harborough.
E J M Briggs	H J Fox	
S P Gay	F M Bishop	Tele 0858 464242

Dear

       I am pleased to inform you that your test is clear and we do not need to take any further action. However, if your bowel habit has recently altered or you have noticed bleeding please let your doctor know. The stool test cannot prevent illness developing in the future so please inform your doctor if you develop these symptoms in the future. Thank you for taking part.

       Yours sincerely,

M F Biggin & Partners   Dr A R Hart

Market Harborough   Leicester General Hospital
Medical Centre.

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