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Implementation of a diagnostic tool for symptomatic colorectal cancer in primary care: a feasibility study

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Background: Colorectal cancer is the third most common cancer in the UK. Referral guidance can help general practitioners (GPs) identify predictive symptoms of colorectal cancer at an earlier stage in primary care. The objectives of this study were to test the feasibility of a paper-based assessment tool incorporating the CAPER score, a clinical prediction rule for patients presenting to primary care with lower gastrointestinal (GI) symptoms. Three different recruitment methods and GP compliance with completing the CAPER score were assessed. **Methods:** Patients aged 45 years and above consulting for bowel-related symptoms were recruited in 25 general practices in five regions in the UK. Two recruitment methods were carried out by practice receptionists and one by the GP (GP-prompted). The assessment tool prompted GPs to calculate a score using CAPER; a score of 35 points or over indicated a study referral. Three audits assessed recruitment success, compliance with the assessment tool and clinical outcomes. **Results:** In total, 122 patients were recruited into the trial. Although overall recruitment was low, GP-prompted recruitment was more successful than the other two methods. Most GPs completed a clinical examination (92.6%) as directed by the assessment tool; however, only 64% of GPs completed a rectal examination. GPs did not comply well with carrying out haemoglobin (48%) and faecal occult blood (FOB) tests (38%). Only 55% of the final CAPER scores were calculated correctly by GPs. Four patients were diagnosed with colorectal cancer; all met the referral criteria for the CAPER score; however, only three met the NICE referral criteria. **Conclusions:** Overall, recruitment into the study was lower than expected. GP-prompted recruitment was the most effective. Assessment tool compliance was low, which indicates that in future trials a more user-friendly design should be developed.

Key words: colorectal neoplasms; feasibility studies; primary health care; referral and consultation; research design

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Introduction

Colorectal cancer is the third most common cancer in the UK after breast and lung cancers, and the second most common cause of death from cancer (Cancer Research UK, 2005). The UK fares poorly when considering survival from common cancers in comparison with other European countries and the United States (Sant *et al*., 2003). This poor performance is in part explained by delays in diagnosis, which occur at different stages in a patient's cancer journey (Gatta *et al*., 2000). Delays can occur between patients experiencing symptoms and presenting to primary care, or between presentation to primary

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Table 1 Scoring system for CAPER

Presenting symptom/investigation	Scoring	Referral guidance
For each consultation with abdominal pain in the last six months	Score 15 points to a maximum of 45 points	
For each consultation with diarrhoea in the last six months	Score 10 points to a maximum of 40 points	
For constipation present for two or more weeks	Score 20 points	Refer urgently if total CAPER score is 35 points or over
For unexplained loss of weight	Score 20 points	
For men and women with haemoglobin (Hb) 12–13 g/dL	Score 20 points	
For men and women with Hb less than 12 g/dL	Score 30 points	
Positive or weakly positive FOB test result		Refer urgently if FOB is positive or weakly positive

FOB = faecal occult blood.

care and referral and diagnosis in secondary care (Funch, 1985; Carter and Winslet, 1998). In primary care, identification of colorectal cancer may be difficult, because the symptoms are common but the disease is rare. A full-time general practitioner (GP) with a list size of 2000 patients will see common gastroenterological symptoms on a weekly basis, but will only see approximately one new case of colorectal cancer each year (Dent *et al*., 1986; Crosland and Jones, 1995; Chaplin *et al*., 2000; Thompson *et al*., 2000). The main referral guidance for GPs in the UK is found in the NICE Guidelines for Suspected Cancer. These aim to assist GPs in making referral decisions for symptomatic patients who may benefit from urgent investigation (NICE, 2005). The current guidelines, however, are imperfect as they concentrate on typical presentations of cancer (Jones *et al*., 2001). Furthermore, their implementation is incomplete; not all patients who fulfil referral criteria are referred urgently by their GPs (Eccersley *et al*., 2003; Barrett *et al*., 2006; Flashman *et al*., 2004).

Earlier diagnosis of colorectal cancer may improve outcomes by allowing the cancer to be recognized at an earlier stage or by avoidance of emergency presentation of colorectal cancer, which has a poorer patient outcome (Mulcahy and O'Donoghue, 1997; Cuffy *et al*., 2004; Tekkis *et al*., 2004). One recent study has shown that almost 60% of emergency admissions with colorectal cancer presented to their GP with at least one symptom a month or more before their emergency, suggesting that these cases could have been recognized earlier (Cleary *et al*., 2007).

Less than half of patients with colorectal cancer present with a high-risk symptom, such as rectal bleeding or severe anaemia (Hamilton *et al*., 2005). The remainder have 'softer' symptoms, such as constipation or abdominal pain. Individually, these symptoms have a risk of colorectal cancer below 2%, and hence are not deemed to warrant urgent investigation. Thus, most patients with symptomatic cancer will not qualify for urgent referral. Every audit of surgical rapid investigation clinics established in the last decade shows the majority of cancers are diagnosed outside the clinics (Rai and Kelly, 2007). To address this issue, a secondary analysis of a study of 349 colorectal cancers in Exeter examined only those patients without a high-risk symptom. This study derived a clinical prediction rule (the CAPER score) for patients presenting to primary care (Table 1) (Hamilton, 2007).

The CAPER score is a theoretical construct, and before it could be considered for clinical practice, it required feasibility testing in primary care. This paper reports data from a pilot study. The aims of the study were to test three different methods of recruiting patients in primary care, to test the feasibility of using a paper-based intervention incorporating the CAPER score, and specifically to assess GP use of the intervention.

Methods

Practice recruitment

Eighty general practices were contacted through the primary care research networks lists associated with Bristol, Edinburgh, Oxford, Sheffield and

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Sunderland Universities. Twenty-five practices of these 80 practices agreed to participate and were recruited into the study.

Intervention

A paper-based assessment tool was developed comprising both the CAPER score and the NICE Referral Guidelines for Suspected Colorectal Cancer (NICE, 2005). The assessment tool required the GP to complete a patient symptom history, clinical and rectal examinations, a full blood count and faecal occult blood (FOB) test (only for patients not reporting passing blood per rectum) on eligible patients before following the referral advice. GPs were instructed to refer patients in the first instance if they met NICE referral guidelines. In addition, the GP was asked to refer patients either if the total CAPER score was equal to or over 35 points or if the patient had a positive FOB test, irrespective of fulfilment of NICE guidelines. A copy of the assessment tool used in this project is available in Appendix 1.

Patient recruitment

Each practice was asked to either recruit 20 patients or run recruitment for a maximum of 12 weeks. Based on data from the Exeter study, it was determined that a total recruitment target of 500 patients, or 20 patients per practice, would be feasible (Hamilton *et al*., 2005). Three recruitment methods were investigated: the questionnaire method, the non-questionnaire method (both reception-based) and GP-prompted recruitment. The main difference between the reception-based and GP-prompted recruitment was that, in the former, receptionists identified each patient aged 45 years arriving for a consultation and provided them with recruitment materials. The patient then determined his/her own eligibility for participation in the trial by reading the recruitment leaflet while waiting to see the GP. In order to participate, patients needed to be aged 45 years and above, with lower gastrointestinal (GI) symptoms, unexplained loss of weight or bleeding from the bowel for at least two weeks, and with no history of colorectal cancer. In the GP-prompted arm only eligible patients, as determined by the GP, received recruitment materials. The three recruitment methods are summarized in Figure 1. Patients in the questionnaire arm also received a short, 14-item symptom questionnaire, which was used to compare patient self-reported symptoms with GP notes-recorded symptoms.

Assessment of recruitment rate and use of the intervention

Research assistants conducted three audits using standardized data collection forms in each practice. The first of these audits was a one-week retrospective audit in the second week of recruitment to estimate how many study-eligible patients had been recruited. The research assistants studied the consultation records for all patients aged 45 years and above for the selected week and identified all eligible patients presenting with bowel symptoms (which was compared with the actual number recruited). One month following patient recruitment, a second audit of patient notes was conducted to obtain data on GP adherence with the assessment tool by checking whether patient symptoms, investigations, test results, and referral guidance were correctly filled in. Three months following patient recruitment, a third audit was conducted to collect the clinical outcomes and any final diagnoses.

Feedback

GPs in each of the practices were approached to be interviewed to discuss the recruitment methods, perceived value of the assessment tool, and any suggestions for improvement. Research assistants in each of the five regions also observed waiting room recruitment and compiled informal feedback from practice managers and receptionists during weekly or bi-weekly visits to collect study packs from each practice.

Results

Recruitment

In total, 122 patients were recruited into the study, 24% of the recruitment target of 500 patients. A breakdown by the recruitment method is shown in Table 2. Practices running GP-prompted recruitment enrolled a higher proportion of patients in the total eligible population aged 45 years and above.

There were a total of 5805 consultations with patients aged 45 years and above during the one-week audit periods. Overall, *any* bowel symptoms

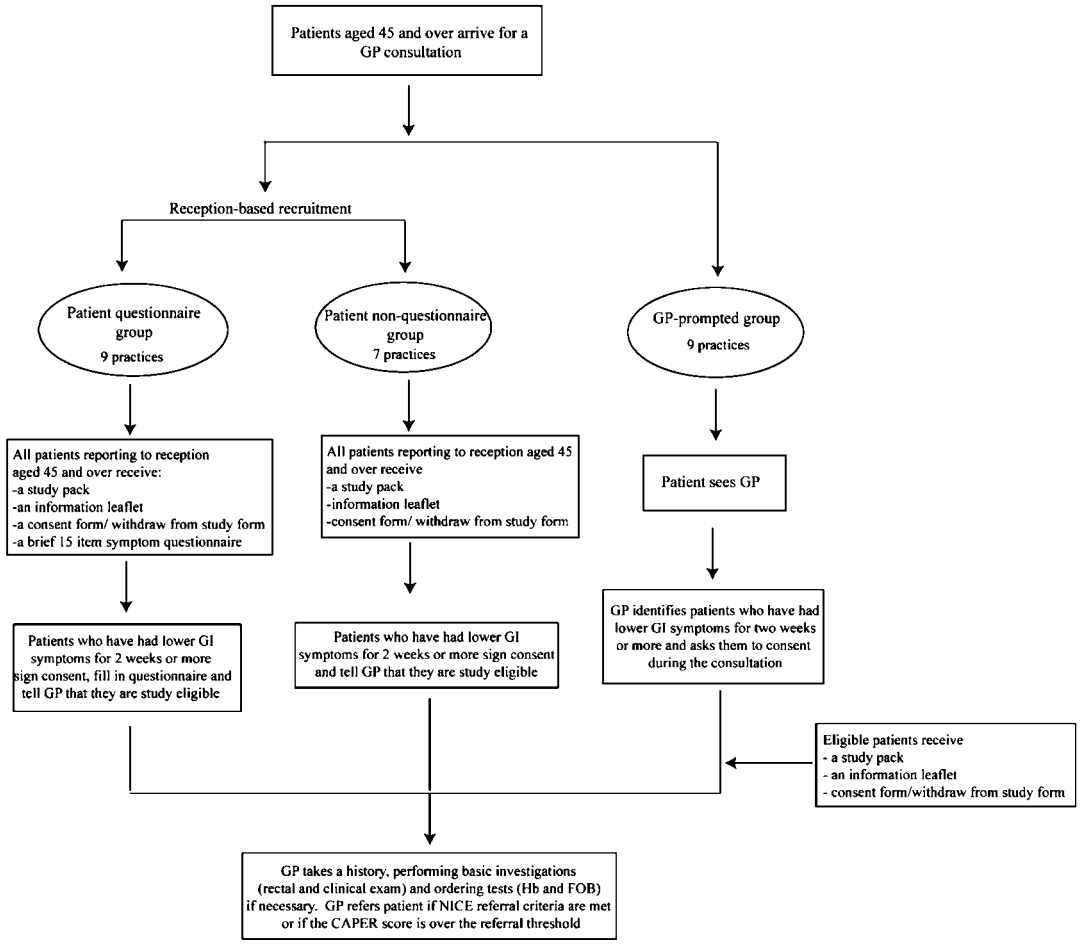

Figure 1 Summary of recruitment methods

were recorded on the clinical record in 149 (2.6%) of these consultations. However, only 61 of the 5805 (1%) bowel symptoms fitted the study-eligibility criteria. In the practices using reception-based recruitment (questionnaire and non-questionnaire practices), 10 out of 50 (20%) patients meeting the study inclusion criteria were recruited over the one-week audit period, compared to seven out of 11 (64%) patients recruited in GP-prompted practices.

Compliance with the assessment tool

Results from the one-month audit are shown in Table 3. GPs who ordered Hb and FOB tests in many cases did not record results from the tests onto the assessment tool, and therefore an accurate CAPER score could not be calculated. For 19 patients, the GP used a previous Hb result conducted an average of eight working days prior to the recruitment date. These were categorised as non-compliant with the study protocol, as GPs were directed to obtain an Hb result in order to complete the CAPER score. In several cases, where tests or referrals were not carried out as directed, the GP noted that the patient had a previous lower GI diagnosis (eg, irritable bowel syndrome) or had already been referred to secondary care.

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Table 2 Summary of patients recruited by the recruitment method

	Total number of practices	Total list size of practices	Total list size aged 45 years and above*	Total number recruited	% recruited by target population (aged 45 years and above)
Patient questionnaire recruitment	9	75 878	28 984	33	0.113
Patient non-questionnaire recruitment	7	75 861	27 337	37	0.135
GP-prompted recruitment	8	61 137	25 242[a]	52	0.206*

GP = general practitioner.
*This is significant ($P = 0.02$, χ^2 2 df).
[a] Imputed average as information on percentage aged 45 years and above in practice 24 is missing.

Table 3 Compliance with the assessment tool

	Test ordered by GP as directed by assessment tool	Test result recorded on assessment tool
Hb test	77 of 122 (64%) patients	58 of 122 (48%) patients
FOB test	44 of 81[a] (54%) patients	31 of 81 (38%) patients
Clinical examination	113 of 122 (93%) patients	
Rectal examination	78 of 122 (64%) patients	

GP = general practitioner; FOB = faecal occult blood.
[a] GPs were directed to only conduct an FOB test if the patient was not experiencing bleeding from the bowel. Eighty-one patients had no bleeding from the bowel.

Overall, 67 out of 122 (55%) of final CAPER scores were calculated correctly by the GPs. If the assessment tool had been completed as directed, 14 additional patients could have been referred to secondary care on the basis of exceeding the CAPER referral threshold. These 14 patients were followed for outcomes over the course of the project; however, none of these patients were referred at the end of the three months of follow-up. Sixty-seven of the 122 (55%) recruited patients were referred to secondary care, of which 24 were referred on the basis of the CAPER score. Thirty-two of the referrals were made on the basis of the NICE two-week referral guidelines, 10 patients were referred routinely and one patient was referred to emergency. Colorectal cancer was diagnosed in four of the 67 patients referred in the study, one as an emergency. All four of the cancers had a positive CAPER score, but only three fulfilled the NICE criteria.

Feedback

Only six GPs from the 25 practices agreed to be interviewed, four of whom were from reception-based practices and two from GP-prompted practices. They were generally positive about the study. GPs in reception-based practices found that patients who did not fit study-eligibility criteria still completed study consent forms, requiring GPs to answer questions regarding bowel symptoms and the research study. Receptionists in nearly all of the sites commented on the difficulties arising from handing out study packs, as there was often not enough time to identify whether a patient was aged 45 years or above, especially in busy periods. Thus, fewer study packs were being handed out by receptionists as the trial progressed. Conversely, in the GP-prompted practices, GPs did not feel that using the assessment tool to make a referral decision added much time to the consultation as only eligible patients received study information; furthermore, the intervention was reasonably similar to their routine practice. Those participating in GP-prompted practices were comfortable with recruiting patients and obtaining patient consent during a consultation.

Discussion

This paper describes a pilot study to test the feasibility of using a paper-based assessment tool

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to provide referral advice for suspected colorectal cancer in primary care. Overall, recruitment was lower than expected. However, of the three arms of the trial, recruitment was higher and more efficient in GP-prompted practices. Practice staff also preferred GP-prompted recruitment, as it was less disruptive.

Recruitment in the pilot study did not achieve our target, both because some eligible patients were not recruited and because we overestimated how many patients would be eligible. The initial recruitment target was based on a prevalence of individual bowel symptoms without the requirement for a duration of symptoms of two weeks. Once this duration is required, fewer patients become eligible. This difference is crucial in the design of future studies, including a definitive trial of the CAPER score. Recruitment figures were low in each arm of the study, but significantly more patients were recruited in GP-prompted practices. The main explanation for this difference is that, in reception-based practices, potential study-eligible patients did not always receive study materials from receptionists and could not be recruited into the study. The one-week audit data indicate that some eligible patients were not recruited by their GPs in GP-prompted practices as well. Nevertheless, reception-based recruitment was unfeasible due to the increasing frustration to GPs and receptionists caused by the general disruption in the practices.

GP adherence with the assessment tool was poor; tests were not ordered when directed for each patient and in many cases test results were not recorded on the assessment tool. These actions may have been justified if the patient was being referred urgently to secondary care, but otherwise could result in the patient not being referred when indicated. Use of a previous but recent Hb result to calculate the CAPER score for 19 cases was considered non-compliant with the assessment tool, but in practical terms is clinically justified.

Four colorectal cancers were identified in this small pilot study. All four cancers fulfilled the criteria for referral under the CAPER score, but only three met the current NICE guidelines. This study was not, however, powered to compare the proportion of cancers with symptoms satisfying the NICE guidelines compared with those meeting the CAPER score criteria.

Limitations

There are several limitations to this study. The majority of practices participating in the project were listed on university research networks, and it is possible that these practices were not representative of general practices as a whole. Similarly, practices agreeing to take part in the project may have had a special interest in colorectal cancer and therefore more experience in selecting appropriate referrals. Despite efforts to interview GPs in each of the 25 practices to gather constructive feedback, only six GPs agreed. Although GPs and receptionists preferred the GP-prompted methodology, we did not talk to patients on their attitudes towards recruitment into a research study during a consultation.

Overall, this study did show that of the three methods trialled in the pilot, the GP-prompted method was the most efficient and least disruptive means of recruiting patients into a trial in primary care. This method was not without its own problems, and issues concerning adherence to the assessment tool will need to be dealt with in any future work. Because recruitment was low, it is difficult to make any firm conclusions on the benefit of using the CAPER score in practice. This pilot project, however, was not intended to demonstrate the validity of the CAPER score, but to investigate the feasibility of its use in general practice.

Implications for future work

Several barriers can prevent effective implementation of clinical guidelines in primary care (Grimshaw and Eccles, 1998). These barriers may exist at a practice-based level, or may arise from the actions of the health care professional. In this study, the results suggest that the main barriers to effective implementation of the assessment tool were GP scoring of CAPER during and after the index consultation and the involvement of receptionists in patient recruitment. In order to design an effective future trial to test the CAPER score in practice, these barriers should be taken into account.

Improvements need to be made both to the design and to the delivery of the assessment tool in primary care. Practical instructions on when to order tests and exclude patients from the trial will guide GPs on use of the CAPER score and recruitment. Computerizing the assessment tool

and making it available on all practice computers may well improve compliance. Computer prompts could direct GPs to fill in each part of the CAPER score, with reminders to order tests and fill in results as they arrive at the practice. There is some evidence that GPs are interested in having guidelines and decision aids available on a computer; however, there still can be barriers to implementation, such as forgetting that aids are available if they are not used regularly (Watkins *et al*., 1999; Short *et al*., 2004). These issues need to be considered when designing a pragmatic version of the assessment tool.

Overall, the receptionists and GPs participating in this pilot study did not fully engage with the research project. Research considering the attitudes of receptionists participating in research is minimal (Lock *et al*., 2000), and it is likely that recruitment into research studies by receptionists is a low priority due to pressure of time. Future projects involving receptionists in research should consider the daily impact of the study on their workload (Lock *et al*., 2000). Factors influencing a GP's willingness to participate in research may include relevance of the research, personal interest in the topic and the time commitment required (Silagy and Carson, 1989; Ward, 1994). However, because only six generally positive GPs agreed to be interviewed, the reasons behind the GPs lack of engagement in this project are largely unknown.

Conclusion

This pilot study comparing three methods of patient recruitment in primary care found that although overall recruitment was lower than initially projected, recruiting patients during a GP consultation was the most effective method. Primary care researchers should be cautious when attempting to recruit patients by handing out study materials in practice waiting rooms. There is a need for high-quality research in primary care to look at mechanisms to improve referrals and achieve earlier diagnosis of colorectal cancer. It is vital to engage the clinicians and practice staff to participate in research in primary care. This study emphasizes the importance of conducting pilot work, as potentially significant issues can be identified and taken into account when designing a main trial.

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Contributors

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Members of the Colorectal Subgroup of the NCRN Primary Care Clinical Studies Development Group took part in the design and implementation of the study, and approved the final manuscript. The membership of the Colorectal Subgroup of the NCRN Primary Care Clinical Studies Development Group includes Joan Austoker, Christine Campbell, Michael Gordon, Willie Hamilton, Moyez Jiwa, Peter Rose, Greg Rubin, Eila Watson, Alison Ward and David Weller.

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Declarations

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Ethics committee and reference number: Ethical approval was granted by the Oxfordshire REC C (ref.: 05/Q1606/108).
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Appendix 1

Universities of Bristol
Edinburgh
Oxford
Sheffield
Sunderland

Study Co-ordinating Centre
Department of Primary Health Care
University of Oxford

Improving the accuracy of diagnosis in patients with bowel symptoms

Assessment Tool

22/09/05, Version 2

Date of consultation _____

GP name _____

Patient name _____

Patient date of birth _____

Patient gender _____

For site use	
Centre ID	
Study ID	
Completed	

For co-ordinating centre use			
A	S		

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Step 1 - Eligibility for study

Inclusion criteria for this study	*Exclude patient (please describe why)*
1. **One or more of the symptoms listed below, present for ≥ 2 weeks** 2. **Aged 45 years or more** 3. **No current diagnosis of bowel cancer** 4. **No previous diagnosis of bowel cancer**	

Step 2 - Patient symptoms (one or more symptom present for 2 or more weeks)

1. Harder or less frequent stool (present for 2 or more weeks)
☐ Yes (do not need number of consultations)
☐ No

2. Looser or more frequent stool
☐ Yes number of consultations in last 6 months _____
☐ No

3. Pain in the lower abdomen
☐ Yes → number of consultations in last 6 months _____
☐ No

4. Unexplained loss of weight
☐ Yes
☐ No

5. Bleeding from the bowel
☐ Yes
☐ No

Step 3 - Clinical investigations

Investigation	Performed	**Results**
Clinical Exam	☐ Yes ☐ No	Abdominal mass present ☐ Yes ☐ No
Rectal Exam	☐ Yes ☐ No	Rectal mass present ☐ Yes ☐ No
FBC	☐ Yes ☐ No	Hb _____ g/dL
FOB Include if no bleeding from the bowel	☐ Yes ☐ No	☐ Negative ☐ Weakly positive ☐ Positive

Did the patient refuse any investigations? *(If so, please specify)* _____

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Step 4 - Referral decision - Please complete this page for every patient

DH Referral guidelines for suspected cancer (June 2005)	Study referral score
Refer under two week referral system if the patient has <u>any</u> of the following: **<u>Any age</u>** ☐ Right lower abdominal mass consistent with involvement of the large bowel ☐ Palpable rectal mass (intraluminal and not pelvic) ☐ Unexplained iron deficiency anemia and a haemoglobin of: ≤ 11 g/dL in **men** **OR** ≤10 g/dL in **non-menstruating women** **<u>Aged 40 years and older</u>** ☐ Rectal bleeding WITH a change in bowel habit towards looser stools and/or increased stool frequency persisting 6 weeks or more **<u>Over age 50 *</u>** ☐ Rectal bleeding persisting for 6 weeks or more WITHOUT a change in bowel habit **<u>Aged 60 years and over</u>** ☐ Change in bowel habit to looser stools and/or more frequent stools persisting for 6 weeks or more WITHOUT rectal bleeding * Consistent with Scottish Referral Guidelines for Suspected Cancer	**If patient does not meet DH guidelines then consider study referral critera:** **Refer immediately if** ☐ **FOB +** **OR if the following score ≥ 35 points** ☐ A **Harder or less frequent stool Score 20 points** (present for 2 or more weeks) ☐ B **Looser or more frequent stool** For each consultation in last 6 months **Score 10 points (max 40 points)** ☐ C **Abdominal pain** For each consultation in last 6 months **Score 15 points (max 45 points)** ☐ D **Loss of weight Score 20 points** ☐ E **Hb (both men & women)** 12-13 g/dL **Score 20 points** 10.1-11.9 g/dL **Score 30 points** **Total score (sum A through E)** ☐ **Refer urgently if total score ≥ 35 points using study referral letter** **If total points < 35 points observe in primary care**

Please make any comments you feel are relevant to your decision

Referral details

Urgency of referral
- ☐ DH two week referral
- ☐ Study referral
- ☐ Routine referral
- ☐ Other, please specify _____

Specialty of referral
- ☐ Surgery
- ☐ Gastroenterology
- ☐ Medicine
- ☐ Gynaecology
- ☐ Other _____

Referred at 1st consultation
- ☐ Yes
- ☐ No

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