COLON CANCER

The Department of Health's ''two week standard'' for bowel cancer: is it working?

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Objective: To determine the effectiveness and efficiency of the Department of Health's new general practitioner referral guidelines for bowel cancer.
Design: One year prospective audit.
Setting: District general hospital serving a population of 550 000.
Subjects: All patients with bowel cancer; all patients referred on the basis of the two week standard and to a routine colorectal surgical outpatient clinic.
Main outcome measures: Proportion of cancers referred on the basis of the two week standard and to other colorectal clinics; the proportion with the higher risk criteria and their diagnostic yields; stage of cancers diagnosed in outpatient clinics; and time to treatment.
Results: A total of 249 cancers were diagnosed in the index year. Sixty five (26.1%) were referred to two week standard clinics, 40 (16.1%) to routine colorectal surgical outpatient clinics, 54 (22%) to other clinics, and 88 (35.3%) were emergencies. Thirteen patients per week were referred to the two week standard clinics and 85% (54/65) of cancers so referred were seen within two weeks. The diagnostic yield of cancer in the two week standard clinic was 9.4% (65/695) compared with 2.2% (40/1815) in the routine colorectal surgical outpatient clinic ($p<0.0001$). Eighty five per cent of patients with cancer referred to outpatients matched the guidelines for the two week standard clinics. Only 46% of this group were so referred. Overall, delay to treatment and Dukes' stage were not improved in patients diagnosed in the two week standard clinics.
Conclusions: Most patients with bowel cancer were not referred on the basis of the two week standard although most fulfilled the referral criteria, which had higher diagnostic yields. The two week standard clinics did not shorten the overall time to treatment or improve the stage of disease because the time lags before referral and after the outpatient appointment are the major causes of delay in the bowel cancer patient's journey.

The UK Government decided that from the 1 July 2000, all patients suspected by their general practitioner of having bowel cancer should be seen by a specialist within two weeks of the date of referral.[1] Guidelines were developed to help general practitioners decide which patients merited referral on this basis.[2 3] Six higher risk age/symptom/sign criteria aimed to identify up to 90% of all bowel cancer patients currently referred to outpatients.

This prospective audit was designed to evaluate:

- The proportion of patients with bowel cancer referred on the basis of the two week standard.
- The percentage of all cancers referred to outpatients fulfilling at least one of the higher risk referral criteria, and the diagnostic yield of cancer in the two week standard clinics compared with a routine clinic.
- The times from general practitioner referral to the outpatient appointment, the overall time to treatment, and stage of disease at diagnosis.
- How the referral criteria were used by general practitioners

METHODS

Patients in the study

The study comprised all patients in Portsmouth diagnosed as having bowel cancer from 1 July 2000 until 30 June 2001, including emergencies, and all other patients referred on the basis of the two week standard and to routine colorectal surgical outpatient clinics.

Two week standard referrals were faxed to a dedicated telephone number using a proforma listing the six Department of Health higher risk criteria (table 1) with a tick box format. This mode of referral was refused by one general practice (76/77) whose patients so referred were seen urgently in the routine clinics. Referrals with criteria 1–5 (table 1) had specially reserved appointments in routine clinics and previously established rapid access flexible sigmoidoscopy clinics run by three consultant colorectal surgeons, two general practitioners, and a colorectal nurse specialist. Patients with criterion 6 (table 1) were referred directly to medical gastroenterology clinics. However, in the text, for simplicity, patients referred on the basis of the two week standard are referred to as having been seen in ''two week standard clinics''.

Measures of delay in the process of care

The time from the date of onset of the first symptom to the date of the general practitioner's referral letter, the time from the general practitioner's referral to the outpatient appointment, and to surgical or definitive treatment.

History and examination

This was recorded in all patients attending the routine colorectal surgical outpatient clinics and two week standard clinics on a data collecting form with a tick box proforma before flexible sigmoidoscopy. This, together with the hospital notes for cancer patients not seen in these clinics, was used to determine the total number of cancers with the higher risk criteria initially referred to outpatients.

Table 1 Department of health higher risk criteria

	Criteria	Elements of the criteria
1	Rectal bleeding *with* a change in bowel habit to looser stools and/or increased frequency of defecation persistent for 6 weeks. All ages	(i) Correct change in bowel habit (ii) Rectal bleeding (iii) Symptoms present for at least 6 weeks (iv) New symptoms; history not exceeding 18 months
2	Change in bowel habit as above *without* rectal bleeding and persistent for 6 weeks. Over 60 y	(i) Correct change in bowel habit (ii) Rectal bleeding not present (iii) Age ⩾60 y (iv) Symptoms present for at least 6 weeks (v) New symptoms; history not exceeding 18 months
3	Rectal bleeding persistently *without* anal symptoms.* Over 60 y	(i) Rectal bleeding (ii) Change in bowel habit not present (iii) No perianal symptoms (iv) Age ⩾60 y (v) Symptoms present for at least 4 weeks (vi) New symptoms; history not exceeding 18 months
4	A definite palpable right sided abdominal mass. All ages	(i) Right sided abdominal mass
5	A definite palpable rectal mass (not pelvic). All ages	(i) Intralumenal rectal mass (not pelvic)
6	Unexplained iron deficiency anaemia All ages for men, postmenopausal women	Women over 50 y (postmenopausal), haemoglobin ⩽10 g; men: haemoglobin ⩽11 g

It was recommended that these age/symptom/sign profiles when they were new and persistent should be used to identify patients for prompt referral on the basis of the two week standard. It was estimated that these higher risk criteria would identify 85–90% of all patients with bowel cancer presenting to the outpatient department.
*Anal symptoms include soreness, discomfort, itching, lumps, and prolapse, as well as pain.

The diagnostic yields of the six higher risk referral criteria

These were determined on the basis of the general practitioner's referral proforma to the two week standard clinics, and the outpatient proforma as completed by the hospital clinicians.

Statistics

The Fisher's exact test and the Mann-Whitney U test were used to determine the significance of differences.

RESULTS

Patients referred and number of cancers diagnosed

A total of 758 patients were referred to the two week standard clinics, of whom 695 attended (13 per week); 303 were male, median age 70 years (range 25–93). A total of 1815 patients attended the routine colorectal surgical outpatient clinics; 801 were male, median age 58 years (range 13–94).

The total numbers of patients attending all colorectal surgical clinics has steadily increased over the past five years from 1598 in 1998 to 1941, 2487, 2437, and 2691 in 2002.

Table 2 Patient pathways to diagnosis of bowel cancer

	No (%)
Emergency admission	88 (35.3)
Two week standard clinics	65 (26.1)
Colorectal surgical outpatient clinics	40 (16.1)
Medical gastroenterology clinics	39 (15.7)
General surgical clinics*	11 (4.4)
Geriatric clinics	4 (1.6)
Other†	2 (0.8)
Total	249 (100)

*Including one patient seen as follow up to previous colorectal cancer surgery and one in a urology clinic.
†One patient was diagnosed in primary care and referred directly, and one other was an incidental diagnosis in a patient admitted for other reasons.

Two hundred and forty nine patients were diagnosed as having bowel cancer in the year of the study (table 2); 35% (88/249) were admitted as emergencies. A total of 159 were seen in outpatient clinics, 65 (41%) of whom were seen in the two week standard clinics (table 2).

The diagnostic yield of bowel cancer was significantly greater in the two week standard clinics compared with the routine colorectal surgical outpatient clinic: 9.4% (65/695) versus 2.2% (40/1815) ($p<0.0001$) (table 3).

Diagnostic yields of the higher risk criteria

The diagnostic yields for each of the higher risk criteria, as defined by the general practitioner from the referral proforma or hospital clinician, are shown in table 3.

Overall, 39% (274/695) of patients referred to the two week standard clinics did not fulfil at least one of the six referral criteria (table 3). The overall diagnostic yield of the criteria was highest (13.8%) when calculated from hospital clinician's data (table 3).

Twenty six per cent (478/1815) of patients referred to the routine colorectal surgical outpatient clinics would have fulfilled one of the higher risk criteria (table 3). The overall diagnostic yield of the higher risk criteria in the routine clinics was lower, mainly due to criterion 1 (table 3) which did not have an age threshold (table 1).

Proportion of cancer patients with the higher risk criteria referred to outpatients

Ninety two per cent (147/159) of cancers diagnosed in outpatients had a complete record of their history and examination. Of these, 85% (125/147) fulfilled at least one of the higher risk criteria, as determined by the hospital clinician (table 4). Forty six per cent (58/125) of cancer patients with the higher risk criteria were referred to the two week standard clinics (table 4).

Cancer patients not fulfilling the higher risk criteria

Fifteen per cent (22/147) of cancers referred to the outpatient clinics did not fulfil at least one of the higher risk criteria.

Table 3 Comparison of the diagnostic yields of the higher risk criteria in patients referred to either the two week standard or routine colorectal surgical outpatient clinics

	Two week standard clinics				Colorectal surgical outpatient clinics	
	General practitioner data		Hospital clinician data		Hospital clinician data	
Criteria	No of cancers/all patients	%	No	%	No	%
1. +B +C	28/202	13.9%	26/170	15.3%	10/294	3.4%
2. +C −B >60 y	17/278	6.7%	11/172	6.4%	6/118	5.1%
3. +B −C −P >60 y	17/160	10.6%	4/31	12.9%	5/33	15.2%
4. Abdominal mass	7/43	16.3%	4/22	18.2%	2/18	11.1%
5. Rectal mass	12/53	22.6%	13/28	46.4%	7/17	41.2%
6. Iron deficiency anaemia	6/55	10.9%	6/53	11.3%	3/10	30.0%
Total	65/695	9.4%	58/421	13.8%	27/478	5.6%
Other referrals	–	–	7/274*	2.5%	12/1326	0.9%
Total					40*/1815	2.2%

*Includes two patients with unknown history.
B, rectal bleeding; C, change in bowel habit; P, perianal symptoms; +, symptom present; −, symptom absent.

One patient was diagnosed by screening. Eleven (11/22; 50%) patients had the correct symptoms or signs but two were below the age threshold, six had too short and two too long a history to fit the criteria, and one presented with an iron deficiency anaemia outside the threshold. Ten patients (10/147; 7%) of all the outpatient cancers presented without any elements of the higher risk criteria: four with a change in bowel habit to harder stools and/or decreased frequency of defecation (one of whom also had rectal bleeding without anal symptoms), two had abdominal pain as a single symptom, one of whom had hepatomegaly from metastatic disease, and four had rectal bleeding with perianal symptoms. Two of these patients had pile symptoms for years and were diagnosed as having polyp cancers which may have been incidental diagnoses.

Incorrect use of guidelines

Of patients referred with criteria 1–3 to the two week standard clinics, 22% (140/640) had too short a history (criterion 3, less than four weeks; criteria 1 and 2, less than six weeks; table 1); 13% (81/640) had too long a history (more than 18 months); 8% (33/438) of patients were too young; and 26% (165/640) had at least one incorrect symptom.

Ninety one per cent (145/160) of patients referred on the basis of criterion 3 had at least one element incorrect, mostly rectal bleeding with anal symptoms.

In 72% (31/43) of patients referred on the basis of having a palpable right iliac fossa mass (criterion 4), this was not confirmed by a hospital clinician, and similarly for 72% (38/53) of patients referred on the basis of an intraluminal rectal mass (criterion 5). In contrast, 95% (52/55) were correctly referred on the basis of an iron deficiency anaemia (criterion 6).

Delays to treatment

Outpatient delays were significantly less when patients were referred to the two week standard clinics compared with the routine colorectal surgical outpatient clinics (12 days *v* 27 days; $p<0.0001$) (table 5). The overall delay to treatment from the date of the referral letter was not significantly different (table 5). Six per cent (9/146) of all cancers referred to outpatients had a wait of longer than 50 days. There were similar delays to treatment for patients with and without the higher risk criteria referred to the routine colorectal surgical outpatient clinics (table 5).

The greatest delays occurred before the referral letter and after the outpatient visit; less than 10% of the total delay was waiting for an outpatient appointment (Table 5).

Dukes' stage of cancer

The Dukes' stage was not affected by referral to the two week standard clinic; two week standard versus other clinics: Dukes' A, 9% versus 15%; Dukes' B, 46% versus 38%; and Dukes' C, 44% versus 46%.

DISCUSSION

The UK Government introduced the two week standard[1] because some bowel cancer patients were experiencing long delays waiting for an outpatient appointment.

The Department of Health suggested six higher risk criteria to help general practitioners select patients who merited

Table 4 Proportion of cancers with each of the Department of Health (DoH) higher risk criteria‡

	Two week clinic		All other clinics		All clinics	
DoH higher risk criteria	No	%	No	%	No	%
1. +B +C	26	40%	23	28%	49	33%
2. +C −B ⩾60 y	11	17%	14	17%	25	17%
3. +B −C −P >60 y	4	6%	8	10%	12	8%
4. Abdominal mass	4	6%	9	11%	13	9%
5. Rectal mass	13	20%	12	15%	25	17%
6. Iron deficiency anaemia	6	9%	16	20%	22	15%
7. Total with at least one of the DoH criteria	58	89%	67	82%	125	85%
8. Cancer with none of higher risk criteria	7	11%	15	18%	22	15%
Total cancers	65*	–	82†	–	147†	–

*Some patients had more than one higher risk criteria.
†In 12 patients the full criteria were unknown.
‡As determined by hospital examination.
B, rectal bleeding; C, change in bowel habit; P, perianal symptoms; +, symptom present; −, symptom absent.

Table 5 Delays in the cancer patient's journey

Clinic	Delay (days) (median (range))				
	No of cancers	PGP	OP	HD	TD
TWS	65	57 (1–3640)	12 (5–64)	56†(21–274)	161 (5.3 m) (54–3821)
CSOP					
Higher risk criteria	27	104 (2–1083)	28 (4–203)	49†(14–332)	252 (8.6 m) (55–1188)
Low risk criteria	12	65 (15–702)	26 (6–96)	49 (16–79)	133 (4.5 m) (38–749)
Total	40*	95 (2–1083)	27 (4–203)	49 (14–332)	227 (7.7 m) (38–1188)
Total	105	76 (1–3640)	13 (4–203)	55 (14–332)	171 (5.7 m) (38–3821)

*One patient had an unknown date of onset of symptoms.
†Two patients were excluded who made a decision not to have treatment at the outpatient appointment and would have been scored as having a zero delay in the hospital part of their cancer journey. If they had been included, the overall values would have changed little.
TWS, two week standard clinic; CSOP, colorectal surgical outpatient clinic; PGP, patient+GP delay; OP, outpatient delay; HD, hospital delay; TD, total delay; m, months.

referral on this basis.[2 3] The effectiveness and efficiency of the new policy depended on the collective sensitivity and specificity of the referral criteria for cancer, the ease with which general practitioners could identify the criteria, and to what extent they chose to use the new service.

In this study, only 41% of cancer patients first seen in outpatients were referred to the two week standard clinics. However, as these had a fivefold greater diagnostic yield of cancer compared with the routine colorectal surgical outpatient clinics (9.4% *v* 2.2%), and 85% of all cancers referred to outpatients had at least one of the six Department of Health criteria, this suggests the guidelines are valid.

Other audits have shown that the proportion of cancers referred to the two week standard clinics is generally less than 50%, that substantial numbers match the referral criteria, and that these have higher diagnostic yields for cancer.[4–28] Some studies[21 24 26 27] have suggested that the guidelines are valid although this has been questioned by others.[29]

In Portsmouth, the number of referrals to the two week standard clinics could be accommodated relatively easily in previously established rapid access flexible sigmoidoscopy clinics and in urgent slots in routine clinics. It is likely that many of these patients would have been referred before the introduction of the two week standard, and as there has been an increase in the numbers of patients attending colorectal surgical clinics before the introduction of the two week standard, it is difficult to determine whether this has resulted in any further increase in referrals.

However, the previously established rapid access flexible sigmoidoscopy clinics may have facilitated the introduction of the two week standard in Portsmouth. The small reduction in outpatient delay achieved by the two week standard clinics had little impact on the overall delay to treatment. The longest delay, as shown previously,[30] occurred between the onset of symptoms and general practitioner referral. As the proportion of patients suffering unavoidable delays for outpatient appointments before the introduction of the two week standard is not known, it is now impossible to assess its overall benefits. In this study, only 6% of patients now suffer outpatient delays of longer than 50 days, which were mainly for patient reasons. This suggests that general practitioners and hospital consultants found little difficulty in prioritisation of the majority of cancer patients not referred to two week standard clinics, which diminishes the potential benefit of this new policy.

It is disappointing that over 50% of cancer patients, who met the referral criteria, were not referred to the two week standard clinics. However, until the reasons for this are determined, it should not be assumed that all of these patients were incorrectly referred.

The Advisory Group developing the referral guidelines emphasised the importance of the way the guidelines were implemented.[3] The simple introduction of guidelines with the conventional forms of continuing medical education has been shown to be ineffective in changing doctors' practice.[31 32] Closer adherence to the guidelines in the future might be improved by personalised feedback from the hospital clinicians to the general practitioners,[33 34] particularly emphasising the importance of not referring patients on the basis of the two week standard with transient symptoms or symptoms of over 18 months' duration, and raising awareness of the diagnostic value of rectal bleeding without anal symptoms. It is also possible that some of the inappropriate referrals to the two week standard clinics could be avoided if it was made clear to general practitioners that patients they felt needed to be seen quickly, but not fulfilling one of the referral criteria, could still be seen promptly in routine clinics on an urgent basis, the "third way" of referral.[2 3 35]

Even if general practitioners could easily identify the 85% of cancer patients with the higher risk criteria for prompt referral, this would still leave 15% of cancers that could experience long delays. The only way to avoid delays for all cancers is to provide sufficient resources for all patients with lower gastrointestinal symptoms to be seen within two weeks. The need for the introduction of the two week standard arose because of the mismatch between the number of referrals and the resources available, and although it is probably important to continue to select those patients most likely to benefit from referral to hospital, the long term solution must be to increase outpatient capacity so that all of those that are referred are seen quickly.

CONCLUSION

Less than 50% of bowel cancers referred to outpatient clinics were seen in the two week standard clinics. However, as 85% of cancers referred to outpatients did fulfil at least one of the higher risk referral criteria, and the criteria had significantly greater diagnostic yields for cancer, this suggests the guidelines are valid. Although cancer patients referred to the two week standard clinics were seen more quickly, this did not reduce the overall time to treatment or stage of disease at surgery. Ultimately, the value of the two week standard is small in the context of a process of care that is slow both before referral and after being seen in outpatients.

The introduction of this new policy should not deter the UK Government from providing adequate resources so that all patients referred, regardless of their cancer risk, can be seen within two weeks.

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