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THE EFFECTIVENESS OF THE 'TWO-WEEK WAIT' REFERRAL SERVICE FOR COLORECTAL CANCER

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2 TITLE PAGE
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8 COLORECTAL CANCER
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2 SYNOPSIS PAGE
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7 **Running title:** Effectiveness of two-week wait service
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910
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13 **Synopsis:**14
15 Stricter inclusion criteria are required
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4041 **Contributions:**

42 EL supervised collection of data, presented the data and researched articles

43 JG wrote the manuscript and performed literature search

44 NB collected data, drawn up abstract

45 LW designed and supervised the project
46
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1
2 ABSTRACT
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7 **Introduction:** The UK government target expects all suspected cancer patients to be seen within 2
8 weeks of referral made by general practitioners. This has significant impact on the workload for
9 colorectal surgeons. The aim of the study is to investigate the effectiveness of this colorectal
10 service.
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21 **Method:** A retrospective study of all patients referred to a two week wait colorectal clinic over a 12
22 month period was assessed, documenting diagnosis and staging. Comparison of patients diagnosed
23 with colorectal cancer presenting via other routes in the same period was made.
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33 **Results:** Over the 12-month period, all 1100 patients were seen in the two-week wait clinic; 938
34 (85%) patients fulfilled the referral criteria but only 81 (7.3%) were diagnosed with cancer.
35 Conversely, 136 colorectal cancer patients presented to the surgeons via urgent referrals (n=86),
36 emergency (n=13), routine colorectal clinic (n=19) and bowel screening (n=18). The two-week
37 cohort had more advanced staging than those referred by standard letter and pilot screening.
38 Cancers in the symptomatic population are predominantly Dukes' B and C where as in pilot
39 screening group predominantly Dukes' A.
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53 **Conclusion:** The effectiveness of two-week wait referral was poor confirming its lack of validity.
54 Further work is required to offer primary care stricter inclusion and exclusion referral criteria.
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INTRODUCTION:

Colorectal cancer (CRC) is the third commonest cause of cancer related death (after breast and lung) in the United Kingdom. Around 100 new cases of colorectal cancer are diagnosed in the UK each day¹. Despite recent advances in medical treatment and diagnostic technology, a high proportion of patients with CRC present with advanced disease with 5-year survival rates of 49.6% in men and 50.8% in women². Furthermore, mortality from CRC in the UK is above that of our European counterparts³.

Some cancer patients were experiencing significant delays waiting for an out-patient appointment in secondary care, which may lead to delay in diagnosis and advancing stage of disease². In order to facilitate access to a colorectal specialist, the Department of Health compiled the NHS Cancer Plan in 2000. Part of this NHS Cancer Plan consisted of the Two-Week Rule (TWR), which states that all units were required to see 95% of potential cancer patients.

The aim of the TWR was in part designed so patients with symptoms highly suspicious of CRC were seen in secondary care within 14 days, leading to prompt assessment and investigation. This in turn may lead to prompt treatment and therefore reduce morbidity and mortality. A set of referral criteria for the TWR was devised for each type of cancer.

These TWR referral criteria for CRC, introduced by the UK Government in 2000, were specifically designed to guide general practitioners (GPs) decide which patients merited referral on this basis, selecting symptomatology that was associated with a high risk of CRC^{2,4} (Table 1). Therefore any patient suspected of having CRC by their GPs will be seen within two weeks of the referral date⁵.

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Table 1: Specific Referral Guidelines for Two Week Rule

1	Patient ≥ 40 with rectal bleeding AND change in bowel habit +/- increased stool frequency for >6 weeks
2	Patients ≥ 60 with change in bowel habit for >6 weeks WITHOUT rectal bleeding
3	Patients ≥ 60 with rectal bleeding for >6 weeks WITHOUT anal symptoms and WITHOUT change in bowel habit
4	Any patient with lower abdominal mass
5	Any patient with palpable rectal mass
6	Men of any age with unexplained iron-deficiency anaemia and Hb $< 11\text{g}/100\text{ml}$
7	Post menopausal women with unexplained iron-deficiency anaemia and Hb $< 10\text{g}/100\text{ml}$

The provision of consulting 95% of referrals by colorectal specialists within 14 days has a significant impact on the workload of any colorectal surgeon. Since all TWR patients are high risk for CRC, therefore, more time for each consultation is required. It increases pressures on clinic times and has a knock-on effect on routine referrals. Chohan *et al*⁴ in 2001 reported that the TWR did accelerate access to specialist colorectal clinic, however, pick-up for CRC in this population of patients was low at 27%.

The aim of this study was to assess the effectiveness of the TWR referral system in terms of CRC detection and the impact it has on cancer staging.

METHODS:

All patients referred to colorectal clinic via the TWR referral system in a national CRC screening centre was assessed over a 12 month period. Data relating to final diagnosis following secondary care investigations and cancer staging was collected retrospectively. Moreover, comparison was made with CRC patients presenting via other routes (i.e. not via the TWR system) during the same time period. Chi square test with Yates' correction was used to assess statistical significance.

Non-TWR referrals were categorised into urgent (consultation occurred within 4 weeks) or routine out-patients referrals (consultation occurred within 18 weeks), patients presented with rectal bleeding referred from other secondary care specialities, pilot CRC screening patients and patients referred by primary care as an emergency. For the purpose of our study, even patients with cancer metastasis were grouped into Dukes C.

RESULTS:

Over the 12 month period of the study a total of 1100 patients were referred to colorectal clinics via the TWR referral system. All of these patients (100%) were seen by the target time of two weeks. Of these, 85.3% (n=938) of patients fulfilled the criteria for referral via the TWR. Of those referred, 7.3% (n=81) of patients were diagnosed with CRC.

MODE OF PRESENTATION:

Over the study period there were 217 patients diagnosed with CRC for the first time. Of these 63% (n=136) were referred via alternative routes to the TWR (Table 2). The two most common referral methods were via the TWR (37%) and urgent out-patient clinic appointments (40%).

Table 2: Different modes of colorectal cancer referrals.

Two-week referral	N=81	37%
Pilot Screening	N=18	8%
Routine out-patient referral	N=12	6%
Emergency presentation	N=13	6%
Rectal bleeding	N= 7	3%
Urgent out-patient referral	N=86	40%

CANCER STAGING:

Dukes A:

Dukes A accounted for 15.7% of all CRC diagnosed in the study year. 14.7% and 8.8% of Dukes' A CRC patients were referred via pilot screening and routine clinic appointments respectively. 41.2% of patients with Dukes A CRC patients were referred via the TWR system (Table 3). There were no Dukes' A those patients, who presented as an emergency. Statistically, TWR referrals identified significantly more Dukes A patients compared with referrals from pilot screening, routine appointments, rectal bleeding and emergency presentation ($p=0.0001$). Urgent referrals had similar share of Dukes A patients ($p=0.24$).

Dukes B:

Dukes B accounted for 32.7% of all CRC diagnosed in the study year. Similarly, TWR and urgent out-patient referrals had similar incidence of Dukes B patients ($p=0.31$). There were significantly more Dukes B patients identified amongst the TWR referrals than other modes of presentation ($p=0.0001$).

Dukes C:

Dukes C accounted for 51.6% of all CRC diagnosed in the study year. This cohort of patients, who were referred via the TWR system, had a significantly higher incidence of Dukes' C cancers (33.0%) than those patients referred by pilot screening (4.5%), routine appointments (6.3%), rectal bleeding (3.6%) and emergency referrals (7.1%) ($p=0.0001$). There was a similar incidence of Dukes' C cancers compared with groups referred via urgent clinic appointments (45.5%) ($p=0.11$).

Table 3: Dukes' Staging According to Referral Method:

REFERRAL	DUKES' A	DUKES' B	DUKES' C
Two-week referral	N=14, 41.2%	N=30, 42.3%	N=37, 33.0%
Pilot Screening	N= 5, 14.7%	N= 8, 11.3%	N= 5, 4.5%
Routine Out-patient Referral	N= 3, 8.8%	N= 2, 2.8%	N= 7, 6.3%
Emergency Presentation	N= 0, 0%	N= 5, 7.0%	N= 8, 7.1%
Rectal Bleeding	N= 1, 2.9%	N= 2, 2.8%	N= 4, 3.6%
Urgent Out-Patient Referral	N=11, 32.4%	N=24, 33.8%	N=51, 45.5%

DISCUSSION:

The TWR referral system was initially introduced so that patients with symptoms suspicious of a CRC were seen within 14 days by a colorectal specialist in order to aid speedy investigations and diagnosis. By achieving faster diagnosis, treatment could be initiated earlier leading to a reduction in morbidity and mortality.

The results of our study have shown that very few patients (7.3%) who were referred via the TWR were actually diagnosed with CRC. This means that more than 90% of patients who fulfilled the set criteria for a TWR referral (see Table 1) actually had benign disease requiring no urgent treatment. Despite all the research that went into formulating the TWR guidelines¹, it would appear that they do not exhibit much specificity and therefore the detection of CRC has been generally low⁶. Such guidelines imposing on these patients being consulted within two weeks, this puts excessive pressure on specialist surgeons despite the fact the majority actually had benign disease. Just as many cancers presented via urgent referrals rather than TWR, but with clinic time emphasis being put on TWR, patients being referred via other means were potentially not seen as quickly.

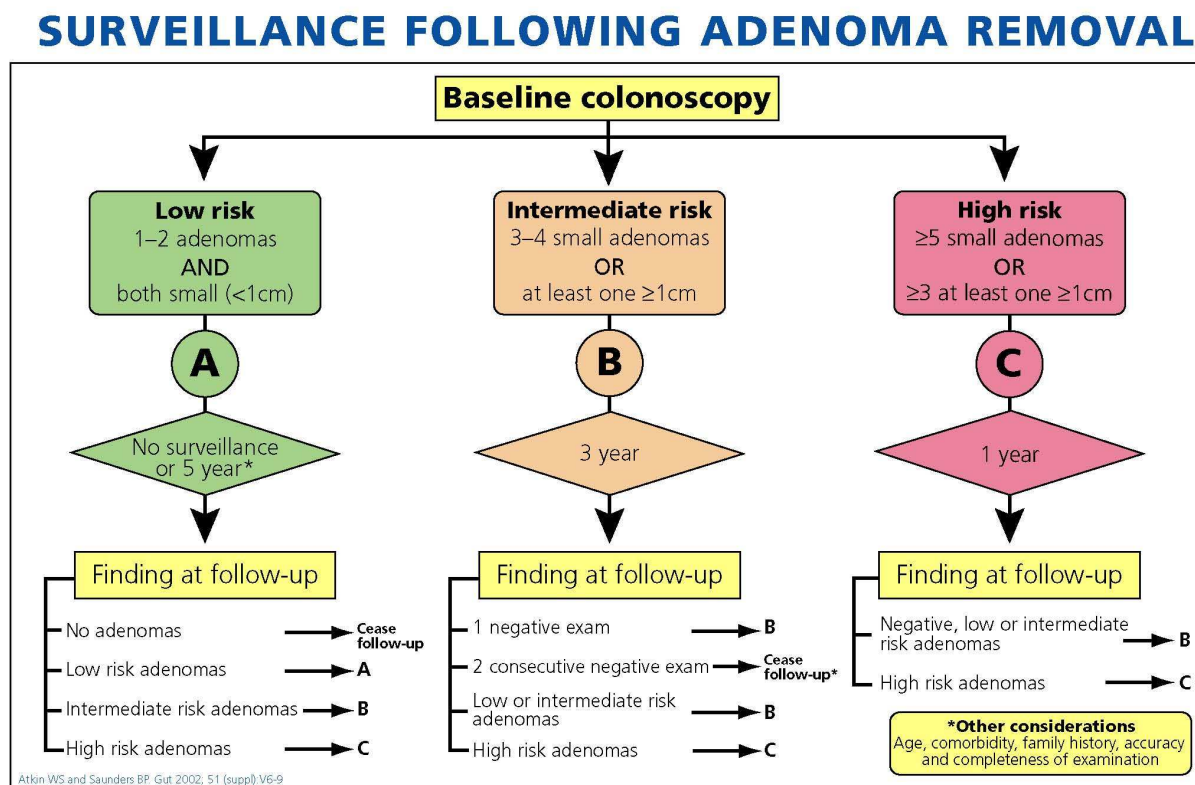
One study⁷ has shown that there is a wide variability in the detection of CRC depending on which primary care trust has referred them. In that study, GP practices that were found to have a low correlation between the number of TWR referrals and CRC diagnosis were also found to be under utilizing the pathway, meaning they were referring actual patients who had cancer via alternative routes. Furthermore, it found that 22% of GPs were unaware of the TWR guidelines and only 8% knew the number of referral criteria. This would account for the large numbers of CRC patients referred via alternative routes and also those referred via the TWR pathway gave a low yield.

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2 Our study has shown that of all patients that were diagnosed with CRC during our study period,
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4 63% patients were referred via a method other than the TWR system. There was no difference in
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6 cancer staging between TWR system and urgent referral, suggesting that selective patients could be
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8 seen within 4 weeks as opposed to 2 weeks. Obviously, the cancer patients detected by pilot
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10 screening would have been asymptomatic and never fulfilled the TWR set criteria.
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16 The TWR system depends solely on the assessment of GPs and appointments given to patients are
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18 then dependent on the referral letters. However, Aljarabah *et al*⁸ concluded in their study that GP
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20 referral letters for patients with suspected CRC were largely inaccurate and appropriate
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22 investigations and suspected diagnosis could only be adequately carried out once a colorectal
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24 specialist had consulted and examined the patient.
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30 It is ostensible that the TWR criteria may require revision in order to increase its specificity and
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32 positive predictive value. With many hospital trusts introducing one-stop clinics with history,
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34 examination and flexible sigmoidoscopy, resources are overwhelmed. One example that is seen
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36 frequently in secondary care is that, despite patients fulfilling the set criteria for TWR referral, these
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38 patients had already been fully investigated within 12 months but were still referred. GPs need to
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40 consider the guidelines set out by the British Society of Gastroenterology (figure 1) for those
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42 previously investigated prior to sending these patients on the TWR system again.
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Figure 1. British Society of Gastroenterology guidelines for surveillance by colonoscopy



Our results on Dukes' staging indicated no evidence to support that the TWR referrals system promoted detection of lower Dukes staging of CRC, which would otherwise reflect better prognosis. The development of CRC takes many years; therefore, by the time patients had symptoms, which fulfilled the TWR criteria they were already likely to have invasive disease. The pilot screening programme, in this study, even at preliminary stage showed detection of more Dukes B than C. This left shift of Dukes staging was observed in the 5-year pilot screening programme in an earlier study⁹. The national screening programme is so far the only mode of referral, which is proven to detect early cancer and improve patient prognosis.

CONCLUSION:

The TWR referral system has a moderate yield for detecting patients with CRC, but did not appear to improve prognosis even if patients were consulted within 14 days. The set criteria for TWR may warrant revision. Our preliminary results suggest that as long as patients were seen reasonably urgently, there would be no significant difference in prognosis.

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