

Updated 'two-week wait' referral guidelines for suspected colorectal cancer have increased referral volumes without improving cancer detection rates

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Abstract

Introduction: In November 2015, the National Institute for Clinical Health and Care Excellence updated its two-week wait (2WW) referral guidelines for suspected colorectal malignancy. This study measured the effect of the change in 2WW referral guidelines on: (i) the volume of 2WW referrals, (ii) the rates of detection of cancer in those patients referred to the 2WW service, and (iii) adherence to the referral guidelines.

Methods and materials: A retrospective case note review of all colorectal cancer 2WW referrals during two periods (July to August 2015 and July to August 2016), to a large inner-city teaching hospital, was undertaken. Cancer detection rates were calculated based on diagnosis obtained from review of patient clinical records and were cross-referenced against the regional cancer registry database.

Results: There was a significant increase in the numbers of patients referred to the colorectal 2WW service in the period following the change in guidelines (193 vs. 268, $p < 0.01$). There was no significant change in the rate of colorectal cancer detection between the two periods observed (8.3% vs. 7.5%, $p = 0.75$), although adherence to the referral guidelines increased (72% vs 89%, $p < 0.01$).

Conclusion: Changes to the 2WW referral criteria have led to an increased number of patients being referred, but have not resulted in a change in the rate of colorectal cancer detection. Further work should seek to assess the impact on survival rates from colorectal cancer, and to contextualise these findings with wider trends in non-2WW routes to diagnosis.

Keywords: Colorectal cancer, Two-week wait

Abbreviations: 2WW - two week wait

Introduction

Colorectal cancer is the fourth most common cancer in the United Kingdom (UK), and accounts for 10% of all cancer deaths.¹ The symptoms of colorectal cancer are often non-specific and in its early stages there may be no symptoms at all. Survival is directly linked to stage of disease at diagnosis – five-year survival falls from 98% for stage I disease down to 40% for stage IV disease.²

Thirty percent of all colorectal cancers are diagnosed via the 'Two-Week Wait' (2WW) referral route in the UK. The remainder are diagnosed following emergency presentation (24%), non-2WW GP referral (24%), bowel cancer screening (9%) or by other pathways (13%).³

The 2WW referrals for patients with suspected cancer were introduced in 2000 by the NHS Cancer Plan,⁴ and built on the earlier recommendations of the Calman-Hine report into commissioning cancer services.⁵ These improvements sought to address the United Kingdom's relatively low cancer survival rates compared to the rest of Europe, and to address the delays in diagnosis and treatment that some patients were encountering. In order to standardise cancer care nationally, 2WW referral guidelines were introduced by the Department of Health in 2000.⁶ These guidelines were reviewed and updated in 2005 by the National Institute for Clinical Health and Care Excellence (NICE).⁷

In November 2015, NICE updated all its 2WW referral guidelines, including those for suspected colorectal malignancy.⁸ The recommendations were developed following a systematic review of the literature which recommended referral for patients with symptoms deemed to have a positive predictive value for colorectal cancer of 3% or more. This was a reduction from the previous guidelines, which used a positive predictive value of greater than 5%.⁹ The original (2005) and updated (2015) NICE colorectal 2WW referral guidelines are outlined in Table 1.

This study measured the effect of the change in colorectal 2WW referral guidelines on the following outcomes:

- Volume of referrals to the colorectal 2WW clinic
- Rate of detection of colorectal cancer
- Rate of detection of non-colorectal cancer
- Adherence to the 2WW referral guidelines

Methods and materials

We undertook a retrospective analysis of referrals to the colorectal 2WW service at a large inner city teaching hospital (Bristol Royal Infirmary, UK). All the patients referred in two-month periods before (July to August 2015) and after (July to August 2016) were included in the study. The referral guidelines changes were identified and their clinical notes were reviewed. The specific variables recorded for each referral

Table 1. Summary of the 2005 and 2015 NICE Two-Week Wait referral guidelines for suspected colorectal cancer ^{7,8}

2005 Criteria	2015 Criteria
Age >40 with rectal bleeding and a change in bowel habit for >6 weeks	Age >40 with unexplained weight loss and abdominal pain
Age >60 with rectal bleeding without a change in bowel habit for >6 weeks	Age >50 with unexplained rectal bleeding
Age >60 with change in bowel habit without rectal bleeding for >6 weeks	Age >60 with change in bowel habit or iron-deficiency anaemia
Right lower abdominal mass consistent with involvement of the large bowel	Positive faecal occult blood test
Palpable rectal mass (intra-luminal)	Palpable rectal or abdominal mass
Unexplained iron deficiency anaemia in: non-menstruating Women with an Hb <10g/100mL men with an Hb <11g/100mL	Age <50 with rectal bleeding and one of: abdominal pain change in bowel habit weight loss iron-deficiency anaemia

Table 2. Summary of the results

	Jul-Aug 2015	Jul-Aug 2016	p value
Patients referred	193	268	<0.01 a
Cancers detected (% of total)	22 11.4%	29 10.8%	0.74 a 0.83 b
Colorectal cancers (% of total)	16 8.3%	20 7.5%	0.58 a 0.75 b
Non-Colorectal cancers (% of total)	6 3.1%	9 3.4%	0.61 a 0.85 b
% of referrals compliant with the guidelines (at that time)	72%	89%	<0.01 b
Mean age in years (Median age, range)	68.2 (69, 24-92)	67.9 (69, 22-93)	0.81 c
Sex ratio (M : F)	43 : 56	46 : 53	
Frequency of referral signs/symptoms (%)			
Change in bowel habit	60	63	0.51 b
Rectal bleeding	33	39	0.18 b
Abdominal pain	37	33	0.37 b
Unexplained weight loss	22	20	0.60 b
Iron deficiency anaemia	27	22	0.21 b

Statistical test used: a Poisson Means Test, b Chi squared test, c Unpaired t-test

included: age, gender, presenting symptoms and signs and subsequent diagnosis. All records were cross-referenced against the regional cancer registry.

Differences between the two groups were assessed for statistical significance using Chi-Squared and unpaired T-tests. Count data was assessed for significance using the Poisson Means test at a 95% confidence interval. Statistical tests were calculated using the MEDCALC statistical software.

Results

A total of 193 and 268 patients were referred in each of the two study periods. The data collection was complete for all patients. The demographics, referral data, and cancer detection rates are summarised in Table 2.

There was a significant increase in the volume of patients referred via the 2WW pathway following the change in the guidelines (193 vs. 268, $p < 0.01$). There was no significant change in the rate of colorectal cancers detected (8.3% vs. 7.5%, $p = 0.75$).

There was no significant difference in the rate of detection of any cancer (including colorectal cancer) following the 2WW referral (11.4% vs 10.8%, $p = 0.83$). The non-colorectal cancers detected (15 in total) were predominantly metastatic cancers;

from lung, ovarian, or prostatic primary malignancies. There was no significant difference in the detection rate of non-colorectal cancers (3.1% vs. 3.4%, $p = 0.85$).

The rate of compliance to the referral guidelines was significantly higher following the update in referral guidelines (72% vs 89%, $p < 0.01$).

In the second study period (July - August 2016), there was a sub-group of 31 patients whose referrals met the new (2015) referral guidelines, but who would not meet the previous (2005) referral guidelines. The mean age in this group was 58.5 and none of these patients had a cancer detected following the 2WW referral.

Discussion

This study has shown that the volume of patients being referred to the colorectal 2WW service has significantly increased in a large inner city unit following the update to referral guidelines in 2015. A significantly greater proportion of referrals are compliant with the new guidelines compared with the previous guidelines. Despite this, we found no significant change in the rate of colorectal cancer detection. Our colorectal cancer detection rates following 2WW referral are similar to the published data series (6-14%).^{10,11,12}

The factors contributing to the increased referral rate includes removal of time constraints and referral for symptoms not previously included within the guidelines (e.g. abdominal pain, unexplained weight loss). The updated guidelines are subsequently less specific and use signs and symptoms with a lower positive predictive value for colorectal cancer than previously.⁸

In their costing statement for the new guidelines, NICE acknowledge that the updated guidelines are likely to increase referral volumes. The justification given is that “benefits are anticipated from earlier diagnosis of cancer”.⁹ This study challenges that supposition – no cancers were detected in the latter group of 31 patients whose referrals met the new guidelines, but would not have met the old referral guidelines.

Studies prior to the update in guidelines have also challenged the view that 2WW referrals lead to earlier detection of cancer. When compared with ‘non-2WW’ outpatient referrals, patients referred via a 2WW pathway had no significant difference in the stage of disease at diagnosis,^{13,14} nor any significant difference in the related outcomes such as 2-year survival,^{15,16} 5-year survival,^{15,17} or proportion undergoing curative surgery.^{14,15}

Bowel cancer screening remains the only method with a strong evidence base for detecting colorectal cancers at an earlier stage.¹⁸ Cancers detected in this manner are disproportionately lower in stage,¹⁹ and are associated with a significant reduction in mortality.²⁰ This study did not assess the impact of screening on cancer detection rates via the 2WW referral process, although the logical effect of increased detection of cancers via screening would be a proportional fall in cancers detected by other routes, including the 2WW pathway.

The findings of this study appear to challenge the anticipated benefits of the new 2WW referral guidelines. A group of patients were identified whose referrals only met the 2015 guidelines; these referrals would have been deemed inappropriate by the 2005 guidelines. This group of patients were generally younger and none went on to a cancer diagnosis. If other units (or multi-centre studies) corroborate these findings then this should prompt urgent review of the 2WW guidelines with regards to cancer stage at diagnosis and longer term outcomes.

Conclusion

The updated 2WW referral guidelines for suspected colorectal cancers have increased the volume of patients being seen via the 2WW service without increasing cancer detection rates. This is anticipated to have secondary effects on waiting times for routine and endoscopic services; this has not been evaluated in this study. Further research is needed to contextualise all of these findings with cancer detection rates via screening and other non-2WW routes to diagnosis.

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Competing Interests

None declared

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References

- Office for National Statistics. Cancer Registration Statistics, England: 2015. <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/cancerregistrationstatisticsengland/2015> (Cited 1 November 2017).
- Office for National Statistics. Cancer survival by stage at diagnosis for England: Adults diagnosed 2012-2014 and followed up to 2015. <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/cancersurvivalbystageatdiagnosisforenglandexperimentalstatistics/adultsdiagnosed20122013and2014andfollowedupto2015> (Cited 1 November 2017).
- National Bowel Cancer Audit. Annual Report 2017. <https://www.nboca.org.uk/reports> (Cited 17 December 2017)
- UK Department of Health. The NHS Cancer Plan: A plan for investment, A plan for reform. London: Stationery Office; 2000.
- UK Department of Health. Expert Advisory Group on Cancer: A policy framework for commissioning cancer services. London: Stationery Office; 1995.
- UK Department of Health. HSC 2000/013: Referral guidelines for suspected cancer. London: Stationery Office; 2000.
- National Institute for Health and Care Excellence. (2005) Clinical Guideline 27 Referral for suspected cancer. <http://www.nice.org.uk/guidance> (Cited 1 November 2017).
- National Institute for Health and Care Excellence. (2015) Suspected cancer: recognition and referral [NG12]. <http://www.nice.org.uk/guidance> (Cited 1 November 2017).
- National Institute for Health and Care Excellence. Costing Statement: Implementing the (2015) NICE guideline on suspected cancer: recognition and referral [NG12]. <http://www.nice.org.uk/guidance> (Cited 1 November 2017).
- Thorne K, Hutchings H, Elwyn G. The effects of the Two-Week Rule on NHS colorectal cancer diagnostic services: A systematic literature review. *BMC Health Serv Res* 2006; 6: 43.
- Bhangu A, Khan M, Roberts L et al. Detection and survival of colorectal cancer from a 2 week wait service. *Surgeon* 2011; 9(2): 78-82.
- Patel RK, Sayers AE, Seedat S et al. The 2-week wait service: a UK tertiary colorectal centre’s experience in the early identification of colorectal cancer. *Eur J Gastroenterol Hepatol* 2014; 26: 1408-14.

13. Aslam M, Chaudhri S, Singh B, Jameson J. The “two-week wait” referral pathway is not associated with improved survival for patients with colorectal cancer. *Int J Surg* 2017; 43: 181-5.
14. Bevis P, Donaldson OW, Longman RJ et al. The association between referral source and stage of disease in patients with colorectal cancer. *Colorectal Dis* 2008; 10(1): 58-62.
15. Thornton L, Reader H, Stojkovic S et al. Has the “Fast-Track” referral system affected the route of presentation and/or clinical outcomes in patients with colorectal cancer? *World J Surg Onc* 2016; 14: 158.
16. Walsh SR, Gilson NL, Brown K, Novell JR. Trends in colorectal cancer survival following the 2 week rule. *Colorectal Dis* 2007; 9(3): 207-9.
17. Schneider C, Bevis P, Longman RJ et al. The association between referral source and outcome in patients with colorectal cancer. *Surgeon* 2013; 11(3): 141-6.
18. Bretthauer M. Evidence for colorectal cancer screening. *Best Prac Res Clin Gastroenterol* 2010; 24(4): 417-25.
19. McClements PL, Madurasinghe V, Thomson CS et al. Impact of the UK colorectal cancer screening pilot studies on incidence, stage distribution and mortality trends. *Cancer Epidemiol* 2012; 36(4): e232-42.
20. Atkin WS, Edwards R, Kralj-Hans I et al. Once-only flexible sigmoidoscopy screening in prevention of colorectal cancer: a multicentre randomised controlled trial. *Lancet* 2010; 375(9726): 1624-33.



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