Pitfalls in the construction of cancer guidelines demonstrated by the analyses of colorectal referrals

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ABSTRACT

INTRODUCTION The aim of this study was to develop a system to compare and validate cancer referral guidelines, identifying the pitfalls in their development and provide a mechanism to evaluate their efficacy.

PATIENTS AND METHODS 3302 patients referred from primary care with colorectal symptoms over a 3-year period were assessed. All participants had a comprehensive history obtained via a questionnaire that incorporated all colorectal symptoms. The questionnaires were completed prior to assessment at the hospital. All patients were then assessed at the Colorectal One Stop Clinic (CROSC), underwent investigation and diagnosis achieved. All data were entered into a databank. Current prioritisation guidelines and tools that are used to assess colorectal referrals were applied to this colorectal databank to test their efficacy for cancer detection and referral prioritisation. Sensitivity and specificity for cancer detection and referral rates were assessed.

RESULTS Cancer was detected in 156 patients (4.7%). All prioritisation models (NHS guidelines, Weighted Numerical Score [WNS], Netherlands, Harvard, Mersey, and Somerset) differentiated cancer from non-cancer patients. The use of a few symptoms as risk predictors (e.g. NHS guidelines) causes a decrease in specificity in contrast to a comprehensive risk tool, for example, the WNS at a score of 50 (NHS 54.1%, WNS 62.9%). This results in a significantly higher referral rate (NHS 47.6%, WNS 39.4%) and identifies fewer cancers (NHS 80.1%, WNS 85.9%). Non-evidence based modifications of the NHS guidelines (Somerset and Mersey) caused a further deterioration in specificity, which was reflected in an increased referral rate. Using the WNS, which is objective and a continuous scale, allows adaptation of the referral threshold, balancing sensitivity and specificity to the resources available within a hospital. For example, the WNS of ≥ 40 has a sensitivity of 96.8% for cancer detection.

CONCLUSIONS Accurate prospective data collection into a data bank allows testing of referral guidelines as well as providing an adjunct to guideline construction.

KEYWORDS

Colorectal neoplasm – Guidelines – Scoring tools – Colorectal symptoms – Patient consultation questionnaire – Weighted Numerical Score

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In recent years, there has been an ‘explosion’ in the number of clinical guidelines for the treatment of cancer patients^{4–7} as governments and organisations attempt to manage the activity of clinicians in a cost-effective manner, minimise error and provide uniformity of care and standardisation of treatment.^{8,9} However, the accuracy and efficiency of many of the current NHS referral cancer guidelines have been questioned.

There have been inherent flaws in the construction of referral guidelines. Although scientific methodology has been applied,^{10,11} the randomised controlled trial (RCT) is usually not feasible for service delivery issues.^{6,12} Furthermore, dissemination and implementation of the key findings have not always received sufficient attention in the design.¹³

In an attempt to facilitate implementation, guidelines often use limited criteria to avoid the problem of the more complex guidelines being ignored by the clinician. There has also been a tendency for national guidelines to be altered to suit local needs in the belief that ‘local ownership’ will improve implementation. In the absence of statistical validation and a pragmatic method for implementation, guidelines will result in failure, with clinicians unable to accept changes in clinical practice.^{14–17} Guidelines not only need to take into account the power of the test but benefits, risks and consequences of different options and costs of alternatives.¹¹

If improvements in the management of cancer referrals are to be achieved, then we must highlight the fundamental problems that guidelines produce. A more scientific

approach must be applied before introducing them into the national clinical forum.

By linking the data that can be obtained from a practical and comprehensive questionnaire with a replicated computer program, it is possible to build a large databank of symptomatology that can be correlated with patient diagnostic outcomes.¹⁸ Accurate testing of scoring systems and guidelines used for the identification of patients with high-risk cancer symptoms^{18–25} in relationship to cancer outcome can be then

be achieved. This highlights the variability and problems associated in their inherent construction and the detrimental effects that this has on their functional ability to predict cancer.

Patients and Methods

The focus of this study was to use colorectal cancer as the cancer example to highlight the problems associated with guidelines.

Table 1 Comparative summary of the criteria used for each group

Prioritisation tool	Risk factors	Type of score	High risk criteria
NHS guidelines ¹⁸	<ul style="list-style-type: none"> Rectal bleeding with change in bowel habit to more frequent defaecation or looser stools (or both) persistent for 6 weeks Age over 60 years and has rectal bleeding persistently without anal symptoms Age over 60 years and has change in bowel habit to more frequent defaecation or looser stools (or both), without rectal bleeding, and persistent for 6 weeks 	High risk versus low risk	Presence of any risk criteria is high risk
Selvachandran <i>et al.</i> ¹⁹ (WNS)	<ul style="list-style-type: none"> See Appendix 1 – all symptoms used 	Continuous	WNS $\geq$ 50
Fijten <i>et al.</i> ²⁰ (Netherlands model)	<ul style="list-style-type: none"> Age > 50 years Mixed blood per rectum Loose motion or frequent stool 	Risk probability	> 0.14
Majumdar <i>et al.</i> ²¹ (Harvard model)	<ul style="list-style-type: none"> Constipation Bleeding per rectum Absence of anaemia Absence of proximal symptom clusters 	Continuous	> 15
Mersey Hospital ²²	<ul style="list-style-type: none"> Increase in bowel frequency/looseness for > 6 weeks at any age Bleeding persistently without peri-anal symptoms Dark blood mixed with stool Abdominal pain is severe, colicky and in association with weight loss, appetite 	High risk versus low risk	Presence of any risk criteria is high risk
Somerset Hospital ²³	<ul style="list-style-type: none"> New rectal bleeding over 65 years Persistent rectal bleeding for 6 weeks aged between 40–65 years without anal symptoms Persons over 40 years with change in bowel habit for 6 weeks, along with increase in bowel frequency (with or without rectal bleeding), including wet wind 	High risk versus low risk	Presence of any risk criteria is high risk
Age	<ul style="list-style-type: none"> Age $\geq$ 60 years 	High risk versus low risk	High risk if age $\geq$ 60

Databank

A comprehensive colorectal databank was initiated in October 1999 and, over a period of 3 years to October 2002, patients referred from primary care with colorectal symptoms were asked to complete a patient consultation questionnaire (PCQ) prior to being seen or investigated at the hospital. The PCQ incorporated all colorectal symptoms and obtained a comprehensive history from each patient (Appendix 1).

All patients were subsequently assessed at the Colorectal Endoscopy Clinic (CREC) with the minimum investigation being a flexible sigmoidoscopy.

Data from the PCQ, clinical and endoscopic findings, treatment, investigations and diagnosis were entered into the Electronic Patient Record (EPR). Definitive histological results, follow-up investigations or treatment were subsequently appended.

Guideline comparisons

The following colorectal scoring systems and guidelines were assessed in the databank:

1. NHS high risk criteria¹⁸
2. Weighted Numerical Score¹⁹
3. Fijten *et al.* 'Netherlands model'²⁰
4. Majumdar *et al.* 'Harvard model'²¹
5. Mersey guidelines²²
6. Somerset guidelines²⁵

The symptoms and criteria selected by each modality were applied (Table 1). Sensitivity, specificity and referral rate in respect to colorectal cancer were tested. Referral rate was defined as the proportion of the population that met the defined high-risk criteria for each guideline/scoring system.

Diagnostic outcome

The ability to differentiate benign and malignant disease, sensitivity to detect serious disease (carcinoma, colitis and

large polyps) and the accuracy of appropriate referral were analysed.

Statistical analysis

All analyses were carried out using the NCSS 2000 statistical software. Except for age, all symptoms in the PCQ were dichotomised (present = 1, absent = 0). The significance of the difference between cancer and non-cancer groups for scoring modalities was assessed using the *t*-test for continuous scores and χ^2 -test for proportions. The significance of the difference in sensitivities and specificities was assessed using the McNemar test (paired χ^2 -test). The discriminatory power for cancer detection was assessed using receiver operator curves (ROC) curve analysis and area under curve (AUC).

Results

A total of 3302 patients were referred over a 3-year period from October 1999 to October 2002. All patients completed the PCQ. The average patient age was 56.8 years: 46% males (average age, 56.1 years) and 54% females (average age, 57.5 years). Of the study group, 156 (4.7%) patients were diagnosed with colorectal cancer, the average age being significantly higher (68.6 years; $P < 0.001$) and with a significant male predominance (63%; $P < 0.001$).

Cancer detection and referral rates

With the Netherlands score, the demarcation between the cancer (mean score, 0.47; SD 0.34) and non-cancer (mean score, 0.19; SD 0.28) patients was achieved but with considerable overlap in the lower score range, whereas the Harvard score provided less clear differentiation between the cancer (mean score, 14.6; SD 2.5) and non-cancer (mean score, 14; SD 2.7) patients with a pronounced overlap. (The box plots in Fig. 1 demonstrate these features).

Figure 1 Box plot charts for the WNS, Netherlands and Harvard models. Boxes represent the inter quartile range. The intersection in the box is the median. Error bars represent the score range.

Figure 2 Receiver operator characteristics (ROC) curve.

The WNS provided the clearest differentiation between cancer and non-cancer patients with average scores being 73.7 (SD 23) and 44.5 (SD 21.3), respectively

To compare the discriminatory power of the different scoring systems, *i.e.* overall effectiveness of cancer detection at any given cut off point, the area under receiver operating characteristic (ROC) curve (AUC) was used. The WNS demonstrated a higher AUC (0.827) than the Netherlands (0.775) and Harvard scores (0.579) as summarised in Figure 2.

In assessing referral rates, a high proportion of all referrals were classified as higher risk using the NHS, Somerset and Mersey prioritisation criteria (47.6%, 57.3%, and 62.3%, respectively).

Work volume is clearly dependent on the sensitivity chosen. The WNS demonstrated that using the lower cut off point of ≥ 40 achieved a 96.8% cancer detection rate with an overall urgent referral rate of 57.1%. If resource management, however, remains the main objective, then a cut off ≥ 50 achieves an urgent referral rate of 39.4%, with cancer detection of 85.9% (Table 2).

Taking a WNS score of ≥ 50 as a criterion for urgent referral, we compared the effectiveness of prioritisation to the NHS, Mersey and Somerset referral guidelines. There was no difference between the WNS and the above guidelines in cancer detection ($P > 0.05$; see Table 2). However, the WNS demonstrated a higher specificity with a significant lower urgent referral rate (39.4%; $P < 0.001$; Table 2).

Of the total referred population of 3302, 1570 (47.6%) patients would have been classified as an urgent referral

using the NHS high-risk criteria detecting 125 of the total 156 cancers (80.1%). The modification of the NHS guidelines significantly improved the sensitivity to cancer detection (Mersey 82.7%; $P = 0.045$; Somerset 88.5; $P = 0.003$) but at the cost of an increase in the referral rate (Mersey 62.3%; $P < 0.001$; Somerset 57.3%, $P < 0.001$).

Assessment of the referred population using an age of 60 years and over as the single criteria for a patient to be classified as an urgent referral, performed as accurately as the NHS guidelines detecting 83.3% of the cancers ($P = 0.45$) with a referral rate of 47.1% ($P = 0.64$).

Diagnostic classification

Categorising benign and malignant disease, the WNS demonstrated clear confidence intervals for all diagnostic groups (Fig. 3). The WNS not only defined cancer but also the clinically important benign groups showing clear classification and scoring highly (*i.e.* large polyps and colitis). This stratification was lost when using the Netherlands and Harvard scoring systems with a large degree of overlap between disease groups (Fig. 3).

Of the total population, 322 patients had significant disease (cancer, large polyps or colitis) of whom 243 (76%) had a WNS ≥ 50 . At a WNS ≥ 50 , the positive predictive value for significant disease is 18.7% (*i.e.* 1 in every 5 patients with a WNS ≥ 50 will have significant disease). This yield was significantly higher when compared to the NHS guidelines (14.7%; $P < 0.001$). At a WNS ≥ 70 , the positive predictive value for significant disease is 30.3% (*i.e.* 1 in 3).

Discussion

Guidelines, scoring systems and protocols are now part of clinical practice. When establishing a new system it is vital to avoid fundamental mistakes in design, to have an efficient implementation strategy and accurate statistical confirmation of efficacy.²⁴

Table 2 Cancer detection and referral rates

Criteria	Sensitivity	Specificity	Referral rate
WNS ≥ 40	96.8	44.9	57.1
WNS ≥ 50	85.9	62.9	39.4
NHS	80.1	54.1	47.6
Somerset	88.5	44.3	57.3
Mersey	82.7	38.8	62.3
Age ≥ 60	83.3	54.7	47.1

In 1992, Sackett and Rennie¹⁵ reiterated the importance of obtaining an accurate clinical history. They also pointed out that a clinical diagnosis seldom resides in a single symptom or sign, but emerges from the patterns of many symptoms and signs.

Using the symptom databank, every detail of a patient's history can be entered into a computer program with the comprehensive data immediately available, including all relevant symptoms, as well as weights and interactions. This system provides the facility to compare modifications and different guidelines for accuracy and assess resultant effects on patient management before being released into the national clinical forum. Clinical findings and test results can be added to the databank to refine the referral process.

The primary goal of developing NHS guidelines and the adaptations of Mersey and Somerset was to speed up the diagnosis of cancer. The balance between sensitivity and specificity is important when considering demand management. If this balance is disturbed, the urgent slots will be saturated with non-specific referrals that have been falsely classified as high-risk resulting in further delays in detecting those cancer patients that exist in both high- and low-risk groups. The detection of patients with serious benign conditions will also be compromised.^{25,26} This distortion is demonstrated by all three referral guidelines due to the selection of non-specific symptoms. Further support for the non-specificity of these criteria is the fact that the age of 60 years and above in the presence of any colorectal symptom performed as accurately when used as the sole criterion.

In contrast to the NHS, and modified versions of the referral guidelines, Fijten *et al.*'s logistic regression model (Netherlands) used specific symptoms of importance and also incorporated the interactions of these symptoms into the design of the model to estimate the risk of colorectal cancer. This clearly provided an advantage, producing a better sensitivity and specificity. However, the number of symptoms in the model was less than incorporated in the WNS, which gave the latter an even higher discriminatory power for colorectal cancer. The WNS has also enabled prioritisation of other relatively important diseases giving a high yield of significant disease from the urgently referred population.²⁷

Mathematical models are not without their inherent drawbacks. Their efficacy depends on the sample from which they were generated and, in cases where the sample is not similar to the target population, they will fail. The system used by the Harvard group exemplifies this. The Harvard system was established on cancer patients only; when applied to the general population, it was shown to fall short in its objective.

The principle of accurate prospective data collection into a data bank allows accurate modelling and testing. This mechanism offers an adjunct to the established systems of

Figure 3 95% confidence intervals for each scoring modality.

guideline construction, highlighting the pitfalls in developing guidelines and projects their efficacy in a scientific environment before dissemination and implementation in the clinical forum.

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APPENDIX 1

Patient consultation questionnaire (PCQ)

Leighton Hospital

Mid Cheshire Hospitals NHS Trust

Middlewich Road, Crewe, Cheshire CW1 4QJ

Bowel Symptoms Assessment Questionnaire

Your G.P. has referred you for bowel investigation.
To give us more information on your symptoms
please fill in this form and return it to us as
soon as possible.

PLEASE AFFIX PATIENT STICKER
(For office use only)

Your Telephone Number: _____

Your Age: Please place a tick ☒ in the appropriate boxes

1. Have you seen blood from the back passage?

(If "Yes" continue below. If "No" go to question 2 on next page.)

YES ☐
NO ☐

a. State whether blood is

Fresh or Bright
Old or Dark
Both Fresh & Old☐
☐
☐

b. Is the blood

Seen on toilet paper only
Separate from stool
Mixed with stool
Separate and mixed in stool
Uncertain separate or mixed☐
☐
☐
☐
☐

c. When you see blood in stool it is

Small amount
Large amount☐
☐

d. How often have you seen blood when opening your bowels?

Every day
Every week
Every month
Only once or twice in the past year☐
☐
☐
☐Every few days
Every few weeks
Every few months☐
☐
☐

e. For how long have you seen blood when opening your bowels?

Less than four weeks
4 – 6 months
1 – 2 years☐
☐
☐1 – 3 months
6 – 12 months
Over 2 years☐
☐
☐

f. During the past four weeks has the bleeding

Got worse
Remained the same☐
☐Improved
Completely Settled☐
☐

Do you have any changes in your bowel habit?

YES ☐
NO ☐

If "Yes" continue below. If "No" go to question 3 below.

a. What changes have there been in your bowel habits?

Loose Motion (or Diarrhoea)
Constipation (that is less frequent and harder stools)
Alternating loose motion and constipation
Normal Motion or Stools☐
☐
☐
☐

b. Do you open your bowels more frequently than normal to you?

Yes, 2 – 4 times more per day
Yes, 5 – 6 times more per day
Yes, 7 – 10 times more per day
No☐
☐
☐
☐

c. Is the increase in opening your bowels worse at any particular time of day?

Yes, in the morning
Yes, at night
No☐
☐
☐

d. Do you have to "rush" to have your bowels open?

YES ☐
NO ☐

e. For how long have you had these symptoms?

Less than four weeks
4 – 6 months
1 – 2 years☐
☐
☐1 – 3 months
6 – 12 months
Over 2 years☐
☐
☐

f. During the past four weeks has the change in bowel

Got worse
Remained the same☐
☐Improved
Completely Settled☐
☐

g. What has been your normal bowel habit?

Normal Motion or Stools
Constipation (that is less frequent and harder stools)
Loose Motion
Alternating loose motion and constipation☐
☐
☐
☐

Do you see

Slime (jelly-like fluid) in your motion
Slime and blood mixed in your motionYES ☐
YES ☐NO ☐
NO ☐

Do you feel that you have not emptied your bowels satisfactorily when your bowels are opened?

YES ☐
NO ☐

5. Do you have symptoms around your back passage ? YES ☐
(If "Yes" continue below. If "No" go to question 6 on next page.) NO ☐

Pain on opening your bowels ☐
Irritation and itching ☐

Lump or swelling at back passage ☐
Leakage or soiling at back passage ☐

How long have you had these symptoms?

Less than four weeks ☐
4 – 6 months ☐
1 – 2 years ☐

1 – 3 months ☐
6 – 12 months ☐
Over 2 years ☐

6. Do you have pain in your tummy (abdomen) ? YES ☐
(If "Yes" continue below. If "No" go to question 7 below.) NO ☐

Lower tummy pain ☐
Left sided tummy pain or discomfort ☐
Pain all over tummy ☐

Spasms of tummy pain ☐
Right sided tummy pain or discomfort ☐

Do you ever get bloating of your tummy? YES ☐
NO ☐

7. Have you lost weight recently ? YES ☐
(If "Yes" continue below. If "No" go to question 8 below.) NO ☐

Over half a stone in three months ☐
Weight loss does not concern you ☐

Due to dieting ☐

8. Do you have loss of appetite ? YES ☐
NO ☐

9. Have you felt excessively tired ? YES ☐
NO ☐

10. Do you take regular medication ?

Iron tablets ☐ Steroids / Prednisolone tablets ☐
Medication for diabetes ☐ Tablets for thinning blood / Warfarin ☐
Any other medication (please state which) _____

11. Have you had any of these illnesses in the past ?

Bowel polyps YES ☐ NO ☐
Colitis (Inflammation of the bowel) YES ☐ NO ☐
Cancer* YES ☐ NO ☐

*If you have had cancer – in which part of the body? _____

12. Have any of your close relatives suffered cancer ? YES ☐
(If "Yes" continue below. If "No" go to question 13 below.) NO ☐

(*When stating grand parents, aunts and uncles please tick father's or mother's side.)

Relation	Father's Side	Mother's side	Age when Cancer found	Part of body

13. Please give us any other information that you think may be relevant

Signature: _____ Date: _____

TO BE COMPLETED BY CLINICIAN - FOR OFFICE USE ONLY

- 1 M Score M1 ☐ M2 ☐ M3 ☐ M4 ☐ M5 ☐
- 2 Priority A+ ☐ A ☐ B ☐ C ☐
- 3 Endoscopy Flexible Sigmoidoscopy ☐ Colonoscopy ☐ Barium Enema ☐
- 4 +/- Other Procedure _____
- 5 Bowel Preparation GS Sups ☐ Phosphate Enema ☐ Picolax ☐
Kleen Prep ☐ Other _____
- 6 Tests to arrange FBC ☐ U&E ☐ FOB ☐ CRP ☐ LFT ☐
- 7 Preoperative assessment Not Required ☐ Postal Information ☐ T-phone ☐
Day Unit POAC ☐
- 8 Sedation Required ☐ Not required ☐ May Require ☐