

# Referral patterns, clinical examination and the two-week-rule for breast cancer: a cohort study

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## ABSTRACT

**Introduction:** Current NHS guidelines require patients with suspected breast cancer to be seen urgently at a specialist breast clinic. The aim of this study was to assess referral patterns and clinical findings of patients referred to a specialist breast clinic.

**Materials and Methods:** A prospective database was maintained for consecutive patients referred. Symptoms and clinical findings in primary and secondary care were recorded. Correlation with final diagnoses was made. Tertiary referral patients were excluded.

**Results:** 1098 patients attended a specialist breast clinic over six months. 588 (54%) were referred as urgent, 285 (26%) routinely and 225 (20%) were unspecified. 492 (45%) patients were referred with the incorrect referral priority. 42 patients were unexamined in primary care. Examination findings in primary and secondary care correlated in only 487 (46%) patients. Examination in primary care when compared with secondary care was highly sensitive for detecting breast lumps, but specificity was low. 86 patients (8%) were diagnosed with breast cancer, 72 (84%) were referred urgently, 6 (7%) routinely and 8 (9%) as unspecified priority. Regardless of the clinical expertise of the referrer, sensitivity and specificity of the two-week guidelines for cancer are low.

**Conclusions:** Examination findings in primary and secondary care correlate in only 46% of referrals. Additionally, 55% of referrals were of the correct priority. The two-week rule guidelines have poor sensitivity and specificity for cancer. The safest and fairest policy would be to abandon the concept of urgent referral criteria and see all patients in a timely fashion. Alternatively, simplifying the referral criteria would improve sensitivity and specificity for cancer without leading to increased waiting times.

**Key words:** Breast neoplasms, referral and consultation, guidelines

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## INTRODUCTION

Breast cancer is the most common malignancy among women with a lifetime risk of 11%.<sup>1</sup> Over 45,000 women are diagnosed with breast cancer each year in the UK.<sup>2-5</sup> Towards the end of the 20<sup>th</sup> century, UK survival rates for breast cancer were among the lowest in Europe, with long waiting lists for both diagnosis and treatment thought to be at least partly to blame.<sup>6-8</sup> In 1998 the Department of Health attempted to address this problem in their circular, "*Breast Cancer waiting times- achieving the two week target*" with the aim to facilitate access to specialist services and ultimately improve survival.<sup>9</sup> Despite the lack of strong scientific evidence this circular stated that, by April 1999, all patients with suspected breast cancer should be referred urgently to secondary care and seen by a specialist within two weeks of referral.<sup>10, 11</sup>

The effectiveness of two-week-wait guidelines for cancer in general and breast cancer in particular continues to be questioned. Of particular concern is the poor predictive value of symptoms and symptom clusters for cancer.<sup>12-14</sup> Additionally, there has been reluctance about switching responsibility for decision making regarding referral priority to the non-specialist.<sup>15, 16</sup> General Practitioners (GPs) express concern about missing a cancer diagnosis and thus have a propensity to refer patients urgently, while specialists

complain of the rule compromising their professional autonomy, report poor adherence to guidelines by primary care and patients with cancer referred outside the two-week-rule experience much anxiety.<sup>13, 16</sup>

An increasing proportion of patients are referred urgently and while two-week targets are currently being met, a corresponding increase in waiting time for the routine group has been reported.<sup>12, 17</sup> Most worryingly, the proportion of cancers detected in patients referred routinely also appears to be on the rise.<sup>12</sup>

The Ulster Hospital Dundonald serves a population of over 260,000 in Belfast and North County Down. It provides services for both secondary and tertiary referral and plays an important role in breast screening. Each year approximately 300 new cases of cancer are diagnosed. At the time of data collection the breast care service included two consultant surgeons, one staff grade breast physician, two specialist registrars and three breast care nurses. The aim of this study

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was to compare clinical findings at the specialist breast clinic with those documented in primary care, examine adherence to referral criteria by primary care and analyse the two-week-rule with regard to appropriate patient selection for cancer.

**MATERIALS AND METHODS**

Data were prospectively collected over a six-month period between 1<sup>st</sup> October 2006 and 31<sup>st</sup> March 2007. All consecutive referrals from primary care were included for analysis. Tertiary referrals, in-hospital referrals and screen-detected cancers were excluded. Data collection sheets were completed for each patient attending the breast clinic. Assessment included information on patient demographics, referral priority, clinical findings and diagnosis. All patients referred urgently were seen within two weeks, and those referred routinely were seen within four weeks.

Referral priority and its accuracy in relation to two-week-wait guidelines were examined while clinical findings in primary and secondary care were compared and correlated with final diagnoses. The predictive value of the two-week-rule was evaluated. Age was expressed as mean and standard deviation. Data were collected on Microsoft Excel (Microsoft Corp, Redmond, WA, USA) and then analysed using SPSS (Version 12, SPSS Inc, Chicago, IL, USA). Differences in age group were analysed using Kruskal-Wallis and the difference in proportions using Chi-squared test, with a p value of less than 0.05 considered significant.

**RESULTS**

During the study period the Ulster Hospital Specialist Breast Service received 1098 referrals from primary care. The mean age at referral was 46.9 years ( $\pm$  15.5) and at cancer diagnosis 65 years ( $\pm$  15.6). No patients were diagnosed with cancer under the age of 30 years. The risk of cancer, as expected, increased with age ( $p < 0.0001$ ) (Figure 1).

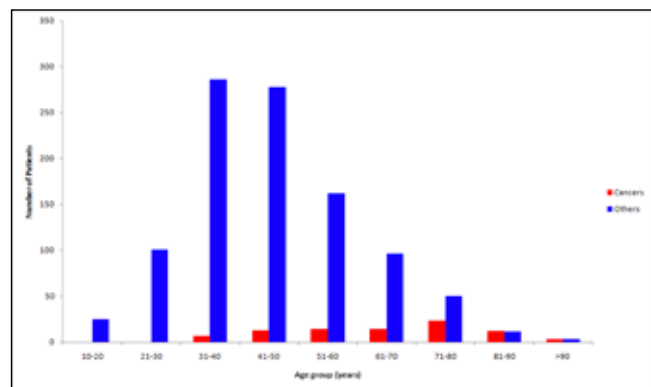


Fig 1. The proportion of patients diagnosed with cancer for age group within the whole cohort.

There were disparities in clinical findings between the breast clinic and primary care. Examination findings in primary and secondary care were significantly different and correlated in only 487 (46%) patients ( $p < 0.0001$ ) (Table 1, Figure 2). Examination in primary care when compared with secondary care was highly sensitive for detecting breast lumps, but specificity was low. Forty-two patients were not examined in primary care with one cancer diagnosed in this group. 48 (87%) of 55 patients with nipple discharge were referred as urgent, with no cancers in this group. It was not recorded

if discharge was blood stained. No significant difference in accuracy of examination findings was found between different healthcare professionals in primary care, compared to the breast clinic.

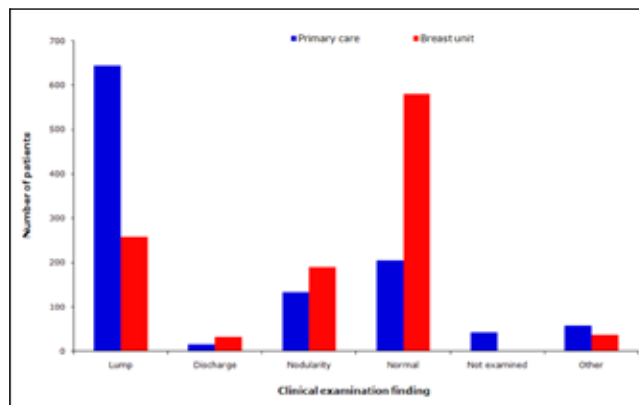


Fig 2. Clinical examination findings in primary and secondary care ( $p < 0.0001$ ).

TABLE 1:

*Sensitivity and specificity of clinical examination in primary care compared with secondary care (To calculate GP sensitivity and specificity Breast Clinic findings were assumed to be both 100% specific and sensitive.)*

	Sensitivity (%)	Specificity (%)
Lump	97	40
Discharge	36	48
Nodularity	24	70
Normal	31	35
Other	46	64

To calculate GP sensitivity and specificity Breast Clinic findings were assumed to be both 100% specific and sensitive.

588 (54%) patients were referred urgently, 285 (26%) routinely and 225 (20%) had an unspecified priority. According to documented symptoms and examination findings in primary care, 492 (45%) patients were referred with an incorrect referral priority; 141 (24%) urgent referrals did not fulfil the necessary criteria; 127 (56%) unspecified priority referrals and 126 (44%) routine referrals should have been referred urgently. All those referred as urgent or routine were seen as such, with the unspecified priority referrals triaged on a daily basis by a Consultant Surgeon. The 127 unspecified priority referrals which should have been referred urgently were seen within 2 weeks, meaning 715 patients were seen within 2 weeks of referral.

Seven hundred and eight (64%) patients referred had no identifiable breast pathology when seen in secondary care; 330 had been referred urgently. 271 (25%) had benign breast problems, such as fibroadenomata and duct ectasia; 168 were referred urgently. Eighty-six (8%) had cancer; 72 had been referred urgently, 6 routinely and 8 were of unspecified priority. Eighteen had other non-breast problems, ranging from eczema to sebaceous cysts.

TABLE 2:

Number of urgent referrals, cancers referred urgently and sensitivity and specificity of current and proposed urgent referral guidelines for breast cancer.

	Number of urgent referrals	Number of cancers referred urgently	Sensitivity	Specificity
<b>Current Guidelines</b>				
Actual GP Priority	588	72	84%	49%
GP priority + triaged referrals	715	79	91%	37%
According to two-week-rule by GP findings <sup>1</sup>	700	78	91%	39%
According to two-week-rule by BC findings <sup>2</sup>	307	74	86%	76%
<b>Proposed Guidelines</b>				
By GP findings i.e. Current clinical expertise <sup>3</sup>	691	82	95%	32%
By BC findings i.e. Ideal clinical expertise <sup>4</sup>	395	85	99%	65%
Statistical significance 1 vs 2- $p < 0.0001$ ; 3 vs 4- $p = 0.0004$ ; 1 vs 3- $p = 0.77$ ; 2 vs 4- $p = 0.58$				

Strict application of current guidelines, based on the primary care clinical findings, would have increased the number of urgent referrals from 588 (54%) to 700 (64%), but decreased the number actually seen on an urgent basis from 715 to 700 ( $p = 0.77$ ). Sensitivity for cancer would have improved from 84% to 91%, while specificity would have decreased. If the breast clinic clinical findings had been used to refer patients according to current guidelines, the priority would have been markedly different, with only 307 (28%) referrals being classified as urgent ( $p < 0.0001$ ). Although specificity of the guidelines for cancer would improve when compared with primary care, sensitivity would only reach 86%, missing 14% of cancers (Table 2).

Proposed Guidelines
Urgent Referrals
1. Female >30years with
a. A breast lump
b. Asymmetric nodularity
2. Male aged >50 years with a palpable unilateral swelling

Fig 3. Proposed alternative two-week referral guidelines

Data were analysed further to assess for any link between particular examination findings and cancer. Alteration of the guidelines (Figure 3) shows a trend towards improved sensitivity and specificity for cancer in primary care (Table 2) ( $p = 0.77$ ). If breast clinic findings are used according to these proposed guidelines, sensitivity and specificity for cancer would improve significantly compared with primary care ( $p < 0.0001$ ).

## DISCUSSION

Since breast cancer is the commonest cancer among women

in Europe, the UK government was justifiably concerned about the low survival rates in comparison to other western countries. The two-week-rule aimed to improve patient access to specialist services and allow rapid diagnosis and earlier treatment. Since its introduction the quality of both guidelines and referrals has been questioned.

In this study, a large number of sub-optimal referrals were received, evidenced not only by the 225 referrals whose priority was unspecified, but also by the incorrect grading of referrals (45%). More than twice the number of patients who would have been referred urgently based on breast clinic findings were seen on an urgent basis, suggesting a tendency to refer urgently in primary care. This may, as other studies have suggested, be due to a decrease in diagnostic accuracy among general practitioners, concern about missing a cancer diagnosis or a lack of assurance in the referral guidelines.<sup>16, 18</sup> Moreover, patient anxiety may pressurise general practitioners into referring urgently.<sup>16</sup>

Clinical findings in primary and secondary care were often contradictory (54%). This can be explained by an expected lower level of clinical experience in primary care and perhaps uncertainty in declaring an examination to be normal.<sup>16</sup> While there will remain to be room for improvement with regard to sensitivity and specificity of examination in primary care, specialist clinical examination applied to the two-week-wait criteria would also yield poor sensitivity and specificity for cancer. Non-urgent referrals would have included 12 (14%) cancers if breast clinic findings had been used to refer. Thus the main areas of concern with the current system lie with either the concept of urgent referrals or the referral guidelines themselves, rather than the clinical expertise of the referrer. As clinics have struggled to meet demands set by the two-week-rule, patients referred routinely are being forced to wait longer for diagnosis and treatment, creating a two-tier referral system. Although our unit is committed to seeing routine referrals within 28 days, other institutions may have significantly longer waiting times.<sup>15</sup>

While rapid access to specialist services is to be welcomed,

the current system would appear to be disadvantaging a significant proportion of patients with cancer.<sup>12,19,20</sup> All patients with suspected breast malignancy experience high levels of anxiety and distress during the period leading up to their assessment and deserve to be seen promptly from both a psychological and oncological perspective.<sup>21</sup>

The safest and fairest policy would be to abandon the concept of urgent referral criteria and see all patients in a timely fashion. Several institutions have suggested seeing all patients within two-weeks of referral.<sup>12</sup> This would require a dramatic increase in capacity and therefore funding to bring the backlog in the system up to date. While this may be an ideal scenario, ongoing budget cuts requiring efficiency savings make this option unlikely. Evidence has shown that significant differences in survival rates may only begin to become apparent after delays of over 3 months<sup>8</sup> Therefore, we would suggest a maximum period of 4 weeks is reasonable from an oncological and psychological point of view, without compromise of patient safety or outcome.

It is clear that government is committed to the principle of an urgent referral system and it is unlikely that the concept will be abandoned. An alternative would be to simplify the referral criteria (Figure 3), improving sensitivity and specificity for cancer without leading to a corresponding increase in urgent referral numbers, thus preventing diagnostic and treatment delay (Table 2). An improvement in clinical expertise in primary care would allow greater diagnostic confidence and reduce the referral of patients who do not need to be seen by a specialist. This would help reduce diagnostic and treatment delays for those who do need referred.

The authors have no conflict of interest.

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