

## IN BRIEF

- Among urgent referrals to an oral medicine unit over a one year period, six were found to have oral cancer.
- The predictive value of referring a suspected cancer marked 'urgent' was estimated to be 8%.
- Among routine referrals, none were diagnosed with cancer.
- Greatest delay in oral cancer diagnosis remains patients seeking advice from a primary care dentist or a physician but with rapid access for cancer further delays could be reduced to a minimum.
- UK guidelines to identify and refer patients with head and neck cancer are available but in light of the findings from this study may need further clarification or revision.

# The two-week wait cancer initiative on oral cancer; the predictive value of urgent referrals to an oral medicine unit

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**Background** The two-week wait cancer initiative was designed to speed up referral of patients suspected of having cancer. The National Institute of Clinical Excellence (NICE) has issued guidelines for head and neck cancers warranting urgent referral.

**Objective** To look at the appropriate use of the two-week wait/urgent referrals by measuring the proportion of urgent referrals found to have cancer, to assess the sensitivity of the clinical guidelines and to explore how practitioners used them in primary care.

**Method** Collection and analysis of urgent referral letters and the clinic outcome for urgently referred cases over a one-year period in an oral medicine department. Screening of the biopsy service database to reveal any routine referrals subsequently found to have cancer.

**Results** None of the routine referrals but eight percent of all urgent patients were found to have cancer, equating to 24% of the group in which malignancy was suspected. The predictive value of referring a case as suspected of oral cancer/with cancer symptoms was low, estimated at 7.9%.

**Conclusion** The referral guidelines on oral cancer symptoms developed by NICE may need further revision. Moreover, development of other appropriate adjuncts that aid visual inspection for the detection of oral cancer may improve the sensitivity of positive detections in primary care.

## BACKGROUND

The UK government white paper (1997) entitled *'The new NHS, Modern and Dependable'* guaranteed that everyone with suspected cancer will be able to see a specialist within two weeks of their GP deciding that they need to be seen urgently.<sup>1</sup>

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The two-week wait cancer initiative in the UK was designed to speed up referral of patients suspected of having cancer and by so doing improve their outcome. This standard was rolled out in several phases and for all suspected cancers of the head and neck was implemented in December 2000.

The UK guidelines were developed under a steering group established by the Department of Health in May 1999 in association with the relevant Royal Colleges. These guidelines were then issued to general practitioners to help them identify and refer urgently those patients who may have cancer.<sup>2</sup>

For head and neck cancers, signs and symptoms warranting urgent referral by NICE<sup>3</sup> criteria are:

- Ulceration of oral mucosa persisting for more than three weeks
- Oral swellings persisting for more than three weeks
- All red or red and white patches of the oral mucosa
- Dysphagia persisting for more than three weeks
- Hoarseness persisting for more than six weeks
- Unilateral nasal obstruction, particularly when associated with purulent discharge
- Unexplained tooth mobility not associated with periodontal disease
- Unresolving neck masses for more than three weeks
- Cranial neuropathies
- Orbital masses.

NHS Trusts were asked to make arrangements to ensure that urgent referrals were dealt with without delay and to enable an appointment to be offered to the patient within two weeks. Trusts were also told that it was vital that monitoring and clinical audit arrangements were in place to ensure the quality of the service.<sup>4</sup>

The oral medicine department at King's College NHS Hospital Trust made provision for such patients to be seen within two weeks by ring fenced 'urgent' appointment slots in each clinical session (one in four new) arranged through the Central Referral Office (CRO) of the Trust.

**OBJECTIVE**

This study was designed to look at the effectiveness of the two-week wait by measuring the number of patients referred urgently for oral cancer or otherwise and seeing what proportion of urgent referrals was found to have cancer. The objective was to assess the sensitivity of the clinical guidelines and assess how practitioners used these guidelines in primary care.

**METHOD**

Referral letters received by the Trust from primary care practitioners between August 2003 and August 2004 marked 'urgent' or received via the two-week cancer wait system to the department of oral medicine at King's College Hospital were reviewed.

Hospital notes for these cases were retrieved and clinic notes made by one of three consultants working in the unit were examined to confirm the clinic diagnoses. If the consultant suspected cancer, all such cases would have received an urgent biopsy. The biopsy reports filed in these case notes were examined to obtain relevant histology data.

We then searched our oral pathology database of all oral squamous cell carcinomas diagnosed during this one year period for any biopsies sent by the three named oral medicine consultants to estimate whether any patients prioritised as 'routine' at the time of receiving the referral letter were later confirmed with oral cancer.

For this audit the collected data was recorded in four main areas:

- Demographic details
- Referral letter content
- Clinical findings on consultation
- Diagnosis.

Referral and clinic findings were entered into a spreadsheet (Microsoft Excel 2000, Microsoft Corporation, Redmond, Washington, US) and analysed. Positive predictive value (PPV) was calculated as the number of subjects with detected cancers as a proportion of total referrals under the urgent category.

**RESULTS**

A total of 76 patients were booked as 'new urgent' over the twelve month period of the study. These were made up of 25 in whom a malignancy was suspected, 25 in whom there were descriptive features of cancer in the referral letter but suspicion of a malignancy was not stated and four patients who were themselves concerned about having cancer. A further 15 patients were marked as urgent for other reasons. Seven patients failed to attend. This is illustrated in Figure 1.

There were 41 female and 28 male patients seen and their mean age was 55.5 years. About half of the referrals were sourced to the general dental practitioner and the other half to the general medical practitioner, excluding two patients who were referred by the community dental service and one by a nurse practitioner. The referrals were mainly delivered by post (23 cases) with a further one case being referred by registered post. Twenty-two referrals were sent by fax and two were hand delivered. The remaining were internal referrals. Six of these urgent letters were received on a pro-formas supplied by the Dental Institute to local practitioners and four on the national

**Table 1 Symptoms stated on the referral letter compared with consultant's diagnosis**

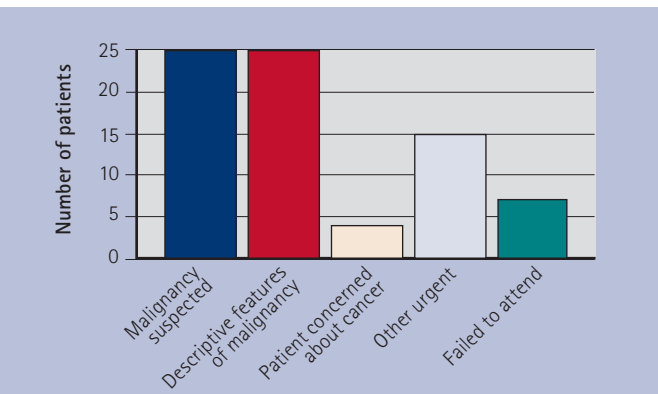
Correlation of remarks in the suspected malignancy/features of malignancy referral letter to the final diagnosis				
What the GMP/GDP wrote*	Clinic diagnosis			
	Cancer	Pre-cancer	Other mucosal disease	Normal variant
Ulceration > three weeks	5	2	20	3
Oral swellings > three weeks	1	1	9	2
Red or red/white patches	2	1	13	1
Unexplained tooth mobility	-	-	-	-
Unresolving neck masses > three weeks	-	-	1	-
Other symptoms related to head & neck	-	-	-	-
Not in the guidelines (eg induration)	-	-	8	-

\*Multiple features noted on the same referral letter exceed case totals in each category; six cases diagnosed with cancer had eight symptoms (see text); 48 cases found not to have a cancer but referred with the three common symptoms in the table had altogether 57 of these symptoms listed

**Table 2 Agreement between cancer diagnoses based on practitioner referral information**

Practitioner's indication of cancer	Consultant Diagnosis		Total
	Positive for cancer*	Negative for cancer	
Urgent referral	6	70	76
Routine referral	0	694	694
All referrals	6	764	770

\*Histologically confirmed (positive predictive value 6/76 = 7.9%)



**Fig. 1 Categorisation of referred patients under 'urgent' categories**

two-weeks wait cancer pro-formas.

All patients marked urgent were offered an appointment within the two-week wait period and 86% of patients suspected or presenting with features of malignancy were seen within the two-week wait target. Failure to obtain 100% was due mainly to patients failing to attend or rescheduling their first appointment.

The results of the analyses of the referral letters (symptoms stated by practitioners), the clinic findings and their concordance for cancer diagnosis are shown in Table 1. Of the 25 suspected malignancy patients, six were found to have histologically confirmed squamous cell carcinomas equating to eight percent of all urgent patients and 24% of all

suspected malignancy patients. The remainder (false positives), were made up of largely lichen planus, chronic hyperplastic candidiasis, erythema migrans and frictional keratosis. Less common diagnoses in the group were a giant cell epulis, a cavernous haemangioma and a reactive lymph node.

Of the six patients found to have cancer, two were referred with the letter indicating ulceration alone, two with ulceration and red and white patches, a further one with ulceration and swelling and one was referred with a white patch without ulceration. None of these letters stated that the patient had any lymphadenopathy.

None of the patients who had one or more of the descriptive features of malignancy in their referral letter (without indicating suspicion of cancer) were found to have a malignancy. These patients were diagnosed of having lichen planus, frictional keratosis, recurrent oral ulceration or fibro-epithelial polyp. Two patients were found to have leukoplakia with mild dysplasia indicating potentially malignant disease.

Of the four patients who were concerned about mouth cancer, three diagnoses were made up of normal variations namely racial pigmentation and raised papillae on the tongue and one had a lichenoid reaction.

During the one-year period, altogether 770 new cases were referred to the unit. Six hundred and ninety-four (90%) were routine referrals with no mention of cancer symptoms. Among these 694 cases, following the search of the oral pathology database, none were reported with oral cancer.

The summary of agreement between practitioner's suspicion for oral cancer at the referral stage and consultant's diagnosis is shown in Table 2. The predictive value of referring a case as suspected of cancer/with cancer symptoms was estimated to be 7.9%. However, for all routine referrals, no cancers were found giving a 100% predictive value for a cancer negative case.

## DISCUSSION

Of the total number of patients referred into the unit as urgent ( $n = 76$ ) over a 52 week period, 66% were suspected of having cancer of the mouth either because their medical/dental practitioner noted a malignancy or because some features of malignancy were stated on the referral letter. Therefore, these were thought to have been appropriately referred using the current guidelines as urgent. Of the group ( $n = 25$ ) where the practitioner indicated suspected malignancy, 24% of patients were found to have oral squamous cell carcinoma, a percentage slightly higher than that found in an audit in an urology unit by Allen *et al.*,<sup>5</sup> where 15% were found to have some sort of urological cancer. The data should be viewed under the context that doctors and dentists are working with patients and for the benefit of their patients, and strictly sticking to referral guidelines may not be appropriate.<sup>6</sup>

From Table 1 it can be seen that the common reasons for referral to our oral medicine unit for urgent cases was a persistent ulcer or swelling or a red or red and white patch. All of the patients diagnosed with a cancer were found to have at least one or more of these three presenting features. On the other hand, 48 out of 76 referrals referred with these three features were diagnosed by the hospital consultant in the non-cancer group, indicating the low specificity of these symptoms to diagnose oral cancer in primary care.

To our knowledge, no pilot study was conducted before

implementation of NHS cancer care referral guidelines for head and neck cancers. It would be timely to review the guidelines through a process of consultation with experts in the field, with a view to refining the symptomatology in the current guidelines.

Khawaja and Allan<sup>7</sup> in their study of the two-week wait for breast cancer found that transferring the power from hospital to practitioner on the urgency of the referral resulted in an increase in the waiting time for patients not deemed urgent. It is possible that referrers are urgently sending patients who could otherwise be seen on a routine basis, particularly the four patients who were found to have normal variations of oral mucosa. Cant and Yu<sup>8</sup> found that the waiting times were increased for those referred routinely due to overloading the hospital system.

Early diagnosis must offer a better chance of cure; therefore, the real measure of success is an improvement in survival. Allen *et al.*<sup>5</sup> concluded that fully complying with the two-week wait is unlikely to improve survival in urological cancer. One of the problems they highlight is the bottleneck that is created further along the diagnostic and treatment pathway following the first assessment, resulting in delays before initiating therapy. A longer wait from first appointment to treatment was also reported for breast cancer in Southeast England following a two-week target on waiting times to see a consultant.<sup>9</sup>

Substantial delays experienced by oral cancer patients are discussed by previous authors.<sup>10</sup> Among 120 oral cancers diagnosed in a hospital setting, only 75% had an indication of a suspected malignancy.<sup>10</sup> White *et al.*<sup>11</sup> speculated that a high proportion of dental practitioners were unaware of the mechanisms in place for urgent oral medicine referrals. The finding that only four of the letters suspecting a malignancy or giving features of a malignancy were received on a two-week wait cancer pro-forma suggest that improvements in communication on cancer referral guidelines by primary care trusts with local medical and dental practitioners is needed. The lag between the announcement of guidelines and application of these healthcare systems in primary care delays healthcare improvement. Awareness of practitioners for the need to refer patients non-urgently for further assessment of a white patch and oral lichen planus, that are not painful or ulcerated, has been recently raised by NIHCE.<sup>12</sup> The same guidelines also indicated that patients with 'unexplained tooth mobility' be referred to a dentist but did not explain what a dentist should do with such an episode.

In the United Kingdom, oral malignancy is a rare finding in primary dental care practice. However, any lesion suspicious of malignancy that has persisted over three weeks to the knowledge of the patient or the practitioner needs urgent referral. This study indicates that the visual signs attributable to an oral malignancy in the cancer guidelines appear not to accurately distinguish cancers from benign lesions and other conditions in the hands of the practitioners. Development of IT/telemedicine may be a way forward to allow specialists to prioritise the referrals appropriately.

## CONCLUSIONS

The mandatory two-week only wait system prior to a cancer diagnosis instigated by the Department of Health in the UK is in a way unique, in that no other country has so far

implemented a national programme of this kind. This provides a fast track referral system to allow persons suspected with cancer to see a hospital consultant without delay. However, in this study only 24% of referrals indicating urgency by a practitioner to see a consultant were later confirmed with cancer. The predictive value of referring a case as suspected of cancer/with cancer symptoms was thus estimated to be 7.9%. Given the enormous resource implications of seeing all patients with a white patch or lichen planus urgently or within two weeks when requested by a general medical practitioner or a dentist, our results raise a number of important points. This may suggest that the referral guidelines on oral cancer symptoms developed by NICE need further revision. Categories of referral under urgent/soon/routine as proposed by the West of Scotland Cancer Awareness Project<sup>13</sup> may need to be reviewed by an expert group in view of the considerable clinical governance implications for all departments of oral medicine and maxillofacial surgery. Moreover, development of other appropriate adjuncts that aid visual inspection for detection of oral cancer may improve the sensitivity of positive detections in primary care.

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