CPD: ONE HOUR

How accurately do members of the dental team detect malignant lesions?

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INTRODUCTION

Role-substitution describes the replacement of one type of healthcare worker for another, typically as a result of an extension of skills or widening of professional duties.[1] This has been used in medicine for some time, where nurses have increasingly taken on some of the clinical tasks performed by doctors. Evidence shows that it results in high quality care and good health outcomes.[1-3] Despite this, dentistry has been relatively slow to adopt these changes.[4-6]

In similarity to medicine, the range of clinical procedures that can be legally undertaken by the dental team is defined by the General Dental Council (GDC) and are detailed in their *Scope of practice*. In 2013, a number of important regulatory changes were made by the GDC, including substantive changes to this document. For the first time in the UK, patients were permitted to access dental hygienists, dental therapists and dental hygiene-therapists (DH-Ts) without a prescription from a primary care dentist (PCD). In addition, they were allowed to examine patients, diagnose and plan treatment within their competency.[7,8] Proponents argue that these types of regulatory changes have the potential to improve practice efficiency, the cost-effectiveness of service provision and release resources to increase the capacity to care.[9-12] Opponents argue that using dental hygienists, dental therapists and DH-Ts in this way is inherently unsafe and commonly cite the potential for missing oral malignancy as a significant danger.

Squamous cell carcinoma is the most frequently occurring oral malignancy and although its incidence is relatively low compared to the other forms of human cancers, such as breast or lung, it has a high mortality and morbidity rate.[13] Mouth cancer can be preceded by visible mucosal changes which represent so called potentially malignant disorders (PMD), many of which contain varying degrees of epithelial dysplasia. The most common form of PMD is leukoplakia, which has an estimated global prevalence of 2.6% (95% CI: 1.72–2.74%) and an estimated malignant transformation rate of between 1–5%.[14,15] However, the extent and rate of progression of dysplasia in leukoplakia is not uniform and can vary according to the clinical variant of the lesion and individual patient. Other forms of PMD include erosive leukoplakia, speckled leukoplakia and erythroplakia, with malignant transformation rates of 28%, 82% and 85% respectively.[16-18]

A study in the UK has shown that PCDs can detect PMD and oral malignancy (sensitivity of 74% and specificity of 99%),[19] while meta-analyses have demonstrated sensitivity and specificity values of 85% and 97% for non-dentists.[20-22] Allied health providers have also been used in population screening programmes, which have resulted in a reduction in mortality rates in high risk groups and high values for sensitivity (93%) and specificity (94%).[23-25] Despite this, doubts over the safety of using dental hygienists, dental therapists and dental hygiene-therapists as a front line health worker with regard to mouth cancer remain.[26]

The aim of this study was to determine the comparative diagnostic test accuracy of different members of the dental team when examining standardised photographs of mouth cancer, PMDs and benign lesions.

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MATERIALS AND METHODS

Participants

Participants were sampled purposively. The study participants were grouped as follows:

- PCDs, including general dental practitioners and community dental officers
- DH-Ts, including dental hygienists, dental therapists and dual qualified dental therapists
- Hospital-based dentists from oral medicine and oral surgery clinics
- Dental nurses.

Design and procedure

Following consultation with the University of Manchester ethics committee, the study was considered to be of low risk and was deemed not to require ethical approval. All participants who took part in the study did so voluntarily. It was delivered at the beginning of a structured continuing professional development event. No coercion or payment for participation was made. All the data was anonymised at source.

The demographic details of all the participants who agreed to take part were recorded and included: age, gender, year of qualification, extent of patient contact, place of work and the number of days per week working for the NHS. Following this, the participants were presented with information about the study and undertook a standardised five minute orientation package devised by three of the authors (PRB, MP and MAOL). This was delivered using a Microsoft Office PowerPoint 2003 presentation and introduced participants to the research task. Ten example slides where presented to the audience of mouth cancer, PMD and benign oral lesions. After each slide the audience were provided with an explanation of the classification of the lesion, within the context of the study. The training was kept deliberately brief to ensure the research team captured the participants' performance before any educational component.

Following orientation, participants were asked to score 90 standardised clinical photographs of mouth cancer, PMDs and benign lesions of the oral mucosa. For each photograph, the participants were asked to determine whether they felt the lesion was representative of mouth cancer or a PMD (test positive) or whether the lesion was benign (test negative) (Table 1). This was the index test. They were also asked to record their confidence in their decision on a 0-10 scale, where a score of ten represented complete confidence in their decision and zero represented no confidence. The photographs were presented under controlled lighting and the time delay between consecutive photographs was set at 12 seconds. Judgement decisions were compared against the known histo-pathological diagnosis of each lesion (reference standard) (Table 1). The study was undertaken during the period of September to December 2013, across four sites: Manchester, Liverpool, Rhyl and Cardiff.

> 'EVIDENCE SHOWS THAT ROLE SUBSTITUTION RESULTS IN GOOD HEALTH OUTCOMES'

Table 1 Criteria for the study

Criteria	Detail
Index test	Visual examination of clinical photographs of mucosal lesions
Judgement task	Is the lesion before you malignant/potentially malignant (test positive) or is it benign (test negative)?
Target condition (test positive and negative)	Positive: oral cancer and potentially malignant disorders, which included: oral carcinoma, speckled leukoplakia, erythroplakia, leukoplakia, chronic hyperplastic candidiasis and atrophic lichen planus. Negative: benign lesions included: frictional keratosis, geographic tongue, salivary mucocoele, reticular lichen planus, pseudo-membraneous candidiasis, minor aphthae and median rhomboid glossitis.
Reference standard	Histological confirmation

Calculation of sample size

Based on a two-sided 95% confidence interval for a single proportion (sensitivity or specificity) using the z-test approximation, with absolute precision of 0.1 and expected sensitivity of 90%, the number of cases that satisfied a power of 0.8 was calculated to be 35 (n ‡ (Z2⁄m2)*p (1-p)).[27] The prevalence of mouth cancer, PMD and benign lesions in general dental practice was reported in a prospective cohort study undertaken by Lim *et al.*[28] This data was used to inflate the sample size to ensure an appropriate number of benign lesions were included (Buderer's method). As a result, 35 malignant or PMDs and 55 benign lesions were included in the test set of photographs.

Analysis

Median sensitivity, specificity and positive and negative predictive values were calculated for each participant within each clinical group

Table 2 Demographics of the participants (n = 192)

Group	N	Male (%)	Female (%)	Age* (years)	Qualified* (years)	Patient contact* (days per week)	Time spent treating NHS patients (%)*
Primary Care Dentists	96	56.3	43.8	40–49	10–19	5	75–100
Hygiene/Therapists	63	1.7	98.3	40–49	10–19	4	25–49
Hospital-based dentists	9	58.3	41.7	30–39	10–19	5	75–100
Nurses	24	0	100	40–49	10–19	5	75–100

*mode

using SPSS (version 20). The minimum, maximum and interquartile ranges (IQR) were calculated for both sensitivity and specificity of each clinical group as a measure of variability, along with the lower bound of the 95% confidence interval. The mean confidence score was calculated for each participant; the mean and standard deviation was then calculated for each category of clinician. Missing results were excluded from the analysis. Median sensitivity and specificity estimates were plotted in ROC space. Percentiles were plotted against sensitivity for each clinical group (using Stata 13).

Although the design was not an *in vivo* diagnostic test accuracy study, elements of the Standard for Reporting Diagnostic Accuracy (STARD) guidance was used as appropriate.

RESULTS

Table 2 presents the demographic data of the 192 dental professionals that completed the study: 96 PCDs, nine hospital-based dentists, 63 DH-Ts and 24 nurses. The mode of the age distribution for the PCDs and DH-Ts was 40-49 years of age, while the hospital staff were 30-39 years of age. The mode of the distribution for the time since their primary dental qualification was 10-19 years. All the participants worked in a primary care environment except for hospital-based dentists. The majority of the participants time was spent working in the NHS (75-100%), bar the DH-Ts who worked for 25-49% of their time in the NHS.

Table 3 highlights the results of the study. The difference between the median sensitivity of the PCDs and DH-Ts was small (80.7% and 77.4% respectively). Again there was very little difference in their median specificity: 72.9% and 67.8% respectively. IQR of sensitivity was similar (19% from x-to-y in PCD group and 19% from x-to-y in DH-T group). This highlights the variance in the individual point estimates between and within the two clinical groups. The mean confidence in decision was higher in the PCD group (6.48 (1.57) compared to 5.88 (1.53)); while hospital-based dental staff had a higher confidence (7.73 (1.9) and nurses lower (3.73 (2.7)).

Figure 1 shows summary plots in receiver operating characteristic space of the individual participant's median sensitivity against false positives (1-specificity), for the PCD and DH-T groups only. A perfect sensitivity and specificity would see a point plotted in the top left corner, whereas the diagonal line represents a plot of sensitivity and specificity equal to chance. Figure 2 highlights the number of participants in the PCD and DH-T groups who missed frank malignancy (oral squamous cell carcinoma) and identifies that 59% of DH-Ts did not miss any frankly malignant lesions compared to 48% of PCDs. Figure 3 presents percentiles of median sensitivity for each of the professional groups. While the 50th percentile identifies PCDs having a median sensitivity of 80.7% compared to 68.7% for the DH-Ts, by the 80th percentile DH-Ts had a higher median sensitivity 94.1% compared to 87.3% for PCDs.

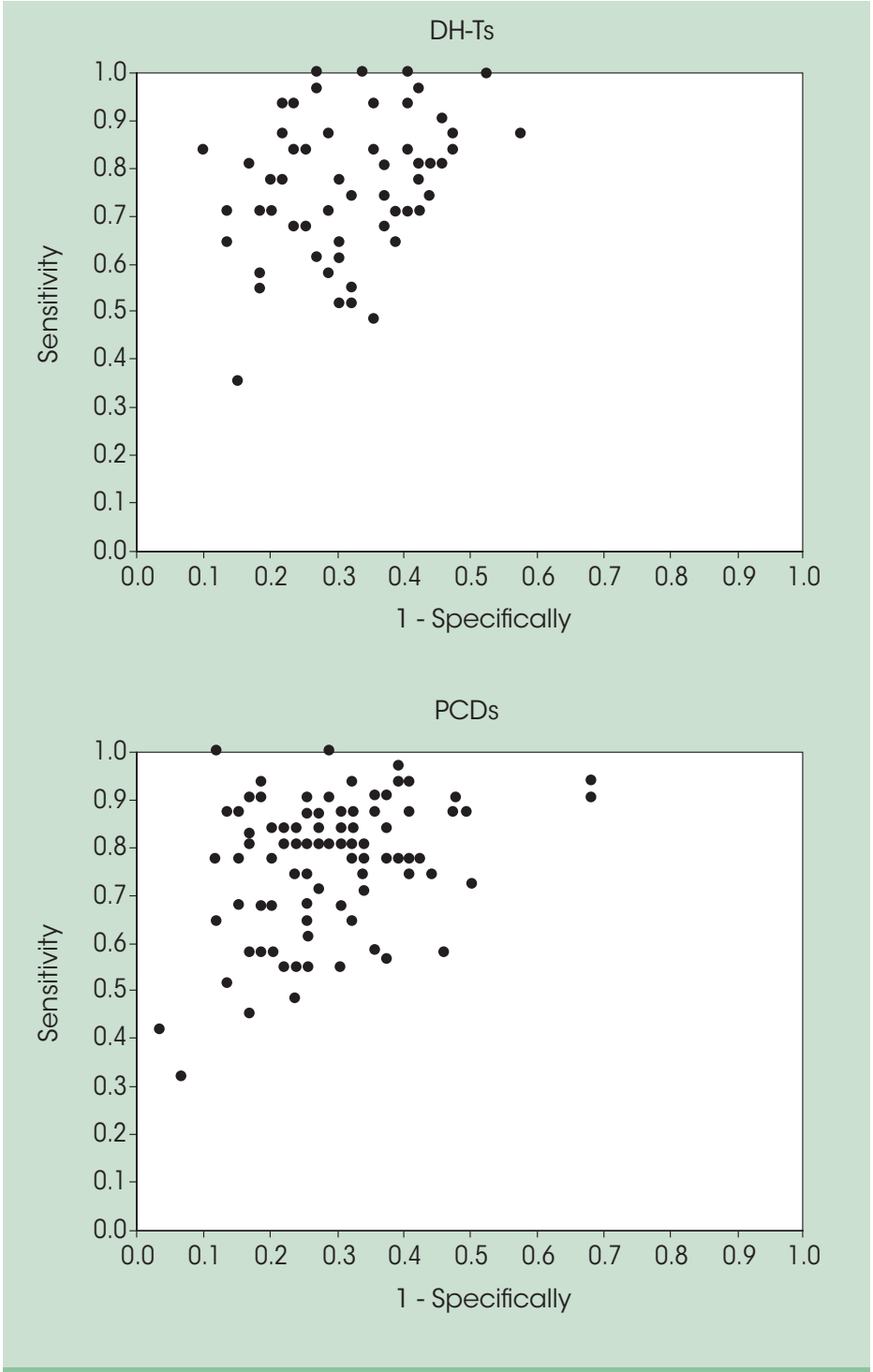

Fig. 1 Scatter plots in receiver operating characteristic space of individual sensitivity and specificity values

DISCUSSION

The results for PCDs and DH-Ts were comparable for both median sensitivity and specificity (Table 3, Fig. 1 and 3). Although the median values for sensitivity and specificity for PCDs were marginally higher than DH-Ts, DH-Ts missed fewer mouth cancers (Fig. 2). Furthermore, at higher percentiles (Fig. 3) the sensitivity of DH-Ts was higher. This suggests that the performance of DH-Ts is comparable with

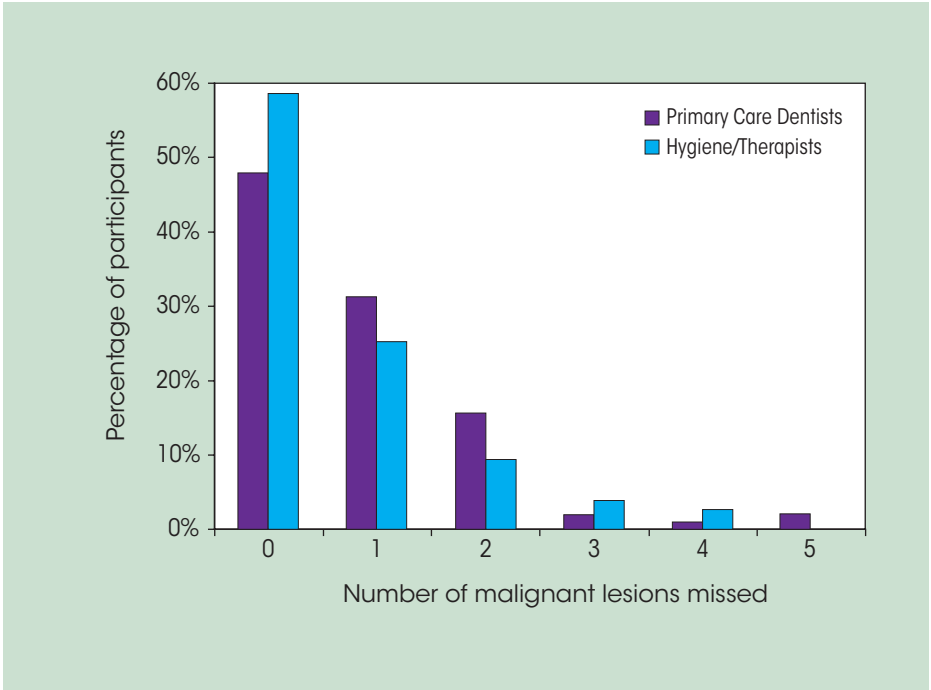

Fig. 2 Number of malignant lesions missed by PCDs and DH-Ts

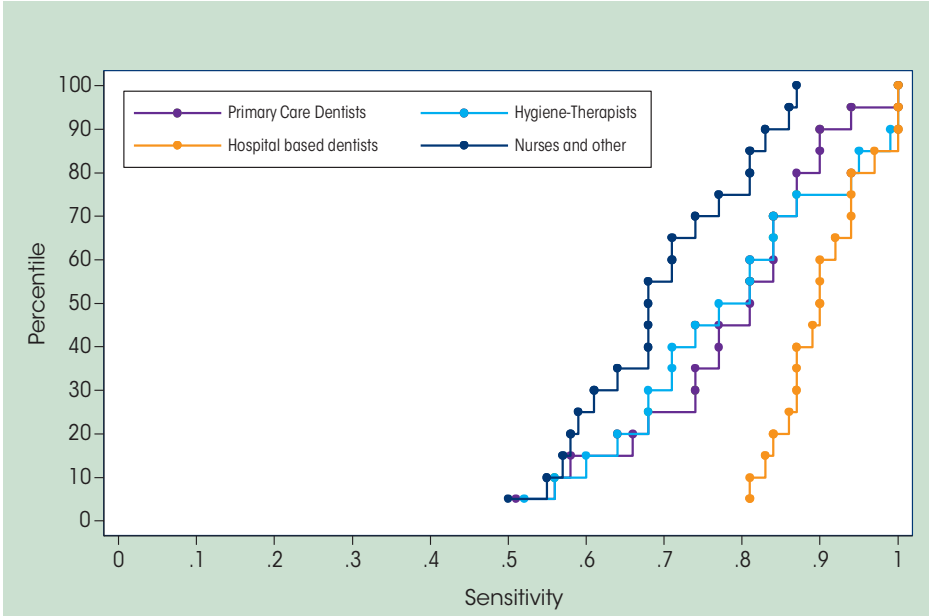

Fig. 3 Percentile of sensitivity compared across all professional groups

'THIS SUGGESTS THAT THE PERFORMANCE OF DH-Ts IS COMPARABLE WITH PCDs AND IS CONSISTENT WITH EARLIER STUDIES'

PCDs and is consistent with earlier studies.[25] For all professional groups, median sensitivity was always higher than median specificity, suggesting that when uncertain participants would assign the lesion in the photograph as test positive. This produces a higher number of false positives and reduces positive predictive values (Table 3). It is intuitive that clinicians would refer on for further investigation if they are unsure and this concurs with the advice from oral medicine experts to refer when in doubt. Similarly the numbers of false negatives suggest that all the professional groups would only classify lesions as test negative when absolutely certain and would prefer to over-refer.

Although the summary estimates were similar, the minimum, maximum and IQR (Table 3, Fig. 1) highlight the variation within groups. This is another important finding and suggests that training remains paramount. This was recently recognised by the GDC in the UK, who now advises that mouth cancer should be considered as an essential part of a structured post-graduate dental education for all members of the dental team. A training programme adapted from the one used by Sankaranarayanan *et al.*[23-25] for health workers could be helpful here in improving the sensitivity and specificity of both PCDs and DH-Ts.[29]

The main weakness of the study is that the use of photographs is artificial when compared to the judgement ecology in a practice environment. The judgement decision was restricted to the visual appearance alone and therefore did not include patient risk factors. In addition, it was not possible to palpate the lesion, which forms an important part of any clinical examination. However, an *in vivo* study is problematic; the low prevalence of oral malignancy and PMD means that a large number of patients would need to be seen in a clinical environment to provide enough lesions in the study to satisfy the power calculation. In practice, the patients that present to PCDs and DH-Ts are predominantly healthy and so the number required to satisfy the parameters described in the power calculation above would be multiplied by the reciprocal of the prevalence of the rarest test condition ($35 \times 100/4.1 = 853$ patients). A further weakness is that the study did not examine the ability of PCDs or DH-Ts to diagnose or manage benign oral mucosal lesions in primary care, only the ability to differentiate between these types of lesions. This would be an important extension. There were also some distinctions made about the classification of the different forms of oral lichen planus. For the purposes

Table 3 Summary measures of sensitivity, specificity and confidence

	Primary care dentists	*Hygiene/ therapists*	*Hospital-based dentists*	*Nurses*
Sensitivity				
Median	81%	77%	90%	68%
Minimum	32%	35%	81%	48%
Maximum	100%	100%	100%	87%
Interquartile range	19%	19%	9%	18%
Lower bound of confidence*	71%	71%	18%	61%
Specificity				
Median	73%	69%	76%	59%
Minimum	32%	42%	68%	41%
Maximum	97%	90%	88%	92%
Interquartile range	16%	17%	10%	18%
Lower bound of confidence*	69%	64%	73%	53%
Confidence				
Mean	6.48	5.88	7.73	3.73
Standard deviation	1.57	1.53	1.9	2.7

*Approximate 95% lower confidence bounds on median

of this study, reticular lichen planus was deemed to be test negative, while erosive and atrophic lichen planus was classified as test positive. This was a pragmatic decision based on the heterogeneity of the evidence in the literature.[30] However, this was made explicit at the start of the study in the orientation phase and would be the same for both clinical groups.

The importance of opportunistic screening for mouth cancer by the primary care dental team is not without its critique. The incidence of mouth cancer is relatively low in many developed countries[13] and is lower still for regular attenders.[31] In addition, the benefit of identifying early disease may not necessarily confer an prognostic advantage due to field change, for example, malignant transformation of mucosa previously unidentified by a screen.[32,33] However, the five-year survival rate for mouth cancer has remained static and the most important determinants remain patient and diagnostic delay.[34,35] Therefore, the need for all front-line health workers to remain vigilant to early disease remains important and was again emphasised by the update of the Cochrane systematic review.[36] However, considerable heterogeneity remains in the behaviour of the dental team. MacPherson *et al.* reported that 63% of PCDs felt that they were not confident enough in their ability to screen and subsequent descriptive studies have found that many still focus on signs of advanced disease rather than PMD.[37-41]

The results from this study suggests that DH-Ts are comparable to PCDs in the detection of mouth cancer and PMDs and that these members of the dental profession should be considered as competent as PCDs in this aspect of front-line healthcare delivery. However, training remains paramount to reduce the variation observed within each group. Further research to explore the ability of DH-Ts to manage benign oral lesions is warranted.

CONCLUSION

DH-Ts performed comparably to PCDs in the detection of mouth cancer. This study confirms that DH-Ts should be considered as safe front-line healthcare workers with regard to mouth cancer. However, considerable heterogeneity was found within both groups of these dental professionals, which suggests training remains essential for all.

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