PILOT STUDY TO ESTIMATE THE ACCURACY OF MOUTH SELF-EXAMINATION IN AN AT-RISK GROUP

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Abstract:  Background. Mouth self-examination (MSE) is a possible method of detecting oral cancer early. This study aimed to determine whether those at risk of developing oral cancer are able to correctly detect potentially malignant oral lesions via MSE.

Methods. Participants (53 smokers aged over 45 years) received an oral mucosal examination by the dentist and then performed MSE after education through a self-read leaflet. The dentist and participant both recorded the presence and absence of potentially malignant oral lesions.

Results. The prevalence of potentially malignant oral lesions was 22%. The sensitivity of MSE was 33% and the specificity was 54%. MSE had a positive predictive value of 17% and a negative predictive value of 73%.

Conclusion. The at-risk group were poor at correctly identifying the presence or absence of potentially malignant oral lesions. A leaflet may be an ineffective training tool to aid self-identification of potentially malignant oral lesions. © 2010 Wiley Periodicals, Inc. Head Neck 32: 1393–1401, 2010

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Oral cancer is the 11th most common cancer in the world, with an estimated 390,000 new cases each year.¹,² Although oral cancers are not common in developed countries, the disease is on the increase in young adults,³ and overall 5-year survival rates have shown little sign of improvement beyond 50%.¹,² Furthermore, many patients who are successfully treated for oral cancer have to cope with the negative consequences of their treatment such as disfigurement, dysphagia, and dysphasia.⁴ Improved survival rates and reduced morbidity are associated with early detection,⁵ yet approximately 50% of patients are diagnosed with advanced-stage disease.⁶ As such, the implementation of initiatives to encourage early diagnosis of oral cancer should be a priority for public health services.

Screening for premalignant or early-stage oral cancers may be an important approach in the secondary prevention of oral cancer.⁷,⁸ Oral
cancer occurs in sites that lend themselves to early detection by visual inspection. For example, in at least 75% of patients, oral cancer involves the anterior of tongue, floor of the mouth, buccal mucosa, gingiva, lips, or palate; hence, sites that can be readily visualized. Systematic visual examination of the surface of the oral mucosa is relatively simple and inexpensive to perform and causes little discomfort to the patient. Although the early signs of oral cancer can be painless, virtually all oral cancers are preceded by visible changes in the mouth such as a white or red patch, an ulcer, or a swelling/lump.

Oral mucosal examination has been found to be a sensitive and specific test. In a study conducted in India, Sankaranarayan et al found a significant reduction in oral cancer mortality rates in high-risk individuals when screening was conducted by trained health workers. A Cochrane systematic review of screening programs for the early detection and prevention of oral cancer concluded that there is insufficient evidence to support or refute a general population oral mucosal screening program. However, a cost-effective analysis concluded opportunistic screening of high-risk individuals at yearly intervals by primary care medical and dental practitioners should be considered.

Unfortunately, those most at risk of oral cancer (those who smoke, regularly drink alcohol, and those over 45 years old) are unlikely to be regular dental attendees and thus are denied the benefits of frequent intra-oral screening opportunities. As such, alternative and adjunct secondary preventative initiatives are warranted. Mouth self-examination (MSE) has been advocated for the early detection of oral cancer. However, the World Cancer Report noted that there is an absence of information and research on MSE. In particular, although the few studies that do exist have shown promising results, they are not without their limitations, and there have been no investigations into the accuracy of MSE. Grabau et al assessed the feasibility of one-to-one instruction for MSE in New York State. Follow-up surveys at 3 and 8 months after individuals had learned the technique indicated a substantial degree of continued self-examination at home. A total of 86% of respondents believed it was important to know how to perform MSE, and 92% reported that they would recommend it to friends and family. Teaching MSE was judged to be feasible for large-scale application. However, with 60% of the sample being women and a mean age of 40 years, this intervention did not reach those most at risk of oral cancer. Furthermore, there was no objective assessment of how well the technique was learned or performed. In India, Mathew et al evaluated MSE within a high-risk population in a large-scale investigation. Brochures describing the risk factors of oral cancer, the appearance of premalignant and malignant lesions of the oral cavity, and the method of MSE were distributed to participants who smoked and/or were 30 years old or older. Of those who identified a change in their mouth and presented to the clinic, 21% had mistaken anatomic landmarks or normal variations for lesions, 39% had benign lesions, 34% had clinical pathology, and 6% had new or recurrent oral cancer. Mathew et al concluded that although larger studies are still required to determine the efficacy of MSE in the reduction of mortality, educating the public about MSE and knowledge about the lesions is feasible and may help in promoting early detection of oral cancer. This study, we believe, was the first study to assess the outcome of MSE, yet because the analyses were only based on those who found a change and reported to the clinic, there is no information as to the proportions of those who found a lesion but did not attend, or those who failed to notice a change but did have a lesion. As such, the accuracy of MSE could not be assessed.

Prior to alerting those at risk of developing oral cancer to regularly examine their mouths, information is required as to whether MSE will allow accurate detection of potentially malignant oral lesions. High levels of sensitivity and specificity are also important because there is a risk of false reassurance for those with false-negative results and unnecessary anxiety for those with false-positive results. The principal aim of this pilot study was to estimate the accuracy of MSE in an at-risk group. The research was primarily a study of diagnostic accuracy comparing the agreement between the participant and dentist in identifying potentially malignant oral lesions.

**MATERIALS AND METHODS**

**Participants.** Participants were recruited from a general practitioner’s list in South East London, UK. Patients who were at risk of oral cancer (aged 45 years or older and who smoked) were
identified as potential participants by their general practitioner. An invitation letter, participant information sheet, participation form, and postage-paid envelope were mailed to 243 eligible patients by the general practitioner. Patients were asked to complete the participation form indicating whether or not they would like to participate in the research and return it to the research team.

**Procedure.** Patients who indicated that they would like to take part in the study were given an appointment to visit the research department. A well-lit room with a mirror mounted on the wall by the window was used to re-create an environment similar to the participants’ own setting for MSE (e.g., the home) but which was standardized for all study participants. At their visit, each participant completed a consent form. Participants were asked to remove any dentures, and an oral mucosal examination was conducted by the dentist (K.R.) in accord with the following steps:

1. With the patient’s mouth partially open, the labial mucosa and sulcus of the maxillary vestibule and frenum and the mandibular vestibule were visually examined.
2. By starting with the right maxillary posterior gingiva and alveolar ridge and then moving around the arch to the left posterior area, the buccal and labial aspects of the gingival and alveolar ridges were examined. This was repeated on the left-hand side. The palatal and lingual aspects, as on the facial side, from right to left on the palatal (maxillary) aspect, and left to right on the lingual (mandibular) aspect were then examined.
3. The right, then the left, buccal mucosa were examined extending from the labial commissure and back to the anterior tonsillar pillar. A disposable tongue depressor was used to retract the cheeks.
4. With the participant’s tongue at rest and the mouth partially open, the dorsum of the tongue was examined. With a piece of gauze, the tip of the tongue was held to assist in full protrusion of the tongue for inspection of the right and left sides.
5. With the tongue elevated, the floor of the mouth was examined.
6. With the patient’s mouth wide open and head tilted back, the hard and soft palates were inspected.

A mask and gloves were worn to ensure infection control and cotton gauze was used for holding the tongue. The dentist did not use an intra-oral mirror. The presence (including site and provisional diagnosis) and absence of potentially malignant oral lesions (ulcers, white or red patches, or lumps/swellings) were noted on a proforma.

After the dentist’s examination (yet before the results of the examination were revealed to the participant), participants were provided with a leaflet on “How to spot mouth cancer early.” The leaflet gave details on oral cancer, risk factors, symptoms, stepwise instructions, and illustrations of MSE (Figure 1 for the section relating to MSE), and information on when and how to seek help for potentially malignant oral lesions. The leaflet had been specifically developed for and piloted with heavy smokers and drinkers and has a reading age of 10 to 12 years and a Flesch reading ease score of 79%, indicating it can be read and understood with ease. Participants were asked to read the leaflet carefully and follow the instructions to check their own mouth for any ulcers, white or red patches, or lumps/swellings. Intra-oral mirrors were not used. The dentist remained in the room but did not assist the participant in conducting the MSE. The dentist completed the oral mucosal examination before the participant rather than after, as piloting indicated that participants often drew the dentist’s attention to their findings, thus invoking potential to bias the dentist’s examination.

The study assessed detection of potentially malignant oral symptoms rather than detection of oral cancer itself. This is because interventions to encourage early detection of oral cancer would advise individuals to look for potentially malignant oral symptoms and present to a healthcare professional if symptoms lasted more than 3 weeks—it is the professional and not the lay public who is expected to differentiate between benign and malignant oral conditions.

Immediately after MSE, participants were asked to complete a self-report brief questionnaire (purposefully designed for this study) which enquired as to the presence and location of potentially malignant oral lesions (Appendix 1 shows example questions), their awareness of the lesion prior to MSE, sociodemographic details (age, sex, marital status, ethnicity, education, and employment) and health-related behaviors.
Check your mouth is OK

Why should I look in my mouth?
You may think that you’d feel that something is wrong in your mouth. However, many of the early signs of mouth cancer (like a red or white patch) do not hurt. So it is important that you look in your mouth to see if it is OK.

Checking your mouth is easy, free, takes one minute, and can save your life by finding mouth cancer early.

How do I look in my mouth?
Wash your hands, stand in front of a mirror in a well-lit room, and if you have dentures (false teeth) take them out. If you wear glasses put them on.

Then follow the five simple steps on the opposite page to check your whole mouth for:
- red patches;
- white patches;
- ulcers; and
- lumps or swellings.

Don’t panic!
Remember that a red patch, white patch, ulcer or lump in your mouth is only a possible sign of mouth cancer if it lasts for more than three weeks.

Step 1: Check your lips and gums
• Pull down your lower lip and look inside your lip and at your gums.
• Repeat this on your upper lip.

Step 2: Check inside your cheeks
• Pull out your right cheek so you can look at the inside of your right cheek.
• Repeat this on your left cheek.

Step 3: Check your tongue
• Stick out your tongue and look at the top surface.
• Stick out your tongue and move it from side to side to look at one side then the other.

Step 4: Check the roof of your mouth
• Open your mouth and tilt your head back to look at the roof of your mouth.

Step 5: Check under your tongue
• Place the tip of the tongue on the roof of your mouth and look at the underside of your tongue and the floor of your mouth.

FIGURE 1. The section of the leaflet on mouth-self examination.

(tobacco and alcohol use, and frequency of dental attendance). Participants were also asked to rate how difficult they found the MSE on a categorical response scale (Appendix 1) from 0 (very easy) to 4 (very difficult). Alcohol intake was measured using the Audit-C.22 The Audit-C is a validated alcohol screening tool that can help identify patients who are hazardous drinkers or have active alcohol use disorders. The Audit-C is scored on a scale of 0 to 12 (score of 0 reflects no alcohol use). In men, a score of 4 or more is considered positive; in women, a score of 3 or more is considered positive. A positive score means the patient is at risk for hazardous drinking. A score of 8 or more indicates active alcohol abuse or dependence.

After participants had completed the questionnaire, they were debriefed. This involved discussions as to whether they or the dentist had noticed anything in their mouth, the provision of reassurance, advice, and steps for action, if required. Each participant received £5 to cover time and travel expenses. The procedure was approved by Bexley and Greenwich Research Ethics Committee.

Data Analysis. Statistical package for the Social Sciences (version 16.0) was used for statistical analysis. Descriptive statistics were used to report sociodemographic details and health-related behaviors. Sensitivity (proportion of participants who identified a potentially malignant oral lesion via MSE of the total number of participants who had a potentially malignant oral lesion), specificity (proportion of participants who identified the absence of a potentially malignant oral lesion via MSE of the total number of participants who do not have a potentially malignant oral lesion), positive predictive values (PPVs; proportion of participants who have a potentially malignant oral lesion of those who identified a potentially malignant oral lesion via MSE), negative predictive values (NPVs; proportion of participants who do not have a potentially malignant oral lesion of those who identified the absence of a potentially malignant oral lesion, via MSE).
oral lesion via MSE), and confidence intervals (CIs) of MSE were calculated to estimate the accuracy of MSE.

**RESULTS**

**Sample Characteristics.** Of the 243 potential participants invited by the general practitioner, 58 participants (24%) agreed to take part in the study. Of the 58 participants, 53 participants (91%) attended their appointment. The sociodemographic details and health-related behaviors of the sample are displayed in Table 1. The ages ranged from 45 to 64 years old. The mean age was 54 years (SD, 5.9 years). Participants smoked between 2 and 60 cigarettes per day (mean, 17 cigarettes; SD, 14.0 cigarettes). Participants had smoked for an average of 31 years (range, 14–50 years; SD, 9.03 years). Twenty-four percent of the participants reported that they had recently stopped smoking but were still included in the study due to their at-risk status (over 45 years old, previous heavy smokers, and/or high alcohol intake).

**Oral Mucosal Examination by the Dentist.** Ulcers were seen in 2 participants (4%). The ulcers were provisionally diagnosed as cold sores (labial mucosa) and frictional keratosis (buccal mucosa). The dentist identified red patches in 2 participants (4%). The size of the lesions were approximately 0.5 cm. The provisional diagnoses were traumatic lesions (palate). White patches were found in 4 participants (8%). Two white lesions were observed on the lower retro-molar regions, while 1 was found on the lip, and 1 on the palate. The lesions were provisionally diagnosed as leukoplakia (n = 1), keratosis (n = 2), and fibrosis (n = 1). Lumps/swellings were seen in oral cavity in 4 participants (8%). The lumps/swellings were found on the buccal mucosa (n = 1), the palate (n = 2), and the tongue (n = 1). The size was 1 to 2 cm and provisionally diagnosed as papules (n = 2) and hyperplastic tissue (n = 2). Overall, 12 potentially malignant oral lesions were noted by the dentist, indicating a prevalence of 22% in this sample.

**Mouth Self-Examination.** Eight participants (15%) noticed an ulcer. Of those who did not see an ulcer, 9 participants (20%) reported that they were unsure about their observation. A total of 75% of those who saw an ulcer indicated that they had not been aware of it before they checked their mouth.

Eight participants (15%) noticed a red patch in their mouth. Of those who did not see a red patch, 11 participants (24%) reported that they were unsure. For those who noted a red patch, 50% were not aware of it before they performed MSE.

Ten participants (19%) noticed a white patch. Of the 35 participants who did not observe a white patch, 7 (16%) reported that they were not sure of their decision. A total of 90% were not aware of the white patch prior to looking in their mouth.

Eleven participants (21%) noticed a lump or swelling in their mouth. Of the 35 participants who did not observe any lump, 8 (19%) were not confident in their decision. A total of 36% reported that they had not been aware of the presence of a lump or swelling before they performed MSE.

Thirty-nine participants (74%) found MSE to be very easy or easy, while the rest found it to be of average ease/difficulty (19%) or difficult.

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*Table 1. Sample sociodemographic details and health-related behaviors.*

<table>
<thead>
<tr>
<th>Variable*</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
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<tr>
<td>Male</td>
<td>36 (68)</td>
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<tr>
<td>Female</td>
<td>17 (32)</td>
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<tr>
<td>Marital status (n = 51)</td>
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<tr>
<td>Single or divorced</td>
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<tr>
<td>Married</td>
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<tr>
<td>Widowed</td>
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<tr>
<td>Ethnic origin (n = 51)</td>
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<tr>
<td>White</td>
<td>37 (70)</td>
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<tr>
<td>Other ethnic origin</td>
<td>14 (26)</td>
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<tr>
<td>Education (n = 49)</td>
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<tr>
<td>No education or compulsory education only</td>
<td>24 (45)</td>
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<tr>
<td>Beyond compulsory education</td>
<td>25 (47)</td>
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<tr>
<td>Employment</td>
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<tr>
<td>Employed</td>
<td>22 (42)</td>
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<tr>
<td>Unemployed</td>
<td>17 (32)</td>
</tr>
<tr>
<td>Retired</td>
<td>14 (26)</td>
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<tr>
<td>Alcohol consumption</td>
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<td>Hazardous drinking score on AUDIT-C</td>
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<tr>
<td>Alcohol-dependent score on AUDIT-C</td>
<td>11 (21)</td>
</tr>
<tr>
<td>Tobacco use (n = 51)</td>
<td></td>
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<tr>
<td>Current smoker</td>
<td>41 (77)</td>
</tr>
<tr>
<td>Used to smoke</td>
<td>12 (23)</td>
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<tr>
<td>Dental attendance (n = 52)</td>
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<tr>
<td>At least every 6 mo</td>
<td>10 (19)</td>
</tr>
<tr>
<td>Every 6–12 mo</td>
<td>17 (32)</td>
</tr>
<tr>
<td>Every 2–5 y</td>
<td>10 (19)</td>
</tr>
<tr>
<td>Emergency only</td>
<td>11 (21)</td>
</tr>
<tr>
<td>Never</td>
<td>4 (8)</td>
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</table>

*n = 53 unless otherwise stated.
No participants found MSE to be very difficult.

**Accuracy of Mouth Self-Examination.** Due to the small numbers of individual types of potentially malignant oral lesions, the accuracy of MSE was calculated for potentially malignant oral lesions as a whole. Overall, 23 participants reported noticing 1 or more potentially malignant oral lesions, whereas the dentist recorded that 12 participants had a potentially malignant oral lesion. Table 2 summarizes the diagnostic accuracy of MSE. The proportion of correct diagnosis was 51%. The sensitivity of MSE was 33% (95% confidence interval [CI], 11% to 65%), and the specificity of MSE was 54% (95% CI, 38% to 69%). The PPV of MSE was 17% (95% CI, 6% to 40%), while the NPV was 73% (95% CI, 54% to 87%). A closer inspection of where the diagnostic errors (ie, false positives and false negatives) occurred, revealed that the most common site within the oral cavity for a participant to mistakenly identify a potentially malignant oral lesion was the tongue. The most common site to miss a potentially malignant oral lesion was the palate.

**DISCUSSION**

MSE has been advocated as a potential tool in the effort to encourage early detection of oral cancer. MSE is thought to be economically feasible because it does not require an appointment with a healthcare professional, it is simple, is noninvasive, and should be easy to perform alongside other oral care behaviors. MSE also has the potential to empower patients by giving them an active role in appreciating what is and what is not a concern in their own mouths. However, there has been lack of research into MSE, and in particular, the accuracy of MSE is unknown. Diagnostic accuracy is imperative in any method of disease detection. The test or procedure should be capable of giving a positive finding when the individual has the condition being sought (sensitivity) and be capable of giving a negative finding when the individual does not have the condition being sought (specificity). This pilot study aimed to estimate the accuracy (and therefore potential) of MSE in detecting potentially malignant oral lesions by at-risk individuals.

The majority of the sample found MSE to be easy, and participants reported that MSE allowed detection of oral lesions (especially white patches and ulcers) for which they were previously unaware. Despite this, the sensitivity of MSE was found to be low (33%) indicating that few participants correctly identified the presence of oral lesions. This was particularly the case when lesions were on the palate, maybe because of the difficulty to see this area when examining oneself. The specificity was found to be 54%. This indicates that people also had trouble in correctly noting the absence of potentially malignant oral lesions, presumably by interpreting normal anatomic structures as pathological changes. The PPV of 17% indicates that there is a low chance that a person who identifies a potentially malignant oral lesion via MSE will actually have one. This has implications for services in that MSE may lead to dental services seeing an increase in help-seeking from the worried well and may cause unnecessary anxiety. The NPV of 73% indicates that there is a higher probability that a person who reports they have no potentially malignant oral lesions to be correct.

These findings reflect the outcomes of evaluations into self-reports for other (benign) oral conditions. For instance, Kononen et al investigated the validity of self-examination for dental information and found that although self-examination results for presence of dentures, and the number of remaining teeth were accurate, self-reports of distribution of remaining teeth “misdiagnosed” 2.1 teeth per person. Patton assessed self-reports (via a questionnaire—patients were not asked to inspect their mouths) of oral infections by patients with human immunodeficiency virus/acquired immune deficiency syndrome. Comparison of the self-reports with results of an examination by an oral medicine practitioner indicated the sensitivity was low, ranging from 11% (changes in the color or texture of the tongue) to 56%
to establish a precise estimation of the accuracy of MSE (see the wide 95% CIs). However the CIs indicate that the maximum sensitivity and specificity of MSE are likely to be 65% and 69%, respectively, values which are still too low to recommend MSE. The small sample size reflects the low response rate to the invitation to take part in this study. This may have resulted in a biased sample. However, all participants were deemed to be at risk of developing oral cancer due to their age, smoking, and drinking habits. The low response rate is similar to that of other research recruiting smokers and drinkers and for oral cancer screening programs in the UK and reinforces the need to find new and effective ways of reaching this hard-to-reach group. By applying the findings of the current study to the nomograms designed by Carley et al to calculate sample size in diagnostic studies, the desired sample size for a definitive study into the accuracy of MSE would require approximately 370 participants to provide a fairly precise estimate (±10%) or 1470 participants for an estimate with a higher degree of precision (±5%). A definitive study would be strengthened by comparing the accuracy of detection of each type of potentially malignant lesion and by investigating sociodemographic factors that may be associated with accuracy, although this, of course, would require a larger sample.

A further limitation to the present study is that the participants performed MSE after the dental examination. This has the potential to impact the MSE as the dentist could have inadvertently provided clues to an area of suspicion by, for example, spending more time examining a given anatomical site. If this were the case, however, one would expect higher rates of sensitivity than seen here. Nevertheless, future work should ask participants to perform MSE at home prior to attending the dentist for an oral mucosal examination. This may produce more generalizable findings. It is also possible that the presence of the dentist during the MSE placed undue stress on the participant to rush the procedure, and in turn decreased the accuracy. Thus an alternative procedure would be to allow the participant to perform the MSE alone. Additional limitations include not controlling for participants’ eyesight and reliance on the dentists’ examination as the “gold standard”. Theoretically, the dentist may have missed an intra-oral lesion that was correctly identified by a participant.

This pilot study concludes that the procedure of MSE learned via a leaflet was felt to be easy
by the majority of participants. However, the analyses of diagnostic accuracy indicated that an at-risk group were poor at identifying the presence or absence of potentially malignant oral lesions. A larger study is required to gain a more precise estimate of MSE. However, this may not be a priority as this pilot study concludes that without further training to allow for differentiation between potentially malignant oral lesions and normal anatomical landmarks, the scope and usefulness of MSE to detect potentially malignant oral lesions may be limited.

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APPENDIX 1

Example questions from self-report questionnaire:

1. How easy did you find checking your mouth?
   - Very easy
   - Easy
   - Average
   - Difficult
   - Very difficult

2(a). Did you notice any red patches in your mouth?
   - Yes
   - No

(b) If yes, did you know you had a red patch in your mouth before you looked today?
   - Yes
   - No

REFERENCES


