Oral Potentially Malignant Disorders in high-risk groups in South Asia: A novel approach to screening and the way forward

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ABSTRACT

Background: Oral cancer is a growing cause of concern, particularly in low- and middle-income countries (LMICs) where the burden is rising due to the continuous use of smokeless tobacco (ST) as well as due to poor access to healthcare for timely detection and management.

Aim: To investigate the causal link between ST and cancer, develop and adapt screening guidelines for Oral Potentially Malignant Disorders (OPMD) and oral cancer and training toolkit for Community Health Workers (CHWs), and evaluate its feasibility and acceptability among CHWs.

Methods: The research comprised 3 studies. Study 1 was a systematic review for assessing the carcinogenic potential of ST. Study 2 proposed a practical solution to tackle ST-related oral cancer in South Asia, involving the adaptation of oral cancer screening guidelines and a training toolkit for CHWs. Study 3 assessed the feasibility and acceptability of remotely training CHWs to screen OPMDs and oral cancer using a pre-post survey and in-depth interviews.

Results: The systematic review found that the level of carcinogens in ST varied widely across the globe, with the highest being in South Asia. Using the ADAPTE framework, oral cancer screening guidelines were contextually adapted, and a toolkit was developed for CHWs engaging experts and stakeholders. Participants recruited from India and Bangladesh were trained remotely. The adapted guidelines and training were found feasible and acceptable by CHWs. The training helped CHWs in acquiring the required competencies and enhanced their capability in screening for OPMD and oral cancer.

Conclusion: ST products, particularly those used in LMICs, are highly carcinogenic and the key reason for the rising oral cancer burden in South Asia. Contextually adapted guidelines and training can enable non-specialist CHWs to screen for OPMD and oral cancer. If scaled up, trained CHWs can play an important role in preventing oral cancer.

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LIST OF ABBREVIATIONS

AAP	Alberta Ambassador Program
AFRO	African Region
AGREE	Appraisal of Guidelines for Research & Evaluation
AMRO	Region of the Americas
ASHA	Accredited Social Health Activists
B[a]P	Benzo[a]pyrene
CEBCPG	Center for Evidence-Based Clinical Practice Guidelines
CHW	Community Health Workers
COE	Conventional Oral Examination
CTA	Cognitive Task Analysis
EMRO	Eastern Mediterranean Region
ETD	Evidence To Decision
EURO	European Region
GATS	Global Adult Tobacco Survey
GDPR	General Data Protection Regulation
GRS	Global Rating Scale
IARC	International Agency for Research on Cancer
ICC	Intraclass Correlation Coefficient
LMIC	Low to Middle-Income Countries
MAGIC	Making GRADE the Irresistible Choice
NAB	N-nitrosoanabasine
NAT	N'-nitrosoanatabine
NCI	National Cancer Institute,
NNK	4-(methylnitrosamino)- 1-(3-pyridyl)-1-butanone
NNN	N'-nitrosonornicotine

NICPR	National Institute of Cancer Prevention and Research
OPMD	Oral Potentially Malignant Disorders
OSMF	Oral Submucous Fibrosis
OVE	Oral Visual Examination
PAH	Polycyclic Aromatic Hydrocarbons
PGEAC	Practice Guideline Evaluation and Adaptation Cycle
PIPOH	Population Intervention Professionals Outcome Health Settings
PLO	Programme learning outcomes
RCN	Royal College of Nursing
SEARO	South-East Asian Region
SDCEP	Scottish Dental Clinical Effectiveness Programme
ST	Smokeless Tobacco
TSNA	Tobacco-Specific- N-Nitrosamines
WHO	World Health Organisation
WHOFCTC	WHO Framework Convention on Tobacco Control
WPRO	Western Pacific Region

DECLARATION

I declare that this thesis is a presentation of original work and I am the sole author. This work has not previously been presented for an award at this, or any other, University. All sources are acknowledged as References.

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Finally, I would like to dedicate this thesis to my father, who is my role model for hard work, resiliency, and pursuing one's passion. His words "If anyone can do it, so can you" have been my guiding light throughout my academic journey. This one is for you, Abbi.

Happy Birthday!

BACKGROUND

CHAPTER 1: BACKGROUND

1.1 CHAPTER OVERVIEW

The literature review presented in this introductory chapter examines the increasing public health burden of oral cancer and smokeless tobacco (ST). There is a particular focus on Oral Potentially Malignant Disorders (OPMDs) as a point of intervention and the potential of training Community Health Workers (CHWs) in its early detection and screening. Section 1.2 defines the problem and examines the epidemiology and impact of oral cancer, while Section 1.3 explores the risk factors associated with the disease, with emphasis on the use of ST, the associated harms, and the need for continuous monitoring of these products. Section 1.4 of the review highlights OPMDs as a window of opportunity for intervention, describing the lesions and current protocols for screening and detection. The review also examines the challenges in the accessibility of screening services in low and low-middle-income countries. Section 1.5 shifts focus to the healthcare delivery systems in the South Asian countries of Bangladesh, India, and Pakistan, and discusses the potential role of CHWs in providing community-based screening services. Integrating all the evidence, Section 1.6 provides a novel solution which will be explored in this thesis. Section 1.7 gives an overview of the next steps followed by aims and objectives in Section 1.8 and reflexivity in research in Section 1.9.

1.2 OVERVIEW OF THE PUBLIC HEALTH CHALLENGE OF ORAL CANCER

Oral cancer, also known as oral cavity cancer, is a malignancy that affects different parts of the mouth such as the lips, gums, buccal mucosa, tongue, the floor of the mouth, and hard palate, and it is a significant global health concern (Neville and Day, 2002). According to the Global Cancer Observatory (GLOBOCAN 2020), an online database and interactive web platform of the International Agency for Research on Cancer (IARC), approximately 377,713 individuals are diagnosed with oral cancer every year, and this disease leads to 177,757 deaths globally. The majority of these cases occur in South Asia which accounts for 60% of the global burden (Thun et al., 2010).

Within South Asia, Bangladesh, India and Pakistan are the most affected countries and together contribute to nearly half of all the new oral cancer cases globally (Sung et al., 2021). India, in particular, bears the highest disease burden, with 135,929 new cases recorded in 2020, accounting for 38.3% of the total (GLOBOCAN 2020). In Bangladesh, oral cancer is the second leading cancer among men and the third among women, with an estimated 13,985 new cases diagnosed annually and 8,137 deaths. Similarly, in Pakistan, oral cancer is the most common malignancy among males and the second most common in females, with an estimated 16,959 people diagnosed and 10,617 deaths annually (Ferlay et al., 2020). Figure 1 shows the most common cancers in men in each country highlighting the higher incidence of oral cancer in South Asia.

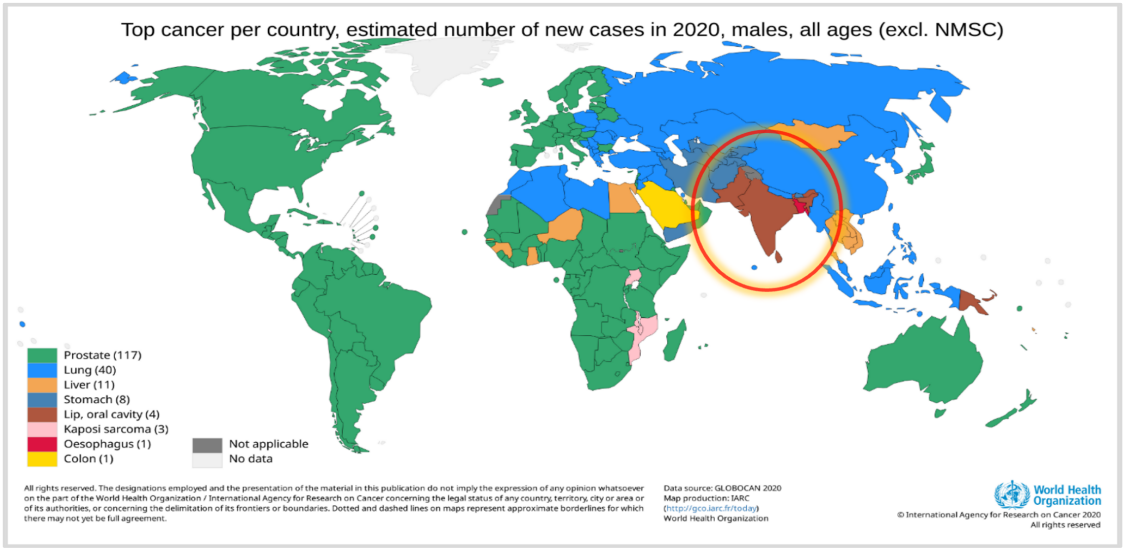


Figure 1: The most common type of cancer incidence in 2020 in each country among men. The numbers of countries represented in each ranking group are included in the legend. Source: GLOBOCAN 2020

1.2.1 FUTURE BURDEN OF ORAL CANCER

The current situation regarding oral cancer not only presents a dire picture but also foretells an even grimmer outlook for the future. According to the IARC Cancer Tomorrow data visualisation tool, which uses data from various sources to estimate cancer incidence, mortality, and prevalence worldwide, the number of annual deaths related to oral cancer is expected to almost double to 261,254 by 2040. Notably, the majority of these deaths are expected to occur in South Asian countries. In India, the mortality rate is projected to rise by 54% to 116,000 deaths per year. Similarly, in Bangladesh, the mortality rate is expected to increase by 80%, resulting in around 14,700 deaths per year. In Pakistan, the mortality rate is projected to increase by 79%, leading to around 19,000 deaths per year. This is further showcased in Figure 2 which provides estimates for both men and women in these countries. These statistics are alarming and highlight the urgent need for increased efforts to prevent and treat oral cancer in these countries. Therefore, this thesis will focus on these low and low-middle-income countries (LMICs), which are in urgent need of effective prevention and control measures.

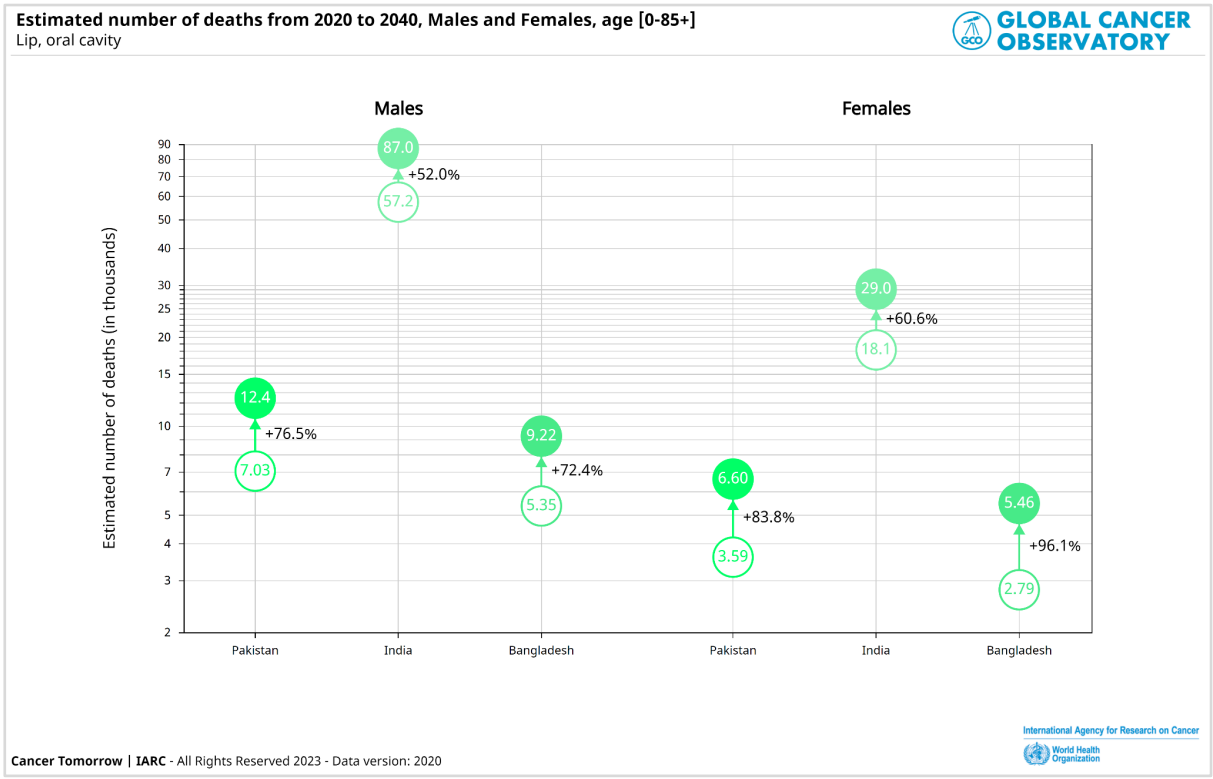


Figure 2: Projected increase in the estimated number of oral cancer deaths from the year 2020 to 2040 in three South Asian countries. Source: GLOBOCAN 2040

1.2.2 RISK FACTORS FOR ORAL CANCER

Addressing such a complex problem requires a multi-faceted approach to address its underlying causes. Looking at the disease aetiology, several risk factors can increase a person's likelihood of developing oral cancer. These include tobacco use, heavy alcohol consumption, Human Papillomavirus (HPV) infection, poor oral hygiene, age, sex, and a family history of oral cancer (Kumar et al., 2015, Johnson et al., 2020).

While all of the known risk factors for oral cancer increase the likelihood of developing the disease, some factors have a higher association with oral cancer than others. Smokeless tobacco (ST) use has been recognised as the primary cause of oral cancer in South Asian countries such as India, Pakistan, and Bangladesh, where the prevalence of ST consumption is high (Kumar et al., 2015, Johnson et al., 2020). In the subsequent section, an in-depth exploration of ST, encompassing its nature and usage, is presented. The association between ST and oral cancer is examined, alongside a thorough analysis of the reasons why this form of tobacco use is such a substantial risk factor for the disease.

1.3 OVERVIEW OF SMOKELESS TOBACCO(ST)

ST refers to tobacco-containing products that are not smoked but rather consumed either orally by chewing, rubbing, sucking, holding in the mouth, or sniffing nasally (National Cancer Institute and Centers for Disease Control and Prevention, 2014). ST products are typically made from ground tobacco leaves and depending upon their form can be broadly categorised as chewing tobacco, snus, snuff, dissolvable products, and non-chewing ST-containing products (IARC, 2007).

Chewing tobacco is one of the most common types of ST; it consists of tobacco leaves that have been shredded and mixed with various flavourings, sweeteners, and binders. Users place a small amount of the tobacco between their cheeks and gums, where it is slowly chewed or sucked. Snuff, on the other hand, is a fine-grained tobacco product that is usually sold in tins and packets and is inhaled through the nose (nasal snuff) or placed in the mouth (oral snuff), and it comes in two forms, dry and moist. Snus is a moist powder tobacco product that originated in Sweden and is popular in Scandinavian countries, and it is placed in the upper lip without the need for spitting. Dissolvable STs

are designed to dissolve in the mouth and do not require spitting or discarding of the product after use. The following sections will delve deeper into the usage of different types of ST products, and how some may pose a higher risk factor than others (Gupta et., 2011, IARC, 2007).

1.3.1 PREVALENCE AND TRENDS OF SMOKELESS TOBACCO USAGE

While ST is a significant public health concern in many parts of the world, its widespread usage in LMICs makes it particularly important when planning measures to address these concerns. A review of data from 140 countries by Sinha et al (2018) reveals that there are approximately 356 million ST users globally, with the majority being in the Southeast Asian region (81.6%), followed by Africa (4.8%), the Americas (4.3%), the Eastern Mediterranean (3.8%), Europe (3.3%), and the Western Pacific (2.2%). Ninety-one percent of ST users live in LMICs with a particular concentration in the South East Asia (SEAR) region (Sinha et al., 2018). This finding was further supported by Siddiqi et al. (2020), who conducted a study estimating the prevalence of ST use in 127 countries based on nationally representative cross-sectional surveys and reported high prevalence in the SEAR region. Within this region, Bangladesh, India, and Pakistan have the highest burden of ST use, with over 237 million users in India alone (Sinha et al., 2018, Trivedy et al., 2002, Asma et al., 2015)

According to Siddiqi et al. (2020), the countries with the highest ST consumption among males were Myanmar (62.2%), Nepal (31.3%), India (29.6%), Bhutan (26.5%), and Sri Lanka (26.0%). Among females, the prevalence was highest in Timor Leste (26.8%), followed by Bangladesh (24.8%) and Myanmar (24.1%), all of which are located in South-East Asia. ST use was also prevalent in Sweden, with a prevalence of 25.0% among males and 7.0% among females, and in Norway, with a prevalence of 20.1% among males and 6.0% among females (Siddiqi et al., 2020).

This is also corroborated by the findings from a study conducted by the Global Burden Disease Chewing Tobacco Collaborators, in which data were collected from 204 countries between 1990-2019 to report age and sex-specific standardised prevalence of ST use among adults aged 15 and older. The study revealed that globally, approximately 273.9 million people used chewing tobacco in 2019, with the majority of users (about

228 million or 83%) residing in the South Asia region. The study also found that the age-standardised prevalence of chewing tobacco use (Figure 3) among females was highest in South Asia (12.13%), while it was lowest in Western Europe (0.15%) (Kendrick et al., 2021). This distribution pattern highlights the need for targeted efforts to address ST use in regions where the burden is highest (Sinha et al., 2018).

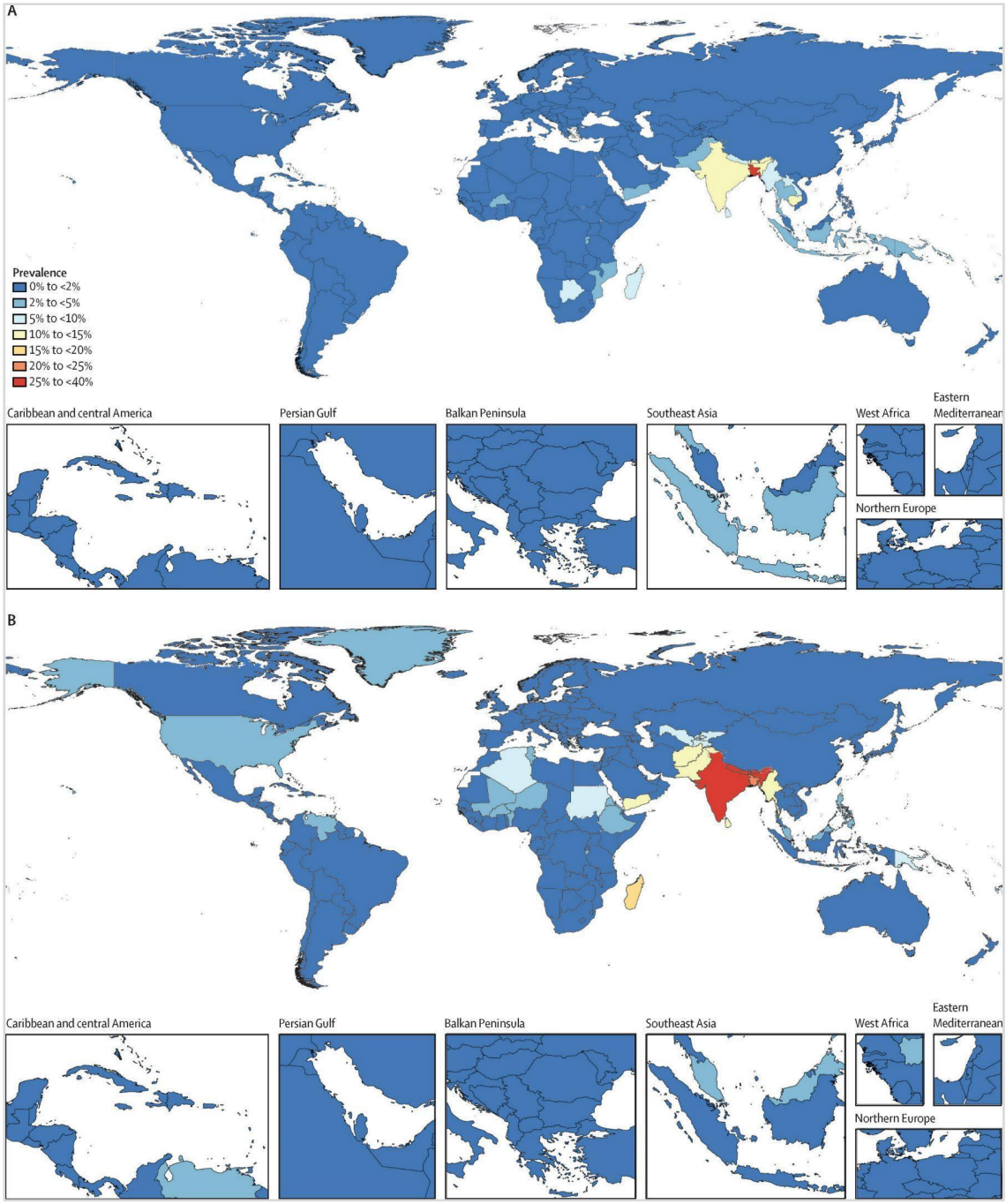


Figure 3: Age-standardised prevalence of chewing tobacco in women (A) and men (B). Source: GBD 2019 Chewing Tobacco Collaborators.

1.3.2 ASSOCIATION BETWEEN ST PRODUCT USE AND ORAL CANCER

ST use has been established as a significant risk factor for oral cancer, but the differences in risks of various types of ST products can provide more insight into strategies for combating the disease. A large body of epidemiological evidence supports the association between ST and oral cancer, with multiple studies demonstrating a strong and consistent link between ST use and oral cancer incidence. Studies from as early as the 1990s, such as the Kerala trial in India, have shown this association (Sankaranarayanan et al., 2000). A systematic review by Critchley and Unal in 2003 found a higher risk of oral cancer in individuals using ST, particularly in chewing tobacco with betel quid, a product popular in South Asia (Critchley and Unal, 2003).

One of the most comprehensive studies on this topic was conducted by Asthana et al. (2019), who looked at data from 37 studies across four WHO regions and found a significant correlation between ST use and oral cancer. The risk varied depending on the specific products and methods of use. The use of pan, a combination of tobacco and areca nut with lime, and other tobacco products, such as chewing tobacco, has been found to be strongly associated with the development of oral cancer in Southeast Asian countries. According to their study, the odds ratio (OR) of developing oral cancer in users of these products was 4.44 (95% Confidence Interval (CI): 3.51 to 5.61, $p<0.001$) compared to non-users. Moreover, the odds ratio of developing oral cancer with chewing types versus non-chewing forms of tobacco was 4.37 (95% CI: 3.27 to 5.83, $p<0.001$) for chewing tobacco and 1.56 (95% CI: 1.04 to 2.36, $p=0.03$) for non-chewing tobacco (Asthana et al., 2019).

Muwonge et al. (2008) conducted a case-control study and found that chewing tobacco was the primary risk factor for oral cancer, with higher odds ratios for men (OR: 3.1; 95% CI: 2.1 to 4.6) and women (OR: 11.0; 95% CI: 5.8 to 20.7) who chewed tobacco compared to non-users. Furthermore, chewing pan, with or without tobacco, also increased the risk of oral cancer for both sexes. These findings are consistent with earlier research that identified chewing tobacco as a significant risk factor for oral cancer (Muwonge et al., 2008, Balaram et al., 2002, Znaor et al., 2018, Sankaranarayanan et al., 1989a, Sankaranarayanan et al., 1989b)

Similarly, a case-control study of 350 cases and 350 controls conducted by Madani et al. (2012) over a period of 19 months, between February 2005 and September 2006 in Pune, India found that the risk of oral cancer was highest for the consumption of gutkha, an ST product popular in the Indian subcontinent (OR = 7.3; 95% CI: 4.5 to 12.1), followed by chewing tobacco (OR = 5.3; 95% CI: 3.7 to 7.6) and pure areca nut (supari) (OR = 4.0; 95% CI: 2.1 to 7.8). The study confirms previous findings by Muwonge et al. (2008) and others that chewing tobacco is a strong risk factor for oral cancer.

Another study by Jayalekshmi et al. (2011) on the Karunagapally cohort in Kerala, India, which included 66,277 men aged 30-84, found that tobacco chewing significantly increased the risk of oral cancer, particularly cancers of the gums and mouth (relative risk [RR] = 4.7; 95% CI: 2.8 to 7.9). The risk increased with higher daily frequencies and a longer duration of tobacco chewing (Jayalekshmi et al., 2011).

Research from Scandinavian countries, where ST is primarily consumed in the form of snus, found a much lower odds ratio of 1.28 (95% CI: 1.04 to 1.56, p=0.02) for the development of oral cancer in users compared to non-users (Asthana et al., 2018). This suggests that the carcinogenic potential of ST products used in Southeast Asia is higher than the ST products used in Scandinavian countries (Asthana et al., 2019, Critchley and Unal, 2003).

Siddiqi et al. (2020) conducted a systematic review of the global burden of disease due to ST in 127 countries, which corroborated the findings of Gupta et al. (2017) regarding the increased risk of oral cancer associated with ST use. The review, which included 36 studies, found a non-specific pooled RR estimate of 3.94 (95% CI: 2.70 to 5.76) for oral cancers. The country-specific relative risk for oral cancers in India was even higher (RR: 5.32, 95% CI: 3.53 to 8.02). However, estimates for the USA (RR: 0.95, 95% CI: 0.70 to 1.28) were statistically insignificant. A sensitivity analysis of the best-adjusted studies showed that the overall risk estimates for oral cancer increased from 3.94 to 4.46 from Siddiqi et al.'s previous review in 2015 to 2019 (Siddiqi et al., 2020, Siddiqi et al., 2015a, Gupta et al., 2017).

In summary, the evidence strongly supports the association between certain ST products and oral cancer, particularly products used in South Asia. It also highlights the need to understand the differences between the diverse types of ST products and the factors

that lead to the variance in the carcinogenic potential of these products. The next section will look at such possible factors that can be associated with this increased risk posed by certain ST products.

1.3.3 DIVERSITY IN ST PRODUCTS

The world of ST products is vast, with a plethora of products being consumed in various regions of the world. From simple cured tobacco to highly processed products with numerous chemical additives, the diversity of ST products is immense (Hatsukami et al., 2014). This diversity can be attributed to a variety of factors, including geographical location, cultural and societal norms, personal preferences, and ingredient availability (Siddiqi and Mishu, 2019, Sinha et al., 2018). Understanding the factors behind this diversity can help us better identify higher-risk ST products. In this section, we will explore some of the different types of ST products used and the reasons for this variation.

Geographical variation

A study was conducted by researchers (ZK and AV) at the University of York in collaboration with the Addiction Group at the University College London to identify and define ST products used worldwide, in order to comprehend the variations among them (Cox et al., 2023). The study involved a comprehensive literature review to identify the various ST products and give each of them a unique definition based on factors such as the type of product (oral/nasal), form (powder/paste), preparation (premade manufactured/premade cottage/custom made vendor/individual), and mode of use. The review identified over 60 different types of ST products used globally showcasing the vast diversity of these products. Figure 4 maps out the different ST products used around the world and highlights the sheer number of ST products from the South Asian region.

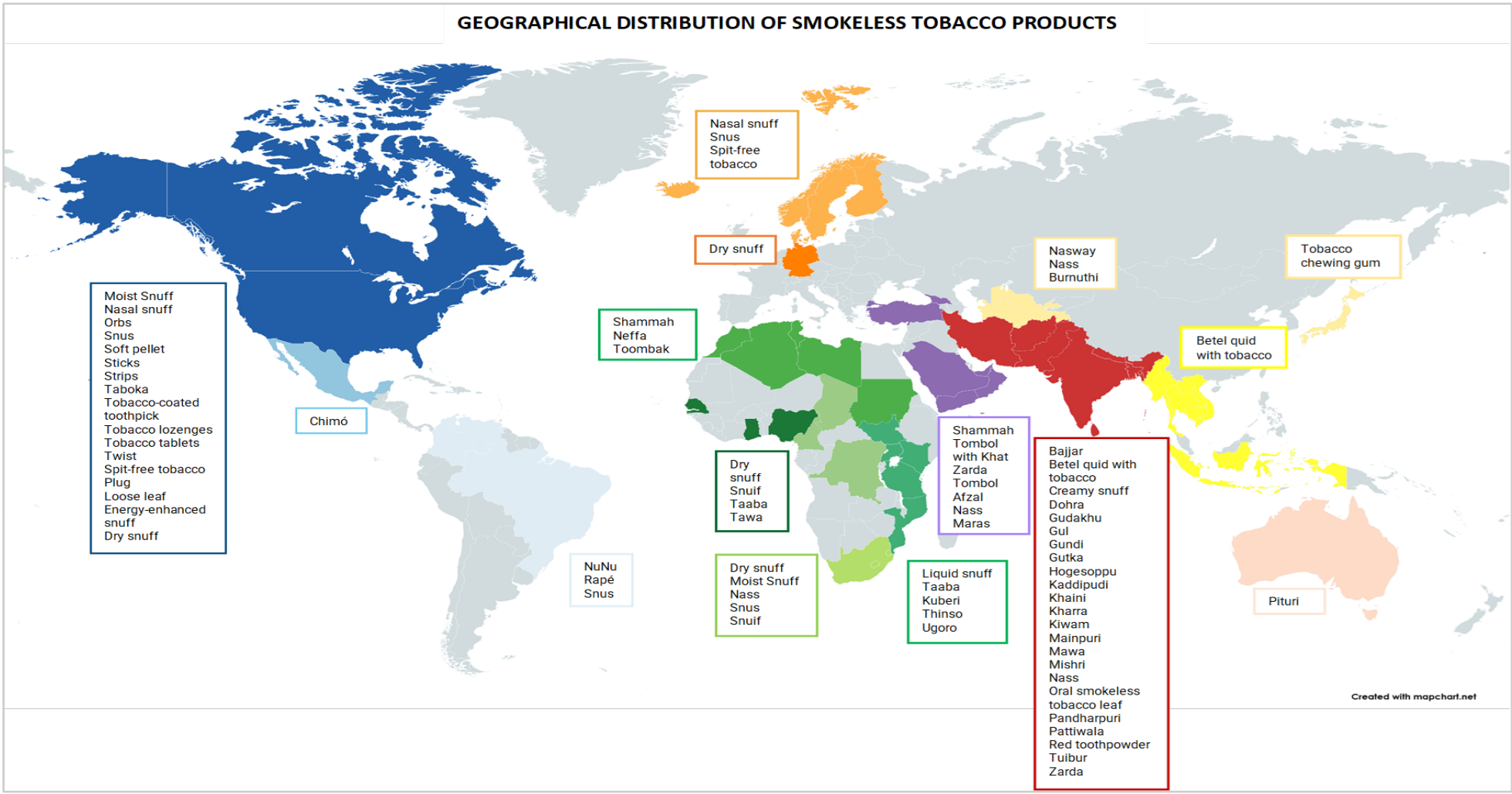


Figure 4: Distribution of ST products used around the world. SOURCE: Data from Addiction Ontology project. Map created by the researcher using mapchart.net

This further shows the significant diversity and complexity of this area of tobacco use, particularly when compared to smoking which typically involves only a handful of products, such as cigarettes or cigars. The findings from this work include a detailed description of various ST products used across the globe along with their definitions, country of origin, tobacco type and composition, final form and preparation, and methods of use. These are available in Appendix 1.

Tobacco type

Globally, there are approximately 70 species of tobacco (Nicotiana), but only a few are commonly used for smoked or ST products. Most commercial tobacco products contain Nicotiana tabacum, however, in many regions of South America, Africa, and Asia, another species of tobacco referred to as Nicotiana rustica, which contains higher concentrations of nicotine and alkaloids is widely grown and used for ST production (IARC 2007). This further highlights the variation between different ST products.

Production and preparation

ST products are categorised into premade and custom-made products based on their production and preparation methods. Premade ST products are available for sale and are generally consumed as purchased. They can be further divided into two subcategories: commercial products that are manufactured in traditional production facilities, and cottage products that are produced in non-traditional settings such as market stalls, shops, and houses and are often sold in non-commercial packaging (IARC, 2007). Depending on how these products are manufactured can also have a significant impact on their chemical profile (Stepanov et al., 2015, Stepanov et al., 2017b).

Additives

ST products contain a variety of ingredients including flavourings, sweeteners, humectants, alkaline agents, fillers, coatings, binders, colourings, and preservatives. Chemical alkaline agents are commonly used to adjust the pH level in manufactured products, while ashes from burning certain materials are used for this purpose among products made in some rural or tribal areas (NCI, 2014).

Research has shown that the use of these additives in ST products can have negative health consequences (Stanfill, 2020). The use of flavourings, sweeteners and other additives can make the product more appealing and easier to use, which can lead to increased use and addiction. The use of alkaline agents to increase the pH level of the product can also increase the amount of free nicotine available to be absorbed by the body, leading to greater addiction potential (Rickert et al., 2009). Additionally, the use of additives such as fillers, coatings, binders, and preservatives in dissolvable tobacco products can lead to increased exposure to potentially harmful chemicals (Villanti et al., 2017).

Method of use

As highlighted in earlier sections, ST products also vary based on their method of use. They can be chewed (betel quid with tobacco, *zarda*, twist, plug, *mawa*), held in the mouth (*chimo, khaini*), sucked (*naswar, chimo, maras*, loose-leaf), applied to teeth or gums (red tooth powder, *mishri*, creamy snuff, *gul*), dissolved in the mouth (tobacco tablets), gargled (*tuibur*), applied to the skin or inhaled (dry snuff, liquid snuff) (IARC, 2004a). Depending on the method of use, the level of exposure to harmful chemicals can vary significantly, resulting in an increased risk of developing adverse health outcomes associated with ST (IARC, 2007).

1.3.4 TOXIC AND CARCINOGENIC AGENTS IN SMOKELESS TOBACCO PRODUCTS

Apart from the additives described in the previous section, ST comprises approximately 4,000 chemical constituents, with the main components being alkaloids, primarily nicotine (85-95%). Other alkaloids present in minor amounts are terpenes, polyphenols, carboxylic acids and alkanes (Rodgman and Perfetti, 2013). ST also contains about 30 carcinogenic compounds which have been linked with several tumours, including those of the oral cavity, nasal cavity, lung, trachea, pancreas, and liver (IARC, 2004b). Amongst these, the major groups are non-volatile alkaloid-derived tobacco-specific nitrosamines (TSNAs) and N- nitrosamino acids. Additionally, carcinogens such as heavy metals, radionuclides, Polycyclic Aromatic Hydrocarbons (PAH), and volatile aldehydes are also present. These compounds vary in terms of their carcinogenicity and are described in

further detail in Section 3.2 of Chapter 3. The following section will describe the factors that lead to the formation of these carcinogens.

1.3.5 FORMATION OF CARCINOGENS IN SMOKELESS TOBACCO PRODUCTS DURING PROCESSING

The chemical composition of tobacco undergoes substantial alterations throughout its life cycle, which includes growing, curing, processing, and storing (Peele et al., 1995, Peele et al., 2001, Bush et al., 2001) and carcinogens are produced/introduced at different stages such as:

At the time of cultivation

Tobacco plants as they grow, absorb chemicals, metals and minerals from the soil. The nitrites and nitrates are converted into alkaloids which are further transformed into TSNAs by the microorganisms present on the tobacco plant (Burton et al., 1989).

At the time of curing

Tobacco curing is a method of drying tobacco leaves before they are ready for the market. There are different methods of curing tobacco, including sun curing, air curing, flue curing and fire curing. During this process, the amount of surface microorganisms increases by 10 to 20 times causing a further increase in the TSNA levels. While this process is universal to all forms of curing, in fire curing, there is additional production of carcinogens like PAH, phenols and volatile aldehydes (Hearn et al., 2013).

During fermentation and ageing

During this process, tobacco leaves are fermented to enhance their flavour. Similar to curing, chemical and biochemical changes occur at this stage, especially in fire-cured tobacco, where the nitrite reacts with alkaloids to produce TSNAs. These are also bacteria-mediated reactions (Tso, 1999, Di Giacomo et al., 2007).

From the above three stages, it is evident that the key stage involved in the formation and increased levels of TSNAs is the presence of microorganisms and their ability to generate nitrite. To reduce this, pasteurisation or heat treatment of tobacco can be undertaken to eliminate microorganisms. This method is used during the production of

certain products like Swedish snus which contain low levels of TSNAs compared to non-pasteurised products like khaini, gutkha etc. Thus, it is clear that the number of carcinogens and toxicants can be reduced by changing the processing methods for tobacco (IARC, 2012a).

1.3.6 REGULATION OF ST PRODUCTS

The regulation of carcinogens and chemicals in ST products varies widely across different regions and countries. In some countries, ST products are subject to the same regulations as cigarettes and other tobacco products, while in others they are subject to different regulations or no regulations at all.

In the United States, for example, ST products are regulated by the Food and Drug Administration (FDA) under the Family Smoking Prevention and Tobacco Control Act. This act gives the FDA the authority to regulate the manufacture, distribution, and marketing of tobacco products, including ST (Deyton, 2011). Under these regulations, ST products must carry warning labels that inform consumers of the health risks associated with their use, and manufacturers must submit information on the ingredients and toxicology of their products to the FDA. The FDA has set limits on the levels of certain carcinogens, such as TSNAs, that are allowed in ST products (U.S. Food and Drug Administration [FDA], 2020).

In Europe, ST products are subject to the same regulations as cigarettes under the Tobacco Products Directive (TPD). This directive sets limits on the levels of certain carcinogens, such as TSNAs and PAH, that are allowed in ST products (Vardavas, 2022). However, these limits have also been criticised for not being strict enough, and for allowing tobacco companies to introduce new products without adequate safety testing (Havermans et al., 2022).

In contrast, in countries such as Bangladesh, India and Pakistan, where ST is culturally ingrained and widely used, regulations are weaker than in the United States and Europe. These countries lack adequate regulatory bodies to oversee the tobacco industry, and there is little public awareness of the health risks associated with ST use. As a result, ST products are often sold without warning labels, and there are few restrictions on their marketing or distribution (Abdullah et al., 2022).

Role of the World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC)

The WHO FCTC through Articles 9 and 10, addresses the regulation of tobacco product contents. These articles call for the implementation of measures to ensure the disclosure of information about the constituents and emissions of tobacco products, as well as the regulation of these constituents and emissions. The WHO has also set up an international network of laboratories called the Tobacco Laboratory Network (TobLabNet) for testing tobacco constituents (WHO, 2008). While these regulations exist, their uptake is only about 50% and the majority of this is for smoking (World Health Organisation, 2012; WHO Study Group on Tobacco Product Regulation, 2009). For ST, these are only implemented in certain high income countries like Sweden which voluntarily comply with the industrial standard to regulate the composition and level of TSNAs in their ST products (Rutqvist et al., 2011).

In conclusion, while regulatory bodies have implemented various regulations and limits on the levels of carcinogens in ST products in the Western world, there is still much work to be done to effectively regulate the tobacco industry in South Asia and reduce the health risks associated with ST use.

1.3.7 THE NEED FOR FURTHER MONITORING

Given the severity and complexity of the risk posed by ST products, as described above, there emerge several reasons highlighting a pressing need to monitor the product composition and carcinogens of ST products. Firstly, ST use is associated with several adverse health effects, including oral cancer, which is a major public health concern. The carcinogens and other harmful chemicals present in ST products are thought to be responsible for these health effects and monitoring the levels of these chemicals is important for understanding and addressing the risks associated with ST use.

Secondly, ST products are not subject to the same level of regulation as cigarettes and other tobacco products in many countries. This means that there may be less oversight of the levels of harmful chemicals in ST products and that consumers may be more vulnerable to exposure to these chemicals. Monitoring the product composition and

carcinogens of ST products is therefore important for ensuring that consumers are aware of the risks associated with these products, and for promoting public health.

Thirdly, monitoring the product composition and carcinogens of ST products is important for assessing the effectiveness of regulatory measures aimed at reducing the health risks associated with ST use.

Fourthly, the monitoring of ST product composition and carcinogens is an ever-evolving field, and new ST products are being developed all the time. For example, in recent years, new types of ST products, such as dissolvable tobacco, have emerged on the market. These products may have different chemical compositions and carcinogenic potential compared to traditional ST products, and it is important to monitor these products to understand their potential health risks.

In addition, the tobacco industry is constantly innovating and developing new ST products, often marketed as "safer" alternatives to traditional cigarettes. These products may contain new chemicals and additives, and it is important to monitor their composition and carcinogenic potential to ensure that they are safe for consumers.

Overall, the monitoring of ST product composition and carcinogens is a crucial aspect of public health efforts to address the risks associated with ST use.

1.4 EXPLORING THE WINDOW OF OPPORTUNITY-FROM SMOKELESS TOBACCO TO ORAL CANCER

The previous section established that oral cancer is a significant public health concern in South Asian countries, with ST use being a widely prevalent risk factor and a major contributor to the burden of oral cancer in these populations. While efforts to reduce ST use and exposure to carcinogens in ST products are important, there is also a need for practical solutions to tackle the growing burden of oral cancer. One such solution is the implementation of community-based oral potentially malignant disorder (OPMD) screening and surveillance programs. These programs have the potential to identify high-risk individuals and provide a window of opportunity for interventions to prevent or treat oral cancer.

The following sections will give an overview of OPMDs, their current prevalence, the association between OPMDs and ST, the challenges in their early detection, and proposed practical solutions.

1.4.1 ORAL POTENTIALLY MALIGNANT DISORDERS (OPMDs)

OPMDs are a group of disorders characterised by genetic mutations and changes in oral epithelial cells, which may lead to the development of oral cancer (Warnakulasuriya, 2018, Warnakulasuriya et al., 2007). They can be caused by various factors, including tobacco, and were previously referred to as oral precancerous lesions and conditions, however, this was later revised to represent all the clinical manifestations that carry a risk to oral cancer as OPMDs (Van der Waal, 2009). However, the new classification acknowledges that not all OPMDs necessarily become cancerous, but they do have an increased potential for malignant transformation and can occur not only at the site of the lesion but also in surrounding normal-appearing oral mucosa. Some common OPMD lesions include leukoplakia, erythroplakia, palatal lesions in reverse smokers, Oral Submucous Fibrosis (OSMF), actinic keratosis, lichen planus, and discoid lupus erythematosus. While all these lesions have a higher risk of malignant transformation, only leukoplakia, erythroplakia, and OSMF are primarily associated with ST use. For a more detailed definition and description of these lesions, please refer to Appendix 2.

1.4.2 ASSOCIATION BETWEEN ST AND OPMDs

The association between ST use and OPMDs has been demonstrated in several studies. As previously discussed in Section 1.3, ST contains various carcinogens, including TSNAs, PAH, and heavy metals, which can cause DNA damage and disrupt normal cellular processes, leading to the development of precancerous lesions (Hecht and Hatsukami, 2022). Earlier studies conducted in Gujarat, India (Smith, 1975), reported that 98% of OPMD cases were associated with ST use, while similar findings were reported in Hungary (Banoczy and Sugar, 1972) and Norway (Lind, 1987) where ST use was associated with 87% and 42% of cases, respectively. Additionally, the regression of lesions after cessation of habits is another factor linking tobacco use with OPMDs. In a cohort of 138 people in Denmark, 78% of the lesions disappeared after a year of ST cessation (Roed-Petersen, 1982).

Looking at more recent evidence, a systematic review by Khan et al. in 2017 observed the risk of developing OPMDs among ST users and non-users in Southeast Asia. The review included 14 case-control studies from India, Pakistan, and Sri Lanka that looked at the odds of developing OPMDs as the primary outcome. The study reported an odds ratio of 15.5 (95% CI: 9.9 to 24.2) for any OPMD with the use of any ST product (Khan et al., 2017). The risk of developing different types of OPMD with ST was highest for Erythroplakia (19.8, 95% CI: 9.8 to 40.0) followed by OSMF (OR=16.2, 95% CI: 8.7 to 30.0) (Hashibe et al., 2000). In addition, a study conducted by Thomas et al. in 2003 in India found that the likelihood of developing multiple OPMDs was 37.8 times higher (95% CI: 16.8 to 88.1) among ST users compared to non-users (Thomas et al., 2003). Similarly, a study conducted in India found that individuals who used ST had a significantly higher prevalence of leukoplakia, a common type of OPMD, compared to non-users (Shah et al., 2017). Another study conducted in Pakistan found that ST users had a higher risk of developing OSMF (Khan et al., 2020). Furthermore, studies have found that the risk of developing OPMDs is dose-dependent, meaning that the more ST an individual uses, the higher their risk of developing these conditions. One study conducted in Bangladesh found that individuals who used ST for more than 20 years had a significantly higher risk of developing leukoplakia compared to those who used it for less than 10 years (Haque et al., 2017).

Overall, these findings highlight the ongoing association between ST use and OPMDs, particularly in Southeast Asia.

1.4.3 PREVALENCE OF OPMDs

The prevalence of OPMDs varies across populations and geographic regions. A systematic review and meta-analysis conducted by Mello et al. (2018) aimed to determine the prevalence of OPMDs among adults. The study included 22 studies reporting the prevalence of leukoplakia, erythroplakia, oral submucous fibrosis (OSMF), and actinic cheilitis, which were confirmed through clinical and histopathological assessments. The study found that the overall prevalence of OPMDs was 4.47% (95% CI: 2.43 to 7.08). OSMF and leukoplakia were the most prevalent OPMDs, with rates of 4.96% (95% CI: 2.28 to 8.62) and 4.11% (95% CI: 1.98 to 6.97), respectively. The study also found that males were more commonly affected by OPMDs (59.99%; 95% CI: 41.27

to 77.30) than females. The prevalence of OPMDs was found to be highest in Asian and South American/Caribbean populations, with rates of 10.54% (95% CI: 4.60 to 18.55) and 3.93% (95% CI: 2.43 to 5.77), respectively.

1.4.4 BUILDING A CASE FOR INTERVENTION AT THE OPMD STAGE

There is evidence to support the importance of intervening at the OPMD stage. One study conducted in India found that individuals with leukoplakia who underwent surgical removal of the affected tissue had a significantly lower risk of developing oral cancer compared to those who did not receive treatment (Lodi et al., 2006). Similar studies found that individuals with OSMF who received treatment had a significantly lower risk of developing oral cancer compared to those who did not receive treatment (Rengaswamy et al., 2019; Rao et al., 2020). Furthermore, studies have found that community-based oral cancer screening programs, which aim to detect early signs of OPMDs and oral cancer in high-risk populations, can lead to earlier diagnosis and treatment, and ultimately reduce the burden of oral cancer (Parak et al., 2022, Villa and Gohel, 2014)(Parak et al., 2022; Villa and Gohel., 2014; Klongnoi et al., 2021).

In addition to being a stage for early detection as presented above, OPMDs also have the potential to serve as a point of intervention for behaviour change in ST users. This area has been explored in previous studies in the realm of smoking cessation. A study by Gray et al. (2019a) assessed the impact of an oral and oropharyngeal cancer diagnosis on smoking cessation. The study was conducted in Saudi Arabia and aimed to determine whether cancer patients received smoking-cessation advice and evaluated the factors that were influential in aiding them to quit or decrease smoking. The study found that the cancer diagnosis was influential in smoking cessation in ever-smoker patients and their cohabiting smokers. Similarly, McBride et al. (2003) in their review on teachable moments for promoting smoking cessation have also recommended approaches to capitalise on the cancer context to promote tobacco cessation. These studies further highlight that the detection of OPMDs can serve as a potential opportunity for promoting ST cessation, especially among users in South Asia, where awareness regarding the negative health consequences of ST consumption is relatively low. As such, healthcare providers can leverage this teachable moment to educate patients about the

hazards of ST use and offer them appropriate resources and support to facilitate cessation.

In conclusion, OPMDs not only serve as an avenue for the timely identification of oral cancer but can also offer a platform for implementing behaviour change interventions and imparting knowledge on the detrimental impacts of ST consumption, hence potentially altering the trajectory of the disease (Figure 5).

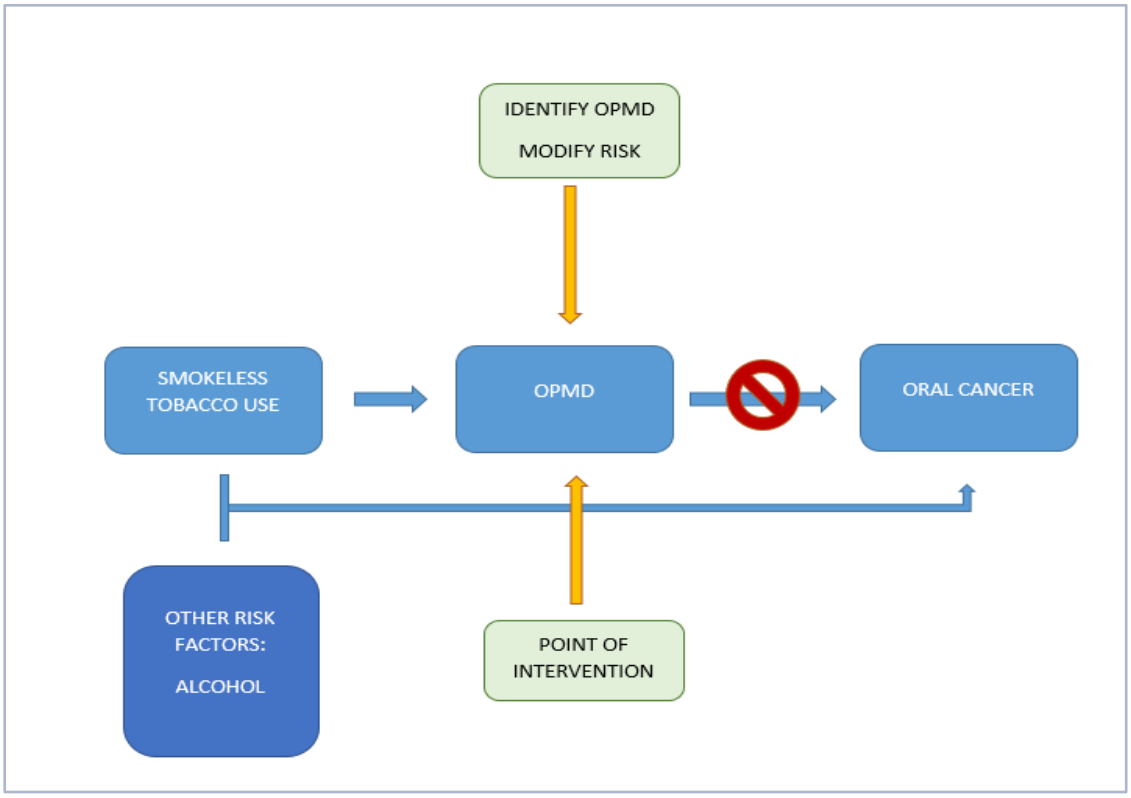


Figure 5: Intervening at the OPMD stage and modifying risk factors to reduce the malignant transformation

In the next section, the challenges to the screening of OPMDs and oral cancer will be further examined, and potential solutions will be proposed to overcome these obstacles.

1.4.5 CHALLENGES TO EARLY DETECTION OF OPMDs

Currently, OPMDs are detected or screened in dental clinics during routine patient visits using a technique called Oral Visual Examination (OVE) which involves visual inspection of the patient's mouth and throat using a light and a mirror or other specialised instruments (Speight et al., 2017, Cheung et al., 2021). Further details on the different techniques for the detection and diagnosis of OPMDs and oral cancer are provided in Appendix 3. While this method has proven effective in opportunistic identification of the disease, several challenges exist in implementing this approach in routine screening,

especially in South Asian countries like India, Pakistan, and Bangladesh, where the need for such screening is the greatest (Kujan et al., 2005). There is limited availability of healthcare resources and trained healthcare professionals, particularly dentists, which poses a significant barrier to implementing routine oral cancer screening programs (Northridge 2020; Semprini 2022). This is especially true in rural areas where there is a shortage of dentists, resulting in limited access to routine dental care (Wall and Brown 2007; Halappa et al., 2014; Vundavalli, 2004; Hazarika 2013). As a result, many cases of oral cancer in these areas are often diagnosed at later stages, leading to poorer treatment outcomes and higher mortality rates.

Additionally, there is a lack of awareness and education about oral cancer among the general population, leading to delays in seeking medical attention and accessing appropriate care (Agrawal et al., 2012; Borse et al., 2020; Elango et al., 2009). This lack of awareness and education about the disease is further compounded by the stigma attached to cancer, which can prevent individuals from seeking medical attention and accessing appropriate care (Akin-Odanye and Husman, 2021).

Furthermore, the high cost of dental fees poses a barrier to accessing timely and effective care, particularly for those at risk of developing oral cancer (Bahadori et al., 2013; Kiyaj and Reichmuth, 2005). This challenge is particularly pronounced in countries with large populations and geographic obstacles, such as India, Pakistan, and Bangladesh, which struggle to provide accessible healthcare facilities, including specialised screening, detection, and diagnosis services for oral cancer. In the following section, potential strategies to address the aforementioned challenges will be discussed, and a proposed solution to overcome the barriers to oral cancer screening and care in South Asia will be presented.

1.4.6 EXPLORING THE POTENTIAL SOLUTION TO EARLY DETECTION

To effectively address the challenges presented above, any proposed solution aimed at improving oral cancer screening must be easily accessible, cost-effective, and acceptable for both providers and patients (Bouvard et al., 2022, Nagao and Warnakulasuriya, 2020).

One potential solution that has been proposed to address the challenges of oral cancer screening in LMICs, such as India, Pakistan, and Bangladesh, is the utilisation of visual screening tools that can be easily administered by non-dental non-specialist healthcare professionals, including Community Health Workers (Sankaranarayanan et al., 2000). These tools are typically cost-effective, portable, and can rapidly identify potential oral cancer cases that require further evaluation by a dental or medical professional. However, to fully comprehend how CHWs can assist with the early detection of oral cancer in LMICs, it is crucial to examine the current health system in these countries and the roles and responsibilities of CHWs within it. This analysis will help identify opportunities to integrate CHWs into the existing healthcare infrastructure to improve access to oral cancer screening and education.

1.5 UNDERSTANDING THE CURRENT HEALTH CARE DELIVERY SYSTEMS IN BANGLADESH, INDIA AND PAKISTAN

This section will discuss the healthcare delivery systems in Bangladesh, India and Pakistan, highlight their similarities and elaborate on the various cadres of CHWs active in these communities. The healthcare system in India is divided into 3 levels - primary care level, secondary care level and tertiary care level. The primary care level is the first level of contact with individuals, in the family and community with the national health system (Peter, 2009).

Similarly, the public health care system in Bangladesh consists of a three-tier system. it comprises Upazila Health Complexes (UHC) at the sub-district level, Union Health and Family Welfare Centres (UHFWC) at the Union (collection of few villages) levels, and Community Clinics (CC) at the village level (Islam et al., 2014, Patel et al., 2015).

Pakistan also has a three-tier system for healthcare delivery. It comprises primary care that provides preventive and promotive health services and secondary and tertiary care that offer curative and rehabilitative services (Liaqat et al., 2019).

In all three countries, the primary care system plays a critical role in delivering healthcare services to the population. It is typically organised around a network of health centres, clinics and dispensaries (van Weel et al., 2016). One of the essential components of primary care in all three countries is CHWs. They are often considered

the backbone of the healthcare systems due to the significant role they play in delivering primary care services, improving access to healthcare in underserved areas, building trust between healthcare providers and local communities, and promoting health education and disease prevention (Braun et al., 2013). The following section will give a brief background on the various cadres of CHWs and their role in each country.

1.5.1 UNDERSTANDING THE ROLE OF COMMUNITY HEALTH WORKERS

The WHO defines CHWs as "members of the community who are chosen by the community to work in the health system, and who are trained to promote, provide, and/or support health care within their community, beyond the confines of a traditional health care facility." (WHO, 2007). This definition emphasises the role of CHWs in bridging the gap between the formal health system and the community, as well as their ability to provide basic health services and support to their communities.

In India, the main cadre of CHWs responsible for delivering primary healthcare services at the community level are:

Accredited Social Health Activists (ASHA): ASHAs are community-based health workers who are responsible for delivering basic healthcare services, promoting health education, and mobilising the community for health-related programs. They are selected from the community and trained to provide basic healthcare services, such as maternal and child health, family planning, and prevention and control of communicable and non-communicable diseases (Singh et al., 2010, Basu et al., 2019).

In Bangladesh, the main cadre of CHWs are:

Shasthya Shebikas (SS): SS are the main cadre of CHWs active in Bangladesh. They are predominantly female workforce who play a crucial role in improving the overall health and socio-economic status of the Bangladeshi population. They promote family planning, immunisation, and oral rehydration therapy, and have contributed significantly to the country's remarkable health improvements since the early 1980s (Quayyum et al., 2013). In recent years, they have also started providing services for Non-Communicable Diseases (NCDs), such as random blood glucose tests for those at risk of developing diabetes and providing health education and counselling services (Rawal et al., 2021).

Health Assistants (HA): HAs are trained to provide basic healthcare services, including health education, disease prevention, and treatment of common illnesses. They work at the union level and are responsible for providing primary healthcare services to their communities (Bosu et al., 2021).

Community Health Care Providers (CHCPs): CHCPs are community-based health workers who are trained to provide primary healthcare services at the community level (Adams et al., 2020).

In Pakistan, there is only one cadre of CHWs which is described below:

Lady Health Workers (LHW): The Lady Health Worker Programme (LHWP) in Pakistan is a community-based health promotion initiative that was established in 1994 to provide essential primary healthcare to individuals and families in the community, particularly focusing on maternal and child health (Lassi et al., 2016). LHWs are recruited based on stringent criteria, receive training and medical supplies, and are linked to a health facility where they work (Nishtar, 2017). They provide basic preventive and curative services, promote health, hygiene, sanitation, family planning, healthy pregnancy, and provide essential drugs for minor ailments. They also work on the implementation of the Extended Programme for Immunisation (EPI) and awareness for the prevention of seasonal diseases such as dengue and malaria (Lassi et al., 2016).

In summary, the primary healthcare system, and the role of CHWs are similar across the three study countries. CHWs in all three countries are trained to provide basic healthcare services, such as health education, family planning, maternal and child health, and disease prevention. They also play a vital role in the referral of patients to higher-level healthcare facilities. Governments in all three countries have recognised the importance of primary care and CHWs in improving health outcomes and have implemented policies and programs to strengthen the primary healthcare system. Despite significant challenges like lack of funding and infrastructure, CHWs programmes in these countries have been internationally recognised as an effective approach to improving access to healthcare services, especially in low-resource settings.

1.5.2 THE CASE FOR BUILDING COMPETENCIES IN COMMUNITY HEALTH WORKERS

The previous sections have highlighted the challenges in LMICs which makes it difficult for people in these regions to access healthcare services, including oral cancer screening. They have also alluded to the presence of a workforce in the form of CHWs who work closely with their communities and are a part of the primary health care system.

The following section will build a case for task shifting to CHWs as a potential solution to address the shortage of dental health professionals in LMICs and increase access to early detection and management services of OPMDs and oral cancer.

Firstly, CHWs have a unique understanding of the communities they serve. They are often from the same community and speak the same language, making it easier for them to build trust and rapport with community members. As a result, they are better positioned to identify individuals who are at risk for oral cancer and encourage them to seek screening and follow-up care (Kok et al., 2015). Secondly, they are already involved in health education and promotion programmes within their communities. They can help to increase awareness and education about oral cancer and encourage individuals to seek medical attention early (O'Donovan et al., 2018). Thirdly, CHWs can also address cultural factors that contribute to the high incidence of oral cancer in these regions by providing education on the risks associated with traditional practices such as the use of ST and betel quid (Umnuaypornlert et al., 2021b). Fourthly, task shifting to CHWs has been shown to improve access to healthcare services, increase efficiency, and reduce healthcare costs in many low-resource settings (Sibeko et al., 2018). Thus, training CHWs to conduct oral cancer screening can be an effective way to increase access to screening and facilitate early detection and treatment of oral cancer in communities where there is a shortage of dental professionals (Birur et al., 2019).

Furthermore, the idea of utilising CHWs such as ASHAs for health screening and specialist care linkage has been recommended in existing studies, such as Birur et al. (2018). Thampi et al. (2022) also recommend using CHW-led oral cancer screening as a lower-cost and scalable alternative. In India, ASHA workers are already engaged in health promotion and disease prevention activities and may be able to undertake oral cancer screening as part of their existing duties (Jeet et al., 2017). Furthermore, CHWs have played a significant role in the implementation of Ayushman Bharat, a national-

level program that includes the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases, and Stroke (Bhargava et al., 2018).

In line with the growing interest in using CHWs for oral cancer screening, a recent review by Nagao and Warnakulasuriya (2020) discussed the strengths and weaknesses of different CHW models for oral cancer screening. They also highlighted the importance of providing adequate training and supervision, authorising CHWs to prescribe medications and render autonomous care, and equipping them with reliable systems to track patient data and consistent medications and supplies.

Moreover, a systematic review of 156 studies that utilised CHWs for the delivery of basic healthcare, including screening for non-communicable diseases, proposed six key recommendations for successfully incorporating CHWs in the delivery of oral cancer screening. These recommendations include selecting qualified CHWs embedded within the community they serve, providing detailed and ongoing training and supervision, authorising CHWs to prescribe medications and render autonomous care, equipping them with reliable systems to track patient data, furnishing them consistently with medications and supplies, and compensating them adequately for their roles (Heller et al., 2019; Warnakulasuriya et al., 2021).

Taken together, these studies make a strong case for incorporating CHWs in oral cancer screening programs, particularly in LMICs, where access to dental care is limited.

1.5.3 ACKNOWLEDGING CHALLENGES OF UTILISING COMMUNITY HEALTH WORKERS FOR ORAL CANCER SCREENING AND LACK OF REFERRAL PATHWAYS

While the potential benefits of utilising CHWs for oral cancer screening in LMICs are evident, there are several challenges that need to be addressed for effective implementation. One significant challenge faced by CHWs in LMICs is the limited education and training they receive. According to Kok et al. (2015), many CHWs in LMICs may have inadequate educational backgrounds, which can impact their ability to provide quality care. In the context of oral cancer screening, this limitation may affect their proficiency in identifying potential oral cancer cases and communicating necessary information to patients.

The isolation of CHWs from healthcare facilities is another substantial challenge. Lewin et al. (2010) noted that CHWs are often stationed in remote or underserved areas, far from healthcare facilities. This isolation can limit their access to essential resources, support, and supervision. In the context of oral cancer screening, this isolation can hinder their ability to access diagnostic tools, receive necessary training updates, and seek guidance from healthcare professionals.

CHWs in LMICs often receive only nominal pay, which can impact their motivation and retention (Kok et al., 2015). Low financial incentives can lead to decreased motivation among CHWs, potentially affecting their commitment to tasks such as oral cancer screening. This challenge highlights the importance of addressing compensation issues to keep CHWs motivated in their roles.

Another challenge in the utilisation of CHWs for oral cancer screening in LMICs is the establishment and maintenance of efficient referral pathways. Referral pathways are an essential component of healthcare systems, ensuring that patients receive appropriate care and treatment. However, in many LMICs, these pathways are often poorly developed or non-existent, leading to delays in diagnosis and treatment, and ultimately, poor health outcomes. As indicated by qualitative data from Ahmed et al. (2021), members of disadvantaged groups in LMICs may encounter significant barriers in following CHW health advice and referrals. These barriers include poverty, lack of access to transportation, and discriminatory treatment at health facilities. For instance, educating individuals about the importance of oral cancer screening may not yield desired results if patients cannot afford transportation to healthcare facilities or if there is a lack of clarity in referral pathways. Additionally, the lack of coordination and communication between different levels of the healthcare system can result in patients being referred to the wrong facility or specialist, or not being referred at all.

Efforts to overcome these challenges should focus on enhancing the education and training of CHWs, providing them with essential resources, improving their compensation packages, and developing strategies to reach remote populations effectively. There is also a pressing need to develop and strengthen referral pathways in LMICs. This involves improving coordination and communication between healthcare system levels, clarifying roles and responsibilities, and investing in the necessary

infrastructure and resources to support the referral process. Active involvement of patients and communities in the development of these pathways is vital to ensure accessibility and alignment with their needs.

In summary, while CHWs play a crucial role in expanding healthcare access, their effectiveness in oral cancer screening and other healthcare services in LMICs can be hindered by various challenges. Recognising and addressing these challenges is essential to ensure that CHWs can effectively contribute to oral cancer prevention efforts. The successful implementation of CHW-led oral cancer screening programs will require careful planning, adequate training, and supervision, as well as a strong commitment to providing CHWs with the necessary resources and support. This is further detailed in the upcoming section.

1.6 THE NOVELTY OF THE SOLUTION

As highlighted by the literature presented in section 1.5, although the use of CHWs for oral cancer screening is gaining momentum, there are still areas that need innovation, particularly in training and implementation. The following section will explore the gaps in knowledge and practice and propose solutions to training and uptake as well as discuss the evolution of the research focus due to the pandemic.

1.6.1 DESIGNING CONTEXTUALLY RELEVANT SCREENING PROGRAMME

CHWs are often considered a viable solution to address the limited availability of healthcare resources in LMICs for oral cancer screening (Ahmed et al., 2022). However, CHWs in such countries do not have the necessary training or resources to identify and screen for potentially malignant disorders in the oral cavity (Warnakulasuriya et al., 2021). Moreover, the current screening protocols for oral cancers are primarily focused on dentists and are developed in high-income countries. These protocols do not take into account contextual factors such as limited access to healthcare, low health literacy, and cultural beliefs, which can affect the feasibility and effectiveness of screening in LMICs. Therefore, developing contextually relevant screening guidance for CHWs and providing them with adequate training and resources can ensure their effective involvement in oral cancer screening programs and help address these gaps and improve access to oral cancer screening and education in underserved communities. The tools

and methods for contextual adaptation are explored in detail in Section 3.2 of Chapter 3.

1.6.2 A NOVEL APPROACH TO IMPLEMENTATION

While previous research in this area has relied on in-person training for CHWs for conducting the oral examination, there are some drawbacks to this approach. Firstly, as these services are not a part of the current responsibilities of CHWs, they typically need to take a leave of absence from their work to attend these in-person training sessions. This not only results in a loss of wages but also incurs additional costs for transport, food, etc (Oliver et al., 2015). Secondly, the advent of the Covid-19 pandemic poses a health risk to both the participants and the researchers conducting in-person training programmes. With community and close contact exposures continuing to drive the number of Covid-19 cases worldwide, alternate solutions are required to make these programmes viable. One of the potential solutions could be the use of remote web applications and software to impart online training. Globally, access to the internet and mobile phone technologies is increasing with the lowering of the cost of phone and internet services. In several LMICs, approximately 90% of the population now has access to a mobile phone and 40% have access to internet services (Gupta et al., 2015). This technological innovation offers unique opportunities for integrating remote training into the CHW workflow. Firstly, it reduces their workload as they no longer have to travel or take a day off to attend training sessions. Secondly, it prevents face-to-face interactions thus lowering the chance of disease transmission. Thirdly, it provides the opportunity for continuous learning and better support and monitoring. Lastly, it provides more potential opportunities for training and refresher training by reducing the cost of conducting such sessions (Naslund et al., 2021).

1.7 THE NEXT STEPS

Based on the literature presented above, it is evident that CHWs can play a crucial role in oral cancer screening, especially in LMICs where resources are limited, and ST is widely prevalent. Despite the known harmful effects of ST products, they continue to be widely used in many countries, including Bangladesh, India and Pakistan with new products coming into the market daily. There is a need for practical solutions to improve the early

detection of oral pre-cancer and cancer. In this regard, utilising CHWs for OPMD screening can be a solution that has the potential to increase screening rates, facilitate early detection and reduce the burden of oral cancer. This approach can be particularly useful in low-resource settings, where there may be a shortage of trained healthcare professionals and limited access to healthcare facilities. Existing studies have recommended the utilisation of CHWs for oral cancer screening. However, there is still a gap in the development of screening materials tailored for CHWs and remote training.

In light of these considerations, the main research goals are to add to the understanding of some of the under-researched areas of ST use and oral cancer detection in these consumers in South Asia. The rationale and objectives of the thesis, along with the approach taken to address them, are presented below.

1.8 THESIS AIMS AND OBJECTIVES

Aim I: Understanding the carcinogenic potential of ST products used across the globe. The first aim was to understand the product composition and carcinogenic potential of ST products used across the globe. The objectives were to identify and describe the chemical concentration of key carcinogens and influencing factors of ST products around the globe.

This aim was accomplished through a systematic review of various ST products to assess their carcinogenic potential. The review identified and described the concentration of key carcinogens and influencing factors and compared the values across different ST products currently in use worldwide. This work also provided the latest estimates of the carcinogens and builds on the National Cancer Institute's (NCI) report on Smokeless Tobacco and Public Health: A Global Perspective published in 2014. This work is presented in Chapter 2 of the thesis.

Aim II: Adaptation of oral cancer screening guidance and development of training curriculum

The second aim was to develop resources for training CHWs on the detection of oral cancers and OPMDs among ST consumers - a high-risk group. The objectives were:

- Identification and selection of a validated framework for guideline adaptation
- Application of the selected framework to adapt the existing Oral visual examination guidelines to the local context
- Development of an OPMD and oral cancer screening toolkit

This was done in three phases. In the first phase, a literature review was conducted to identify frameworks for trans-contextual adaptation of oral cancer screening guidance. This work is presented in Chapter 3 of the thesis. In the next phase, the selected framework was used to adapt guidance for screening using the methodology for trans-contextual adaptation. This forms Chapter 4 of the thesis. In the final phase, a toolkit was designed around the adapted screening guidance using a participatory approach to train and build competencies in CHWs. This forms Chapter 5 of the thesis.

Aim III: Feasibility of training CHWs for oral cancer screening

The third aim was to test the feasibility of training CHWs remotely in 3 South Asian countries namely, Bangladesh, India, and Pakistan on detecting OPMDs in high-risk individuals. The objectives were -

- To assess the feasibility of training CHWs remotely in identifying oral lesions associated with tobacco use
- To explore the attitude and experience of CHWs towards remote learning of clinical skills

This was achieved by conducting a multi-method study incorporating quantitative and qualitative methods. This work is presented in Chapter 6 of the thesis.

1.9 REFLEXIVITY

Navigating the research journey

I embarked on this research journey driven by a deep concern for the rising oral cancer burden, particularly within LMICs. My initial encounters as a dentist with the realities faced by patients in rural parts of India, marked by both the continuous use of ST and inadequate access to timely healthcare, served as a motivation to undertake this work.

Witnessing the pressing need for actionable solutions to address this health crisis, I became committed to exploring interventions to mitigate this alarming trend.

Positionality

As the researcher, I recognise my unique position within this study. My academic background in dentistry and dental public health equipped me with the necessary tools to undertake this work. However, I approached this research with an open and understanding mindset, aware of the ethical and cultural complexities inherent in such a study. My positionality was shaped by my role as a link between existing academic knowledge and the CHWs who would be instrumental in implementing the findings. It is important to note that I assumed a dual role as a researcher and a collaborator, engaging with diverse stakeholders to ensure the contextual relevance and practicality of the proposed solutions.

Researcher reflexivity

Throughout this research, I engaged in continuous self-reflection and reflexivity, recognising the potential biases, preconceptions, and assumptions that might influence the research process and outcomes. My engagement with both quantitative and qualitative research methods required introspection and self-awareness to minimise potential biases. By maintaining transparency about my role and perspective in this research, I sought to enhance the credibility and trustworthiness of the findings.

Engagement with participants

In my interactions with CHWs, experts, and other stakeholders, I aimed to establish collaborative partnerships built on mutual respect and trust. I recognised that my position as the researcher could impact these interactions and the information shared. To mitigate this, I maintained an open dialogue, welcomed diverse perspectives, and actively sought feedback from participants to refine the research process.

Finally, I acknowledged the dynamic and evolving nature of this research journey. I was aware that my role extended beyond data collection and analysis; it included the responsibility of advocating for positive change in oral cancer prevention and

management. This approach ensured that the research findings remain grounded in the realities of the CHWs as well as those affected by oral cancer and ST use.

In navigating this research journey, my commitment to transparency, ethical conduct, and cultural sensitivity guided every aspect of the study. By embracing reflexivity, I aimed to contribute to the development of contextually relevant solutions that hold the potential to reduce the burden of oral cancer, particularly in LMICs.

METHODS AND RESULTS

CHAPTER 2: STUDY 1 - SYSTEMATIC REVIEW OF CARCINOGENIC POTENTIAL OF SMOKELESS TOBACCO PRODUCTS

2.1 CHAPTER OVERVIEW

This is the first study of the thesis, and it aims to systematically review the literature on the analysis of harmful chemicals present in ST products used across the globe. This chapter begins with Section 2.2, which provides a background on the toxicants and carcinogens present in ST and the research aims and objectives. Section 2.3 describes the methodology of the systematic review, including the study selection criteria, search strategy, data extraction, and quality assessment. The findings of the narrative synthesis are presented in Section 2.4. Section 2.5 is dedicated to the discussion of the evidence, summarising the key points. Finally, Section 2.6 presents the conclusion, providing a summary of the main findings and their significance.

2.2 BACKGROUND

Smokeless tobacco products have been associated with increased risks of various cancers, including those of the oral cavity, nasal cavity, pharynx, larynx, oesophagus, pancreas, and liver (Hecht, 1998, Gupta et al., 2017, Gupta et al., 2018). The carcinogenicity of ST is attributed to its chemical constituents, which are formed during the manufacturing process. Chapter 1 of this thesis highlighted the variations in ST products depending on their preparation method, mode of use, and ingredients, including additives that affect taste, aroma, pH, and nicotine content. It also explained how various chemical compounds are formed during the manufacturing process, leading to high addiction and carcinogenicity. The upcoming section will provide further insights into the specific carcinogens and their contributing factors.

2.2.1 CARCINOGENS IN SMOKELESS TOBACCO

The International Agency for Research on Cancer (IARC) has classified ST as a carcinogen, meaning it has the potential to cause cancer in humans. The carcinogenic properties of ST are attributed to the presence of various chemical compounds, including tobacco-specific nitrosamines (TSNAs), polycyclic aromatic hydrocarbons (PAHs), metals and metalloids, and radioactive substances (Kaur et al., 2019). The following section will discuss these in detail.

Tobacco-specific nitrosamines

TSNAs are a group of potent carcinogens that are specific to tobacco products, including ST. They are formed by the reaction of nitrite and nitrate with tobacco alkaloids, particularly nicotine (IARC, 2007). Among all the carcinogens, TSNAs are the most important group due to their high concentration and strong carcinogenicity (Stepanov et al., 2008). Out of the five TSNAs present in ST, the two potent IARC group 1 carcinogen are N'-nitrosonornicotine (NNN) and 4-(methylnitrosamino)- 1-(3-pyridyl)-1-butanone (NNK) (Moghbel et al., 2016). These chemicals are formed from nicotine alkaloids during several stages of manufacturing and their concentration depends upon the type of tobacco, processing techniques and blending approaches used. They vary largely across the spectrum of ST products, with Sudanese toombak having the highest concentration of NNN and NNK (3085 and 7870 µg/g) and Swedish snuff having the lowest (135 and 17.8µg/g) (Hecht, 1998, Hecht and Hoffmann, 1988, Idris et al., 1996).

Polycyclic Aromatic Hydrocarbons

Polycyclic aromatic hydrocarbons are chemicals that are formed due to the incomplete combustion of ST products. While there are more than 86 different PAH compounds present in tobacco, the most widely researched compound is Benzo[a]pyrene (B[a]P) which has been identified as an IARC Class 1 (McAdam et al., 2013). ST products contain several PAHs, including benzo[a]pyrene (B[a]P), which is a potent carcinogen. These chemicals are introduced to ST at different stages of curing. Research has shown that the level of carcinogenic PAH is higher in fire-cured tobacco than in air-cured since exposure to fire not only causes chemical changes but leads to the production of smoke-related chemicals (Stepanov et al., 2010, Miller and Fowlkes, 1999, Borgerding et al., 2012). Across the different ST products, the PAH levels range from 210ng/g for the hard pellet to 10039 ng/g for moist snuff.

Heavy metals

ST contains several carcinogenic metals and metalloids such as arsenic, beryllium, chromium, cadmium, lead and nickel compounds. These compounds are absorbed through the oral mucosa and can accumulate in the body, leading to various health effects, including cancer. The concentration of these metals and metalloids depends on the pH of the soil, its composition and the presence of industrial contamination (Adamu et al., 1989, IARC, 2012b). The concentration of these metals varies across products. For example, products available in the USA and Canada have arsenic levels of 0.1-3.5µg/g whereas products from Pakistan such as naswar have arsenic levels ranging from 0.15-14.04 µg/g (Pappas, 2011, Sajid and Bano, 2017). Similarly, average levels of cadmium and nickel in Swedish snus are 0.6µg/g and 1.3µg/g respectively which is significantly lower than levels in Pakistani naswar (0.25-9.2 µg/g and 2.2-64.85 µg/g) (Sajid and Bano, 2017, Rutqvist et al., 2011).

Volatile aldehydes

Volatile aldehydes, such as formaldehyde and acetaldehyde, are formed during the heating and combustion of tobacco. These compounds are highly reactive and can damage DNA and other cellular components, leading to mutations and cancer.

Formaldehyde has been classified as a human carcinogen by IARC and has been linked to nasopharyngeal cancer (IARC, 2007).

Radionuclides

ST products contain several radionuclides, including polonium-210 (Po-210) and lead-210 (Pb-210), which are formed during the decay of radium-226 (Ra-226) in the soil. Tobacco plants while growing are exposed to these compounds either through uptake from soil or direct deposition on tobacco leaves. These compounds are absorbed through the oral mucosa and can accumulate in the body, leading to various health effects, including cancer. The emissions from these compounds have been known to cause DNA damage and cell mutations. The concentration of radionuclides also varies across products. For example, Danish chewing tobacco contains a lower concentration (8–240 × 10^{-19} g/g) than Indian snuff (7.4–19.1 × 10^{-6}g/g). This has been attributed to the addition of harmful agents like ash and calcium hydroxide (IARC, 2012b, Lal et al., 1987).

2.2.2 FACTORS AFFECTING TOXICITY OF SMOKELESS TOBACCO

Several factors can influence the chemical composition and toxicity of ST products, thereby impacting their health effects. The following section will discuss some of the key factors that influence the addictiveness and toxicity of ST products.

Nicotine

Nicotine is the primary alkaloid present in ST products, constituting 85-95% of the total alkaloid content. It is a highly addictive substance that acts as a central nervous system stimulant (Moghbel et al., 2017). Nicotine is rapidly absorbed through the oral mucosa, and its level in the blood reaches a peak within a few minutes of use. The amount of nicotine delivered to the bloodstream depends on the amount of tobacco used, the pH of the product, its moisture content, and the duration of use (Pickworth et al., 2014).

pH

pH is an important factor that affects the chemical composition and toxicity of ST products. The pH of ST varies depending on the type of product and its method of preparation. Most ST products have an alkaline pH ranging from 7.5 to 12.5, which is

higher than the pH of saliva (around 6.5 to 7.5) and oral mucosa (around 6.8) (Timberlake et al., 2015).

The alkaline pH of ST products facilitates the release of free nicotine from tobacco, which increases its absorption in the body. The absorption of nicotine in the oral cavity is pH-dependent, and the bioavailability of nicotine increases as the pH of the product increases (Benowitz et al., 1988). Moreover, the alkaline pH of ST products also promotes the formation of TSNAs, which are potent carcinogens. The pH of ST products can be modified by the addition of various chemicals, such as sodium carbonate, which is commonly used in the manufacturing of Swedish snus. The pH of ST products can also be influenced by the method of use. For example, the use of lime (calcium hydroxide) with betel quid in South Asia increases the alkalinity of the product, which enhances the absorption of nicotine and other alkaloids. The use of lime has been associated with an increased risk of oral cancer (IARC, 2004b).

Moisture content

Moisture content is another important factor that can affect the toxicity of ST products (Prabhakar et al., 2013). The moisture content of ST products can range from 5% to 70%, with different products having different moisture levels. Moisture can affect the physical properties of ST products, such as their texture and pliability. Moisture content can also influence the bioavailability of tobacco constituents, including nicotine (IARC, 2007).

High moisture levels in ST products can increase the rate of nicotine absorption through the oral mucosa, which can lead to increased addiction potential (Mishra et al., 2015). This is because the absorption of nicotine is faster and more efficient in the presence of water. In addition, high moisture levels can also contribute to the growth of microorganisms, which can produce toxins that can further increase the toxicity of ST products (IARC, 2007).

On the other hand, low moisture levels in ST products can lead to dryness and harshness, which can irritate the oral mucosa. This can lead to an increased risk of oral lesions and other oral health problems (NCI, 2014).

2.2.3 LIMITS FOR CARCINOGENS IN ST

As ST products vary greatly based on their level of toxicants, the WHO Study Group for Tobacco Regulation (TobReg) has recommended limits for toxic chemicals like NNN, NNK and B[a]P. The recommendations stipulate that NNN and NNK should not exceed 2 micrograms per gram of dry-weight tobacco and B[a]P levels shouldn't exceed 5 nanograms per gram of dry-weight tobacco (Stanfill et al., 2011).

Even though ST is the main form of tobacco for a fourth of all tobacco users in the world, there are challenges in its regulation due to the sheer diversity of its composition, toxic potential, production, distribution, and sale (Siddiqi et al., 2020). Because of such heterogeneity, lack of standardisation and knowledge about the toxic effects of constituents, some products have been shown to contain enormously high levels of nicotine and carcinogenic nitrosamines. This is especially true in LMICs that also carry the highest burden of ST use (Gupta and Mehrotra, 2020, Gupta et al., 2019).

As this is such a rapidly changing field with new forms of ST products being introduced in the market and changes being made to the existing products in terms of their manufacturing and processing methods, it is important to keep evaluating and updating the public health implications of these products. The main implications relate to the harms associated with the consumption of these products due to the wide variety of carcinogens present in them.

In light of the above points, this chapter aims to present the latest estimates of the chemical profiles of ST products used around the globe, with the main objective of understanding their product composition and carcinogenic potential.

The next section will detail the methodology employed in this systematic review. This will include the search strategy used to identify relevant studies, the criteria used for study selection, and the data extraction and synthesis methods. The section will also outline the quality assessment process for the included studies and any potential limitations of the review.

2.3 METHODOLOGY

The systematic review was undertaken using a predetermined methodology, and the review process adhered to the systematic review-specific Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) reporting guidelines as specified by Moher et al. (2010).

2.3.1 REVIEW QUESTIONS

1. What are the chemical profiles of ST products used around the globe, and how do they vary in terms of carcinogenic potential?
2. How do the factors that influence the carcinogenic potential of ST products vary across different products and regions?

2.3.2 TYPE OF STUDIES INCLUDED

The review includes primary studies that reported laboratory test results on the selected ST constituents and chemicals. The inclusion criteria for the studies were as follows:

1. Studies reporting on the chemical composition of ST products, including the concentration of key carcinogens and influencing factors such as pH and moisture content.
2. Studies conducted using laboratory-based methods for testing ST products, including chromatography, spectrometry, and other quantitative analytical techniques.
3. Studies published in the English language (While initially, this criterion was not strictly enforced, it was eventually put in place due to a lack of resources for translating studies in other languages translation)

The exclusion criteria were as follows:

1. Studies that did not report on the chemical composition of ST products.
2. Studies that were conducted on humans or animals.
3. Studies conducted using non-laboratory-based methods for testing ST products, including surveys and qualitative studies.
4. Studies published in languages other than English.

The review did not initially exclude any studies based on their publication type to avoid any potential bias. For studies that were only available as conference abstracts, the authors were contacted to inquire about the availability of full-text publications. However, if the full-text publication was not available then the studies were excluded. Also, the quality of the eligible studies was assessed, but no exclusions were made based on the assessment.

2.3.3 EXPOSURE

The systematic review only included studies that investigated the use of ST products. Both oral and nasal forms of ST products were included in the review because of the possibility of dual use. While the primary focus of the PhD is on oral forms of tobacco, including only oral forms would exclude individuals who may use both oral and nasal forms of ST products.

In addition, studies reporting on other forms of tobacco and nicotine delivery systems such as smoking, vaping, electronic nicotine delivery systems (ENDS), and traditional forms of tobacco such as cigarettes were excluded. This was done to maintain the focus of the review on ST products and to ensure that the findings were specific to this particular type of tobacco use. Studies reporting on the use of other tobacco products may have different chemical compositions and carcinogenic potential, which would affect the generalisability of the review findings.

2.3.4 OUTCOME

In order to be included in the review, primary studies must have reported quantitative measurements of at least one of the following ST constituents or chemicals: nicotine (total and free), TSNAs (NNN and NNK), PAH, heavy metals, and radionucleotides. In addition, studies reporting values for pH and moisture content were also eligible for inclusion, as these factors are known to influence the overall carcinogenicity of ST products. Studies reporting only qualitative data or lacking quantifiable measurements of the selected constituents or chemicals were excluded from the review. The values were reported in a variety of measurements such as µg/kg, ng/g, ng/pouch, ng/g dwt, and ng/g wet wt. For ease of comparison, where possible, the values were converted to ng/g.

2.3.5 SEARCH STRATEGY

The following section outlines the search strategy used to identify relevant studies on the health effects of ST use for this systematic review including the electronic databases searched, the search terms used, and any additional search methods employed. The search was conducted using a combination of electronic databases, and the search terms and inclusion/exclusion criteria were pre-specified in advance to ensure a transparent and rigorous process.

The systematic review under consideration relied primarily on electronic databases as the principal source for conducting the literature search. MEDLINE, Embase and Cochrane Library were the selected databases used to identify relevant studies. These databases were chosen based on their wide coverage of health-related literature and their accessibility to a broad audience.

In addition to the electronic database searches, the review also employed a secondary method of reference list scanning. The reference lists of eligible studies were examined to identify any additional studies that may have been missed by the electronic database searches. This process was necessary to ensure that the review captured all relevant studies, regardless of the initial search method employed.

Searching the electronic databases

The present study utilised a systematic approach to searching multiple electronic databases for relevant literature on the topic of interest. A comprehensive search strategy was developed and executed by the researcher in Medline, which was then adapted across 14 databases to ensure a thorough literature search. The databases included major indexed databases such as Ovid MEDLINE(R), Embase, APA PsycINFO, EBSCO CINAHL Complete, Web of Science, The Cochrane Library, and SCOPUS, which are widely known for their coverage of health-related literature.

In addition, regional databases including Latin American and Caribbean Health Sciences Literature (LILACS), African Journals Online (AJOL), WHO Index Medicus of the Eastern Mediterranean Region (IMEMR), and PakMediNet Pakistan, as well as IndMED for India,

were also searched. This approach was necessary to ensure that relevant literature from different regions of the world was captured.

To ensure the search strategy was comprehensive, the researchers also searched for grey literature sources. Open Grey and ProQuest Dissertations & Theses Global were searched to ensure relevant literature from non-indexed sources were not overlooked.

In addition, the study also employed hand searching of reference lists to identify any relevant literature that may not have been captured in the initial database searches. This approach was necessary to ensure that all potentially relevant literature was identified and considered for inclusion in the review.

Overall, the extensive electronic database search strategy ensured that a wide range of literature sources was captured, allowing for a comprehensive review of the literature. The use of multiple databases and the inclusion of regional and grey literature sources ensured that a diverse range of studies was considered for inclusion in the present review.

Search Terms

The search strategy involved the use of both free text and subject headings, with a focus on two key areas: ST (exposure) and carcinogens (outcome).

To identify relevant studies on ST, the search terms were developed based on a published systematic review by Vidyasagaran et al. (2016), the National Cancer Institute's report on "Smokeless tobacco and public health: A global perspectives (NCI, 2014), and the International Agency for Research on Cancer (IARC) monograph titled "Smokeless tobacco and some tobacco-specific N-Nitrosamines" (IARC, 2007). These sources were selected based on their reputation for providing comprehensive and reliable information on the topic of interest.

The search terms used for ST were designed to capture a range of relevant keywords and subject headings. This approach ensured that the search strategy was comprehensive and inclusive of all potentially relevant studies. In addition, the search strategy included terms for carcinogens as the outcome of interest.

In order to ensure a comprehensive search for relevant literature, appropriate search functions were employed in the present study. Boolean operators, truncation, and wildcards were utilised to maximise the accuracy and specificity of the search strategy. These search functions allowed for the combination of multiple search terms and the identification of variations of key terms, thereby minimising the risk of missing relevant literature.

The search strategy for all the databases is included in Appendix 4. The use of a standardised search strategy across multiple databases ensured that all relevant literature sources were identified and included in the review.

Overall, the use of appropriate search functions, along with hand searching of reference lists, ensured that the search strategy for this study was comprehensive and inclusive of all potentially relevant literature.

To facilitate the systematic management of the studies retrieved from the searches, the present study utilised the EndNote X20 software (EndNote, 2020). This software was chosen due to its comprehensive features, including the ability to import, organise, and format references according to specific citation styles.

After the completion of the search process, all studies were imported into EndNote X20 (EndNote, 2020). This allowed for the efficient management of large volumes of literature, with the software enabling easy identification and removal of duplicates. The software also facilitated the screening process, with the ability to add notes and labels to individual studies, as well as export and share reference lists with other researchers.

2.3.6 DATA EXTRACTION

Once all the references were imported to EndNote, a rigorous process of screening was conducted to assess the eligibility of the studies. The screening process was carried out in two stages, namely title and abstract screening and full-text screening utilising a screening form (Appendix 5).

During the title and abstract screening stage, a single researcher (Zainab Kidwai) screened the studies for eligibility. The studies that were not related to the topic were

removed at this stage. The full texts of the studies identified as potentially eligible were retrieved for full-text screening.

In the full-text screening stage, two researchers (Zainab Kidwai and Aishwarya Vidyasagaran) independently screened the full texts of the studies using the aforementioned screening form. Any discrepancies on whether to include or exclude a study were resolved through discussion. The studies that did not meet the predetermined inclusion criteria were eliminated at this stage.

After the completion of the screening process, the full texts of the included studies were subjected to data extraction. A data extraction form was created, piloted on the first 10 included studies, and refined accordingly. The form included information on key study characteristics, study design, methods, and key findings, including exposure and outcome data. A sample of the data extraction form is presented in Appendix 6.

Following data extraction, a descriptive overview of the ST products and variations in the levels of key harmful constituents across ST products is reported. This includes a synthesis of the findings from the included studies, highlighting any commonalities or differences across studies. The data is presented in a tabular or graphical format, as appropriate.

2.3.7 QUALITY ASSESSMENT

To ensure the methodological quality of the studies included in the systematic review, a risk of bias assessment was conducted using an adapted version of the Joanna Briggs Institute (JBI) critical appraisal tool for analytical cross-sectional studies (Moola et al., 2015). The JBI tool was specifically adapted to fit the purpose of this review and was used to critically appraise the quality of all the papers that met the inclusion criteria.
The JBI tool has been extensively used in systematic reviews and has been found to have good inter-rater reliability and validity (Moola et al., 2015; Peters et al., 2013). The tool consists of a series of questions that assess the quality of the study design, methodology, data analysis, and presentation of results.

The adapted JBI tool used in this review was designed to assess the risk of bias in analytical cross-sectional studies, which is the type of study design included in the

review. The tool was used to assess the quality of the studies based on criteria such as the representativeness of the study sample, the reliability and validity of the data collection instruments, and the appropriateness of the statistical analysis. Table 1 provides the quality assessment criteria used in the study. The criteria are divided into two categories: quality of reporting and quality of conducting the study. The purpose of the assessment is to determine the extent to which the studies have addressed the possibility of bias in their design, conduct, and analysis.

Table 1: Quality Assessment Criteria

A. Quality of reporting criteria	**Reason for selection**
Were the types of ST products clearly specified?	This criterion ensures that the authors provide clear details of the inclusion criteria i.e., the type of ST included in the study.
Was information given on product origin?	This criterion requires that the study clearly describes where the sample was collected from i.e., the geographical region.
Was the time frame for the sample selection specified?	As new ST brands keep getting introduced in the market with varying constituents which change over time due to the change in the manufacturing process, the authors should specify when the samples were collected.
Were sample storage conditions and the time frame for the sample analysis specified?	The chemical constituents of ST products are affected by temperature and moisture. Therefore, the authors should specify the sample storage methods and how long after sample collection, were they analysed.
Were the outcomes reported validly and reliably?	This criterion ensures that the authors specify the units of measurement as well as whether the measurements were given on a dry weight or wet weight basis.
B. Quality of conducting the study criteria	**Explanation of criterion**
Were attempts made to collect a representative sample?	This criterion specifies whether the authors attempted to get a representative sample (i.e., collect multiple samples from multiple sites to get a representative sample).

Was a reference/control group used for calibration?	Reference or control groups are used for the development and validation of analytical chemical and toxicological testing methods, as internal laboratory controls in ongoing analytical work and as a common factor during the comparison and interpretation of results from different laboratories (TJIReport, 2013). This criterion requires that reference or control groups are used for the analytical chemical and toxicological testing methods.
Was the outcome measured in a standard and reliable way?	This criterion ensures that the study clearly describes the method of measurement of the chemical constituents. It also ensures that the study was done in a standard and reliable way with standard instruments, reagents and labs used to conduct the analysis.

The quality assessment was conducted by two reviewers independently (ZK and AV) and any disagreements that arose were resolved through discussion, with a third reviewer (FS) invited to settle issues where necessary. Each category was assessed on a Yes (Green), No (Red) and Unclear (Yellow) criteria. These were compiled to give an overall study quality score which ranged from low, medium, and high. The results of the critical appraisal and risk of bias were used to inform data synthesis by providing insight into the quality of the included studies and to guide the interpretation of the results of the systematic review.

2.3.8 DATA SYNTHESIS

Narrative synthesis involves the identification of patterns across studies, exploring similarities and differences in study designs, sample characteristics, exposure and outcome measures, and key findings (Popay et al., 2006). It allows for a comprehensive and descriptive summary of the available evidence, highlighting the strengths and weaknesses of the included studies, and providing an overall interpretation of the findings.

In this review, the findings from the included studies were synthesised using a narrative approach. The key findings were grouped according to the types of ST products and variations in the levels of key harmful constituents across ST products. In the upcoming

section, the findings of the systematic review will be presented and discussed in detail. The studies included in the review were assessed for their quality and risk of bias, and the data were synthesised using a narrative synthesis approach. The findings will be presented according to the research questions and objectives stated in the introduction. The results will provide insights into the variations in harmful constituents in ST products and their potential health effects.

2.4 FINDINGS

In this section, the findings of the narrative review are presented. A total of 43 studies were included in the review, as identified through the screening process. A comprehensive search strategy yielded a total of 7062 records, which were screened for relevance. In addition, 11 records were identified through other sources, bringing the total number of records to 7078. After removing duplicates and screening the titles and abstracts, 3640 records were assessed for eligibility, and 72 full-text articles were assessed for inclusion. Following this process, a total of 43 studies were deemed suitable for inclusion in the final synthesis. A summary of the study selection process is presented in Figure 6.

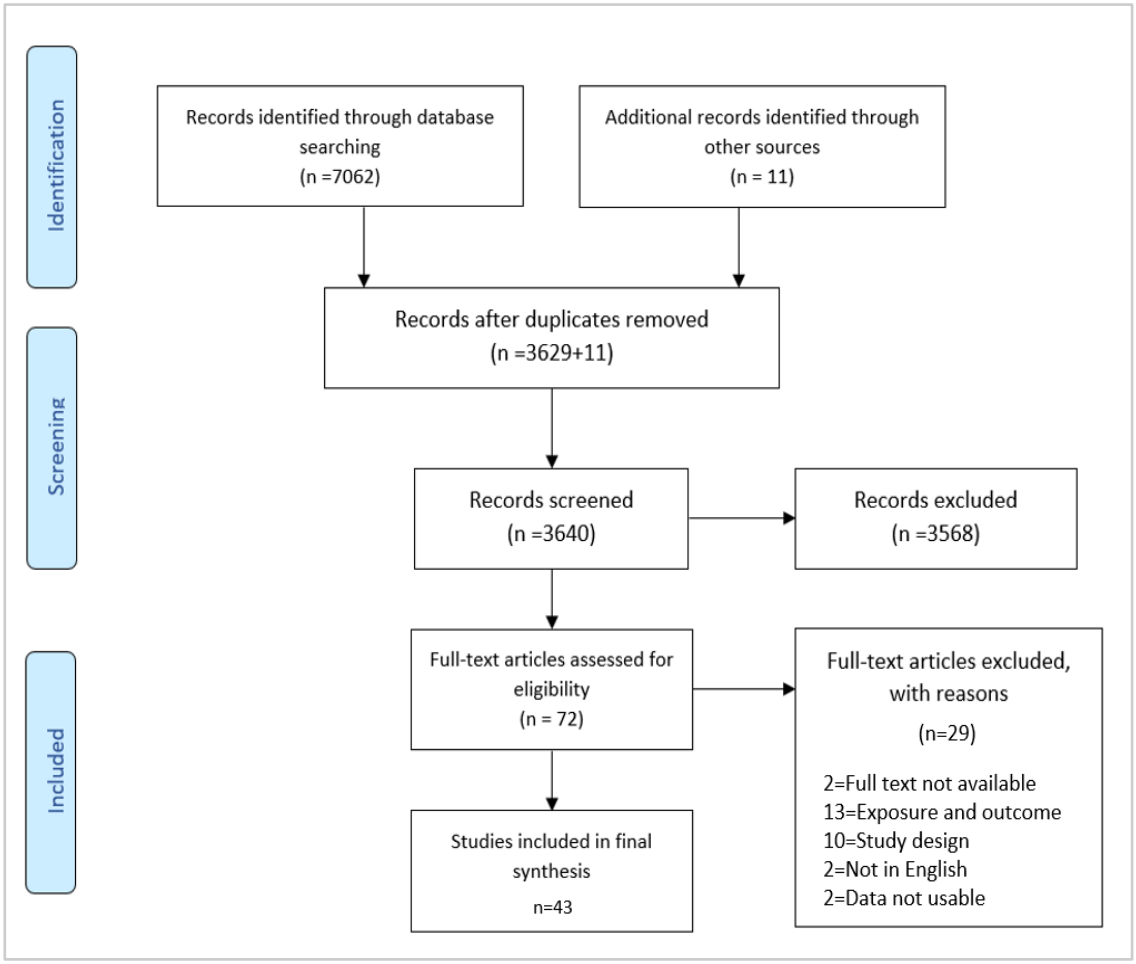


Figure 6:Flow diagram of the study selection process

2.4.1 EXCLUDED AND INCLUDED STUDIES

Out of these 29 were excluded for one of the following reasons:

- Full text not available or withdrawn (2 studies)- Adogu et al (2015), Mehrotra et al. (2018)
- Not meeting the exposure and/or outcome criteria (13 studies)- Alsanousi et al. (2019), Bhartiya et al. (2018), Jabba et al. (2019), Hellinghausen et al. (2018), McAdam et al. (2015), Nnorom et al. (2015), Quayle et al. (2016), Shaik et al. (2019), Khalid et al. (2019), Majewska et al. (2018), Inaba et al. (2017), Vincent at al. (2011).
- Not meeting the study design criteria (10 studies)- Ashley et al. (2015), Desalu et al. (2010), Gupta et al. (2020), Gupta et al. (2019), Gupta et al. (2020), Qin et al. (2018), Stanfill et al. (2017), Guezguez et al. (2019), Nasrin et al. (2019), Stepanov et al. (2020)
- Not in the English language (2 studies)- Duan et al. (2017), Li et al. (2018)
- Data not usable (2 studies)- Mohamed et al. (2020), Alhazmi et al. (2019)

Out of the 43 included studies, 3 included ST products from Nigeria (Orisakwe et a., 2014, Orisakwe et al., 2015, Akinyose et al., 2018), 1 included products from South Africa, the USA and Sweden (Song et al., 2016), 9 were from the USA alone (Ammann et al., 2016, Caraway et al., 2013, Moldoveanu et al., 2019, Oldham et al., 2020, Rainey et al., 2013, Stepanov et al., 2014, Stepanov et al., 2013, Lawler et al., 2013, Hearn et al., 2013), 1 included products from the USA and Northern Europe (Lawler et al., 2020), 2 included products from USA and Sweden (McAdam et al., 2017, McAdam et al 2013) and 1 from Brazil (Stanfill et al., 2015). There was 1 study each from Sweden (Digard et al., 2013), the UK (Stanfill et al., 2018) and Kyrgyzstan (Stepanov et al., 2017).

The review also included 3 studies from Oman (Al-Mukhaini et al., 2014, Al-Mukhaini et al., 2016, Al-Mukhaini et al., 2015); 2 from Saudi Arabia (Alhazmi et al., 2018, Brima et al., 2016); 4 from Pakistan (Arain et al., 2015, Arain et al. 2015, Atta et al., 2015, Kazi et al., 2013); 1 from Iran (Farhadmollashahi et al., 2014) and 1 from Tunisia (Houas et al., 2017).

There were 2 studies from Bangladesh (Hossain et al., 2018, Nasrin et al., 2020); 9 were from India (Amith et al., 2018., Hegde et al., 2017, Jain et al., 2017, Nigam et al., 2013., Prabhakar et al., 2013, Sharma et al., 2015, Stepanov et al., 2015, Stepanov et al., 2017, Vini et al., 2017). Only 1 study was based in Australia (Moghbel et al., 2016).

In order to provide a comprehensive understanding of the prevalence and characteristics of ST products across different regions, the findings below are presented based on the WHO regions. Specifically, this approach is taken to highlight the similarities and differences across the different regions and maintain the focus on the current context of the study on South Asia.

Across the studies, the majority of the products sampled were moist snuff (9 studies), snus (9 studies) and *gutkha* (7 studies). There was a diverse variety of products from the different WHO regions with the majority of the products from the Southeast Asia (SEARO) region. These included paan masala containing tobacco, plain tobacco, *khaini, gul, zarda, sada patta, mishri, kaddipudi, tambaakhu,* and betel quid (Amith et al., 2018 Hegde et al., 2017, Jain et al., 2017, Nigam et al., 2013., Prabhakar et al., 2013, Sharma et al., 2015, Stepanov et al., 2015, Stepanov et al., 2017, Vini et al., 2017, Hossain et al., 2018, Nasrin et al., 2020., Nasrin et al., 2020). From the Eastern Mediterranean (EMRO)

region, the most common ST products were *nisvai, afzal, shammah, mainpuri, mawa,* and *dripping niswar* (Stepanov et al., 2017, Al-Mukhaini et al. 2014, Alhazmi et al., 2018, Arain et al., 2015, Atta et al., 2016). There were also some country-specific products like *nisvai* from Kyrgyzstan (Stepanov et al., 2017a), *pituri* from Australia (Moghbel et al., 2016), Nigerian snuff (Akinyose et al., 2018) and Nigerian ST (Orisakwe et al., 2014 and Orisakwe et al., 2015)

A summary of study characteristics including the author, geographical region based on the WHO classification, country of product origin, ST product used and carcinogen and influencing factors are presented in the following Table 2.

Table 2: Characteristics of studies included in the review.

First Author	WHO Region	Country of product origin	ST products	Carcinogens and influencing factors
Orisakwe et al. (2014)	AFRO	Nigeria	Nigerian smokeless tobacco	Heavy metals (cadmium, chromium, cobalt, lead)
Orisakwe et al. (2015)	AFRO	Nigeria	Nigerian smokeless tobacco	PAH
Akinyose et al. (2018)	AFRO	Nigeria	Nigerian snuff	Radionuclides
Song et al. (2016)	AFRO, AMRO, EURO	South Africa, USA, Sweden	Moist snuff, snus	pH, nicotine, TSNAs, heavy metals (lead, nickel, chromium)
Ammann et al. (2016)	AMRO	USA	Moist snuff, snus, loose leaf, plug, twist	TSNAs
Caraway et al. (2013)	AMRO	USA	Snus	Nicotine, TSNAs, PAH, heavy metals (arsenic, cadmium, chromium)
Moldoveanu et al. (2019)	AMRO	USA	Moist snuff	PAH
Oldham et al. (2020)	AMRO	USA	Smokeless tobacco	TSNAs
Rainey et al. (2013)	AMRO	USA	Dissolvable tobacco products	pH, nicotine
Stepanov et al. (2014)	AMRO	USA	Snus, dissolvable products	pH, moisture, nicotine, TSNAs

Stepanov et al. (2013)	AMRO	USA	Moist snuff, novel ST products	Moisture, TSNAs
Lawler et al. (2013)	AMRO	USA	Plug, Loose-leaf, Twist, Dry snuff, Snus, Dissolvable tobacco	Nicotine, Total Nicotine, pH, Total TSNAs, NNN, NNK, NAT, NAB, Total Moisture
Hearn et al. (2013)	AMRO	Alaska	*Iqmik*	Nicotine, Total Nicotine, pH, PAH, Total TSNAs
Stanfill et al. (2015)	AMRO	Brazil	*Rapé*	pH, moisture, total nicotine, nicotine, TSNAs, PAH.
Lawler et al. (2020)	AMRO, EURO	USA, Northern Europe	Snus	Moisture, pH, nicotine, TSNAs
McAdam et al. (2017)	AMRO, EURO	USA, Sweden,	Chewing tobacco, dry and moist snuff, hard and soft pellets, plug, loose and portion snus	Radionuclides
McAdam et al. (2013)	AMRO, EURO	USA, Sweden	Chewing tobacco, dry and moist snuff, hard and soft pellets, plug, loose and portion snus	PAH
Digard et al. (2013)	EURO	Sweden	Snus	TSNAs, pH
Stanfill et al. (2018)	EURO	UK	*Gutkha, zarda, quiwam*	Moisture, pH, nicotine, TSNAs
Stepanov et al. (2017)	EURO	Kyrgyzstan	*Nisvai*	Moisture, pH, nicotine, TSNAs
Al-Mukhaini et al. (2014)	EMRO	Oman	*Afzal*	Heavy metals (chromium, nickel, cadmium, lead)
Al-Mukhaini et al. (2016)	EMRO	Oman	*Afzal*	TSNAs
Al-Mukhaini et al. (2015)	EMRO	Oman	*Afzal*	Nicotine, pH
Alhazmi et al. (2018)	EMRO	Saudi Arabia	*Shammah*	Heavy metals (arsenic, lead, cadmium)
Arain et al. (2015)	EMRO	Pakistan	Moist snuff, *gutkha, mainpuri*	Heavy metal (nickel)
Arain et al. (2015)	EMRO	Pakistan	Moist snuff, *gutkha, mainpuri*	Heavy metal (arsenic)
Atta et al. (2016)	EMRO	Pakistan	*Paan, zarda, wet gutkha, dry gutkha, mawa, sniffing niswar,* dripping product	Heavy metals (lead, nickel, cadmium, arsenic, chromium)
Brima et al. (2016)	EMRO	Saudi Arabia	*Shammah*	Heavy metals (lead, arsenic, cadmium)

Farhadmolla shahi et al. (2014)	EMRO	Iran	Blended tobacco	TSNAs
Houas et al. (2017)	EMRO	Tunisia	Neffa	Heavy metals (cadmium, nickel, chromium)
Kazi et al. (2013)	EMRO	Pakistan	Moist snuff	Heavy metals (cadmium, nickel, lead)
Amith et al. (2018)	SEARO	India	Pan masala containing tobacco	Nicotine
Hegde et al. (2017)	SEARO	India	Plain tobacco, *gutkha, khaini, pan masala*	Nicotine, pH
Hossain et al. (2018)	SEARO	Bangladesh	*Gul, zarda*	Heavy metals (lead, cadmium, chromium)
Jain et al. (2017)	SEARO	India	*Pan masala, gutkha*	pH, Moisture, Alkaloids
Nasrin et al. (2020)	SEARO	Bangladesh	*Zarda, gul, sada patta*	Nicotine, TSNAs,
Nigam et al. (2013)	SEARO	India	*Blended Indian Pan Masala*	PAH
Prabhakar et al. (2013)	SEARO	India	*Khaini*	pH, Moisture, heavy metals (lead, cadmium, zinc, nickel)
Sharma et al. (2015)	SEARO	India	*Mishri, khaini, kaddipudi, tambaaku, gutkha*	pH, nicotine
Stepanov et al. (2015)	SEARO	India	Snus	Nicotine, TSNAs
Stepanov et al. (2017)	SEARO	India	*Mawa, khaini, tambakhu,* betel quid	pH, moisture, TSNAs
Vini et al. (2017)	SEARO	India	Local ST products	Heavy metals (cadmium, chromium, nickel, arsenic, lead)
Moghbel et al. (2016)	WPRO	Australia	*Pituri or mingkulpa*	Nicotine, TSNAs

2.4.2 QUALITY OF THE INCLUDED STUDIES

The findings (Table 3) revealed that out of the 43 studies included in the review, 15 studies scored as low risk, 25 as medium risk, and 3 as high risk for bias, indicating a significant variation in study quality based on the geographical location and specific criteria evaluated.

Notably, the three high-risk studies were conducted in India, Iran, and the USA, suggesting that the quality of research may vary based on cultural and contextual factors. The most common issues relating to the quality of the studies were the absence of control/reference samples for instrument calibration and insufficient information on sample storage methods and the time frame for analysis. These factors contributed to lower quality ratings and were observed across multiple studies.

The quality assessment of studies from the SEARO region revealed that the majority of studies (8 out of 11) were rated as medium or high risk. Similarly, out of the 11 studies in the EMRO region 10 out of 11 studies were medium or high risk. Out of the 4 studies from the AFRO region, 3 were a medium risk. In contrast, studies from the EURO and AMRO regions were overall higher quality. Out of the 7 studies from EURO, only 2 were medium risk, whereas out of the 14 from the AMRO region, only 3 were medium risk and 1 high risk. All studies from the EMRO and AFRO regions were rated as medium to high risk. Interestingly, studies by the same authors demonstrated similar limitations in methodology.

In summary, the study suggests significant variations in the quality of research studies included in the analysis, with studies from EURO and AMRO regions demonstrating higher quality than others. The findings underscore the importance of standardised protocols in research studies and adherence to established criteria to minimise potential biases and limitations. The implications of these findings underscore the need for continued efforts to improve research quality and methodology in the future.

Table 3: Risk of Bias Assessment

First Author	WHO Region	Country of product origin	Were the types of ST clearly specified?	Was information given on product origin?	Were attempts made to collect a representative sample?	Was the time frame for the sample selection specified?	Was sample storage and time frame for the sample analysis specified?	Was information given on instruments/reagents/laboratory used to conduct the analysis?	Was a reference/control group used for calibration?	Were the results reported in a valid and reliable way with appropriate units of measurement?	Overall risk of bias
Orisakwe et al. (2014)	AFRO	Nigeria	🟢	🟢	🟢	🟢	🟡	🟢	🔴	🟢	Medium
Orisakwe et al. (2015)	AFRO	Nigeria	🟢	🟢	🟢	🟢	🟡	🟢	🔴	🟢	Medium
Akinyose et al. (2018)	AFRO	Nigeria	🟢	🟢	🟢	🔴	🟡	🟡	🟢	🟢	Medium
Song et al. (2016)	AFRO, AMRO, EMRO	South Africa, USA, Sweden	🟢	🟢	🟢	🟢	🟡	🟢	🟢	🟢	Low
Ammann et al. (2016)	AMRO	USA	🟢	🟢	🟢	🟢	🟢	🟢	🟢	🟢	Low
Caraway et al. (2013)	AMRO	USA	🟢	🟢	🟢	🔴	🔴	🟢	🟢	🔴	High
Moldoveanu et al. (2019)	AMRO	USA	🟢	🟢	🟢	🟢	🟢	🟢	🟢	🟢	Low

Oldham et al. (2020)	AMRO	USA	🟢	🟢	🟢	🟢	🟢	🟢	🔴	🔴	Medium
Rainey et al. (2013)	AMRO	USA	🟢	🟢	🟢	🔴	🔴	🟢	🟢	🟢	Medium
Stepanov et al. (2014)	AMRO	USA	🟢	🟢	🟢	🟢	🟡	🟢	🟢	🟢	Low
Stepanov et al. (2013)	AMRO	USA	🟢	🟢	🟢	🟢	🟡	🟢	🟢	🟢	Low
Lawler et al. (2013)	AMRO	USA	🟢	🟢	🟢	🟢	🟡	🟢	🟢	🟢	Low
Stanfill et al., (2015)	AMRO	Brazil	🟢	🟢	🟢	🟢	🟢	🟢	🟢	🟢	Low
Hearn (2013)	AMRO	USA	🟢	🟢	🟢	🔴	🟡	🟢	🟢	🟢	Medium
Lawler et al. (2020)	AMRO, EURO	USA, Northern Europe	🟢	🟢	🟢	🟢	🟡	🟢	🟢	🟢	Low
McAdam et al. (2017)	AMRO, EURO	USA, Sweden,	🟢	🟢	🟢	🟢	🟡	🟢	🟢	🟢	Low
McAdam et al. (2013)	AMRO, EURO	USA, Sweden	🟢	🟢	🟢	🟢	🟡	🟢	🟢	🟢	Low

Digard et al. (2013)	EURO	Sweden	🟢	🟢	🔴	🟢	🟡	🟢	🟢	🔴	Medium
Stanfill et al. (2018)	EURO	UK	🟢	🟢	🟢	🔴	🔴	🟢	🟡	🟢	Medium
Stepanov et al. (2017)	EURO	Kyrgyzstan	🟢	🟢	🟢	🟢	🟡	🟢	🟢	🟢	Low
Al-Mukhaini et al. (2014)	EMRO	Oman	🟢	🟢	🔴	🟢	🟢	🟢	🟢	🟢	Medium
Al-Mukhaini et al. (2016)	EMRO	Oman	🟢	🟢	🔴	🟢	🟢	🟢	🟢	🟢	Medium
Al-Mukhaini et al. (2015)	EMRO	Oman	🟢	🟢	🔴	🟢	🟢	🟢	🟢	🟢	Medium
Alhazmi et al. (2018)	EMRO	Saudi Arabia	🟢	🟢	🟢	🔴	🟡	🟢	🟢	🟢	Medium
Arain et al. (2015)	EMRO	Pakistan	🟢	🟢	🟢	🟢	🟡	🟢	🟢	🟢	Low
Arain et al. (2015)	EMRO	Pakistan	🟢	🟢	🟢	🟢	🟡	🟢	🟢	🟡	Medium
Atta et al. (2016)	EMRO	Pakistan	🟢	🟢	🟢	🔴	🟡	🟢	🔴	🟢	Medium
Brima et al. (2016)	EMRO	Saudi Arabia	🟢	🟢	🟢	🔴	🟡	🟢	🟢	🟢	Medium

Farhadmollashahi et al. (2014)	EMRO	Iran	🟢	🟢	🔴	🔴	🔴	🟢	🟢	🔴	High
Houas et al. (2017)	EMRO	Tunisia	🟢	🟢	🟢	🔴	🟡	🟢	🟢	🟢	Medium
Kazi et al. (2013)	EMRO	Pakistan	🟢	🟢	🟢	🟢	🔴	🟢	🟢	🟢	Medium
Amith et al. (2018)	SEARO	India	🟢	🟢	🟢	🟢	🟢	🟢	🟢	🔴	Medium
Hegde et al. (2017)	SEARO	India	🟢	🟢	🟡	🔴	🔴	🟢	🟢	🔴	High
Hossain et al. (2018)	SEARO	Bangladesh	🟢	🟢	🟢	🔴	🟡	🟢	🔴	🟢	Medium
Jain et al. (2017)	SEARO	India	🟢	🟢	🟢	🔴	🔴	🟢	🟢	🟢	Medium
Nasrin et al. (2020)	SEARO	Bangladesh	🟢	🟢	🟢	🟢	🟡	🟢	🟢	🟢	Low
Nigam et al. (2013)	SEARO	India	🟢	🟢	🟢	🔴	🔴	🟢	🟢	🟢	Medium
Prabhakar et al. (2013)	SEARO	India	🟡	🟢	🟢	🟢	🔴	🟢	🟡	🟢	Medium

Sharma et al. (2015)	SEARO	India	🟢	🟢	🟢	🔴	🟡	🟢	🟢	🟢	Medium
Stepanov et al. (2015)	SEARO	India	🟢	🟢	🟢	🟢	🟡	🟢	🟡	🟢	Low
Stepanov et al. (2017)	SEARO	India	🟢	🟢	🟢	🟡	🟢	🟢	🟢	🟢	Low
Vini et al. (2017)	SEARO	India	🟢	🟢	🟢	🔴	🔴	🟢	🟢	🟢	Medium
Moghbel et al. (2016)	WPRO	Australia	🟢	🟢	🟡	🔴	🟡	🟢	🟢	🟢	Medium

2.4.3 CHEMICAL CONSTITUENTS

The 43 studies reported findings on 14 chemical constituents in 36 varieties of ST products comprising 1277 samples. To make the results in this section more accessible, they have been written by the constituent, starting with an overall summary that reports the total number of studies, the number of ST products analysed and the countries they are from. Additionally, the summary highlights the range of pH values observed across all products, with a breakdown of the products with the lowest and highest pH values. Each constituent will be described in detail, discussing the individual studies that have analysed the pH levels and highlighting any regional variation observed for the values discussed. By breaking down the results in this way, it is hoped that the findings will be easier to understand and interpret.

pH

A total of 19 studies reported on the pH of approximately 20 ST products from across 8 countries. The overall pH of the various products ranged from 5.17 to 11. The lowest pH levels were reported in the following products: snus and dissolvable products from the USA, commercial *rapé* from Brazil, plain tobacco and *sada patta* and betel quid with tobacco from India. In summary, the findings show that the pH levels of several ST products vary widely depending on the region and type, and sometimes even within a particular type. These findings are further explored in the section below.

Stepanov et al (2014) analysed the pH levels in 180 samples of snus from three brands in the USA and found values ranging from 6.55 to 7.61. Lawler et al (2020) reported similar values in eight samples from the USA (pH range: 5.87-7.66, mean pH=6.62). Lawler et al (2013) analysed three snus samples and found values ranging from 7.55 to 7.77. Other studies analysed snus products from Sweden and India and found higher pH levels (Digard et al 2013, pH=8.2; Lawler et al 2020, mean pH=7.93; Stepanov et al 2015, pH range: 9.01-9.99; Prabhakar et al 2013, pH=10.01 ± 0.01). Although four products were sold under the same name, their pH values differed significantly.

Three studies analysed the pH levels of dissolvable products consisting of orbs, sticks, and strips in the USA. Overall, the pH values of these products ranged from 7.23 to 8.04.

Rainey et al (2013) reported pH values ranging from 7.44 to 7.79 for strips, sticks, and orbs in 9 samples. Stepanov et al (2014) analysed 4 samples of orbs with an average pH of 7.62, 28 samples of sticks with a pH range of 7.30 to 8.04, and 4 samples of strips with an average pH of 8.00. Similarly, Lawler et al (2020) analysed 21 samples of dissolvable products and reported pH values ranging from 7.23 to 7.88. Overall, the pH values of dissolvable products were found to be slightly alkaline, with variability between different types of dissolvable products.

Stanfill et al (2015) analysed the pH levels of commercially manufactured *rapé*, reporting values ranging from 5.17 to 6.42 across 10 samples from different brands. In addition, they also analysed two samples of custom-made *rapé, rapé nu-nu* and *rapé kashinawa*, which had some of the highest pH levels ranging from 9.75 to 10.02, highlighting the variability in pH levels depending on the processing method, even with the same products from the same region.

Moist snuff from six countries was analysed for pH levels in two studies. The pH range of moist snuff from the USA was found to be 6.5-8.44, with conventional products having a higher pH range than low-TSNA products. Low TSNA moist snuff from Sweden and South Africa were found to have higher pH ranges than similar products from the USA. Prabhakar et al (2013) reported a pH value of 9.27±0.03 for madras snuff sold in India, which was similar to moist snuff sold in Pakistan with pH values ranging from 8.4-8.7 (Kazi et al., 2013).

Sada patta sold in Bangladesh had pH levels ranging from 6.9 to 7.1, as reported by Nasrin et al (2020). Zarda, another product from Bangladesh, had a pH ranging from 5.5 to8.0. Gul, also sold in Bangladesh, had the highest pH value (9.3-9.8) among all the products. In India, Stanfill et al (2018) analysed 12 brands of *zarda* products and found the pH levels considerably lower than those reported in Bangladesh, ranging mostly from 4.99 to 6.16.

Plain tobacco sold in India was found to have a pH of 5.24 in a study conducted by Hegde et al. in 2017. *Mawa*, another ST from India, was analysed by Stepanov et al. (2017) who found that the pH values ranged from 5.95 to 7.55 in 6 samples from two different

brands. Stepanov et al. (2017) also analysed *banarsi paan*, a form of betel quid sold with tobacco, and reported pH values ranging from 6.35 to 6.78 for 3 samples.

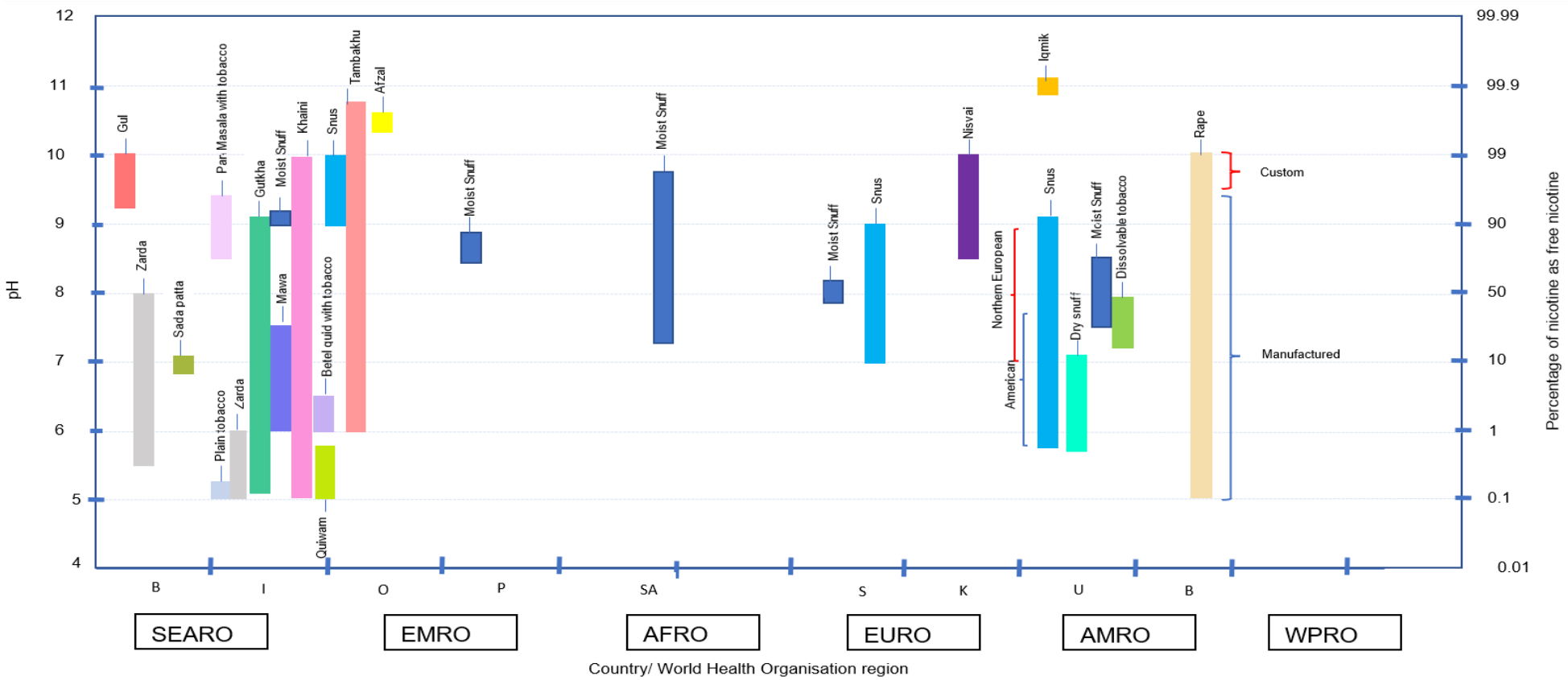
Gutkha, a widely consumed ST product in India, had variable pH values in different studies. Hegde et al (2017) reported a pH of 5.24 in one sample, whereas Jain et al (2017) found values ranging from 8.5 to 8.6 in their samples. Stanfill et al (2018) analysed three samples of *gutkha* from different brands and reported a pH ranging from 8.62 to 9.57, similar to the value reported by Prabhakar et al (2013) in a sample of *gutkha* with a pH of 8.68.

Khaini, an ST product from India, has been analysed in four different studies to determine its pH. Among the studies, there was a high variation in the pH values reported. Stanfill et al (2018) found that while one sample of *khaini* had a pH of 5.24, other samples had much higher values ranging from 9.17 to 10. Hegde et al (2017) reported a pH value of 9.47 for an unbranded *khaini* sample, and Prabhakar et al (2013) reported pH values ranging from 9.20 to 10.02 for three different brands. Stepanov et al (2017) analysed three samples of *khaini* and reported a mean pH of 9.43±0.32.

Quiwam, a tobacco product from India, was found to have pH levels ranging from 5.19 to 5.76 in a study conducted by Stanfill et al. (2018). Two different brands of *pandharpuri* had pH levels ranging from 5.17 to 5.25 (Stanfill et al., 2018). *Pan masala* had pH levels ranging from 8.71 to 9.19. *Tambakhu*, another Indian tobacco product, showed a significant variation in pH levels with pH levels of *tambakhu* samples ranging from 6.22 to 10.75.

Products with the highest pH levels reported are Alaskan *iqmik*, which had a pH of 11 in all varieties analysed (Hearn et al., 2013). Afzal, a tobacco product popular in Oman, had a pH of 10.46 (Al-Mukhaini et al., 2015). Another product, *nisvai*, popular in Kyrgyzstan, had a pH ranging from 8.66 for pre-packaged to 10.02 for bulk custom-made products (Stepanov et al., 2017).

Figure 7 below represents the summarised version of the above findings showcasing the range of pH in different ST products by country and within a region and highlighting the vast variation in ranges between products.



Country abbreviations: B=Bangladesh, I= India; P= Pakistan; SA= South Africa; S= Sweden, K= Kyrgyzstan; U= United States of America, B= Brazil
World Health Organization regions: SEARO = South-East Asia Region; EMRO = Eastern Mediterranean Region; AFRO = African Region; EURO = European Region; AMRO = Region of the Americas; WPRO=Western Pacific Region.

Figure 7:pH levels of various ST products used across the globe

Moisture content

The moisture content of ST was analysed in eight studies conducted across seven countries, revealing that different types of ST have varying moisture levels ranging from 3.5% for hard pellets (McAdam et al., 2013) to 62.9% for *khaini* (Prabhakar et al., 2013). The products with the lowest moisture content (i.e., less than 10%) were dry snuff, hard pellet, *rapé, pan masala* containing tobacco and gutkha whereas the products with the highest moisture content (i.e., greater than 50%) were moist snuff, snus and *afzal*.

Hard pellet, a type of ST used in the USA, was found to have a moisture content between 3.5-4.4% according to McAdam et al (2013). Meanwhile, dry snuff, another type of ST, was analysed by Lawler et al (2013) who reported moisture content ranging from 5.79% to 7.46%. *Rapé*, a type of ST from Brazil, had a moisture content ranging from 5.56% to 9.46% for manufactured products and 3.68%-4.91% for custom-made products. *Pan masala* containing tobacco, another tobacco product from India, was found to have a moisture content ranging from 6.1-8.45% according to Jain et al (2017) and even higher moisture content (31.16% and 49.31%) in two brands according to Prabhakar et al (2013). *Gutkha*, a mixture of chewing tobacco and areca nut, was found to have a moisture content ranging from 4.05-6.62% by Stanfill et al (2018) and 7.1-7.6% by Jain et al (2017), while Prabhakar et al (2013) reported a higher moisture content of 28.8% in a sample of *gutkha*.

Moist snuff products from two countries were analysed in five studies. Four of these studies reported on samples from the USA, while one reported on a sample from India. The moisture content in moist snuff from the USA ranged from 21.4-54.8% (Ammann et al., 2016), 49.05-54.25% (Moldoveanu et al., 2019), 52.3-62.4% (Stepanov et al., 2013), and 50.0-56.2% (McAdam et al., 2013). Prabhakar et al. (2013) reported the moisture content in a sample of Madras snuff (a brand of moist snuff sold in India) as 33.68%.

Afzal, a tobacco product, reportedly had a moisture content of 52% as analysed in three samples from Oman by Al-Mukhaini et al. (2015).

Chewing tobacco from the USA had moisture content ranging from 7.2 to26.4% (Ammann et al., 2016; McAdam et al., 2013), while loose leaf, plug, and twist from the USA had moisture content ranging from 20.0%, 15.8-19.3%, and 11%, respectively

(Ammann et al., 2016; McAdam et al., 2013). Dissolvable and novel tobacco products sold in the USA had moisture content ranging from 6.1-10.4% and 11.3-33.8%, respectively (Stepanov et al., 2013). *Nisvai* had varied moisture content depending on the method of preparation, with pre-packaged *nisvai* having a lower moisture content (12.8%) compared to bulk *nisvai* (49.3%) (Stepanov et al., 2017). *Gul, zarda,* and *sada patta*, which are widely used products in Bangladesh, had moisture content ranging from 12-17%, 15-40%, and 20-25%, respectively (Nasrin et al., 2020).

Khaini, pandharpuri, betel quid with tobacco, and *mawa* are popular tobacco products in India, with varying moisture content ranging from 21.5-27.9%, 16.7-19.0%, 29.6-45.5%, and 12.8-20.7%, respectively.

In summary, the analysis of moisture content in ST products showed that there is considerable variation in moisture levels between different types of products.

Total nicotine and free nicotine

A total of 16 studies reported on the nicotine content of tobacco products. Nicotine was reported in terms of total nicotine or free nicotine or both. The values were mostly reported as mg/g dry weight or wet weight apart from a few studies which reported the values as ng/pouch (Caraway et al., 2013), mg/g wet weight in the least square mean (Lawler et al., 2020), ng/g per pouch (Digard et al., 2013), ug/g (Stepanov et al., 2017), and as a percentage (Prabhakar et al., 2013). Most ST products had a total nicotine content of 30 mg/g or less but products such as *rapé, zarda, gul, afzal,* and *nisvai* had nicotine concentrations as high as 74 mg/g. The lowest nicotine content was seen in products from the USA and Sweden.

Moist snuff from the United States had values that ranged from 17.84 to 27.43 mg/g in a study by Song et al (2016). The total nicotine in conventional moist snuff ranged from 17.84 to 27.43 mg/g whereas the low TSNA moist snuff had lower values ranging from 15.01 to 20.26 mg/g. Other products from the US included snus and dissolvable products. Low-TSNA moist snuff from South Africa had total nicotine content varying from 19.38 to 24.52 mg/g (Song et al., 2016).

The nicotine content in snus ranged from 10.83 to 20.26 mg/g as reported in 3 studies. Caraway et al (2013) analysed 3 brands of snus which had nicotine content ranging from 10.83 to 12.2 mg/g. Another study by Stepanov et al (2014) reported the nicotine content in 12 brands of snus ranging from 13.18 to 26.92 mg/g. Lawler et al (2020) analysed 8 samples of snus sold in the US and reported a range varying from 8.02 to 13.6 mg/g wet weight.

Dissolvable tobacco products from the USA such as sticks, orbs, and strips had a nicotine content ranging from 2.60 to 7.81 mg/g in studies by Stepanov et al. (2014) and Rainey et al. (2013). However, *iqmik* from the USA and *rapé* from Brazil had much higher nicotine content. Hearn et al. (2013) reported nicotine content ranging from 35.0 to 42.7 mg/g in 4 types of *iqmik* products. Similarly, Stanfill et al. (2015) reported total nicotine content ranging from 6.72 to 50.9 mg/g in 10 samples of manufactured *rapé*, while custom-made *rapé* had lower nicotine content ranging from 15.4 to 18.5 mg/g.

Swedish snus had a total nicotine content ranging from 6.81 to 20.6 mg/g wet weight in 56 samples (Lawler et al., 2020). Low-TSNA Swedish snus had a nicotine content ranging from 16.22 to 31.67 mg/g in 3 samples (Song et al., 2016). On the other hand, *nisvai* from Kyrgyzstan had a total nicotine content ranging from 6.21 mg/g for pre-packaged products and 55.2 mg/g for bulk *nisvai* (Stepanov et al., 2017).

Afzal from Oman had a high nicotine content of 48.77 mg/g, while blended tobacco from Iran had a much lower nicotine content of 6.2 mg/g. The most analysed tobacco products were from the Southeast Asian region. These included *gul, zarda,* and *sada patta* from Bangladesh, as well as pan masala with tobacco, plain tobacco, *gutkha*, *khaini, mishri, kaddipudi, zarda, tambakhu,* snus, *pandharpuri,* betel quid with tobacco, and *mawa* from India.

Among these products, the highest nicotine content was found in *gul* (19-63 mg/g), *zarda* (16-74 mg/g in products from Bangladesh and 20.35 mg/g in products from India) and *pandharpuri* (44.3-53.4 mg/g). On the other hand, the lowest nicotine content was reported in *pan masala* containing tobacco (0.107 mg/g), plain tobacco (2.23 mg/g), *gutkha* (1.85-4.3 mg/g), *mishri* (5-5.1 mg/g), *kaddipudi* (4.9-5.7 mg/g), and betel quid with tobacco (6.7-8.4 mg/g).

Pituri, a product popular among indigenous people in Australia, had a nicotine level of around 4.89 mg/g according to a 2016 analysis.

Free nicotine

The amount of free nicotine was generally less than 20 mg/g, except for mg/g for *iqmik* (38.3 mg/g for air-cured and 38.9mg/g for fire-cured), bulk manufactured *nisvai* (54.63 mg/g), and *afzal* (48.59 mg/g). Moist snuff products sold in South Africa had free nicotine concentrations ranging from 5.39-19.08 mg/g, while those in the USA ranged from 6.34 to 12.92 mg/g. On the other hand, snus had a much lower free nicotine content, ranging from 0.83 to 4.06 mg/g (Stepanov et al., 2014) and 0.49-5.32 mg/g (Song et al., 2016) in products from the USA and 8.20 to 14.74 mg/g in products from Sweden. Dissolvable products from the USA had free nicotine ranging from 0.80 to 3.82 mg/g (Stepanov et al., 2014) and 0.57-1.24 mg/g (Rainey et al., 2013). In Brazil, the free nicotine content in commercially prepared *rapé* products ranged from 0.03 to 0.56 mg/g, while custom-made products had a higher content of 15.98-19.44 mg/g. Pre-packaged and commercially prepared *nisvai* from Kyrgyzstan had free nicotine content of about 5.06 mg/g, while bulk *nisvai* had a much higher nicotine content of 55.2 mg/g.

Products from the Southeast Asian region also showed variation in free nicotine content, ranging from 10-16.6 mg/g for *khaini*, 0.6-0.8 mg/g for *pandharpuri*, 0.18-0.40 mg/g for betel quid with tobacco, and 0.07-0.61 mg/g for *mawa*. Nasrin et al. (2020) analysed the free nicotine content and reported it as a percentage of total nicotine. *Gul* had the highest bioavailability of free nicotine, ranging from 96 to 99% of total nicotine (which was 19-63 mg/g), followed by *zarda* which had 0.38-48% free nicotine (out of 16-74 mg/g total nicotine) and 9.1-14% of free nicotine (out of 9.2-28 mg/g total nicotine) for *sada patta.*

TSNAs

The concentration of TSNAs varied greatly across different products worldwide. In total, 17 studies reported the levels of total TSNAs across 24 products from 10 countries. The highest levels of total TSNAs were found in products from Southeast Asia such as Indian snus, *pandharpuri*, *khaini*, and *gul*, while the lowest levels were found in products from

Europe and the USA such as snus and dissolvable products. These TSNA values are presented in the table and are reported as ug/g wet or dry weight, allowing for comparison with wider studies. Table 4 provides information on the country, product, number of samples, and the reported levels of TSNAs, including NNK, NNN, NAB, NAT, NNAL, and total TSNAs. These values illustrate the variation in TSNA content across different types of ST products worldwide.

Table 4: Country, product, number of samples, and the reported levels of TSNAs, including NNK, NNN, NAB, NAT, NNAL, and total TSNAs

COUNTRY	Product	Samples	REPORTED AS	NNK	NNN	NAB	NAT	NNAL	TOTAL TSNA's	REFERENCE
South Africa	Moist Snuff	2[3]	ug/g dwt[3]	0.11-0.51[3]	0.79-2.43[3]	0.03-0.06[3]	0.57-0.93[3]		1.50-2.97[3]	Song et al. (2016)[3]
USA	Moist snuff	18[1] 14[2] 7[3] 6[13]	ug/g dwt[1] ug/g wet wt[2] ug/g dwt[3] ug/g wet wt[13]	0.96-3.04[3] 0.65-1.9[13]	1.03-9.5[1] 1.35-4.25[2] 2.93-5.82[3] 1.9-3.9[13]	0.20-0.49[3] 0.34-0.61[13]	3.06-8.48[3] 1.2-4.2[13]		7.18-16.13[3] 4.9-9.8[13]	Ammann et al. (2016)[1] Stepanov et al. (2013)[2] Song et al. (2016)[3] Nasrin et al. (2020)[13]
	Snus	4[1] 18[4] 180[5] 8[6] 7[3]	ug/g dwt[1] ug/g wet wt [4] (converted from ng/pouch) ug/g dwt[5] ng/g wet wt. Range (Least square mean)[6] ug/g dwt[3] ug/g wet wt[7]	0.13-0.24[4] 0.18-0.73[5] 0.145-0.572[6] 0.20-0.40[3]	0.63-2.19[1] 0.65-0.71[4] 0.68-2.41[5] 0.50-1.60[6] 0.89-1.39[3] 0.72-1.79[7]	0.047-0.048[4] 0.034-0.169[5] 0.018-0.109[6] 0.03-0.08[3]	0.36-0.37[4] 0.50-2.24[5] 0.35-1.82[6] 0.58-0.79[3]	.0094-.046[6]	1.19-1.37[4] 1.48-5.26[5] 1.14-3.72[6] 1.92-2.52[3]	Ammann et al. (2016)[1] Caraway et al. (2013)[4] Stepanov et al. (2014)[5] Lawler et al. (2020)[6] Song et al. (2016)[3] Stepanov et al. (2013)[7]
	Loose leaf	4[1]	ug/g dwt[1]		0.92-3.94[1]					Ammann et al. (2016)[1]
	Plug	2[1]	ug/g dwt[1]		1.69-2.75[1]					Ammann et al. (2016)[1]
	Twist	2[1]	ug/g dwt[1]		1.61-4.6[1]					Ammann et al. (2016)[1]
	Dissolvable products	36[5]	ug/g dwt[5]	0.25-1.13[5]	0.26-2.30[5]	0.018-0.128[5]	0.18-2.30[5]		0.72-5.98[5]	Stepanov et al. (2014)[5]
	Dry snuff	4[1]	ug/g dwt[1]		5.91-12[1]					Ammann et al. (2016)[1]

COUNTRY	Product	Samples	REPORTED AS	NNK	NNN	NAB	NAT	NNAL	TOTAL TSNA's	REFERENCE
	Iqmik		ug/g dwt[8]	.34[8]	2.7[8]	.23[8]	3.9[8]	.034[8]		Hearn et al. (2013)[8]
Brazil	*Rapé*	12[9]	ug/g wetwt[9] (changed from ng/g)	0.012-3.30[9]	0.029-145[9]	0.0229-.742[9]	0.0213-7.290[9]	0.00235-.554[9]	0.088-24.2[9]	Stanfill et al. (2015)[9]
Sweden	Snus	56[6] 3[3]	ug/g dwt[3] ug/g wet wt[6] (changed from ng/g)	0.25-0.46[3] 0.037–0.696[6]	0.77-2.43[3] 0.049– 1.930[6]	0.03-0.1[3] 0.0062–0.157[6]	0.38-1.33[3] 0.080– 2.21[6]	.00314-.0523[6]	1.43-4.31[3] 0.39–4.91[6]	Song et al. (2016)[3] Lawler et al. (2020)[6]
Kyrgyzstan	*Nisvai*	2[10]	ng/g wet wt[10]	.071-.192[10]	.642-1.189[10]			.0017-.0028[10]		Stepanov et al. (2017)[10]
Oman	*Afzal*	3[11]	ug/g[11] (think wet weight)	1.009-1.018[11]	1.177-1.216[11]	0.486-0.624[11]	0.802-0.818[11]		3.513-3.627[11]	Al-Mukhaini et al. (2016)[11]
Iran	Blended tobacco	1	ug/g dwt[12] (unspecified)		6.3[12]					Farhadmollashahi et al. (2014)[12]
Pakistan	*Manipuri*	1[13]	ug/g wet wt[13]	0.14[13]	0.18[13]	ND[13]	0.07[13]		0.38[13]	Nasrin et al. (2020)[13]
	Naswar	1[13]		0.22[13]	0.46[13]	0.51[13]	0.06[13]		1.2[13]	Nasrin et al. (2020)[13]
Bangladesh	*Gul*	4[13]	ug/g wet wt [13]	3.7-9.7[13]	13-25[13]	1.6-5.4[13]	10-19[13]		35-56[13]	Nasrin et al. (2020)[13]
	Zarda	22[13]	ug/g[13]	0.72-34[13]	2.8-59[13]	0.53-13[13]	2.1-45[13]		6.3-114[13]	Nasrin et al. (2020)[13]
	Sada patta	2[13]	ug/g[13]	0.15-0.55[13]	1.1-2.2[13]	0.04-1.2[13]	0.79-1.9[13]		2.1-5.9[13]	Nasrin et al. (2020)[13]
India	*Khaini*	2[15] 3[14]	ug/g dwt[14] ug/g wet wt[15]	3.17-4.51[14] <0.5-1[15]	24.9-37.0[14] 25-35.2[15]	10.0-16.8[14] 4.2-6[15]	7.46-14.2[14] 3.2-4.2[15]	2.7-4.1[15]	48.7-79.5[14] 37.5-48.1[15]	Stepanov et al. (2017)[14] Stanfill et al. (2018)[15]
	Snus	12[17]	ug/g wet wt	1.2-5[17]	13.2-29.4[17]	3.9-12.9[17]	2.8-11.6[17]		23.1-60.8[17]	Stepanov et al. (2015)[17]

COUNTRY	Product	Samples	REPORTED AS	NNK	NNN	NAB	NAT	NNAL	TOTAL TSNA's	REFERENCE
	Pandharpuri	6[14]	ug/g dwt[14]	1.71-4.57[14]	3.66-6.37[14]	1.24-1.55[14]	3.63-5.51[14]	0.160-0.333[14]	10.4-17.2[14]	Stepanov et al. (2017)[14]
	Betel quid with tobacco	3[14]	ug/g dwt[14]	0.01-0.101[14]	0.068-0.767[14]	0.063-0.088[14]	0.048-0.816[14]	0.039-0.32[14]	0.171-2.09[14]	Stepanov et al. (2017)[14]
	Tambakhu	6[14]	ug/g dwt[14]	0.109-3.39[14]	2.61-16.5[14]	.82-6.49[14]	1.20-24.8[14]	0.167-1.48[14]	4.97-52.5[14]	Stepanov et al. (2017)[14]
	Zarda	5[13] 7[15]	ug/g wet wt[15]	0.17-3.6[13] <0.5-0.9[15]	1.8-11[13] 1-2.6[15]	0.2-4.1[13] <0.4[15]	0.15-3.0[13] <0.7-1.5[15]	<0.2[15]	2.3-27[13] 1.6-5.5[15]	Stanfill et al. (2018)[15] Nasrin et al. (2020)[13]
	Gutkha	1[13] 3[15]	ug/g wet wt[15] ug/g wet wt[13]	1.1[13] <0.5[15]	1.7[13] 1.3[15]	1.6[13] <0.4[15]	2.2[13] <0.7[15]	0.4[15]	6.6[13] 2.4[15]	Stanfill et al. (2018)[15] Nasrin et al. (2020)[13]
	Mawa	6[14]	ug/g dwt[14]	0.14-2.97[14]	0.45-6.77[14]	0.076-0.723[14]	0.31-5.25[14]	0.05-0.634[14]	1.14-16.3[14]	Stepanov et al. (2017)[14]
Australia	*Pituri*		ug/g wet wt[16]	6.91[16]	8.37[16]					Moghbel et al. (2016)[16]

Overall, the levels of total TSNA varied from 0.088 ug/g in a sample of custom-made Brazilian *rapé (Rapé Nu-nu)* to 114ug/g in a sample of *zarda* from Bangladesh.

NNK

The highest content of NNK was found in products from Bangladesh and India. Calculations based on wet weight values reported by Nasrin and colleagues in 2020 reveal that NNK content in some samples of *gul* was as high as 9.7ug/g and in zarda as high as 34 ug/g. Similarly, for products from India, the NNK values ranged from 3.17-4.51 for *khaini* (Stepanov et al., 2017), 1.71-4.57 for *pandharpuri* (Stepanov et al., 2017), 1.2-5.0 ug/g in snus (Stepanov et al., 2015). High values were also reported for a sample of moist snuff in the USA (3.04 ug/g) in a study by Nasrin et al., 2020 and *pituri* from Australia (6.91 ug/g wet wt., Moghbel et al 2016). Products with a range under 1ug/g for NNK include moist snuff from South Africa (0.11-0.51, Song et al., 2016), snus from the USA (0.13-0.24 ug/g wet wt., Caraway et al., 2013, 0.18-0.73 ug/g dwt, Stepanov et al., 2014,0.145-0.572 ug/g wet wt., Lawler et al., 2020, 0.20-0.40 ug/g dwt, Song et al., 2016), Alaskan *iqmik* (0.34 ug/g dwt, Hearn et al., 2013), Swedish snus (0.25-0.46 ug/g dwt, Song et al., 2016, 0.037–0.696 ug/g wet wt, Lawler et al., 2020), *nisvai* from Kyrgyzstan (.071-.192 ug/g wet wt., Stepanov et al., 2017), *manipuri* and *naswar* from Pakistan with values ranging from 0.14 ug/g wet wt. and 0.22 ug/g wet wt. (Nasrin et al., 2020), *sada patta* from Bangladesh (0.15-0.55 ug/g, Nasrin et al., 2020) and betel quid with tobacco from India (0.01-0.101 ug/g dwt, Stepanov et al., 2017).

NNN

Similarly, the highest levels of NNN were found in dry snuff, manufactured *rapé*, blended tobacco*, gul, zarda, khaini*, Indian snus*, pandharpuri, tambhaku*, and *pituri*. Apart from 3 of these products (dry snuff, manufactured *rapé* and *pituri*), the rest were from Central or Southeast Asia.

NAT AND NAB

NAT and NAB were reported in approximately 22 products with the highest values reported in *tambakhu*, *khaini*, snus, *pandharpuri*, *mawa* and *gutkha* from India and *gul* and *zarda* from Bangladesh.

NNAL

NNAL was reported in 12 products with the highest values ranging from 2.7-4.1 in *khaini* from India (2.7-4.1 ug/g wet wt.) as reported by Stanfill et al in 2018 and the lowest values ranging from 0.0094-0.0466 ug/g wet wt. in snus from USA and 0.00314-0.05236 ug/g wet wt. in Swedish snus (Lawler et al., 2020). Other products with low values were *nisvai* (0.0017-0.0028 ug/g wet wt.) and Alaskan *iqmik* (0.034 ug/g dwt).

PAH

The PAH levels were reported in 15 products across 9 studies. The lowest levels were found mostly in products from the USA and Brazil such as plug, hard pellet, *iqmik*, and *rapé* and ranged from 1.4 (Air cured *iqmik*) to 898ng/g (Portion Snus). The highest levels were found in traditional ST from Nigeria which ranged from 1.09-225.84 ng/g, soft pellet (13972 ng/g dwt), moist snuff (4151 – 19354 ng/g dwt), dry snuff (573 – 11869 ng/g dwt) and chewing tobacco (309 – 1251 ng/g dwt) (Orisakwe et al., 2015, McAdam et al., 2013). Products with fire-cured tobacco had higher values than products cured using other forms.

Among products with detectable levels of B[a]P (Figure 8), conventional moist snuff from the USA had higher B[a]P levels (32.71-106.73 ng/g) than low TSNA snus (0.55–0.74 ng/g) from the USA; however, snus from Sweden and South Africa had higher value (i.e., B[a]P levels above the detectable limit of 1.6 ng/g) ranging from 1.35 to 3.13 ng/g and 1.7-5.1 ng/g respectively. In a study on 30 samples of dry snuff by Orisakwe et al., 2015, the B[a]P levels ranged from 0.45 to 9.88 ng/g. It also shows the GothiaTEK limit and that majority of the products don’t meet it.

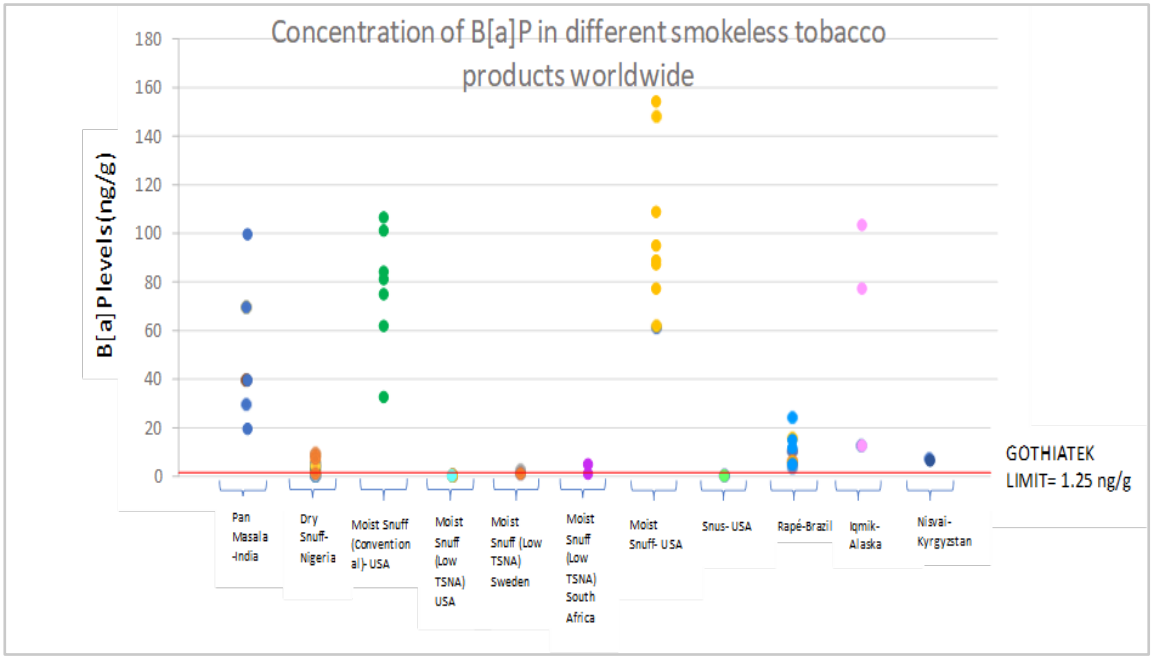


Figure 8:The product concentration of B[a]P in different products. It also shows the current GothiaTEK limit

Alkaloids

Only one study reported on Alkaloid levels in ST products. Jain et al (2017) conducted a study in 6 samples of *pan masala* and 2 samples of *gutkha* and reported on 4 key alkaloids such as guvacine, arecaidin, guvacoline and arecoline. The values of guvacine ranged from 2.1 to 3.5 mg/g dwt for *pan masala* and between 2.48 and 3.19 for *gutkha*; arecaidin ranged from 0.95 to 1.68 mg/g dwt for *pan masala* and 1.1-1.21 for *gutkha*; guvacoline ranged from 0.19 to 0.25 mg/g dwt for *pan masala* and 0.23-0.31 for *gutkha* and arecoline ranged from 0.64 to 1.25 mg/g dwt for *pan masala* and 0.74-1.16 mg/g dwt for *gutkha*. The total alkaloid levels between the two products were quite similar and ranged from 4.48 to 6.51 mg/g dwt for *pan masala* and 4.55-5.86 mg/g dwt for *gutkha*.

Heavy Metals

Heavy metals analysis was reported in a total of 14 studies. Out of the total, 12 studies analysed cadmium (Cd), 11 analysed chromium (Cr) and lead (Pb), 4 analysed cobalt (Co), 8 analysed nickel (Ni) and 6 analysed arsenic (As). Overall, the concentration of heavy metals in ST was in the following descending order: Chromium > Nickel > Lead > Cadmium > Arsenic > Cobalt.

Chromium

The chromium content ranged from 0.043 ug/g in a sample of conventional moist snuff from the USA to 19.09 ug/g in sniffing products from Pakistan. The products with high chromium content included ST from Nigeria with a range of 2.7 to 11.4 ug/g and mean levels of 6.38 ug/g (Orisakwe et al., 2014), *afzal* from Oman with a range of 15.02 to 16.38 and mean levels of 15.75 ug/g (Al-Mukhaini et al., 2014) and various products from Pakistan such as *zarda* (mean 8.24 ±5.10 ug/g) and dipping tobacco (mean 11.40 ±1.92 ug/g). Chromium content in *zarda* from Pakistan was three times higher than that present in *zarda* from Bangladesh which had mean levels of 2.64 ug/g (range 1.23-7.29 ug/g) as reported by Hussain et al (2018) in 15 samples.

Song et al (2016) analysed 7 samples of conventional snuff and 12 samples of low TSNA snuff and found low TSNA snuff (mean value 0.12 ug/g) had twice the concentration of chromium than its conventional counterpart (mean 0.05 ug/g). Another low TSNA product in the US market referred to as Snus also had much higher concentrations, approximately 7 times higher than conventional snuff (Caraway et al., 2013). Two studies analysed the chromium content in *shammah* from Saudi Arabia and found a wide variation. Brima et al (2015) analysed 33 samples of *shammah* including brown, red, white and yellow varieties and reported overall mean levels of 4.25ug/g with no significant difference between any of the varieties. This was much higher than reports from Alhazmi et al (2018) who analysed 21 samples of *shammah* with mean levels of 0.062 ug/g.

Nickel

The highest nickel content was found in products from Pakistan as reported by Arain et al (2015) who analysed 23 brands of moist snuff (brown and green), 11 brands of *gutkha* and 12 brands of *mainpuri*. The nickel contents were found in the range of 10.7–14.1 and 7.56–11.4 ug/g in brown moist snuff and green moist snuff, respectively, while the levels of nickel in *gutkha* and *mainpuri* products were found in the range of 1.01–2.71 and 10.1–17.3 ug/g, respectively. A previous study by Kazi et al (2013) on brown and green moist snuff, reported similar ranges of 9.33-14.8 ug/g for brown moist and 8.03-

10.8 ug/g for green moist snuff. They also analysed dry brown and black snuff and found the range of 9.08-9.81 and 5.99-8.69 ug/g respectively.

Higher values were also reported by Atta et al. (2016) in 8 different ST products from Pakistan which included 12 samples of the dipping product (5.24 ±0.65 ug/g), 12 samples of sniffing product (4.55 ±1.77 ug/g), 9 samples of *mawa* (1.66 ±0.31 ug/g), 30 samples of dry *gutkha* (1.40 ±0.82 ug/g), 12 samples of *zarda* (9.60 ±0.96 ug/g), 9 samples of *pan* (4.37 ±0.00 ug/g) and 30 samples of unspecified tobacco brands (5.72 ±4.41 ug/g). The only product from Pakistan with values below the detection limit was wet *gutkha*.

Comparatively, lower nickel content was found in Nigerian ST (mean level 0.04 ug/g), conventional snuff (mean level 0.13 ug/g), low TSNA snuff (mean level 0.10 ug/g) and snus (mean level 0.60 ug/g). A product with an extremely wide range of observations was *shammah* with nickel content ranging from 0.6 to 267 ug/g (mean level 40.6) in 4 varieties analysed. Similar to chromium levels, there was no difference in nickel content in any of the four variations (Brima et al., 2016).

Lead

The levels of lead in ST products ranged from 0.0 ug/g in Nigerian ST to 15.2 ug/g in brown moist snuff. Low levels were typically reported in products from Western countries such as conventional snuff and snus and higher levels were found in products from India and Pakistan. For example, lead levels in conventional snuff from the USA ranged from 0.009 to 0.091 ug/g and in snus from 0.11 to 0.12 ug/g, whereas similar products from South Asian countries had much higher levels like 9.33-15.2 ug/g in brown moist snuff, 7.46-9.89 ug/g from green moist snuff, 4.72-5.97 ug/g in dry brown and 6.24-8.42 ug/g from Pakistan and 4.33 ug/g in snus (brand Cool lip) from India. Other products with high lead content were *khaini* (mean 3.90 ug/g), *pan masala* (3.56 ug/g), spit tobacco (4.86 ug/g), *zarda* (10.02 ug/g) and betel quid (4.84 ug/g).

Cadmium

The cadmium levels in ST products ranged from 0.0 to 3.53 in *zarda* (Hossain et al., 2018). The lowest concentration was seen in Nigerian ST (Orisakwe et al 2014), conventional snuff (Song et al., 2016), snus (Caraway et al., 2013), and *shammah*

(Alhazmi et al., 2018). The highest cadmium content was found in products from Pakistan such as moist brown snuff and dry brown snuff, *zarda* (Hossain et al., 2018), *afzal* (Al-Mukhaini et al., 2014) and *gul* (Hossain et al., 2018).

Arsenic

The arsenic levels ranged from 0.009 ug/g to 1.46 ug/g. Similar to cadmium, the lowest levels were found in conventional and low TSNA snuff and snus from USA and Sweden and the highest levels were found in brown and green moist snuff from Pakistan. Interestingly again, there was wide variation in *shammah* levels in the two studies (Arain et al., 2015, Brima et al., 2016, Atta et al., 2016)..

Cobalt

The cobalt content ranged from 0.01 to 26.2 ug/g. The lowest levels were seen in Nigerian ST whereas the highest levels were seen in *zarda*, wet *gutkha* and sniffing products from Pakistan and *shammah* from Saudi Arabia.

2.5 DISCUSSION

The present review provides a comprehensive evaluation of the current literature on carcinogens present in ST products. Notably, the review uncovered previously unreported regional disparities in carcinogenic content. The following text summarises the key findings from the systematic review and places them within the broader context of relevant literature.

Summary of main findings

This systematic review analysed 43 studies that reported on 14 chemical constituents in 36 varieties of ST products comprising 1,277 samples. 19 studies reported on the pH of approximately 20 ST products from 8 countries, with the overall pH of the various products ranging from 5.17 to 11. Snus products from Northern Europe and India generally have higher pH levels than those from the USA. The pH values of dissolvable products were found to be slightly alkaline, but there was some variability in the pH levels of different types of products. The variability in pH levels was related to differences in manufacturing processes, types of tobacco used, processing methods, and

regions. The pH levels of commercially manufactured *rapé* varied from 5.17 to 6.42 across 10 samples from different brands, and custom-made *rapé* had some of the highest pH levels ranging from 9.75 to 10.02. Moist snuff from the USA had a pH range of 6.5-8.44, with conventional products having a higher pH range than low-TSNA products. The pH levels of *sada patta* and *zarda* sold in Bangladesh varied from 6.9-7.1 and 5.5-8.0, respectively, and *gul* had the highest pH value (9.3-9.8) among all the products. Plain tobacco sold in India had a pH of 5.24, and *banarsi paan*, a form of betel quid, had a pH of 7.77-8.32. Based on the comparison between the current findings and the 2014 NCI report, it appears that the range of pH values for ST products has not changed significantly over the years. The 2014 report also noted a wide range of pH values for various ST products, with the lowest pH values found in chewing tobacco and some forms of dry snuff, *zarda*, and snus, and the highest pH values found in products such as *iqmik* and *nass*. The current findings also reported similar pH values for different types of ST products.

The systematic review examined the nicotine content of various tobacco products, which were reported in terms of total nicotine or free nicotine or both. The values were reported in different units, such as mg/g dry weight or wet weight, ng/pouch, and as a percentage. Most ST products had a total nicotine content of 30 mg/g or less, but some products such as *rapé*, *zarda*, *gul*, *afzal*, and *nisvai* had nicotine concentrations as high as 74 mg/g. The lowest nicotine content was seen in products from the USA and Sweden. The highest free nicotine content was found in *iqmik*, bulk-manufactured *nisvai*, and *afzal*, with the amount generally less than 20 mg/g in other products. The study also identified the highest and lowest nicotine content in different tobacco products from various regions, such as Southeast Asia, Bangladesh, India, Oman, and Australia.

The review also found that the concentration of TSNAs varied greatly across different tobacco products worldwide. The highest levels of total TSNAs were found in Southeast Asian products such as Indian snus, *pandharpuri*, *khaini*, and *gul*, while the lowest levels were found in products from Brazil. NNK content was highest in products from Bangladesh and India, with values ranging from 3.17 to 34.0 ug/g. Products with low NNK content included moist snuff from South Africa and snus from the USA and Sweden. The highest levels of NNN were found in Central or Southeast Asian products, and NAT

and NAB were reported in approximately 22 products, with the highest values in products from India and Bangladesh. NNAL was reported in 12 products, with the highest values in *khaini* from India and the lowest values in snus from the USA and Sweden.

The PAH levels were reported in 15 ST products across 9 studies. The lowest levels were found in products from the USA and Brazil, while the highest levels were found in traditional ST from Nigeria. Products with fire-cured tobacco had higher values than those cured using other methods. Conventional moist snuff from the USA had higher B[a]P levels than low TSNA snus from the USA, but snus from Sweden and South Africa had higher levels. The B[a]P levels in dry snuff ranged from 0.45 to 9.88 ng/g. Most of the products did not meet the GothiaTEK limit. Only one study reported on alkaloid levels in ST products, and the total alkaloid levels in *pan masala* and *gutkha* ranged from 4.48 to 6.51 mg/g dwt.

The review looked at the heavy metal content and found that chromium content varied widely among different ST products, with the lowest levels found in a sample of conventional moist snuff from the USA and the highest levels found in sniffing products from Pakistan. ST from Nigeria and *afzal* from Oman also had high chromium levels. Low TSNA snuff and snus from the USA had twice and seven times higher chromium concentrations than conventional snuff, respectively. *Shammah* from Saudi Arabia also had a wide variation in chromium content. In terms of nickel, the highest levels were found in ST products from Pakistan, including brown and green moist snuff, *gutkha*, and *mainpuri*. Nigerian ST, conventional snuff, low TSNA snuff, and snus had relatively lower levels of nickel. *Shammah* had a wide range of nickel content, with no significant difference between any of the four varieties analysed. Lead levels varied widely among different ST products, with the lowest levels found in Nigerian ST and the highest levels found in brown moist snuff from South Asian countries. Conventional snuff and snus from the USA had low lead levels, while products from India and Pakistan had higher levels.

There was also observed variation in the quality of studies, with Europe and the USA having higher quality studies than South Asia and the Middle East thus highlighting the

difference in adherence to established criteria and standardised protocol in these regions. Overall, this research showcases the high carcinogenic content of ST products used in South Asia. These findings can be attributed to several reasons such as variations in:

a) Tobacco leaf type: ST products in South Asia are made from *N. rustica* leaves, which contain higher levels of nicotine and other alkaloids compared to *N. tabacum* which is used for products in Europe and USA (IARC, 2007)
b) Tobacco storage: Due to a lack of regulation and quality control, ST products in South Asia are often stored improperly, which can have an impact on the levels of carcinogenic compounds present in the final product. When tobacco is stored improperly, it can be exposed to high temperatures, humidity, and other factors that promote chemical reactions, leading to increased levels of carcinogens like nitrosamines (Gray et al., 2010).
c) Tobacco curing methods: While products in Europe, such as Swedish snus, are made from pasteurized and air-cured tobacco, those in South Asia use a combination of curing methods including sun-cured and fire-cured and are often fermented. This results in a rise in bacteria, which can further convert nitrate to nitrite, leading to an increase in the final carcinogenic levels of products sold in these regions (Giacomo et al., 2007)
d) Manufacturing methods: The manufacturing methods of ST products in South Asia differ significantly from those in Europe and the USA, where regulations such as GothiaTek are followed. In South Asia, ST products are less regulated and less compliant, and manufacturing standards are often inadequate leading to higher carcinogen levels (Siddiqi et al., 2015).
e) Preparation: ST products in South Asia are also prepared in small cottage industries, where the production process can vary significantly from one producer to another. These cottage industries rely on traditional methods and local knowledge for preparing ST products and quality control measures are not adhered to (Hecht and Hatsukami, 2022). Many products are also hand prepared at the point of sale. These variations can result in differences in the amount and distribution of carcinogens present within the ST products.

f) Other ingredients: ST products used in South Asia often contain a range of ingredients, including areca nut, slaked lime, and spices, which are not commonly used in other parts of the world. These ingredients may react with tobacco and other compounds in the product to create new, potentially harmful compounds (World Health Organization, 2012; Gupta and Johnson, 2014; Mehrtash et al., 2017).

g) Consumption patterns: ST products in South Asia are typically chewed, sucked, or applied to the gums, resulting in prolonged contact with the oral cavity. Furthermore, they have higher pH levels and contain more additives, including carcinogens like areca nut, compared to those from other regions. The prolonged contact of ST products with the oral cavity, coupled with their high pH levels, can facilitate the entry of carcinogenic substances into the bloodstream, hence increasing their carcinogenic potential (Gupta et al., 2017; Mehrotra et al., 2020).

Strengths of the study

The systematic review presents several strengths that enhance its impact and credibility. Firstly, it followed a rigorous and transparent methodology in selecting relevant studies for inclusion. The comprehensive search strategy employed in this study, which included searching multiple databases and hand-searching reference lists, ensured that a wide range of studies was identified and considered. Additionally, the selection criteria were clearly defined and applied consistently, ensuring that only the studies that met the criteria were included in the review.

Secondly, the study included a wide range of ST products from across the globe, including products that are not typically used in Western countries. This approach provides a comprehensive picture of the carcinogenic potential of ST products, which is crucial for informing global health policy and interventions.

Thirdly, the review was further strengthened by incorporating the latest evidence from the researcher's project on Addiction ontology. The project utilised the most up-to-date definitions and search terms for ST products, which added to the accuracy and relevance of the review's findings. Through the ontological work conducted, over 70 ST products were identified and defined, resulting in the most exhaustive resource on ST

terminology to date. The integration of this information in the review ensured that no tobacco product was missed, thereby enhancing the comprehensiveness and rigour of the study.

Fourthly, the systematic review used a rigorous process of quality assessment by adapting the Joanna Briggs Institute critical appraisal tool for analytical cross-sectional studies to include criteria specific to the research question and inclusion criteria. This tailored tool ensured that all studies were evaluated using the same set of criteria, reducing variation, and increasing the relevance and accuracy of the quality assessment. The adapted tool also facilitated the comparison of studies and provided a robust and reliable method for assessing the quality, addressing the risk of bias in the studies.

Lastly, the systematic review is timely and relevant, given the global increase in ST product use, particularly among young people. It examined the most recent evidence regarding the carcinogenic potential of ST products and provided an overview of any changes in the levels of these products since previously published findings from the NCI and IARC reports. This approach significantly strengthened the review by ensuring that the latest evidence and trends were incorporated, thereby enhancing the relevance and significance of the findings.

Limitations of the study

One of the methodological limitations of the systematic review was the inability to perform a meta-analysis due to the heterogeneity of the included studies. The studies varied greatly in terms of study design, and outcome measures, making it difficult to compare and combine the results. As a result, only a narrative synthesis of the findings was provided, which may not be as precise or conclusive as a meta-analysis.

Another limitation was the incomplete reporting of data. Some studies did not report data in a consistent manner or in a way that allowed for easy extraction and comparison of results. This made it difficult to draw definitive conclusions. While every effort was made to include as much data as possible and convert the units of measurements where sufficient data and conversion formulas were present, this was not possible for all the data.

Some studies were conducted in high income countries but used products from other countries. This made it difficult to determine the original manufacturing location of the product, which can impact its composition and potential health effects. This limitation may have introduced some bias or uncertainty in the results of the review. A critical appraisal checklist for systematic reviews (Adapted CASP tool) was used by ZK to further appraise the review.

Despite these limitations, every effort was made to carefully assess the quality and consistency of the evidence and provide a comprehensive overview of the available data.

2.6 CONCLUSION

In conclusion, this systematic review provides a comprehensive analysis of the chemical composition of ST products and their potential carcinogenicity. The review identified a wide range of harmful chemicals present in ST products, including TSNAs, PAH, and heavy metals such as cadmium and lead. These chemicals have been linked to various forms of cancer, especially oral cancer.

CHAPTER 3: STUDY 2 - IDENTIFICATION AND SELECTION OF A VALIDATED FRAMEWORK FOR GUIDELINE ADAPTATION

3.1 CHAPTER OVERVIEW

The previous chapter has identified high levels of carcinogens in several ST products currently used in South Asia, posing a significant risk to oral cancer in the vast majority of individuals who consume these products. In response to this pressing issue, the second study within the thesis explores practical solutions for the early detection and management of the affected populations. These include the development of contextually and culturally adapted OPMD and oral cancer screening guidelines and training toolkit. This study comprises three chapters, of which this is the first. In this chapter (Chapter 3), a framework for adapting the OPMD and oral cancer screening guidelines is assessed and selected. Chapter 4 details the adaptation of the guidelines utilising the selected framework, and in Chapter 5, a training toolkit is developed using the adapted guidelines. The current chapter starts with Section 3.2 which gives a brief description of the need for adaptation of oral cancer guidelines and the existing types of adaptations for health-related guidelines and best practice statements. Following this, Section 3.3 delves into the methods section which identifies and maps out existing frameworks for guideline adaptation. Based on pre-selected criteria such as guidance on the adaptation process, and time and resource requirements, these frameworks are appraised, and the results are presented in Section 3.4. Section 3.5 discusses the findings and their implications for LMICs, while the chapter concludes with Section 3.6.

3.2 ADAPTATION OF ORAL CANCER SCREENING GUIDELINES: A TRANS-CONTEXTUAL APPROACH

As highlighted in Chapter 1, oral cancer is a significant cause of cancer mortality in South Asia. Detection and management at the stage of OPMDs is a solution however, there are no national screening programs in South Asia. The existing guidelines have been developed in high-income countries and are targeted at dentists and their use poses challenges to acceptability and applicability in low-income community-based settings, thus highlighting a need for guideline adaptation. Therefore, the subsequent sections delve deeper into the different approaches to adapting guidelines.

Providing high-quality healthcare involves using the best available evidence, and evidence-based guidelines are important tools that translate synthesised evidence into practical recommendations for clinical practice (Amer et al., 2015). The World Health Organisation (WHO) defines guidelines as "systematically developed evidence-based statements which assist providers, recipients and other stakeholders to make informed decisions about appropriate health intervention" (Darzi and Evans, 2016). While guideline development considers the best evidence, it is a high-time, resource, and expertise-intensive process. (Fervers, Burgers et al., 2011). The alternatives to *de novo* or new development are guideline adoption and adaptation.

Guideline adoption involves choosing the best guideline and accepting all of its recommendations whereas adaptation involves choosing the most appropriate recommendations from the original guideline and "repackaging" them into a new local guideline (Graham and Harrison, 2005). Guideline adaptation is defined as the "systematic approach to considering the use and/or modification of guidelines produced in one cultural and organisational setting for application in a different context" (Harrison and Van Den Hoek, 2012).

Tailoring high-quality guidelines for local use reduces the duplication of effort and improves their relevance. This involves incorporating local evidence, such as specific health concerns, local needs, priorities, legislation, policies, available resources, and the scope of practice within the local healthcare services. The incorporation of local

evidence is expected to enhance the adoption of guidelines (Brouwers, Kho et al., 2010, Fervers, Burgers et al., 2011, Harrison, Légaré et al., 2010, Wang, Norris et al., 2015).

There are different forms of guideline adaptation depending on the context. These forms can be broadly classified as informal or formal depending on their methodology (Wang, Norris et al., 2018).

Informal guideline adaptation: This form of adaptation is usually done at an individual provider or patient level. It does not follow a framework for adaptation. This form of adaptation usually involves the identification and selection of an international guideline followed by its quality assessment using a tool and then translation into the local language (Wang et al., 2018). There is evidence in the literature for use of this process of adaptation. For example, some hospital settings in Lebanon and Sudan have used this process to adapt health-related guidelines for their doctors (Elsadig, Weiss et al., 2018, Maroun, Aouad et al., 2010). While informal adaptation may be practical in certain situations, it poses a risk to the validity and integrity of the original guideline with evidence-based recommendations, especially if the implemented interventions are outside the scope of the original recommendations. To avoid this, an active, systematic, and participatory process is recommended to adapt existing guidelines.

Formal guideline adaptation: This form of systematic guideline adaptation incorporates the use of an established framework developed by a guideline adaptation group. This process ensures the methodological rigour and quality of the adapted guidelines (Fervers, Burgers et al., 2006). The formal process of adaptation can be used to perform both cross-cultural as well as trans-contextual adaptation.

3.2.1 TRANSCONTEXTUAL ADAPTATION

The complexity of healthcare systems, available resources, and cultural nuances in LMICs necessitates an approach that considers both cross-cultural and broader contextual factors. In the case of oral cancer screening, it is essential to acknowledge that creating effective, relevant, and feasible guidelines involves accounting for a multitude of factors that extend beyond culture alone.

Trans-contextual adaptation is a comprehensive process that goes beyond mere translation or cross-cultural adaptation. It assimilates existing evidence or guidelines while also considering the contextual differences in the study site, setting, target population, and other relevant factors, including cultural nuances. This broader perspective ensures that the adapted guidelines are not only culturally appropriate but also tailored to the specific healthcare environment and resources available in the LMICs where the screening program will be implemented. Given the significance of these contextual and cultural factors in the adaptation of oral cancer screening guidelines, the trans-contextual approach is particularly well-suited for this study.

Therefore, the present chapter aims to identify and select a validated framework for the trans-contextual adaptation of OVE guidelines. The specific objectives of the chapter are:

- To identify existing frameworks for guideline adaptation
- To appraise the frameworks against pre-defined criteria
- To select a framework for OVE guideline adaptation for CHWs in low-resource settings.

3.3 METHODS

The following section will describe the method of identifying and selecting a published framework for the trans-contextual adaptation of OVE guidelines. The sequential steps in this process are depicted in the form of a flowchart in Figure 9.

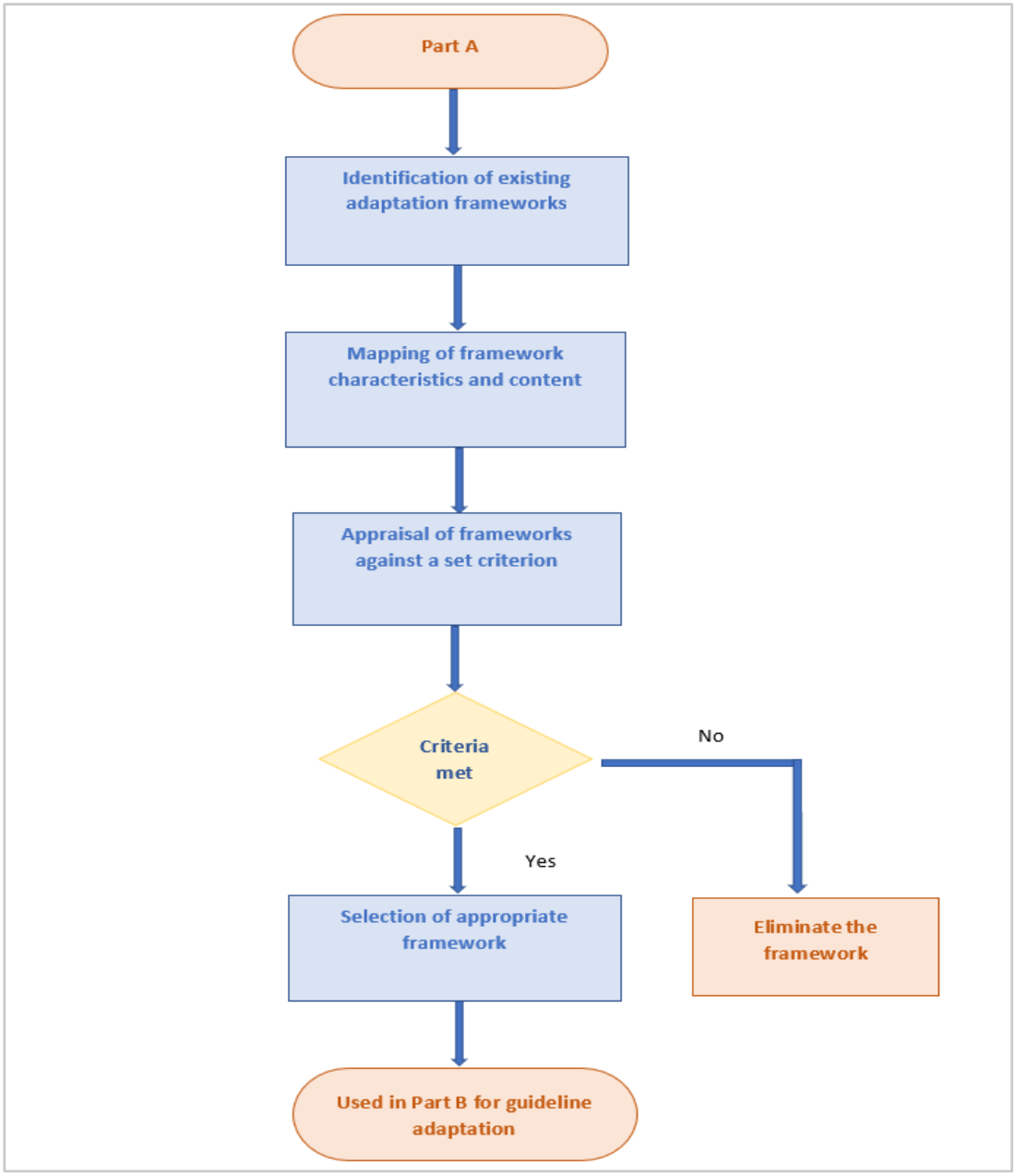


Figure 9:Summary of steps for framework selection

3.3.1 IDENTIFICATION OF EXISTING FRAMEWORKS

A scoping literature search was performed to identify studies on guideline adaptation frameworks. The following section provides details on the databases searched, search terms used and the eligibility criteria:

Database searched: Searches were performed in July 2019 in the following databases- Medline (Ovid), Embase and CINAHL, Google Scholar. The search strategy was developed on Medline (Ovid).

Search terms: The following keywords were used to perform the searches- method, guidance, framework, guideline, practice statement, adaptation, adoption, trans-contextual, contextual, national, regional, society, institute, board, ministry, and department. Relevant wildcards, truncations, proximity operators, Boolean operators AND/OR were used to narrow down the search. Restrictions were placed on language (English only) and population (Humans NOT animals). The time frame was selected from 2002 onwards based on a previous study which claimed that guideline adaptation was a fairly new area and not much work had been done prior to 2002 (Wang et al., 2018).

Inclusion criteria: The inclusion criterion was studies that had described frameworks for guideline adaptation.

Exclusion criteria: Studies that had described methods for de novo development of guidelines were excluded.

3.3.2 MAPPING DOWN THE EXISTING FRAMEWORKS

The identified frameworks were mapped onto a table for their characteristics and content using a template from an earlier study by Wang et al (2018). The framework characteristics included Year, Author/ Developer, Publisher, and Country. Guideline content included the recommended committee structure, description of the adaptation process, process for selecting the recommendations, provision for external peer review and timeframe to complete the adaptation work.

3.3.3 APPRAISAL OF FRAMEWORKS

Appraisal of the frameworks was done using a checklist designed for this study to rate the completeness of reporting on key aspects highlighted in previous studies (Darzi et al., 2017; Abou-Jaoude et al., 2017; Wang et al., 2018). This was done to determine the strengths and weaknesses of each framework, especially in the context of the current study, and inform better judgement for its selection. Table 5 provides further details on the appraisal criteria, the considerations as well as justification for using the criteria in this work.

Table 5: Appraisal criteria for adaptation frameworks

APPRAISAL CRITERIA	CONSIDERATIONS	COMMENTS/JUSTIFICATION
1. Development Process	-Is the process of framework development explained?	This ensures the robustness of the findings
2. Committee Structure	-Are committees involved to carry out the adaptation exercise? -If yes, how many are recommended?	Having a well-defined governance structure helps streamline the adaptation process.
3. Method and Process summary	-Is the framework focussed on adaptation, adoption, implementation, or de novo development? -Is the adaptation process explained in detail? -Is sufficient guidance available within the framework to carry out the adaptation exercise?	As a researcher using this methodology for the first time, frameworks which explain the adaptation process in detail and provide necessary guidance and tools must be considered.
3. External Peer Review during the development process	Are external stakeholders/ target audiences involved in this exercise?	Having members from external stakeholders or target audience improves the uptake of the recommendations.
4. Timeframe for adaptation work	Do the frameworks mention the financial resources and the time needed to follow the adaptation process?	The current study is part of a PhD project; thus, it is important to know the time and resource requirements before starting with the adaptation work.

3.3.4 SELECTION OF APPROPRIATE FRAMEWORK

The frameworks that met the above criteria were eligible for a detailed review to select the one most suitable for a) adapting the existing Oral Visual Examination guidelines and b) which can be tailored to best fit the resources requirements for this study. The suitability was determined by operationalising three criteria. Firstly, the framework had to focus on adaptation and not de novo development. Secondly, it had to offer sufficient guidance to effectively carry out the adaptation exercise. Thirdly, it had to be flexible and resource efficient.

3.4 FINDINGS

The following section presents the findings on the identification, appraisal, and selection of a framework suitable for the adaptation of OVE guidelines in low-resource settings for use by CHWs.

3.4.1 FRAMEWORKS FOR TRANS-CONTEXTUAL ADAPTATION:

The literature search identified 10 frameworks for guideline adaptation. These are listed below:

1. Royal College of Nursing (RCN) (Rycroft-Malone and Duff, 2000)
2. Practice Guidelines Evaluation and Adaptation Cycle (Graham and Harrison, 2005)
3. Systematic Guideline Review Method (Muth et al., 2009)
4. ADAPTE (Attia et al., 2013; Fervers et al., 2006)
5. The Alberta Ambassador Program (AAP) Adaptation Process (Harstall et al., 2011)
6. CAN-IMPLEMENT (Harrison et al., 2012)
7. Making GRADE the Irresistible Choice (MAGIC) (Kristiansen et al., 2014)
8. Adapted ADAPTE (Amer et al., 2015)
9. RAPADAPTE (Alper et al., 2016)
10. GRADE–ADOLOPMENT (Schünemann et al., 2017)

3.4.2 CHARACTERISTICS AND CONTENT OF THE FRAMEWORKS

The characteristics and content of the identified frameworks have been described in Table 6. The table shows that the majority of the frameworks had been developed with multi-disciplinary committees and stakeholder groups. All of them had listed out the steps for the adaptation process apart from two frameworks (CAN-IMPLEMENT and Adapted ADAPTE) which were modifications of an existing framework (ADAPTE). All the frameworks required some kind of consensus-building as part of the adaptation process. Six out of 10 frameworks mentioned the time duration required to carry out the adaptation work which ranged from 6 months to 3 years. The development timeline of each of these frameworks is presented in Appendix 7.

Table 6: Characteristics and content of trans-contextual frameworks (Adapted from Wang et al., 2018; Rycroft-Malone & Duff, 2000; Darzi et al.,2016)

FRAMEWORK (YEAR PUBLISHED)	DEVELOPER	COMMITTEE STRUCTURE	ADAPTATION PROCESS	CONSTRUCTION OF RECOMMENDATIONS	EXTERNAL PEER REVIEW	DURATION OF ADAPTATION PROCESS
Royal College of Nursing (2000)	The Royal College of Nursing (RCN)	Described for guideline development but not adaptation.	It comprises of 5 key steps (Rycroft-Malone & Duff, 2000) - 1. Identifying a priority topic. 2. Locating a guideline on the chosen topic. 3. Appraising the quality of the guideline. 4. Appraising the applicability of the clinical guideline. 5. Adapting it for local use.	By consensus process.	No information available	No information available
Practice Guidelines Evaluation and Adaptation Cycle (2005)	This framework was initially developed to adopt best practices in organisations. However, the authors suggest that most of the steps in this can be used to appraise, adopt and adapt guidelines.	Key stakeholders from a single local interdisciplinary guideline evaluation group	It consists of 10 steps which are listed down below- 1. Identify a clinical area to promote best practice. 2. Establish an interdisciplinary guideline evaluation group. 3. Establish a guideline appraisal process. 4. Search for and retrieve guidelines using the PICO approach. 5. Assess the quality (using AGREE tool), currency and content (using the recommendation matrix) 6. Adopt or adapt guidelines for local use. 7. Seek external review from practitioners and policy makers. 8. Finalise local guidelines.	Consensus (guideline evaluation group)	Local practitioners, other stakeholders, and organisational policymakers were invited to provide feedback through a review and comment process.	No information available

			9. Obtain official endorsement and adaptation of local guidelines. 10. Schedule review and revision of local guidelines.			
Systematic Guideline Review Method (2009)	Systematic Guideline Review Method group	Most steps conducted by the 5 authors	The adaptation process consists of 6 steps described as follows: 1. Systematic guideline search 2. Guideline selection 3. Quality appraisal of the guideline using the AGREE instrument. 4. Framework and data extraction 5. Consistency analysis by a reviewer 6. Validation 7. Formulation of draft guidelines and identification of evidence for further research	Consensus by the authors	A formal consensus process involving multiple professionals and disciplines, including a patient representative and a pilot testing phase, was used.	8.5 man-months
ADAPTE (2011)	The ADAPTE group and the Practice Guideline Evaluation and Adaptation Cycle (PGEAC) group	Two committees: the organising committee and a panel of content experts.	This process consists of six key steps for the adaptation of guidelines. 1. Definition of the clinical questions using the PIPOH tool 2. Definition of the clinical questions 3. Assessment of clinical content in the source guidelines 4. Assessment of the quality and coherence of the source guidelines using the AGREE instrument. 5. Adaptation of the recommendations	Consensus by the panel	The process involved consultation with relevant endorsement bodies, developers of source guidelines, and targeted users.	12-18 months

			6. External review of the adapted guideline 7. Adoption, endorsement, and implementation of the adapted guideline			
The Alberta Ambassador Program (AAP) Adaptation Process (2011)	The Alberta Ambassador Program was developed through a collaborative process, involving multiple committees and partnerships.	Potentially six different committees involved in the process of adapting clinical guidelines	The steps in the adaptation process are- 1. Identify and recruit the Guideline Development Group participants. 2. Formulate research questions according to local needs. 3. Identify and screen seed guidelines using AGREE instrument. 4. Extract data into evidence inventory table 5. Draft the guideline document. 6. Review and refine the draft guideline. 7. Finalise and endorse the guideline. 8. Disseminate guidelines. 9. Plan update	Consensus by the guideline development group	The adaptation process involved clinical experts, methodologists, and potential guideline users who did not participate in its development.	No information
CAN-IMPLEMENT (2013)	The CAN-IMPLEMENT Guideline Adaptation and Implementation Planning Resource were proposed following the Canadian Guideline Adaptation Study. It is based on the ADAPTE method.	2 or more committees including a steering committee and working panel(s)	This method maintains the original foundational rigour and elements of ADAPTE with additional reorganisation and expansion to include a three-phase approach addressing the knowledge application cycle. It focuses on adapted guideline implementation and targets novices and less experienced groups. The original resource stating the steps could not be accessed however due to subscription charges.	Consensus by the panel	Stakeholder groups who are affected by the recommendations	No information available

Making GRADE the Irresistible Choice (MAGIC) (2014)	Making GRADE the Irresistible Choice (MAGIC) research program.	An editorial committee consisting of method experts and content experts.	The adaptation process consists of 5 key steps: 1. Planning 2. Initial assessment of the recommendations 3. Modification 4. Publication 5. Evaluation	Consensus by the panel	By relevant medical speciality organisations.	12 months.
Adapted ADAPTE (2015)	The Alexandria Center for Evidence-Based Clinical Practice Guidelines (CEBCPG) group at Alexandria University.	Committee structure that includes both an organizing committee and a panel.	This method follows the overall original ADAPTE framework with changes in 6 key steps. Some of the changes and updates are- Use of AGREE II tool, modified search strategy, modified PIPOH tool, and inclusion of a checklist for inclusion/exclusion selection criteria for source guidelines.	Consensus by the panel	Same as ADAPTE	2.5-3 years in the first 3 projects and 1.5-2 years in 8 projects.
RAPADAPTE (2016)	Not reported	Panel of experts	Consists of the following 12 steps: 1. Identifying and selecting the team and allocating the resources. 2. Training the team members in both content knowledge and evidence-based methodology. 3. Defining the clinical questions. 4. Identifying potential guidelines for adaptation. 5. Selecting the most useful guidelines for adaptation. 6. Identifying available summarised evidence for each of the clinical questions. 7. Searching for evidence for clinical questions where it is insufficient or not available. 8. Grading the quality of the evidence.	Consensus development using the RAND/UCLA Appropriateness Method	By local stakeholders	6 months

			9. Drafting the recommendations taking into consideration evidence on benefits and harms, values, preferences, and cost. 10. Providing draft recommendations and supporting evidence to the expert review panel to discuss. 11. Modifying recommendations as needed based on decisions made by an expert panel. 12. Providing the resulting guidelines for external review.			
GRADE–ADOLOPMENT (2017)	GRADE members at McMaster University.	A group of methodologists from McMaster University formed a part of the methodologist group, while the guideline panels were comprised of local expert members with diverse multidisciplinary backgrounds, including representation from patient groups.	The framework consists of 8 main steps: 1. General organisation and planning. 2. Groups and roles. 3. selection of guideline topics. 4. Prioritising questions for selected guidelines. 5. Using the GRADE Evidence to Decision Frameworks. 6. Updating systematic reviews of health effects and identifying local data 7. Preparing GRADE evidence tables and evidence to decision frameworks 8. Formulating and rating the strength of recommendations.	Evidence to Decision (EtD) tables	This framework concludes with the decision to either adopt or adapt the source recommendation/evidence, or to start the development of a new guideline from scratch.	18 months

3.4.3 APPRAISAL OF FRAMEWORKS

The results of the appraisal, which assessed the frameworks based on their development process, committee recommendations, detailed process for adaptation work, and appropriateness for the current study, are presented in Table 7. The findings highlight that out of the 10 frameworks, 5 met all the appraisal criteria and are highlighted below.

Table 7: Appraisal of guideline adaptation frameworks

Framework (year published)	Development process explained	Committee structure explained	Methods and process summary explained with a focus on adaptation	External peer review	Timeframe for adaptation work	The number of criteria met
Royal College of Nursing (2000)	✓	×	✓	×	×	2
Practice guideline evaluation and adaptation cycle (2005)	✓	✓	✓	✓	×	4
Systematic guideline review (2009)	✓	✓	✓	✓	✓	5
ADAPTE (2011)	✓	✓	✓	✓	✓	5
The Alberta Ambassador Program (AAP) adaptation process (2011)	✓	✓	✓	✓	×	4
CAN-IMPLEMENT (2013)	✓	✓	×	✓	×	3

MAGIC (2014)	✓	✓	✓	✓	✓	5
Adapted ADAPTE (2015)	✓	✓	✓	✓	✓	5
RAPADAPTE (2017)	✓	✓	✓	✓	✓	5
GRADE-ADOLOPMENT (2017)	✓	✓	✓	×	✓	4

3.4.4 SELECTION OF THE APPROPRIATE FRAMEWORK

The following highest scoring frameworks were selected for detailed review based on the results of the appraisal in the previous section:

1. Systematic guideline review method.
2. ADAPTE
3. MAGIC
4. Adapted ADAPTE
5. RAPADAPTE

These frameworks were evaluated in-depth based on the criteria specified in section 3.3.2 to highlight their respective advantages and limitations. The assessment outcomes are presented below.

Systematic guideline review (2009)

This framework takes into consideration the methodological shortcomings and content-specific issues of the original guidelines. The advantage of using this method is that it aims to include guidelines from different health settings with both mainstream recommendations as well as the not-so-common recommendations which form the grey zones of clinical practice (Muth et al., 2009). While being similar to the ADAPTE process (mentioned in the next section), it additionally includes the construction of a guideline framework, consistency analysis and validation. The disadvantage of using this framework is that it is quite resource intensive.

ADAPTE (2011)

ADAPTE was found to be a widely used framework for guideline adaptation, particularly in healthcare settings. It has been used in the development of many guidelines, such as the end-of-life care in patients with cancer (Irajpour et al., 2022), treatment of patients with late-stage colorectal cancer (Chiorean et al., 2020), treatment of patients with early-stage colorectal cancer (Costas-Chavarri et al., 2019), assessment and management of cancer pain (Lovell et al., 2015), non-pharmacological care for cancer therapy-induced mucositis (Salarvand et al., 2020), management of urinary incontinence (Hoedl et al., 2018), and non-pharmacological interventions in dementia (Mack et al., 2019). Most of the frameworks that developed after this, were built on its methodology. The advantages of using ADAPTE are that it's a widely validated tool and comes with detailed guidance notes and a resource toolkit. It has already been used in various cancer-related guidelines in a multitude of settings. While it is a 24-step process, it gives the user the flexibility to pick out essential components from the framework and tailor them for their project (Fervers et al., 2006). One of the limitations associated with the use of ADAPTE is that the complete process, which involves carrying out all 24 steps, can be a time-consuming and resource-intensive endeavour.

MAGIC

MAGIC, which stands for "Making GRADE the Irresistible Choice," is a framework that builds upon the ADAPTE process and is specifically designed for the adaptation of guidelines using the GRADE methodology. This five-step process aims to provide a structured and transparent approach to guideline adaptation, and it involves identifying the source guidelines, evaluating the quality of the evidence, developing recommendations, and planning for implementation and dissemination (Abdul-Khalek et al., 2017).

One advantage of using the MAGIC framework is that it provides a standardised and rigorous approach to guideline adaptation, ensuring that the final product is based on high-quality evidence and is applicable to the target population. However, a potential disadvantage of using this framework is that it may limit the scope of guidelines that can

be adapted, as it requires that the source guidelines have been developed using the GRADE methodology. This could potentially exclude guidelines that have not undergone this process, even if they are still considered to be high-quality and relevant to the target population (Wang et al., 2018).

Adapted ADAPTE

This was proposed following an evaluation of the original ADAPTE framework. The rationale behind developing this framework was to improve the utilisation of the existing ADAPTE framework and provide a more clear, more simple and more practical approach to guideline adaptation that has been further "adapted" for local settings. The framework proposed changes to ADAPTE that included using three modified and three new tools for adaptation, as well as providing alternative steps for four ADAPTE processes to enhance their utilisation (Amer et al., 2015). The advantage of using this framework is that it is a simplified version with fewer steps that are designed to be used in healthcare settings with low resources. However, the disadvantage is that it's quite a time-consuming process and can take up to 3 years for guideline adaptation.

RAPADAPTE

This is another modification of the ADAPTE framework. While the ADAPTE framework involves the adaptation of existing guidelines, the RAPADAPTE framework is an accelerated process of guideline development. The advantage of using the framework is that it is a less time-consuming process compared to other frameworks and can be utilised in limited-resource settings. The disadvantage of this framework is that it has been retrospectively derived from a study conducted for the Costa Rican National Health Care provider (Caja Costariccense de Seguro Social [CCSS]) for the development of breast cancer treatment guidelines (Alper, Tristan et al., 2016). The tool has not been validated in any study yet.

3.5 DISCUSSION

This chapter aimed to identify and describe published frameworks for the adaptation of health-related guidelines. In this regard, a scoping search was conducted to identify

these frameworks. The search identified 10 frameworks for the adaptation of clinical, public health and health services guidelines. Based on a pre-defined set of criteria that included flexibility, adaptability, and efficiency in terms of time and resource consumption, the ADPATE framework was selected as the preferred framework for the study. The framework was published in 2011 and while many frameworks have been developed post-2011, most of them have either been built on or are a modification of the original ADAPTE work. The framework has since then been used in many studies across different geographical regions and is a valid tool for guideline adaptation (further details provided in Section 4.2 of Chapter 4).

With regards to the similarities and differences between the different frameworks, it was observed that the majority of the frameworks shared similar steps in their set-up and finalisation phases. In the set-up phase, these frameworks typically involved identifying the health question and guideline topic, as well as identifying resources and establishing organisational committees to oversee the adaptation process. The finalisation phase, on the other hand, commonly entailed a review by a multidisciplinary team of experts, stakeholder groups, and the intended audience. However, the area in which these frameworks diverged was the adaptation phase, which varied significantly in terms of the specific processes and methods employed. It was found that among all the frameworks identified, ADAPTE had the most comprehensive adaptation phase, which comprised a 12-step process that evaluated guidelines based on various factors, such as their quality, currency, content, consistency, acceptability, and applicability of recommendations. Although the specific steps varied across frameworks, quality appraisal appeared to be a crucial aspect of the adaptation process in most of the studies reviewed. Notably, five frameworks, including ADAPTE, recommended the use of the AGREE tool for quality appraisal.

The implication of findings

The process of developing healthcare guidelines is known to be a demanding and resource-intensive undertaking, with significant investment required in terms of time, finances, and human resources. While this process has been successfully carried out in

high-income settings for a variety of healthcare guidelines, it presents a considerable challenge for LMICs with limited budgets for healthcare expenditures. Unfortunately, these countries often bear a disproportionately high disease burden compared to high-income countries, making it even more crucial to establish evidence-based disease management protocols that ensure optimal care for an optimal price. Recent studies have emphasised the importance of building on the work done in high-resource settings and adapting it to local contexts as a cost-effective alternative to de novo development. (Vos et al., 2020; Roser, 2021; Reidpath and Allotey, 2012). Overall, guideline adaptation frameworks provide a structured approach to this process, which can increase transparency, methodological rigour, and the quality of the adapted guideline (Wang et al., 2018).

3.6 CONCLUSION

The current literature review identified a number of such frameworks and presented their advantages and limitations of the selected frameworks and highlighted ADAPTE as a suitable framework. This framework while being quite comprehensive provides the flexibility to modify and adapt it according to the context. It will be discussed in detail in the next chapter and applied to adapt guidelines for OVE.

CHAPTER 4: STUDY 2 - ADAPTATION OF ORAL VISUAL EXAMINATION GUIDELINES

4.1 CHAPTER OVERVIEW

This chapter focuses on adapting OVE guidelines using the ADAPTE framework. Section 4.2 provides an overview of the ADAPTE framework and its application in the adaptation process. Section 4.3 describes the methodology used in the adaptation process. The methods section is divided into three phases corresponding to the three phases of ADAPTE, namely the Set-up phase, the Adaptation phase, and the Finalisation phase. Section 4.4 presents the findings of the adaptation process. Section 4.5 discusses the evidence and the implications of the adapted guideline. The strengths, limitations, and potential for further research are also discussed. Finally, Section 4.6 concludes the chapter with a summary.

4.2 INTRODUCTION

The previous chapter identified the ADAPTE guideline framework as a suitable approach for adapting the existing oral cancer screening guidelines for CHWs in low-resource settings. In this chapter, the ADAPTE framework will be used to carry out the adaptation exercise. The following section provides a description of the ADAPTE framework and its key features to provide a better understanding of its applicability to this project.

The ADAPTE collaboration has defined guideline adaptation as a "systematic approach for considering the endorsement or modification of guidelines produced in one setting for application and implementation in another as an alternative to de novo guideline development or as a first step in the process of implementation while preserving evidence-based principles" (Fervers et al., 2011). The process for adaptation is based on some core principles like- following consistent methods to ensure the robustness of the adapted guideline, participatory approach to enhance ownership, transparent reporting of the recommendations, consideration of local context to enhance uptake etc.

In recent years, the ADAPTE framework has been applied to various clinical areas, such as mental health, cancer, and cardiovascular diseases, among others. In a study conducted in Mexico, the ADAPTE framework was used to adapt high-quality clinical practice guidelines for osteoporosis to a primary healthcare context (Coronado-Zarco and Olascoaga-Gómez de León, 2017). Another example of ADAPTE being used in existing studies is the development of a guideline for the management of acute exacerbations of chronic obstructive pulmonary disease (AECOPD) in Vietnam. The study, conducted by Nguyen et al. (2016), aimed to develop an evidence-based guideline for AECOPD management that is applicable to the Vietnamese context using the ADAPTE process. The authors found that the ADAPTE process provided a systematic and transparent approach to guideline adaptation, and the resulting guideline was well-accepted by healthcare professionals in Vietnam.

In the context of the current study, while guidelines for OVE, which is a simple and non-invasive screening method for oral cancer and other oral diseases exist, there is a need to adapt them for use by CHWs in low-resource South Asian settings. Therefore, the aim

of this study is to adapt existing OVE guidelines using the ADAPTE framework and to evaluate the process and outcomes of the adaptation.

4.3 METHODOLOGY

In this section, I will present the methodology for the adaptation process. The methods section is divided into 3 phases corresponding to the 3 phases of ADAPTE.

4.3.1 SETUP (PHASE I)

The ADAPTE process begins with the set-up phase, which is a preparatory phase that outlines a list of tasks that need to be completed before adaptation can be undertaken. Figure 10 presents a summary of the tasks in this phase, which revolve around the feasibility of undertaking the adaptation, organising a committee, identifying resources, and drafting a protocol for the adaptation work. The figure highlights the steps for this phase, the skills and tools needed, as well as the outcome of the work.

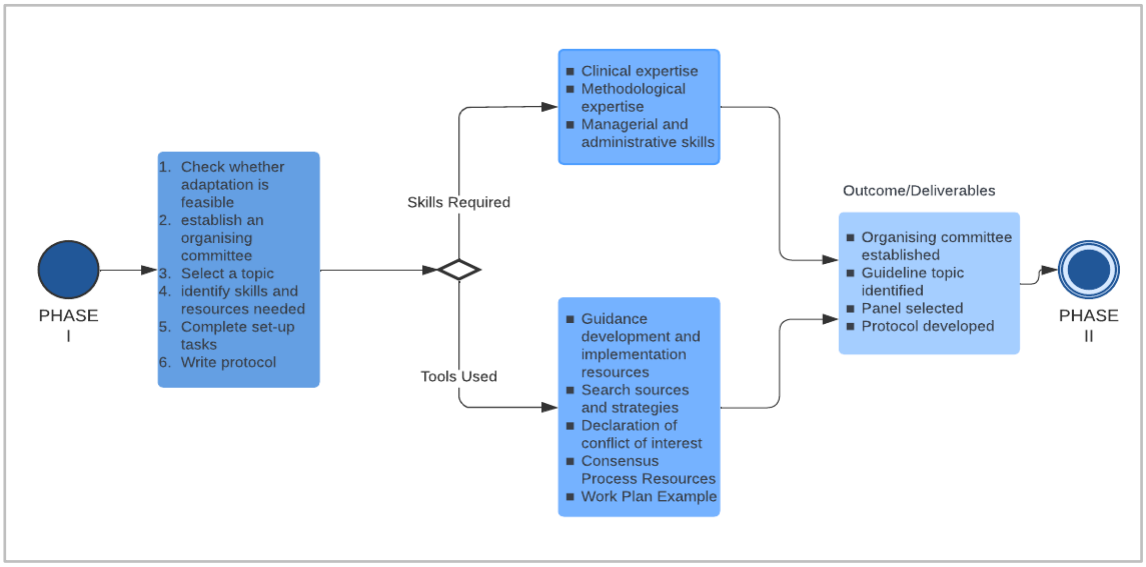


Figure 10:Steps for the set-up phase

The initial step involved the establishment of a well-defined governance structure to oversee the adaptation process. To achieve this, a multidisciplinary panel was constituted, referred to as the Steering Committee for the rest of the process, with the primary objective of facilitating input, acceptance, and applicability of the recommendations. The following section will describe the panel selection process.

Panel selection: The roles of the committee, along with the panel's terms of reference and the adaptation plan, were established prior to panel selection. The potential members of the Steering Committee were identified from the Department of Health Sciences, University of York and invited to participate via email. Table 8 provides a comprehensive description of the Steering Committee's objectives, requirements, identification process, and approach.

Table 8: Setting up of an organising committee.

Setting up of Steering Committee	
Objective	The main objective of setting up the steering committee was to help with the first two phases of the ADAPTE process i.e., the Set-Up phase and the Adaptation Phase
Considerations for potential panel members and key skills required	Relevant background in Dentistry or Medicine. Based in the University of York for logistical reasons.
Identification and approach	Identified through the network in the Department of Health Sciences, the University of York Approached via email

The members were given details about the project and its objectives, their role as committee members, time commitments required of them and possible honorariums as co-authors to cover their time spent appraising guidelines and providing feedback. For the members who consented to participate in this exercise, a work plan on adaptation was shared (attached in Appendix 8). This was followed by the signing of a Declaration of Conflict of Interest (Appendix 9) which was drafted to ensure that the committee was aware of any potential bias/conflict of interest of a panel member involved in the development of one of the original guidelines. To ensure the completion of the adaptation process, relevant resources and skills for the adaptation work were identified and the panel discussed the consensus-building process.

Following the completion of the set-up tasks, an adaptation plan was formalised in the form of a study protocol. The draft protocol outlining the topic area, panel terms of

reference and timeline for completion was shared with the committee. The protocol has been attached in Appendix 10.

4.3.2 ADAPTATION (PHASE II)

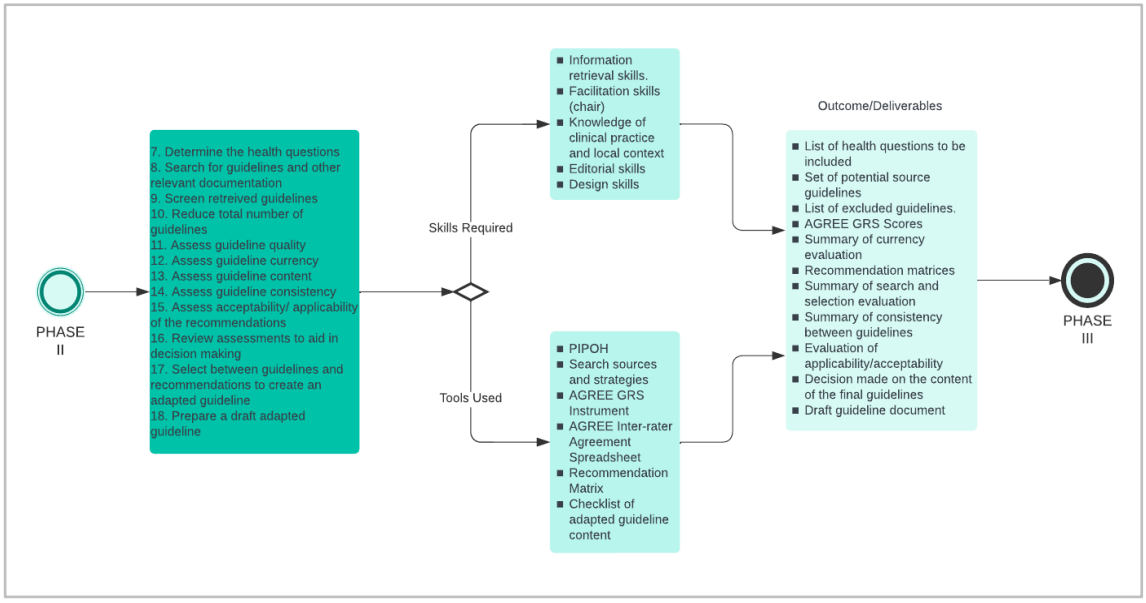


Figure 11: Steps of adaptation process

This phase involved the majority of the work related to adaptation beginning from identifying relevant guidelines to assessing them through different criteria, picking out recommendations and finally preparing a draft guideline. Figure 11 represents the 12 steps of the adaptation process, the skills and tools required as well as the outcomes of this process.

As part of the adaptation phase, a five-item "PIPOH" tool which stands for Population, Intervention, Professionals, Outcome, and Healthcare setting of evidence, was used to identify specific health questions. The purpose of using the tool was to determine the scope of the guidelines and develop a search strategy accordingly. The items of the tool include

Population- Which refers to the patient population as well as the disease characteristics within the population

Intervention- Which refers to the diagnostic test of interest

Professionals- Which refers to the intended audience of the guideline

Outcome- Which refers to the benchmark against which the impact of the guideline can be assessed. It can also refer to the outcome expected from publishing this guideline

Healthcare setting- This refers to the settings and context where the adapted guidelines will be delivered/implemented.

Searching for guidelines and other relevant documentation

To ensure that high-quality guidelines are not missed, a scoping search for all relevant guidelines on the topic of Oral Visual Examination was performed using the following databases and search terms.

Databases searched: Searches were performed on the following databases- PubMed, Embase, Medline, Google Scholar. In addition, search was also done on websites of guideline clearinghouses, speciality organisations, and well-credentialed international and national guideline development groups such as the National Institute for Health and Care Excellence (NICE)(National Institute for Health and Clinical Excellence, 2009), the Scottish Intercollegiate Guidelines Network (SIGN) (Scottish Intercollegiate Guidelines Network, 2008), the World Health Organisation (WHO) (World Health Organization, 2011) and the Australian National Health and Medical Research Council (NHMRC)(NHMRC NHaMRC, 1999). Searches were also conducted on the websites of national dental associations such as the British Dental Association (BDA), and the American Dental Association (ADA), as well as cancer charities such as the Oral Cancer Foundation (OCF) and the Mouth Cancer Foundation to look for existing guidelines on OVE. In addition to these, reference lists of key papers and publication lists of notable authors in the field were scanned for additional literature. These were identified by conducting a search on academic search engines and databases using relevant keywords and author names.

***Search terms* used:** The key search terms were grouped into 3 concepts.

- **Terms related to the disease:** Oral potentially malignant disorders, OPMDs, Oral precancer, precancerous lesion, a precancerous condition, leukoplakia, leukoplakia, erythroplakia, submucous fibrosis, head and neck neoplasm, facial neoplasm, carcinoma, tumour, oral malignancy, squamous cell carcinoma.

- **Terms related to screening**: Oral Visual Examination, oral screening, screening, OVE, Conventional oral examination, oral exam, screening, early detection, mouth mapping, early diagnosis, opportunistic screening.

- **Terms related to guidelines:** Guideline, guidance, method, steps, practice statement, manual.

Inclusion criteria: This comprised of guidelines related to the detection of OPMDs or oral cancer, which were published in the English language.

Exclusion criterion: This comprised of guidelines on oral screening using adjunct techniques such as fluorescence, toluidine blue staining and diagnostic methods. The rationale is that these techniques require additional resources and equipment, which may not be readily available in low-resource settings. By focusing on OVE using minimal instruments, such as a mouth mirror and a good light source, CHWs can effectively screen for oral diseases without the need for expensive equipment or advanced diagnostic techniques. This approach is more practical and feasible in resource-limited settings and can help to improve access to oral health care for underserved populations.

Screening the retrieved guidelines

Based on the number of retrieved guidelines, the committee decided to include up to 10 guidelines in the study for logistical and resource purposes. Committee members also decided that if the total number of guidelines exceeds 10 then they would use the rigour score from the AGREE instrument to select the high-scoring guidelines (Brouwers et al., 2010). In the next step of adaptation, the retrieved guidelines were appraised using a set of 5 criteria: quality, current relevance, content, consistency, and acceptability/applicability. The following section will explore each of these criteria in detail.

Assessing guideline quality

Based on the recommendation of the ADAPTE framework, the AGREE (Appraisal of Guidelines Research & Evaluation) tool which is a standardised tool used for the assessment of the methodological rigour and transparency of clinical practice guidelines was initially considered for the quality appraisal (Brouwers, Kho et al., 2010). The AGREE is a 23-item instrument that was developed to address the issue of variability in guideline quality, provide a methodological strategy for the development of guidelines and inform what information and how the information ought to be reported in guidelines (AGREE, 2003, Alonso-Coello, Irfan et al., 2010, Burgers, Cluzeau et al., 2003, Cluzeau, Burgers et al., Grol and Burgers, 2000). The 23 items are organised into 6 domains which include scope and purpose, stakeholder involvement, the rigour of development, clarity of presentation, applicability, and editorial independence. However, due to time constraints, a shorter version of AGREE called the Global rating Scale (GRS) tool was identified and used. An agreement was sought regarding the use of the AGREE GRS tool (Appendix 11) from the members of the Steering Committee. The following section gives a description of the AGREE GRS tool. The tool consists of four core items that assess:

1. Process of development
2. Presentation style
3. Completeness of reporting
4. Clinical validity

The items were rated on a 7-point scale ranging from a score of 0 which represented the lowest quality to a score of 7 which represented the highest quality. When relevant information was inadequately reported, not provided, or deemed to be irrelevant, a score of 1 was assigned. When reporting did not match all of the criteria or considerations for an item, scores were allocated from 2 to 6, with higher scores given as more criteria and factors were met. When the reporting quality was extraordinary and all criteria and considerations for an item were met in full, the item received a score of 7.

Guideline appraisal training: Since the panel members were unfamiliar with the AGREE GRS instrument, a sample guideline appraisal was done for familiarisation with the process. The members individually scored the sample guideline, following which questions were discussed regarding the scoring criteria and other dimensions of the tool. Discussions were also done to clarify discrepancies such as differing interpretations of the evaluation criteria.

Main appraisal: For the main appraisal, each member received a copy of the AGREE GRS tool, a copy of the selected guidelines and a sample worksheet. Since the developers of the AGREE instrument suggest that four or more appraisers should be involved to ensure adequate inter-rater reliability (Graham and Harrison, 2005), each member of the panel scored all guidelines independently. Once scoring of the four core items was done, an overall assessment of the guideline was done by the Committee members on i) whether they would recommend the guideline for use in their practice and ii) whether they would make use of a guideline in their own professional decisions. The committee members reviewed the guidelines and filled out the worksheet. A sample of the AGREE worksheet and the appraiser sheet are attached in Appendix 12 and 13.

Inter-rater reliability

The inter-rater reliability was measured with IBM SPSS Statistics 27 (IBM Corp, 2020) using the Intraclass Correlation Coefficient (ICC). ICC is a statistical measure used to assess the degree of consistency between multiple raters or observers in their ratings or measurements of the same target. It combines intra-observer and inter-observer variability, resulting in two coefficients with respective 95 percent confidence intervals. By using ICC, the level of agreement between the different steering committee members in their assessments was determined. A two-way mixed effects model (McGraw and Wong, 1996) was employed in this study to assess consistency, using the ICC 3,k convention proposed by Shrout and Fleiss (1979). The reason for selecting this model rather than a random effects model was that the selected raters were the only raters of interest, and they were not chosen from a large population with similar characteristics. The ICC values were interpreted as follows, 0–0.2 (poor agreement); 0.3–0.4 (fair

agreement); 0.5–0.6 (moderate agreement); 0.7–0.8 (strong agreement); and >0.8 (almost perfect agreement) (Koo and Li, 2016).

Assessing guideline content

The first step in the assessment of guideline content was the identification of key considerations relevant to the setting and the procedure for Oral Visual Examination. These were identified by reviewing the existing guidelines as well as recommendations mentioned in the WHO publication "Oral health surveys: Basic methods-5th Edition" (World Health Organisation, 2013). The identified considerations were then entered into a recommendation matrix. The following subsection gives a brief overview of the recommendation matrix and highlights the process used to create one for this chapter.

Recommendation matrix: These are tables drawn from the guidelines under review. They are particularly useful when multiple source guidelines are under consideration as recommendations from all these guidelines can be compared simultaneously. These matrices helped the Steering Committee in decision-making by i) helping assess the similarities and differences between the recommendations for each area ii) providing a basis for discussion about the relevance of the recommendations and iii) comparing the wordings between different recommendations (Harrison et al., 2010).

Creating recommendation matrix:

The template of a recommendation matrix was made with key areas of consideration down the left column and the name of the source guideline on the top. The researcher (ZK) filled out the evidence for the included source guidelines in the respective cells. These were then reviewed by the Steering Committee and any disagreements were resolved via discussion. The recommendation matrix is available in Appendix 14.

Assessing the acceptability/ applicability of the recommendations.

Acceptability is defined as "the extent to which users are likely to adopt a recommendation" while applicability is defined as "the extent to which users are able to put a recommendation into practice" (Shiffman, Dixon et al., 2005). The acceptability and applicability of the guidelines were evaluated through a set of questions as outlined by Harrison et al. (2010). These questions included determining whether the population described for eligibility matched the targeted population in the local setting, whether the intervention met patient views and preferences, whether the necessary expertise and equipment were available, and whether any constraints or organisational barriers would impede implementation. Additionally, the compatibility of the recommendation with the local culture and values and the potential benefits of implementing the recommendation were also assessed.

Reviewing the assessments

To facilitate an informed and transparent decision-making process, the Steering Committee was presented with all the assessment phase results during a face-to-face meeting. Table 9 displays the primary documents related to the assessment of quality, acceptability, and applicability, as well as the final recommendation matrix, and how they were utilised in the decision-making process.

Table 9: Available assessments and their possible use by the committee

Assessment Related to Quality	Possible Use By
Overall AGREE GRS scores	Elimination of guidelines that the committee would not recommend.
Raw AGREE GRS scores	Used to assess the inter-rater agreement and ensure that the committee's scores are reliable.
Summary of AGREE GRS dimension graphs	Used to compare guidelines across the different AGREE GRS domains.

Recommendation matrices	Compare recommendations from all the potential guidelines for content and wording.
Assessment Related to Acceptability and Applicability	Possible Use
Results of the applicability evaluation	Used to decide whether the recommendations are applicable and can be implemented in the user's context.

Selecting between guidelines and recommendations to create an adapted guideline

The Steering Committee reviewed the aforementioned documents and decided on: a) whether to reject the complete guideline, b) accept the guideline as is, c) accept the description of the evidence (or parts of it) but reject the interpretation of it, and d) accept specific recommendations or modify specific recommendations.

Preparing draft adapted guideline

Following the completion of the decision-making process by the Steering Committee, a draft guideline document for OVE by CHWs was produced. The document included ten key sections: an introduction and background, the scope and purpose of the guideline, the target audience for the guideline, the target population, target settings, recommendations, supporting evidence and information for the recommendations, an external review and consultation process, references for all the materials used in creating the guideline, and a list of panel members and their credentials along with a declaration of conflict of interest.

4.3.3 FINALISATION (PHASE III)

During this phase, feedback on the draft document was obtained from stakeholders, including the expert panel and CHWs. Additionally, a process was established to review and update the adapted guideline, as well as create the final guideline document. Figure 12 presents a visual summary of the Finalisation Phase, outlining the critical steps involved in finalising the guideline document. This phase requires a range of skills and tools, which are detailed below. The outcomes of the finalisation phase include an

adapted OVE guideline document that incorporates stakeholder feedback and is ready for dissemination and implementation.

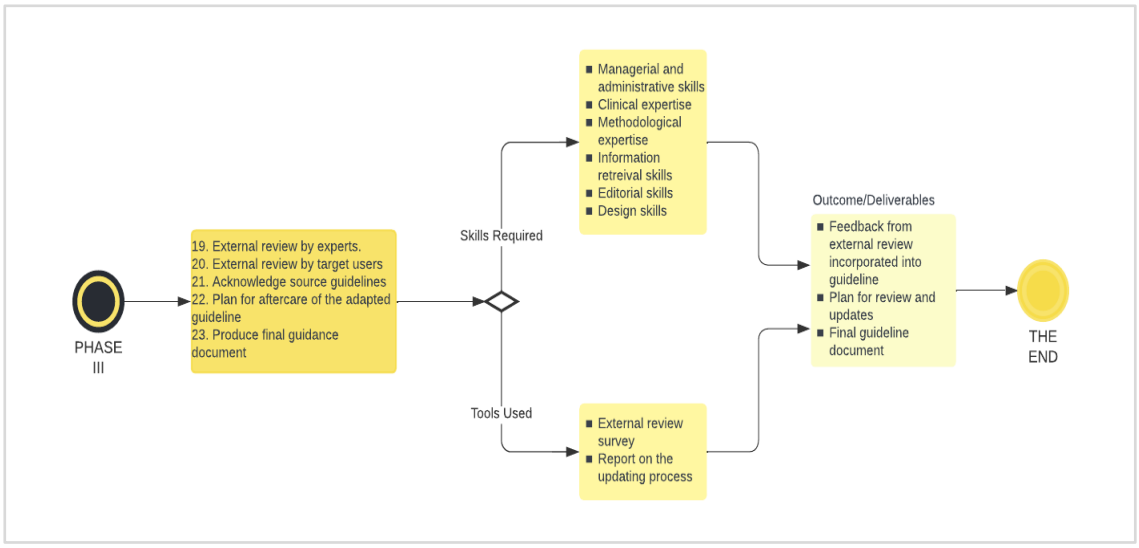


Figure 12:ADAPTE Finalisation Phase

External review by Experts' Panel

Once the draft guideline had been produced on OVE, it was sent to a panel of experts in the field of head and neck cancer research for review (selection process described in the upcoming section). The method of the panel selection is detailed in the upcoming sections. The expert panel was asked for recommendations on additional guidelines for performing OVE and the preferred method of recording data collected through Oral Visual Examination. They were also requested to provide feedback on a few additional topics such as

- Preferred name for the examination procedure.
- Preferred method of recording the examination data.
- Recommended light source for conducting the examination.
- Appropriate examination position.

These topics are related to performing OVE and implementing the guideline. Feedback was sought on these topics to gain valuable insights into the practical aspects of implementing the guideline in a real-world setting. It was also to ensure that the guideline was feasible and relevant for the target audience, thus improving the likelihood of its successful implementation and uptake. With regards to the draft

recommendations, the expert panel was asked to rate the recommendations on a 3-point Likert Scale ranging from not at all important, moderately important to absolutely essential where the terms were defined as:

> **Not at all important**- The selected recommendations are not suitable for inclusion in an OVE guideline document.
>
> **Moderately important**- The selected recommendations are suitable for inclusion in an OVE guideline document, however, may not necessarily be applicable in the given context.
>
> **Absolutely essential**- The recommendations should be included in an Oral Visual Examination process and are mandatory in the given context.

With regards to the preferred method of recording the examination data, the experts were asked to select amongst the following categories: Mouth maps, grids, photographs, and photos on mobile phones. This was multiple choice so the experts could recommend more than one method.

With regard to the preferred name for the examination procedure, the experts were asked to select amongst the following categories: oral cancer check, oral cancer exam, oral cancer examination, visual and tactile intra-and extra-oral examination, oral cancer screening and oral examination.

With regard to the preferred light source in this setting, the experts were asked to select amongst the following categories: fixed or head-mounted examination lights, handheld flashlights, blue-white LED lights, natural light and dental lights.

With regard to their knowledge of the presence of additional guidance on OVE, the experts were asked to rate their responses as Yes, No and Maybe.

Selection of Expert Panel:

Table 10 depicts the identification and selection process of the panel members. The panel members were invited via email to take part in the study.

Table 10: Setting up of Expert Panel

	Setting up of Expert Panel
Objective	The main objective of setting up the expert panel was to help with the Finalisation Phase of the ADAPTE process.
Considerations for potential panel members and key skills required	-Key stakeholders involved in the care of people suffering from oral cancer or OPMDs. -Members with multidisciplinary (e.g., community dentistry, psychology, social work etc.) backgrounds. -Members working in intersectional settings (e.g., primary care setting, tertiary hospital, ministry of health and social services) -Members with experience working in a geographically diverse population, particularly in Southeast Asia.
Identification and approach	-Identified as main authors from key publications on oral cancer screening, and early detection. Also identified through an existing network of senior researchers in the field. -Approached via email.

Decision-making and consensus-building: The panel members were asked to fill out a 24-item questionnaire on Google forms. The questionnaire consisted of 14 sections in total. The measures for operationalising the level of agreement/consensus among participants were defined ahead of time. There is no standard consensus criterion in the literature, with levels ranging from 55% to 100% (Williams and Webb, 1994, Heiko, 2012, al Rashida et al., 2019). For this study, the cut-off point for consensus was set at 70%. While traditional and classical methods of building consensus use the Delphi technique involving multiple rounds, due to the timescale for the project we used a modified method with one round of data collection, followed by a presentation of the findings to the Steering Committee. Any changes or new recommendations were discussed, and a decision was taken on whether to incorporate them or leave them out from the next stage of review. At this stage, the final document was translated into the local language for further review. The documents were not back-translated due to logistical reasons.

Data analysis

The statistical analysis was carried out using IBM SPSS Statistics 27 software (IBM Corp, 2020). The survey data from Google forms from the expert panel were imported into a CSV file. Summary statistics were produced for all the variables using descriptive analysis including cross-tabulations to identify the highest-rated recommendations. Categorical data were reported using percentages and data was represented as graphs and tables where necessary.

External review by CHWs

Once feedback was received from the experts, a stakeholder workshop was conducted with the CHWs. The purpose of this external review was to foster ownership and ensure that the end users of this guideline will have the opportunity to review this and provide feedback. CHWs were identified and approached through their supervisor in the researcher's hometown of Lucknow, India. The Head Principal of a local government school was identified as a gatekeeper who could facilitate contact with the CHW supervisor. The researcher contacted the Head Principal and explained the scope of the project and their interest in engaging with local CHWs to obtain their views on the local context related to oral health. The Head Principal then facilitated contact between the researcher and the CHW supervisor.

The researcher explained the objectives and scope of the project to the CHW supervisor as well and obtained their agreement to participate in an informal discussion. The CHW supervisor then identified potential CHWs who had the necessary knowledge and experience to provide insights into the local context related to oral health. The CHWs were then invited to attend a two-hour workshop in the local language (Hindi) where they were explained the scope and purpose of the study and were given a copy of the guideline. They were asked to review the guideline and provide feedback on any language, jargon, or difficult words that needed to be clarified or simplified. The workshop also provided an opportunity for the CHWs to share their experiences and insights related to oral health in their communities. The workshop was designed to make the CHWs feel comfortable and encourage active participation, by making the guideline

accessible in their local language, providing snacks and refreshments during the workshop, and reimbursing them with Rs 200 each (£2) as compensation for their time. The compensation rate was decided after consultation with the CHW supervisor and was in line with the current incentive and reimbursement protocol.

The workshop was held in-person, and the CHWs were presented with a translated version of the draft guideline document. The CHWs were given 30 minutes to familiarise themselves with the contents. To facilitate the discussion, a topic guide (Appendix 15) was used which had the following key categories:

1. Clarity of recommendations
    - Were the recommendations clear and easy to follow?
    - Did the CHWs understand the recommendations?
2. Terminology
    - Was the terminology used in the guideline clear?
    - Were there any words or phrases that the CHWs found difficult to understand?
3. Feasibility for CHWs
    - Could the guideline be effectively incorporated by CHWs?
    - Were the recommendations practical and feasible for CHWs to implement in their daily work?

The goal was to solicit feedback from the CHWs to ensure that the guideline was accessible and understandable to its intended audience. The discussion points were recorded and fed back to the Steering Committee and final changes to the guideline document were produced. All source documents were acknowledged and referenced in the final version of the document. The committee also decided that the guideline should be updated every two years in case new evidence or technologies emerged. As this work is beyond the scope of the PhD it is not discussed here.

4.4 FINDINGS

4.4.1 SET UP PHASE

The initial scoping search revealed the existence of 4 guidelines on OVE aimed for use by dental professionals. Since sufficient evidence was present, a decision was taken to proceed with the adaptation exercise. The next step in this process involved setting up the Steering Committee. A total of 4-panel members were approached to be a part of the Steering Committee; 3 had a background in Dentistry and 1 in Medicine. Two were working in the Department of Health Sciences, University of York as Research Associates and two were current PhD students. All of them accepted the invitation to be a part of the Steering Committee. Since the chair (ZK) was also involved in the adaptation process, the committee included a total of 5 members. To successfully undertake and complete this exercise, key skills and resources were identified. Figure 13 displays the essential skills that each of the panel members brought to the adaptation process.

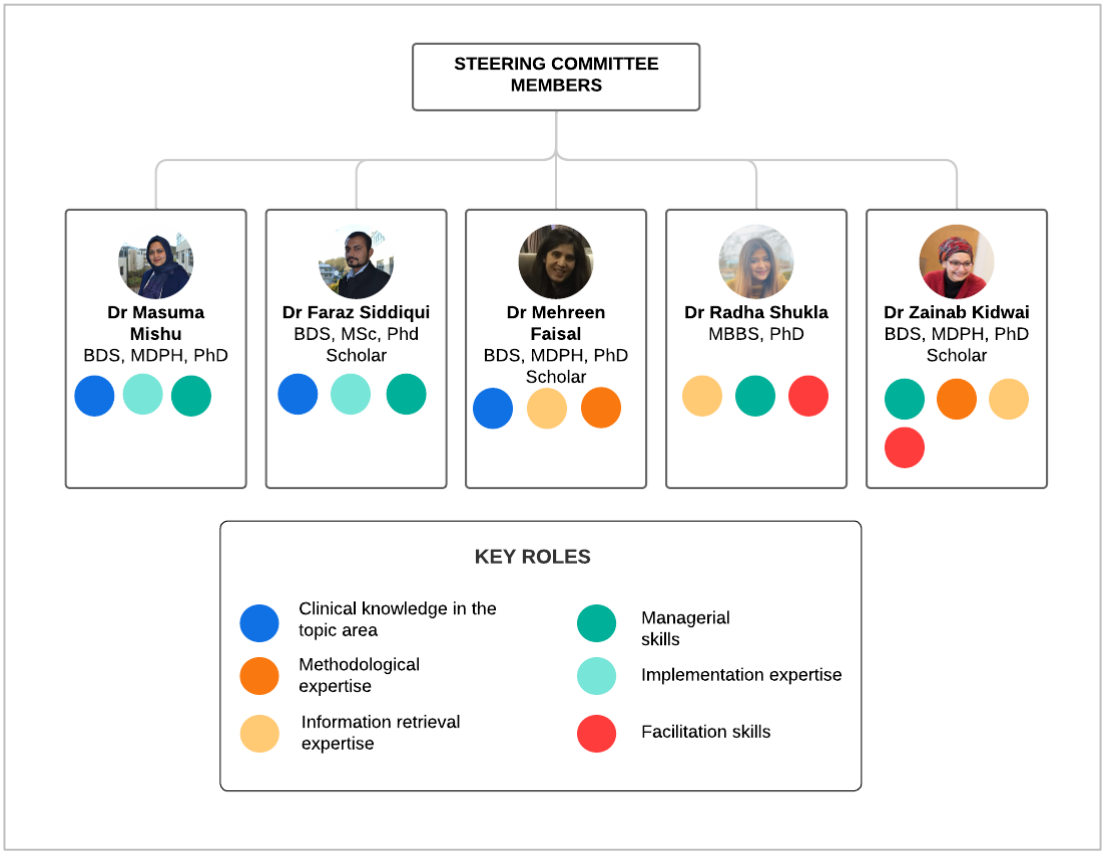


Figure 13:Steering Committee structure and their roles

Once the Committee had been set up, a Declaration of Conflict of Interest (attached in Appendix 9) was signed, and the adaptation plan was shared with the members.

4.4.2 ADAPTATION PHASE

This phase started by determining the health question. The PIPOH tool was used to identify the key health questions and topics for guideline search relevant to the current study. This information is presented in Table 11.

Table 11: Describing health questions using the PIPOH tool

Population	Adult tobacco users in India
Intervention	Screening for Oral Potentially Malignant Disorders
Professionals	Community Health Workers
Outcome	Detection of OPMDs
Healthcare setting	Community-based setting

Using the PIPOH tool, the Steering Committee decided on the following question for guideline search, "What is the method of identifying OPMDs in a community-based setting in tobacco users by CHWs?"

Following the systematic search of the different databases, 10 guidelines were identified out of which 8 met the eligibility criteria. These are

1. Guidelines on Oral Examination by the Oral Cancer Foundation (Oral Cancer Foundation, n.d.)
2. Oral Examination by Alessandro Villa (Villa et al, 2017)
3. Oral mucosal Tissue Examination Procedure by the Centre for Disease Control and Prevention (Westat, 1992)
4. Oral Health Assessment and Review Dental Clinical Guidance by Scottish Dental Clinical Effectiveness Programme (SDCEP) (Scottish Dental Clinical Effectiveness Programme, 2012)

5. Screening for and Diagnosis of Oral Premalignant Lesions and Oropharyngeal Squamous Cell Carcinoma by Joel Epstein (Epstein, 2008)
6. Guideline for the Early Detection of Oral Cancer by British Columbia Oral Cancer Prevention Programme (BC Cancer Agency, 2008)
7. A Digital Manual for the Early Diagnosis of Oral Neoplasia by the World Health Organisation (World Health Organization, 2013)
8. Chairside guide on Conventional Visual and Tactile exam by American Dental Association (American Dental Association, 2017)

These guidelines are further described based on their characteristics and content which is summarised in Table 12.

Table 12: Summarising the characteristics of the guidelines

GUIDELINE	TITLE	AUTHOR/ DEVELOPER	PUBLISHER	COUNTRY, LANGUAGE	PUBLICATION DATE OF THE GUIDELINE
CPG #1	Cancer Screening Protocols	-The Oral Cancer Foundation	Available on the Oral Cancer Foundation website. Accessed in September 2019.	United States of America, English.	No information was available.
CPG #2	Oral Examination	-Alexandro Villa (Harvard School of Dental Medicine) -Michael J Wells (The Surgery Center at Plano Dermatology) -Drore Eisen (Dermatology of Southwest Ohio) -Jeff Burgess (University of Washington School of Dental Medicine) -James J. Nordlund (University of Cincinnati College of Medicine)	Marquette University (e-Publications @Marquette) The School of Dentistry Faculty Research and Publications	United States of America, English.	May 2, 2017
CPG #3	Oral Examination Component	-Westat, Inc. 1650 Research Boulevard Rockville, MD -Developed in collaboration with the National Institute of Dental and Craniofacial Research, the National Center for Chronic Disease Prevention and Health Promotion Division of Oral Health, and the National Center for Health Statistics	Centre for Disease Control and Prevention	United States of America, English	March 1992

CPG #4	Oral Health Assessment and Review Dental Clinical Guidance	Guidance development group comprising of: -Nigel Pitts (University of Dundee) -Phil Higginson (GDP, Dundee) -Nicola Innes (University of Dundee) -Lorna Macpherson (University of Glasgow) -Mary McCann (GDP, Glasgow) -Charles Ormond (GDP, Falkirk) -Derek Richards (University of Dundee) -Margaret Ross (Edinburgh Dental Institute) -Petrina Sweeney (University of Glasgow)	Scottish Dental Clinical Effectiveness Programme.	Scotland, English.	May 2012
CPG #5	Screening for and diagnosis of oral premalignant lesions and oropharyngeal squamous cell carcinoma	-Joel B. Epstein (University of Illinois) -Meir Gorsky (University of Illinois) -Robert J. Cabay (University of Illinois) -Terry Day (University of South Carolina) -Wanda Gonsalves (University of South Carolina)	Canadian Family Physician	Canada, English	June 2008
CPG #6	Guideline for the Early Detection of Oral Cancer	-British Columbia Oral Cancer Prevention Program	British Columbia Cancer Agency.	British Columbia, English	March 2008
CPG #7	A digital manual for the early diagnosis of oral neoplasia	-Kunnambath Ramadas -E. Lucas -G. Thomas -B. Mathew -A. Balan -S. Thara -Rengaswamy Sankaranarayanan	International Agency for Research on Cancer, World Health Organisation.	France, English	2008
CPG #8	Clinical Practice Guideline for the Evaluation of Potentially Malignant Disorders in the Oral Cavity	-American Dental Association (ADA) Council on Scientific Affairs	American Dental Association	United States of America, English	2017

Quality Appraisal of guidelines:

Table 13 presents the mean AGREE GRS scores for each domain.

Table 13: Summary of quality appraisal using the AGREE GRS tool

AGREE GRS Domain	Domain considerations	CPG #1	CPG #2	CPG #3	CPG #4	CPG #5	CPG #6	CPG #7	CPG #8
		Mean Scores (SD)							
Process of development	-Were the appropriate stakeholders involved in the development of the guideline? -Was the evidentiary base developed systematically? -Were recommendations consistent with the literature?	4.2(1.3)	5.4(1.5)	6.2(1.3)	6 (1.41)	6.2(0.83)	5.6(0.54)	5.83(1.17)	5.5(1.3)
Presentation style	Was the guideline well organised? -Were the recommendations easy to find?	5.6(1.3)	5.8(0.84)	4.2(1.09)	5.2(1.3)	4.4(0.89)	5.4(0.54)	6.4(0.89)	6.75(0.5)
Completeness of reporting	-Was the guideline development process transparent and reproducible? -How complete was the information to inform decision-making?	5.6(1.3)	5.8(0.84)	4.2(1.09)	5.2(1.3)	4.4(0.89)	5.4(0.54)	6.4(0.89)	6.75(0.5)
Clinical validity	-Are the recommendations clinically sound? -Are the recommendations appropriate for the intended patients?	5.8(0.83)	5(1.73)	5(1.41)	5.6(0.89)	4.8(1.30)	5.4(0.89)	6.4(0.55)	6.2(0.45)
Overall AGREE scores		5.2(0.84)	5.6(1.14)	4.8(0.84)	4.8(1.09)	4.8(0.84)	5.6(0.55)	6(0.71)	5.8(0.45)

The overall AGREE GRS scores ranged from 4.8 to 6.0. With each domain the scores ranged from 4.2 to 6.2 for the process of development, 4.2 to 6.7 for presentation style,

4.2 to 6.7 for completeness of reporting and 4.8 to 6.4 for clinical validity. While the results were varied for the domain, the guidelines that consistently scored higher across the 4 domains were CPG #1, #2, #6, #7 and #8. These results were also reflected in the overall AGREE scores. The ICC was calculated using the overall AGREE scores as represented in Figure 14.

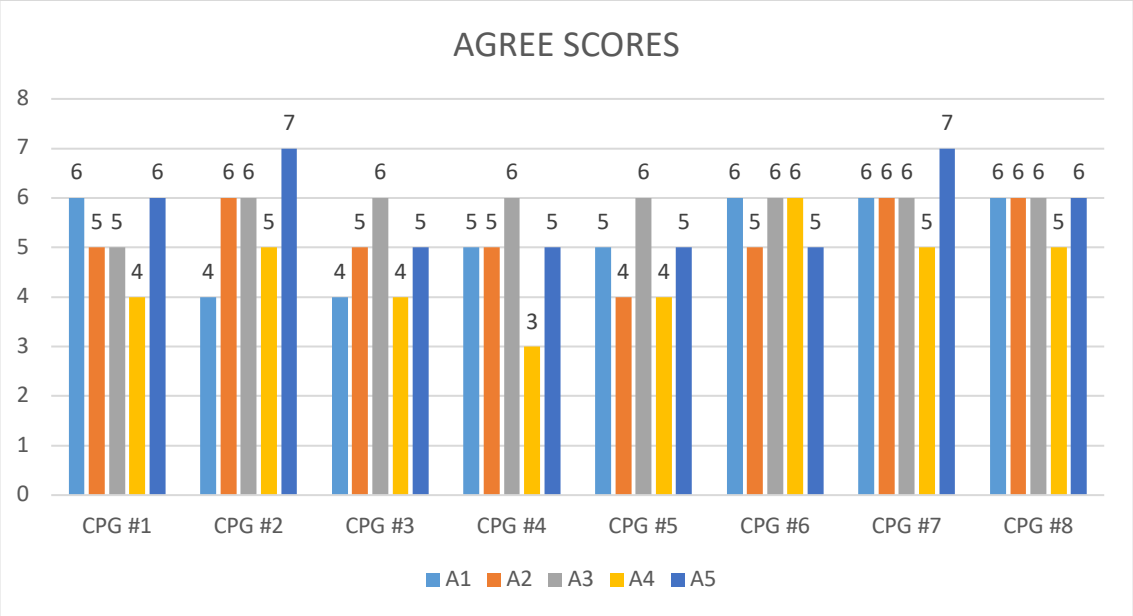


Figure 14:Graphical representation of the overall AGREE scores

The ICC analysis revealed that there was a moderate level of agreement (0.612) among all appraisers who participated in this study (Appendix 16). Additionally, the 95% confidence interval was found to range from -.080 to .911. These findings indicate that the appraisers' evaluations were relatively consistent and reliable.

Content appraisal of the guidelines:

After completing the quality appraisal, the guidelines underwent content appraisal based on several key areas of consideration. These areas included instruments and supplies, lighting, examination position, extra-oral examination, intra-oral examination, examination of lips, examination of the buccal mucosa, examination of the tongue, examination of the floor of the mouth, and examination of the hard and soft palate.

The Steering Committee reviewed the content of the guidelines and identified the ones that had information on these key areas. Two guidelines (CPG #1 and #7 highlighted

green) had recommendations on all 10 key areas followed by CPG #2 and #8 which reported information on 8 areas each. These findings are summarised in Table 14.

Table 14: Summarising guideline content

Key areas of consideration	**The actual content of the guideline** (indicate ☑ if included in the guideline)							
	CPG #1	**CPG #2**	**CPG #3**	**CPG #4**	**CPG #5**	**CPG #6**	**CPG #7**	**CPG #8**
Details on Instruments and supplies	✓		✓		✓		✓	✓
Details on Lighting	✓	✓			✓		✓	
Examination Position	✓						✓	
Extra-oral examination	✓	✓		✓	✓	✓	✓	✓
Intra-oral examination	✓	✓	✓		✓	✓	✓	✓
Examination of Lips	✓	✓	✓	✓			✓	✓
Examination of Buccal Mucosa	✓	✓	✓				✓	✓
Examination of Tongue	✓	✓	✓				✓	✓
Examination of Floor of mouth	✓	✓					✓	✓
Examination of Hard and soft palate	✓	✓	✓				✓	✓

After the content appraisal, the guidelines were reviewed on the acceptability and applicability of the recommendations. To do this, a recommendation matrix was filled out which contained relevant entries from each guideline. Two committee members (ZK and FS) reviewed the matrix and answered a series of questions (mentioned in the

earlier sections) to assess the acceptability and applicability of recommendations. Any disagreement was brought forward to the rest of the Committee and resolved through discussion. A summary of the guideline acceptability and applicability process is shown in Table 15.

Table 15: Summarising guideline acceptability and applicability

Acceptability and applicability of recommendations	CPG #1	CPG #2	CPG #3	CPG #4	CPG #5	CPG #6	CPG #7	CPG #8
Does the population described (tobacco users) match the population to which the guideline recommendation is targeted in the local setting (acceptable)?	Yes	Not clear	Not clear	Yes	Not clear	Yes	Yes	No
Does the intervention (Oral Visual Examination) meet patient views and preferences in the context of use (acceptable)?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Are all the equipment available in the context of use i.e., low resource settings (applicable)?	No	Yes	Yes	Yes	No	Not clear	Yes	Yes
Is the necessary expertise (knowledge and skills) available in the context of use (applicable)?	No (developed for clinicians)	No	Maybe	No	No	No	Maybe	No
Is the recommendation compatible with the culture and values in the setting where it is to be used i.e., a community-based setting (acceptable and applicable)?	Yes	Yes	Yes	Yes	No	No	Yes	No
Does the benefit to be gained from implementing this recommendation make it worth implementing (acceptable)?	Yes	Yes	Yes	Yes	Maybe	Yes	Yes	Yes

After reviewing the results, the panel decided that none of the guidelines could be accepted as a whole, however, specific recommendations could be selected from the chosen guidelines. In this regard, the panel reviewed the recommendation matrix and selected the appropriate recommendations from each guideline (Appendix 14). The

recommendations matrix with the selected recommendations is available in Supplementary table 1. Once the recommendations had been selected, they were further appraised by the Expert Panel and CHWs as part of the Finalisation Phase.

4.4.3 FINALISATION PHASE

This last phase involves obtaining feedback from the experts and the users of the guidelines on the selected recommendations, updating the guideline and creating a final adapted document. Initially, 12 Experts (4 from the UK, 3 from Bangladesh, 2 from Pakistan and 3 from India) were approached via email to take part in the questionnaire survey. Due to an initial low response rate, the Experts were requested to reach out to their network and suggest more participants. With their help, a further 23 were identified and invited to participate in the survey, thereby bringing the final count to 35. Out of this, 27 consented to take part, 6 were non-responsive and 2 declined due to prior commitments. Table 16 presents the distribution of Experts by expertise, number, and geographical distribution.

Table 16: Distribution of Experts

Expertise/Area of Specialisation	No of Experts	Geographical Region
Oral Pathology	2	India
Oral Medicine and Radiology	4	India
Oral and Maxillofacial Pathology, Oral Microbiology	8	India
Premalignant lesions and conditions, Oral malignancies, Oral and Maxillofacial Pathology	1	India
Oral and Maxillofacial Surgery	3	India
Oral Medicine, Global Health	1	Pakistan
Oral Medicine, Oral and Maxillofacial Surgery	1	India

Dental Public Health, Global Health	1	UK
Prognostication of Potentially Malignant lesions and oral squamous cell carcinomas, Oral Pathology, Global Cancer Control	1	India
Dental Public Health	1	India
Dental Public Health	1	UK
Oral and Maxillofacial Surgery	2	Bangladesh
Oral Medicine and Radiology, Clinical Oncology, Early detection and prevention of oral cancer, Tobacco Cessation	1	India

The following is a summary of the data collected from the Experts from the period of July 2020 to September 2020.

EXTRA ORAL EXAMINATION

Of the five key recommendations/steps proposed by the Steering Committee for performing an extra-oral examination, 81% to 89% of experts rated each recommendation as 'absolutely essential' across all five steps. All five recommendations met the cut-off criteria and were thus included in the final guideline. Table 17 provides a summary of these findings.

Table 17: Expert panel rating on steps for extraoral examination

DESCRIPTION	ABSOLUTELY ESSENTIAL	MODERATELY IMPORTANT	NOT AT ALL IMPORTANT	TOTAL
Step 1: Observe the face and neck looking for facial asymmetry, masses, skin lesions, facial paralysis, swelling or temporal wasting.	24 (88.9%)	3(11.1%)	0	27(100%)
Step 2: If an extra-oral lesion is present, take note of asymmetry, border irregularity, colour changes, diameter greater than six mm and evolution of the lesion on both sides.	23(85.2%)	4(14.8%)	0	27(100%)

Step 3: Inspect the lips, both moving and at rest and look for changes in colour or texture.	24(88.9%)	2(7.4%)	1(3.7%)	27(100%)
Step 4: Listen for a "hot potato", raspy or hoarse voice.	22(81.5%)	3(11.1%)	2(7.4%)	27(100%)
Step 5: Palpate the submandibular, neck and supraclavicular regions for lymph nodes, paying particular attention to size, number, tenderness, and mobility.	23(85.2%)	4(14.8%)	0	27(100%)

INTRAORAL EXAMINATION

The section on performing intraoral examination comprised five key recommendations. Across all recommendations, 78% to 93% of experts rated them as 'absolutely essential'. As all five recommendations met the cut-off criteria, they were included in the final guideline. Table 18 summarises these findings.

Table 18: Expert panel rating on steps for intraoral examination

DESCRIPTION	ABSOLUTELY ESSENTIAL	MODERATELY IMPORTANT	NOT AT ALL IMPORTANT	TOTAL
Step 1: Ask denture-wearing patients to remove their prostheses.	25(92.6%)	2(7.4%)	0	27(100%)
Step 2: Observe the alveolar process and look for changes in colour, consistency, loose teeth, and excessive bone loss.	23(85.2%)	4(14.8%)	0	27(100%)
Step 3: Systematically inspect and palpate all oral soft tissues (details in the following sections)	22(81.5%)	5(18.5%)	0	27(100%)
Step 4: Evaluate possible lesions for size, extent, thickness, texture, colour, consistency, and tenderness.	22(81.5%)	5(18.5%)	0	27(100%)
Step 5: Inspect and palpate for masses or enlargement of salivary glands.	21(77.8%)	6(22.2%)	0	27(100%)

EXAMINATION OF LIPS

Of the five key recommendations proposed by the Steering Committee for performing an examination of the lips, 74% to 89% of experts rated each recommendation as absolutely essential. All 5 recommendations met the cut-off criteria and were included in the final guideline. Table 19 presents a summary of these findings.

Table 19: Expert panel rating on steps for examination of lips

DESCRIPTION	ABSOLUTELY ESSENTIAL	MODERATELY IMPORTANT	NOT AT ALL IMPORTANT	TOTAL
Step 1: First, revert the lower lip and inspect the inner surface.	22(81.5%)	5(18.5%)	0	27(100%)
Step 2: Notice the frenum of the lip in the midline.	20(74.1%)	4(14.8%)	3(11.1%)	27(100%)
Step 3: With the lip still retracted, inspect the gingivolabial sulcus, the gingival mucosa, and the teeth.	24(88.9%)	3(11.1%)	0	27(100%)
Step 4: Palpate the lip with your thumb and index finger.	23(85.2%)	3(11.1%)	1(3.7%)	27(100%)
Step 5: Repeat these steps for the upper lip.	24(88.9%)	2(7.4%)	1(3.7%)	27(100%)

EXAMINATION OF BUCCAL MUCOSA

This section consisted of 3 key recommendations on performing the examination of the buccal mucosa. Overall, 63% to 89% of experts rated the recommendations as absolutely essential. While two of the recommendations (Steps 2 and 3) met the cut-off criteria, a consensus was not reached on the first recommendation (Step 1) which was later added as a discussion point for the Steering Committee and the final review by target users. Table 20 presents a summary of these findings.

Table 20: Expert panel rating on steps for examination of buccal mucosa

DESCRIPTION	ABSOLUTELY ESSENTIAL	MODERATELY IMPORTANT	NOT AT ALL IMPORTANT	TOTAL
Step 1: Ask the subject to partially open the mouth	17(63%)	9(33.3%)	1(3.7%)	27(100%)
Step 2: Examine the buccal mucosa by stretching it with a pair of tongue depressors or mouth mirrors	22(81.5%)	5(18.5%)	0	27(100%)
Step 3: With the mouth open wide, examine first the right, then the left buccal mucosa extending from the labial commissures and back to the anterior tonsillar pillar.	24(88.9%)	2(7.4%)	1(3.7%)	27(100%)

EXAMINATION OF THE DORSAL SURFACE OF THE TONGUE

This section consisted of 3 key recommendations on performing the examination of the dorsal surface of the tongue as well as one optional recommendation. Overall, 59% to 85% of experts rated the recommendations as absolutely essential. While all the key recommendations met the consensus criteria for inclusion in the final guideline, the alternate recommendation for Steps 1 and 2 combined did not reach an agreement. Table 21 presents a summary of these findings.

Table 21: Expert panel rating on steps for examination of the dorsal surface of the tongue

DESCRIPTION	ABSOLUTELY ESSENTIAL	MODERATELY IMPORTANT	NOT AT ALL IMPORTANT	TOTAL
Step 1: Ask the subject to protrude the tongue and attempt to touch the tip of the chin.	22(81.5%)	5(18.5%)	0	27(100%)
Step 2: Examine the entire dorsal tongue by asking the subject to move the tongue from left to right.	23(85.2%)	3(11.1%)	1(3.7%)	27(100%)
Combined Steps 1 and 2 (Optional): Hold the tip of the tongue gently by the fingers and a gauze sponge and move it left to right.	16(59.3%)	9(33.3%)	2(7.4%)	27(100%)
Step 3: Depress the tongue with a mouth mirror and ask the patient to say “ahh” to visualise the uvula and tonsillar pillars.	22(81.5%)	4(14.8%)	1(3.7%)	27(100%)

EXAMINATION OF THE LATERAL BORDERS OF THE TONGUE

This section consisted of 2 key recommendations and 2 alternative/optional recommendations on performing the examination of the lateral borders of the tongue. Overall, 63% to 89% of experts rated the recommendations as absolutely essential. The consensus was reached on the inclusion of both the key recommendations (Steps 1 and 2) and one optional recommendation (Alternate Step 2). Table 22 presents a summary of these findings.

Table 22: Expert panel rating on steps for examination of lateral borders of the tongue

DESCRIPTION	ABSOLUTELY ESSENTIAL	MODERATELY IMPORTANT	NOT AT ALL IMPORTANT	TOTAL
Step 1: Retract the buccal mucosa with a mouth mirror.	22(81.5%)	4(14.8%)	1(3.7%)	27(100%)
Step 2: Examine the margins by asking the subject to touch the opposite buccal mucosa with the tip of the tongue.	24(88.9%)	3(11.1%)	0	27(100%)
Alternate Step 1: Grasp the tip of the tongue with a gauze sponge and extend and rotate it laterally.	17(63%)	10(37%)	0	27(100%)
Alternate Step 2: Retract the buccal mucosa on the same side with the tongue depressor and examine the margins.	20(74.1%)	6(22.2%)	1(3.7%)	27(100%)

EXAMINATION OF THE VENTRAL SURFACE OF THE TONGUE AND FLOOR OF THE MOUTH

This section consisted of 5 key recommendations and one optional recommendation on performing the examination of the ventral surface of the tongue and the floor of the mouth. Overall, 59% to 89% of the experts rated the recommendations as absolutely essential. The consensus was reached on all the recommendations apart from Step 3 which gained 60% votes as absolutely essential and 40% as moderately important. It is also worth noting that while both Step 1 and its alternative reached an agreement, the key recommendation as identified by the Steering Committee received much higher (89% absolutely essential and 11% moderately important) votes than its alternative (70% absolutely essential, 15% moderately important and 15% not at all important). Table 23 presents a summary of these findings.

Table 23: Expert panel rating on steps for examination of the ventral surface of the tongue and floor of the mouth

DESCRIPTION	ABSOLUTELY ESSENTIAL	MODERATELY IMPORTANT	NOT AT ALL IMPORTANT	TOTAL
Step 1: Ask the subject to elevate the tongue by touching the tip to the roof of the mouth.	24(88.9%)	3(11.1%)	0	27(100%)
Step 1 (Optional): Wrap a piece of gauze around the tip of the tongue and pull the tongue gently forward and to one side. With the other hand, use a tongue blade or gloved finger to push the middle of the tongue up and out of the way.	19(70.4%)	4(14.8%)	4(14.8%)	27(100%)

Step 2: Dry the floor of the mouth with gauze.	16(59.3%)	11(40.7%)	0	27(100%)
Step 3: Inspect the lingual frenulum in the mid-line.	20(74.1%)	5(18.5%)	2(7.4%)	27(100%)
Step 4: Inspect the openings of the submandibular glands (Wharton ducts), present symmetrically on either side of the lingual frenum.	18(66.7%)	9(33.3%)	0	27(100%)
Step 5: Inspect the sublingual glands.	21(77.8%)	5(18.5%)	1(3.7%)	27(100%)
Step 6: Insert a gloved finger beneath the tongue, and another under the chin on the exterior skin, and bimanually palpate the submandibular glands and the entire submental region.	21(77.8%)	6(22.2%)	0	27(100%)

EXAMINATION OF HARD AND SOFT PALATE

This section consisted of 3 key recommendations on performing the examination of the hard and soft palate. Overall, 78% to 85% of experts rated the recommendations as absolutely essential. A consensus was reached on all the recommendations. The following Table 24 presents a summary of these findings.

Table 24: Expert panel rating on steps for examination of the hard and soft palate

DESCRIPTION	ABSOLUTELY ESSENTIAL	MODERATELY IMPORTANT	NOT AT ALL IMPORTANT	TOTAL
Step 1: Ask the subject to open widely and tilt his or her head backwards to provide an adequate view of the hard and soft palate.	21(77.8%)	5(18.5%)	1(3.7%)	27(100%)
Step 2: Examine the anterior portion of the hard palate with an intraoral mirror.	23(85.2%)	3(11.1%)	1(3.7%)	27(100%)
Step 3: Examine the soft palate by depressing the base of the tongue with a tongue depressor and asking the subject to say "aah".	23(85.2%)	4(14.8%)	0	27(100%)

RECORDING EXAMINATION DATA

Majority of the participants (50%) selected photographs followed by the use of mouth maps (32%). A small number of participants selected “Grids” (18%). These findings are presented in Table 25.

Table 25: Ratings on recording examination data

Mouth maps	11	32%
Grids	6	18%
Photographs	17	50%
Total	34	100%

NAME OF THE EXAMINATION METHOD

The majority of the participants selected "Visual and tactile intra- and extra-oral examination" (61%) followed by "Oral cancer examination" (18%) and "Oral cancer screen" (14%). Oral examination and Oral cancer screening received one vote each whereas "oral cancer check" didn't receive a vote at all. These findings are presented in Table 26.

Table 26: Summary of ratings on the name of the examination method

Oral cancer check	0	0%
Oral cancer screen	4	14.3%
Oral cancer examination	5	17.8%
Visual and tactile intra- and extra-oral examination	17	60.7%
Oral cancer screening	1	3.6%
Oral examination	1	3.6%
Total	28	100%

LIGHT SOURCE NEEDED

The majority of the participants selected "Fixed or head-mounted examination lights" (38%) followed by "Natural light" (25%), "Blue white LED light" (23%) "Handheld flashlight" (13%) and "Other" (3%). These findings are presented in Table 27 below.

Table 27: Summary of ratings on light source needed

Fixed or head-mounted examination lights	15	37.5
Hand-held flashlights	5	12.5
Blue-white LED light	9	22.5
Natural light	10	25
Other	1	2.5
Total	40	100%

EXAMINATION POSITION

The majority of the participants (82%) rated the first position as extremely appropriate, 15% as somewhat appropriate and 4% as not at all appropriate. Compared to this, the second position was less favourable with 39% rating it as extremely appropriate, 19% as somewhat appropriate and 42% as not at all appropriate. These findings are presented in Table 28 below.

Table 28: Summary of rating on examination position

DESCRIPTION	EXTREMELY APPROPRIATE	SOMEWHAT APPROPRIATE	NOT AT ALL APPROPRIATE	TOTAL
Position 1: The subject can be seated in a chair (with a high backrest), with the examiner standing behind or in front of the chair and the subject seated at eye level.	22(81.5%)	4(14.8%)	1(3.7%)	27(100%)
Position 2: The subject can be examined while laying down on a table or covered floor with the examiner seated cross-legged behind the subject's head.	10(38.5%)	5(19.2%)	11(42.3%)	26(100%)
TOTAL	32(60.4%)	9(17%)	12(22.6%)	53(100%)

RECOMMENDATIONS ON OTHER GUIDELINES

Overall, 78% of the participants were satisfied with the list of guidelines included. Additional guidelines were recommended by 19% of the Experts. These findings are presented in Table 29 below.

Table 29: Summary of results on recommendations of other guidelines.

Yes	5	18.5%
No	21	77.7%
Maybe	1	3.7%
Total	27	100%

Overall, the Experts were asked to vote on 32 key recommendations, 2 alternative and 2 optional recommendations. Out of these, a consensus was reached on 29 of the key recommendations and 1 of the alternate recommendations. In terms of additional topics, there was not a clear consensus on a preferred method of recording the data, the name of the examination process and the lighting source. The panel did however reach an agreement on the examination position. Overall, the majority of the panel members voted to recommend this guideline as it is.

External review by target users

Out of the 15 CHWs invited, 12 participated in the workshop. The discussion with the CHWs revealed the following themes:

Name of the examination method

Community Health Workers found the name of the guidance "Visual and tactile intra- and extra-oral examination" to be overly complex. In response, the CHWs were presented with several alternative options and subsequently reported that the name "Oral Visual Examination" was easier to comprehend as it could be easily translated in the local language.

Instruments and lighting

The CHWs expressed their unfamiliarity with some of the suggested instruments (mouth mirror, tongue blade) for the oral examination. Despite this, they showed a willingness to use these instruments upon receiving proper training. The CHWs expressed concerns regarding the use of head-mounted light and blue light as they were not easily accessible in the field. Instead, they recommended the inclusion of a torch or natural light in the guideline, citing the availability of these resources as a key factor in their preference.

Examination Position

The CHWs expressed their agreement with the examination position chosen by the committee without proposing any modifications.

Intraoral Examination

The CHWs were satisfied with the recommendations for the intraoral examination but suggested that a practical or video demonstration be added to the training program to enhance comprehension.

Overall, the CHWs agreed with the majority of the recommendations and expressed their willingness to learn more.

The recommended changes put forth by the CHWs underwent further review by the Steering Committee and were subsequently integrated into the final guideline. The resulting document included references to the source guidelines and was translated into three languages (Bangla, Hindi, and Urdu). This guideline is presented in Appendix 20 as part of the training handbook (designed in Chapter 5 as part of the OPMD screening toolkit).

4.5 DISCUSSION

This study aimed to adapt guidelines for Oral Visual Examination using the ADAPTE framework selected in the previous chapter. The ADAPTE framework was used to conduct adaptation under 3 phases i.e., the Set-Up phase, the Adaptation phase, and the Finalisation phase. Key findings and modifications are discussed in this section.

The Set-Up Phase

The preparatory phase of the ADAPTE framework involved setting up a multi-disciplinary Steering Committee and an Expert Panel which was responsible for steering the organisation process and providing expert knowledge in the subject area. The author found this to be a critical step for undertaking the adaptation and finalisation phase of this process. While the step ensured that the contextual adaptation was done systematically with key inputs from the experts, this study found recruitment of the committee members to undertake such a comprehensive exercise, was a challenging process. Alterations were made in the roles of the Steering Committee and the Expert Panel to suit the confines of the current study. While the original ADAPTE recommends involving the Steering Committee and the Expert Panel right from the start of the adaptation phase with most of the meetings carried over face-to-face, the author recommended a few key changes in this direction based on the logistics. Firstly, rather than involving both committees from the onset of the adaptation work, it was decided that the Steering committee would overlook the workings of the adaptation phase while the expert panel will give its feedback in the finalisation phase. With regards to conducting meetings, the author opted for face-to-face meetings for all Steering Committee gatherings, while the Expert panel meetings were conducted electronically,

via email. This decision was based on logistical considerations. Since the Steering Committee members were all based at the Department of Health Sciences, University of York, in-person meetings were more feasible and convenient to coordinate, especially for discussing important topics and making decisions. On the other hand, communicating via email was a more practical option for the Expert panel who were from different geographical regions.

The Adaptation Phase

The ADAPTE framework recommends using the PIPOH tool, to identify specific health questions. While the broad guideline topic included methods for carrying out Oral Visual Examination, this tool helped clarify the specific objectives and parameters of the topic area. Laying out a clear and set definition of the key health questions early on ensured that considerations were made along the way to address all of these factors while contextually adapting for our target population.

One of the factors unique to the ADAPTE framework is the multidimensional assessment of guidelines in terms of quality, currency, content, acceptability, and applicability. While the original ADAPTE recommends using the 23 items AGREE tool for quality assessment with at least 4 appraisers appraising each guideline, due to time constraints, it was decided that the committee would use a simplified 4 items shorter version called the AGREE GRS tool. The committee still referred to the comprehensive AGREE tool to identify relevant considerations while scoring the GRS tool.

For the assessment of the content, the guidelines were rated based on the information available on the key recommendation areas. It was observed that the majority of the guidelines that scored higher on their quality (CPG #1, CPG #2, CPG #7 and CPG #8) also scored well on their content. The only exception to this was CPG #6 which scored quite high on quality but only met two criteria for content. This goes on to show that just relying on the quality to select a guideline may not be sufficient. Equal consideration has to be placed on other criteria as well. In the end, the panel made a well-informed decision based on all these factors to select the most appropriate guideline/ recommendation for their target audience.

Strengths of the study

The adaptation and developmental work conducted as part of this research project has several notable strengths. Firstly, the research was conducted in collaboration with a diverse group of stakeholders, including CHWs and head and neck experts from the target countries. By involving these stakeholders in the adaptation process, the study was able to ensure that the adapted guideline was both culturally appropriate and feasible to implement in the target settings. Additionally, the process of soliciting and incorporating feedback also helped to identify potential challenges or barriers to implementation, which were addressed before the guideline was finalised.

Secondly, the adaptation work was led by a steering group (separate from the stakeholders) who were able to provide valuable insights and guidance throughout the process and helped ensure that the process was transparent, accountable, and inclusive, with all members having a voice and opportunity to provide input and feedback.

Limitations of the study

The involvement of stakeholders in the adaptation process, while a strength, may also be a methodological limitation. The stakeholder groups involved may have had differing opinions or priorities, which could have introduced bias into the adaptation process. Additionally, certain stakeholder groups such as the Expert panel may have had a disproportionate influence. This could have led to certain adaptations being prioritised over others, potentially affecting the overall effectiveness of the adapted guideline.

Another limitation of the study was the composition of the steering committee, which primarily consisted of early-career researchers. This composition may have influenced the decision-making process and the depth of expertise available within the committee. A more diverse committee with senior experts from relevant fields could have provided additional insights and perspectives during the adaptation process.

Using a cut-off limit instead of building consensus through methods like the Delphi or Nominal Group Technique is also a limitation of the adaptation study. While using a cut-off limit saved time, it also limited the diversity of perspectives and ideas that are

considered in the adaptation process. This could potentially result in adaptations that are not fully representative of the needs and perspectives of all stakeholders. Additionally, using a cut-off limit may not allow for the refinement of adaptations over time, which may lead to less optimal adaptations in the long run.

Consultation with CHWs was only conducted in India, and not in Pakistan or Bangladesh. While this limitation was due to logistical challenges, it may have impacted the generalisability and applicability of the adapted guideline in these other countries. The perspectives and experiences of CHWs in Pakistan and Bangladesh may differ from those in India, which could have affected the relevance and suitability of the adapted guideline. Therefore, the study findings may not be fully representative of the needs and preferences of CHWs in other low- and middle-income countries.

4.6 CONCLUSION

The present study provides evidence to support the case for contextually adapting existing guidelines for OVE. The results of the study indicate that a "one size fits all" guidelines are not feasible, as each context presents unique challenges that require tailored solutions. Nevertheless, the study did identify strengths in each of the guidelines studied, as well as areas where they may be improved to increase implementation and uptake at the local level. By building on these strengths and addressing identified gaps, contextually adapted guidelines can be developed to meet the specific needs of LMICs, without having to reinvent the wheel. The following chapter will provide a detailed account of the process involved in developing an OPMD and oral cancer screening toolkit.

CHAPTER 5: STUDY 2 - DEVELOPMENT OF OPMD AND ORAL CANCER TRAINING TOOLKIT

5.1 CHAPTER SUMMARY

The previous chapter explained the adaptation of OPMD and oral cancer screening guidelines for CHWs. The current chapter describes the development of a culturally adapted training toolkit to equip CHWs with screening skills for high-risk groups. Cultural adaptation was done throughout the toolkit development process. Section 5.2 provides a brief introduction to the competencies required for oral cancer screening and the existing competencies in CHWs. The aims and objectives of the chapter are described in Section 5.3. Section 5.4 outlines the steps for designing the training materials and measures for assessing the competencies required for performing oral cancer screening. The finalised training and assessment components are presented in Section 5.5. Section 5.6 discusses the training development process, as well as the strengths and limitations of the work. The chapter concludes with a summary in Section 5.7.

5.2 INTRODUCTION

This section gives a brief background on the need to develop a training toolkit for the CHWs. It explores the competencies required to conduct OPMD screening, their current delivery as well as ways in which these can be built in the CHWs.

5.2.1 THE NEED FOR DEVELOPING A SCREENING TOOLKIT FOR HIGH-RISK GROUPS

The implementation of evidence-based guidelines for clinical practice has been met with both successes and failures (Grol, 2001). Despite the increasing number of guidelines available, their practical application is often unpredictable, slow, and complex. In fact, research has shown these guidelines are frequently not implemented as intended (Sheldon et al., 2004; Rycroft-Malone et al., 2012). Factors influencing the implementation of clinical guidelines for healthcare professionals have been studied systematically and it has been recognised that the mere development of guidelines does not necessarily lead to a change in clinical practice (Knops, 2010; Fischer et al., 2016). To effectively implement guidelines, it is imperative to provide individuals with the necessary resources and training (Harris et al., 2013). The central element of successful strategies for guideline implementation includes the dissemination of educational materials, such as written materials, didactic presentations, and interactive conferences (Barosi, 2006). These materials play a crucial role in raising awareness, increasing familiarity, and agreement with the guideline and recommendations (Francke et al., 2008). The supply of such materials is essential to ensure the successful implementation of clinical guidelines by healthcare professionals as well as non-professionals. Fischer et al (2016) in their review of barriers and strategies in guideline implementation also highlighted the importance of developing and implementing strategies for the dissemination of educational materials that are tailored to the cognitive styles of the users. They argued that by doing so, the chances of successful guideline implementation are increased, leading to better patient outcomes and improved quality of care (Fischer et al., 2016).

In the context of OPMD screening, while the adapted guidelines can provide a valuable framework for identifying individuals at risk for oral cancer, they do not address the

practical challenges of screening and follow-up care, such as how to use screening tools, how to interpret screening results, and how to refer patients for further testing or treatment.

While oral cancer screening resources do exist, such as the “Oral Cancer Toolkit” by the British Dental Association, the utilisation of these toolkits for CHWs, however, presents several challenges (Scully, 2005). Firstly, these toolkits are typically concise and intended for professionals with prior training in the subject matter, potentially lacking fundamental information that CHWs require due to their lack of formal training in this area. Thus, these toolkits may not be applicable for training CHWs who are inexperienced in this domain. Secondly, these toolkits have been developed in the context of western countries and contain visual aids that CHWs in LMICs may struggle to relate to. Thirdly, the level of complexity in these toolkits is often geared towards professionals and may present a barrier for CHWs to comprehend and internalise the material. Given these challenges, there is a need to develop tailored resources for CHWs that consider their unique educational backgrounds and contextual factors. Doing so may help to ensure that CHWs are adequately trained and equipped with the necessary knowledge and skills to deliver effective OPMD screening services.

Additionally, the present toolkit is designed for screening high risk groups. These high-risk groups are individuals who exhibit specific characteristics or engage in particular behaviours such as use of tobacco and alcohol that increases their susceptibility to oral cancer. Several studies suggest that screening, especially when directed at high-risk groups has proven to be a cost-effective strategy (Warnakulasuriya and Kerr, 2021; Sankaranarayanan et al., 2005; Chuang et al. 2017; Speight et al., 2006). To effectively develop a toolkit for OPMD screening, it is essential to identify the competencies required for successful screening. Competencies in this context refer to the knowledge, skills, and attitudes required for effective OPMD screening, such as the ability to perform an oral exam, identify oral lesions or abnormalities, and communicate screening results to patients. These competencies can be developed through training and education, and the development of a toolkit should take into account the specific competencies that

CHWs need to effectively screen for oral cancer. The following section will discuss broadly the competencies required for screening and how they are currently built.

5.2.2 COMPETENCIES REQUIRED FOR ORAL CANCER SCREENING

Screening has been defined as "the identification of unrecognised disease by the application of a test to people who are asymptomatic, to identify those who probably have the disease and to distinguish them from those who probably do not" (Warnakulasuriya et al., 2021). Within the context of oral cancer, screening involves the application of an oral exam or a test to identify changes, which may precede or predict, with a high likelihood, the development of oral cancer (Speight et al., 2017). Screening criteria for oral cancer are designed to capture not only patients with oral cancer but also detect and manage those patients who show early signs and are at risk of developing cancer i.e., OPMDs (Warnakulasuriya et al., 2021).

In order to perform oral cancer screening effectively, certain competencies are required. To this end, organisations such as the Quality Assurance Agency for Higher Education (UK) have issued guidelines for all Dental Care Professionals (DCPs). According to these guidelines, DCPs should possess knowledge and understanding of the epidemiology, aetiology, pathogenesis, behaviour, histopathological changes, and management of lesions and disorders with malignant potential and oral cancer (Odell et al., 2004; Macluskey et al., 2008). This knowledge is essential for recognising clinical features that may indicate the presence of oral cancer or malignant potential, as well as for effectively counselling patients on cancer prevention strategies, including smoking cessation.

Moreover, DCPs must have the ability to refer patients to secondary care when necessary and deliver appropriate preventive advice (Odell et al., 2004; Macluskey et al., 2008; Farthing et al., 2018). These competencies are vital for ensuring that patients receive timely and effective treatment, and for improving outcomes in cases of oral cancer.

In addition to these technical competencies, effective communication is also an essential part of patient management following oral cancer screening. DCPs must be able to

communicate effectively with patients and their families, as well as with other members of the healthcare team. This includes providing patients with clear and accurate information about their diagnosis and treatment options, as well as addressing any questions or concerns they may have (Farthing et al., 2018). Effective communication is also important for ensuring that patients receive appropriate follow-up care and support, which can be crucial for their recovery and overall well-being.

5.2.3 CURRENT ORAL CANCER COMPETENCY DEVELOPMENT

Although there is a considerable body of evidence regarding the competencies necessary for oral cancer screening, the development of these competencies has been traditionally centred on the education of dentists, who are typically trained in this area through dental school or continuous development programs. Their curriculums are governed by national-level dental councils, associations, and organisations such as the General Dental Council in the UK (GDC), the Dental Council of India (DCI), Pakistan Medical and Dental Council (PMDC) and the Bangladesh Medical and Dental Council (BMDC).

While this training has gradually been extended to other healthcare professionals such as dental therapists, hygienists, clinical dental technicians, and general medical practitioners in high income countries, there is still a lack of resources for non-specialist health workers (Farthing et al., 2018). This highlights the need for developing context-specific training for CHWs to ensure that they possess the necessary skills and knowledge to effectively contribute to the early detection and referral of oral cancer cases.

Thus, this chapter aims to develop an OPMD and oral cancer screening toolkit for high-risk groups that is feasible, acceptable, and effective for use by non-specialist CHWs in LMICs. The objectives of the chapter are

- Identifying and selecting the learning outcomes i.e., knowledge and skills required to acquire competencies in CHWs
- Developing the toolkit elements

- Finalising and contextually adapting the toolkit for the purpose of feasibility testing in Bangladesh, India, and Pakistan

5.3 METHODOLOGY

In this section, the process used to develop the culturally and contextually adapted training toolkit is described. This includes the identification of learning outcomes, selection of toolkit elements, and the development of these elements. Throughout the toolkit's adaptation, consideration was given to the unique cultural values, beliefs, and practices of the CHWs in Bangladesh, India, and Pakistan, ensuring that the toolkit remains relevant and useful to them. The development process involved a series of consultations with experts in head and neck cancer research, and the finalisation was achieved through engagement with local stakeholders, including dentists and CHWs. The following sub-section provides a step-by-step overview of this process, categorised under the two main objectives as headings.

5.3.1 IDENTIFYING LEARNING OUTCOMES AND SELECTING TOOLKIT ELEMENTS

Learning outcomes and toolkit elements were identified in a 3-step process, with Step 1 setting up the consultation with the experts during an NIHR-funded placement at the University of Glasgow. The learning outcomes and competencies required by CHWs for oral cancer screening were identified in Step 2, which were then used to select the appropriate toolkit components in Step 3.

Step 1: Engaging experts to initiate the process

Oral cancer experts affiliated with the Community Oral Health Group at the University of Glasgow were consulted for this study, based on existing professional connections with the researcher. Specifically, Professor David Conway (Director of Dental Research, and Lead of the Community Oral Health Research Group), who served on the thesis advisory panel of the researcher, facilitated introductions to other members of the group. An initial approach was made to gauge their interest and availability for the project. This approach was made via email and included an overview of the project, its objectives, and a request to schedule a meeting to discuss the project in more detail.

The first meeting was held with the selected oral cancer experts to provide them with a comprehensive understanding of the project's aims and objectives, as well as the specific tasks they were being requested to perform. This was followed by a one-month placement of the researcher at the School of Dentistry, the University of Glasgow with the experts. The placement was supposed to be in-person, but due to the pandemic, it had to be done virtually. During the placement, a total of 5 sessions were conducted of 1-2 hours duration each. The placement allowed the researcher to work closely with the team and seek their guidance and input throughout the process of preparing the toolkit. The data were collected as notes and meeting minutes and a final placement report was prepared to detail all the sessions conducted, their objectives and outcomes. This is presented in the Appendix 17.

Step 2: Identifying the learning outcomes

This next step involved identifying the key knowledge, skills, and attitudes that the CHWs would require to conduct oral cancer screening in the field. To identify the competencies, the researcher used a mix of attending one on one teaching sessions to gain knowledge on the oral cancer screening continuum, her own background as a dentist working in an LMIC, reviewing the existing literature as well as the reading list provided during the teaching session. Through a discussion with experts, the final competencies were selected and mapped onto a logic model using a template by Barkman (2002) which is further explained below.

Step 3: Selecting appropriate elements to deliver the learning and building competencies

Using the findings from Step 2, a logic model was developed with inputs, activities, outputs, and outcomes, which provided a comprehensive overview of the components of the toolkit and their links with expected learning outcomes (Knowlton et al., 2012).

Mapping out the logic model further helped identify the toolkit components. These were then refined through discussion with the experts during which the rationale for using each was discussed. At this stage, it was also determined how each of these elements would target the individual competencies. The final toolkit elements included:

1. A training handbook and slideshow to guide the audience through the training
2. A mouth map to help identify any signs of oral cancer or precancerous conditions
3. A screening proforma to record the examination results in
4. A training video to provide visual instructions for an oral cancer screening examination
5. Learning activities to enhance the learning of CHWs

5.3.2 DEVELOPING THE TOOLKIT ELEMENTS

Once identified in Step 3, the training elements were further developed and adapted for use by CHWs in Steps 4 to 11. The method for developing each of these elements is described in this subsection, beginning with the training handbook.

Step 4: Training handbook

The training manual for building competencies in oral cancer screening was developed by utilising feedback from experts as a guiding point. As part of the development process, a scoping literature search was conducted to identify existing training programs and resources on oral cancer screening. The search was conducted using online databases such as PubMed, Scopus, and Google Scholar. Keywords used in the search included “oral cancer screening”, “early detection of oral cancer”, “community health workers”, “dentists”, “dental hygienists”, “dental nurses”, “training”, “competencies”, “training module”, “continuing professional development” and “training course”. The search results were reviewed, and a combination of sources was used to design the final handbook. The final handbook was also converted to a slideshow to provide an engaging method for guiding the audience through all the information included.

Step 5: Mouth map

A mouth map for oral cancer screening is a tool used by healthcare professionals to assess and document oral structures and identify any signs of oral cancer or precancerous conditions. It typically includes the diagram of the mouth showing

anatomical structures including the lips, tongue, gums, cheeks, roof, and floor of the mouth.

A scoping search was done on Google, Google Scholar, and PubMed to identify existing mouth maps. A decision was taken by the expert panel that in the presence of existing mouth maps, one will be adapted. If a suitable (here it means clear with well-defined anatomical structures) mouth map is not found then it would be graphically designed by the researcher.

Step 6: Screening proforma

An oral cancer screening recording form is a document or form used by healthcare professionals to record the results of an oral cancer screening examination. This form typically includes a set of questions and fields to document the patient's medical history, habits, and risk factors for oral cancer, as well as a physical examination of the mouth and surrounding areas.

The purpose of the oral cancer screening recording form is to help healthcare professionals identify any signs or symptoms of oral cancer early on so that appropriate treatment can be provided as soon as possible. The form may include specific questions about the patient's tobacco and alcohol use, as well as their family history of cancer.

To design a tailored screening proforma for CHWs, a focussed literature search was undertaken on Google, Google Scholar, and PubMed using a combination of search terms such as “screening”, “oral cancer”, “proforma”, and “recording form”. The resulting proforma was put through two stages of content and quality testing. Firstly, the pre-selected domains of the forms were mapped out. Here the term “domain” refers to the categories that the form collects information on. This was to help differentiate comprehensive forms from less comprehensive ones and assess which ones collected complete information. It also helped give the researcher an overview of the different form elements and the way it is structured. The selected forms were also assessed for their quality and rigour using the AGREE GRS assessment across multiple domains, including the scope and purpose of the forms, the rigour of their development, the

clarity of presentation, and their applicability in clinical practice. The quality assessment was only done by the researcher due to logistical constraints.

After reviewing and applying the AGREE GRS tool to evaluate the quality of the included forms, the results were presented to the experts which included the results of the AGREE GRS assessment for each included form, and a table or matrix displaying the scores for each domain of the tool. The expert panel then engaged in a discussion to identify which of the key domains should be incorporated into the final form for the CHWs.

Step 7: Training video

A training video is a visual tool that is used to deliver educational or instructional content to learners. In the given context, an oral cancer screening was designed to provide education and training to CHWs on how to conduct an oral cancer screening examination. The video was recorded with a fellow PhD colleague to demonstrate how to perform a thorough examination of the mouth, as well as how to palpate the neck and examine the lymph nodes for any signs of swelling or tenderness. The researcher sourced the equipment and resources for recording and compensated the colleague for their time with a £10 voucher.

Step 8: Activities

Based on the learning outcomes, a discussion was held with the experts to select appropriate activities to enhance the learning of the CHWs. These included role-playing activities, charting a mouth map, identifying risk factors, among others. Some of the activities were designed specifically for this workshop while others were adapted from previous training.

Step 9: Assessment form

Competency assessment forms are tools used in a training toolkit to evaluate an individual's knowledge, skills, and abilities related to a specific competency or set of competencies. For the toolkit, once the competencies had been identified in Step 2, the criteria (Knowledge, Skills, and Attitudes) for the assessment form were developed to

reflect the goals of the toolkit. Using existing question banks, appropriate rating scales were selected for each of these criteria. The objectives were mapped out to include at least 10 questions on key concepts, facts, and skills. The 3 key areas assessed were

1. Questions on disease epidemiology and awareness of risk habits
2. Targeted clinical signs and symptoms and lesion appearance
3. Image-based questionnaires categorised into different suspicious and non-suspicious lesions

Step 10: Language adaptation

This refers to translating the content of the toolkit into the local language(s) of the target audience. For the purpose of this research, the toolkit was translated into three languages - Hindi, Urdu and Bangla. Due to the researcher's proficiency in Hindi, these translations were done by the researcher. In order to facilitate the translation of the toolkit into Urdu and Bangla languages, assistance was solicited from individuals within the social network of the researcher who had a background in Dentistry and were proficient in these languages. This was done to ensure accuracy and precision, as these individuals possessed both linguistic and specialised subject matter expertise. As an additional quality check, these translated resources were further reviewed by the stakeholders in the next step.

Step 11: Stakeholder engagement

Local stakeholders (dentists and CHWs) were engaged to ensure that the toolkit was culturally appropriate and check it for further adaptation, including

Visual adaptation: Modifying the design and layout of the toolkit to be more visually appealing and appropriate for the target audience, content, and contextual adaptation.

Content adaptation: Modifying the toolkit's content to reflect the target audience's unique cultural values, beliefs, and practices.

Contextual adaptation: Modifying the examples, case studies, and scenarios used in the toolkit to reflect the target audience's local context and cultural norms.

This work was done through stakeholder engagement. The method of recruitment, selection, and engagement of each group of stakeholders (dentists and CHWs) is described below.

The study employed a purposive sampling strategy to recruit dentists from various organisations in Bangladesh, India, and Pakistan. The organisations were selected based on the logistical feasibility of conducting the study and utilised the researcher's personal and professional networks. The initial approach was made via email and/or phone and included an overview of the project, its objectives, as well as the work required from participants. The study recruited dentists from the National Institute of Cancer Prevention and Research (NICPR) and the Career Postgraduate Institute of Dental Sciences in India, the University of Dhaka in Bangladesh, and Dow Medical College in Karachi, Pakistan. Each dentist who participated in the study was sent a copy of the training materials and was asked to comment on the language, context, jargon, and overall clarity of the materials prior to obtaining their feedback. The feedback was collected as meeting notes via Zoom meetings and WhatsApp text messages. This feedback was incorporated into the final version of the training materials.

The engagement of the CHWs for the adaptation of the guideline (developed in Chapter 4) as well as the review of the toolkit was done at the same time to optimise time and resources. The process for recruitment of CHWs has been described in Section 4.3. During the two-hour workshop conducted in Hindi, the scope and purpose of the work were explained. CHWs were given a copy of the translated toolkit materials and were asked to review the materials and provide feedback on any language, jargon, or difficult words that needed to be clarified or simplified. The feedback was collected as meeting notes and the discussion was audio recorded with verbal consent obtained prior to data collection. Due to logistical constraints and limited resources, the CHW workshop was only conducted in India.

The upcoming section will provide a detailed review of the findings of this process.

5.4 FINDINGS

The following section presents the findings of the toolkit development work.

5.4.1 SELECTING COMPETENCIES FOR THE TOOLKIT

A set of three experts from the University of Glasgow participated in the toolkit development process: DC, GC, and AR. One of the experts (DC) led one-on-one teaching to ZK on the oral cancer continuum, while GC and AR shared relevant knowledge and findings from the research project, HEADSpAcE study. Through a discussion guided by the study objectives and context, the following key knowledge and competencies were identified (Table 30).

Table 30: Knowledge and competency domains

KNOWLEDGE DOMAINS	ASSOCIATED COMPETENCY
Knowledge and understanding of the disease (oral cancer and OPMDs)	-
Knowledge of risk factors	Ability to identify high-risk people by recording medical and dental history
Knowledge of warning signs and symptoms	Ability to conduct extra and intraoral examination
Knowledge of exam position, lightening.	Ability to place the patient in the correct examination position
Knowledge of instruments required	Ability to identify the instruments Ability to correctly use the instruments in the patient's mouth
Knowledge of infection control and cross contamination	Ability to do this safely
Recording screening information	Ability to chart lesions and record screening information
Knowledge of referral pathway and decision-making process	Ability to refer patients appropriately based on their screening results
Duty of care with a particular focus on delivering Very Brief Advice for ST cessation	Ability to communicate effectively with the patient the results of the screening Ability to counsel the patient on tobacco cessation

Findings on knowledge elements:

Stakeholder engagement with experts on the knowledge elements required by the CHWs for oral cancer screening yielded several key findings. Firstly, the experts recommended that CHWs should be equipped with basic knowledge of oral cancer and OPMDs, as well as a focus on key risk factors for these conditions, including smoking, ST use, and alcohol consumption. Additionally, the experts suggested that CHWs should be provided with sufficient knowledge of the different types of ST products used in their population to enable them to identify high-risk individuals.

Regarding the identification of warning signs and symptoms, the experts recommended that CHWs be trained to conduct both extra and intraoral examinations, including palpation techniques, to identify suspicious lesions. While the experts acknowledged that CHWs are not expected to make a diagnosis or differentiate between different types of lesions, they suggested that the focus should be on the identification of suspicious and non-suspicious lesions, as well as a healthy mouth. The experts also recommended that CHWs have a simple understanding of OPMDs, such as erythroplakia, leukoplakia, and OSMF, and be able to identify common signs and symptoms, such as red or white patches or difficulty opening the mouth.

In terms of instruments, the experts suggested that CHWs be taught to use only a mouth mirror and a tongue blade, with particular attention paid to infection control and cross-contamination. CHWs should be instructed on the importance of wearing the appropriate gear, including a mouth mask and gloves, and using sanitisers. The experts also recommended that CHWs be trained to ask key questions and look for specific features when recording screening information, with a particular focus on taking the tobacco history and asking about the frequency, duration, and type of tobacco used.

Regarding the knowledge of referral pathways and decision-making processes, the experts suggested that CHWs be trained on the decision tree and provided with different case scenarios where they would need to refer a patient for further follow-up or perform routine follow-up. Finally, the experts laid emphasis on CHWs being a point of intervention for behaviour change, with a particular focus on delivering Very Brief

Advice (VBA) for ST cessation. The experts recommended that CHWs be trained to deliver VBA, as it has been shown to be effective, and they should also be able to counsel patients, offer support, and give advice on healthy eating, tobacco cessation, and quitting alcohol (Papadakis et al., 2020). Overall, the stakeholder engagement with experts yielded important findings on the knowledge elements required by CHWs for oral cancer screening, which can inform the development of effective training programs.

Findings on competencies

The stakeholder engagement with experts on skills elements required by CHWs for oral cancer screening highlighted several crucial competencies necessary for the CHWs. The experts emphasised that since CHWs are non-health professionals, they should be competent in detecting OPMDs and not diagnosing them.

One of the most important competencies identified by the experts was communication. CHWs should be skilled in asking questions to screen high-risk individuals and building rapport with people. They should also be competent in conducting an OVE, instructing people to open their mouths, and examining different things as mentioned in the adapted guidance developed in Chapter 4.

The experts recommended that CHWs should be familiarised with a proforma and be competent in recording medical and dental history, signs and symptoms, and lesion characteristics on a recording form. They should also be able to identify lesion location and chart it on a mouth map. This will enable them to record information accurately and efficiently.

Another crucial skill identified by the experts was the ability to refer patients appropriately based on their screening results. CHWs should be made aware of the referral pathways in their current health systems. The experts suggested getting in touch with local dentists or authorities to get a better understanding, so this can be tailored accordingly.

The experts emphasised that one of the most important things was to teach and build competencies in CHWs regarding ST cessation. CHWs should be able to counsel patients

on tobacco cessation and offer support and advice on healthy eating, tobacco cessation, and quitting alcohol. The experts recommended using existing resources that have been tailored for use in LMICs.

In conclusion, the stakeholder engagement with experts on skills elements required by CHWs for oral cancer screening identified communication, conducting OVE, recording information, the ability to refer patients appropriately, and counselling patients on tobacco cessation as crucial competencies for CHWs. The findings of this engagement exercise with the experts can be used to develop training programs and guidelines for CHWs to enable them to perform oral cancer screening more effectively.

5.4.2 IDENTIFYING TOOLKIT COMPONENTS

Table 31 provides the findings from the filled logic model which informed the development of the specific elements of the toolkit. This included a training handbook and slideshow, screening proforma, training video, activities, and assessment tools. The upcoming sections provide details of how each of these components was developed.

Table 31: Logic model to identify training outcome (Barkman, 2002)

INPUTS	OUTPUT		OUTCOMES-IMPACT		
	Activities	**Participation**	**Learning**	**Action**	**Impact**
What do we need to achieve our goals?	What do we have to do to ensure our goals are met?	Who needs to -participate -be involved -be reached	What do we think the participants will know, feel, or be able to do after participation in the training?	How do we think the participants will behave or act differently after participation in the training?	What kind of impact can result if the participants behave or act differently after participation in the training?
CHWs **Lead Researcher** **Research Team (Collaborating site)** **Training resources**	Design OPMD screening toolkit which includes: Handbook PowerPoint Video Activities Screening Proforma Assessment Recruit CHWs to deliver training	**CHWs**: Trained to perform an oral visual examination using the available resources **Lead researcher along with research team**: Conduct the training along with practical demonstration with CHWs.	**CHWS**: Gain knowledge regarding the oral visual examination and develop relevant skills to conduct the mouth examination. Build confidence to do the examination **Researcher**: Gauge the basic skill level of the CHWs and assess the amount of training required.	**CHWs** will be: Able to identify high-risk populations as well as risk factors for OPMDs. Able to perform an oral visual examination Detect OPMDs in the mouth Refer participants to referral clinics	**Short term**: CHWs will be recruited for the feasibility study which can further lead to a pilot study followed by a trial. **Long-term:** Change in health policy whereby CHWs along with their current duties, also perform screening for OPMDs on a routine basis in a high-risk population.

Training manual

The literature search to identify existing training programs identified over 15 potential training resources, all aimed at developing knowledge and competencies in oral cancer screening. These programs varied in scope and focus, with durations ranging from 60 minutes to 15 weeks. Some of the existing training programs that were identified included Early Detection of Mouth Cancer, Oral Cancer - Early Recognition and Management, Oral Cancer - Early Detection, and BDA-CRUK Oral Cancer Recognition Toolkit CPD, among others.

After reviewing these existing programs, materials from some of the programs were adapted and a training manual specifically for the target population was developed. The adapted materials were refined and revised based on feedback from experts in the field of oral cancer screening.

Mouth map

A literature search was conducted for mouth maps as well, revealing the existence of five mouth maps that could potentially be used in the development process. These included Oral Cancer Screening Charts by the British Dental Health Foundation, a Map of the oral cavity by Laronde et al. (2013), an Anatomy checklist by Velscope (Mehta et al., 2015), an Anatomical diagram by Rey et al. (2016) and Mouth Map by ViziLite Plus (Zila Pharmaceuticals)

The Mouth Map by ViziLite Plus was selected as it was designed to be simple, clear, and easy to use during oral cancer screening. The map included labels for different areas of the mouth and the corresponding anatomical structures (Douglas et al., 2015).

Screening proforma

The literature search for existing oral cancer screening proformas identified 15 screening forms which are listed as follows:

1. Oral cancer screening referral form by the American College of Prosthodontics
2. Boston Screening Form
3. Oral Health Questionnaire by the Centers for Disease Control (2012)
4. National Oral Health Survey by the Dental Council of India
5. Extra and Intraoral examination form by Cambridge Consultants
6. Good Practice Referral Form by NHS Oral Cancer Care Toolkit
7. Oral Cancer Screening Form by Western Michigan University
8. Oral Health Survey Questionnaire by Public Health England
9. Oral Health Questionnaire for Adults by World Health Organisation
10. Clinical Format for Screening Primary Prevention and Early Detection of Oral Potentially Malignant Disorders and Oral Cancers by Ministry of Health, Malaysia
11. Oral Cancer Screening Referral Form by The Oral Cancer Foundation
12. Oral Health Assessment Tool by SA Dental Service
13. Screening Form by Head and Neck Cancer Alliance
14. Assessment of Oral Mucosal Tissue by SDCEP

15. The Serbian Version of the Oral Health Questionnaire for Adults by Margareta Lekić and Dragana Daković

With the help of experts, a total of 9 key domains/categories were identified which were needed to record the relevant information during oral cancer screening. These were: dental history, history of tobacco and alcohol use, signs and symptoms, extra oral examination, intraoral examination, lesion appearance (colour, texture, margins), palpation (consistency), dimensions and mouth map/grid to chart the lesions. Further details on the screening proforma are available in Appendix 18 and 19.

5.4.3 INTEGRATING SMOKELESS TOBACCO CESSATION

Incorporating ST cessation information into the training materials was a critical component of the toolkit development process. This information was designed to equip CHWs with the knowledge and skills necessary to identify high-risk individuals and counsel them on quitting ST effectively. The integration of ST cessation content was achieved through various means such as:

Dedicated training modules

Within both the training manual and the accompanying PowerPoint presentation, specific modules and sections were devoted to ST cessation. These modules served as focal points for delivering essential information on the health risks associated with ST use and counselling techniques for quitting. This included knowledge about the detrimental effects of ST on oral health, including the development of OPMDs and oral cancer. The training content emphasised the significance of ST cessation in reducing these risks, thereby highlighting the importance of their role as counsellors.

Identification of high-risk individuals

Within the toolkit, a key focus area was to train CHWs on the identification of high-risk individuals (i.e., people consuming any form of tobacco and or alcohol) during oral cancer screening activities. This included information on recognising signs of tobacco use, such as lesions or discolouration in the mouth or oral cavity and asking relevant questions about tobacco and alcohol consumption during patient interactions.

Counselling techniques

The training materials included practical guidance on counselling techniques tailored to ST cessation. This included training in the principles of Very Brief Advice (VBA), a well-established approach used for smoking and ST cessation in healthcare settings (Nethan et al., 2018; West et al., 2015). This approach was based on the 3As model (Ask, Advice, Act) for tobacco cessation. Additionally, training included information on how to ask individuals about their tobacco product usage, advise them on the harms associated with it, and guide them in creating quit plans. The incorporation of VBA principles provided CHWs with a structured and effective approach to address tobacco use during their interactions with individuals.

Role-playing exercises

To ensure that CHWs could apply their knowledge effectively, role-playing exercises were incorporated into the training. The aim of these exercises was to provide CHWs with practical experience in initiating conversations about ST use, delivering VBA, and responding to common challenges or questions from individuals seeking to quit ST.

Referral protocols

The toolkit also provided clear guidelines on how CHWs should handle high-risk individuals. This involved addition of decision-making pathways for referring patients to healthcare professionals for further evaluation.

5.4.4 ENGAGING LOCAL STAKEHOLDERS

Engaging the dentists

Once the training materials were finalised with the input of the experts, the next step was to have them reviewed by the dentists who would be using them in their practice. During the consultation with local dentists, they made several recommendations to improve the effectiveness of the training program. These recommendations included suggestions related to the logistics of collecting data, the mode of training delivery, and the use of case photographs.

Firstly, the dentists suggested that collecting data in hard copy form would be more appropriate than online forms. This recommendation was made with the understanding that many CHWs may not have access to digital devices or may not be familiar with online data collection tools. By using hard copy forms, the dentists believed that CHWs would be more comfortable and efficient in collecting and recording data. This recommendation aligns with the need to tailor the training program to the local context and the practical constraints that exist in the field.

Secondly, the dentists recommended that the training program should be delivered in a venue rather than remotely. This recommendation was made with the understanding that not all CHWs may have access to smartphones and laptops, which may be required for remote training. By inviting CHWs to a venue, the dentists believed that more individuals would have the opportunity to participate in the training program.

Finally, the dentists recommended using case photographs from South Asia as part of the training program. The rationale behind this suggestion was that CHWs would be able to relate better to photographs from their region.

Engaging the Community Health Workers

In addition to the recommendations made by local dentists, the CHWs also made valuable suggestions during the development of the oral cancer screening training program. These recommendations included suggestions related to the logistics of collecting data, the mode of training delivery, and the use of the local language.

When asked about the medium of the training, the CHWs raised concerns about the lack of access to mobile phones and laptops. Out of the 12 CHWs who took part in the discussion group, only 3 had smartphones. The CHWs mentioned that remote training would be difficult without access to technology. Further discussions with CHWs revealed that the government has only recently started providing smartphones to new CHWs.

Additionally, some of the CHWs mentioned that they were not comfortable with technology and that it may be difficult for them to learn through remote training methods. Another concern raised by the CHWs was the issue of connectivity. In some

areas, there is limited access to electricity and the internet, which can make it difficult to access online training materials. Furthermore, even if CHWs have access to technology, they may struggle with connectivity issues due to poor network coverage in their areas. The CHWs also mentioned that the cost of technology was a barrier for them. Smartphones and laptops can be expensive, and many CHWs may not have the financial means to purchase them.

When discussing the training curriculum, the CHWs were eager and willing to learn about oral cancer screening and were satisfied with the content of the training materials provided. However, they offered some suggestions for improving the content of the training materials. Firstly, the CHWs suggested that some of the medical terminology used in the training materials could be confusing for them. They recommended that simpler language be used to make the materials more accessible and easier to understand. This suggestion was incorporated into the final training materials.

Secondly, the CHWs emphasised the importance of adding photographic depictions of the procedures and techniques described where possible in the training materials. They explained that photographs would help them better understand and absorb the training. The suggestion to add photographs was also incorporated into the final training materials.

Finally, the CHWs recommended using local names of tobacco products in the training materials. This suggestion was made with the understanding that CHWs would be more familiar with the local names of tobacco products and be better able to relate to the training materials.

In conclusion, the recommendations made by the local dentists and the CHWs during the development of the training program highlighted the importance of considering the practical constraints, local needs, and cultural relevance when designing and implementing a training program.

5.5 DISCUSSION

The overall aim of the chapter was to develop a context-specific oral cancer screening toolkit for CHWs to improve their knowledge and skills in identifying OPMDs and oral cancer. This chapter utilised a mix of literature review and consultation with experts, local dentists, and CHWs. The literature review helped identify the most relevant and up-to-date information on oral cancer screening and the existing training materials available. The consultations with experts, local dentists, and CHWs allowed me to gain insights into the local context and to develop a culturally appropriate and context-specific toolkit.

The use of a mix of focussed literature review and consultations with experts, local dentists, and CHWs was a strength of the study. This approach ensured that the toolkit was tailored to the local context and culturally appropriate. It also allowed for the incorporation of viewpoints and experiences from experts, dentists, and CHWs from all three countries involved in the study. Additionally, this approach enabled the identification and addressing of any potential barriers to implementing the toolkit in the local context.

Logistical considerations and lack of time were also limitations of the study. Despite various frameworks for building knowledge, skills, and competencies, the researcher was unable to incorporate them into the development process due to time and resource constraints.

Despite these limitations, this study provides a valuable contribution to the field of healthcare training for CHWs. By involving CHWs in the development process and incorporating their feedback, the training materials are more likely to be effective and relevant to the needs of CHWs.

5.6 CONCLUSION

This chapter outlines the development of training materials for oral cancer screening for CHWs, aimed at improving their knowledge and skills in identifying early signs of oral cancer in low-resource settings. The development process involved a literature review

and a collaborative approach with experts, local dentists, and CHWs to design accessible and easy-to-understand training materials for CHWs with varying levels of education and training.

The feedback received from experts, dentists, and CHWs during the development process played a critical role in ensuring the relevance and effectiveness of the training materials. This work underscores the importance of collaboration and community engagement in healthcare initiatives, emphasising the need for healthcare professionals to work closely with CHWs to design and implement effective training programs that enhance the quality of healthcare services provided by CHWs.

It is hoped that the training materials designed in this chapter will contribute to the early detection of oral cancer in low-resource settings. These resources will be used in the next chapter which assesses the feasibility and acceptability of training a cohort of CHWs.

CHAPTER 6: STUDY 3 - FEASIBILITY AND ACCEPTABILITY OF TRAINING COMMUNITY HEALTH WORKERS

6.1 CHAPTER SUMMARY

In the previous chapter, a toolkit was developed to train CHWs to screen for OPMDs and oral cancers. The current chapter focuses on assessing the feasibility and acceptability of using this toolkit to train CHWs in conducting OPMD and oral cancer screening. The chapter begins with Section 6.2 which gives a brief overview of feasibility studies, including a definition of feasibility in the context of this study, its importance, and previous research on feasibility. The aims and objectives of the study are also outlined in this section. Section 6.3 then describes the multi-method approach used to achieve the study's aims, starting with the quantitative method, and followed by the qualitative method. The findings of the pre-and post-survey assessing the knowledge and competencies, as well as the in-depth interviews exploring CHWs' attitudes towards the training are presented in Section 6.4. In Section 6.5, the discussion summarises the main findings and interprets them in relation to the existing literature. Finally, the chapter concludes in Section 6.6, which provides a concise summary of the key findings and emphasises the implications of the study.

6.2 INTRODUCTION

In Chapter 1 of this thesis, the utilisation of CHWs as a solution for community-based OPMD screening in resource-limited settings was highlighted. CHW training has been acknowledged as an effective approach to improving healthcare delivery in such contexts. However, the success of delivering an intervention through CHW programs depends on their feasibility and acceptability within the target community. In this regard, this section provides an overview of what constitutes feasibility and acceptability for this thesis, highlights the importance of conducting feasibility studies and provides the aim and objectives of the feasibility study described in this chapter.

6.2.1 UNDERSTANDING FEASIBILITY AND ACCEPTABILITY IN RESEARCH

Feasibility in research refers to evaluating whether a proposed study or intervention can be conducted successfully within the available resources and constraints (Karch, 2004). This assessment involves examining the practicality of the study design, the availability of participants, the adequacy of study measures, and the feasibility of conducting the study within the proposed timeline and budget (Eldridge et al., 2016; Proctor et al., 2011). Assessing feasibility in the context of the study means evaluating whether it is feasible to effectively train CHWs on OPMD screening in South Asia given the available resources and constraints. It involves examining factors such as the availability and accessibility of training materials, the time required to deliver training, the recruitment and retention rate and the CHWs' capacity to learn and implement new skills.

Acceptability refers to the suitability and desirability of a proposed intervention or program by the target population or stakeholders (Milat et al., 2016; Lewis et al., 2015). For this study, acceptability evaluates the extent to which CHWs in South Asia find the OPMD and oral cancer training program agreeable and desirable. This includes assessing the CHWs' willingness to engage with the program, satisfaction with the program, and perceived benefits and drawbacks. It also involves examining factors that may affect implementation, such as cultural context and logistical constraints.

Thus, by evaluating feasibility and acceptability, potential barriers can be identified, and adjustments made to improve the intervention's feasibility and effectiveness, increasing

the likelihood of future scaling up and sustained use of OPMD and oral cancer screening skills.

6.2.2 IMPORTANCE OF CONDUCTING FEASIBILITY STUDIES

Feasibility studies are valuable in research for several reasons. Firstly, they enable researchers to identify potential problems with the study design, intervention, or recruitment early on, before investing significant time and resources in a larger study (Gadke et al., 2021; Ioannidis et al., 2014). Secondly, they can help researchers refine study procedures, making the study more efficient and effective in the long term (Bower et al., 2014). Thirdly, by assessing feasibility, researchers can optimise study procedures and interventions, increasing the chances of success in a larger study and contributing to the development of effective interventions (Skivington et al., 2021; O'Cathain et al., 2019). Additionally, they can assist in ensuring ethical considerations are met by evaluating the safety and well-being of participants before embarking on a larger study (Van Wijk & Harrison, 2013). Lastly, they can demonstrate the value of an intervention or program by providing evidence that it is feasible and acceptable to the target population (Bowen et al., 2009). This can show stakeholders, including funders and policymakers, that the intervention is worthwhile and has the potential to positively impact the health and well-being of the target population. This has further been highlighted by the recommendation given by The UK Medical Research Council (MRC) published updated guidance on complex interventions, which explicitly recommends conducting feasibility studies. The guidance suggests that feasibility and pilot studies can aim to test the acceptability of procedures, estimate recruitment and retention rates, and calculate appropriate sample sizes. In the upcoming section, the focus will be on the rationale for conducting feasibility studies with CHWs, supported by evidence from existing literature.

6.2.3 CONDUCTING FEASIBILITY STUDIES IN CHWs

CHWs are increasingly recognised as a key element in addressing health disparities, particularly in underserved and marginalised communities. A feasibility study can help to determine whether a proposed intervention for delivery by CHWs is viable, what the

potential challenges and barriers are, and how to address them. It can also provide valuable information about the costs, logistics, and potential impact of delivering the intervention.

There is a substantial body of research supporting the value of feasibility studies as a critical step in the development and implementation of CHW training programs. For example, a systematic review by Padmanathan and De Silva (2013) which focused on the acceptability and feasibility of task-sharing for mental healthcare by CHWs in LMICs emphasised the need to assess the acceptability and feasibility of CHW programs to ensure that they are effective in addressing healthcare challenges and sustainable in the long term.

In addition, a mixed-methods evaluation of the feasibility, acceptability, and impact of a pilot project ECHO (Extension for Community Healthcare Outcomes) for CHWs conducted by Damian et al. (2018) found that ECHO is a viable means of increasing access to training resources for CHWs. The study demonstrated that attending training sessions led to an improvement in CHWs' self-efficacy to perform their job duties and address social determinants of health (SDOH). It also highlighted the need to explore the feasibility and acceptability of implementing such training in different settings.

In terms of integrating CHWs as part of the team, Vaughan et al. (2018) conducted a randomised controlled feasibility study and found that integrating CHWs as part of a comprehensive diabetes group visit program is a feasible and effective system-level intervention to improve glycaemic control and achieve guideline concordance.

Furthermore, a study by Kwong et al. (2019) on the feasibility of delivering culturally aligned training programs for cervical and breast cancer screening in CHWs in South Asia demonstrated that while the training program was effective in increasing knowledge, self-efficacy, and competence of CHWs in delivering interventions for cancer prevention, there were challenges in recruitment and further improvements needed for the program's effectiveness. This underscores the importance of assessing feasibility to identify potential challenges in delivering the intervention and ensuring its success.

Overall, the evidence suggests that feasibility studies are valuable in research for several reasons, including identifying potential problems, refining study procedures, optimising interventions, ensuring ethical considerations, and demonstrating the value of an intervention. These benefits can increase the likelihood of success in larger trials.

Hence, in light of the above evidence, the aim of the present chapter was to evaluate the feasibility and acceptability of delivering training to CHWs in conducting OPMD screening in South Asia using a remote model of training. The specific objectives were

- To assess the feasibility of delivering the training to CHWs remotely
- To assess the acceptability of delivering the training by exploring the attitudes and experiences of CHWs
- To assess the effectiveness of training in building competencies in CHWs for OPMD screening by assessing their change in knowledge and skills

6.3 METHODS

The following section will provide a detailed description of the study design, study site and settings, participant recruitment, the sample size for the study, the intervention for the study, and the data collection and analysis methods.

6.3.1 STUDY DESIGN

This was a multi-methods study design with two components, a quantitative part utilising pre- and post-surveys and a qualitative component utilising semi-structured in-depth interviews.

6.3.2 STUDY SITE AND SETTINGS

The study was conducted in two South Asian countries, specifically Bangladesh and India, with an original plan to include Pakistan. However, the plan was revised due to a delay in obtaining ethics approval. In the upcoming section, the characteristics of the study sites and the rationale for their selection will be described.

The study sites were located in urban settings in two cities, Dhaka in Bangladesh and Noida in India. Dhaka is the capital and largest city of Bangladesh, located in the central part of the country. It has a population of over 21 million people, making it one of the most densely populated cities in the world. Noida, on the other hand, is a planned city located in the northern part of India, in the state of Uttar Pradesh. It is part of the National Capital Region of India and is adjacent to New Delhi, the capital of India. The city has a population of around 0.6 million people and is considered one of the fastest-growing cities in India.

The selection of study sites in both countries was based on logistical feasibility, availability of research infrastructure, and access to the target population. The fieldwork was conducted through an existing collaboration between the researcher (ZK), the University of Dhaka in Bangladesh, and the National Institute of Cancer Prevention and Research in India. These institutions provided the necessary support and resources for conducting the study, including access to the target population and research infrastructure. The collaboration also ensured adherence to ethical considerations and guidelines and regulations of the respective institutions.

6.3.3 PARTICIPANT RECRUITMENT

The study population for this research comprised diverse cadres of CHWs, who were included based on a set of specific eligibility criteria. These criteria consisted of the following factors: (1) being aged 18 years or over, (2) currently engaged in employment at the designated participating sites, (3) having the ability to communicate and read in the local dialect (Bangla or Hindi), (4) having the capability to travel to the study site for the two-day training program or having access to technology for remote participation, and (5) demonstrating a willingness to actively engage in the training workshop.

Participant recruitment in Bangladesh was carried out by a team from the University of Dhaka, which targeted individuals from the Mirpur/Pallabi areas in Dhaka through three NGOs. The recruitment process lasted for two months, from December 2021 to January 2022. In India, participants were recruited from the Hoshiarpur and Sector 39 areas in Noida through NICPR's existing network, and the recruitment process lasted for three

months, from December 2021 to February 2022. The selection of study sites in both countries took into consideration potential risks and challenges associated with conducting the study in each location, including research infrastructure availability, accessibility of the target population, and cultural and social factors that might affect participation. In the next section, the enrolment process and recruitment strategies are discussed.

Enrolment in the study was voluntary and participants were not charged any fees to participate. To confirm their enrolment, participants were required to complete a registration form. Participants were also reimbursed for their time and travel expenses, with the amount of reimbursement (£3 per participant per day) determined based on the duration of the training program and the cost of travel. Upon completion of the training workshop, participants were awarded a Certificate of Attendance as recognition for their participation, which aimed to enhance participation and ensure that participants were adequately informed about the study requirements. The provision of refreshments and lunch, as well as complimentary oral cancer screening instruments, such as disposable mouth mirrors, tongue blades, gauze, mouth masks, and gloves, aimed to create a supportive environment for learning and engagement. Overall, these recruitment strategies were intended to encourage participation and ensure that participants were fairly compensated for their involvement in the research.

6.3.4 INFORMED CONSENT

The study followed ethical guidelines to ensure that potential participants were well-informed about the study and gave their informed consent to participate. To ensure that participants were well-informed, a Participant Information Leaflet was provided, which gave details about the purpose and intent of the study. The participants were given adequate time to read the leaflet and had the opportunity to ask questions and clarify any doubts with the research team. Once participants were satisfied and had resolved any queries, they were asked to sign the Consent Form (Appendix 21). The Participant Information Leaflet (Appendix 22) and the Consent Form were translated into local languages to ensure that all participants could understand the contents.

6.3.5 SAMPLE SIZE

While a feasibility study does not require a specific sample size calculation, the recruitment of 33 participants in the current study provides an initial indication of the feasibility of the training program and the potential impact on participants' knowledge of oral cancer screening. By using a similar study conducted by Patrick et al. (2019) i.e., "Knowledge assessment of ASHAs for technology-enabled early oral cancer screening" as a reference, the effect size of 1.076 was calculated using G*Power 3.1.9.4 software to achieve 95% power and a 99% confidence interval (Faul et al., 2009). This resulted in a range of sample sizes from 14 to 38. To ensure high statistical power, the largest estimated sample size of 38 was initially selected for this feasibility study. To account for the non-response rate, the sample size was increased by 15%, resulting in a final sample size of 45 (Suresh and Chandrashekara, 2012); with 15 participants per country. However, due to logistical challenges in conducting the study in Pakistan, the final sample size was 33, with 15 participants from Bangladesh and 18 from India. A table showing these calculations is presented in Appendix 23.

The sample size for qualitative interviews was determined with the goal of achieving comprehensive coverage of perspectives and experiences within the study population. This approach is aligned with the practice of ensuring that a sufficient number of interviews are conducted to capture the diversity of insights and insights related to the research objectives (Guest et al., 2006; Morgan, 1996). Initially, the intention was to interview all 33 participants. By exceeding the recommended threshold of 12 interviews, the study aimed to capture the diverse perspectives and experiences of the CHWs. However, while all participants who took part in the training workshop in India agreed to participate in the interviews, logistical constraints arose during the study in Bangladesh. Specifically, the beginning of Ramadan and duties in other programmes made it impossible to conduct interviews with all participants from Bangladesh. Therefore, to ensure a representative sample from Bangladesh, a purposive subsample of participants was selected based on their sex, years of experience, and the centres they were from. This approach ensured that the sample was diverse and representative of the broader CHW population in Bangladesh. A total of 25 participants were finally

selected, with 18 from India and 7 from Bangladesh, with the final sample count still exceeding the recommended threshold of 12 interviews.

6.3.6 TRAINING

This section aims to elaborate on the practical implementation of the OPMD screening toolkit developed in Chapter 5 of the thesis, specifically its use in the delivery of the training workshop. The toolkit was designed to aid CHWs in the early detection and management of OPMDs through the utilisation of simple and easy-to-use screening tools. In order to facilitate effective dissemination and utilisation of the toolkit, a training workshop was conducted with CHWs in India and Bangladesh. The following section will provide further detail on the programme of the workshop, and the novel mode of online delivery and give an overview of how each toolkit component was covered during a two-day training workshop.

Outline of the training workshop

The training program was carefully designed to ensure that the CHWs were equipped with the knowledge and skills needed to effectively conduct OPMD screenings in their communities. The two-day workshop included a range of activities that aimed to engage the participants and facilitate their learning. The first day of the training workshop began with an ice-breaking activity, allowing participants to introduce themselves and become familiar with each other as well as the facilitators (ZK in India and trainers in Bangladesh). Following this, the facilitators provided an overview of the training program and the learning outcomes for the day. The participants were then introduced to the concepts of oral cancer and OPMDs, clinical signs and symptoms, and the various risk factors associated with these conditions. Additionally, the importance of taking the medical and dental histories of the patients was taken into consideration. The training also covered various oral cancer screening tools and techniques. The participants engaged in role-playing activities to practise recording medical and dental histories, as well as completing written activities to identify various risk factors, including different types of ST.

On the second day of the training workshop, the focus shifted towards developing practical skills among the CHWs. This included hands-on practice sessions with OPMD screening tools, where they were taught lesion classification and shown the screening proforma. They were also shown a video demonstration of conducting OPMD screening within their settings and informed on various lesion characteristics. They were introduced to the mouth map and invited to take part in an activity on charting lesions in the mouth map and filling out case proforma to record the lesion characteristics. Additionally, the duty of care to patients was discussed in detail, and the participants were shown the decision-making pathway for referrals. To reinforce the learning outcomes of the training, the participants were also engaged in various role-play activities on the aforementioned topics. During these activities, the participants were able to apply the knowledge and skills they had acquired in a simulated setting, allowing them to practise and receive feedback from the trainers and their peers. This provided a safe and supportive environment for the participants to develop their skills and confidence in conducting OPMD screening and delivering Very Brief Advice (VBA) for tobacco cessation (Siddiqui et al., 2022).

Finally, the participants were provided with an opportunity to ask further questions and comments. Overall, the training workshop was designed to provide the CHWs with the knowledge and skills necessary to conduct OPMD screening and deliver VBA for tobacco cessation in their communities, and to empower them to be advocates for oral cancer prevention and early detection.

The workshop ended with a formal thank you to the participants for their active participation and engagement throughout the training workshop. The facilitators encouraged the participants to continue practising the skills and knowledge they had acquired and to share them with their colleagues and communities. Finally, the researcher (ZK) thanked the local partners and organisations who had helped to facilitate the training program and reiterated their commitment to supporting the ongoing efforts towards oral cancer prevention and early detection in the region.

Mode of delivery

The workshop was delivered using two online models in Bangladesh and India. The following sections provide details of each of the models below:

a) Train the trainer model (Bangladesh)

The "train the trainer" model is a teaching strategy that involves experienced trainers or teachers instructing less experienced trainers or teachers on how to effectively deliver a training program or workshop. The focus of this model is on building the capacity of the trainers to deliver the training content to a wider audience (Orfaly et al., 2005).

In the context of the workshop held in Bangladesh, the researcher (ZK) did not speak the local language (Bangla) and was unable to directly communicate with the participants. Therefore, a group of bilingual research staff fluent in Bangla and English based at the Ark Foundation, Dhaka was trained in English to deliver the training on behalf of ZK to the CHWs. This was used to ensure that the trainees who would be delivering the training had a thorough understanding of the content and were equipped with the necessary skills to effectively communicate the information to the participants.

Selection of trainers

The selection of trainers for this initiative followed specific criteria to ensure effectiveness and proficiency in workshop delivery. The chosen trainers were researchers affiliated with the Ark Foundation and possessed several key qualifications as detailed below.

The trainers demonstrated proficiency in both Bangla and English, allowing them to effectively communicate with a diverse range of participants. Each trainer had a background in dentistry and public health research, with more than three years of experience in the field. The process of selecting bilingual research staff members to serve as trainers was conducted through a nomination process. The principal collaborator (RH) played a central role in identifying and nominating suitable trainers based on their qualifications and expertise. A total of four trainers (MN, SL, MF, SK) were chosen to fulfil the trainer roles.

Training the trainers

Before the workshop, a two-day “train the trainer” session was held on Zoom, an online video conferencing platform. During the training sessions, they were introduced to the content of the training and were familiarised with the OPMD screening toolkit including the handbook, PowerPoint presentation, training video, activities, and assessment forms. The trainers also had the opportunity to ask questions and clarify their queries on any of the training materials or workshop plans. This approach ensured that the training was delivered in a culturally appropriate manner and that any language or cultural barriers were addressed, ensuring the effectiveness of the training program. The trained "trainers" then delivered the workshop in a conference room at the University of Dhaka, utilising a projector and a screen to present the training content to the participants. The training session was also recorded and shared with ZK to ensure quality control.

b) Online direct training model (India)

The direct training model is a training strategy that involves a trainer delivering training content directly to the participants. This approach is often used in situations where the trainer has specialised knowledge and expertise in the subject matter and is familiar with the local language and the cultural context.

In the context of the workshop held in India, the direct training model was employed to deliver an online training program to the participants. The training was conducted online and led by the researcher (ZK) who is a native Hindi speaker. The participants attended the training via Zoom. To facilitate the online training, a projector and screen were set up in a conference room at NICPR, India. An audio system and a conference microphone were provided to aid in live interaction between the researcher and the participants. Additionally, two laptops were set up in the room, each with a webcam to provide multiple viewpoints of the room and make the training as real and immersive as possible. This approach to delivering the training program was designed to provide the participants with a rich and interactive learning experience, which would enhance their engagement and understanding of the training content.

Session times and duration

The training sessions delivered at both sites had the same duration of four hours per day. However, the session times varied depending on the convenience of the CHWs in each country. In Bangladesh, the training was held in the late afternoon, between 2 pm to 6 pm, while in India, the training was held mid-day, between 10 am to 2 pm. The session times were decided after consulting with the collaborators on the ground, who in turn consulted the CHWs to determine the most suitable time for them to attend the training. This approach ensured that the participants were able to attend the training without compromising their other responsibilities and commitments. The participants were also provided with two refreshment breaks of 20 minutes each during the workshop. This approach was done to ensure that the participants remained energised and motivated throughout the training, which may contribute to their retention of the training content.

6.3.7 DATA COLLECTION

Data was collected using both quantitative and qualitative methods, and the subsequent sections provide detailed information on each of the measures recorded, as well as the procedures employed for data collection.

Quantitative data collection

The quantitative data was collected through a pre-and post-questionnaire survey, which is a commonly used method to evaluate learning outcomes, especially in educational programs. The assessments involve measuring the initial knowledge level of the participants followed by measuring the knowledge after their training, thus helping to gauge the knowledge they gained from the workshop/training session (Schilling and Applegate, 2012). The questionnaire (Appendix 24) was developed based on the learning objectives identified in Chapter 5 and assessed the competencies in OPMD screening, as well as changes in participants' attitudes and confidence pre-and post-training. The pre-training assessment was conducted before the workshop, while the post-training assessment was conducted at the end of the two-day training workshop.

The assessment was designed to take no longer than 15-20 minutes to complete and included a mix of true/false and multiple-choice questions to increase rigour, as suggested by Wood, Cole et al. (2004). The survey and assessments were administered face-to-face in both countries and were conducted in the local language (Bangla in Bangladesh and Hindi in India). The following sections describe each of the measures assessed and their response scale in detail:

Knowledge (Pre- and post-training)

The knowledge component of the questionnaire included questions on risk factors, signs and symptoms of oral cancer and OPMDs, affected age groups, location and characteristics of lesions, OPMD screening as well as referral pathway. Responses were collected using a mix of multiple-choice answers.

Skills (Post-training only)

Case vignettes were used as a tool to assess the skills and knowledge of participants in a simulated clinical setting post-training. The case vignettes were presented in the form of case studies, which included images of the mouth and brief descriptions of patient history, particularly tobacco history. Participants were asked to review the case vignettes and provide answers related to tobacco use, including frequency, type, and duration of tobacco, as well as the presence or absence of suspicious lesions. If lesions were present, participants were asked to identify the location and characteristics of the lesions and chart them on a mouth map. Additionally, participants were questioned on their duty of care and the referral pathway based on their assessment.

Attitudes regarding the training (Pre- and post-training)

To assess participants' attitudes in the study, various questions were used to gather information on their preferences and opinions. These included questions about their interest in attending future oral cancer screening workshops, their preferred format for such workshops, and the perceived importance of Community Health Workers in the prevention and diagnosis of early signs of oral cancer. In addition, participants were asked to rate the usefulness of early detection of oral cancer and OPMDs in improving

disease prognosis on a 5-point Likert scale, ranging from "not at all useful" to "extremely useful." They were also asked to rate their level of knowledge on prevention and early detection of oral cancer and OPMDs on a 5-point Likert scale, ranging from "informed" to "very informed."

Confidence in conducting OPMD screening (Pre- and post-training)

Participants' confidence was assessed to gain insights into their perceived readiness to effectively carry out screening and related tasks using a 5-point Likert scale, with questions focused on different aspects of their skills and knowledge related to oral cancer screening. Specifically, participants were asked to rate their confidence levels in performing screening procedures, taking medical and dental histories, communicating screening results to patients, referring patients to healthcare services, and providing educational advice to patients following the screening. The scale ranged from "Not at all confident" to "Completely confident."

Qualitative data collection

Qualitative data was collected through semi-structured in-depth interview which is a frequently used interview technique in qualitative research particularly in the healthcare context (DiCicco-Bloom and Crabtree, 2006; Gill et al., 2008). This approach offers distinct advantages, notably fostering reciprocity between the interviewer and participant (Galletta, 2012). It allows the interviewer to adapt and pose follow-up questions based on participant's responses and verbal expressions (Hardon et al., 2004; Rubin and Rubin, 2005; Polit and Beck, 2010). The questions were established prior to the interview and formulated using a topic guide (Appendix 25) that was developed for this chapter.

Development of the topic guide

The semi-structured interview topic guide was developed systematically following established methods (Kallio et al., 2016). First, an initial draft guide was created through a review of relevant literature on CHW training and oral cancer screening programs (Thampi et al., 2022; Nethan et al., 2020; Kedar et al., 2021; Rawal et al., 2021). This

helped identify appropriate themes and questions to cover based on previous research. Next, the draft guide was shared with experts in qualitative methodology from the Social Research Association (KO) and the Community Oral Health Research Group from the University of Glasgow. Their feedback supported refining the wording, flow, and framing of questions and probes to be engaging and context specific.

The revised draft was then piloted in practice interviews with colleagues at the Department of Health Sciences, University of York who were experienced in qualitative research. Conducting test interviews allowed assessment of the timing, flow, clarity, and relevance of the guide. Final adjustments were made based on insights gained during piloting. To prepare for data collection, ZK completed an in-depth qualitative interviewing course through the SRA and conducted mock interviews using the final guide.

This iterative development process incorporating literature review, expert consultation, piloting, and interviewer training helped ensure a comprehensive, qualitatively robust topic guide tailored to the study purpose and population.

Language and mode of interviews

In Bangladesh, due to language barriers, the interviews were conducted in Bengali by the local trainers who provided the training, while in India, ZK conducted all the interviews. The interviews in Bangladesh were conducted in person, while in India, they were conducted online via a video platform. Zoom was used for 11 interviews with participants attending from NICPR, and for participants who were unable to visit NICPR, interviews were conducted over WhatsApp video call. All interviews were audio recorded and transferred to the virtual desktop services provided by the university's IT (Information Technology) department.

Outcome measures

The main outcomes of the study were the feasibility and acceptability of delivering the training, as well as assessing the potential effectiveness of the training in improving

competency in OPMD screening. The following sections describe the outcomes in detail as well as how they were collected:

Feasibility of registration and recruitment

The feasibility of recruitment was evaluated using measures like recruitment rates which refer to the number of eligible participants recruited within a given timeframe. This was also explored in in-depth interviews to get an insight into the potential barriers to recruitment, such as lack of interest or availability. Participants were asked to talk through their registration process and provide feedback on their experience. They were asked whether the registration process was easy or difficult and why they felt that way. Furthermore, they were asked to provide suggestions on ways to improve the registration process.

Feasibility of training and learning

The outcome measures for feasibility and learning were assessed by exploring several factors related to the training. Firstly, the medium of training was assessed by asking participants about their views on attending the training face-to-face (in Bangladesh) and online (in India). This was further explored by asking them their preferred medium for future training as they may have different preferences and needs depending on their learning style, availability, and technological literacy. Secondly, the training centre and environment were assessed by asking participants about the location and settings of the training. This included questions about the physical environment, such as lighting, noise level, and comfort, and the availability of resources, such as seating arrangements and refreshments. Thirdly, the length and timing of the training were assessed by asking participants about the duration of the training and whether the timing was convenient for them. Participants were also asked if the training was too long or too short and if there was enough time allocated for questions and practical demonstrations. Participants about the frequency and duration of breaks during the training. Participants were also asked whether they found the breaks adequate and whether they helped to enhance their learning.

Fourthly, the content of the training was assessed by exploring participants' views on the use of photos and videos, training activities, written materials, and practical demonstrations. Their experience of training, the language used, the information given, and the opportunity to ask questions was also explored in-depth. Participants were asked about the effectiveness of these materials and activities in enhancing their learning and whether they found the language used and information provided to be clear and relevant.

Effectiveness of training in the improvement of knowledge, attitude, and confidence

Improvement of knowledge, attitude and confidence was assessed using a pre-post assessment. These measures were also explored through interviews and participants were asked about the change in their knowledge, attitude, and confidence in conducting OPMD screening following the training.

Effectiveness of training in improving the competencies

Competency refers to the ability of an individual to perform a specific task or skill to a predefined standard. In this study, competency was assessed using case vignettes following the training. It was further explored in the interviews where participants were presented with case scenarios about spotting a suspicious lesion in the patient and asked how they would proceed. Participants were further questioned about their competencies in advising people to quit tobacco. They were asked whether they currently advise people on quitting tobacco, what strategies would they use, and how they would advise those who do not quit.

Feasibility of collecting the data

This was explored qualitatively. Participants were asked to provide feedback on their experience with filling out questionnaires and charting the mouth map. They were asked about the clarity of the questions, the relevance of the topics covered, and the time required to complete the questionnaire. They were also asked to provide feedback on the format of the questionnaire and the assessments, such as whether it was easy to

read and navigate or if they had difficulty understanding any of the questions. Similarly, participants were asked about their experience with charting the mouth map.

Acceptability of the training programme and its perceived impact/sustainability

The participants' views on acceptability were assessed by exploring the degree to which they found the training, its content, delivery and medium acceptable and satisfactory. The measures for perceived sustainability and impact of the training were explored by asking their views on the feasibility and practicality of conducting the training on a larger scale, its perceived benefit and impact. They were also asked about their willingness to attend future training and the impact of conducting the OPMD screening in their communities, the challenges they could face as well as the support they would require delivering such an intervention.

6.3.8 DATA ANALYSIS

The present chapter follows a multi-method research design, utilising both qualitative and quantitative data analysis to report findings related to study objectives. This approach allows for a comprehensive exploration of the research questions and objectives, as it provides the opportunity to gather data through various sources and methods and to analyse and synthesise findings from different perspectives.

Quantitative data

Descriptive data analyses were performed using IBM SPSS Version 25 (IBM Corp, 2020) to summarise the baseline characteristics of the participants. The categorical variables included in the analysis were sex (male/female), the highest level of education (middle/ secondary/higher), work experience (less than 12 months/between 1-3 years/ between 4-5 years/more than 5 years), previous experience attending oral cancer screening workshop (yes/no). There was only one continuous demographic variable used in the analysis - age (years). Summary statistics were reported for the variables, including means, standard deviations, medians, and ranges, to provide a comprehensive overview of the sample.

To assess the impact of the training intervention on knowledge scores, quantitative pre-post assessment data were collected from the participants. For the assessment of paired data on knowledge, attitude, and confidence in the event that the assumption of normality is met, the paired t-test would be employed. However, if normality cannot be assumed, the Wilcoxon signed-rank test would be utilised as a robust alternative. The decision to employ this non-parametric test stems from the nature of the data, which were not normally distributed.

The increase in knowledge scores was specified in percentages, which allowed for a standardised comparison of the magnitude of change across participants. Additionally, Delta scores (calculated as (Post-training score - Pre-training score)/Pre-training score x 100) were measured to show the improvement between the pre-training and post-training assessments. This was done as a way to quantify the magnitude of change and help determine the effectiveness of the training program. A higher Delta score indicates a greater improvement in performance, while a negative Delta score indicates a decline in performance.

Qualitative data

Qualitative data analysis from the semi-structured in-depth interviews in this study was conducted using Thematic Framework Analysis, a method for analysing qualitative data that allows for the identification and exploration of patterns or themes within the data (Gale et al., 2013). For coding, development of framework matrix and data management, the Quirkos software was used (Quirkos Ltd, 2016).

The first stage was transcription: The interviews from India were translated and transcribed verbatim by ZK to allow a better understanding of the interview content. The interviews from Bangladesh were translated and transcribed by the fieldwork collaborators at the University of Dhaka due to language constraints.

The second stage was familiarisation with the interview: In this stage, the researcher became immersed in the data by reading and re-reading transcripts of interviews, taking notes, and identifying preliminary ideas and patterns that emerge from the data. This

stage was crucial in helping the researcher gain a comprehensive understanding of the data and its context.

The third stage involved generating codes: In this stage, the researcher systematically reviewed the data and coded it based on the identified patterns or themes. These codes were generated inductively, i.e., emerging from the data, as well as deductively, based on pre-existing theories or concepts. The codes were used to label segments of text that related to particular ideas or concepts.

The fourth stage involved developing a working analytical framework: A preliminary thematic framework matrix was developed based on themes that emerged from previous studies on similar topic and the interview topic guide. This initial framework was then applied to code several transcripts using an open coding method. The framework was refined as needed to incorporate any new themes emerging from the open coding. Additional categories and codes were added to fully capture the content of the initial transcripts. The final analytical framework matrix comprised the defined categories, codes, and themes to be systematically applied in indexing the remaining transcripts.

The fifth stage involved applying the analytical framework: The analytical framework was systematically applied to all transcripts by indexing them with the relevant codes.

The sixth stage involved charting the data into the framework matrix: In this stage, relevant passages of texts from the transcripts were charted into the framework matrix organised by the categories and codes.

The seventh stage involved interpreting the data: The charted data in the matrix was reviewed to identify patterns, associations, concepts, and explanations in the data. Interpretation of the data was done to understand the attitudes of CHWs and their acceptability of attending the oral cancer screening training workshop. Data was reported as summary of responses and verbatim quotes.

6.3.9 REFLEXIVITY

The stages of framework analysis outlined in the previous section demonstrate a structured approach to data analysis that can help mitigate potential researcher bias. In contrast, the subsequent section on reflexivity emphasises the need for researchers to critically reflect on their potential biases and assumptions, which can influence each stage of the analysis.

Reflexivity involves acknowledging the researcher's positionality, beliefs, and values that can influence their data collection, analysis, and interpretation and provide insights into the research process. It enables researchers to develop a more comprehensive understanding of the social phenomena they are investigating.

As a clinical dentist from India, I incorporated reflective practice during data collection, analysis, and reporting of qualitative data for their study. Recognising the significance of reflexivity in qualitative research, I engaged in continuous critical self-reflection to identify potential biases and assumptions that could influence their interpretation of the data. During data collection, I made an effort to set aside any preconceived notions about the participants and their experiences. Instead, I approached each interview with an open mind and listened carefully to what the participants had to say, allowing their narratives to shape their understanding of the topic at hand.

Similarly, during data analysis, I remained self-aware and reflective of their subjectivity, actively seeking to identify potential biases that may impact their interpretations. For instance, as a clinical dentist, I may have been inclined to focus solely on dental health aspects, possibly overlooking other factors that may influence participants' views and beliefs. As a result, I consciously attempted to broaden their perspective and examine the data from various angles, including social, cultural, and economic factors that may influence participants' experiences.

In reporting the qualitative data, I made an effort to remain transparent about my own biases and assumptions. I acknowledged the limitations of my background and training as a dentist and the potential impact that may have had on my interpretations. By

incorporating reflexivity into reporting, I sought to enhance the credibility and trustworthiness of my research findings.

6.3.10 DATA MONITORING AND MANAGEMENT PLAN

Data monitoring was done to ensure that the data collected was of high quality and completeness. To achieve this, the researcher conducted regular checks of the data collected, including reviewing the completeness and accuracy of the data and checking for errors or inconsistencies. The data monitoring process was done in real-time to allow for any necessary adjustments or corrections to be made promptly.

Data management was done in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018. The study team ensured that all data was collected, stored, and processed in compliance with these regulations. The confidentiality and anonymity of the data were maintained by assigning unique identification numbers to the study participants. The identity numbers were used to identify the data rather than the participants' names or any other identifiable information. All anonymisation processes were done by ZK.

The data was uploaded on a secure University of York server on the day of collection. The server was accessed only by ZK. All audio files and anonymised transcripts were uploaded on the University of York server, and a backup was created on a secured password-protected laptop, which was only accessed by ZK. All data was backed up regularly, and the backup files were stored in secure locations. The data files were also password-protected to prevent unauthorised access.

6.3.11 QUALITY ASSURANCE

In order to ensure the robustness and credibility of the research findings, several strategies were employed to address potential biases, enhance data quality, and maintain consistency and transparency throughout the study. This section outlines the various measures taken to uphold the quality of the research.

Reflexivity

Reflexivity, as a key principle of qualitative research, was embedded throughout the study. The researcher was aware of her own potential biases and preconceptions and took steps to manage them. This process is described in detail in Section 6.3.9

Researcher training and debriefs

To ensure a consistent and standardised approach to data collection, all researchers involved in the fieldwork from Bangladesh (MN, SL, MF, SK) and India (EG, RM, WK) underwent two training sessions prior to the workshop. Training encompassed the study objectives, research questions, training materials, pre and post assessment forms, topic guide and interview techniques (Bangladesh only), ethical considerations, and proper handling of data. Researchers from Bangladesh also participated in mock interviews to familiarise themselves with the protocols and to address any ambiguities or challenges.

A total of 4 debriefing sessions each were also conducted with the teams in Bangladesh and India. These were held following the first and second day of the workshops as well as during and end of the interviews. These sessions allowed researchers to openly discuss their experiences, challenges, and insights encountered during fieldwork.

Member checks

To enhance the validity and credibility of the findings, member checking was incorporated into the study procedures. A sub-sample of 5 participants from India were provided with summarised transcripts of their individual interviews over WhatsApp. They were invited to review the summaries to verify that their experiences were accurately captured and interpreted. Ideally, member checks would have been conducted with all the interview participants in Bangladesh and India. However, due to logistical constraints with the CHWs in accessing and reviewing summaries, only a sub-sample could feasibly participate in this process.

Audit trail

An audit trail was maintained in the form of a research log to document the decisions made during the research process. This log included detailed records of procedures used

to collect and analyse the data as well as changes made during the process. Information regarding issues and challenges that arose during the fieldwork as well as steps taken to address them was also recorded.

6.3.12 ETHICAL CONSIDERATIONS

Ethical approval

Ethical approval was obtained from four different ethics committees before the start of the feasibility study. Approval was first sought from the Health Sciences Research Governance Committee (HSRGC), University of York. Following this, further approvals were obtained from the Institutional Ethics Committee, NICPR, India, the Institutional Review Board, Institute of Health Economics, University of Dhaka, Bangladesh. Ethics applications were also submitted to the National Bioethics Committee, Pakistan and the Ethics Review Committee, the Aga Khan University (AKU), Pakistan however, due to logistical delay, these were not pursued further. A copy of the obtained ethics forms is attached in Appendix 27.

Respect for participant autonomy and informed consent

As detailed in Section 6.3.4 voluntary informed consent was obtained from all participants prior to their participation. They were provided with information sheets detailing the study purpose, procedures, risks and benefits. Participants could withdraw consent at any time without penalty. Consent procedures were designed and administered in a culturally appropriate manner based on community norms.

Beneficence and non-maleficence

Every effort was made to maximise benefits and minimise potential harm to participants. The research aimed to develop knowledge that ultimately benefits communities through training and capacity building in oral cancer screening and tobacco cessation. Potential risks were minimal given the nature of the workshop and data collection. Participants' privacy and confidentiality were protected through secure data

practices as detailed in Section 6.3.10. Procedures for reporting and handling any distress were established.

Cultural sensitivity and contextual appropriateness

The study aimed to ensure that all interactions, procedures, and materials were culturally sensitive and adapted to the local context at each site. Local collaborators from both Bangladesh and India provided guidance to confirm methods were culturally appropriate and acceptable to the CHWs. Interview guides used clear local dialects understandable to participants.

Gender dynamics were considered when planning data collection to ensure both men and women felt comfortable participating. Culturally appropriate norms informed the logistical planning of training workshops, including factors such as meals and scheduling. Overall, the research sought to build local capacity through collaborative partnership and not merely extract data.

6.4 FINDINGS

The results of this chapter are presented as quantitative findings first and then qualitative findings. The following section provides a detailed breakdown of the results:

6.4.1 PARTICIPANT CHARACTERISTICS

A total of 33 CHWs (15 from Bangladesh and 18 from India) consented to take part in the two-day training workshop. The age of the CHWs ranged from 18 years to 50 years with the mean age being 39 (SD=8.2) years. The mean age of CHWs from Bangladesh was 35 (SD=9.3) years and in India was 42 (SD=5.6) years. In terms of sex distribution, out of the total CHWs, 85% were female and 15% were male. Within the two sites, there were 10 females and 5 males in Bangladesh whereas, in India, all the CHWs were female. The majority of the CHWs (64%) had received higher education i.e., class 11 and above. With regards to work experience, out of the total number of CHWs, 70% had more than 5 years of experience, 12% between 4-5 years, 12% between 1-3 years and 6% less than 12 months. Between the two sites, the distribution was similar, with 67% from the

Bangladesh site reporting more than 5 years of experience and 72% from India reporting more than 5 years of experience.

CHWs were asked if they had any prior experience attending oral cancer screening training, workshop or an awareness programme. A total of 32 CHWs responded to this question. Out of that, 67% responded yes. Within each site, 27% attended from Bangladesh while all the CHWs from India (100%) had attended an oral cancer screening programme. Table 32 presents a summary of the participant characteristics.

Table 32: Summary of participant characteristics

Participant Characteristics	Categories	Bangladesh	India	Total
Total CHWs		15	18	33
Age (Mean, SD)		35 (9.3)	42 (5.6)	39 (8.2)
Sex N (%)	Female	10 (66.7%)	18 (100%)	28 (84.8%)
	Male	5 (33.3%)	-	5 (15.2%)
Education N (%)	Higher (Class 11 and above)	11 (73.3%)	10 (55.6%)	21 (63.6%)
	Secondary (Class 9-10)	-	6 (33.3%)	6 (18.2%)
	Middle Class (Class 6-8)	4 (26.7%)	2 (11.1%)	6 (18.2%)
	Primary (Class 1-5)	-	-	-
Work Experience N (%)	More than 5 years	10 (66.7%)	13 (72.2%)	23 (71.9%)
	Between 4-5 years	1 (6.7%)	4 (22.2%)	4 (12.5%)
	Between 1-3 years	2 (13.3%)	1 (5.6%)	3 (9.4%)
	Less than 12 months	2 (13.3%)	0	2 (6.2%)
Prior oral cancer training	Yes	3 (21.4%)	18 (100%)	20 (64.5%)
	No	11 (78.6%)	0	11 (35.5%)

6.4.2 EFFECTIVENESS OF TRAINING IN IMPROVING KNOWLEDGE

Based on self-assessment

Based on the reported results, there was a significant increase in the self-assessment of the CHWs' knowledge. With regards to the knowledge of risk factors of oral cancer and OPMDs, the pre-training mean score was 2.42 (SD=1.032), indicating that, on average, participants had a fair level of knowledge regarding the risk factors for oral cancer and OPMDs prior to the training program.

After the training program, the post-training mean score was 1.83 (SD=0.747), indicating that the participants had a good level of knowledge after completing the training program. The mean difference between the pre-training and post-training scores was 0.59, indicating a statistically significant improvement in knowledge levels (p-value=0.001).

As for knowledge of clinical signs and symptoms, the pre-training mean score was 2.53 (SD=1.047), and the post-training mean score was 1.74 (SD=0.815), indicating that participants had a good level of knowledge after completing the training program. The mean difference of -0.79 (p-value <0.001) indicates that there was a significant improvement in knowledge levels after the training program, with participants on average scoring nearly one point lower on the post-training assessment.

Similarly, the pre-training mean score for knowledge of early detection and screening was 2.50 (SD=0.984), and the post-training mean score was 1.84 (SD=0.688). The mean difference of -0.66 (p-value <0.001) again displays a significant improvement in knowledge l, with participants scoring nearly 0.7 points lower on the post-training assessment on average.

Lastly, with regards to the knowledge of diagnosis and referral, there was a change in mean score from 2.44 (SD=1.076) pre-training to 1.94 (SD=0.854) post-training indicating an improvement of 0.5 points. In conclusion, the findings suggest that the training was effective in improving participants' self-assessment of knowledge regarding screening, see Table 33 for detailed findings of the assessment.

Table 33: Pre- and post-training knowledge change in CHWs

Items	Responses	Pre-training		Post-training		Pre-training Mean (SD)	Post-training Mean (SD)	Mean difference	p-value
		N	%	N	%				
Knowledge of risk factors of oral cancer and OPMDs	Excellent	9	27.3%	11	33.3%	2.42 (1.032)	1.83 (0.747)	-0.59	0.001
	Good	5	15.2%	13	39.4%				
	Fair	15	45.5%	6	18.2%				
	Poor	4	12.1%	-	-				
Knowledge of clinical signs and symptoms	Excellent	7	21%	15	45.5%	2.53 (1.047)	1.74 (0.815)	-0.79	<0.001
	Good	7	21%	9	27.3%				
	Fair	12	36.4%	7	21.2%				
	Poor	6	18.2%	-	-				

Knowledge of early detection and screening	Excellent	6	18.2%	10	30.3%	2.50 (0.984)	1.84 (0.688)	-0.66	<0.001
	Good	9	27.3%	16	48.5%				
	Fair	12	36.4%	5	15.2%				
	Poor	5	15.2%	-	-				
Knowledge of diagnosis, referral	Excellent	9	27.3%	12	36.4%	2.44 (1.076)	1.94 (.854)	-0.50	0.012
	Good	5	15.2%	9	27.3%				
	Fair	13	39.4%	10	30.3%				
	Poor	5	15.2%	-	-				

While the previous section reported self-reported knowledge scores, the upcoming section will present findings based on the pre-training and post-training assessments.

Knowledge about oral cancer and OPMDs

The analysis of the knowledge assessment in the five domains showed an increasing trend in post-training results compared to pre-training results. The highest increase was in knowledge about the age group (84.5% change) as well as lesions with the highest rate of malignant transformation (75.2%). There was no change in scores on knowledge of early signs of oral cancer and OPMDs suggesting that CHWs had prior knowledge. Overall, the average improvement in knowledge about oral cancer and OPMDs was 31.3%. Table 34 presents the results of the pre-and post-training scores as well as the difference between them.

Table 34: Pre- and post-training knowledge scores

Q No.	Description of question	Pre-training %CHWs with correct responses (N)	Post-training %CHWs with correct responses (N)	Delta score (% of difference/pre-training score)
1.	What are the common sites for developing oral cancer and Oral Potentially Malignant Disorders?	63.6 (21)	90.9 (30)	42.9
2.	What is the predominant age group in which these lesions occur?	39.4 (13)	72.7 (24)	84.5
3.	Which of the following is **NOT** an early sign of oral cancer and Oral Potentially Malignant Disorders?	72.7 (24)	72.7 (24)	0
4.	Which of the following is **NOT** the risk factor for oral cancer and Oral Potentially Malignant Disorders?	81.8 (27)	90.9 (30)	11.1
5.	Which of the following potentially malignant lesion has the highest rate of malignant transformation?	24.2 (9)	42.4 (14)	75.2
Average knowledge (%)		56.3	73.9	31.3

Knowledge about oral cancer screening

Analysis of the knowledge assessment of oral cancer screening also showed an increased trend post-training. Overall, the percentage change was the highest for the knowledge of steps for conducting oral cancer screening (400% increase) as well as the most feasible screening method for population-based screening (108%). A slight decrease in knowledge was reported in questions on extraoral examination (-15.8%). Overall, there was an increase in the knowledge regarding oral cancer screening by 44%. Table 35 presents the results of the pre- and post-training scores and the difference between the scores.

Table 35: Pre-and post-training knowledge scores

Q No.	Description of question	Pre-training %CHWs with correct responses	Post-training %CHWs with correct responses	Delta score (% of difference/pre-training score)
1.	Which of the following is the most affordable, feasible, and effective method for population-based screening of oral cancer?	36.4 (12)	75.8 (25)	108
2.	Which of the following instruments should be used for conducting thorough oral screening?	66.7 (22)	87.9 (29)	31.7
3.	Which of these should be the first step in conducting oral screening?	12.1 (4)	60.6 (20)	400
4.	Which of these will you observe during the extra-oral examination?	57.6 (19)	48.5 (16)	-15.8
5.	When observing a suspicious lesion, which of these will you note?	78.8 (26)	100 (31)	26.8
6.	What should be the first step when examining the lips?	24.2 (8)	42.4 (14)	75.2
7.	If you detect a suspicious lesion, where should you first refer the case?	60.6 (20)	69.7 (23)	15
Average knowledge (%)		48.1	69.3	44

6.4.3 EFFECTIVENESS OF TRAINING IN IMPROVING ATTITUDE TOWARDS THE TRAINING

Attending future oral cancer screening workshops

A total of 87.5% of CHWs said in the pre-training assessment that they would attend such a workshop in the future. This number rose to 93.5% in the post-training assessment.

The preferred format for the workshop

The CHWs were also asked for the preferred format for the workshop. In the pre-training survey, the majority of the participants (94%) preferred face-to-face workshops both in Bangladesh (93%) and in India (94%). However, in the post-training survey, there was a marked change in India with 53% preferring face-to-face, 40% hybrid and 7% online.

The importance of community health workers in the prevention and diagnosis

The CHWs were asked about their opinion on the role of CHWs in the prevention and diagnosis of oral cancer and OPMDs. Out of the 32 CHWs who responded, 79% of CHWs from Bangladesh and 72% of CHWs from India considered the level of importance to be high.

6.4.4 EFFECTIVENESS OF TRAINING IN IMPROVING CONFIDENCE OF THE PARTICIPANTS

Confidence in screening for oral cancer and OPMDs

The analysis of CHWs confidence levels in screening for oral cancer and OPMDs revealed a statistically significant improvement after the training program. The mean confidence level increased from 3.50 (SD=1.270) in the pre-training to 4.38 (SD=1.040) in the post-training. The mean difference was 0.88 with a p-value of 0.005, indicating that the increase in confidence was not due to chance alone.

Confidence in taking a medical and dental history of a patient

The results indicate a significant increase in confidence levels of CHWs in taking medical and dental history of a patient after the training. The mean score for confidence level increased from 3.94 (SD=1.014) in the pre-training phase to 4.66 (SD=0.602) in the post-training phase, with a mean difference of 0.72 (p-value=0.005). The majority of CHWs reported being fairly confident to completely confident in taking medical and dental history after the training. This suggests that the training program has been effective in improving the CHWs' confidence in this area of oral health screening.

Confidence in talking to a patient and telling them the results of screening

The results suggest that there was a significant improvement in the confidence of CHWs in talking to patients and telling them the results of screening after the training. Before the training, the mean confidence level was 4.09 (SD=0.995), indicating that CHWs were somewhat confident in this area. After the training, the mean confidence level increased to 4.60 (SD=0.724), indicating that CHWs were fairly confident. The mean difference was 0.51, and the p-value was 0.039, indicating a statistically significant increase in the confidence levels after the training.

Confidence in referring patients to healthcare services

The confidence level in referring patients to healthcare services showed a slight increase after the training. The pre-training mean (SD) was 4.35 (.839), and the post-training mean (SD) was 4.58 (.672), resulting in a mean difference of 0.23 (P-value = XXXX).

Confidence in giving educational advice to the patient

The results show a significant improvement in confidence in giving educational advice after training, with a mean difference of 0.68 between pre-training and post-training scores. The post-training mean score of 4.71 indicates that, on average, CHWs felt "completely confident" in giving educational advice after the training. The p-value of 0.006 suggests that this improvement is statistically significant.

Table 36 presents the detailed results of the assessment of confidence levels of CHWs pre-and post-training.

Table 36: Table representing confidence levels pre- and post-training of CHWs

Items	Responses	Pre-training		Post-training		Pre-training Mean (SD)	Post-training Mean (SD)	Mean difference	p-value
		N	%	N	%				
Confidence in screening for oral cancer and OPMDs	Not at all confident	2	6.3	1	3.1	3.50 (1.270)	4.38 (1.040)	0.88	0.005
	Slightly confident	5	15.6	1	3.1				
	Somewhat confident	10	31.3	4	12.5				
	Fairly confident	5	15.6	5	15.6				
	Completely confident	10	31.3	21	65.6				
Confidence in taking a medical and dental history of a patient	Not at all confident	-	-	-	-	3.94 (1.014)	4.66 (.602)	0.72	.005
	Slightly confident	4	12.5	-	-				
	Somewhat confident	5	15.6	2	6.3				
	Fairly confident	12	37.6	7	21.9				
	Completely confident	11	34.4	23	71.9				
Confidence in talking to a patient and telling them the results of screening	Not at all confident	-	-	-	-	4.09 (.995)	4.60 (.724)	0.51	.039
	Slightly confident	4	12.5	-	-				
	Somewhat confident	5	15.6	4	13.3				
	Fairly confident	12	37.5	4	13.3				
	Completely confident	11	34.4	22	73.3				
Confidence in	Not at all confident	-	-	-	-	4.35 (.839)	4.58 (.672)	0.23	.052

referring patients to healthcare services	Slightly confident	1	3.2	-	-				
	Somewhat confident	4	12.9	3	9.7				
	Fairly confident	9	29	7	22.6				
	Completely confident	17	54.8	21	67.7				
Confidence in giving educational advice to the patient	Not at all confident	-	-	-		4.03 (.983)	4.71 (.643)	0.68	.006
	Slightly confident	2	6.5	1	3.2				
	Somewhat confident	8	25.8	-					
	Fairly confident	8	25.8	6	19.4				
	Completely confident	13	41.9	24	77.4				

6.4.5 EFFECTIVENESS OF TRAINING IN BUILDING SKILLS FOR OPMD SCREENING

Ability to record case history

The results showed that the majority of CHWs were able to accurately record the presence or absence of oral cancer risk factors, with 86% of CHWs correctly identifying the presence of at least one risk factor in the patient's history. In terms of specifying the type of risk factors, 33% of CHWs correctly identified the type of tobacco product used (e.g., gutkha, khaini etc). When asked to specify the frequency of tobacco use i.e., how frequently in a day the patient reported the use of tobacco, 52% of the CHWs overall accurately recorded this information. Similarly, when asked to specify the duration of tobacco use i.e., the length of time the tobacco product is consumed, 53.3 % of CHWs accurately recorded this information. Table 37 presents the findings for each case.

Table 37: Ability to record case history

	% Of CHWs correctly identifying risk factor N (%)	% Of CHWs correctly recording risk factor information		
		Type	**Frequency**	**Duration**
CASE 1	30 (90.9%)	24.24%	45.45%	45.45%
CASE 2	30 (90.9%)	21.21%	54.55%	51.52%
CASE 3	32 (96.7%)	33.33%	57.58%	57.58%
CASE 4	28 (84.8%)	42.42%	45.45%	54.55%
CASE 5	29 (87.9%)	42.42%	51.52%	51.52%
CASE 6	28 (84.8%)	36.36%	57.58%	60.61%
CASE 7	23 (69.7%)	No risk factor present	No risk factor present	No risk factor present

Ability to identify the presence/absence of the lesion

Across the 7 cases, on average 83% CHWs were able to correctly identify the presence or absence of a lesion correctly. When asked to identify the location of the lesion, 72% of the CHWs were able to correctly identify the location of the lesion. They were further asked to chart the lesion location on the mouth map. A total of 57.6% of the CHWs were able to correctly chart the mouth map. Table 38 presents the findings of below each case for identification of lesions.

Table 38: Table representing the percentage of cases correctly identified pre- and post-training

	% Of CHWs correctly identifying the presence/absence of a lesion	% Of CHWs correctly identifying the location of the lesion	% Of CHWs correctly charting the lesion in a mouth map
CASE 1	31 (93.9%)	21 (63.64%)	24 (66.67%)
CASE 2	26 (78.8%)	20 (60.6%)	17 (51.5%)
CASE 3	30 (90.9%)	28 (84.8%)	17 (51.5%)
CASE 4	28 (84.8%)	27 (81.8%)	18 (54.5%)
CASE 5	25 (75.8%)	24 (72.7%)	16 (48.9%) left buccal 9 (27.3%) right buccal
CASE 6	27 (81.8%)	24 (72.7%)	15 (45.4%)
CASE 7	25 (75.8%)	NA (no lesion present)	NA (no lesion present)

Ability to differentiate between suspicious and non-suspicious lesions

Among these CHWs, 27 (94%) were able to correctly identify the presence of suspicious lesions, while 3 (6%) incorrectly identified non-suspicious lesions as suspicious. Table 39 presents the findings of pre and post knowledge scores.

Table 39: Pre- and post-training knowledge scores

	% Of CHWs correctly identifying the suspicious lesion	% Of CHWs referring for routine follow-up	% Of CHWs referring for further head and neck evaluation	% Of CHWs correctly referring for counselling and support services	% Of CHWs referring for tobacco cessation
CASE 1	22 (66.6%)	7 (21.2%)	7 (21.2%)	11 (33.3%)	15 (45.4%)
CASE 2	26 (78.8%)	5 (15.2%)	10 (30.3%)	14 (42.4%)	13 (39.4%)
CASE 3	29 (87.9%)	7 (21.2%)	9 (27.3%)	12 (36.4%)	20 (60.6%)
CASE 4	28 (84.8%)	8 (24.2%)	8 (24.2%)	15 (45.4%)	16 (48.5%)
CASE 5	21 (63.6%)	12 (36.4%)	6 (18.2%)	11 (33.3%)	10 (30.3%)
CASE 6	23 (69.7%)	8 (24.2%)	4 (12.1%)	14(42.4%)	10 (30.3%)
CASE 7	Lesion absent	18 (54.5%)	5 (15.2%)	12 (36.4%)	8 (24.2%)

RESULTS FROM QUALITATIVE STUDY

The purpose of the qualitative study was to explore the experiences and perceptions of CHWs in taking part in the oral cancer screening training workshop in two countries, Bangladesh and India. Semi-structured interviews were conducted with 25 CHWs, seven from Bangladesh and 18 from India. The results of the analysis are presented below under the following themes:

6.4.6 FEASIBILITY OF CONDUCTING THE TRAINING PROGRAM

Feasibility of participant recruitment

In Bangladesh, participants reported that they were selected for the training by the Khulna Mukti Seba Sangstha (KMSS) authorities which is a non-governmental organisation (NGO) and were interested in participating in the study. One participant noted that it was very easy to participate in the study, while another rated the recruitment process as “easy enough”. Similarly, in India, participants reported that they

were informed about the study via phone calls from their superiors or researchers from NICPR.

When asked if anything could be done to improve the recruitment process, one participant remarked on making the selection process more inclusive.

"It seemed alright. The only thing I did not like was that those who did not know how to write were removed from the training. They also had an interest in this training. Through them, more people could have known about the training. But they were rejected because they could not write. They felt sad about this. We should have been more inclusive so that everyone could learn. We enjoyed the training while they were sad." (CHW 07 from Bangladesh).

The CHWs were also asked about how taking part in the training affected their other responsibilities. Some participants reported facing challenges such as this participant from India

"The patient that I was telling you about, I had to make excuses to her that today the hospital is closed. Today the test won't happen. We don't get a fixed salary the only money we get is the incentives when we take the patient to get the check-up done. So that was the only thing that we lost." (CHW 12 from India)

One participant also shared that she had to ask a patient to wait for two days to get her haemoglobin checked, while another mentioned that she had to leave slightly earlier to take a pregnant woman for her check-up. While these findings highlight the challenges faced by CHWs in managing their responsibilities and attending training programs, most of the participants reported being able to manage both comfortably. Some participants reported finishing their work responsibilities in advance, waking up earlier, or leaving the training temporarily to attend to other duties.

When asked how we could improve on this so their responsibilities do not get affected, participants suggested that if they were informed about the training well in advance, it would have been easier for them to plan their schedules and responsibilities accordingly. One participant further said,

"If you had been informed much in advance then it would have been better. Although I do understand that the training won't be postponed because of us. So, we have to leave one or the other. Either leave the training or leave the fieldwork and I decided to leave the fieldwork for the training." (CHW 18 from India)

Another participant suggested that if they were informed earlier, they could have informed the people they work with within the community and made arrangements for their responsibilities. She said,

"Yes ma'am if we know in advance then we can go in the field and tell people that this is our number and don't allot this to anyone else and go and get vaccinations done." (CHW 16 from India)

These suggestions highlight the importance of effective communication and planning when it comes to scheduling training sessions for CHWs. Providing timely and clear information to CHWs about the training can help them manage their responsibilities better, and this, in turn, can lead to better attendance and engagement during training sessions.

Views on the registration process

Overall, participants found the process of registering for the study to be relatively easy. Several participants mentioned that they were contacted by partner organisations in Bangladesh and India, who explained the study and the registration process to them. This initial contact was seen as helpful, as it provided participants with a clear understanding of what was required of them and what they could expect from the study.

Some participants rated the process as very easy, while others found it to be easy enough. The selection process was also viewed positively, with participants stating that it was not too rigid or strict, allowing everyone to take part. Participants appreciated the way they were introduced to the registration process and found it easy to register without facing any difficulties.

One participant mentioned that the fact that they were selected for the training was special to them, given that not everyone gets the chance to attend such training.

"Seeing all the people registering for the training, I was worried whether I would get selected. Everyone has a job. Not everyone gets the chance to attend the training. There were I.A., B.A. pass people there. They do not get a chance to attend this training. On the other hand, I had just passed class 9. The fact that I was selected for this training was so special to me." (CHW 05 from Bangladesh)

In terms of the registration procedure, some participants appreciated the detailed information collected during registration, such as job descriptions and region of work. Additionally, some participants were already registered with the organisation and were called to attend the training based on their prior contact.

"The process of registration was quite easy. We have taken training here before, so our name was in the register. When he called, I came here, I felt that it is necessary to come here to attend this workshop, that's why we came." (CHW 01 from India)

Overall, the findings suggest that the participants had a positive perception of the registration process for the training program. The initial contact with the partner organisations, clear communication from the study team, and availability of support and accommodations for logistical barriers were cited as key factors contributing to the ease of the registration process. The findings provide insights into the participants' experiences and can be useful for improving the registration process for future programs.

6.4.7 FEASIBILITY OF TRAINING

Medium of training

The training was conducted in person in Bangladesh, where participants were invited to attend the training institute, and it was delivered via Zoom in India. The views of the participants on the medium of training (in-person vs. online) revealed that the majority of the participants from Bangladesh preferred in-person training over online training.

They felt that in-person training was easier to understand, communicate, and remember, and provided the opportunity for practical learning. Some participants expressed concerns about technical problems and difficulty in asking questions during online training. Others felt that eye contact and personal interaction were important for understanding and learning effectively, which was not possible in online training.

It is interesting to note that all participants who expressed a preference for in-person training did not mention any difficulty in attending in-person training due to logistical or technical issues. However, participants did mention that they would not have been able to participate in online training due to a lack of access to smartphones, computers, or laptops.

Overall, the findings suggest that participants from Bangladesh preferred in-person training over online training due to its practical nature and the opportunity for better understanding and communication.

Most participants from India reported that they had a good experience attending the training and appreciated the simplicity and ease of understanding the training provided. They also reported that they learned everything that was taught to them and that the model used for training was as effective as in-person training. Some participants mentioned that they did not feel any difference in the quality of learning between the two mediums of training and that they were able to learn the same things regardless of the medium.

"I had a very good experience. If you had come here physically, you would have taught us the same things. You taught us on the Internet in a very simple and easy-to-understand way. If you were here we would have enjoyed it more for sure, however, we still learned everything that you taught us." (CHW 06 from India)

"Ma'am I really liked it. I couldn't even tell that you were not physically there with us because this felt like we were talking face-to-face. So, I enjoyed attending this workshop." (CHW 08 from India)

"Ma'am whatever we're taught face to face we were taught the same thing online. It is up to us to pay attention because sometimes people don't pay attention. I really enjoyed online training." (CHW 12 from India)

A significant number of participants reported that this was their first time attending such a workshop/training online. Participants were further asked if they would be able to attend such training from home. The responses given by the participants show differing opinions and perspectives. Some participants expressed that attending the training from home would be feasible and convenient for them; however, they shared concerns about getting distracted during online training due to phone calls, children's activities, and other disturbances.

"Ma'am I can attend it but at home, the children are studying so they take our phones. I was just saying that it may have been possible to attend from home, but the children would take our phones. They start doing their work and they also disturb us in between. So, we will not be able to pay attention to you" (CHW 08 from India)

"If I do it from home then I will get disturbed. I have kids who will disturb me. Here we could completely focus on the workshop and watch and listen to you. This won't be possible at home because the kids can come in at any time or someone else can come in at any time. We also get calls on our mobile phones all day so we will get disturbed at home. Here, we have to study like its class" (CHW 10 from India)

On the other hand, some participants mentioned that attending the training from home would not be possible due to not having a suitable phone or device to attend the training.

"We don't know how to use a laptop. Also, when we know that we have a training on a certain day then we can give two hours or a fixed 4 hours to it otherwise you know how busy we are in the field. When we are at home people come looking for us but when we go somewhere for training they know that we're gone away for a fixed time, and we will be able to pay attention properly". (CHW 15 from India)

The participants emphasised the benefits of face-to-face training such as the ability to learn practically, convenience, and ease of learning. One participant even mentioned that attending face-to-face training allowed them to establish a better rapport with the trainer and made it easier for them to communicate with her. This highlights the importance of human interaction and building relationships in the learning process.

Apart from their preference for face-to-face training, the participants also emphasised the importance of attending the training together. Many of the CHWs felt that attending the training together helped to raise their motivation and attitude towards learning. For instance, one participant said

"Yes ma'am I will be able to attend from home. However, when we see each other then our motivation gets raised. When we meet each other and the doctors then our attitude towards learning also changes." (CHW 06 from India)

This sentiment was echoed by several other participants who felt that attending the training together helped to create a sense of community and camaraderie among them. They felt that they could learn from each other's experiences and share their own knowledge and insights. Additionally, attending the training together also helped to create a supportive learning environment where they could ask questions and receive feedback from their peers.

The importance of attending the training together was also highlighted in the quote from another participant who said,

"See ma'am, I attended it from the institute, so talking to you feels easier now but if I had not attended it from there, then it would have been harder. I think it's better to go to the institute and attend it from there. You can do interviews from home but for training, it would be better if we go to the institute. It won't be possible to do this from home. This is my opinion and experience." (CHW 13 from India)

Overall, the participants believed that attending the training together helped to create a more engaging and interactive learning experience. They felt that it helped to improve their motivation and attitude towards learning and that it helped to create a sense of

community and support among them. While they were open to the idea of online training, they highlighted the need for a conducive learning environment free from distractions. Thus, it is important to consider the various factors that may affect the ability of CHWs to attend training, such as access to suitable technology, family responsibilities, and workload. Providing flexibility and accommodating these factors can help ensure that CHWs can attend training and continue to improve their knowledge and skills to better serve their communities.

Training centre and training environment

The findings revealed that the majority of the participants had a positive view of the training centre and environment. Most participants found the training centre was well-organised and good, with adequate space, light, and air circulation. They appreciated the respectful behaviour of the doctors and staff, who served food and refreshments. However, a recurring concern was the lack of a fan in the training centre in India, which made the room hot and uncomfortable for some participants. A few participants also mentioned that the lighting could have been better.

"Ma'am it was very well organised. Everything was good apart from one thing. They didn't have a fan, so we were feeling a bit hot but other than that everything was good." (CHW 07 from India)

"Ma'am, it was all very good, but the only thing was that we felt a bit hot there. Other than that, everything was better." (CHW 15 from India)

Overall, the participants emphasised the importance of focusing on the positive aspects of the training and work, rather than finding faults or negatives. This sentiment was reflected in a participant's comment that "There isn't anyone who is faultless."

Timing of training

The timing of the workshop varied between Bangladesh and India. Participants found the timing of the training to be convenient for them. They appreciated the fact that the training did not conflict with their fieldwork or family responsibilities. Some participants

suggested that the training could be conducted after 2:00 pm or 3:00 pm, as they are less occupied during this time.

"The time from 3 pm to 5 pm is alright. This timing is fine. Even if you can increase 1 hour, I do not think that would be an issue. We do not have that much work from 3 pm anyways. Now different people may have different responsibilities. But the timing seemed alright." (CHW 04 from Bangladesh)

"Yes, it was alright for us. We work till 2 pm. So, the timing of training was alright for us." (CHW 05 from Bangladesh)

However, one participant mentioned that it would be difficult to attend training after 2:00 pm due to the hot weather. Participants from India expressed a preference for morning sessions as they felt fresher and could concentrate better.

"Ma'am training should only be done in the morning when our mind is fresh. That way we can understand you well. So, the time for your training was perfectly fine. Also, most of our other training are in the morning. Whatever calls we get we tell them that we can meet you at this time and you can come directly to the hospital, and we will meet you there." (CHW 05 from India)

Additionally, one participant mentioned that the morning sessions were more feasible for them as they did not want to leave patients in the middle of their treatments. Overall, the majority of the participants found the training timing adequate and suggested increasing the length of the training days to learn more.

<u>Length of training</u>

The response of the participants to their experience on the length of the training revealed three themes: 1) The timing was appropriate, and 2) Participants wanted the training to be longer.

The majority of the participants from Bangladesh and India believed that the timing of the training was appropriate, and they did not have any issues with it. For instance, one participant said,

"Yes, the timing was alright. It was perfect. Any less than this wouldn't help us learn better. Fewer days would mean we would be taught more things in less time, which wouldn't help our learning process." (CHW 16 from Bangladesh)

Another participant concurred, saying,

"Ma'am two days are sufficient because it won't affect our patients in the field a lot and we will also be able to attend the training and get knowledge." (CHW 07 from India)

Some participants also wanted the training to be longer. They believed that a longer training period would provide more information and make it easier for them to understand the concepts. One participant said,

"Ma'am if you took more time, you would give us more information. So, if you conduct a workshop for five days, you can explain more things, and you can give us more information." (CHW 05 from India) Another participant added, *"If we had more days, we would have got more information, we would have told our patient more." (CHW 02 from India)*

Only one participant overall thought that the training was too lengthy and suggested that it should be shorter.

"It would be better if it were less lengthy. I had lots of other responsibilities that needed attending." (CHW 13 from Bangladesh)

In conclusion, the analysis showed that participants held different views on the length of the training program. While a few thought it was too lengthy, the majority believed that the timing was appropriate, and others wanted the training to be longer. The study suggests that training programs should be designed to meet the diverse needs of participants.

<u>Content of the training</u>

a. Using photos and videos

Participants expressed their views on the training photos, presentations, and videos, using a range of quotes that suggest a consensus that these visual aids helped facilitate their learning. Participants described feeling positive about their experience with the training materials, using words such as “good,” “great,” and “very good” to express their appreciation. Additionally, participants reported that the visuals used in the training were instrumental in helping them understand complex concepts, such as the signs and symptoms of various oral health conditions.

“Yes, ma’am I understood everything. I was able to look at the pictures and understand them. I will be honest with you I have never seen cancer or any other lesions in real life in a patient. So, when I saw the photos I thought that this is possible, and this is what lesions can look like in people. It was very clear, and you also explained it very well.” (CHW 13 from India)

In particular, participants found the PowerPoint presentations and videos to be the most useful, as these mediums provided clear and detailed explanations of the material being covered. According to one participant,

“The PowerPoint presentation, especially the visual explanations made things easier for us to understand.” (CHW 02 from Bangladesh)

Others highlighted the practical benefits of the videos, such as the ability to practise screening techniques on their own, which they found to be a valuable learning experience. Another participant noted that *“the videos helped us in learning practically. We could practise among ourselves, which helped a lot.” (CHW 16 from Bangladesh)*

Participants from India also concurred saying,

“Ma’am the video you showed on how to examine the patient and what to look for was very good we learned a lot from it. You showed us the patient, all the instruments that are needed, and the kit, so I found it really good, and I was able to learn from it.” (CHW 12 from India)

"The video was very easy to follow. You had shown in the video the instrument needed for screening. There was a stick for retracting the cheeks, a mirror, gloves and a mask. This was very good." (CHW 05 from India)

b. Training activities

The participants were asked to provide their feedback on the training activities that they had taken part in. The findings suggest that the training activities were generally well-received. Most of the participants found the activities helpful in understanding how to check patients for symptoms, where to look in the mouth to detect oral lesions and how to deal with them. Participants found the practical use of tools and mirror to be helpful in examining patients and their teeth. They appreciated the hands-on learning approach and felt more confident in applying their newly learned skills. Participants repeatedly mentioned that they felt more confident and capable after engaging in these activities and that they appreciated being able to practise their skills in a safe and supportive environment.

"It was a very good experience ma'am. We practised how we should act in the field." (CHW 09 from India)

"The activities were really good. It helped us understand things better and also gave us the courage to talk and ask." (CHW 07 from India)

"We felt that after getting the information, we will be able to see the people, we will be able to suggest them and they will be able to get their treatment properly, they will be treated properly, we will see them soon and they will reach the doctor soon, this can save their life." (CHW 01 from India)

"It was done like how first aid is given. We did everything practically. How to examine patients, what physical symptoms indicate what, we practised all these practically while role-playing. It was good." (CHW 05 from Bangladesh)

Participants in particular highlighted the importance of the training activities in helping them to identify oral cancer symptoms that they may not have previously been aware

of. This suggests that the training activities were effective in increasing participants' knowledge and awareness of these lesions, which is a positive outcome.

However, there were some areas where participants felt that improvements could be made. Some participants felt that there could have been more roleplaying or "nukkad natak" and that more activities would have helped engage everyone better and improve learning outcomes.

"*Yes it needs to be increased. More role plays would help us understand better." (CHW 11 from Bangladesh)*

"Yes, more activities would help engage everyone better." (CHW 02 from Bangladesh)

"There should have been a few more activities, the more the better it is." (CHW 09 from India)

"Ma'am, it was very good. However, if it was possible to do a nukkad natak then it would have been even better. If there are people who don't understand something, they're able to understand through nukkad natak. Not everyone is alike, not everyone has the same learning capacity. However, through this, we will be able to retain something." (CHW 06 from India)

These suggestions indicate that the participants were interested in gaining more practical experience and may have benefitted from additional opportunities to practise and apply their knowledge.

c. Written materials:

Participants' views on the provision of written materials revealed varied responses. Participants from Bangladesh generally found the handbooks helpful, with one participant noting that it contains all kinds of useful information. However, some participants expressed their preference for coloured photos instead of black and white photos. On the other hand, participants from India had mixed views on the provision of written materials. Some participants mentioned that they were not given any materials

to take home, while others reported being provided with materials that they studied in the institute.

"We were not given any materials to take home. We were only given a pre-test and a pro test. We were given the materials that we sat and studied in the institute" (CHW 03 from India)

"No ma'am I did not receive any such materials." (CHW 04 from India)

"No ma'am we were not given training material to read or take home we were only given a questionnaire on the first day. We had a pre-test and a post-test. It would be better if we were given written materials because we would be able to revise more." (CHW 10 from India)

One participant found the materials to be really good but mentioned that they understood more after the actual training. Another participant reported taking photos of the materials on their mobile phone and going through them later during their journey.

Interestingly, some participants expressed a desire for written notes to be provided so that they could revise the information at a later time. One participant noted that they were able to answer the assessment questions after having seen the photographs but mentioned that it would have been even better if they had been given written notes to revise the information. Another participant reported being too busy to take out time to read anything after their household work.

"Ma'am see, ASHA bahus don't get so much time to read. When we come from outside, we also have to do our household work, so we don't get a lot of time. At least I know that I'm very busy. We don't have a fixed time, we keep on going from one place to the other all day and get tired, so I don't think that after coming home we will be able to take out time to read anything. But some of them can read as well if they want." (CHW 13 from India)

In conclusion, the findings suggest that the participants had largely positive views of the training photos, presentations, and videos. The training activities were generally effective in achieving their intended purpose. While there were some areas where improvements could be made, the feedback from the participants highlights the value of hands-on learning and the practical use of tools in training programs. Future training sessions could potentially incorporate more roleplays and practical activities to enhance the participants' learning outcomes. It also highlights the importance of providing written materials to participants, as it can help them revise and retain information better and the need to consider the participants' preferences, such as the use of coloured photos, to improve the effectiveness of the materials provided.

d. Practical demonstration

In Bangladesh, where the workshop was face-to-face, the participants found the practical demonstration very helpful. However, in India, where the workshop was conducted online, participants had differing views.

Some participants believed that the practical demonstration provided through videos was enough, while others believed that it would have been better if more practical demonstrations were done. Participants who believed that more practical demonstrations were required suggested that they should have been given an opportunity to see each other do it. One participant mentioned that they should have been given one or two hours to demonstrate a practical where one person becomes the patient, and the other person becomes the doctor.

"Ma'am what you taught online was OK. What you showed in the video was practical. You showed us how to examine and what to look for. If in the future you want to show us the practical in person then I am happy to attend that too." (CHW 12 from India)

"Ma'am, personally I think that I will be able to do it, but I think we should have been given an opportunity to see each other do it. One or two hours should have been kept to demonstrate a practical where one person becomes the patient and the other person becomes a doctor. See ma'am even if the way we talk is not 100%, at least the practical

parts, the way we do examination should be really good. This is only my opinion. I don't know about others." (CHW 13 from India)

"Ma'am I can't say anything for sure until I do it myself. That's why I was saying that there should have been a practical too. I think I can do it and maybe when I go on my shift I will be able to do it but I'm not sure where I will be making errors. This is just my opinion even if we had taken half an hour more we should have done a practical to see whether we are able to do it properly or not. First, we should have done it on each other and then the third person or the patient." (CHW 18 from India)

Participants also mentioned that they would have absorbed the practical knowledge even more if it was done face-to-face. A few believed that the most important focus should be on the practical, and the training felt short in that aspect. Some participants mentioned that the training should have included a practical demonstration of oral cancer screening.

Overall, participants suggested that doing a practical is important as it helps in remembering the subject matter better. They believed that practical demonstrations should have been included in the training to ensure that they were able to do it correctly. Participants were of the opinion that just watching or doing a survey won't be able to tell exactly what disease it is.

<u>Experience of training</u>

a. Language used

The results of the qualitative analysis of participants' views on the language used in the training indicate that the participants found the language to be easy to understand and comprehend. The language was described as simple, clear, and easy to follow by most participants. Participants appreciated the trainers' method of using language that was similar to their own and not using difficult or complex words that they might not understand. They also appreciated the trainers' friendly and approachable manner of teaching, which made it easier for them to understand and learn.

"No ma'am the language used was very good. You used the same language as us. There was no problem in understanding." (CHW 05 from India)

"Ma'am the language was very easy to understand. In the beginning, I thought that we might not be able to do this. We won't be able to understand things online but then once it started, I really liked it. You may have seen in the video, that I couldn't stop looking at you on the screen. If you ever see the full video, you know I didn't get distracted even for a minute." (CHW 13 from India)

"No ma'am, it was very good because we don't understand English. You taught us very well in Hindi. You did not use even a single word of English that we couldn't understand. It was very simple and easy. Your method was very good." (CHW 15 from India)

Some participants from India specifically mentioned that the trainers' use of Hindi made it easier for them to understand, as they did not understand English. Others mentioned that they were initially worried about being able to understand the online training, but the language used by the trainer was so clear and easy to follow that they were able to focus on the content without getting distracted.

Overall, the participants' positive feedback on the language used in the training indicates that the trainer was successful in communicating the material effectively and making it accessible to participants with varying levels of language proficiency. The trainers' approach of using simple and clear language and making efforts to connect with the participants on a personal level was appreciated by the participants and contributed to a positive learning experience.

b. Information given

Most participants felt that the information provided was adequate, with some participants suggesting that additional information would be beneficial. Some participants noted that they found the training challenging at first, but that they were able to understand the information more easily as the training progressed.

"Yes, at first it seemed hard. Then when we were taught the same thing twice, then we could understand those. When they would teach us the way we could understand, then it was easy to understand." (CHW 05 from Bangladesh)

"I found everything tough on the first day. But from the 2n^{d} day, when everything was being shown via PowerPoint presentation, I started to be able to understand and learn. I am not that educated to be honest. I am just experienced in my field." (CHW 08 from Bangladesh)

"Ma'am, this is very important information. How do I say this.. until someone doesn't have anything, everything is fine. As soon as someone gets a problem, it can mean the difference between life and death and only a patient can tell that. So according to me, this was very important. If someone's life can be saved or their money can be saved or their time, then it is the most important thing to us. This information was very useful." (CHW 13 from India)

Several participants emphasised the importance of being able to help people quit tobacco and suggested that additional information on how to do so would be beneficial.

"We meet a lot of tobacco users in the field, so a lot of people suffer from these kinds of problems. So, it was very important for us to know about these things." (CHW 14 from India)

Participants expressed the view that the information provided was important and useful, and that it would enable them to better serve patients in their communities. Overall, participants appeared to have a good understanding of the information provided and were enthusiastic about putting it into practice in their work.

c. Opportunity to ask questions

The participants generally had positive views on the opportunity to ask questions during the training. Many of them stated that they were able to ask questions and get their desired answers. Some participants appreciated the trainers for explaining answers in detail, repeating information when needed, and helping them understand better.

There were also a few participants who suggested that more questions could have been asked, either from them or from the trainers to the participants, to enhance learning. One participant specifically mentioned that "weaker students" should be given more opportunities to answer questions to assess their understanding. Overall, the results suggest that the opportunity to ask questions during the training was perceived positively by the participants and that it helped them to better understand the training content.

d. Break time

It seems that the majority of participants were satisfied with the breaks given during the training. Many of them reported that they used the break time to discuss the topics covered in the training, refresh themselves with tea and snacks, and attend to their personal needs such as using the washroom.

A few participants suggested that the break time length could be increased to 20 minutes instead of 10 minutes, but the majority did not express any dissatisfaction with the length of the breaks. Some participants even noted that if the breaks were any longer, too much time could be wasted.

Overall, the participants seemed to appreciate the breaks given during the training as a necessary breather and time to refresh and concentrate on the training again.

6.4.8 FEASIBILITY OF DATA COLLECTION METHODS

Filling out the assessment questionnaire

When asked about their views on the pre-post training assessment questionnaire, participants had different views. Some participants found the questionnaire challenging to understand before the training, but after the training, they were able to understand and fill out the questionnaire easily. Some participants thought that the questionnaire had too many questions and suggested that it should be shortened. Others found the language of the questions difficult to understand and suggested that simpler language would be better. For example, one participant said, *"Some of the questions were tough*

to understand. Simpler language would help." Other participants echoed this sentiment, with comments such as *"Simpler question language would help. Many questions were tough to understand*" and *"Simpler language would be better."* However, not all participants had difficulty with the language, with some stating that the language was easy enough to understand, such as *"The language was also easy enough to understand"* and *"No, it was simple enough.*" Some participants also noted that the trainers helped them understand better.

Some participants felt that even if the questions were tougher, they would be able to understand them because of the training they received.

Upon further exploration of participants' views on the length of the questionnaire, some participants found the number of questions to be excessive, while others felt that it was appropriate. One participant suggested that shortening the questionnaire could be helpful. Another participant mentioned that the questions were too lengthy and would have preferred smaller questions. However, some participants felt that the length of the questionnaire was adequate and that the provided options were suitable. One participant expressed that the lengthy questionnaire was necessary for proper understanding and learning, and another participant left the questionnaire unfinished, finding it too long. Therefore, it can be concluded that while some participants were satisfied with the length of the questionnaire, others found it to be too long or cumbersome, and suggested that it could be shortened or made more manageable.

When asked if they were given sufficient time to fill out the questionnaire, some participants felt that the time given to complete the questionnaire was adequate, and they were able to finish within the given time frame. Others felt that the time limit could have been longer, as they rushed to answer some questions without thinking. One participant suggested that a higher time limit could have been helpful. Some participants could not remember exactly how much time they took to complete the questionnaire, while others estimated it to be around 20-30 minutes. One participant expressed that the time given was sufficient, while another suggested that more time

could have been beneficial, as participants may have forgotten some things after the training.

In order to understand if the participants' experiences were generalised or varied based on whether they filled out the questionnaire pre- or post-training, it was found that many participants experienced nervousness while filling out the pre-training questionnaire, but after the training, it became easier for them to answer the questions. Some participants mentioned that they had a better understanding of the questions after the training and could answer them with ease. One participant mentioned that the questions were initially hard to understand, but after the training, they could answer them easily. Another participant expressed that they did not find it hard initially as they were from the health sector but had a better understanding of everything after the training. Some participants suggested that the timing and number of questions were not an issue after the training, and it was not too lengthy. Overall, the participants had a positive experience after the training while filling out the questionnaire.

When asked about suggestions for improving the questionnaire, one suggestion was to make the questionnaire shorter as it could be time-consuming for some participants. Another suggestion was to have coloured photos instead of black and white ones to better understand the questions and see everything clearly. One participant recommended including written instructions along with the photos in the questionnaire to avoid confusion. Additionally, some participants suggested taking more time to explain the questions in the case studies.

Training on using mouth map

Participants were also asked about their views on using the mouth map. Some participants found it to be very useful, saying that it helped them to understand the different parts of the mouth and to identify lesions more easily. For example, one participant stated that *"If we go and do a check-up using a mouth map then we will know clearly what parts we need to check,*" while another said that *"When you have a mouth map then it's easier to understand."* However, some participants struggled to understand the mouth map initially, with one participant saying that *"There were some*

things that I didn't understand" and another suggesting that it could have been explained more simply. Nevertheless, many participants did eventually come to understand and appreciate the mouth map, with one participant stating that *"Ma'am you taught us about the mouth map. Initially, we didn't understand it but then the second time when you repeated it, I was able to understand it."* Overall, it seems that the mouth map was a useful tool for many participants, but that some may have needed more guidance or explanation to fully understand its benefits. Additionally, several participants suggested that the mouth map should be included in future training programs, indicating that they believe it to be an important tool for use in the field to perform oral cancer screening.

6.4.9 ASSESSMENT OF KNOWLEDGE

The participants reported gaining new knowledge from the training that they did not have before. The training improved their ability to identify the symptoms of oral cancer and provided them with a deeper understanding of how to counsel patients who may be affected by the disease. They also gained knowledge of the harmful effects of tobacco substances and the importance of early detection and treatment of oral cancer.

One participant reported, *"I also learnt many new things. Like where this cancer can affect or how this looks like. In what situation do we have to refer to?*" Another participant shared, *"After the training, I think I can identify [problems] better.*" Participants also reported learning about the various signs and symptoms of oral cancer, such as white lesions, red lesions, and lumps in the mouth. As one participant noted, *"The training showed what happens when tonsil turns worse. Why is it worrying? Without attending this training, I would not be able to know and see all these."*

Participants also gained knowledge about the relationship between tobacco use and oral cancer. One participant stated, *"I did not know long-term smoking and abusing tobacco substances could cause gums to swell or other negative side effects and gradually lead to cancer. So, after attending this training, I am better informed."* Another participant shared, *"I can also tell them what harmful practices like tobacco substances*

lead to cancer. I can advise them on how to stay away from such habits. So, the training was helpful enough."

Participants also felt more confident in their ability to detect and counsel patients with oral cancer after completing the training. As one participant noted, *"I felt like I was a doctor. I felt that I know a lot and can apply them. I felt happy knowing new stuff. Actually, it felt so good the way we were taught these. You see, I am now able to mention everything. I gained this knowledge from the training. This is why I could say all these."*

6.4.10 ASSESSMENT OF COMPETENCY

Scenarios-based situations

During the training, participants' competency was assessed in identifying suspicious oral lesions using case studies. The interviews further explored their competency by giving them case scenarios and asking what they would do. Based on the interviews, the participants in the training seemed to have a good understanding of how to approach patients with oral lesions. They were able to identify potential red flags and knew when it was necessary to refer patients to a specialist for further evaluation.

The participants were also knowledgeable about the proper steps to take during oral cancer screening. They mentioned using a mouth mirror to examine the tongue, palate, and cheeks, and looking for lesions, checking the colour, size, and shape.

When asked about what they would do next if they approached a suspicious lesion, most of the participants agreed on the need to refer the patients to healthcare centres or hospitals. For instance, some mentioned that they would refer patients to dental hospitals or government hospitals, while others said they would advise patients to visit nearby urban healthcare centres or addiction cessation centres. Some participants also suggested that they would provide the patients with detailed information about what to do next, such as giving them addresses, telling them what public transport to take, or recommending them to visit specific doctors/dentists.

Counselling the patients'

Participants were assessed on their competency in counselling patients after conducting oral cancer screening. Some common themes among the participants' responses included:

Encouraging patients to seek medical treatment: Many of the participants said they would advise patients to visit a doctor or healthcare centre if they were experiencing symptoms or had concerns about their oral health. Some participants also emphasised the importance of getting regular check-ups and screenings.

"I will try to make them understand. If needed, I will take the patient's family's help if they understand." (CHW 11 from Bangladesh)

Educating patients about health risks: Several participants spoke about the harmful effects of tobacco use and its link to cancer. They emphasised counselling participants regarding the importance of quitting tobacco and other addictive substances to improve ones' health.

"I will say that life is very precious. These things are useless. Try to slowly get rid of this habit. This will lead to the loss of your life it will destroy your life. Your kids' lives will be affected. This is a very bad thing. We tell people about not using tobacco. We have this knowledge that tobacco is responsible for a lot of cancers. When we go to a home and see people, we always tell them about the ill effects of tobacco use." (CHW 03 from India)

"Of course, I will not mention cancer to them. But I will warn them of harmful practices. Tell them that such practices may lead to cancer in 10 years. I advise them to go visit a doctor and seek treatment." (CHW 02 from Bangladesh)

Using empathy and compassion: Some participants acknowledged that patients might be scared or hesitant to seek medical treatment and emphasised the importance of being supportive and understanding. They also spoke about the need to listen to patients' concerns and address them in a caring manner.

"Ma'am I would tell them that this is just the beginning, this is the right time for you to get yourself checked. With the right treatment, you can get better. Make sure you eat and drink properly. So, get yourself checked at the right time." (CHW 08 from India)

"Ma'am I will tell them that first of all, it is an early lesion and if they take medicine and get treatment then it will get better. If they go to the doctor and get the proper check-up done, the doctor will give them the right medicine and they will get better." (CHW 09 from India)

Overall, the participants' responses suggest that they have a basic understanding of how to counsel patients about oral cancer-related health issues.

Tobacco cessation advice

Participants were also asked about how they would advise people to quit tobacco use. Some of the themes that emerged from their responses were:

Emphasising the harmful consequences of tobacco use: Most participants said they would advise their patients to quit using tobacco substances, citing the health risks and harmful effects they can cause, such as cancer, tuberculosis, and decreased immunity. They highlighted the risk of passive smoking and advised them to avoid places where people smoke or abuse tobacco products.

Personal experiences: Some participants shared their personal experiences of helping their family members or friends to quit using tobacco substances. They talked about their efforts in the past to make their loved ones aware of the risks and consequences of tobacco use and how they tried to make them quit.

Persistence and follow-up: Several participants mentioned that convincing people to quit using tobacco products requires persistence and follow-up. In the past, they tried to visit people who did not take them seriously, and some even informed the manager of the fieldwork centre to keep an eye on them. They advised someone in the family to ensure that the patient does not smoke.

Encouragement: Many participants said they would try to encourage patients to quit tobacco use by suggesting alternative activities. They would also motivate patients by telling them that giving up tobacco use would make them healthier and happier in the long run.

Challenges: Participants were aware of the challenges they may face when giving tobacco cessation advice in the field. Some participants mentioned that it will be challenging to convince people to quit using tobacco products, as some may not believe in the harmful effects or may not want to give up the habit. They also mentioned that some people might take their advice but not act on it. Participants said they would use various strategies, such as recommending alternative snacks or gradually reducing tobacco intake, to help patients quit. However, participants also acknowledged the challenges of convincing people to quit and the need for effective communication and education to bring about behaviour change.

When asked if there were any alternate strategies they would use to help people quit in their communities, participants shared a few. One strategy was to seek support from influential figures in the community, who could encourage people to listen to them and raise awareness about the harmful effects of tobacco. They believed that the support of respected community leaders could make their job easier and help them to gain patients' trust. Participants also suggested involving family members in the process to ensure the person gives up the harmful practice. Some participants also mentioned the importance of providing medicine to patients who want to quit smoking as just talking or advising alone might not work for everyone. They suggested that patients need medication to help them overcome their addiction, and the availability of medication could create a significant difference in the success rate of smoking cessation programs. One participant even talked about their personal experience, stating that despite being aware of the harmful effects of tobacco, they were unable to convince their husband to quit smoking. This highlights the challenges faced by health workers in encouraging people to quit smoking and the need for effective strategies to overcome these challenges.

Despite the difficulties, the majority of participants were committed to promoting good health in their communities and believed that their efforts could make a difference.

6.4.11 CONFIDENCE IN CONDUCTING ORAL CANCER SCREENING

The participants expressed a varying degree of confidence in their ability to apply the knowledge and skills gained from the training. Some participants stated that they felt confident enough to detect oral cancer and OPMDs, while others felt they needed more training or field experience to feel fully confident.

One participant mentioned that *"It's not possible to be 100% accurate all the time. But I believe I am confident,*" suggesting that despite knowing the limitations of their skills and knowledge, they were still confident in their ability to make a difference. Another participant mentioned, *"I feel very confident about applying the lessons learnt in the field,"* indicating that they were confident in their ability to use the knowledge and skills they had acquired.

Overall, the participants expressed a positive attitude towards their increased confidence in their ability to detect oral cancer. One participant stated, *"I would rate my confidence level 5,"* indicating that they were very confident in their ability to apply the knowledge and skills gained from the training. Another participant said, *"I feel very confident,*" while another mentioned, *"I feel confident enough.*" These quotes indicate that the training had a positive impact on the participant's confidence in their ability to detect oral cancer.

However, some participants still felt they needed more training or experience to feel fully confident. One participant mentioned, *"I believe I am still not fully confident enough to detect oral cancer. With time my confidence will increase.*" Another participant said, *"Increasing the number of days for training would help."* These quotes suggest that while the participants felt more confident after the training, they still recognised the importance of continued learning and experience to further increase their confidence level.

6.4.12 ACCEPTABILITY OF THE TRAINING PROGRAM AND ITS PERCEIVED IMPACT/SUSTAINABILITY

Perceived benefits and impact of the training

The participants in the training expressed a range of perceived benefits from their participation. Many participants highlighted the value of the training in improving their knowledge about oral cancer, its causes, symptoms, and risk factors. For example, one participant commented that *"The training helped us a lot to know about it in detail,*" while another participant stated that *"After the training, my knowledge gaps were filled. I know the symptoms of oral cancer now.*" Participants also spoke about how the training had equipped them with the skills and tools needed to detect oral cancer and advise patients on appropriate measures. One participant stated, *"I can now detect this disease in the field, properly advise on taking necessary measures and refer them to appropriate doctors.*" Participants also noted that the training had improved their ability to educate others about oral cancer and the importance of self-care practices. Several participants expressed their belief that the training would have a positive impact on the communities they serve. For example, one participant stated that *"If people are health conscious in the communities that we work, it is good for us,*" while another commented that *"The way you organised it if you can continue this, I believe it will reduce the risks of cancer in people."* However, some participants also acknowledged the limitations of their efforts, given the scale of the problem and the need for broader systemic changes, such as improved healthcare infrastructure and government action. Overall, the participants expressed a desire to share their knowledge with others and called for more widespread dissemination of the training to other CHWs as they believed that it had provided them with valuable knowledge and skills to benefit both themselves and the communities they serve.

Participants future recommendations

The participants provided valuable feedback on the training program and suggested various improvements. One participant suggested that the training should be conducted in various sectors like in different camps to help health workers better. Another

participant stated that while the current training was good enough they would benefit from recurring training. The suggestion of conducting follow-up orientation programs and supplying health workers with instruments and tools like mirrors, gloves, and hand sanitiser so they could carry out this work in the field was also recommended. Many participants emphasised the need for longer training sessions, up to 4-5 days, one week or 15 days, and the importance of locally influential people's support. One participant suggested that if the trainers kept following up with them on the lessons covered in the training and kept them updated, it would greatly benefit them. Some participants also felt that the training was sufficient and did not need any changes. Overall, the participants' feedback indicated that the training program was effective but needed some improvements, such as longer training sessions, follow-up orientation programs, and supplying associated tools.

6.5 DISCUSSION

This chapter aimed to explore the feasibility and acceptability of training CHWs for oral cancer screening in two urban communities in Bangladesh and India. The findings of the study provide important insights into the potential for CHWs to be trained effectively for OPMD screening in these countries. The following sections present the summary of the key findings of the study under its respective themes.

Feasibility of recruitment and registration

Recruitment and training are essential components of any community-based health intervention program for CHWs. The aim was to recruit and train 15 CHWs from each site in Bangladesh and India. However, 33 CHWs were successfully recruited, which was a positive outcome. Over-recruitment in India could be attributed to NICPRs' direct links through previous CHW training programs conducted there, providing access to a larger pool of potential CHWs. In both institutes gatekeeping was utilised. While in Bangladesh, gatekeepers were utilised by working with NGOs who had direct contact with potential CHWs, resulting in successful recruitment within a short period. In contrast, NICPRs' direct links with CHW training programs were leveraged in India, resulting in successful recruitment.

Gatekeeping is a widely used strategy in community-based health interventions for recruiting participants, including CHWs. The gatekeeping approach involves working with local community leaders and healthcare providers who have direct contact with potential CHWs to help recruit them for the study (Patterson et al., 2010).

Several studies have demonstrated the effectiveness of the gatekeeping approach in recruiting participants for community-based health interventions. For example, a study by Patterson et al. (2011) found that engaging with gatekeepers was an effective way to recruit young adults from vulnerable populations for a research study. The authors noted that gatekeepers were able to provide valuable insights into the recruitment process and help identify potential participants.

In terms of the registration process, registration of CHW for the study proved to be a feasible process. Participants found the registration process to be straightforward and easy to follow, which facilitated their involvement in the study. In addition to the ease of registration, participants also appreciated the initial contact they had with the study team. This provided them with a clear understanding of the study requirements and what they could expect from their involvement in the study. This is consistent with previous studies that have shown that providing clear and concise instructions to potential study participants can help to increase recruitment rates and promote participant engagement (Patel et al., 2003).

Feasibility of training CHWs

Training for CHWs was delivered using two different models in Bangladesh and India. The results showed that, while the majority of the participants preferred face-to-face training before the training (93% from Bangladesh and 95% from India), there was a marked change in preference following the training. Post-training, all participants from Bangladesh preferred face-to-face training. Conversely, in India preference for hybrid and online training increased by almost 50% indicating that the format in which the training was delivered had an impact on the participants. Upon further exploration during the interviews, participants from Bangladesh remarked that in-person training was easier to understand, communicate, and remember, and provided the opportunity

for practical learning. They expressed concerns about technical problems and difficulty in asking questions during online training and felt that eye contact and personal interaction were important for effective understanding and learning, which was not possible in online training.

In contrast, participants from India reported that they learned everything that was taught to them and found the model used for training to be as effective as in-person training. These participants mentioned that they did not feel any difference in the quality of learning between the two modes of training and that they were able to learn the same things regardless of the medium. However, it was observed that while participants did prefer online or hybrid modes of training, the majority of them still preferred to attend the training at the institute. At first, it appeared that lack of technology was the key reason, but further exploration found that even participants who had access to technology at home preferred to attend training in a group setting. They cited an increase in motivation towards learning and the ability to avoid disturbances at home as reasons for this preference.

Several studies have investigated the effectiveness of different modes of training for CHWs. A study conducted in Pakistan found that face-to-face training was more effective than online training in improving CHWs' knowledge and skills related to maternal and child health (Khowaja et al., 2016). Similarly, a study in Ethiopia found that face-to-face training was more effective than online training in improving CHWs' knowledge and skills related to malaria prevention and treatment (Banteyerga et al., 2004).

Moreover, other studies have found that online training can be just as effective as face-to-face training for CHWs. For example, a study in Kenya found that CHWs who received online training had similar levels of knowledge and skills related to malaria prevention and treatment as those who received face-to-face training (Wafula et al., 2018). Another study in India found that online training was as effective as face-to-face training in improving CHWs' knowledge and skills related to HIV prevention and treatment (Raj et al., 2016).

The findings from these studies are consistent with the results presented in this chapter, which suggest that the effectiveness of training for CHWs can vary depending on the mode of delivery and the preferences of the participants. Therefore, it is essential to consider the context and needs of the participants when deciding on the mode of training for CHWs, as it can significantly impact the success of the training.

Effectiveness of training in improving the competencies in CHWs'

Knowledge and skills

The present chapter has found that the training program was effective in improving participants' knowledge of the learning outcomes. The self-reported outcome showed that participants had a fair level of knowledge regarding the risk factors, clinical signs and symptoms, early detection and screening, as well as diagnosis and referral of oral cancer and OPMDs prior to the training. However, after completing the training program, participants reported a good level of knowledge in these areas. The findings from the questionnaire revealed a significant increase in participants' knowledge after completing the training program. The average improvement in knowledge about oral cancer and OPMDs was 31.3%, with a 44% increase in knowledge regarding oral cancer screening. These results suggest that the training program successfully enhanced participants' knowledge of oral cancer and OPMDs, which could potentially lead to earlier detection and treatment of these conditions.

The findings of the present chapter provide evidence that the training program was effective in enhancing CHWs' skills in various aspects of OPMD screening. Specifically, the majority of CHWs accurately recorded the presence or absence of oral cancer risk factors, and a significant number specified the type, frequency, and duration of tobacco use. A high percentage of CHWs correctly identified the presence or absence of a lesion, charted the location of the lesion on the mouth map, and differentiated between suspicious and non-suspicious lesions. In interviews, the participants demonstrated the proper steps for oral cancer screening, including using a mouth mirror to examine the tongue, palate, and cheeks and checking for lesions, colour, size, and shape. They also

had a clear plan of action for referring patients to healthcare centres or hospitals for further evaluation.

This is also evidenced in a study by Thampi et al. (2022) which assessed the feasibility of using CHWs for screening and early detection of oral cancer using a mobile application capturing system in resource-deficient regions of India. The study found that trained CHWs were able to perform oral cancer screening programs effectively. These results suggest that CHWs can effectively contribute to the early detection and screening of oral cancer in resource-constrained settings, highlighting the potential impact of training programs in improving the knowledge and skills of CHWs.

Moreover, the participants displayed a good understanding of the health risks associated with tobacco use and the importance of counselling patients to quit. They emphasised the need for empathy and compassion when communicating with patients, and the importance of persistence and follow-up in helping patients to quit tobacco use. The participants acknowledged the challenges they may face when giving tobacco cessation advice and suggested alternative strategies, such as involving community leaders and family members and providing medication, to increase the success of smoking cessation programs. These findings suggest that the participants have the necessary knowledge and skills to effectively counsel patients on tobacco cessation and oral cancer-related health issues. The study by Sarkar et al. (2017) on the effectiveness of a brief community outreach tobacco cessation intervention delivered by CHWs further supports that CHWs can be effective in promoting tobacco cessation in LMICs.

Overall, these findings suggest that training programs for CHWs can be effective in improving their skills and knowledge regarding oral cancer screening, which is critical for the early detection and treatment of these conditions.

Attitude and confidence

The majority of CHWs in the study expressed a positive attitude towards the training, indicating their willingness to attend future workshops and the high level of importance in the prevention and diagnosis of oral cancer and OPMDs. The results also showed a

statistically significant improvement in the participants' confidence levels in screening for oral cancer and OPMDs, taking medical and dental histories, talking to patients, telling them the results of screening, and giving educational advice. Upon further exploration through interviews, some participants still felt the need for more training or experience to feel fully confident. These findings suggest the importance of continued learning and experience to further increase the CHWs' confidence levels in oral health screening.

The existing literature also supports the evidence that training programs can improve CHWs' attitudes and confidence. Abdel-All et al. (2017) conducted a systematic review of CHW training for cardiovascular disease management, and Sibeko et al. (2018) conducted a study on mental health training for CHWs, both of which showed that training can improve CHWs' knowledge level, confidence, and attitudes towards the care of patients. Abdel-All et al. (2017) found that all eight studies included in their review showed improved knowledge levels after training, and two studies demonstrated knowledge retention six months after the intervention. Sibeko et al. (2018) showed that most CHWs demonstrated significant improvement in knowledge, which was sustained at three months. In addition, there was a significant improvement in confidence, along with changes in attitude, indicating improved benevolence, reduced social restrictiveness, and increased tolerance for the rehabilitation of the mentally ill in the community. The training programs in both studies were also found to be acceptable and feasible.

Acceptability of training

The acceptability of the training program was demonstrated by the high level of participation and engagement among the CHWs. The results showed that overall, participants were satisfied with the centre where they attended the training, the duration, and the length of the training. Having the training at two different times, based on prior discussion, worked well for the participants. Participants in Bangladesh who attended in the late afternoon remarked that they had finished their responsibilities and could attend the training. Similarly, participants from India remarked that they preferred

morning sessions because once they are in the field, it is hard to leave their patients or duties. This emphasises the need to consider the schedules of CHWs and the importance of scheduling training sessions with the flexibility to accommodate their availability

The acceptability of the training contents was assessed based on the use of photos and videos in the training materials. CHWs in both Bangladesh and India expressed positive feedback on the use of visual aids in facilitating their learning. They found the training photos, presentations, and videos to be effective, great, and very helpful in comprehending complex concepts related to oral health conditions. The importance of using visual tools, such as photos, videos, and presentations, in facilitating learning and increasing knowledge retention has also been demonstrated in studies by Shabiralyani et al., (2015) and Bobek and Tversky (2016). In their study, Bobek and Tversky found that creating visual explanations improved learning compared to verbal explanations. Similarly, a review of the literature on the use of visual aids in health education programs found that these aids can improve knowledge retention and facilitate the transfer of learning into practice in people with low literacy (Mbanda et al., 2021).

CHWs in this study suggested incorporating more hands-on learning and practical activities as they could enhance their learning outcomes. In Bangladesh, where the workshop was conducted face-to-face, participants found the practical demonstrations to be particularly helpful. However, in India, where the workshop was conducted online, some participants believed that the practical demonstrations provided through videos were enough, while others suggested that more practical demonstrations could be done, and participants could have been given the opportunity to see each other do it.

Hands-on learning and practical activities have also been found to be effective in increasing knowledge and skills among participants in health training programs. For example, a study conducted in Germany found that a training program that incorporated practical exercises, such as roleplaying and case scenarios, was effective in increasing interest and engagement along with the knowledge and skills of participants (Holstermann et al., 2010). These findings support the results of the current study, which found that the use of visual aids and practical activities in the training program was

positively received by participants and was effective in increasing their knowledge and awareness of key oral health concepts. The feedback from participants in the current study also highlights the value of incorporating more practical activities into future training sessions to enhance learning outcomes.

Overall, the use of CHWs as screeners for oral cancer has great potential to improve access to screening services and reduce the burden on healthcare systems in low-resource settings.

Strengths of the study

This feasibility work had several strengths. Firstly, the use of multiple formats to deliver the training such as the handbook, slides, and videos ensured that CHWs with varying levels of education and training could effectively learn and implement the screening process. The handbook provided a comprehensive reference guide for CHWs, while the PowerPoint presentations and training activities allowed for interactive and engaging learning experiences.

Secondly, the successful recruitment and retention of CHWs for training is a strength of the research. The study employed effective recruitment strategies and provided reimbursement, incentives (such as screening tools, Certificate of Participation) and other support (refreshments and lunch) to encourage participation and retention.

Thirdly, the study utilised a multi-methods approach to evaluate the feasibility and acceptability of oral cancer training. This approach allowed for a more comprehensive understanding of the impact of the training, as it captured not only the feasibility of recruitment and retention, delivering training, and acceptability of the training but also highlighted changes in knowledge, skills, attitudes, and confidence. By utilising a combination of methods such as surveys and interviews, the study was able to provide a more complete assessment of the effectiveness of the training module, which strengthens the overall findings of the study.

Limitations of the study

One of the key limitations of the feasibility study was the inability to assess the feasibility of delivering the intervention. Although this was the original research plan, it was not possible due to the onset of the Covid-19 pandemic

Another limitation was the inconsistencies in the implementation of the study protocol. In one of the sites, it was observed that participants were not given handbooks to take home, which could have potentially impacted their ability to recall and practise the information they were trained on. Additionally, some participants were provided with black-and-white printouts of the questionnaire, which may have made it challenging for them to identify oral lesions. The issue was addressed by presenting coloured case photographs on the screen. However, it may have caused some confusion among the participants, which could have potentially influenced the accuracy of the results obtained. This limitation highlights the importance of careful consideration when selecting data collection tools and methods to ensure the quality and reliability of the data collected.

6.6 CONCLUSION

In conclusion, this chapter aimed to evaluate the feasibility and acceptability of training CHWs for OPMD screening in urban communities in India and Bangladesh. The chapter found that the training program was feasible and acceptable to CHWs and that the majority of CHWs were able to effectively screen the case studies for suspicious lesions using the training provided.

The results of this chapter highlight the potential of building competencies in CHWs using novel models of training. Moreover, the study also identified areas for improvement such as addressing logistical and cultural barriers and ensuring the sustainability of CHW-led OPMD screening programs.

DISCUSSIONS AND CONCLUSIONS

CHAPTER 7: OVERALL DISCUSSIONS AND CONCLUSIONS

7.1 CHAPTER OVERVIEW

This chapter summarises and synthesises the evidence from Chapters 2-6 of the thesis and provides a comprehensive overview and explanation of the research findings. Section 7.2 provides a summary of key research findings, while Section 7.3 gives an overview of methodological considerations, including Covid-19 related challenges and opportunities, as well as the strengths and limitations of the research. In addition, Section 7.4 discusses the importance of the research undertaken and its contributions. Furthermore, Section 7.5 examines the overall implications of the research for policy and practice. Based on the findings, recommendations for action are made in Section 7.6, and areas, where further research is needed to address the growing burden of oral cancer in South Asia, are identified. Section 7.7 includes reflections on the learning process. Finally, the chapter concludes in Section 7.8 by summarising the key contributions of the thesis.

7.2 SUMMARY OF KEY FINDINGS

The thesis aimed to investigate the carcinogenic potential of ST products used in South Asia, develop, and test a tailored intervention for OPMD and oral cancer detection for CHWs, and assess the feasibility of delivering remote training to CHWs in Bangladesh and India. By combining the evidence from these studies, a comprehensive understanding of the issues surrounding oral cancer detection and treatment in South Asia is gained, and potential solutions to reduce the burden of this disease are identified. The following section starts by summarising the key research findings of the thesis.

High carcinogenicity of South Asian ST products

A systematic review of studies from different global regions was conducted to analyse the carcinogenic potential of ST products. The findings revealed significant regional disparities, with ST products from South Asia exhibiting the highest levels of pH, moisture content, nicotine, and potent carcinogens such as TSNAs, volatile aldehydes, and heavy metals.

This comprehensive analysis established South Asia as the region with the most carcinogenic and harmful ST products globally. With widespread cultural use, these products are putting millions at a high risk of developing oral cancer in these countries. The systematic review provided a strong rationale for the need to improve early detection services through novel approaches like training CHWs in oral screening.

Contextually adapted guidelines for oral cancer screening

To develop appropriate guidelines for oral cancer screening in the target South Asian communities, the ADAPTE framework was utilised. This allowed adapting existing high-quality guidelines to the local context through a systematic, evidence-based process. A multidisciplinary steering committee oversaw the adaptation process.

A total of 8 existing oral cancer screening guidelines were identified from the literature search and selected for further adaptation. Quality assessment of the guidelines using the AGREE GRS tool revealed variation in overall scores between the guidelines with some scoring higher than others. Together with the results of further appraisal on

content, acceptability and applicability, all of which were predefined criteria, the steering committee selected 10 key recommendations on conducting OPMD and oral cancer screening and presented them to an Expert Panel for their review. A total of 27 Experts from the field of Head and Neck Cancer research (with speciality training in areas of Oral Surgery, Oral Medicine, Dental Public Health and Oral Pathology) from Bangladesh, India, Pakistan and the UK took part in a survey to select the recommendations on the final guideline. The recommendations that were deemed absolutely essential for the given context and received a consensus of 75% were selected for the final guideline.

To tailor the guidelines further, they were evaluated by 15 CHWs from the target regions who provided key feedback on relevance, clarity, and feasibility. Their inputs helped refine the guidelines into a practical, context-specific resource for CHWs to effectively screen these high-risk communities.

Comprehensive oral cancer screening training toolkit for CHWs

Along with adapted guidelines, a comprehensive training toolkit was developed to build CHWs' knowledge and competencies in oral cancer screening. The toolkit was designed using input from head and neck cancer experts, local dental professionals, and CHWs. It comprised a training handbook, a presentation, screening proforma, mouth map, video demonstration, and activity sheets. Together, these elements provided comprehensive knowledge and competencies on oral cancer and OPMDs, including identification of risk factors, the importance of early detection, and detailed step-by-step instructions on how to conduct an oral visual examination, take a medical and dental history, record and chart lesions, perform the duty of care, and refer patients appropriately.

The collaborative development process helped ensure the toolkit was tailored to the educational needs, language, culture, and healthcare settings of target communities in South Asia.

Feasibility and acceptability of remote training CHWs for OPMD and oral cancer screening

To equip CHWs with the competencies required to conduct the screening accurately and confidently in the communities they serve, a training workshop was organised. To ensure that the training was as accessible as possible, the curriculum was designed to include both in-person and remote delivery. In Bangladesh, a “train the trainer” model was used, where local researchers were trained remotely to deliver in-person training to CHWs. In India, a remote model was used where ZK delivered an online workshop directly to CHWs. The feasibility and acceptability of different outcome measures were assessed using pre-and post-training assessments and in-depth interviews.

The results for recruitment and registration demonstrated that the target sample size for the study was successfully achieved. A total of 33 CHWs were recruited from Bangladesh and India. The participants reported that the registration process was simple and easy to follow, which facilitated their participation in the study. Additionally, the participants expressed their appreciation for the initial contact they had with the fieldwork team at both University of Dhaka (Bangladesh) and NICPR (India), highlighting the importance of good communication and engagement in establishing a positive working relationship.

The findings from the feasibility of training showed that all the participants preferred face-to-face workshops in Bangladesh, whereas in India, there was a mixed response with half preferring face-to-face workshops and half preferring hybrid and online workshops. The results of the pre-and post-training assessments showed that there was a significant increase in knowledge and skills related to oral cancer screening among the participants in both study sites. The semi-structured interviews provided deeper insights into the feasibility and acceptability of the training. The participants were highly satisfied with the training workshop and found it valuable in enhancing their understanding and abilities in oral cancer screening. They also reported that the workshop increased their confidence in conducting OPMD and oral cancer screenings and improved their ability to communicate with patients about the importance of screening and the harms associated with tobacco use.

Overall, the research demonstrates that CHWs can be trained in screening for OPMDs and oral cancers and a remote approach to training in LMICs is feasible and acceptable.

Most importantly, it highlighted the positive attitude of CHWs towards oral cancer screening and their willingness to participate in future training and include this work in their regular responsibilities.

Collectively, these studies advance the goal of oral cancer prevention in underserved populations burdened by high disease rates and limited healthcare access. The findings reveal the imperative for screening given widespread ST use, provide tailored protocols for resource-appropriate early detection, and demonstrate an effective capacity building model. Together, they offer actionable steps to address the oral cancer burden through community-based screening powered by CHWs equipped with context-specific guidelines and skills.

7.3 IMPORTANCE OF RESEARCH AND CONTRIBUTIONS

The systematic review of the carcinogenic potential of ST products makes an important contribution to the field of tobacco and oral cancer research. The review provides a comprehensive analysis of the existing literature on the harmful constituents of ST products, which are widely used across the globe. It adds to this literature by analysing a broader range of ST products and including studies from a wider geographical area. This review also aligns with the findings from the systematic review conducted by Siddiqi et al (2020) on the global burden of disease due to ST consumption in adults that found that ST use is a significant public health concern, causing a substantial burden of disease globally. They reported that ST use is prevalent in many countries, particularly in South Asia, and is a leading cause of oral cancer in these populations. Thus, supporting the current reviews' emphasis on the harmful constituents of ST products and highlighting the need for greater awareness and prevention of oral cancer, particularly in populations where ST use is prevalent.

Another important contribution of the review is its focus on the carcinogenic potential of ST products. It provides evidence that many of these products continue to have known carcinogens, including TSNAs and PAHs. These findings highlight the need for greater regulation and control of ST products, particularly in countries where they are widely used and are supported by findings of a systematic review and meta-analysis of

113 studies by Sinha et al (2018) which reported that ST use was associated with a significantly increased risk of all-cause mortality, as well as mortality from various causes including oral and pharyngeal cancer. These findings emphasise the need for greater awareness and prevention efforts to reduce the health burden associated with ST use and support the importance of continued research and advocacy efforts aimed at reducing the use of ST products and improving public health outcomes.

The review identified several gaps in the existing literature, particularly concerning the carcinogenic potential of newer ST products, such as dissolvable products. This highlights the need for further research in this area, particularly given the increasing popularity of these products in many parts of the world. Additionally, the review also brought attention to the lack of research conducted in many countries with a high prevalence of ST such as Myanmar, Papua New Guinea, Afghanistan, Tajikistan, and Algeria.

The adaptation study on selecting an appropriate framework (ADAPTE) for adaptation and tailoring oral cancer screening guidelines for CHWs is an important contribution to the field of public health, as it addresses a significant gap in the literature regarding the selection and adaptation of context-specific evidence-based guidelines for use in low-resource settings.

The study builds on existing research on guideline adaptation, which has shown that the process of adapting guidelines for use in different settings is complex and requires careful consideration of the local context, culture, and available resources. The importance of the feasibility study lies in its contribution to the development of remote training programs for CHWs to enhance their knowledge and skills in oral cancer screening, patient referral, and tobacco cessation advice. The study provides evidence that CHWs can be trained remotely, and it can be an alternative to in-person training, especially in situations where travel is difficult or impossible, such as during the COVID-19 pandemic.

Several studies have shown the feasibility and effectiveness of remote training programs for CHWs in various health fields. For instance, a study by José et al., (2020) found that

remote training was an effective way to improve CHWs' knowledge of tuberculosis and increase screening rates. Similarly, a study by Willems et al. (2021) showed that remote training improved CHWs' knowledge and skills in delivering mental health care at the community level. These studies support the feasibility of remote training in improving CHWs' knowledge and skills in oral cancer screening and lay the groundwork for assessing the effectiveness of this training approach potentially through a randomised controlled trial.

Moreover, the study provides valuable insights into the challenges and opportunities of training for CHWs in LMICs. Research has shown that CHWs in LMICs face various challenges, such as limited resources, lack of training, and high workload (Kok et al., 2015). However, a study by Naslund et al. (2021) shows that remote training of CHWs is possible through the use of technology. This study details a case example from India where CHWs were trained to provide treatment for depression in primary care using a remote coaching and technology platform. The results showed that the CHWs were able to effectively deliver the intervention with high fidelity and fidelity scores. These findings suggest that remote training can be a feasible and effective approach to improving CHWs' knowledge and skills in LMICs, hereby, supporting the findings of the current study.

Furthermore, the study's contribution extends beyond just OPMD and oral cancer screening to include tobacco cessation as well. The CHWs in the study were trained to identify high-risk individuals, such as ST users, by taking a medical history, and providing tobacco cessation advice as part of their duty of care. The CHWs demonstrated eagerness in learning to deliver Very Brief Advice (VBA). The WHO recognizes the critical role CHWs can play in tobacco cessation and this study's contribution reinforces that recommendation (WHO, 2021). The effectiveness of CHWs in promoting tobacco cessation is also supported by a study by Umnuaypornlert et al. (2019) which found that CHWs were able to effectively motivate and support smokers to quit in their home villages.

In conclusion, the feasibility study's contributions lie in its evidence-based approach to developing remote training programs for CHWs in oral cancer screening, patient referral,

and tobacco cessation advice. The study's findings add to the growing body of literature supporting the feasibility and effectiveness of remote training programs for CHWs in various health fields, particularly in LMICs.

7.4 CHALLENGES AND OPPORTUNITIES

The COVID-19 pandemic posed significant challenges for many researchers, including myself, particularly in terms of methodological considerations and related impacts on research plans. In my case, my original research proposal focused on identifying and addressing gaps in the literature around oral cancer and OPMD screening and detection in India through three studies. These were a) Identification and adaptation of an oral cancer screening tool for community-based screening in India- A trans contextual adaptation study, b) Assessing the feasibility and acceptability of using the screening tool for detection of oral cancer and OPMDs in a cohort of tobacco users by CHWs- A multi-method feasibility study and c) Exploring attitudes and motivation to quit towards ST cessation following the diagnosis of oral Cancer and OPMDs- A cross-sectional survey.

Due to the pandemic, the research plan was revised. As a result, two key changes were made to the existing research project. Firstly, a new study, the systematic review, was included in the project and secondly, in light of the persistent travel restrictions and lockdowns, the research questions and methodology of the feasibility study were adapted to incorporate remote fieldwork. These changes allowed me to utilise the time available and continue progressing with the research despite the limitations posed by the pandemic.

Despite the modifications made to the project and the inclusion of new studies, some challenges remained. Firstly, an in-person placement at the School of Dentistry, University of Glasgow to develop fieldwork resources was no longer possible due to the second lockdown in the UK resulting in the closure of the institution. This posed a challenge in terms of developing the necessary fieldwork resources. Secondly, my collaborating institute in India, where I had originally planned to conduct fieldwork, was converted into a COVID-19 speciality hospital, and all research-based activities were

indefinitely halted. This posed a significant challenge as I had to identify and establish new collaborations and re-apply for ethics in the midst of a global pandemic.

In response to these challenges, I decided to alter my placement for the development of fieldwork resources, opting to do it virtually. During this period, I utilised the time to concentrate on the systematic review and sought new partnerships for ethics and applied for approval. I established new fieldwork collaborations with the existing partners of the National Institute of Health Research (NIHR) Global Health Research (GHR) group, ASTRA (Addressing Smokeless Tobacco and Building Research Capacities in South Asia) in Bangladesh, India, and Pakistan. As a result, the University of Dhaka in Bangladesh, the National Institute of Cancer Prevention and Research in India, and the Aga Khan University in Pakistan were chosen as the fieldwork locations.

While the pandemic forced me to seek new partnerships for the project and modify the research design, the resulting collaborations allowed me to expand the scope of the project and broaden its reach beyond its original location to include Bangladesh, which added to the diversity and generalisability of the findings and allowed me to explore cross country variations. This was a valuable opportunity that may not have been possible under normal circumstances.

In addition to the new collaborations, the pandemic also necessitated a change in data collection methods. As travel restrictions and lockdowns were still in place, I had to collect my data remotely. This approach presented new opportunities, as I was able to collect data from participants who may not have been accessible if face-to-face interviews were conducted and allowed me to explore the feasibility of remote data collection in the context of oral cancer screening and detection. This resulted in a more flexible and cost-effective approach to data collection. Additionally, conducting remote training for CHWs in LMICs presented a unique opportunity to explore the potential of telemedicine and virtual health interventions in oral cancer screening and detection. This is an area of research that has gained traction in recent years but has been accelerated by the pandemic. Going forward, this could have significant implications for increasing the reach and accessibility of oral cancer screening programs in resource-

limited settings and potentially lead to more cost-effective and scalable solutions, particularly in LMICs.

In conclusion, while the impact of the pandemic on my research has been substantial, requiring significant flexibility, adaptation, and patience, it also presented unique opportunities to establish new fieldwork collaborations, explore remote data collection, and investigate the potential of telemedicine and virtual health interventions in oral cancer screening and detection. These strengths enriched my research study and allowed me to address new research questions that were not originally planned.

7.5 STRENGTHS OF THE RESEARCH

This thesis presents a comprehensive study on the early detection of OPMDs in South Asia, which is a critical public health issue given the high burden of oral cancer in the region. Overall, the thesis provides valuable insights into the challenges and opportunities of early detection of oral cancer in South Asia. The chapters are grounded in research and use appropriate methods to address specific research questions. In the following subsections, I present the strengths of the thesis.

Comprehensive and systematic approach

The thesis utilised rigorous and established methodologies (e.g., systematic review, ADAPTE framework) to address key research questions related to oral cancer screening in South Asia. This enhances the credibility and impact of the findings. Each study within the thesis adheres to rigorous research methodologies. The systematic review employs transparent criteria and a comprehensive search strategy, enhancing the credibility of its findings. The adaptation of oral cancer screening guidelines and the development of a toolkit involve diverse stakeholder input, contributing to the cultural appropriateness and feasibility of the guidelines. The feasibility study employs multiple training formats and a multi-methods approach to evaluate the training's impact.

Context-specific focus

The research was tailored to the needs, culture, and healthcare settings of target communities in South Asia. Involving local stakeholders ensured the adapted guidelines

and training resources were practical, acceptable, and implementable in the real-world context.

Novel contributions

The thesis provides valuable new insights into training and task-shifting approaches to improve early detection of OPMDs and oral cancer in underserved regions. Demonstrating feasibility of remotely training CHWs is an important advance.

Collaborative approach

The studies involved diverse collaborations with international experts, local stakeholders and CHWs This strengthened the research quality, relevance, and potential for knowledge translation.

Capacity building

The thesis helped build capabilities in oral cancer screening and prevention in the target regions through CHW training. This supports sustainability and scalability.

Timeliness

The thesis addresses a timely issue, given the rising global use of ST products and the continually evolving landscape of oral cancer. By incorporating the latest evidence and trends, the research maintains its relevance to public health policymaking and practice.

7.6 LIMITATIONS OF RESEARCH

Like any research study, this thesis also has certain limitations which are presented below.

Limited generalisability

The studies were conducted in specific settings and may not be generalisable to other regions or populations. There was also limited regional representation within the study. Consultations with CHWs were primarily conducted in India, which may not fully represent the perspectives and needs of CHWs in other South Asian countries such as

Bangladesh and Pakistan, potentially affecting the suitability of the adapted guideline in those settings.

Potential stakeholder bias

While stakeholder engagement in the research was a strength, it could also introduce bias if differing opinions or priorities among stakeholders were not adequately addressed. The use of cut-off limits instead of consensus-building methods may have limited the diversity of perspectives considered in the adaptation process.

Fieldwork constraints

There were some inconsistencies between the study sites in how the study protocol was implemented due to real-world constraints such as availability of resources, conflicting schedules of CHWs etc. These types of limitations highlight the challenges of doing research across different under-resourced community settings.

Pandemic related constraints

The Covid-19 pandemic-imposed restrictions that necessitated modifications to the fieldwork plan and prevented exploring certain avenues of research. For examples, case simulations in the form of vignettes had to be used to assess the competencies of CHWs. Most notably, the feasibility study was unable to assess the delivery of the oral cancer screening intervention by CHWs. Evaluating the implementation of the adapted guideline and training in a real world setting was the original plan and could not be carried out due to the unforeseen circumstances.

In conclusion, the strengths, and limitations of the thesis demonstrate the complexity and challenges of conducting research in the field of oral cancer screening and detection in low- and middle-income countries. While each study has its unique strengths and limitations, they collectively contribute to the growing body of evidence in this field. It is essential to acknowledge the limitations of the study to ensure that future research addresses these gaps and builds upon the strengths of previous studies. Nonetheless, the strengths of this thesis offer valuable insights and lessons learned for future researchers in this field. Overall, this thesis contributes to advancing the knowledge and

understanding of oral cancer screening and detection in resource-limited settings and highlights the potential of task shifting and remote training in improving health outcomes for underserved populations. In the following section, I will further discuss the importance of this research and its contributions to the field.

7.7 IMPLICATIONS AND RECOMMENDATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

Systematic review of carcinogenic potential of ST

The findings highlight the urgent need for increased public awareness of the harmful effects of ST products, especially in regions where they are commonly used. The review found higher carcinogens in ST products from South Asia with wide variation between the products. This information can be used to develop effective public health campaigns and policies aimed at reducing the use of ST products and improving oral health outcomes.

Studies in Bangladesh, India and Pakistan found that a large proportion of the population, especially in rural areas, uses ST products and that there is a lack of knowledge about the harmful effects of these products among both users and non-users (Hossain et al, 2014; Karuppusamy et al., 2021; Huque et al., 2017; Goyal et al., 2016). Recent studies by Mishu et al. (2021) and Shukla et al. (2021) further support these findings. Mishu et al. (2021) found that ST consumption was prevalent among adolescents in South Asia, and there was a lack of awareness about the harmful effects of these products. Similarly, Shukla et al. (2021) reported that ST use was widespread among women of reproductive age in 42 low- and middle-income countries, including Bangladesh, India, and Pakistan, with low levels of knowledge about the health risks associated with these products. Overall, these studies highlight the urgent need for targeted interventions to raise awareness and reduce the use of ST products in these populations.

In addition, the findings of the review can be used to inform public health policies aimed at regulating the manufacture, sale, and distribution of ST products. A study by Siddiqi et al. (2016) found that the ST supply chain in South Asia is complex and involves multiple

actors, including manufacturers, wholesalers, retailers, and street vendors. The study also revealed that the regulatory framework for ST products is weak and that there is a lack of compliance with tobacco control laws in Bangladesh, India, and Pakistan. The authors recommended strengthening the regulatory framework and enhancing enforcement to control the supply of ST products in South Asia. Thus, by providing evidence of the carcinogenic potential of these products, my review can support the development and implementation of stronger regulatory policies to protect public health.

Furthermore, the findings of my review can also inform clinical practice, particularly in the area of oral cancer screening and detection. Healthcare professionals should be aware of the increased risk of oral cancer associated with ST use and should provide appropriate education and counselling to patients who use these products. A study in India found that healthcare professionals had limited knowledge about the harmful effects of ST products, highlighting the need for targeted training and education programs (Panda et al., 2014).

In addition to the implications for public health policy and practice mentioned earlier, the findings of this systematic review also have significant policy implications for the tobacco industry. ST products are often marketed as a safer alternative to smoking, but this review highlights the carcinogenic potential of these products. Therefore, policymakers should consider implementing regulations on ST products to reduce their harmful effects on public health.

The World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC) provides a policy framework for governments to implement measures to reduce tobacco use, including ST products. For example, Article 9 of the FCTC recommends that parties regulate the contents and emissions of tobacco products, including ST products, to reduce their harmful effects (Roemer et al., 2005; WHO, 2013). The FCTC also recommends measures to reduce the demand for tobacco products, such as increasing taxes and implementing comprehensive tobacco control programs.

Several studies have shown that implementing policies to regulate tobacco products can lead to significant reductions in tobacco use and related health outcomes. For example, a study conducted in the United States found that implementing comprehensive smoke-free air laws and increasing tobacco taxes were associated with significant reductions in smoking prevalence and tobacco-related deaths (Hopkins et al., 2001).

Another study conducted in India found that implementing tobacco control policies, such as increasing taxes and banning advertising, led to a reduction in tobacco use among youth (Levy et al., 2018). Furthermore, a study conducted in Sweden found that implementing policies to regulate the use of snus, a type of ST product, was associated with a reduction in the incidence of oral cancer (Foulds et al., 2003).

Overall, the findings of the systematic review provide compelling evidence and justification for the stronger regulation of ST products.

Adaptation Study

The findings of the adaptation work carry significant implications to public health practice not only within the context of oral cancer screening and prevention but also more broadly in the development and implementation of health interventions in LMICs. A key implication is a necessity for a standardised approach to adapting and tailoring guidelines for use by CHWs. The ADAPTE framework offered a clear and systematic approach to adapting existing oral cancer screening guidelines, which can be relevant to other health domains. This standardised approach can ensure that interventions are evidence-based, culturally appropriate, and effective in the local context, especially in resource-limited settings where resources are scarce. This approach may contribute to more efficient use of resources and improve healthcare delivery in LMICs. The study's findings also provide evidence in support of task shifting from specialists to non-specialists for OPMD and oral cancer screening. Specifically, the study demonstrates that CHWs can be effectively trained to develop competencies for conducting such screenings. By showing that CHWs can be trained to identify and refer patients with OPMDs and oral cancer, the study highlights the potential of task shifting as a viable

strategy for improving access to oral healthcare services in resource-constrained settings.

Furthermore, this study emphasises the importance of a multi-disciplinary approach to guideline adaptation for oral cancer screening and prevention. Collaborating with diverse stakeholders, including experts, dentists, public health researchers, and CHWs, is essential for the effective development and implementation of training programs for oral cancer screening.

Feasibility and acceptability of training CHWs for oral cancer screening

The feasibility study conducted to remotely train CHWs in India and Bangladesh for oral cancer screening has several implications for public health policy and practice. The study showed that remote training of CHWs using hybrid or digital platforms is feasible in enhancing their knowledge and skills in oral cancer screening, referring patients, and giving tobacco cessation advice. If proven effective through further research and scaled up, this could help improve the early detection of oral cancer in LMICs where the burden of the disease is high, and resources are limited.

Moreover, the findings of this study have implications for the integration of oral cancer screening into primary healthcare settings, particularly in LMICs where access to specialised healthcare services may be limited. Empowering CHWs to provide screening and prevention services not only has the potential to bridge the gap between the availability and accessibility of oral cancer screening services but also to be an efficient and scalable approach. By utilising CHWs, who are already embedded in the community and have established trust, the approach has the potential to reach a larger population. Thus, the study provides evidence that the task-shifting approach has the potential to be scaled up and implemented in a cost-effective manner, leading to improved access to oral healthcare services in resource-constrained settings.

Effective training and support for CHWs in the implementation of the adapted guidelines are crucial, and comprehensive training programs that include both theoretical and practical components, as well as ongoing support and supervision, should be provided

to ensure that CHWs have the knowledge, skills, and confidence to effectively screen for oral cancer, refer patients for further evaluation, and provide tobacco cessation advice.

Involving CHWs and using community-based approaches can also promote awareness and acceptance of oral cancer screening services, leading to increased uptake, and ultimately reducing the burden of oral cancer in the community. These findings have important policy implications for public health in LMICs. National oral cancer screening programs should consider incorporating training programs for CHWs as part of their policy to increase the number of trained healthcare providers and improve the quality of care delivered for oral cancer screening in resource-limited settings. Furthermore, integrating tobacco cessation services into OPMD and oral cancer screening programs can help patients quit tobacco use and reduce their risk of developing oral cancer. Early detection of oral cancer provides a critical window of opportunity to address risky behaviours, including tobacco use, and to initiate appropriate interventions that may reduce the incidence of oral cancer. By integrating tobacco cessation services into OPMD and oral cancer screening programs, patients who may have never considered quitting tobacco use may be more willing to engage with cessation services, leading to increased rates of successful quitting. Additionally, offering tobacco cessation services as part of these programs can help to raise awareness about the harmful effects of tobacco use and its link to oral cancer, and encourage patients to seek further support and advice on quitting tobacco use.

Overall, this research has generated insights to accelerate progress in oral cancer prevention for high-risk populations in low-resource settings. The methodology for collaborative, localised adaptation of clinical guidelines is broadly applicable across health domains. Exploring task shifting and technology enabled training provides a framework to develop CHW capacity efficiently. Together, the studies advance understanding and contribute actionable steps to address context-specific cancer control needs through enhanced service delivery pathways.

7.8 RECOMMENDATIONS FOR FURTHER RESEARCH

Based on the findings of the systematic review, the following recommendations are suggested for further research. Firstly, there is a need for further studies to investigate the long-term health effects of using ST products, particularly in regions where these products are widely consumed, and epidemiological data are scarce. Such studies should aim to provide more comprehensive evidence on the risks associated with the use of ST products, including both traditional and newer forms, and the impact of different patterns and levels of use on health outcomes. Longitudinal studies that follow users over time would be particularly valuable in this regard.

In addition, as new ST products are being developed and marketed, there is a need for ongoing analysis of these products to determine their potential health risks and to inform public health policies and regulations.

Finally, given the global nature of the ST industry, it is important to continue to monitor and document the marketing and promotion strategies used by the industry to promote these products. This can help inform policy and advocacy efforts aimed at regulating the industry and reducing the use and health effects of ST.

The adaptation work has highlighted the importance of tailoring oral cancer screening guideline for CHWs in LMICs.

Based on the findings of the feasibility study, there are several recommendations for future research to improve the feasibility and effectiveness of oral cancer screening and prevention efforts among high-risk populations, particularly in LMICs. One important area for future research is to conduct a randomised controlled trial to evaluate the effectiveness of training CHWs in oral cancer screening, patient referral, and tobacco cessation advice using different models of learning as well as to determine the impact of the training program on patient outcomes. Additionally, future research could explore the potential for using telemedicine and virtual health interventions in oral cancer screening and detection, as well as the use of mobile health technologies to enhance the delivery and uptake of oral cancer screening services. Moreover, future research could investigate the factors that influence the uptake and sustainability of oral cancer

screening programs in LMICs, as well as the barriers and facilitators to implementing remote training programs for CHWs.

Overall, these areas of future research could help to further advance our understanding of oral cancer screening and detection in low- and middle-income countries and inform the development of effective and sustainable oral cancer screening programs that can help to reduce the burden of this disease.

7.9 REFLECTIONS ON LEARNING

Reflecting on my PhD journey, I realise that it was a transformative experience that allowed me to grow both personally and professionally. As a dentist by training, my clinical background was both an asset and a challenge as I navigated the research landscape. I chose to use a range of methods including a systematic review, adaptation framework, and multi-method feasibility study. Each of these methods presented unique learning opportunities and challenges.

The adaptation work was a novel and demanding aspect of my PhD journey. I had to quickly learn the methodology and concepts behind it to be able to effectively implement it in my research. At first, I found the work daunting and overwhelming. It required not only adapting an intervention designed for dentists in high-income countries to CHWs in LMICs but also understanding the nuances of the adaptation process and how to apply it in a research setting. Additionally, I had to work with the steering group and stakeholders throughout the process, which added to the complexity of the task. However, this experience taught me several valuable lessons and reinforced the importance of cultural sensitivity and understanding the local context in research. It required me to conduct extensive literature reviews, engage with stakeholders, and conduct discussions with CHWs to better understand their needs and perspectives. This experience has instilled in me a deep appreciation for the value of community engagement and partnership in research.

The systematic review was borne out of the necessity for desk-based research during Covid. While I had read and cited several systematic reviews during my literature

review, using this methodology to conduct my review was not something that I had initially planned. To gain knowledge and skills, I relied on relevant course modules from the Master of Public Health (MPH) programme at the University and consulted with researchers who had prior experience conducting systematic reviews. Additionally, I had the opportunity to be the second reviewer on a colleague's systematic review, which helped me gain more insight into the methods. The experience of conducting a systematic review during my PhD journey taught me the importance of conducting a rigorous and transparent search, selection, and synthesis process and highlighted its significance as a means of synthesising and summarising evidence for decision-making in healthcare, which has implications for both research and clinical practice.

Coming from a clinical background, I was also completely new to qualitative research. Attending training courses like the SRA (Social Research Association) training on qualitative methods and the qualitative module provided by the University of York was immensely helpful in giving me a solid grounding in qualitative research methods. I was grateful to have received feedback and guidance from experts (KO and SB) in helping refine my topic guides and synthesis methods. This work allowed me to build my skills and become more confident in conducting qualitative research. It developed in me a deep respect for the insights that can be gained from qualitative research and how it can complement and enrich quantitative data.

Conducting research in the middle of a global pandemic was a learning experience that taught me to be flexible and adaptable to change. I realised that being able to pivot quickly is a valuable skill in academia and beyond. I also learned that it's essential to stay positive and focus on the solutions instead of dwelling on the problems. This realisation helped me stay motivated and focused on my goals, even when things got tough. Reflecting on my journey, I have learned that resilience, adaptability, and having a support system are critical components of success in any endeavour. Even the challenges I faced during my PhD journey were all opportunities for growth and development and helped me build my skills, my character, and my confidence.

7.10 CONCLUSION

In conclusion, this PhD thesis aimed to test the feasibility of training CHWs for screening oral cancer and OPMDs in a community-based setting in Bangladesh and India. The findings suggest that ST products, particularly those used in low and low-middle-income countries, are highly carcinogenic. The study also identified a trans-contextual framework to adapt guidelines into a simple step-by-step process for CHWs. The feasibility study successfully recruited and trained CHWs in oral cancer screening, demonstrating that CHWs can be effective in conducting such screenings. The results of this research have significant implications for improving the accessibility of oral cancer and OPMD screening in low-resource settings, which can ultimately contribute to early detection and better management of these diseases. Overall, this research contributes to the field of global health by highlighting the potential of CHWs in addressing the growing burden of oral cancer and OPMDs.

APPENDIX 1

Table 40: Ontology of ST products used across the globe.

	Product name (alphabetical)	Synonyms	WHO Region (Countries)	Method of Consumption	Tobacco type and Composition	Final form & preparation	Method of use	Definition
1	Afzal	Sweekah	EMRO (Oman); SEARO (India)	Oral	Tobacco-containing (Dried tobacco mixed with different additives)	Moist, ground product; some premade ingredients are used to make a custom-made product	Afzal is used by placing a pinch of the product between the lips and the upper or lower gums. Users then suck the juice from the afzal for varying periods of time, often up to 30 min, and subsequently spit out the rest.	A smokeless tobacco-containing product that is designed for oral use in which dried tobacco is mixed with varied additives to create a moist form.
2	Bajjar	Bajar, Tapkeer, Tapkir	SEARO (India)	Oral or Nasal	Tobacco-containing (Fermented, roasted, and powdered tobacco, flavourings may be added)	Dry, finely powdered product; frequently prepared by individual users at home (custom-made)	The product is typically rubbed on the teeth and gums to clean teeth. Sometimes used nasally.	A smokeless tobacco-containing product that is designed for both oral and nasal use, in which fermented, roasted tobacco (sometimes with flavourings) is made into a dry, fine powder.

3	Betel quid with tobacco	Pan/paan with tobacco, Khilli pan/paan, Kun Yar (Myanmar)	EMRO (Pakistan, United Arab Emirates); SEARO (India, Sri Lanka, Bangladesh, Myanmar, Thailand, Indonesia, Nepal, Maldives); WPRO (Lao Democratic People's Republic, Palau, Cambodia, Malaysia, Vietnam, Federal States of Micronesia)	Oral	Tobacco-containing (Different types e.g., sada pata (plain tobacco flakes), zarda (flavoured tobacco flakes), kiwam (tobacco paste), half a cigarette, etc. and other ingredients -—usually areca nuts, slaked lime, and catechu)	Wrapped in betel leaf; custom-made vendor/individual	The product is placed in the mouth and chewed or held. Some users swallow the juices produced from chewing betel quid.	A smokeless tobacco-containing product that is designed for oral use, in which different types of tobacco, with or without other ingredients (usually areca nuts, slaked lime, and catechu), are wrapped in a betel leaf.
4	Bitter tombol	-	EMRO (Middle East)	Oral	Tobacco-containing (Different types), mixed with flavouring and ingredients such as noura, slaked lime, areca nut, catechu, sometimes powdered khat (Catha edulis), and wrapped in tombol (betel) leaf	Custom-made vendor/individual	Placed in the mouth and sucked and chewed.	Tombol, with ingredients that provide a bitter flavour/taste
5	Black shammah	-	EMRO (Saudi Arabia, Yemen); AFRO (Algeria)	Oral	Tobacco containing (Tobacco, slaked lime, ash, black pepper, oil, flavourings, bombosa (sodium carbonate))	White shammah is sold as a dry product whereas black shammah is sold as a wet product; Custom-made vendor/ individual	Shammah is placed between the gum and the lower lip or cheek. In Algeria, users may wrap shammah in paper before putting it in their mouth. Orally chewed or held in the mouth	Shammah with ingredients that give it a black colour

6	Brown shammah	Shamma Gabra, Shammah adani	-	-	-	-	-	Shammah with ingredients that give it a brown colour
7	Burnuthi*	-	Georgia	Nasal	Tobacco containing	-	-	-
8	Chimó	-	AMRO (Venezuela, Colombia)	Oral	Tobacco-containing (Tobacco leaves are crushed and boiled into a sticky, heavy black liquid, which is allowed to mature and seasoned with different ingredients (baking soda/sodium bicarbonate, brown sugar, ashes from the Mamón tree (Meliccoca bijuga), and vanilla and anisette flavouring) -– vary according to region)	Matured paste, is usually produced by small family-operated factories, but commercial, industrial manufacturing of chimó is increasing in Venezuela	A small amount of chimó is placed between the lip or cheek and the gum and left there for some time, usually 30 minutes. The mixture of chimó and saliva is spat out.	A smokeless tobacco-containing product that is designed for oral use, in which tobacco leaves are crushed and boiled into a sticky, heavy black liquid, which is allowed to mature and seasoned with different ingredients (that vary according to region) to create a tobacco-based paste.
9	Creamy snuff	Tobacco toothpaste	SEARO (India)	Oral	Tobacco-containing (Finely ground and mixed with aromatic substances such as clove oil, glycerine, spearmint, menthol and camphor, salts, water, and another hydrating agent)	Tobacco-based paste sold in toothpaste-like tubes; premade manufactured	Creamy snuff is orally applied and used to clean teeth like regular toothpaste. Some products' instructions recommend holding the paste in the mouth for a little while before rinsing.	A smokeless tobacco-containing product that is designed for oral use, in which finely ground tobacco is mixed with aromatic substances, salts, water, and other hydrating agents to form a tobacco-based paste that is sold in toothpaste-like tubes.

10	Dissolvable tobacco product	-	-	-	-	-	-	A smokeless tobacco-containing product that is designed to dissolve in the mouth and does not require spitting or discarding of the product after use
11	Dohra	Dhora	SEARO (India -– UP)	Oral	Tobacco-containing (Different types -—often zarda (flavoured tobacco flakes) or surti -—mixed with the contents of a second packet containing areca nut, catechu, and other flavourings such slaked lime (calcium hydroxide), peppermint, cardamom)	The wet mixture is normally sold in a plastic bag with a rubber band tied around it; custom-made vendor/individual	A small amount of the product is placed in the mouth and chewed or sucked on.	A smokeless tobacco-containing product that is designed for oral use, in which different types of tobacco (often zarda or surti) are combined with a mix of areca nut, catechu, slaked lime (calcium hydroxide) and flavourings such as peppermint, cardamom to form a wet mixture.
12	Dry snuff	Scotch snuff, Snuff	AMRO (Canada, USA); AFRO (South Africa, Nigeria); EURO (Germany)	Oral OR Nasal	Tobacco-containing (Fire-cured, fermented and processed into dry fine powder; it may also be sweetened)	Contains less than 10% by weight of moisture; commercially manufactured	A small amount of the product is usually sucked by the user and held orally, but it may also be inhaled through the nostrils.	A smokeless tobacco-containing product that is designed for either oral or nasal use, in which tobacco is fire-cured, fermented, and processed into dry fine powder.

13	Energy-enhanced snuff	-	AMRO (USA)	Oral	Tobacco-containing (Leaf, stems, and seeds are fermented, air- and/or fire-cured, mixed with different flavourings and augmented with stimulants (caffeine, ginseng), taurine, and vitamins B and C)	The product may be processed into fine particles “fine cut” or strips “long cut”; premade manufactured	It is placed between the lip or cheek and the gum and left there for about 30 minutes.	Oral snuff in which the tobacco leaf, stems, and seeds are fermented, air- and/or fire-cured, mixed with different flavourings, augmented with stimulants (caffeine, ginseng), taurine, and vitamins B and C, and processed into moist fine particles (fine cut) or strips (long cut).
14	Gudakhu	Gudhaku, Gudahku, Gudahka	SEARO (India)	Oral	Tobacco-containing (Fine leaf dust, mixed with molasses, red soil, lime, and water)	Tobacco-based paste; premade manufactured, but can also be made by individuals for personal use	Gudakhu can be rubbed on the teeth and gums with a fingertip and may be left in the mouth. It may be used to clean teeth. Some swallow the exact while others spit it out.	A smokeless tobacco-containing product that is designed for oral use, in which fine-leaf tobacco dust is mixed with molasses, red soil, lime, and water to form a tobacco-based paste.
15	Gul	-	SEARO (India, Bangladesh)	Oral	Tobacco-containing (Pyrolyzed -–burned and decomposed -– tobacco leaves, mixed with the ash of tendu leaves)	Powder; commercially manufactured and sold in small tin cans	Gul is applied to teeth and gums; it is usually used to clean teeth.	A smokeless tobacco-containing product that is designed for oral use, in which pyrolyzed (burned and decomposed) tobacco leaves are mixed with the ash of tendu leaves to form a fine powder.

16	Gundi	Kadapan	SEARO (India)	Oral	Tobacco-containing (Cured and mixed with coriander seeds, other spices, and aromatic, resinous oils -—each constituent is fried separately, powdered coarsely and mixed, and the product is scented with resinous oils)	Coarse powder; premade cottage industry	Chewed or added as an ingredient in betel quid.	A smokeless tobacco-containing product that is designed for oral use, in which cured tobacco, coriander seeds, and other spices are fried separately and ground, then mixed with aromatic resinous oils to form a coarse powder.
17	Gutka	Gutkha, pan/paan masala with tobacco	EMRO (Pakistan); SEARO (India, Bangladesh, Nepal, Myanmar, Sri Lanka); Also, SA diaspora	Oral	Tobacco-containing (Sun-dried, roasted, finely chopped tobacco is mixed with areca nut, slaked lime (calcium hydroxide), catechu, and other condiments, sweeteners, and flavourings)	Granular product; premade commercial or cottage industry	Gutka is held in the mouth and chewed. Saliva is generally spat out, but it is also sometimes swallowed.	A smokeless tobacco-containing product that is designed for oral use, in which sun-dried, roasted, and finely chopped tobacco is mixed with areca nut, slaked lime (calcium hydroxide), catechu, and other condiments, sweeteners, and flavourings to create a dry granular product.
18	Hogesoppu	-	SEARO (India)	Oral	Tobacco-containing (Fresh, unprocessed, and crushed leaves)	Bundled in strands; premade cottage industry	Chewed without additional ingredients or added as an ingredient in betel quid.	A smokeless tobacco-containing product that is designed for oral use, in which unprocessed and crushed tobacco leaves are bundled in strands.

19	Iq'mik	Blackbull, Dediguss	AMRO (USA –– Alaska)	Oral	Tobacco-containing (Fire- or air-cured leaves are mixed with tree fungus ash (also known as punk, araq, or buluq ash), or other ash derived from burning driftwood, alder bush or willow bush)	Chew: prepared by the individual user or a family or community member to share	Chewed; users may pre-chew the iqmik and place it in a small box for later use by the maker or to share with others, including elders, children, and infants.	Chewing tobacco product in which fire- or air-cured tobacco leaves are mixed with tree fungus ash or other ash derived from burning driftwood, alder bush or willow bush to form a thick chewable product.
20	Kaddipudi	-	SEARO (India)	Oral	Tobacco-containing (Dried raw tobacco stalks and petioles, sometimes mixed with molasses and water)	Loose-dry sticks; premade cottage industry	Chewed or added as an ingredient in betel quid.	A smokeless tobacco-containing product that is designed for oral use, in which dried raw tobacco stalks and petioles (sometimes mixed with molasses and water) form loose dry sticks.
21	Khaini	Khoinee, Surti	SEARO (India, Bangladesh, Nepal, Bhutan)	Oral	Tobacco-containing (Sun-dried or fermented coarsely cut tobacco leaves, mixed with slaked lime and sometimes areca nut)	Flaky product; Custom-made, cottage industry, and commercial: Khaini is usually prepared by the individual user from basic ingredients at the time of use, but commercially manufactured khaini is also available	Placed in the mouth between the gums and cheeks and sucked slowly for 10 – 15 minutes. Occasionally, left overnight in the mouth.	A smokeless tobacco-containing product that is designed for oral use, in which sun-dried or fermented coarsely cut tobacco leaves are mixed with slaked lime and sometimes areca nut to create a flaky form.

22	Kharra	-	SEARO (India -– Maharashtra)	Oral	Tobacco-containing (Combination of tobacco, areca nut, lime, and catechu with additional ingredients)	Coarse powder; custom-made by vendor/individual or premade cottage industry	Held in the mouth, sucked, and chewed.	A smokeless tobacco-containing product that is designed for oral use, in which tobacco is mixed with areca nut, lime, catechu and additional ingredients to form a coarse powder.
23	Kiwam	Khiwam, Qiwam, Qimam, Kimam	EMRO (Pakistan); SEARO (Nepal, India, Bangladesh)	Oral	Tobacco-containing (The stalks stems, and veins of tobacco leaves are removed, then the remaining leaves are boiled, soaked in water, and flavoured with powdered spices (cardamom, saffron, and/or aniseed), and additives such as musk)	Prepared to form a thick paste that may be formed into granules or pellets; commercially manufactured	Kiwam may be used alone or inserted into a betel quid.	A smokeless tobacco-containing product that is designed for oral use, in which boiled tobacco leaves (minus stalks, stems and veins) are soaked in water, then flavoured with powdered spices (e.g., saffron, cardamom, aniseed) and additives such as musk and then prepared into a thick paste that may also be formed into granules or pellets.
24	Kuberi*	-	AFRO(Tanzania)	Oral	Tobacco-containing (Moist oral snuff)	-	-	-
25	Liquid snuff*	-	AFRO (Kenya, East Africa)	Nasal	Tobacco containing	-	Used nasally	-
26	Loose leaf	Loose leaf chew, Loose leaf chewing tobacco	AMRO (USA)	Oral	Tobacco-containing (Leaf tobacco -–air-cured, stemmed, and cut or granulated, then sweetened and flavoured with sugar and liquorice, accounting for the high	Strips of shredded tobacco; commercially manufactured and usually sold in pouches	A piece of tobacco 0.75 to 1 inch in diameter is either chewed or held in place. Saliva is usually spat out, but it can also be swallowed.	Chewing tobacco product in which leaf tobacco is air-cured, stemmed, sweetened, and flavoured with sugar and liquorice, and cut or granulated into small strips of shredded tobacco

					average sugar content -–approximately 35% of its weight)			
27	Loose snus	-	-	-	-	-	-	Snus in a loose form, portioned with fingers
28	Mainpuri	Kapoori	SEARO (India)	Oral	Tobacco-containing (Mixture of finely cut betel nut and small pieces of tobacco leaves treated in slaked lime and flavouring agents such as powdered cloves, cardamom, Kewara and sandalwood powder.)	Premade cottage industry	-	A smokeless tobacco-containing product that is designed for oral use, composed of small pieces of tobacco leaves treated in slaked lime, finely cut betel nut, flavouring agents and sandalwood powder to form a coarse granular mixture.
29	Maras	-	EURO (Turkey)	Oral	Tobacco-containing (Sun-dried tobacco mixed with ashes from oak, walnut, or grapevine)	Custom-made vendor/individual	The tobacco mixture is sprinkled with water and applied between the lower labial mucosa and gingiva for 4-5 minutes	Oral snuff in which sun-dried tobacco is mixed with ashes from oak, walnut and grape wine and then sprinkled with water to form a moist powder
30	Mawa	-	SEARO (India)	Oral	Tobacco-containing (Sun-cured tobacco flakes mixed with thin shavings of areca nut and slaked lime)	-	Mawa is placed in the mouth and chewed for about 10 to 20 minutes and may be used as many as 5 to 25 times per day	Chewing tobacco products are composed of sun-cured tobacco flakes, thin shavings of areca nut and slaked lime.

31	Mishri	Misri, Masheri	SEARO (India)	Oral	Tobacco-containing (Toasted, powdered)	Custom-made vendor/ individual	Mishri is rubbed on the teeth and gums, often to clean the teeth. It is generally used twice a day, but users who become addicted may apply it more frequently or hold it in their mouths.	A smokeless tobacco-containing product that is designed for oral use, composed of toasted tobacco in a powdered form.
32	Moist Snuff	Dip, Moist snuff spit tobacco	AMRO (USA, Canada, Mexico); AFRO (South Africa)	Oral	Tobacco-containing (Fermented, air- or fire-cured fine particles or strips of tobacco mixed with flavourings (spices, essential oils, extracts), sweeteners, inorganic salts, humectants, preservatives)	Premade manufactured	Moist snuff is commonly used loose but also comes in small, ready-to-use pouches. It is usually held in the mouth for about 30 mins. Saliva is spat out but can be swallowed. A pinch (called a dip) or a pouch is placed and held between the lip or cheek and gum. Saliva maybe swallowed or more commonly spat out.	Oral snuff which is composed of fermented, air- or fire-cured tobacco mixed with flavourings (spices, essential oils, extracts), sweeteners, inorganic salts, humectants, and preservatives and processed into moist fine particles (fine cut) or strips (long cut).
33	Nasal snuff	luktsnus, luktesnus, Scotch snuff	EURO (Sweden, Norway); AMRO (USA)	Nasal	Tobacco containing (Dry, powdered form of snuff. Can be mentholated)	Premade manufactured	It is insufflated- sniffed but not deeply snorted through the nose.	A smokeless tobacco-containing product that is designed for nasal use, formed of dried and finely-ground tobacco

34	Nass	Naswar, Niswar	EMRO (Pakistan, Iran, Afghanistan, UAE) AFRO (South Africa) EURO (Turkmenistan)	Oral	Nass: Tobacco containing (Dried tobacco leaves, ash, cotton or sesame oil, water and sometimes gum) Naswar: Tobacco containing (Dried tobacco leaves, slaked lime, ash, indigo, oil, water, and sometimes flavourings such as cardamon and menthol)	Custom-made vendor/ individual	The mixture is rolled into balls and placed in the mouth for 10 to 15 minutes and chewed slowly.	A smokeless tobacco-containing product that is designed for oral use, composed of dried tobacco leaves, ash, cottonseed or sesame oil, water and sometimes gum which are rolled into balls.
35	Nasway	Nasvay, Nisvai	EURO (Uzbekistan, Kyrgyzstan, Tajikistan)	Oral	Tobacco containing (Sun-dried and heat-dried tobacco leaves mixed with slaked lime, water, ash from tree bark, oil or butter flavourings and colouring agents)	Custom-made vendor/ individual	Rolled into a ball and placed under the tongue or in the cheek. Held in the mouth and sucked for 10 to 15 minutes.	A smokeless tobacco-containing product that is designed for oral use, composed of sun, or heat-dried tobacco leaves mixed with slaked lime, water, ash from tree bark, oil or butter flavourings and colouring agents that are rolled into a ball.
36	Neffa	Naffa, Nufha, Tenfeha, Tumbaco	AFRO (Algeria, DRC); EMRO (Libya, Tunisia, Morocco)	Nasal	Tobacco-containing (Type of dry snuff)	Premade cottage industry or custom-made vendor/individual	Used nasally to induce sneezing or lighten the head	A smokeless tobacco-containing product that is designed for nasal use, composed of dried tobacco that is made into a fine powder (But NOT SURE -— please see notes)

37	NuNu	-	AMRO (Brazil)	Nasal	Tobacco containing (Inner bark of Mocambo tree, cacahuilo tree and dark-coloured Mapacho (Nicotiana rustica)	extremely fine dust; Premade cottage industry	-	Nasal snuff in which dark coloured Mapacho tobacco, inner bark of Mocambo tree and cacahuilo tree are mixed to form an extremely fine dust
38	Oral smokeless tobacco leaf	Leaf tobacco, Sada pata, Chadha	SEARO (India, Bangladesh, Myanmar, Bhutan)	Oral	Tobacco-containing (Raw tobacco leaf usually dried and left unprocessed)	Powdered, flaked, or sold in bundles of several long strands (about 115 cm long and 5 cm thick); custom-made vendor/individual	Chewed, chewed in betel quid or other custom-made product. A regular user consumes one 15-cm piece of the strand per day.	A smokeless tobacco-containing product, in which raw tobacco leaf is powdered, flaked or sold in bundles of several long strands.
39	Orbs	-	AMRO (USA)	Oral	Tobacco containing (Pellets made of finely ground tobacco with mint or cinnamon flavouring)	Premade manufactured	Placed in the mouth and dissolved like breath mints	Dissolvable tobacco product in which finely ground tobacco, mint or cinnamon flavouring are mixed to form pellets.
40	Pandharpuri	Sweekah, Afzal (brand)	EMRO (Oman); SEARO (India)	Oral	Tobacco containing (Mixture of different tobacco flakes and lime)	Premade manufactured	The tobacco flakes are mixed with lime as per the required proportions to moisten the dried tobacco flakes before it is chewed	A smokeless tobacco-containing product that is designed for oral use, composed of dried tobacco flakes mixed with required proportions of lime and other additives to create a moist form.
41	Pattiwala	-	SEARO (India)	Oral	Tobacco containing (sun-cured or flaked tobacco leaf used with or without lime)	Custom-made vendor/individual	-	Chewing tobacco products are composed of sun-dried flaked tobacco mixed with or without lime.

42	Pituri	Mingkulpa	WPRO (Australia)	Oral	Tobacco containing (fresh, sun/fire dried tobacco leaves mixed with ash)	Pituri is prepared by breaking up fresh or sun/fire-dried tobacco leaves into pieces, mixing them with ash and chewing to form a quid Custom-made/individual	The quid is held in the lower lip and buccal cavity or the cheek for extended periods of time	A smokeless tobacco-containing product that is designed for oral use, in which sun/fire-dried tobacco leaves are mixed with ash to form a quid.
43	Plug	Plug chewing tobacco, Chaw, Plug spit tobacco, Pressed leaf	AMRO (USA, Canada)	Oral	Tobacco containing (Burley and bright tobacco or cigar tobacco leaves, liquorice, and sugar)	Premade manufactured	A piece of the plug is cut off and chewed or held between the cheek and gum. Saliva is usually spat out, but it can also be swallowed	A smokeless tobacco-containing product that is designed for oral use, in which Burley and bright tobacco or cigar tobacco leaves, liquorice, and sugar are mixed to form a moist product.
44	Portion snus	-	-	Oral	Tobacco containing	Packaged moist powder in small teabag-like sachets Premade manufactured	-	Snus that is packaged into small teabag-like sachets.
45	Rapè	-	AMRO (Brazil)	Nasal	Tobacco-containing (Dried toasted tobacco leaf, flavourings such as tonka bean, clove, cinnamon powder, camphor, and in some cases, ashes from select trees)	powdered into fine dust; premade cottage industry or custom-made vendor/ individual)	The tobacco and other ingredients are finely powdered and then blown or snorted high into each of the nostril cavities through a ceremonial pipe made of bone or bamboo	Nasal snuff in which dried tobacco leaves, flavourings such as tonka bean, clove, cinnamon powder, camphor, and in some cases, ashes from select trees are mixed to form a fine powder.

46	Red shammah		-	-	-	-	-	Shammah with ingredients that give it a red colour
47	Red toothpowder	Lal dant manjan, Tobacco toothpowder	SEARO (India)	Oral	Tobacco containing (Tobacco mixed with herbs, and flavourings. Additional plant-related ingredients such as ginger, pepper, and camphor, among others, may be used.)	Fine red tobacco powder; premade manufactured	Used to clean teeth	A smokeless tobacco-containing product that is designed for oral use, in which tobacco, herbs and flavourings are mixed to form a fine red powder.
48	Shammah	El-shamma, Bajeli, Haradi, Sharaci, Al-shammah (Saudi Arabia), Chemma (Algeria), Shamma, Alqat, Yemeni snuff, Makla, Bardaga	EMRO (Saudi Arabia, Yemen); AFRO (Algeria)	Oral	Tobacco containing (Tobacco, slaked lime, ash, black pepper, oil, flavourings, bombosa (sodium carbonate))	White shammah is sold as a dry product whereas black shammah is sold as a wet product; Custom-made vendor/ individual	Shammah is placed between the gum and the lower lip or cheek. In Algeria, users may wrap shammah in paper before putting it in their mouth. Orally chewed or held in the mouth	Oral snuff in which powdered tobacco is mixed with slaked lime, ash, black pepper, oils and flavourings and placed in the mouth as a quid
49	Smokeless tobacco cartridge*	-		-	-	Premade manufactured	-	-
50	Snuif	Traditional South African snuff	AFRO (South Africa, Lesotho, Swaziland)	Oral OR Nasal	Tobacco containing (Hand mixed finely ground sun-dried tobacco leaf with ash from local plants like amaranthus and aloe vera)	Cottage; custom	Held in the mouth or used nasally	A smokeless tobacco-containing product that is designed for either oral or nasal use, in which sun-dried tobacco leaf and ash from local plants are hand mixed to form a finely ground powder.

51	Snus	-	EURO (Sweden, Norway, Iceland, Finland, Denmark); AMRO (USA, Canada, Brazil); AFRO (South Africa)	Oral	Tobacco containing (Heat treated or pasteurised tobacco mixed with sodium carbonate, moisturisers, salt (sodium chloride), sweeteners, flavourings and water)	Premade manufactured	Snus can either be packaged into small, ready-to-use sachets or sold in loose tobacco form. One portion of snus is usually held in the mouth for 30 minutes or more and does not require chewing, sucking, or spitting. In Sweden, the average user keeps snus in their mouth for 11 to 14 hours per day.	Oral snuff in which air-cured tobacco is mixed with salt, water, humectants, alkaline agents, and flavourings to form a moist product which is placed behind the lip, either loose or in portioned sachets
52	Soft pellete	Pellet	AMRO (USA)		Tobacco containing	Ground tobacco shaped into compressed pellets; Premade manufactured	-	Dissolvable tobacco products in which ground tobacco, humectants, preservatives, and flavours are compressed into soft pellets.
53	Spit-free tobacco*	-	EURO (Sweden); AMRO (USA)	-	Tobacco containing	Premade manufactured	-	-
54	Sticks	-	AMRO (USA)	Oral	Tobacco containing (Tobacco, humectants, preservatives, flavours)	Ground tobacco shaped into compressed sticks; Premade manufactured	Used orally, held in the mouth and it is dissolved	Dissolvable tobacco products in which ground tobacco, humectants, preservatives, and flavours are compressed to form sticks.
55	Strips	-	AMRO (USA)	Oral	Tobacco containing (Tobacco, humectants, preservatives, flavours)	Ground tobacco shaped into compressed strips; Premade manufactured	Used orally, held in the mouth and it is dissolved	Dissolvable tobacco products in which ground tobacco, humectants, preservatives, and flavours are compressed into strips.

56	Sudanese saute*	-		Nasal	Tobacco containing	-	-	-
57	Sweet tombol	-	EMRO (Yemen)	Oral	Tobacco-containing (Different types), mixed with flavouring and ingredients such as noura, slaked lime, areca nut, catechu, sometimes powdered khat (Catha edulis), and wrapped in tombol (betel) leaf	Custom-made vendor/individual	Placed in the mouth and sucked and chewed.	Tombol, with ingredients that provide a sweet flavour/taste
58	Taaba	Nigerian Traditional Snuff	AFRO (Nigeria, Cameroon, Senegal, Chad, Uganda)	Oral OR Nasal	Tobacco containing (Dry fermented tobacco mixed with natron (a mixture of sodium bicarbonate and sodium chloride)	Premade cottage industry or custom-made vendor/individual	Held in the mouth or used nasally to induce sneezing to lighten the head	A smokeless tobacco-containing product that is designed for either oral or nasal use, in which dry fermented tobacco is mixed with natron (a mixture of sodium bicarbonate and sodium chloride) and ground into a fine powder.
59	Tabaco en cuerda*	-	North of Argentina	-	-	-	-	-
60	Taboka	-	AMRO (USA)	Smokeless tobacco	Tobacco-containing (Smoke-free, spit-free tobacco)	Small teabag-like pouches that are placed under the upper lip	By holding it under the upper lip	Oral snuff is composed of tobacco which is sometimes flavoured with menthol and sold as small teabag-like pouches.

61	Tawa	Ghana traditional snuff	AFRO (Ghana)	Oral OR Nasal	Tobacco containing (Dried tobacco leaves with saltpetre (potassium nitrate) and ashes.	Ground into a fine powder; premade cottage industry or custom-made vendor/individual	Held in the mouth or used nasally to induce sneezing to lighten the head	A smokeless tobacco-containing product that is designed for either oral or nasal use, which is composed of dried tobacco leaf with, saltpetre (potassium nitrate) and ashes which are ground into a fine powder.
62	Thinso*	-	AFRO(Tanzania)	Oral	Tobacco containing (Gutka)	-	Either placed in the cheek or chewed, together with areca nut	-
63	Tobacco chewing gum	-	WPRO (Guam, Japan)	Oral	Tobacco containing (Finely ground tobacco with chewing gum base and xylitol)	Chewing gum; Premade manufactured	Chewed	Chewing tobacco product which is composed of finely ground tobacco, chewing gum base and xylitol.
64	Tobacco coated toothpick	-	AMRO (USA)	Oral	Tobacco containing (Nicotine with flavours like strawberry, peppermint, spearmint, coffee, cinnamon etc.)	Premade manufactured	Placed in the mouth like a toothpick. Sometimes chewed to increase the speed of nicotine release	A smokeless tobacco-containing product that is designed for oral use, which is composed of nicotine with flavours like strawberry, peppermint, spearmint, coffee, cinnamon etc and is placed in the mouth like a toothpick.
65	Tobacco lozenges	-	AMRO (USA)	Oral	Tobacco-containing (Sugar-free tablet with various flavouring agents like cinnamon, fruit and mint)	Ground tobacco shaped into compressed lozenges; Premade manufactured	Lozenge is placed in the mouth and allowed to dissolve over the course of 20 to 30 mins.	Dissolvable tobacco product in which ground tobacco is mixed with various flavouring agents like cinnamon, fruit and mint to form a sugar-free tablet.

66	Tobacco tablets	Cigalet, Ariva	AMRO (USA)	Oral	Tobacco containing (Tobacco, humectants, preservatives, flavours)	Premade manufactured	Used orally, held in the mouth and it is dissolved	Dissolvable tobacco products in which ground tobacco, humectants, preservatives, and flavours are compressed to form tablets.
67	Tombol	-	EMRO (Middle East, Yemen)	Oral	Tobacco-containing (Different types —dry, thin pieces of Yemeni tobacco, called socha (similar to Indian pattiwalla), or zarda, a scented tobacco from India). Mixed with flavouring and ingredients such as noura, slaked lime, areca nut, catechu, and sometimes powdered khat (Catha edulis), and wrapped in tombol (betel) leaf	Custom-made vendor/individual	Placed in the mouth and sucked and chewed.	A smokeless tobacco-containing product that is designed for oral use, in which different types of tobacco, with flavouring and other ingredients, are wrapped in a tombol (betel) leaf
68	Tombol with Khat*	-	EMRO (Yemen)	Oral	Tobacco containing (Tobacco with areca nut, slaked lime, noura, betel leaf, catechu and khat)	Custom-made vendor/individual	-	-

69	Toombak	Sauté, Sute, Ammari, Saood, Saffa	EMRO (Sudan); AFRO (Chad)	Oral	Tobacco-containing (Sun-dried, fermented, then ground and aged tobacco mixed with a solution of baking soda (sodium bicarbonate) and water)	A moist form that can be rolled into a ball (called a saffa); Cottage industry and custom-made/Premade ingredients used to make a custom-made product. In addition to selling ready-made toombak, vendors may sell dry toombak leaves and baking soda separately so that customers can prepare their own toombak	A small portion of the toombak, weighing about 10 grams, is rolled into a ball called a saffa. It is sucked slowly for 10 to 15 minutes; the saliva that is produced is then spat out or swallowed. Users usually rinse their mouths with water after the saffa is removed.	Oral snuff in which sun-dried, fermented, then ground and aged tobacco leaves are mixed with a solution of baking soda and water to create a moist form that can be rolled into a ball (called a saffa).
70	Tuibur	Tuiber, Tobacco water, Hidakphu	SEARO (India -–NE states)	Oral	Tobacco-containing? (Tobacco smoke)	Passed through water and sold in glass bottles; Premade cottage industry	Tuibur is either sipped from a bottle or through cotton soaked with tobacco water. It is retained in the mouth or gargled for 5 to 10 minutes before it spits out.	A smokeless tobacco-containing product that is designed for oral use, in which tobacco smoke is passed through water and the resulting tobacco water is sold in glass bottles.

71	Twist	Twist chewing tobacco, Chew, Chaw, Roll	AMRO (USA)	Oral	Tobacco-containing (Air- or fire-cured burley tobacco leaf, treated with a tar-like tobacco leaf extract and sometimes sweeteners and other flavourings. The tobacco is then twisted into rope-like strands that are dried.)	The final product is a pliable, but dry, rope. The twist is sold by piece in varying sizes, depending on the number of leaves in the twist; handmade by commercial manufacturers	Users typically cut off a piece, place it in their mouth, and chew. Saliva is usually spat out, but it can also be swallowed.	A smokeless tobacco-containing product that is designed for oral use, in which air- or fire-cured burley tobacco leaf is treated with a tar-like tobacco leaf extract and sometimes sweeteners and other flavourings, then twisted into rope-like strands that are dried and braided.
72	Ugoro*	-	AFRO(Tanzania)	Oral or nasal	Tobacco-containing (Moist oral snuff)		Placed under the tongue or sniffed	-
73	Watery tobacco*	-	SEARO (Myanmar)	Oral	Tobacco-containing (Tobacco mixed with water)	Liquid; Premade cottage industry	-	-
74	White shammah		-	-	-	-	-	Shammah with ingredients that give it a white colour
75	Yellow shammah	Safra Bardaga, Safra Suhaila	-	-	-	-	-	Shammah with ingredients that give it a yellow colour
76	Zarda	Dokta, Vizapatta, Surti, Sukla, Gundi, Pheri, Kharsan	EMRO (Yemen); SEARO (India, Bangladesh, Myanmar, Nepal, Bhutan); Also, SEA diaspora	Oral	Tobacco-containing (Boiled and dried leaves mixed with lime, spices and vegetable dyes; sometimes areca nut and silver flecks)	Tobacco flakes; commercially manufactured but usually used in user- or vendor-made paan	Zarda may be chewed by itself, but it is usually chewed with chopped areca nuts and spices. In South-East Asia it is often used in paan, and in Yemen, it is used in tombol.	A smokeless tobacco-containing product that is designed for oral use, in which boiled and dried tobacco leaves are mixed with lime, spices and vegetable dyes (sometimes areca nut and/or silver flecks) to make a flaky product.

APPENDIX 2

LEUKOPLAKIA

Leukoplakia has been defined as “White plaques of questionable risk having excluded other known diseases or disorders that carry no increased risk for cancer” (Van der Waal, 2009). It is classified into two main types depending on the appearance, Homogenous leukoplakia (white lesion) and non-homogenous leukoplakia (red and white lesions). Homogenous leukoplakia is characterised by a white well-demarcated plaque with an identical reaction pattern throughout the entire lesion while non-homogenous leukoplakia consists of white patches intermixed with red tissue elements. Non-homogeneous varieties carry a greater risk of malignant transformation than homogenous varieties (Warnakulasuriya, Johnson et al., 2007).

ERYTHROPLAKIA

Erythroplakia has been defined as “A fiery red patch that cannot be characterised clinically or pathologically as any other definable disease” (Pindborg, Reichart et al., 1997). Erythroplakia, although uncommon carries the highest risk of potential malignant transformation (Warnakulasuriya, Johnson et al., 2007).

ORAL SUBMUCOUS FIBROSIS

Oral Submucous Fibrosis (OSMF) is a chronic disease that affects the oral mucosa as well as the pharynx and the upper two-thirds of the oesophagus. It is characterised by the formation of distinctive fibrous bands in the mouth. Other clinical features include blanching and leathery texture of mucosa, restricted mouth opening, distortion of uvula and woody changes to mucosa and tongue (Warnakulasuriya, Johnson et al., 2007)

APPENDIX 3

Table 41: Methods of detection and diagnosis of oral cancer and OPMDs

TECHNIQUE	PROCESS	ADVANTAGES	DISADVANTAGES	DURATION OF PROCEDURE	LEVEL OF EXPERTISE REQUIRED	TOOLKIT REQUIRED
Conventional Oral Examination(COE)	A standard visual and tactile examination of the oral mucosa performed under normal (incandescent) light(Walsh, Liu et al., 2013)	Minimally invasive procedure that is applicable in primary care settings; can be used by trained non healthcare professionals; quick to perform and cost effective(Speight, Epstein et al., 2017)	Results depend upon training and calibration of the examiner; cannot differentiate between benign, pre malignant and malignant lesions.	Short	None; relatively minimal training required for non-professionals	Diagnostic instruments, basic light source
Oral Cytology	Includes brush biopsy; surgical removal of the abnormal tissue followed by histopathological evaluation.	Gold standard test for diagnosis; high sensitivity and specificity.	Invasive procedure; performed only by clinicians.	Long	Clinicians only	Instruments for biopsy as well as
Vital Staining	It involves the use of dyes such as Toluidine blue or Tolonium chloride to stain oral mucosa tissues for detecting OPMDs or malignancy(Lestón and Dios, 2010)	Identifies and defines abnormal and malignant areas that may be missed by (COE).	Results based on uptake of colour by the abnormal cells; difference in interpretation of results based on examiner's experience.	Short	Training required for non-healthcare professionals	Staining dyes
Light based detection system	Direct visual examination under a specific light source (mostly blue white light). Includes Chemiluminescence (ViziLite) and tissue fluorescence spectrometry (VELscope)(Lingen, Kalmar et al., 2008b)	Distinguishes normal epithelium from abnormal epithelium; identifies lesions that maybe missed under normal light; simple to use; non-invasive; consumables not required.	Costly light source and initial set up; need for dark environment for examination; not tested in primary care settings.	Short	Done only by clinicians as of now	Specific light source like ViziLite, VELscope etc.

APPENDIX 4

SEARCH STRATEGY

DATABASE: Ovid MEDLINE(R) <1946 to February 01, 2021>

Table 42: Search strategy (Ovid MEDLINE)

	SEARCH QUERY	RESULTS
1	smokeless tobacco*.mp. or Tobacco, Smokeless/ [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	4479
2	(oral* adj3 tobacco*).mp.	716
3	(chew* adj3 tobacco*).mp.	1307
4	(spit* adj3 tobacco*).mp.	55
5	(dip* adj3 tobacco*).mp.	85
6	(p?an adj3 (masala or quid)).mp.	126
7	(quid adj3 (betel or tobacco*)).mp.	970
8	k?aini.mp.	35
9	tumbaku.mp.	1
10	tambak*.mp.	5
11	gutk?a.mp.	162
12	(zarda or vizapatta).mp.	27
13	gul.mp.	80
14	kharra.mp.	2
15	kiwam.mp.	1
16	mishri.mp.	16
17	m?sheri.mp.	24
18	mawa.mp.	18
19	gudak?u.mp.	4
20	(n?swar or nas?ay).mp.	45

21	tuibur.mp.	6
22	toombak.mp.	38
23	mainpuri.mp.	16
24	chimo.mp.	14
25	(shamma or shammah or el-shama or chemma or al-shammah).mp.	41
26	(black bull adj3 tobacco).mp.	1
27	iqmik.mp.	15
28	(tawa adj3 tobacco).mp.	2
29	snuf*.mp.	1508
30	snus.mp.	543
31	(maras adj3 (powder or tobacco*)).mp.	34
32	((twist* or plug*) adj3 tobacco*).mp.	17
33	((loose leaf or toothpaste*) adj3 tobacco*).mp.	15
34	((pouch* or mix* or powder*) adj3 tobacco*).mp.	301
35	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34	7291
36	nitrosamines.mp. or exp Nitrosamines/	13819
37	Nitrates/ or Nitroso Compounds/ or N-nitrosamino acid*.mp.	34240
38	polycyclic aromatic hydrocarbons.mp. or exp Polycyclic Aromatic Hydrocarbons/	453289
39	exp Alkaloids/ or alkaloids.mp.	469566
40	radionucleotide*.mp.	230
41	exp Nicotine/ or nicotine.mp.	44618
42	exp Lead/ or metalloid.mp. or exp Arsenic/ or exp Metalloids/ or exp Metals, Heavy/ or exp Cadmium/ or exp Metals/	1143503
43	exp Carcinogens/ or carcinogen*.mp.	244597
44	exp Volatile Organic Compounds/ or exp Aldehydes/ or volatile aldehyde*.mp.	111911

45	chemical*.mp.	1754261
46	toxic*.mp.	898112
47	36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46	4053568
48	35 and 47	3614
49	limit 48 to yr="2013 -Current"	895

DATABASE: Embase 1974 to 2021 February 01

Table 43: Search strategy (Embase)

	SEARCH QUERY	RESULTS
1	smokeless tobacco*.mp. or Tobacco, Smokeless/ [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	5847
2	(oral* adj3 tobacco*).mp.	998
3	(chew* adj3 tobacco*).mp.	2155
4	(spit* adj3 tobacco*).mp.	68
5	(dip* adj3 tobacco*).mp.	104
6	(p?an adj3 (masala or quid)).mp.	198
7	(quid adj3 (betel or tobacco*)).mp.	1382
8	k?aini.mp.	70
9	tumbaku.mp.	2
10	tambak*.mp.	18
11	gutk?a.mp.	357
12	(zarda or vizapatta).mp.	36
13	gul.mp.	171
14	kharra.mp.	5
15	kiwam.mp.	4
16	mishri.mp.	36

17	m?sheri.mp.	29
18	mawa.mp.	36
19	gudak?u.mp.	6
20	(n?swar or nas?ay).mp.	97
21	tuibur.mp.	8
22	toombak.mp.	49
23	mainpuri.mp.	26
24	chimo.mp.	17
25	(shamma or shammah or el-shama or cqmikor al-shammah).mp.	64
26	(black bull adj3 tobacco).mp.	1
27	iqmikmp.	22
28	(tawa adj3 tobacco).mp.	2
29	snuf*.mp.	1978
30	snus.mp.	734
31	(maras adj3 (powder or tobacco*)).mp.	64
32	((twist* or plug*) adj3 tobacco*).mp.	21
33	((loose leaf or toothpaste*) adj3 tobacco*).mp.	18
34	((pouch* or mix* or powder*) adj3 tobacco*).mp.	462
35	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34	10611
36	nitrosamines.mp. or exp Nitrosamines/	19134
37	Nitrates/ or Nitroso Compounds/ or N-nitrosamino acid*.mp.	12573
38	polycyclic aromatic hydrocarbons.mp. or exp Polycyclic Aromatic Hydrocarbons/	80360
39	exp Alkaloids/ or alkaloids.mp.	492515
40	radionucleotide*.mp.	367
41	exp Nicotine/ or nicotine.mp.	67991

42	exp Lead/ or metalloid.mp. or exp Arsenic/ or exp Metalloids/ or exp Metals, Heavy/ or exp Cadmium/ or exp Metals/	1556523
43	exp Carcinogens/ or carcinogen*.mp.	475578
44	exp Volatile Organic Compounds/ or exp Aldehydes/ or volatile aldehyde*.mp.	159862
45	chemical*.mp.	1662493
46	toxic*.mp.	1450145
47	36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46	4937217
48	35 and 47	3729
49	limit 48 to yr="2013 -Current"	1610

DATABASE: APA PsycInfo 1806 to January Week 4 2021

Table 44: Search strategy (APA PsycInfo)

	SEARCH QUERY	RESULTS
1	smokeless tobacco*.mp. or Tobacco,Smokeless/ [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	1385
2	(oral* adj3 tobacco*).mp.	81
3	(chew* adj3 tobacco*).mp.	328
4	(spit* adj3 tobacco*).mp.	29
5	(dip* adj3 tobacco*).mp.	21
6	(p?an adj3 (masala or quid)).mp.	8
7	(quid adj3 (betel or tobacco*)).mp.	88
8	k?aini.mp.	5
9	tumbaku.mp.	4
10	tambak*.mp.	2
11	gutk?a.mp.	24
12	(zarda or vizapatta).mp.	2

13	gul.mp.	50
14	kharra.mp.	0
15	kiwam.mp.	0
16	mishri.mp.	1
17	m?sheri.mp.	0
18	mawa.mp.	0
19	gudak?u.mp.	0
20	(n?swar or nas?ay).mp.	5
21	tuibur.mp.	2
22	toombak.mp.	0
23	mainpuri.mp.	0
24	chimo.mp.	0
25	(shamma or shammah or el-shama or cqmikor al-shammah).mp.	13
26	(black bull adj3 tobacco).mp.	0
27	iqmikmp.	6
28	(tawa adj3 tobacco).mp.	1
29	snuf*.mp.	285
30	snus.mp.	304
31	(maras adj3 (powder or tobacco*)).mp.	4
32	((twist* or plug*) adj3 tobacco*).mp.	0
33	((loose leaf or toothpaste*) adj3 tobacco*).mp.	6
34	((pouch* or mix* or powder*) adj3 tobacco*).mp.	70
35	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34	1992
36	nitrosamines.mp.	115
37	(N-nitrosamino acid* or nitroso compound* or nitrate*).mp.	796
38	polycyclic aromatic hydrocarbons.mp.	114
39	alkaloids.mp. or exp Alkaloids/	46913

40	radionucleotide*.mp.	1
41	exp Nicotine/ or nicotine.mp.	22790
42	exp Metals/ or metalloid.mp.	19897
43	exp Carcinogens/ or carcinogen*.mp.	1018
44	(volatile organic compound* or volatile aldehyde*).mp.	141
45	chemical*.mp.	25218
46	toxic*.mp.	22864
47	36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46	118791
48	35 and 47	1410
49	limit 48 to yr=”2013 -Current”	617

DATABASE: EBSCO CINAHL Complete

Table 45: Search strategy (EBSCO CINAHL)

	SEARCH QUERY	RESULTS
1	(MH “Tobacco, Smokeless”) OR “smokeless tobacco”	2231
2	oral* N3 tobacco*	321
3	chew* N3 tobacco*	396
4	spit* N3 tobacco*	27
5	dip* N3 tobacco*	35
6	p#an N3 (masala or quid)	34
7	(quid N3 (betel or tobacco*)	314
8	k#aini	5
9	tumbaku	1
10	tambak*	2
11	gutk#a	78
12	zarda or vizapatta	10
13	gul	33

14	kharra	1
15	kiwam	0
16	mishri	6
17	m#sheri	1
18	mawa	7
19	gudak#u	0
20	(n#swar or nas#ay)	12
21	tuibur	2
22	toombak	10
23	mainpuri	3
24	chimo	1
25	shamma or shammah or el-shama or cqmikor al-shammah	13
26	black bull N3 tobacco	0
27	iqmik	4
28	tawa N3 tobacco	0
29	snuf*	448
30	snus	363
31	maras N3 (powder or tobacco*)	11
32	(twist* or plug*) N3 tobacco*	3
33	(loose leaf or toothpaste*) N3 tobacco*	6
34	(pouch* or mix* or powder*) N3 tobacco*	101
35	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34	3262
36	(MH “Nitrosamines+”) OR “nitrosamines”	427
37	(MH “Nitrates+”) OR (MH “Nitrogen Compounds+”) OR N-nitrosamino acid*	25657
38	(MH “Polycyclic Hydrocarbons, Aromatic”) OR “polycyclic aromatic hydrocarbon*”	700
39	(MH “Alkaloids+”) OR “alkaloids”	42305

40	radionucleotide*	39
41	(MH “Nicotine+”) OR nicotine	12949
42	(MH “Metals, Heavy+”) OR (MH “Metals+”) OR “heavy metals” OR “metalloid*”	64778
43	(MH “Carcinogens+”) OR “carcinogen*”	12770
44	“volatile organic compound*” OR (MH “Aldehydes+”) OR “volatile aldehyde*”	6138
45	“chemical*”	131772
46	“toxic*”	70299
47	S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46	326943
48	S35 AND S47	786
49	limit S48 to yr=”2013 -Current”	416

DATABASE: Web of Science

Table 46: Search strategy (Web of Science)

	SEARCH QUERY	**RESULTS**
1	TS=(“smokeless tobacco”)	3869
2	TS=(oral* Near/3 tobacco*)	945
3	TS=(chew* Near/3 tobacco*)	1426
4	TS=(spit* Near/3 tobacco*)	78
5	TS=(dip* Near/3 tobacco*)	127
6	TS=(p$an Near/3 masala) OR TS=(p$an Near/3 quid)	173
7	TS=(quid Near/3 betel) OR TS=(quid Near/3 tobacco*)	1301
8	TS=(k$aini)	46
9	TS=(tumbaku)	1
10	TS=(tambak*)	56
11	TS=(gutk$a)	234

12	TS=(zarda) OR TS=(vizapatta)	35
13	TS=(gul)	332
14	TS=(kharra)	1
15	TS=(kiwam)	2
16	TS=(mishri)	12
17	TS=(m$sheri)	28
18	TS=(mawa)	56
19	TS=(gudak$u)	7
20	TS=(n$swar) OR TS=(nas$ay)	45
21	TS=(tuibur)	11
22	TS=(toombak)	62
23	TS=(mainpuri)	32
24	TS=(chimo)	36
25	TS=(shamma) OR TS=(shammah) OR TS=(el-shama) OR TS=(cqmik OR TS=(al-shammah)	71
26	TS=(black bull Near/3 tobacco)	0
27	TS=(iqmik	20
28	TS=(tawa Near/3 tobacco)	2
29	TS=(snuf*)	1987
30	TS=(snus)	763
31	TS=(maras Near/3 powder) OR TS=(maras Near/3 tobacco*)	55
32	TS=(twist* Near/3 tobacco*) OR TS=(plug* Near/3 tobacco*)	19
33	TS=(loose leaf Near/3 tobacco*) OR TS=(toothpaste* Near/3 tobacco*)	20
34	TS=(pouch* Near/3 tobacco*) OR TS=(mix* Near/3 tobacco*) OR TS=(powder* Near/3 tobacco*)	513
35	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34	9081
36	TS=(nitrosamine*)	8381

37	TS=(nitrate*) OR TS=(nitroso compound*) OR TS=(N-nitrosamino acid*)	213512
38	TS=("polycyclic aromatic hydrocarbons") OR TS=(polycyclic aromatic hydrocarbon*)	63984
39	TS=("alkaloids") OR TS=("alkaloid*")	94521
40	TS=(radionucleotide*)	203
41	TS=(nicotine)	56394
42	TS=(lead) OR TS=(metalloid*) OR TS=(arsenic) OR TS=(metal*) OR TS=("heavy metal*") OR TS=(cadmium)	5584731
43	TS=(carcinogen*)	169654
44	TS=("volatile organic compound*") OR TS=(aldehyde*) OR TS=("volatile aldehyde*")	173119
45	TS=(chemical*)	2065427
46	TS=(toxic*)	881170
47	#46 OR #45 OR #44 OR #43 OR #42 OR #41 OR #40 OR #39 OR #38 OR #37 OR #36	8339333
48	#47 AND #35	3256
49	#48[Timespan2013-2021]	1581

DATABASE: The Cochrane Library

Table 47: Search strategy (The Cochrane Library)

	SEARCH QUERY	RESULTS
1	("smokeless tobacco"):ti,ab,kw (Word variations have been searched)	331
2	MeSH descriptor: [Tobacco, Smokeless] explode all trees	144
3	(oral* near/3 tobacco*):ti,ab,kw (Word variations have been searched)	58
4	(chew* near/3 tobacco*):ti,ab,kw (Word variations have been searched)	82
5	(spit* near/3 tobacco*):ti,ab,kw (Word variations have been searched)	24
6	(dip* near/3 tobacco*):ti,ab,kw (Word variations have been searched)	2

7	(p*an near/3 (masala or quid)):ti,ab,kw (Word variations have been searched)	31
8	(quid near/3 (betel or tobacco*)):ti,ab,kw (Word variations have been searched)	34
9	(k*aini):ti,ab,kw (Word variations have been searched)	10
10	(tumbaku):ti,ab,kw (Word variations have been searched)	0
11	(tumbaku):ti,ab,kw (Word variations have been searched)	0
12	(gutk*a):ti,ab,kw (Word variations have been searched)	13
13	(zarda or vizapatta):ti,ab,kw (Word variations have been searched)	1
14	(gul):ti,ab,kw (Word variations have been searched)	18
15	(kharra):ti,ab,kw (Word variations have been searched)	0
16	(kiwam):ti,ab,kw (Word variations have been searched)	0
17	(mishri):ti,ab,kw (Word variations have been searched)	3
18	(m*sheri):ti,ab,kw (Word variations have been searched)	2
19	(mawa):ti,ab,kw (Word variations have been searched)	1
20	(gudak*u):ti,ab,kw (Word variations have been searched)	2
21	(n*swar or nas*ay):ti,ab,kw (Word variations have been searched)	24
22	(tuibur):ti,ab,kw (Word variations have been searched)	0
23	(toombak):ti,ab,kw (Word variations have been searched)	0
24	(mainpuri):ti,ab,kw (Word variations have been searched)	0
25	(chimo):ti,ab,kw (Word variations have been searched)	1
26	(shamma or shammah or el-shama or cqmikor al-shammah):ti,ab,kw (Word variations have been searched)	5
27	(black bull near/3 tobacco):ti,ab,kw (Word variations have been searched)	0
28	(iqmik:ti,ab,kw (Word variations have been searched)	2
29	(tawa near/3 tobacco):ti,ab,kw (Word variations have been searched)	0
30	(snuf*):ti,ab,kw (Word variations have been searched)	117
31	(snus):ti,ab,kw (Word variations have been searched)	91

32	(maras near/3 (powder or tobacco*)):ti,ab,kw (Word variations have been searched)	2
33	((twist* or plug*) near/3 tobacco*):ti,ab,kw (Word variations have been searched)	2
34	((“loose leaf” or toothpaste*) near/3 tobacco*):ti,ab,kw (Word variations have been searched)	0
35	((pouch* or mix* or powder*) near/3 tobacco*):ti,ab,kw (Word variations have been searched)	32
36	#35 OR #34 OR #33 OR #32 OR #31 OR #30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1	696
37	(nitrosamines):ti,ab,kw (Word variations have been searched)	72
38	MeSH descriptor: [Nitrosamines] explode all trees	29
39	(“N-nitroso compound*”):ti,ab,kw (Word variations have been searched)	29
40	(“polycyclic aromatic hydrocarbon*”):ti,ab,kw (Word variations have been searched)	70
41	MeSH descriptor: [Polycyclic Aromatic Hydrocarbons] explode all trees	34669
42	(alkaloids):ti,ab,kw (Word variations have been searched)	807
43	MeSH descriptor: [Alkaloids] explode all trees	32109
44	(“radionucleotide*”):ti,ab,kw (Word variations have been searched)	19
45	(nicotine):ti,ab,kw (Word variations have been searched)	8898
46	MeSH descriptor: [Nicotine] explode all trees	2653
47	(metalloid* or metal*):ti,ab,kw (Word variations have been searched)	8275
48	MeSH descriptor: [Metalloids] explode all trees	170
49	MeSH descriptor: [Metals, Heavy] explode all trees	7407
50	(carcinogen*):ti,ab,kw (Word variations have been searched)	1589
51	MeSH descriptor: [Carcinogens] explode all trees	50
52	(“volatile organic compound*” or “volatile aldehyde*”):ti,ab,kw (Word variations have been searched)	153
53	MeSH descriptor: [Volatile Organic Compounds] explode all trees	45
54	(chemical*):ti,ab,kw (Word variations have been searched)	35648

55	(toxic*):ti,ab,kw (Word variations have been searched)	52216
56	#55 OR #54 OR #53 OR #52 OR #51 OR #50 OR #49 OR #48 OR #47 OR #46 OR #45 OR #44 OR #43 OR #42 OR #41 OR #40 OR #39 OR #38 OR #37	150593
57	#56 AND #36	299
58	#57 (with Cochrane Library publication date from Jan 2013 to Feb 2021)	186

DATABASE: SCOPUS

1. (TITLE-ABS-KEY (smokeless AND tobacco*)) OR (TITLE-ABS-KEY (oral* W/3 tobacco*)) OR (TITLE-ABS-KEY (chew* W/3 tobacco*)) OR (TITLE-ABS-KEY (spit* W/3 tobacco*)) OR (TITLE-ABS-KEY (dip* W/3 tobacco*)) OR (TITLE-ABS-KEY (p*an W/3 masala) OR (TITLE-ABS-KEY (p*an W/3 quid))) OR (TITLE-ABS-KEY (quid W/3 betel) OR (TITLE-ABS-KEY (quid W/3 tobacco*))) OR (TITLE-ABS-KEY (k*aini)) OR (TITLE-ABS-KEY (tumbaku)) OR (TITLE-ABS-KEY (tumbaku)) OR (TITLE-ABS-KEY (gutk*a)) OR (TITLE-ABS-KEY (zarda)) OR (TITLE-ABS-KEY (vizapatta)) OR (TITLE-ABS-KEY (gul)) OR (TITLE-ABS-KEY (kharra)) OR (TITLE-ABS-KEY (kiwam)) OR (TITLE-ABS-KEY (mishri)) OR (TITLE-ABS-KEY (m*sheri)) OR (TITLE-ABS-KEY (mawa)) OR (TITLE-ABS-KEY (gudak*u)) OR (TITLE-ABS-KEY (n*swar)) OR (TITLE-ABS-KEY (nas*ay)) OR (TITLE-ABS-KEY (tuibur)) OR (TITLE-ABS-KEY (toombak)) OR (TITLE-ABS-KEY (mainpuri)) OR (TITLE-ABS-KEY (chimo)) OR (TITLE-ABS-KEY (shamma)) OR (TITLE-ABS-KEY (shammah)) OR (TITLE-ABS-KEY (el-shama)) OR (TITLE-ABS-KEY (cqmik)) OR (TITLE-ABS-KEY (al-shammah)) OR (TITLE-ABS-KEY (black AND bull W/3 tobacco)) OR (TITLE-ABS-KEY (iqmik)) OR (TITLE-ABS-KEY (tawa W/3 tobacco)) OR (TITLE-ABS-KEY (snuf*)) OR (TITLE-ABS-KEY (snus)) OR (TITLE-ABS-KEY (maras W/3 powder) OR (TITLE-ABS-KEY (maras W/3 tobacco*))) OR (TITLE-ABS-KEY (twist* W/3 tobacco*) OR (TITLE-ABS-KEY (plug* W/3 tobacco*))) OR (TITLE-ABS-KEY (“loose leaf” W/3 tobacco*) OR (TITLE-ABS-KEY (toothpaste* W/3 tobacco*))) OR (TITLE-ABS-KEY (pouch* W/3 tobacco*) OR (TITLE-ABS-KEY (mix* W/3 tobacco*)) OR (TITLE-ABS-KEY (powder* W/3 tobacco*))) -**12445**

2.(TITLE-ABS-KEY (nitrosamines*)) OR (TITLE-ABS-KEY(“N-nitroso compound*”)) OR (TITLE-ABS-KEY(“polycyclic aromatic hydrocarbon*”)) OR (TITLE-ABS-KEY(alkaloids*)) OR (TITLE-ABS-KEY(“radionucleotide*”)) OR (TITLE-ABS-KEY(nicotine)) OR (TITLE-ABS-KEY(metalloid*)) OR (TITLE-ABS-KEY (metal*)) OR (TITLE-ABS-KEY (carcinogen*)) OR (TITLE-ABS-KEY(“volatile organic compound*”)) OR (TITLE-ABS-KEY (“volatile aldehyde*”)) OR (TITLE-ABS-KEY(chemical*)) OR (TITLE-ABS-KEY(toxic*))-**8882133**

3. Combining 1 AND 2= **4893** documents

4. Limiting 3 by year (2013-2021) = **1718** documents

DATABASE: African Journals Online (AJOL)

1. (smokeless tobacco*) OR (oral* tobacco*) OR (chew* tobacco*) OR (snuf*) OR (toombak) OR (quid)- **1130** results

2. (nitrosamine*) OR (chemical*)- **138** results

3. Combining 1 and 2- **58** results

(smokeless tobacco*) OR (oral* tobacco*) OR (chew* tobacco*) OR (snuf*) OR (toombak) OR (quid) AND (nitrosamine*) OR (chemical*)

DATABASE: Latin American and Caribbean Health Sciences Literature (LILACS)

1. “SMOKELESS TOBACCO/” or “CHEWING TOBACCO/” or “GUTKHA” or “PAAN” or “CHIMO” or “SNUS” or “SNUFF” or “KHAINI” or “MARAS” or “QUID” or “RAPE (TABACO)/”-**148** results

2. “NITROSAMINES/” or “POLYCYCLIC AROMATIC HYDROCARBONS/” or “ALKALOIDS” or “RADIONUCLEOTIDE” or “NICOTINE” or “METALLOIDS/” or “CARCINOGEN/” or “VOLATILE ORGANIC COMPOUNDS/” or “CHEMICAL” or “TOXIC”-**51353** results

3. Combining 1 and 2- **27** results

DATABASE: WHO Index Medicine of the Eastern Mediterranean Region (IMEMR)

Not accessible

DATABASE: PakMediNet

1. smokeless tobacco OR chewing tobacco OR oral tobacco – **59** results

2. nitrosamine OR polycyclic aromatic hydrocarbons OR nicotine OR carcinogen OR chemical- **10** results

3. Combining 1 and 2- No references.

DATABASE: IndMed

No references

APPENDIX 5

SCREENING FORM FOR FULL-TEXT ARTICLES

Table 48: Screening form for full-text articles

Study Details (citation)

General Information

Date of form completion	
Reviewer (Initials only)	
Study author's contact details	

Study eligibility

Study characteristic	**Eligibility Criteria**	**Criteria met? (Yes/No/Unclear)**
Type of Study	Laboratory reports	
Exposure	Any form of ST	
Comparison	None	
Outcome	Concentration of Nicotine Concentration of TSNA's Concentration of PAH Concentration of heavy metals Values for pH Values for moisture content	

Decision

Include/Exclude	
Reasons if excluded	

APPENDIX 6

DATA EXTRACTION FORM

Table 49: Data Extraction form

Study Details (citation)

General information

		Comments
Form completion date		
Author Details		
Date of publication		
Publication Type		
DOI		
Citation		
Country, Region		
Sources of funding		
Conflict of interest		

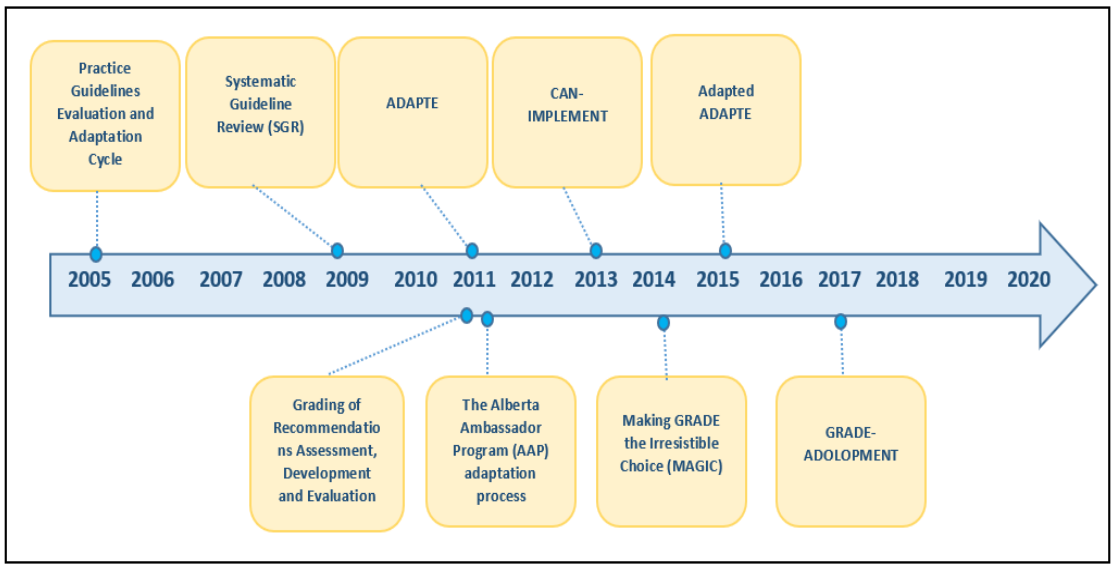
Study characteristics and product profile

		Comments
Author		
Aim of the study		
Study design		
Type of tobacco		
Brand name		
Total number of samples		
Product Origin		
Date of purchase		

Nicotine determination (Free and bound nicotine in mg/g wt.)		
pH determination		
PAH determination (ng/g)		
TSNA determination (Total TSNA, NNN, NNK, NAT, NAB in ng/g wt.)		
Total moisture content		
Metal and Metalloid determination		

APPENDIX 7

TIMELINE OF DEVELOPED TRANS CONTEXTUAL FRAMEWORKS



APPENDIX 8

WORK PLAN- GUIDELINE ADAPTATION PANEL

Table 50: Workplan for guideline adaptation panel

GUIDELINE PHASES	TASKS	ASSIGNED TO	TIMELINE
	• Decide on a broad topic area • Assess the feasibility of adaptation • Identify resources needed • Establish multidisciplinary panel • Write protocol	• Lead researcher	
	• Decide on terms of reference • Establish guideline inclusion/exclusion criteria • Identify key search terms • Identify key documents/sources • Complete guideline search	• Lead researcher	
Initial meeting (face to face)	• Project Introduction	• Steering Committee	
Second meeting (face to face)	• Sample guideline appraisal	• Steering committee	
Third meeting (face to face)	• Assessment of quality and content.	• Steering committee	
Fourth meeting (face to face)	• Prepare recommendation matrix • Assess acceptability and applicability	• Lead researcher • Steering committee	
Fifth meeting (face to face)	• Review all data • Select recommendations for adapted guideline	• Steering committee	

	Sixth meeting (via email)	• Send recommendations for external review and consultation • Write draft guideline	• Expert Panel	
	Seventh meeting	• Approval of draft by the panel. • Create final adapted guideline	• Lead researcher	

APPENDIX 9

UNIVERSITY of York

DECLARATION OF CONFLICT OF INTEREST

Steering Committee for guideline adaptation

I hereby declare that there are no known conflicts of interest associated with this project and there has been no financial support for this work that could have influenced its outcome.

Member name: FARAZ SIDDIQUI

Signature:

Date: 07/02/2020.

Member name: Masuma Pervin Mishu

Signature:

Date: 18.2.2020

Member name: MEHREEN FAISAL

Signature: Mehreen Riaz

Date: 05/02/2020

Member name: Radha Shukla

Signature: Radha S.

Date: 10/02/2020.

APPENDIX 10

PROTOCOL

TOPIC AREA

There are several guidelines available for the oral visual examination method. However, all the current guidelines for screening have been developed in Western countries and are for use by dental professionals. Despite the quality of the guidelines, there are several challenges to the acceptability and applicability that would limit the widespread uptake of recommendations such as the target population (non-healthcare professionals), the scientific format of the guidelines and language issues for a majority non-English speaking country.

PANEL TERMS OF REFERENCE

FOR STEERING COMMITTEE

Name of Group: Steering Committee

Title: Terms of reference

Purpose/Role of Group:

The broad purpose of the group is to help in the quality assessment of the screened guidelines for Oral visual examination and pick out recommendations to be taken to the expert panel.

The group has been convened by the PI of the study, Dr Zainab Kidwai.

Membership

The membership is open to health professionals and PhD candidates from the Department of Health Sciences, University of York.

The membership will extend till the period of completion of the Adaptation Phase of the study.

Working methods

The group will meet on a bimonthly basis in a face-to-face meeting.

The meetings will be organised and chaired by the PI.

Topics for the agenda of the meeting will be circulated by email 2 days in advance of the meeting.

The meetings will be held as small group discussions with a PowerPoint presentation wherever necessary.

Sharing of information and resources

All the documents for the adaptation work including retrieved guidelines, quality appraisal tools and assessment forms will be shared in a dedicated Google drive folder with all the committee members. This will be facilitated by the PI.

All the paper documents will be converted into an electronic format and uploaded on Google Drive.

FOR THE EXPERT PANEL

Name of group: Expert panel

Title: Terms of reference

Purpose/Role of Group

The main purpose of the panel is to select between the recommendations put forward by the Steering Committee to be included in the final guidance document.

Membership

The membership is open to (1) key stakeholders involved in the care of people suffering from oral cancer or oral potentially malignant disorders; (2) members from multidisciplinary fields (e.g., community dentistry, psychology, social work etc; (3) intersectionality (e.g., primary care setting, tertiary hospital, ministry of health and social services and (4) geographically diverse membership

Working Methods

The expert committee will be contacted via three emails by the PI. The first email will be an introductory email with details about the adaptation work done so far, the protocol and the expectations from them. In the second email, recommendations from the steering committee will be shared for their feedback. In the third email, finalised version of the adapted guidelines will be shared.

Sharing of information and resources

The working documents will be uploaded to a Google Drive folder and shared with the members of the Expert Panel.

TIMELINE FOR COMPLETION OF THE ADAPTATION PROCESS

		Jul'19	Aug'19	Sept'19	Oct'19	Nov'19	Dec'19	Jan'20	Feb'20	Mar'20
	Designing the protocol									
	Setting up the organising committee									
	Identifying health question									
	Searching and screening of guidelines									
	Quality appraisal of guidelines									
	Assessing currency and content									
	Assessing acceptability and feasibility									
	Selecting between recommendations									
	External review of guidelines									
	Final guideline document									

Figure 15: GANTT Chart

APPENDIX 11

GUIDELINE APPRAISAL USING AGREE GLOBAL RATING SCALE

All AGREE II items are rated on the following 7-point scale

Agree Score of 1 (Strongly Disagree). A score of 1 should be given when there is no information that is relevant to the AGREE II item if the concept is very poorly reported, or if the authors state explicitly that criteria were not met.

Score of 7 (Strongly Agree). A score of 7 should be given if the quality of reporting is exceptional and where the full criteria and considerations articulated in the User's Manual have been met.

Scores between 2 and 6. A score between 2 and 6 is assigned when the reporting of the AGREE II item does not meet the full criteria or considerations. A score is assigned depending on the completeness and quality of reporting. Scores increase as more criteria are met and considerations addressed. The "How to Rate" section for each item includes details about assessment criteria and considerations specific to the item.

PROCESS OF DEVELOPMENT

(Rate the overall quality of the guideline development methods)

Table 51: Process of development

CONSIDERATION	DECISION	INFORMATION TO SUPPORT DECISION	COMMENTS
Were the appropriate stakeholders involved in the development of the guideline?			
Was the evidentiary base developed systematically?			
Were recommendations consistent with the literature?			

Lowest Quality					Highest Quality	
1	**2**	**3**	**4**	**5**	**6**	**7**

PRESENTATION STYLE

(Rate the overall quality of the guideline presentation)

Table 52: Presentation style

CONSIDERATION	DECISION	INFORMATION TO SUPPORT DECISION	COMMENTS

Was the guideline well organised?			
Were the recommendations easy to find?			
The recommendations are specific and unambiguous.			
Key recommendations are easily identifiable			

Lowest Quality					Highest Quality	
1	**2**	**3**	**4**	**5**	**7**	**7**

COMPLETENESS OF REPORTING

(Rate the completeness of reporting)

Table 53: Completeness of reporting

CONSIDERATION	DECISION	INFORMATION TO SUPPORT DECISION	COMMENTS
Was the guideline development process transparent and reproducible?			
How complete was the information to inform decision-making?			

Lowest Quality					Highest Quality	
1	**2**	**3**	**4**	**5**	**8**	**7**

CLINICAL VALIDITY

(Rate the overall quality of the guideline recommendation)

Table 54: Clinical validity

CONSIDERATION	DECISION	INFORMATION TO SUPPORT DECISION	COMMENTS
Are the recommendations clinically sound?			
Are the recommendations appropriate for the intended patients?			

The overall objective(s) of the guideline is (are) specifically described.			
The health question(s) covered by the guideline is (are) specifically described.			
The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.			

Lowest Quality					Highest Quality	
1	**2**	**3**	**4**	**5**	**9**	**7**

APPENDIX 12

GUIDELINE APPRAISAL USING AGREE GRS INSTRUMENT

Table 55: Guideline appraisal using the AGREE GRS instrument (Appraiser 1)

GUIDELINES	PROCESS OF DEVELOPMENT	PRESENTATION STYLE	COMPLETE-NESS OF REPORTING	CLINICAL VALIDITY	OVERALL QUALITY OF THE GUIDELINE (1=Lowest quality, 7=Highest quality)	I WOULD RECOMMEND THIS GUIDELINE FOR USE IN PRACTICE (1=Strongly disagree, 7=Strongly agree)	I WOULD MAKE USE OF A GUIDELINE OF THIS QUALITY IN MY PROFESSIONAL DECISIONS (1=Strongly disagree, 7=Strongly agree)
1. ORAL CANCER FOUNDATION	3	7	4	6	6	6	6
2. ALESSANDRO VILLA	3	5	4	2	4	4	4
3. CENTRE FOR DISEASE CONTROL AND PREVENTION	7	4	7	4	4	5	5
4. SDCEP	7	7	7	6	5	4	4
5. JOEL EPSTEIN	7	5	7	6	5	4	4
6. BRITISH COLUMBIA	5	5	5	6	6	6	6
7. WORLD HEALTH ORGANISATION	4	7	5	6	6	5	5
8. AMERICAN DENTAL ASSOCIATION	7	7	7	7	6	6	6

APPRAISER NAME: FARAZ SIDDIQUI

TOP 5 GUIDELINES SELECTED BY THE APPRAISERS

APPRAISER NAME: MASUMA MISHU

Table 56: Guideline appraisal using the AGREE GRS instrument (Appraiser 2)

GUIDELINES	PROCESS OF DEVELOPMENT	PRESENTATION STYLE	COMPLETE-NESS OF REPORTING	CLINICAL VALIDITY	OVERALL QUALITY OF THE GUIDELINE (1=Lowest quality, 7=Highest quality)	I WOULD RECOMMEND THIS GUIDELINE FOR USE IN PRACTICE (1=Strongly disagree, 7=Strongly agree)	I WOULD MAKE USE OF A GUIDELINE OF THIS QUALITY IN MY PROFESSIONAL DECISIONS (1=Strongly disagree, 7=Strongly agree)
1. ORAL CANCER FOUNDATION	5	5	2	5	5	5	5
2. ALESSANDRO VILLA	6	6	2	5	6	6	6
3.CENTRE FOR DISEASE CONTROL AND PREVENTION	6	4	2	4	5	5	5
4. SDCEP	6	4	2	5	5	4	4
5. JOEL EPSTEIN	6	5	2	5	4	4	4
6. BRITISH COLUMBIA	5	6	2	6	5	6	6
7. WORLD HEALTH ORGANISATION	6	6	2	6	6	6	6
8. AMERICAN DENTAL ASSOCIATION	6	-	2	6	6	6	6

APPRAISER NAME: MEHREEN FAISAL

Table 57: Guideline appraisal using the AGREE GRS instrument (Appraiser 3)

GUIDELINES	PROCESS OF DEVELOPMENT	PRESENTATION STYLE	COMPLETE-NESS OF REPORTING	CLINICAL VALIDITY	OVERALL QUALITY OF THE GUIDELINE (1=Lowest quality, 7=Highest quality)	I WOULD RECOMMEND THIS GUIDELINE FOR USE IN PRACTICE (1=Strongly disagree, 7=Strongly agree)	I WOULD MAKE USE OF A GUIDELINE OF THIS QUALITY IN MY PROFESSIONAL DECISIONS (1=Strongly disagree, 7=Strongly agree)
1. ORAL CANCER FOUNDATION	4	5	5	6	5	5	5
2. ALESSANDRO VILLA	6	6	5	6	6	6	6
3. CENTRE FOR DISEASE CONTROL AND PREVENTION	7	6	6	7	6	6	6
4. SDCEP	7	6	6	7	6	7	7
5. JOEL EPSTEIN	6	5	5	6	6	6	6
6. BRITISH COLUMBIA	6	6	5	6	6	6	6
7. WORLD HEALTH ORGANISATION	6	7	5	7	6	6	6
8. AMERICAN DENTAL ASSOCIATION	4	7	5	6	6	5	5

APPRAISER NAME: RADHA SHUKLA

Table 58: Guideline appraisal using the AGREE GRS instrument (Appraiser 4)

GUIDELINES	PROCESS OF DEVELOPMENT	PRESENTATION STYLE	COMPLETE-NESS OF REPORTING	CLINICAL VALIDITY	OVERALL QUALITY OF THE GUIDELINE (1=Lowest quality, 7=Highest quality)	I WOULD RECOMMEND THIS GUIDELINE FOR USE IN PRACTICE (1=Strongly disagree, 7=Strongly agree)	I WOULD MAKE USE OF A GUIDELINE OF THIS QUALITY IN MY PROFESSIONAL DECISIONS (1=Strongly disagree, 7=Strongly agree)
1. ORAL CANCER FOUNDATION	3	4	6	5	4	3	4
2. ALESSANDRO VILLA	5	5	7	6	5	4	3
3. CENTRE FOR DISEASE CONTROL AND PREVENTION	6	4	3	4	4	2	3
4. SDCEP	5	4	5	5	3	4	3
5. JOEL EPSTEIN	6	4	5	4	4	4	3
6. BRITISH COLUMBIA	6	5	7	5	6	6	6
7. WORLD HEALTH ORGANISATION	5	5	6	6	5	5	5
8. AMERICAN DENTAL ASSOCIATION	6	6	3	6	5	5	6

APPRAISER NAME: ZAINAB KIDWAI

Table 59: Guideline appraisal using the AGREE GRS instrument (Appraiser 5)

GUIDELINES	PROCESS OF DEVELOPMENT	PRESENTATION STYLE	COMPLETE-NESS OF REPORTING	CLINICAL VALIDITY	OVERALL QUALITY OF THE GUIDELINE (1=Lowest quality, 7=Highest quality)	I WOULD RECOMMEND THIS GUIDELINE FOR USE IN PRACTICE (1=Strongly disagree, 7=Strongly agree)	I WOULD MAKE USE OF A GUIDELINE OF THIS QUALITY IN MY PROFESSIONAL DECISIONS (1=Strongly disagree, 7=Strongly agree)
1. ORAL CANCER FOUNDATION	6	7	4	7	6	7	7
2. ALESSANDRO VILLA	7	7	7	6	7	7	7
3. CENTRE FOR DISEASE CONTROL AND PREVENTION	7	3	6	6	5	6	6
4. SDCEP	7	5	6	5	5	4	4
5. JOEL EPSTEIN	7	3	6	3	5	3	3
6. BRITISH COLUMBIA	5	5	5	4	5	4	4
7. WORLD HEALTH ORGANISATION	7	7	6	7	7	7	7
8. AMERICAN DENTAL ASSOCIATION	5	7	5	6	6	7	7

APPENDIX 13

VOTING SHEET FOR GUIDELINES

Table 60: Voting sheet for guidelines

	FS	MM	MF	RS	ZK	TOTAL VOTES
1. ORAL CANCER FOUNDATION						3
2. ALESSANDRO VILLA						3
3.CENTRE FOR DISEASE CONTROL AND PREVENTION						4
4. SDCEP						1
5. JOEL EPSTEIN						1
6. BRITISH COLUMBIA						3
7. WORLD HEALTH ORGANISATION						5
8. AMERICAN DENTAL ASSOCIATION						5

APPENDIX 14

able 61: Recommendation matrix

	THE ORAL CANCER FOUNDATION	ORAL EXAMINATION BY ALESSANDRO VILLA	BRITISH COLUMBIA	WHO	CDC	ADA (video)
INSTRUMENTS AND SUPPLIES	Suggested tools for the oral, head and neck cancer exam include: an adequate light source, mirrors (laryngeal and nasopharyngeal), gloves, tongue blades, 2×2 gauze pads, anaesthetic nasal spray, flexible nasopharyngolaryngoscope, otoscope, and nasal speculum.			Instruments for oral examination: plane mouth mirrors; metallic periodontal probes (Community Periodontal Index (CPI) probe) that conform to WHO specifications, i.e., 0.5 mm ball tip; a black band between 3.5 and 5.5 mm and rings at 8.5 and 11.5 mm from the ball tip; and several pairs of tweezers Containers (one for used instruments and one for disinfecting or sterilizing instruments) and concentrated disinfecting solution in sufficient quantity Rubber gloves; wash basin for either water and soap or disinfectant solution; cloth or paper hand towels; and gauze. Generally, a minimum of 30 mouth mirrors and 30 periodontal probes per examiner should be provided, as this will permit some instruments to be sterilized while the others are being used. Used instruments should be placed in disinfectant solution, then washed and drained well before sterilization	2 mouth mirrors 2 2x2 gauze squares	
LIGHTING	It is imperative that the mouth be examined with an external light source, which allows both hands free for bimanual palpation or to hold gauze or tongue blade(s) for improved visualization. If a hands-free light source is not available, an assistant may provide invaluable help in visualization of difficult areas such as the posterolateral border of the tongue and floor of mouth.	A good light source is fundamental for a good intraoral examination. Dental offices are equipped for such examinations; however, medical practitioners who do not normally utilize fixed or head-mounted examination lights may be forced to rely on hand-held flashlights or a penlight, supplemented by the ambient room lighting.		Examination of the oral cavity should be carried out with adequate lighting from an external source such as fixed or head-mounted examination lights or hand-held flashlights, supplemented by room lighting. The lighting should be as consistent as possible throughout the survey. If electricity is available at all locations, a lightweight portable examination light (in the blue-white colour spectrum) should be used. Inflammatory and structural changes of the oral tissues are more difficult to detect under normal artificial light (yellow red in colour) than under natural or corrected artificial light. If electricity or battery-operated lights are not available at some survey sites, natural light should be used at all locations.		

				□ If an artificial light source is used, the location of the electrical supply points will affect the positioning of the tables and chairs. The subject should face away from any natural light source to avoid variation in illumination. However, if natural light alone is being used, the subject should be positioned so as to receive maximum illumination, while avoiding discomfort from direct sunlight to both the subject and the examiner. □ The chair or table should face the opening (e.g., window) through which the light is entering the room and be placed as close to it as possible.		
EXAMINATION POSITION	□ Position the patient so that he or she is comfortably sitting and is at your eye level. □ For intra oral part of the exam patient positioning can vary. Dental patients tend to lie on their backs, while their dentist exams their oral cavity. Physicians, on the other hand, usually have their patients sit up straight and face them eye-to-eye during the exam.			□ The examination position of the subjects will depend on the furniture available. The most comfortable situation is for the subject to lie on a table or bench with the examiner seated behind the subject's head. □ Subjects can also be examined seated in a chair with a high backrest with the examiner standing behind or in front of the chair. □ If no furniture is available, subjects can be examined lying on a cloth on the ground with the examiner seated cross-legged behind the person's head.		
EXTRA ORAL EXAMINATION	□ A thorough oral, head and neck cancer examination can easily be completed in less than 5 minutes. □ The initial physical evaluation of a patient actually begins as soon as you meet the patient. While taking the patient's history it is helpful to note any facial asymmetry, masses, skin lesions, facial paralysis, swelling or temporal wasting. Inspection of the lips,	□ The physical examination begins with an extra oral examination to identify possible lesions (such as rash, erythema, and pigmentation), swelling or facial asymmetry. □ The head and neck should be palpated to identify any tenderness, masses and lymphadenopathy. All muscles of mastication and temporomandibular joint should be palpated for tenderness; patients	• Inspect the head and neck region for asymmetry, tenderness or swelling. • Palpate the submandibular, neck and supraclavicular regions for lymph nodes, paying particular attention to size, number, tenderness and mobility. • Inspect and palpate the lips and perioral tissues for abnormalities.	□ Clinical examination of the head and neck is an integral part of oral examination and provides valuable information on the overall assessment of possible oral diseases. □ The examination for cervical lymph glands is carried out by standing behind the individual and slightly flexing and bending the neck to the side so that the sternocleidomastoid muscle becomes relaxed and palpation and identification of any enlarged nodes will be easier. The presence of neck masses is not an uncommon finding, especially in subjects with oral infections or cancer. □ The submandibular, submental and upper deep cervical lymph nodes are commonly involved, although other		□ Begin the extra oral exam by examining the head and face with both the front and the back taking note of any asymmetries and the presence of pigmented lesions. For such lesions

	both moving and at rest, can also be performed while first meeting the patient. Again, look for any asymmetry or gross lesions on the lips. Listening in an important part of this examination. The sound of one's voice and speech are important in consideration of the location of tumors as a "hot potato" voice may signal the presence of an oropharyngeal tumor whereas a raspy, hoarse voice could be the first sign of a laryngeal neoplasm.	should be asked to open and close the mouth multiple times to evaluate any limited opening, deviations or asymmetries. The cranial nerve examination should be performed to assess possible neurosensory and neuromuscular deficits.		regional lymph nodes may be enlarged as well. Lymphadenopathy secondary to infection will be tender and mobile, while metastatic lymph nodes are often asymptomatic, hard in consistency, and may be fixed to the underlying structures. The next most common head and neck mass found on palpation is a salivary gland tumour. Bimanual palpation is useful in differentiating submandibular salivary gland swellings from enlarged submandibular lymph nodes. Parotid neoplasm is observed as a diffuse swelling in front of the ear or over the angle of the jaw, often lifting the ear lobule. Extension of oral cancer into the oral soft tissues and to the skin of the face may be evident as diffuse swelling of the cheek or maxillary area, skin induration, skin nodules, ulceration, and in extreme cases as orocutaneous fistula. Temporomandibular joint pain and dysfunction, as characterized by the presence of crepitation, clicking and popping of the joints, may be detected by placing the tip of the little finger in the external auditory canal and having the person open and close the mouth and by moving the mandible laterally from side to side.		use the American cancer Society's ABCDE rule to assess for melanoma risk. Look for asymmetry, border irregularity, colour changes, diameter greater than six mm and evolution of the lesion on both sides. Next palpate the neck on both sides. If lymph nodes are identified pay attention to the size, consistency, whether they are painful and whether they freely move or are fixed in place.
INTRAORAL EXAMINATION	Before beginning this part of the examination, ask the patient to remove all dental appliances. When examining mucosal surfaces, it is important to	The intraoral examination should be performed in a systematic manner. If patients wear removable prostheses these should be removed	Systematically inspect and palpate all oral soft tissues, paying particular attention to the high-risk sites for the development of oral cancer including the lateral and ventral aspects of the tongue, floor of	Oral mucosa is generally pink in colour. Highly keratinized, firm, stippled and pale masticatory mucosa cover the hard palate, dorsal surface of tongue, and gingiva. Thin, less keratinized and more pinkish non-masticatory mucosa cover the remaining intra-oral structures.	The examination procedure follows a systematic assessment of the lips; labial mucosa and sulcus; commissures,	Ask your patient to open their mouth and begin the intraoral exam by

	gently dry those surfaces with a gauze or air syringe, so that color or texture changes will become more obvious.	to perform a thorough intraoral examination. Dentures should be evaluated for fit, general appearance and hygiene. Each anatomic structure should be visually inspected and palpated; possible lesions should be evaluated with respect to size, extent, thickness, texture, color, consistency, and tenderness. The oral mucosa has traditionally been described as salmon-pink in color; however, great variation exists depending on race, vascularity, and keratinization.	mouth and the soft palate complex. Evaluate the specific characteristics of each lesion with particular attention to size, colour, texture and outline. Particular attention to predominantly white, red and white, ulcerated and/or indurated lesions is indicated. At the time of initial assessment and at each re-evaluation appointment, it is recommended that an image of any clinically visible lesion be obtained, and a lesion tracking sheet be completed. This document is available at www.orcanet.ca Adjunctive visual tools can enhance contrast between the clinical lesion and the adjacent normal oral tissue. Techniques currently used by the BC Oral Cancer Prevention Program affiliated clinics include toluidine blue staining and direct fluorescence visualization. Mucosal changes staining positively with the application of toluidine blue or showing loss of fluorescence occur in premalignant or malignant conditions but are not restricted to only these changes.	The examiner should be alert during the entire procedure to identify any change in colour and/or texture of the mucous membrane, inflammatory areas, erythema, hyperpigmentation, macules, papules, vesiculobullous lesions, white lesions, greyish white lesions, red lesions, induration, ulceration, swellings, and growth in the oral mucosa.	buccal mucosa and sulcus; gingiva and alveolar ridges, tongue; floor of the mouth; and hard and soft palate.	siding the cheeks. Retract the tissue with your thumbs and gently pinch the cheeks between your fingers looking for hidden masses. Use a mirror to examine the alveolar processes and gingiva. Look for changes in colour, consistency, or a tooth with bone loss out of proportion with the rest of the arch. Pay special attention to the presence of a lesion with a history of poor healing.
LIPS	The lips should be evaluated with the mouth open and closed noting any abnormalities in symmetry, contour, color or texture.	Evert the lips and inspect the labial mucosa. The labial mucosa is typically smooth and glistening. If the mucosa is dry, pinpoint mucosal secretions from the minor salivary glands may become apparent. In healthy		Oral examination commences with the visual examination of the lips and the vermilion border and by palpation after removing any lipstick. The lip is usually smooth and pliable. Maceration and cracking of the corners of the lips indicate angular cheilitis.	Begin examination by observing the lips with the mouth both closed and open. Note the colour, texture, and any surface abnormalities of	When evaluating the lips note any change in the vermillion border, mucosa,

	Pay special attention to the vermilion border of the lower lip, as this is a prime site for oral cancers. First revert the lower lip and inspect the inner surface. The labial mucosa should be smooth and uniform in color. Notice the frenum of the lip in the midline. Note any signs of smokeless tobacco use (ulcers, red or white discolorations, texture variations) on the labial mucosa. With the lip still retracted, one can also inspect the gingivolabial sulcus, the gingival mucosa, and the teeth. Next palpate the lip with your thumb and index finger, noting any firm or nodular submucosal areas. Repeat these steps for the upper lip.	individuals, the labial mucosa appears as smooth, soft, and well lubricated by the minor salivary glands. Anxiety regarding the examination ("white coat syndrome) may result in a transient hyposalivation. In such cases, the mucosa may become sticky to the touch. The minor salivary glands of the lower lip frequently are palpable. The lower lip is frequently subjected to injury that can cause trauma to the minor salivary gland ducts, resulting in the formation of a mucocele, a lesion most frequently found in lower labial mucosa/lip.		Evert the lips and carefully inspect the labial mucosa. It should be smooth, soft, and well-lubricated by minor salivary glands that can be palpated. One may observe a mucocele in the lower lip resulting from trauma to the minor salivary gland ducts, as the lower lip is frequently prone to injury, particularly from accidental biting.	the upper and lower vermilion borders. With the mouth partially open, visually examine the labial mucosa and sulcus of a. the maxillary vestibule and frenulum, and b. the mandibular vestibule. Observe the colour and any swelling or other abnormalities of the vestibular mucosa and gingiva.	commissures as well as colour, contour, consistency and function. Look for indurations and ulcerations.
BUCCAL MUCOSA	The inside of the cheek or buccal mucosa must be spread away from the teeth and gums to visualize the sulcus which connects this area to the gums (gingiva). Examine one side and then the other. It is not uncommon to see a white line here from a habit of biting the	Examination of the buccal mucosa is most easily accomplished by having the patient partially open the mouth, followed by stretching of the buccal mucosa with a mouth mirror or tongue blade. The orifice of the parotid gland (i.e., the Stensen duct) can be found as a		The buccal mucosa is examined by stretching it with a pair of tongue depressors or mouth mirrors after the subject partially opens the mouth. In people with dark skin, one may frequently observe a benign condition called leukoedema, which is characterized by a diffuse greyish white opalescence in the buccal mucosa; this disappears when the tissue is stretched. A horizontal white or grey line, along the buccal mucosa, called linea alba buccalis may be observed in some persons. This is a benign, hyperplastic	Using the two mouth mirrors as retractors and with the mouth open wide, examine first the right, then the left buccal mucosa extending from the labial commissures and back to the	

	inside of the cheek. Any irregularity in texture or color or other signs listed above should be noted. □ Be sure to examine the entire buccal mucosa from the labial commissure back to the anterior tonsillar pillar. Stenson's duct from the parotid gland is a small protrusion in this area opposite the upper second molar and should secrete clear saliva from both sides when the parotid gland is milked. This area is easy to examine when two tongue blades are used to spread the lining from the gingiva or gauze is used to pull the lips apart. □ With your index and middle fingers inside the patient's mouth on the buccal mucosa and with your thumb on the cheeks, carefully pull laterally, and inspect both gutters along the upper and lower jaws. Next gently pinch the cheek between your fingers and thumb; this allows you to palpate the buccal mucosa for any hidden masses.	small punctate soft tissue mass on the buccal mucosa adjacent to the first permanent molar teeth. □ Some patients may present with mild grey-white lacy lines on the buccal mucosa that disappear with stretching of the mucosa (leukoedema). Another common finding of the buccal mucosa or labial mucosa are the Fordyce granules. These represent ectopic sebaceous glands. □ Linea alba ("white line") is also often observed on the buccal mucosa as a result from chronic trauma against teeth. Linea alba manifests as a horizontal white streak along the buccal mucosa at the level of the occlusal plane bilaterally. □ The orifice of the Stensen duct is superior to the linea alba, adjacent to the first permanent maxillary molar. Gentle palpation of the parotid gland results in the expression of serous saliva from the duct. □ Saliva should be able to be expressed from the duct; however, extraoral massaging of the gland may be necessary. The		reaction resulting from the chronic irritation from the teeth cusps at the level of the interdigitation of the teeth. □ The opening of the parotid salivary gland duct, the Stensen duct, may be observed as a small papillary or punctate soft tissue mass on the buccal mucosa adjacent to the maxillary second molar tooth. Milking of the parotid gland may expel saliva at the duct opening. □ Ectopic sebaceous glands may be observed on the buccal or labial mucosa as whitish-yellow, pinpoint papules; this developmental anomaly is termed as Fordyce conditions or granules. □ Minor salivary glands and Fordyce granules may lead to a granular feel on palpation of the buccal mucosa.	anterior tonsillar pillar. □ Note any change in pigmentation, colour, texture, mobility and other abnormalities of the mucosa, make sure that the commissures are examined carefully and are not covered by the mouth mirrors during retraction of the cheek.	

		saliva should be clear and watery, and the patient should not experience any discomfort with the procedure. As with the lips, the buccal mucosa should also be well lubricated with saliva. Minor salivary glands and Fordyce granules may impart a granular texture to the buccal mucosa.				
TONGUE	Ask the patient to open wide while relaxing the tongue; note any ulcerations, swellings, or other abnormalities. Then have the patient stick out his or her tongue and move it from side to side. It should move easily and completely to both sides without spasm or asymmetry. When there is a nerve paralysis of the hypoglossal nerve, the tongue will usually deviate to the side of the lesion. Observe the dorsum of the tongue, noting any discolorations, irregularities, or limitations to movement, all of which may be a sign of cancer. Notice the circumvallate papillae and lingual tonsils, which are often mistaken for pathologic lesions. One of the most common sites of oral cancer is on the lateral aspect of the tongue,	All surfaces of the tongue should be examined including the dorsum, sides and ventral tongue. The dorsal surface of the tongue is most easily visualized by having the patient protrude the tongue and attempt to touch the tip of the chin. Alternatively, the tip of the tongue can be grasped by the fingers and a 2 X 2-in gauze. The dorsal surface of the tongue is uniformly covered by numerous filiform papillae. Interspersed among the filiform papillae are dozens of mushroom-shaped fungiform papillae, each of which contains one or more taste buds, as shown below. The dorsal surface of the tongue is an admixture of thin, keratinized, filiform papillae interspersed with pink mushroom-shaped fungiform papillae.		After examination of the buccal mucosa, the dorsal surface of the tongue is examined by asking the subject to protrude the tongue and attempt to touch the tip of the chin; alternatively, the tip of the tongue may be held gently by the fingers and a gauze sponge. The dorsal surface of the tongue is normally uniformly covered by numerous fine-pointed and cone-shaped filiform papillae; dozens of mushroom-shaped fungiform papillae, each of which contains one or more taste buds are interspersed among them. The filiform papillae may occasionally become elongated (hairy tongue) and collect oral debris, which can lead to bad breath (halitosis) and an uncomfortable palatal sensation that may lead to gagging. The papillae containing numerous taste buds, 8–10 in number arranged in a V-shaped fashion, are located at the junction of the anterior two thirds and posterior third of the tongue. Occasionally, fissuring of the dorsal surface of the tongue may be observed. Nutritional deficiencies may lead to atrophy of the tongue with altered taste sensations or even complete loss of taste. The lateral borders of the tongue are examined by grasping the tip of the tongue with a gauze sponge, extending and rotating it laterally and retracting the buccal mucosa on the same side with the tongue depressor. Alternatively, the lateral border of the tongue can be examined by asking the person to touch the opposite buccal mucosa with the tip of the tongue and retracting the buccal mucosa with a mouth mirror.	With the tongue at rest, and mouth partially open, inspect the dorsum of the tongue for any swelling, ulceration, coating or variation in size, colour or texture. Also note any change in the pattern of the papillae covering the surface of the tongue and examine the top and the tip of the tongue. The subject should then protrude the tongue, and the examiner should note any abnormality of mobility. With the aid of mouth mirrors, inspect the margins of the tongue. Grasping the tip of the tongue with a	While depressing the tongue with the mirror, ask the patient to say “ahh” to have better access to the uvula and tonsillar pillars. Using gauge move the tongue to the left and to the right to examine the entire dorsal tongue. Pay attention to the lateral and ventral tongue as well.

	and it must be evaluated completely. This often requires using gauze to pull the tongue out and roll it from side to side while retracting the cheek with a tongue blade. Alternatively, two tongue blades can be used to push the tongue away from the lower teeth allowing visualization of every part of the mucosal lining to the tonsil and base of tongue. A dental mirror may be necessary to visualize the base of the tongue (part of the oropharynx). This area is best viewed by pulling the tongue forward while holding it with 2X2 gauze and will roll it up into a position enabling clearer view. Next, palpate the dorsum and lateral margins of the tongue, paying special attention to any masses or firm/fixated areas. Being careful not to gag the patient, palpate the lingual tonsils. Finally, have the patient touch the roof of their mouth with the tip of their tongue. This will allow the examiner to	Each of the pink mushroom-shaped fungiform papillae is associated with several taste buds. The circumvallate papillae are at the junction of the anterior two thirds and posterior one third of the tongue. These structures normally are 8-12 in number and are arranged in a V-shaped pattern anterior to the foramen cecum, a shallow depression which represents a developmental remnant of the thyroglossal duct. Like the fungiform papillae, the circumvallate papillae also contain numerous taste buds. Coated or hairy tongue is characterized by hyperplastic filiform papillae and accumulation of keratin due to increased retention and reduced exfoliation secondary to dehydration. Patients may complain of bad breath and even gagging especially if the coating is localized to the posterior tongue near the circumvallate papillae. Fissuring of the dorsal surface of the tongue has been described in dry mouth or syndromic patients (e.g., trisomy 21);		Vertical fissuring may be observed more along the lateral border of the tongue. Collections of accessory lymphoid tissue (lingual tonsil), with a bosselated surface, can be found at the base of the tongue, posteriorly. This is a component of the Waldeyer ring and may become enlarged in the presence of infection or inflammation.	piece of gauze will assist full protrusion and will aid examination of the margins. Then observe the ventral surface.	Complete this assessment palpating the tongue and nearby salivary glands. This aspect of the exam is important as nearly half of all potentially malignant lesions are usually found in this area.

	inspect the ventral surface of tongue.	however, the presence of fissuring is of no clinical significance in the vast majority of cases. □ Atrophy of the dorsal surface of the tongue can be secondary to nutritional deficiencies, some medications (e.g., hydroxyurea), erythematous candidiasis and other mucocutaneous diseases. In addition to discomfort, patients often report altered taste sensations. □ *Foliate papillae* are structures present on the posterolateral aspect of the tongue and contain additional taste buds. These can be often mistaken for abnormal tissue as they may vary in size and appearance. □ The lateral borders of the tongue can be examined by grasping the tip of the tongue with a gauze sponge, extending it, and rotating it laterally. The lateral borders of the tongue are not covered by a large number of papillae. The mucosa is more erythematous and, as one moves more posteriorly along the lateral border of the tongue, vertical fissuring becomes more prominent. Collections of mucosal-coloured tissue				

		with a bosselated surface can be found at the base of the tongue. This accessory lymphoid tissue (lingual tonsil) is a component of the Waldeyer ring and may become enlarged in the presence of infection or local inflammation. □ The lateral border of the tongue occasionally has some associated vertical corrugations, but it may appear smooth and glistening. Lingual tonsils at the posterior-lateral base of the tongue represent the anterior extension of the Waldeyer ring. These tissues may become enlarged secondary to inflammation, infection, or neoplasia. □ The ventral surface of the tongue is most easily visualized by having the patient touch the tip of the tongue to the roof of the mouth. The sublingual vasculature often is prominent, especially in older individuals. Fronds of tissue, the plica sublingualis, can frequently be observed extending from the ventral surface of the tongue, as shown below. The floor of the mouth, similar to the buccal mucosa, is salmon-pink in color. The orifices of the				

		submandibular glands (i.e., the Wharton ducts) are present as 2 midline papillae on either side of the lingual frenum. The lingual frenum is the primary soft tissue attachment of the tongue to the floor of the mouth. Over-attachment of the frenum may result in speech impediments. The ostia of the Wharton ducts, which are located at the base of the lingual frenum, appear as two bilateral punctate structures. Mucous saliva can be expressed from the ducts with bimanual palpation of the submandibular glands.				
FLOOR OF MOUTH	The floor of the mouth is the horseshoe-shaped area that extends from the alveolar ridge of the mandible to the ventral aspect of the tongue. Inspect this area while the tongue is elevated. If needed, wrap a piece of gauze around the tip of the tongue and pull the tongue gently forward and to one side. With the other hand, use a tongue blade or gloved finger to push the middle of the tongue up and out of the way.	Saliva frequently pools in the floor of the mouth during an oral examination. This pooled saliva is removed most easily with a gauze. Subsequent bimanual palpation of the submandibular and sublingual glands should result in the expression of saliva from the Wharton ducts. This saliva generally is more viscous than the one from the parotid glands because of the higher percentage of mucous saliva.		The ventral surface of the tongue and the floor of the mouth are most easily visualized by having the person touch the tip of the tongue to the roof of the mouth. A high level of clinical alertness is required when examining these sites, where oral cancers may be missed as red or white innocuous-looking lesions. Folds of tissue, the plica sublingualis, can frequently be observed extending from the ventral surface of the tongue. The saliva pooled in the floor of mouth during an oral examination is removed with a gauze sponge. The openings of the submandibular ducts, the Wharton ducts, are usually visualised as midline papillae on either side of the lingual frenum. Saliva oozes out of the Wharton ducts when the submandibular salivary glands are bimanually palpated.	With the tongue still elevated, inspect the floor of the mouth for swellings or other abnormalities.	Ask the patient to touch the top of their teeth with the tip of their tongue so that the floor of the mouth can be inspected and palpated. Use two hands when palpating this area. After the exam clinicians

	□ Notice the frenulum in the midline and the ducts from the submandibular glands symmetrically on either side. □ Also note the sublingual glands. It is helpful to first dry this area with a gauze before looking for any surface abnormalities. Next, insert a gloved finger beneath the tongue, and another under the chin on the exterior skin, and bimanually palpate the submandibular glands and the entire submental region. □ Keep in mind that this one of the most common places for oral cancers to hieratical attention should be paid to any mass that feels firm or fixated in position.	□ Both the ventral/lateral surface of the tongue and the floor of the mouth are common sites for oral cancer. An incisional biopsy remains the gold standard to rule out dysplasia or invasive squamous cell carcinoma.				
HARD AND SOFT PALATE	□ Ask the patient to open widely and tilt his or her head backward to provide an adequate view of the hard and soft palate. □ If needed, depress the base of the tongue with a tongue blade to provide a better view of the soft palate.	□ The palate is divided into the soft palate posteriorly and the hard palate anteriorly. □ Direct visual inspection of the hard palate is accomplished most easily with the use of an intraoral mirror. The hard palate, similar to the attached gingiva, normally is less pink than other oral mucosal sites because of		□ The anterior portion of the hard palate is better visualised using an intraoral mirror. The anterior portion of hard palate is covered by many fibrous ridges. The presence of a large number of minor salivary glands makes the hard palate a common location for minor salivary gland tumours. The soft palate is examined by depressing the base of the tongue with a tongue depressor and asking the subject to say “aah”. Part of the oropharynx, particularly the accessory lymphoid tissues in the posterior pharyngeal wall that appear as pale mucosal papules, is visible during this procedure.	□ With the mouth wide open and the subject’s head tilted backwards, gently depress the base of the tongue with a mouth mirror. First inspect the hard, and then the soft palate. Mucosal or facial tissues that seem to be	□ Carefully inspect and palpate the hard and soft palate looking for abnormalities.

	□ Loose teeth, red spots, white spots, ulcerations, rough areas, asymmetry, growths, or other masses may be the first sign of a cancer in this area as in all areas of the head and neck. □ The uvula should hang down in the midline. Its deviation may indicate a vagal nerve palsy. □ Some patients have a torus palatinus, or bony outgrowth from the midline of their hard palate. This should not be mistaken for a malignancy.	its increased keratinization. □ The anterior hard palate is covered by numerous fibrous ridges or *rugae*, and many individuals may present with a prominent midline incisive papilla anteriorly (the opening of the incisive canal). □ The hard palatal mucosa is characterized by keratinized epithelium and covered by a series of fibrous ridges or rugae. The mucosa overlays several minor salivary glands. □ Note the midline incisive papilla posteriorly to the maxillary incisives. This represents the inferior aspect of the nasopalatine duct and overlay a substantial neurovascular bundle that supplies the anterior hard palate. □ Minor salivary glands are abundant in the hard palate; because of this, a high incidence of minor salivary gland neoplasms, both benign and malignant, is found in this location.			abnormal should be palpated	

APPENDIX 15
INTERVIEW WITH COMMUNITY HEALTH WORKERS - TOPIC GUIDE

INTRODUCTION

Thank you for participating in this discussion. I'm Zainab Kidwai and I will be guiding this conversation. The purpose of this research is to gather insights from Community Health Workers like you regarding your experience with the provided guideline. This discussion is informal and completely confidential. Your identity will not be disclosed. With your permission, I'd like to record this discussion for accurate analysis. The recording will be securely stored and shared only with the research team. This conversation is expected to last around 30 minutes. Are you comfortable with participating and allowing recording?

ICEBREAKER

- Could you please start by introducing yourself?
  - Why did you decide to become a Community Health Worker?
  - How long have you been working in this role?
  - How has your experience as a CHW been so far?

CLARITY OF RECOMMENDATIONS

- Let's discuss the guideline content. Were the recommendations clear and easy for you to understand?
- Were there any recommendations that you found difficult to comprehend?
- How well do you think you understood the guideline's recommendations?
- Did any part of the guideline seem confusing or unclear?

TERMINOLOGY

- How clear was the language used in the guideline?
- Were there any words or phrases that you found challenging to understand?
- Were there any terms that you think could be explained better?

FEASIBILITY FOR CHWs

- Could you share your thoughts on how practical and feasible the guideline's recommendations are for Community Health Workers like yourself?
- Do you think you could effectively incorporate the guideline's recommendations into your daily work?
- Were there any specific recommendations that you think might be challenging to implement?
- Can you identify any aspects of the guideline that align well with your usual tasks and responsibilities?

IMPACT ON PRACTICE

- If you were to adopt the guideline's recommendations, how do you think it would impact your work as a Community Health Worker?
- Are there any specific aspects of the guideline that you feel would enhance the quality of care you provide?

- Do you foresee any challenges in integrating the guideline's recommendations into your routine tasks?

RECOMMENDATIONS FOR IMPROVEMENT

- Based on your experience, do you have any suggestions for improving the guideline's content or presentation?
- Are there any additional topics or aspects that you believe should be covered in the guideline?
- Is there anything that could be added or modified to make the guideline even more useful for CHWs like yourself?

CLOSING REMARKS

- Is there anything else you would like to share about your experience with the guideline?
- Are there any final thoughts or considerations you would like us to take into account regarding the guideline and its applicability for CHWs?

Thank you for participating in this discussion. Your insights are valuable and will contribute to improving the guideline for Community Health Workers.

APPENDIX 16

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.240[a]	-.015	.673	2.577	7	28	.035
Average Measures	.612[c]	-.080	.911	2.577	7	28	.035

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

Figure 16: Intraclass Correlation Coefficient for Inter-rater reliability

APPENDIX 17

OVERALL SUMMARY AND FEEDBACK

DAY 1

Date: 15th Feb 2021

Attendees: DC, GC, ZK

Session 1 (9:30-11:30 am)

Introductions and talk on the oral cancer continuum

During this session, DC presented a talk on oral cancer. The talk featured epidemiology of oral cancer, public health messaging on oral cancer awareness, oral cancer inequalities, definition, common sites and risk factors, incidence and prevalence rates, mortality associated with oral cancer, survival data, changing trends in the cancer incidence worldwide, oral cancer prevention principles and early detection, current policies, and major research areas/ cancer research groups around the world. Following this, results were discussed from the ARCAGE and INHANCE study.

One of the key highlights from the presentation was the differentiation between oral cancer, oral cavity cancer and oropharyngeal cancer and how anatomical sites and risk factors play an important in the differentiation of these. The key feedback was to clearly define which oral cancer was being addressed in my PhD.

Further reading:

John Diamond- Because cowards get cancer too

Michael L. Goskey- Let me explain

Michael Marmot- The Health Gap

Kawachi et al 2000- Social cohesion, social capital, and health.

Chaturvedi et al 2013-Worldwide trends in incidence rates for oral cancer

Session 2 (12:30-1:30)

Headspace/ Healthcare system overview

During this session, GC gave an introduction to the HEADSpAce project which stands for translational studies of Head and Neck Cancer in South America and Europe; a consortium of 15 partner institutions with a long and successful record of collaboration in the study of head and neck cancer. The project aims to investigate multiple reasons for the poor prognosis of head and neck cancers, including individual and structural reasons for late diagnosis; the influence of lifestyle, infectious, and genetic factors on the poor outcome; and the adherence to clinical guidelines in various settings. GC explained the various research streams, study design, data collection tools and methods used for achieving the research objectives.

DAY 2

Date: 22nd February 2021

Attendees: AR, DC, GC, ZK

Session 1 (10:00-10:30am)

Introduction to the PhD project

During this session, ZK gave an introduction to her PhD thesis on "Early detection of Oral Potentially Malignant Disorders- A novel approach to screening and the way forward". The talk explored aims, objectives, research methods, planned studies, changes due to Covid and revised studies. Discussion on the oral cancer resource toolkit was held. The advice was given to include a review component so that each resource is developed as systematically as possible.

Session 2 (10:30-12:00)

Review of related research

The discussion was carried out around the link between these existing pieces of toolkit and the current. Common methodologies were discussed in detail and lessons were shared from each of their fieldwork/ review experiences.

DAY 3

Date: 24th February 2021

Attendees: DC, ZK

Session 1 (9:30-11:30)

Development of oral cancer resource toolkit

During this session, resources for oral cancer screening toolkit were identified.

These included:

1. Step by step guidance on performing oral cancer screening

2. A proforma for recording oral history and charting of lesions.

3. Development of a grid and mouth map.

4. Training materials for Community Health Workers.

5. A bank of case studies including photographs and oral history.

6. Assessment forms measuring knowledge and competency.

7. Interview guides assessing the feasibility and acceptability of training as well as in-depth decision-making process on lesion identification and charting.

DAY 4

Date: 1st March 2021

Attendees: Community Oral Health Group

Session 1 (12:30-1:30)

Presentation to the Community Oral Health Group

During this session, ZK gave a presentation on her work to the wider Community Oral Health Group.

The groups also gave suggestions on research objectives for the feasibility study. One of the suggestions was to train CHWs to deliver VBA and assess the impact of training. Another suggestion was to do an in-depth review of behaviour change factors and develop training on Brief Advice for ST cessation tailored for CHWs.

DAY 5

Date: 3rd March 2021

Attendees: AR, DC, GC, ZK

Session 1 (9:30-10:30am)

The main objective of this session was to review the plan for systematically designing the training curricula for the CHWs. Some of the key suggestions/ recommendations were to-

1. Keep the planned training sessions short (maximum up to 90 mins duration)

2. Develop tools on logging the history of the tobacco behaviours/ self-reported ST use behaviour, frequency, duration, previous quit attempts and incorporate them into the assessment.

3. Keep the assessments low tech, perhaps limited to pictures and written text so they can be easily accessed by the CHWs.

4. Perform an assessment based on simulation. E.g., Get a panel of cases for charting on a grid or mouth map. The bank of images can be obtained from Glasgow Dental School and NICPR, India. First, get these charted by some clinicians and then use them for assessment of the CHWs.

6. Collect questionnaire data online on either MS Teams, Survey Monkey, Microsoft forms etc. Present cases in the form of PowerPoint slides. E.g., Case 1 with history and images. Within the cases, get a spread of oral lesions, including their healthy equivalent. There is no need to get into the diagnostic accuracy of the lesion. They just need to be recorded as red, white, or speckled. It is more whether CHWs can record these accurately after being trained.

7. Workshop can be conducted live or as a recording (with slides and case presentations). The latter would be preferred more as the CHWs can access it as and when they want.

8. Be cautious on the knowledge aspect and what type of knowledge is being assessed. The focus should be more around knowledge of ST products, knowledge of the process and method of recording the data.

APPENDIX 18

Table 62: A quality appraisal of screening instrument using the AGREE GRS score

INSTRUMENT	DEVELOPED BY (YEAR)	HISTORY		SIGNS AND SYMPTOMS	EXTRA ORAL EXAMINATION	INTRAORAL EXAMIN-ATION	APPEARANCE (COLOUR/TEXTURE/MARGINS)	PALPATION (CONSISTENCY)	DIMENSION	MOUT-H MAP
		DENTAL	ALCOHOL/TOBACCO USE							
1. Oral Cancer Screening Referral Form	American College of Prosthodontics	N	Y	Y	Y	Y	Y	Y	Y	Y
2. Boston screening form	-	N	Y	Y	Y	Y	N	N	N	N
3. Oral Health Questionnaire	Center For Disease Control (2012)	Y	N	Y	N	N	N	N	N	N
4. National Oral Health Survey	Dental Council of India	Y	Y	N	Y	Y	N	N	N	N
5. Extra and Intraoral Examination	Cambridge Consultants	Y	Y	Y	Y	Y	Y	Y	Y	N
6. l Cancer Care Toolkit	NHS	Y	Y	Y	Y	Y	N	N	N	Y
7. l Cancer Screening Form	Western Michigan University (1996)	Y	N	N	N	Y	N	N	N	Y

INSTRUMENT	DEVELOPED BY (YEAR)	HISTORY		SIGNS AND SYMPTOMS	EXTRA ORAL EXAMINATION	INTRAORAL EXAMIN-ATION	APPEARANCE (COLOUR/TEXTURE/MARGINS)	PALPATION (CONSISTENCY)	DIMENSION	MOUT-H MAP
		DENTAL	ALCOHOL/TOBACCO USE							
8. Oral health survey questionnaire	Public Health England (2017-18)	Y	Y	N	N	N	N	N	N	N
9. Oral Health Questionnaire for Adults	World Health Organization	Y	Y	Y	N	N	N	N	N	N
10.Clinical Format For Screening Primary Prevention And Early Detection Of Oral Potentially Malignant Disorders And Oral Cancers	Oral Health Programme, Ministry Of Health Malaysia	N	Y	N	Y	Y	Y	Y	Y	Y
11. Oral Cancer Screening - Referral Form	The Oral Cancer Foundation	Y	Y	Y	N	Y	Y	Y	Y	Y
12. Oral Health Assessment Tool	SA Dental Service 2009	N	N	N	Y	Y	Y	N	N	N
13. Screening Form	Head And Neck Cancer Alliance	Y	Y	Y	Y	Y	N	N	N	N
14. Assessment of Oral Mucosal Tissue	SDCEP	N	N	N	N	Y	Y	N	N	Y
15. THE SERBIAN VERSION OF THE "ORAL HEALTH QUESTIONNAIRE FOR ADULTS"	Margareta Lekić[1], Dragana Daković	Y	Y	N	N	N	N	N	N	N

APPENDIX 19

Table 63: Quality assessment of screening proforma

Instrument	Process of development	Presentation style	Completeness of reporting	Clinical validity	Rate the overall quality of the instrument	I would recommend this instrument for use in practice	I would make use of an instrument of this quality in my professional decisions
1. Oral Cancer Screening Referral Form	6	6	6	6	6	6	6
2. Boston screening form	1	5	3	6	4	3	3
3. Oral Health Questionnaire	7	3	2	4	4	2	2
4. National Oral Health Survey	7	4	3	7	5	4	4
5. Extra and Intraoral Examination	3	6	6	4	5	6	6
6. Oral Cancer Care Toolkit	7	6	5	6	6	6	6
7. Oral Cancer Screening Form	6	5	3	5	4	2	2
8. Oral health survey questionnaire	7	6	2	2	4	2	2
9. Oral Health Questionnaire for Adults	7	6	2	5	5	4	4
10. Clinical Format For Screening Primary Prevention And Early Detection Of Oral Potentially Malignant Disorders And Oral Cancers	7	7	6	7	7	6	6
11. Oral Cancer Screening - Referral Form	6	6	6	6	6	6	6
12. Oral Health Assessment Tool	2	4	2	1	3	3	3

13. Screening Form	4	6	3	5	5	4	4
14. Assessment of Oral Mucosal Tissue	6	7	3	6	5	3	3
15. The Serbian Version of the “Oral Health Questionnaire for Adults”	7	5	2	2	4	3	3

APPENDIX 20

ORAL CANCER SCREENING TOOLKIT

A Community Health Worker Training Resource for Preventing Oral Cancer and Oral Potentially Malignant Disorders

UNIVERSITY of York

ASTRA

NIHR | National Institute for Health Research

Dear Community Health Workers:

Oral cancer or mouth cancer is one of the deadliest forms of cancer in India. Every year more than 13 lakh people are diagnosed with it and around 75000 lose their lives due to it (GLOBOCAN 2020). This number is set to rise and it is estimated that by 2030, more than 95000 people will be dying every year from this disease.

Research by leading international cancer agency, IARC has shown that oral cancer can be prevented in the population by addressing the risk factors and detecting the disease early on while it is still in its precancerous form. This can be done by identifying and screening high-risk people and helping them quit tobacco, restrict alcohol use, make lifestyle changes, and eat a healthy diet.

Currently, oral cancers and associated lesions can only be detected and diagnosed in a dental setting. However, due to the shortage of dentists and high costs of treatment, people are not able to access healthcare services on time. This leads to advanced cancer with severe complications often resulting in death. Early detection and timely management, while the disease is still in its precancerous stage, is the key to saving lives. Community Health Workers can play a huge role in this by identifying and screening high-risk people for this disease in their local communities and referring them for further diagnosis and treatment.

A Community Health Worker Training Resource for early detection of oral cancers is a user-friendly guide that has been developed with the help of researchers based at the University of York and experts in the field of oral cancer from around the globe. It is designed for Community Health Workers for use in low resource community-based settings. This training resource offers basic information on developing skills in detecting early signs of oral cancers and helping people quit their risky habits.

As a front link worker with link to both the community and the local healthcare services, you can help prevent this deadly disease by-

1. Identifying high-risk people by taking a thorough medical and dental history.
2. Examining the mouth for early signs of oral cancer by performing an Oral Visual Examination.
3. Giving advice and referring patients to the nearest healthcare facilities.

I thank you for your interest in this resource and welcome your feedback on your experience in putting it to use.

Sincerely,

Zainab Kidwai, MSc, BDS

PhD Scholar, Department of Health Sciences,

University of York, UK

OVERVIEW OF COMMUNITY HEALTH WORKERS TRAINING RESOURCE

The following resource contains information and activities for the identification and prevention of Oral Cancer and Oral Potentially Malignant Disorders (OPMDs).

It has been divided into the following 4 sections-

SECTION 1: INTRODUCTION

- Oral cancer and Oral Potentially Malignant Disorders (OPMDs)
- Risk factors for Oral cancer and OPMDs

SECTION 2: IDENTIFYING PEOPLE AT RISK

- Warning signs and symptoms
- Taking medical and dental history

SECTION 3: DETECTING THE DISEASE

- Introduction to Oral Visual Examination
- Examination Setting
- Performing Extraoral and Intraoral examination

SECTION 4: PREVENTING THE DISEASE

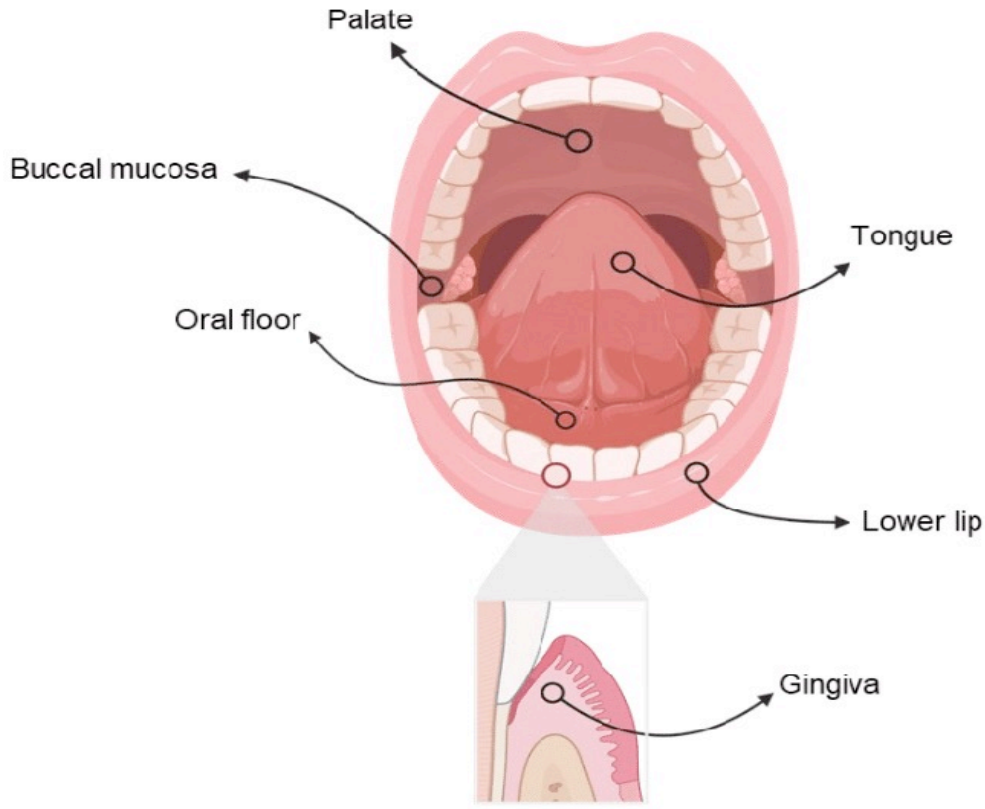
- Record keeping
- Duty of care
- Referral pathway

SECTION 1

INTRODUCTION

ORAL CANCER

Oral cavity cancer, or as it is often referred to as oral cancer is the cancer of the mouth. It can occur on lips, the inside lining of the lips and cheeks (buccal mucosa), the teeth, the gums, the front two-thirds of the tongue, the floor of the mouth below the tongue, and the bony roof of the mouth (hard palate).



ORAL POTENTIALLY MALIGNANT DISORDERS

Oral Potentially Malignant Disorders or OPMDs are lesions that are associated with an increased risk of occurrence of cancers of the lip and oral cavity. These appear as red, white or mixed red and white lesions in the mouth. They serve as warning signs of oral cancer. These play an important role because, in majority of the cases, early identification and management of these lesions prevents their progression to cancer. While there are many forms of OPMDs, the ones we are particularly interested in detecting are Leukoplakia, Erythroplakia and Oral Submucous Fibrosis as these are commonly associated with high risk habits like tobacco and alcohol use. These lesions are explained in detail in Section 2.

RISK FACTORS

Risk factors are things that increase the chance of developing a disease. It's important to know the risk factors for oral cancer as they help in identifying people who are at a greater risk. The risk factors for oral cancers are:

1. Use of tobacco

This is one of the main risk factors for oral cancer formation. It includes both smoking and the use of smokeless tobacco. The risk increases depending upon the type of tobacco, the duration and frequency of use.

TOBACCO AND ORAL CANCER:

- There are almost 267 million tobacco users in India.
- India accounts for 70% of the global burden of smokeless tobacco.
- Use of smokeless tobacco products like Gutkha, Khaini, Zarda, Naswar, Mawa, Mainpuri, Pan Masala, Tambakhu kills over 230,000 Indians every year.
- Nearly 90% of oral cancers in India are associated with the use of smokeless tobacco.
- Oral cancers are also linked to smoking tobacco products like Cigarettes, Cigars, Pipes, Bidis.

2. Alcohol consumption

Frequent and long-standing consumption of alcohol can also cause oral cancer.

ALCOHOL AND ORAL CANCER:

- Risk of oral cancer increases by 2 times in the population consuming alcohol.
- Those who smoke and drink to excess put themselves at risk by up to 30 times.

3. Other factors include-

-Infection with Human Papilloma Virus.

-Poor diet and deficiency of vitamin A, C and E and minerals like iron, selenium and zinc.

-Long-standing irritation due to sharp teeth and faulty dentures.

-Prior history of oral cancer or other aerodigestive tract cancer and history of cancer in the family.

COMMON MYTHS AND FACTS ABOUT ORAL CANCER

MYTHS ✘	FACTS ✓
Tobacco helps with pain relief	Tobacco should not be considered as a remedy for tooth pain. One can start warm saline rinses or take medicines as prescribed by a qualified doctor and visit the dentist at the earliest to identify the cause of dental pain and seek dental treatment.
Tobacco based powders like gul manjan, coal, red toothpowder are good for cleaning teeth	These substances have abrasives that wear out the tooth structure at a fast rate and are not recommended to clean your teeth. Gul manjan has nicotine as one of its components and can get one addicted to the use of tobacco therefore, it must be avoided altogether.
Young people are not at risk of developing oral cancer	A growing number of young people are developing oral cancer due to increasing use of cigarettes and chewing tobacco.
Only smokers get oral cancer	Oral cancer can develop with the use of any form of tobacco. In fact, it is strongly associated with the use of smokeless tobacco like gutkha, khaini, zarda, mawa etc. Other factors include alcohol consumption, poor diet, chronic tooth irritation and infection with Human Papillomavirus.
If I have oral cancer, I will know because I will have symptoms	Oral cancer often progresses without pain or other symptoms until it's in advanced stages. Usually they start as a red or white patch in the mouth. Therefore, it's important to do regular cancer screening especially in high risk people. The next sections contain more details on identifying early signs and symptoms.

SECTION 2

IDENTIFYING PEOPLE AT RISK

WARNING SIGNS

Oral cancers and Oral Potentially Malignant Disorders can be identified in people by checking the warning signs and symptoms. Look for the following signs in the mouth-

- A long-standing non-healing ulcer in the mouth for more than 3 weeks.
- A white or red patch on the tongue, gums, tonsils, the lining of the mouth or lips.
- A lump in the neck caused by swelling of one or more lymph nodes.
- A lump or growth in the mouth.
- Hoarseness in voice or sore throat that lasts for 6 weeks or more.
- Restriction in mouth opening.

SYMPTOMS

People may also complain of the following symptoms-

- Pain or discomfort while moving jaw or tongue.
- Problem while swallowing or chewing, or trouble in speaking.
- Change in taste.
- Burning sensation while eating and difficulty opening mouth.
- Numbness of tongue.

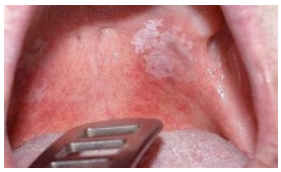
The next section describes the early signs of the disease when it appears as Oral Potential Malignant Disorders as well as late signs which represent oral cancer.

EARLY SIGNS

Oral cancer is generally preceded by benign lesions and conditions for a varying length of time. These share the same risk factors, particularly tobacco use and exhibit the same site and habit relationship. These usually present as-

A whitish (Leukoplakia), reddish patch (Erythroplakia) or fibrous bands in cheek (Oral submucous fibrosis).

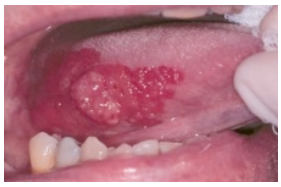
LEUKOPLAKIA



This is the most common precancerous lesion. It is often described as a white patch associated with the use of tobacco. It can appear as a homogenous white patch, ulcerative patch or a nodular patch. The latter two can appear as greyish white or speckled (red and white) patches.

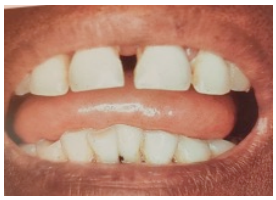
ERYTHROPLAKIA

Erythroplakia is a rare but severe precancerous lesion. It appears as a bright red velvety plaque in the mouth.



ORAL SUBMUCOUS FIBROSIS

This is a chronic condition characterised by formation of fibrous bands in the cheek. It is often accompanied by burning sensation in the mouth and restricted mouth opening.



LATE SIGNS

These are associated with malignant transformation of precancers into oral cancer. These can appear as an outwardly growing tumour or deep burrowing ulcers. They are often associated with changes in function caused by the growth in mouth such as slurring of speech or difficulty in chewing.

SECTION 3

DETECTING THE DISEASE

TAKING A THOROUGH MEDICAL AND DENTAL HISTORY

Taking medical and dental history helps to identify risks and patterns and assists with delivering lifestyle counselling and education and setting recall times. You should consider asking the following-

QUESTIONS TO ASK WHILE TAKING MEDICAL AND DENTAL HISTORY

Name: _____ Age: _____ Gender: _____

Address: _____ Contact Number: _____

MEDICAL HISTORY

1. Are you being treated for any medical condition at present or have been in the past year? If so, why?

2. Has there been any change in your general health in the past year? If yes, please explain.

3. Are you taking any medications? If yes, what for and since how long?

4. Do you have or ever had any of the following- Asthma, high blood pressure, heart disease, diabetes, stroke, bleeding disorder, cancer.

5. Are there any diseases that run in your family (e.g., diabetes, cancer, heart disease)?

6. Did you or do you smoke? If yes, what do you smoke (e.g., chillum, hookah, cigars, cigarettes, bidis or other) How many times do you smoke normally? How long have you been smoking for?

7. Did you or do you use smokeless tobacco? If yes, what do you chew (e.g., gutkha, khaini, zarda, mawa, gul, pan masala with tobacco, any other) consume alcohol? How many times in a day? How long have you been in the habit of using smokeless tobacco?

8. Did you or do you take alcohol? How often do you take alcohol? Since how many years?

DENTAL HISTORY

1. When was your last visit to the dentist?

2. Have you suffered from any mouth or tooth problems in the last one year? If yes, what were or was the problem?

3. Who was or were consulted?

4. Have you noticed any of the following?

Pain on swallowing, mouth ulcer, sore throat, persistent hoarseness, lump/swelling in the mouth or neck, bleeding in the mouth, white patch, red patch, burning sensation in the mouth, difficulty opening the mouth?

ORAL SCREENING

Once medical and dental history has been taken, oral screening should be done. Screening can be described as carrying out one or more tests to identify the presence of disease. In this case, it is oral cancer screening and it includes the use of a clinical oral visual exam to identify signs of disease.

Please note that screening examination is not a diagnostic exam but aims to identify abnormalities that should be referred for further investigation, diagnosis and management.

EXAMINATION SETTING

When conducting an Oral Visual Examination, attention should be paid to the examination setting. The examination should be conducted from a suitable height with the person comfortably seated in a chair and facing adequate light. Natural sunlight can be used, however, if there isn't sufficient sunlight, then a torchlight should be used.

The following instruments should be used while conducting an oral exam-

A mouth mirror for visualisation and retraction of tissue, a wooden spatula or tongue blade, a piece of gauze, a mouth mask and gloves for infection control.

Mouth Mirror

Wooden Spatula

Gauze

Mouth mask

Gloves

EXTRAORAL EXAMINATION

Step 1: Observe the face and neck looking for facial asymmetry, masses, skin lesions, facial paralysis or swelling.

Step 2: If an extraoral lesion is present, take note of asymmetry, border irregularity, colour changes, diameter greater than six mm and evolution of the lesion on both sides.

Step 3: Evaluate possible lesions for size, extent, thickness, texture, colour, consistency, and tenderness.

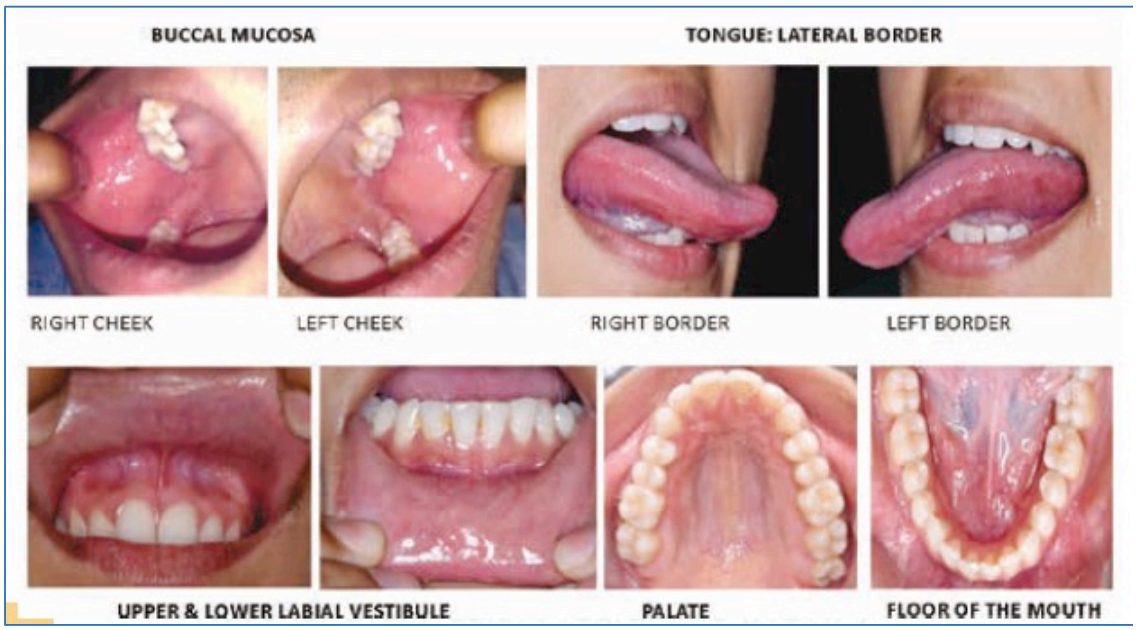
Step 4: Inspect and palpate for masses or enlargement of salivary glands.

INTRAORAL EXAMINATION

Step 1: Ask denture wearing patients to remove their dentures.

Step 2: Observe the alveolar process and look for changes in colour, consistency, loose teeth and excessive bone loss.

Step 3: Systematically inspect and palpate all oral soft tissues (details in the following sections)



EXAMINATION OF LIPS

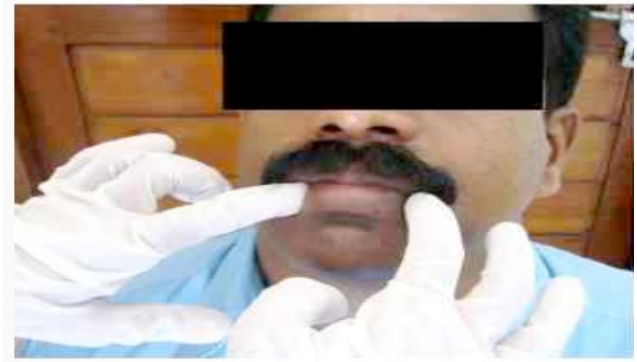
Step 1: First, revert the lower lip and inspect the inner surface.

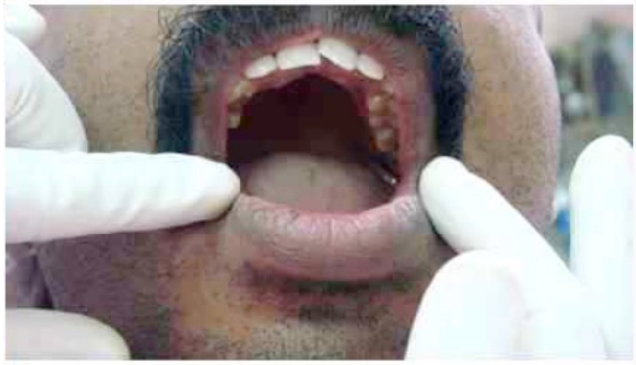
Step 2: Notice the frenum of the lip in the midline.

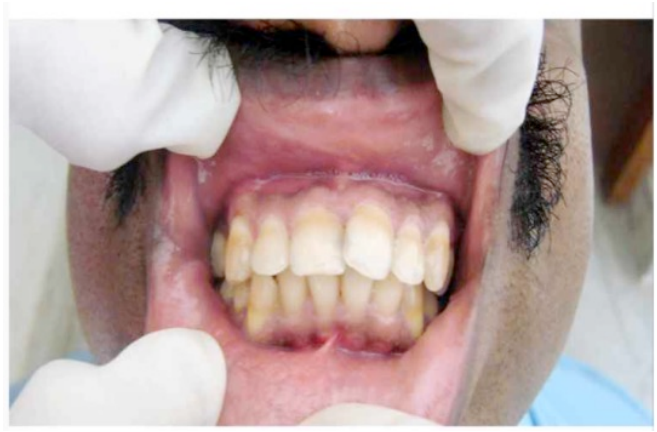
Step 3: With the lip still retracted, inspect the gingivolabial sulcus, the gingival mucosa, and the teeth.

Step 4: Palpate the lip with your thumb and index finger.

Step 5: Repeat these steps for the upper lip.





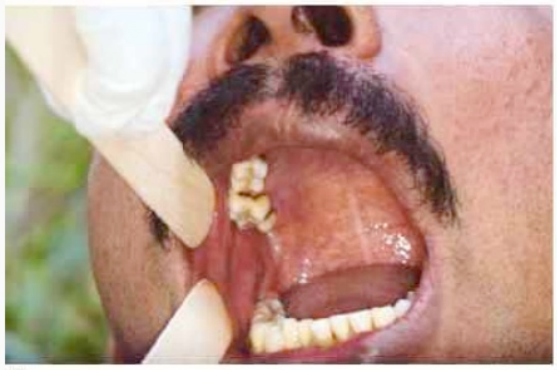


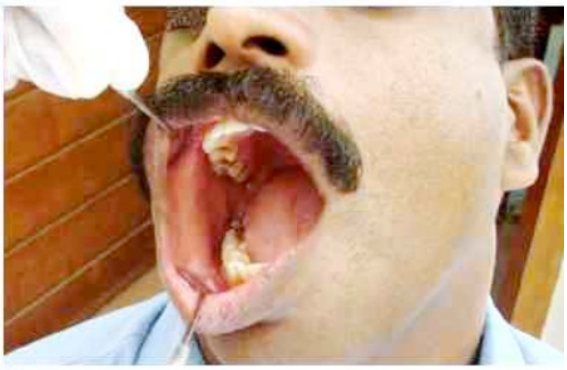
EXAMINATION OF BUCCAL MUCOSA

Step 1: Ask the subject to partially open the mouth.

Step 2: Examine the buccal mucosa by stretching it with a pair of tongue depressors or mouth mirrors.

Step 3: With the mouth open wide, examine first the right, then the left buccal mucosa extending from the labial commissures and back to the anterior tonsillar pillar.



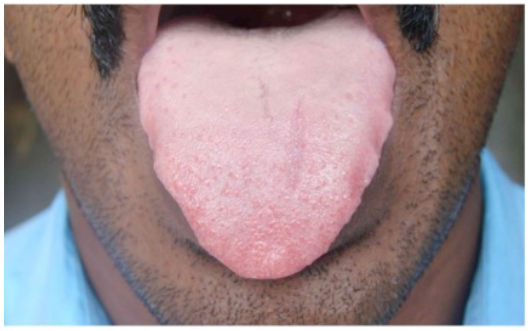


EXAMINATION OF DORSAL SURFACE OF TONGUE

Step 1: Ask the subject to protrude the tongue and attempt to touch the tip of the chin.

Step 2: Examine the entire dorsal tongue by asking the subject to move the tongue left to right.

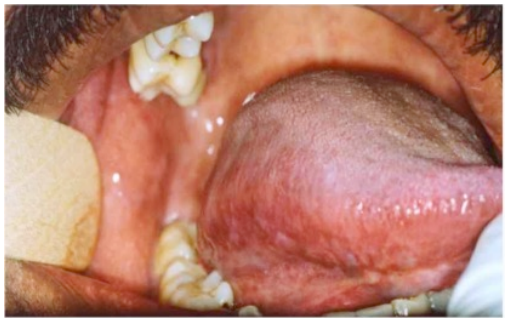
Step 3: Depress the tongue with a mouth mirror and ask the patient to say “ahh” to visualise the uvula and tonsillar pillars.

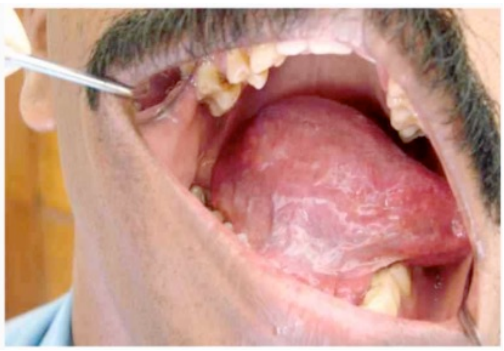


EXAMINATION OF THE LATERAL BORDERS OF THE TONGUE

Step 1: Retract the buccal mucosa with a mouth mirror.

Step 2: Examine the margins by asking the subject to touch the opposite buccal mucosa with the tip of the tongue.





EXAMINATION OF VENTRAL SURFACE OF TONGUE AND FLOOR OF THE MOUTH

Step 1: Ask the subject to elevate the tongue by touching the tip to the roof of the mouth.

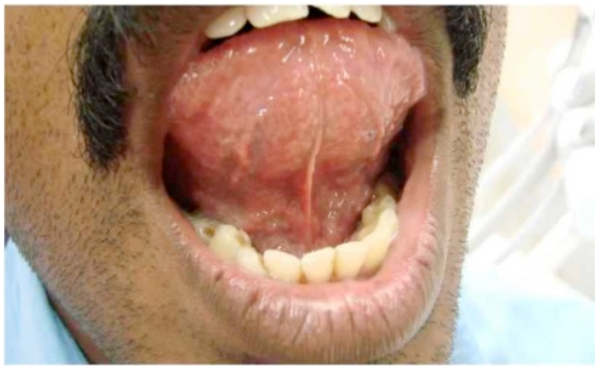
Step 2: Dry the floor of the mouth with gauze.

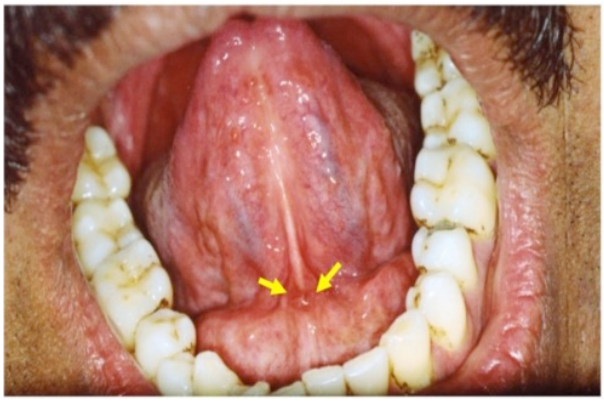
Step 3: Inspect the lingual frenulum in the mid-line.

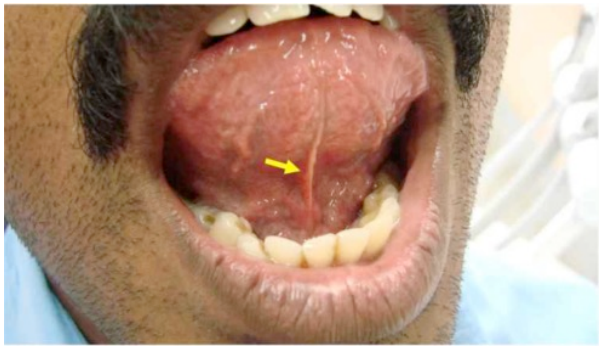
Step 4: Inspect the openings of the submandibular glands (Wharton ducts), present symmetrically on either side of the lingual frenum.

Step 5: Inspect the sublingual glands.

Step 6: Insert a gloved finger beneath the tongue, and another under the chin on the exterior skin, and bimanually palpate the submandibular glands and the entire submental region.





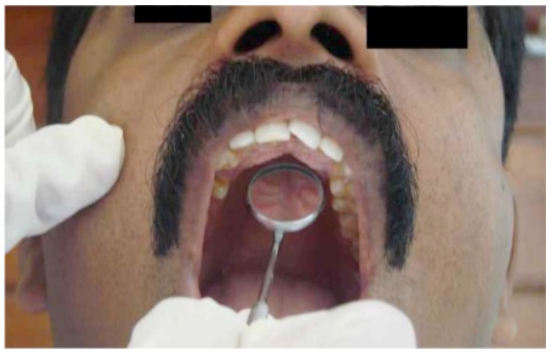


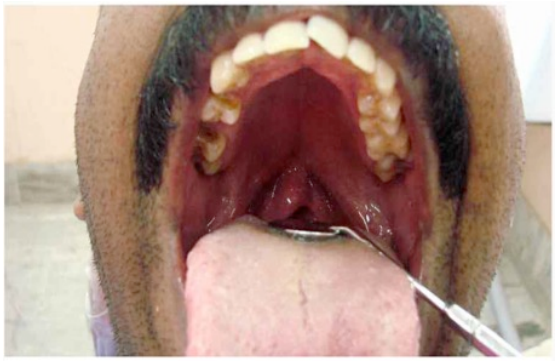
EXAMINATION OF HARD AND SOFT PALATE

Step 1: Ask the subject to open widely and tilt his or her head backwards to provide an adequate view of the hard and soft palate.

Step 2: Examine the anterior portion of the hard palate with an intraoral mirror.

Step 3: Examine the soft palate by depressing the base of the tongue with a tongue depressor and asking the subject to say "aah".





SECTION 4
PREVENTING THE DISEASE

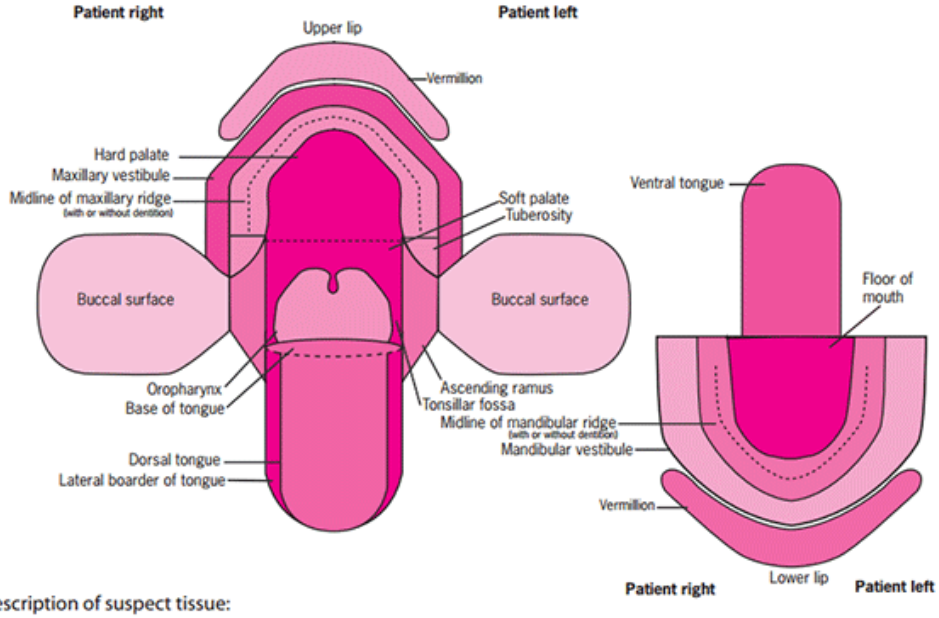
RECORD KEEPING

All information including visual and palpatory examination, soft tissue conditions, head and neck examination should be recorded. Soft tissue charts and mouth maps should be used as they help to identify patients who are at higher risks. Following is an example of a recording form-

Oral cancer screening referral form

We have found the below detailed abnormality. We believe this area requires further evaluation, and if warranted a biopsy for definitive diagnosis.

Patient name_____
Address_____
City_____Sate____Zip_____
Phone contact number_____ Age_____Sex_____



Description of suspect tissue:

_____
_____
_____
_____
_____
_____

DUTY OF CARE

Once the oral history, a checkup and discussions have been held with the person, the knowledge gained should be used to formulate an education plan.

Patient education can be very effectively applied when the patient is willing to change the behaviour. It may also bring about a change in attitude over time if they are provided with information they were previously unaware of. Based on the history given, kindly give the following advice.

TOBACCO CESSATION

Advise all individuals during interactions to not initiate tobacco consumption and to quit the use of all forms of tobacco (smokeless or smoking), betel nut and any such regular chewing habit.

DELIVERING VERY BRIEF ADVICE FOR TOBACCO CESSATION

3A'S OF VERY BRIEF ADVICE

- ASK – about the type of tobacco product used
- ADVISE – on stopping tobacco use
- ACT – by talking about, and offering self-help material on quit planning

1. ASK

- All participants/individuals will be ST users - Products used may vary
- **ASK** the participant about the **type of product(s)** they use
- Opportunity to build rapport, initiate conversation

2. ADVICE

- Focus on building/reinforcing individuals' knowledge - Discuss ST related harms to emphasise quitting
- **ADVISE** participants to stop using smokeless tobacco.

  "ST use is harmful to health; therefore, it is important that you try to stop consuming it immediately. For e.g. ST is linked with several diseases such as … [identify some of the harms associated with ST use]

3. ACT

- Acknowledge that people may use different methods to quit
- Emphasise on planning a quit date
- Support quit planning by providing information (self-help leaflet)

"Quitting ST can be hard for many people, and different people may try to do it in different ways. This may include…[discuss examples]. One way of quitting ST is to set a quit date; this means identifying a date from when you stop using ST completely."

"I would like to provide you with this leaflet which can help you think about some important things as you plan your quit date"

MODERATING ALCOHOL INTAKE

Drinking; Heavy drinking should be cut down. People who smoke and drink should be told of the combined dangers. All of these apply particularly to those in late and middle and old age.

EATING A HEALTHY DIET AND EXERCISING

- Consumption of a healthy balanced diet should be recommended that includes plenty of fruit, vegetables and cereals. In people with signs of precancerous lesions, advice should be given on avoiding spicy food to reduce discomfort.

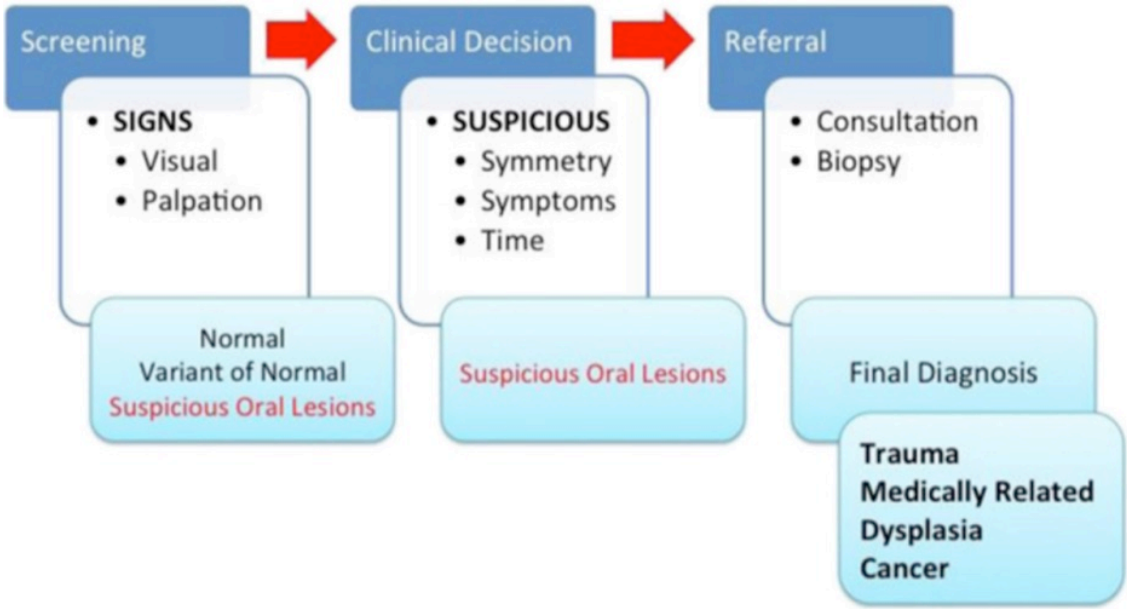
- Exercise: Lifestyle changes should be recommended as they can have a direct benefit in reducing the chances of getting oral cancer later in life-the better a person's general health, the more likely their oral health is good too.

REFERRAL PATHWAY

A multi-disciplinary team approach, involving dentists, oral health advisors and therapists may be required while referring the patient. All suspicious lesions should be referred to the nearest Primary Health Care centre.

Where Community Health Workers are unable to deal with the issue themselves, referrals to external qualified staff should be made, for example, referral to a nutritionist for diet advice.

A smoking cessation officer may be needed for advice and support through the patient's journey when trying to give up tobacco.



COMIC – ORAL SCREENING IN THE COMMUNITY (PUTTING THEORY INTO PRACTICE)

Characters- Adult 1, Adult 2, Health Worker, Dentist

Adult 1: Would you like to have some? (Offers a pack of chewing tobacco to adult 2)
Adult 2: No thanks, last week a Community Health Worker (CHW) told me how bad tobacco is for health, I have decided to quit. No tobacco for me!
Adult 1: I am sure a little bit will not do any harm! It's not like smoking.
Adult 1: My mouth has had a burning sensation for some days. I spotted an ulcer too. I like placing tobacco there to help with the pain.
Adult 2: Since when do you have the ulcer?
Adult 1: It's been over 3 weeks now. It's not healing.
(A Community Health Worker is walking past the area when Adult 2 calls out to her)
Adult 2: Hello ASHA Didi! Do you have two minutes, please?
(Community Health Worker comes near to the two adults conversing)
Adult 2: My friend here is having an ulcer for around 3 weeks, do you think it can be trouble?
Health Worker: I can examine it and suggest a remedy after that
(Health Worker sets out some gloves and single-use wooden sticks from the bag/kit she is carrying. She takes a medical and oral history, examines the mouth and says)
Health Worker: There is a white patch in the area where you habitually place your tobacco. Your ulcer too is around the same area, you should have reported earlier your problem. We must not waste any time, I have to refer you to the dentist!
(Adult 1 looks nervous and anxious and leaves the area with CHW to visit the Dentist)

Dentist: Hello! Who have you brought along?
CHW: Doctor I have noticed a white patch in this person's mouth. It has not healed in the past 3 weeks. Could you take a look, please?
Dentist: I see. Why did you not come as soon as your problem started?
Adult 1: I thought it was normal and keeping tobacco in the area of the ulcer would help it heal sooner. My friend did the same doctor!
Dentist: You must know that all forms of tobacco are very harmful. What you consumed for so long has led to a change in that area-now this area is at a high risk of developing cancer. We will have to do a biopsy and manage further. You must promise to never take tobacco again.
Adult 1: I quit from this moment. I want life, not tobacco.

Dentist: Thank you, Health Worker for detecting this lesion and for bringing this person to my attention. You may have saved a life today!

मुख कैंसर स्क्रीनिंग टूलकिट

मौखिक कैंसर और मौखिक संभावित घातक विकारों को रोकने के लिए एक सामुदायिक स्वास्थ्य कार्यकर्ता प्रशिक्षण संसाधन

प्रिय सामुदायिक स्वास्थ्य कार्यकर्ता:

मुख कैंसर या मुंह का कैंसर भारत में कैंसर के सबसे घातक रूपों में से एक है। हर साल 13,00,000 से अधिक लोगों को यह बीमारी होती है और लगभग 75,000 लोग इसके कारण अपनी जान गंवा देते हैं (ग्लोबोकैन 2020)। यह संख्या बढ़ने वाली है, और यह अनुमान लगाया गया है कि 2030 तक इस बीमारी से हर साल 95,000 से अधिक लोगों की मौत हो जाएगी।

प्रमुख अंतरराष्ट्रीय कैंसर एजेंसी, आईएआरसी द्वारा किए गए शोध से पता चला है कि मुख कैंसर के प्रारम्भिक घावों का जल्दी पता लगाने से और इसके जोखिम कारकों के प्रबंधन से कैंसर के गठन को रोका जा सकता है।यह उच्च जोखिम वाले लोगों की पहचान और स्क्रीनिंग करके और उन्हें तंबाकू छोड़ने, शराब के उपयोग को प्रतिबंधित करने, जीवनशैली में बदलाव करने और स्वस्थ आहार खाने में मदद करके किया जा सकता है।

वर्तमान में, मौखिक कैंसर और उसके प्रारम्भिक घावों का केवल दंत चिकित्सा सेटिंग में पता लगाया जा सकता है । हालांकि, दंत चिकित्सकों की कमी और उपचार की उच्च लागत के कारण, लोग समय पर स्वास्थ्य सेवाओं तक पहुंचने में सक्षम नहीं हैं। समय पर जांच और इलाज ना होने की वजह से कई लोगों को इससे जान गवानी पड़ती है। प्रारंभिक पहचान और समय पर प्रबंधन, जबकि बीमारी अभी भी अपने पूर्व-कैंसर चरण में है, जीवन को बचाने की कुंजी है। सामुदायिक स्वास्थ्य कार्यकर्ता अपने स्थानीय समुदायों में इस बीमारी के लिए उच्च जोखिम वाले लोगों की पहचान और स्क्रीनिंग करके और उन्हें आगे के निदान और उपचार के लिए संदर्भित करके इसमें एक बड़ी भूमिका निभा सकते हैं।

मुख कैंसर स्क्रीनिंग टूलकिट एक आसान गाइड है जिसको यॉर्क विश्विद्यालय (इंग्लैंड) के शोधकर्ताओं और मुख कैंसर के विशेषज्ञों द्वारा विकसित किया गया है। इसे खासकर सामुदायिक स्वास्थ कार्यकर्ताओं के लिए बनाया गया है। ये गाइड आपको मदद करेगी मुख कैंसर के शुरुवाती लक्षणों और घावों की जांच करने में और मरीज़ों को आगे की जांच ke liye सही सलाह देने के लिए।

क्यूंकि आप समुदाय और स्थानीय स्वास्थ सेवाओं से जुड़े हैं, आप इस घातक बीमारी को रोकने के लिए निम्नलिखित तरीके से मदद कर सकते हैं-

1. चिकित्सा और दन्त इतिहास द्वारा उच्च जोखिम वाले लोगों की पहचान करके।
2. मौखिक दृश्य परीक्षण द्वारा मुख कैंसर के शुरुवाती लक्षणों की पहचान करके।
3. मरीज़ को जोखिम कारकों को छोड़ने की सलाह देकर और उन्हें आगे जांच के लिए संदर्भित करके।

मैं इस संसाधन में आपकी रुचि के लिए धन्यवाद करती हूं और इसे उपयोग करने के अनुभव पर आपकी प्रतिक्रिया का स्वागत करतीहूं।

भवदीय

जैनब किदवई, एमएससी, बीडीएस

पीएचडी विद्वान, स्वास्थ्य विज्ञान विभाग,

सामुदायिक स्वास्थ्य कार्यकर्ताओं के प्रशिक्षण संसाधन का अवलोकन

निम्नलिखित संसाधन में मुख कैंसर और मौखिक संभावित घातक विकारों (मुख कैंसर के प्रारम्भिक घाव) की पहचान और रोकथाम के लिए जानकारी और गतिविधियाँ शामिल हैं। इस संसाधन का उद्देश्य है:

1. मुख कैंसर और मौखिक संभावित घातक विकारों (मुख कैंसर के प्रारम्भिक घाव) के लक्षणों की पहचान करने में सामुदायिक स्वास्थ्य कार्यकर्ताओं को सक्षम करना ।

2. मरीज़ को जोखिम कारकों को छोड़ने की सलाह देकर और उन्हे आगे जांच कराने के लिए संदर्भित करने में सक्षम करना।

3. मुख कैंसर और मौखिक संभावित घातक विकारों (मुख कैंसर के प्रारम्भिक घाव) से जुड़े संकेतों, लक्षणों और जोखिम कारकों के बारे में जागरूकता बढ़ाना ।

4. उच्च जोखिम वाले रोगियों के साथ मुख कैंसर और मौखिक संभावित घातक विकारों (मुख कैंसर के प्रारम्भिक घाव के बारे में बात करते समय संलग्न होने के तरीके पर अच्छे अभ्यास को बढ़ावा देना ।

संसाधन को निम्नलिखित 4 खंडों में विभाजित किया गया है-

अनुभाग 1: परिचय

- मुख कैंसर का संक्षिप्त विवरण
- मौखिक संभावित घातक विकारों (मुख कैंसर के प्रारम्भिक घाव) का संक्षिप्त विवरण

अनुभाग 2: जोखिम वाले लोगों की पहचान करना

- मुख कैंसर और मौखिक संभावित घातक विकारों (मुख कैंसर के प्रारम्भिक घाव) के लिए जोखिम कारक
- चेतावनी संकेत और लक्षण
- चिकित्सा और दंत इतिहास लेना

अनुभाग 3: बीमारी का पता लगाना

- मौखिक दृश्य परीक्षा का परिचय
- प्रशिक्षण
- चेहरे का बहरी और अतिरिक्त मुख परीक्षण

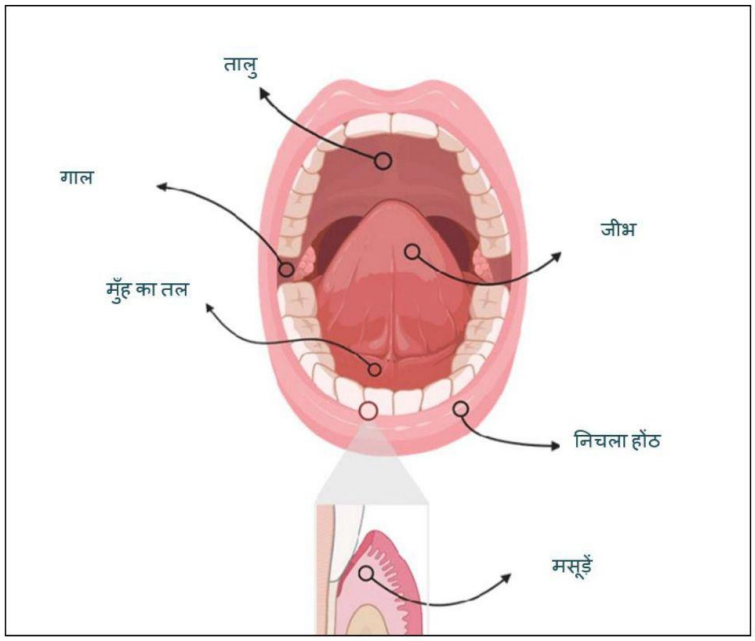
अनुभाग 4: बीमारी को रोकना

- परीक्षण परिणाम रिकॉर्ड रखना
- देखभाल का कर्तव्य
- मरीज़ को आगे की जांच के लिए भेजना

अनुभाग 1
परिचय

मौखिक कैंसर

मुख में होने वाले कैंसर को मुख कैंसर कहते हैं। यह होंठों, होंठ और गालों की भीतरी सतह, दांत, मसूड़े, जीभ के सामने के दो-तिहाई हिस्से, जीभ के नीचे मुंह के ताल और कठोर और नरम तालु पर हो सकता हैं।

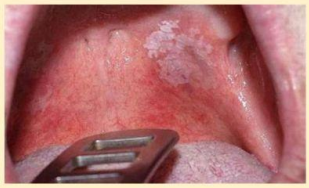


मौखिक संभावित घातक विकार (मुख कैंसर के प्रारम्भिक घाव)

मौखिक संभावित घातक विकार या मुख कैंसर के प्रारम्भिक घाव वो घाव हैं जो होंठ और मुख कैंसर की घटना के बढ़ते जोखिम से जुड़े होते हैं। ये मुंह में लाल, सफेद या मिश्रित लाल और सफेद घावों या चकत्तों के रूप में दिखाई देते हैं। ये मुख कैंसर के चेतावनी संकेतों के रूप में काम करते हैं। ये प्रारम्भिक घाव या लक्षण महत्यपूर्ण भूमिका निभाते हैं क्योंकि, अधिकांश मामलों में, इन घावों की प्रारंभिक पहचान और प्रबंधन से मुख कैंसर को रोका जा सकता है । इन घावों के कई रूप होते हैं जैसे की लोकोपलाकिआ (सफ़ेद चिकत्ते), एरीथ्रोप्लेकिआ (लाल चिकत्ते) और मौखिक सुब्मकौस फाइब्रोसिस (मुँह में कठोर रेशे) जो की तम्बाकू और शराब के उपयोग से जुड़े होते हैं।

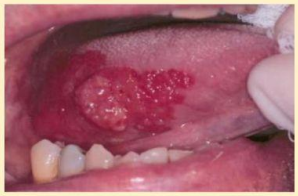
निम्नलिखित हिस्से में मुख कैंसर और मौखिक संभावित घातक विकारों का उदाहरण दिया हैं -

ल्यूकोप्लाकिया



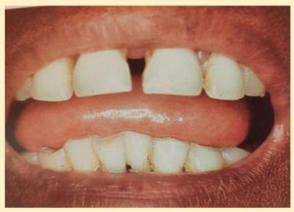
यह सबसे आम घाव हैं प्रारम्भिक मुख कैंसर के। इन्हे अक्सर तंबाकू के उपयोग से जुड़े एक सफेद पैच के रूप में वर्णित किया जाता है। ये कभी कबार घूसर सफ़ेद या सफ़ेद और लाल मिश्रित चालों की तरह भी नज़र आ सकते हैं।

एरिथ्रोप्लैकिया



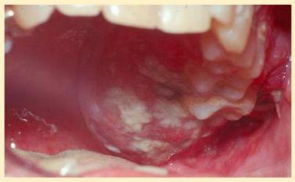
एरिथ्रोप्लैकिया एक दुर्लभ लेकिन गंभीर प्रारम्भिक मुख कैंसर घाव है। यह मुंह में एक उज्ज्वल लाल मखमली चकत्ते के रूप में दिखाई देता है।

मौखिक सुब्मकौस फाइब्रोसिस



इन घाव में गाल के अंदर रेशेदार ऊतक का गठन होता है। इसमें मरीज़ मुँह में जलन की शिकायत करते हैं और उन्हें मुँह खोलने में दिक्कत का सामना करना पड़ता है।

मौखिक कैंसर



अगर मौखिक संभावित घातक विकारों का सही समय पे इलाज नहीं होता हैं तो ये मुख कैंसर में परिवर्तित हो जाते हैं। ये गहरे घाव, चालों या सूजन की तरह नज़र आते है। इसमें खाने, चबाने और मरीज़ को बात कर्म में दिक्कत का सामना करना पद सकता हैं।

अनुभाग 2

मुख कैंसर से जोखिम की पहचान

जोखिम कारक

जोखिम कारक ऐसी चीजें हैं जो एक बीमारी के विकास की संभावना को बढ़ाती हैं। मौखिक कैंसर के लिए जोखिम कारकों को जानना महत्वपूर्ण है क्योंकि वे उन लोगों की पहचान करने में मदद करते हैं जो अधिक जोखिम में हैं। मुख कैंसर के लिए जोखिम कारक हैं:

1. तम्बाकू का उपयोग

यह मुख कैंसर के गठन के लिए मुख्य जोखिम कारकों में से एक है। इसमें धूम्रपान और धुआं रहित तंबाकू का उपयोग दोनों शामिल हैं। तम्बाकू के प्रकार, उपयोग की अवधि और आवृत्ति के आधार पर जोखिम बढ़ जाता है। निम्नलिखित डिब्बे में तम्बाकू और मुख कैंसर के जोखिम के बारे में बताया गया हैं-

तम्बाकू और मुख कैंसर में सम्बन्ध

- भारत में लगभग 26.7 करोड़ तम्बाकू उपयोगकर्ता हैं।
- धूम्रपान रहित तम्बाकू के वैश्विक बोझ का 70% हिस्सा भारत पर है।
- गुटखा, खैनी, जर्दा, नसवर, मावा, मैनपुरी, पान मसाला, तंबाखू किल्लों जैसे तम्बाकू उत्पादों का उपयोग हर साल 230,000 से अधिक भारतीयों को प्रभावित करता है।
- भारत में लगभग 90% मौखिक कैंसर धूम्रपान रहित तंबाकू के उपयोग से जुड़े हुए हैं।
- मुख कैंसर सिगरेट, सिगार, पाइप, बीड़ी जैसे धूम्रपान तंबाकू उत्पादों से भी जुड़ा है।

2. शराब का सेवन

शराब के लंबे समय तक सेवन करने से भी मुख कैंसर की संभावना बढ़ सकती है। निम्नलिखित हिस्सा शराब के उपयोग और मौखिक कैंसर के बीच संबंध दिखाता है-

शराब और मौखिक कैंसर:

- शराब का सेवन करने वाले लोगों में मुख कैंसर का खतरा 2 गुना बढ़ जाता है।
- जो लोग शराब के साथ धूमपान का इस्तेमाल करते हैं उनमे ये खतरा लगभग ३० गुना ज़्यादा बढ़ जाता है।

3. अन्य कारकों में शामिल हैं-

- मानव पैपिलोमा वायरस से संक्रमण
- खराब आहार और विटामिन ए, सी और ई की कमी और आयरन, सेलेनियम और जिंक जैसे खनिजों की कमी।
-मुंह के कैंसर का पिछला इतिहास या परिवार में कैंसर का इतिहास।

चेतावनी संकेत एवं लक्षण

मुख कैंसर और मौखिक संभावित घातक विकारों को चेतावनी के संकेतों और लक्षणों की जांच करके लोगों में पहचाना जा सकता है। इस रोग के लक्षण हैं-

- जीभ, मसूड़ों, गाल या होंठों के अंदर सफेद या लाल चकत्ते या छाले ।
- गर्दन में एक या एक से अधिक लिम्फ नोड्स की सूजन के कारण होने वाली गांठ ।
- मुंह में गांठ या सूजन ।
- मुंह खोलने में प्रतिबंध।

मुंह में इन संकेतों की जांच करने के तरीके पर चरण-दर-चरण निर्देशों को धारा 3 में विस्तार से समझाया गया है।

इसके अलावा मरीज़ निम्नलिखित शिकायत भी कर सकते हैं-

- 3 सप्ताह से अधिक समय तक मुंह में गैर-उपचार छाला।
- जबड़े या जीभ को हिलाते समय दर्द या असुविधा।
- निगलने या चबाने के दौरान समस्या, या बोलने में परेशानी।
- स्वाद में परिवर्तन।
- खाने के दौरान जलन और मुंह खोलने में कठिनाई।
- जीभ का सुन्न होना।
- आवाज में कर्कशता या गले में खराश जो 6 सप्ताह या उससे अधिक समय तक रहती है।

इन लक्षणों को चिकित्सा और दंत इतिहास लेते समय अच्छी तरह से पूछा और रिकॉर्ड किया जाना चाहिए जो अगले खंड में समझाया गया है।

चिकित्सा और दंत इतिहास लेना

चिकित्सा और दंत इतिहास लेने से जोखिम की पहचान करने में मदद मिलती है। इससे जीवन शैली परामर्श और शिक्षा प्रदान करने में सहायता मिलती है। आपको निम्नलिखित पूछने पर विचार करना चाहिए-

चिकित्सा अवं दन्त इतिहास लेते समय पूछे जाने वाले सवाल

नाम: _____ आयु: __ लिंग: _____

पता: ____

चिकित्सा इतिहास

1. क्या आपका वर्तमान में किसी भी चिकित्सा स्थिति के लिए इलाज किया जा रहा है या पिछले एक साल में किया गया है? यदि हां, तो क्यों?

2. क्या पिछले एक साल में आपके सामान्य स्वास्थ्य में कोई बदलाव आया है? यदि हां, तो कृपया समझाएं।

3. क्या आप कोई दवा ले रहे हैं? यदि हां, तो किसलिए और कब से?

4. क्या आपको इनमे से कोई बीमारी है या हो चुकी है- अस्थमा, हृदय रोग, मधुमय, कैंसर, स्ट्रोक इत्यादि

5. क्या आपके परिवार में किसी को ये बीमारी है (जैसे, मधुमेह, कैंसर, हृदय रोग)?

6. क्या आप धूम्रपान करते हैं? यदि हां, तो आप कौन सा धूम्रपान करते हैं (जैसे, चिलम, हुक्का, सिगार, सिगरेट, बीड़ी या अन्य) आप कितनी बार सामान्य रूप से धूम्रपान करते हैं? आप कितने समय से धूम्रपान कर रहे हैं?

7. क्या आप धूम्रपान रहित तम्बाकू का उपयोग करते हैं? यदि हां, तो आप क्या चबाते हैं (जैसे, गुटखा, खैनी, जर्दा, मावा, गुल, तम्बाकू के साथ पान मसाला, कोई अन्य) एक दिन में कितनी बार? आपको धूम्रपान रहित तम्बाकू का उपयोग करने की आदत कब से है?

8. क्या आप शराब का सेवन करते हैं? आप कितनी बार शराब पीते हैं? कितने वर्षों से?

दंत इतिहास

1. आप आखिरी बार दन्त चिकित्सक के पास कब गए थे ?

2. क्या आप पिछले एक साल में किसी भी मुंह या दांत की समस्याओं से पीड़ित हैं? यदि हां, तो समस्या क्या थी या क्या है?

3. आपने इस समस्या के लिए किस्से परामर्श किया था ?

4. क्या आपने निम्नलिखित में से किसी पर भी ध्यान दिया है?

निगलने पर दर्द, मुंह में छाले, गले में खराश, लगातार कर्कशता, मुंह या गर्दन में गांठ/सूजन, मुंह में खून आना, सफेद पैच, लाल पैच, मुंह में जलन, मुंह खोलने में कठिनाई?

अनुभाग 3

बीमारी का पता लगाना

मौखिक दृश्य परीक्षा

चिकित्सा और दन्त इतिहास लेने के बाद आप मुँह की जांच का आरम्भ कर सकते हैं। इस जांच को स्क्रीनिंग या मौखिक दृश्य प्रशिक्षा कहते हैं। स्क्रीनिंग ऐसी प्रक्रिया है जिससे हम बीमारी की उपस्थिति का एक विभिन्न स्तर पर पता लगा सकते हैं। इस मामले में, यह मौखिक कैंसर स्क्रीनिंग है और इसमें बीमारी के संकेतों की पहचान करने के लिए मौखिक दृश्य परीक्षा का उपयोग शामिल है।

कृपया ध्यान दें कि स्क्रीनिंग परीक्षा एक नैदानिक परीक्षा नहीं है, लेकिन इसका उद्देश्य असामान्यताओं की पहचान करना है जिन्हें आगे की जांच, निदान और प्रबंधन के लिए संदर्भित किया जाना चाहिए।

परीक्षा सेटिंग

एक मौखिक दृश्य परीक्षण आयोजित करते समय, परीक्षा सेटिंग पर ध्यान दिया जाना चाहिए। परीक्षण एक उपयुक्त ऊंचाई से आयोजित किया जाना चाहिए जिसमें मरीज़ आराम से कुर्सी पर बैठा हो और पर्याप्त प्रकाश का सामना कर रहा हो। रौशनी के लिए प्राकृतिक सूर्य के प्रकाश का उपयोग किया जा सकता है, हालांकि, यदि पर्याप्त सूरज की रोशनी नहीं है, तो टोर्च की रोशनी का उपयोग किया जा सकता है।

मौखिक परीक्षा आयोजित करते समय निम्नलिखित उपकरणों का उपयोग किया जाना चाहिए-

ऊतक के विज़ुअलाइज़ेशन और पीछे हटने के लिए एक मुख दर्पण, जीभ को दबाने के लिए जीभ ब्लेड या लकड़ी की छड़ी, मुँह सूखने के लिए रुई या गौज का टुकड़ा और संक्रमण नियंत्रण के लिए दस्ताने और मुँह का मास्क।

मुंह दर्पण

जीभ ब्लेड

गौज

मुँह का मास्क

दस्ताने

मौखिक दृश्य परीक्षण दो भागों में किया जाता है। सबसे पहले मरीज़ के चेहरे और गर्दन की जांच की जाती है और फिर मुँह के अंदर की जांच की जाती है।

मुँह के बाहर का परीक्षण

चरण 1: विषमता (चेहरा बराबर ना होना), त्वचा के घावों, चेहरे के पक्षाघात (सुन्न होना) या सूजन के लिए चेहरे और गर्दन का निरीक्षण करें।

चरण 2: यदि घाव मौजूद है, तो विषमता, सीमा अनियमितता, रंग परिवर्तन, छह मिमी से अधिक व्यास और दोनों पक्षों पर घाव के विकास पर ध्यान दें।

चरण 3: आकार, सीमा, मोटाई, बनावट, रंग, स्थिरता और कोमलता के लिए संभावित घावों का मूल्यांकन करें।

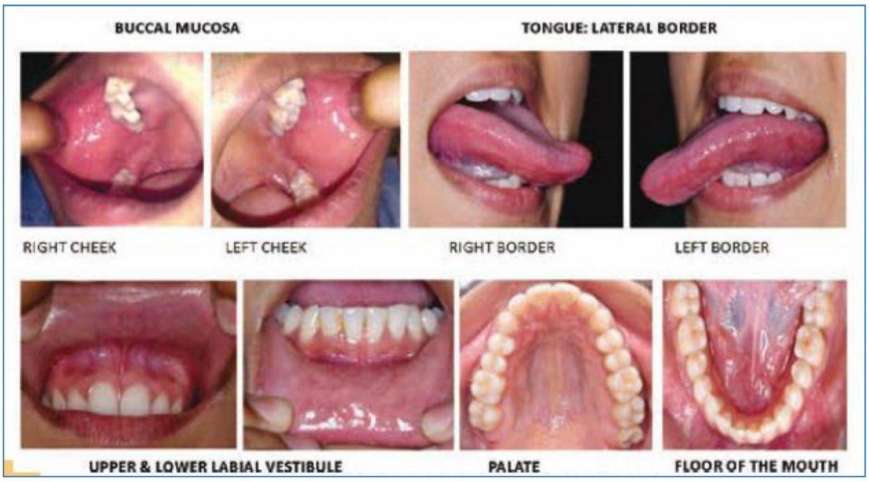
चरण 4: बढ़े हुए लार ग्रंथियों के लिए निरीक्षण करें।

आंतरिक मुख परीक्षण

चरण 1: अगर मरीज़ के पास नकली दांत या कृतिम दन्तावली है तो पहले उसे हटाने के लिए कहें।

चरण 2: जबड़े की हड्डी का निरीक्षण करें और रंग, स्थिरता, ढीले दांतों और अत्यधिक हड्डी के गलने के परिवर्तन पर ध्यान दें ।

चरण 3: फिर बारी बारी से मुँह के विभिन हिस्सों की जांच करें। सबसे पहले जांच शुरू करिये होंठों के परीक्षण से।



होंठों का परीक्षण

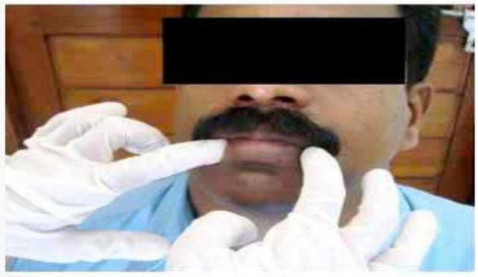
चरण 1: सबसे पहले, निचले होंठ को पीछे लाएं और आंतरिक सतह का निरीक्षण करें।

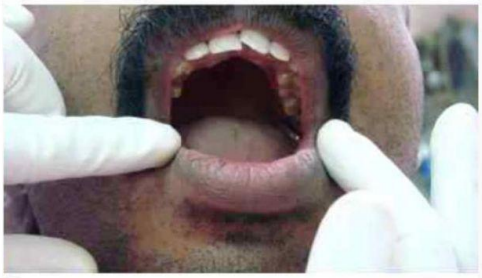
चरण 2: होंठ की मध्यरेखा पर ध्यान दें।

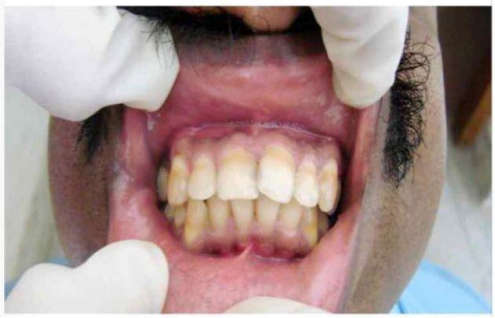
चरण 3: दांतों, मसूड़ों और होंठो और मसूड़ों के बीच की गहराई का निरीक्षण करें।

चरण 4: अपने अंगूठे और तर्जनी उंगली se होंठ को टटोलें या थपथपाएं.

चरण 5: इसी तरह ऊपरी होंठ के लिए इन चरणों को दोहराएं।





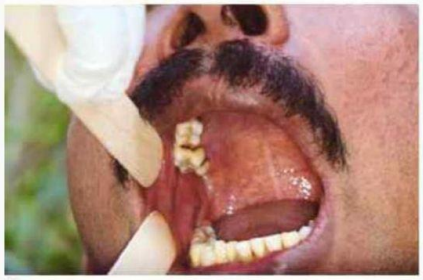


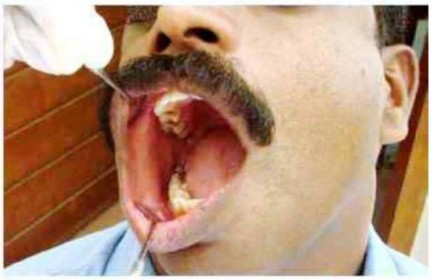
गालों का परीक्षण

चरण 1: मरीज़ को मुंह खोलने के लिए कहें।

चरण 2: जीभ की ब्लेड और मुँह दर्पण के साथ गाल की अंदरूनी सतह की जांच करें।

चरण 3: पहले दाएं ओर फिर बाएं गाल की अंदरूनी सतह की जांच करें।



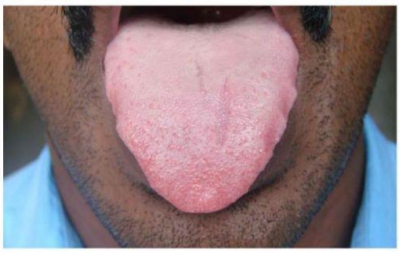


जीभ की उप्परि सतह का परीक्षण

चरण 1: मरीज़ को जीभ को बाहर निकालकर और ठुड्डी को छूने का प्रयास करने के लिए कहें ।

चरण 2: मरीज़ को जीभ को बाएं से दाएं स्थानांतरित करने के लिए कहकर पूरी पृष्ठीय जीभ की जांच करें।

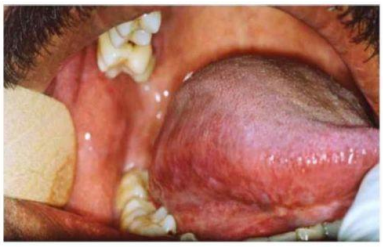
चरण 3: मुंह दर्पण के साथ जीभ को दबाएं और मुँह के पिछले हिस्से को देखने के लिए मरीज़ को "आह" कहने के लिए कहें।

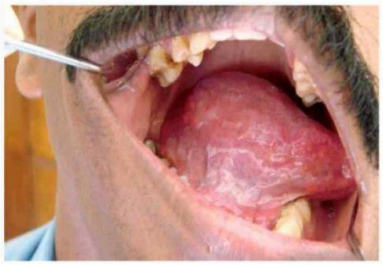


जीभ की पार्श्व या किनारे की सीमाओं का परीक्षण

चरण 1: मुंह दर्पण के साथ गाल को बहार की तरफ खीचें।

चरण 2: मरीज़ से जीभ को विपरीत गाल को छूने के लिए कहें और पार्शव सीमाओं की जांच करें।





जीभ की उदार या निचली सतह और मुँह के तल का परीक्षण

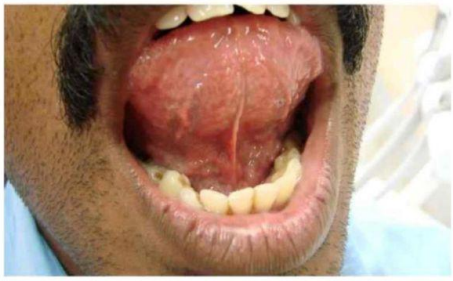
चरण 1: मरीज़ को जीभ के सिरे से तालु को छूने को कहें ।

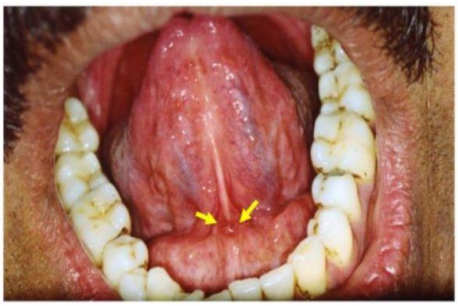
चरण 2: मुँह के तल को गौज या रुई से सुखाएं ।

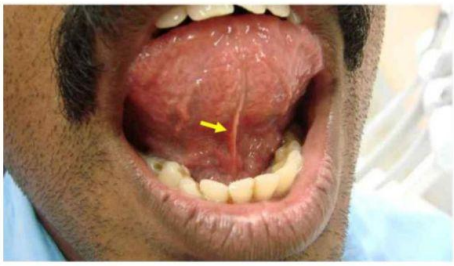
चरण 3: जीभ की निचली सतह के बीच वाली मध्य-रेखा का निरीक्षण करें।

चरण 4: जीभ की निचली सतह की मध्य रेखा के पास मौजूद लार ग्रंथियों का निरीक्षण करें।

चरण 5: जीभ के नीचे ऊँगली डालें और ठुड्डी के नीचे हाथ रख कर लार ग्रंथियों को मेहरूस करें। बीच वाली मध्य-रेखा का निरीक्षण करें।





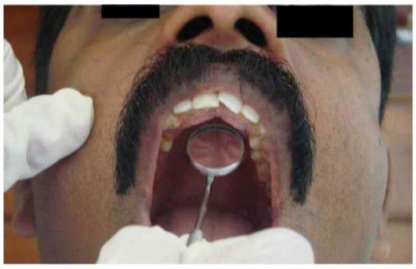


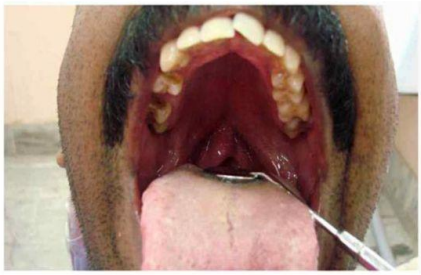
कठोर और नरम तालु की परीक्षण

चरण 1: मरीज़ के कठोर और नरम तालु का निरीक्षण करने के लिए सर को पीछे की ओर झुकाने के लिए कहें।

चरण 2: मुख दर्पण के साथ कठोर तालु के आगे के हिस्से की जांच की जांच करें।

चरण 3: नरम तालु की जांच करने के लिए जीभ को मुख दर्पण के साथ निचे करें और मरीज़ को "आह" कहने के लिए कहें।



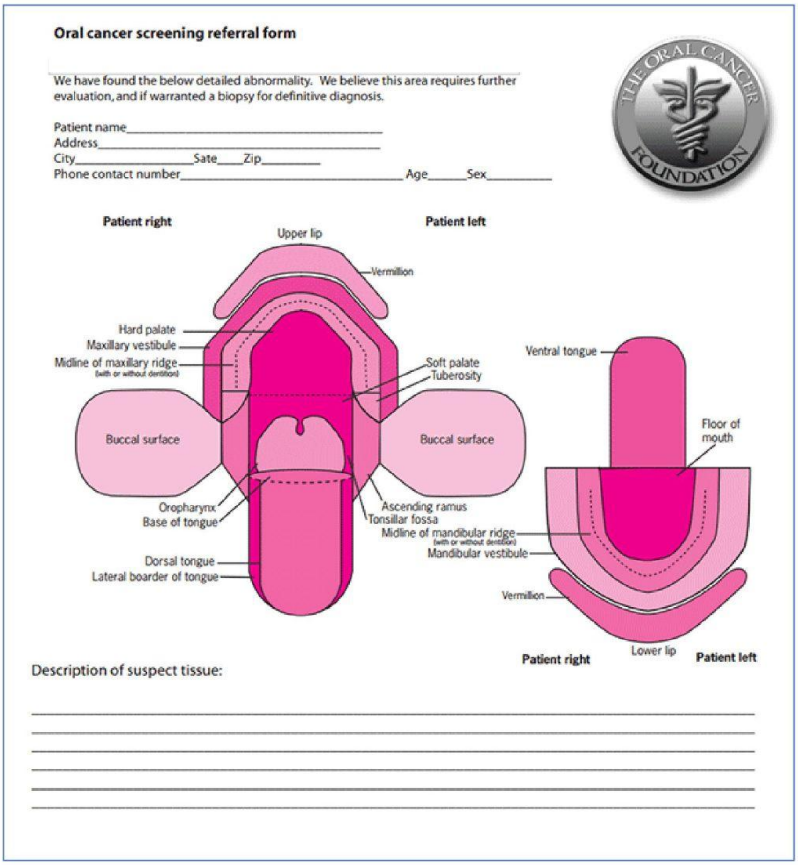


धारा 4

रोग की रोकथाम

अभिलेख रखना

दन्त दृश्य परीक्षण करने के बाद आपको जांच के परिणामो को रिकॉर्ड करना है। दंत रिकॉर्ड आधिकारिक चार्ट है जो चिकित्सा और दंत इतिहास, संकेतों, लक्षणों, आगे की जांच और मरीज़ को दी गई सलाह पर सभी जानकारी रिकॉर्ड करता है। अपने मरीज़ के साथ परामर्श करते समय यह महत्वपूर्ण है कि आप नैदानिक स्थिति, संकेत, लक्षण, आगे की जांच कि प्रक्रिया और आपने मरीज़ को मौखिक रूप से और लिखित रूप से कौन सी जानकारी और सलाह दी है का अभिलेख रखें। यह हमें मरीज़ को आगे की जांच और उपचार के लिए भेजने में मदद करता है मरीज़ के अतीत और वर्तमान मौखिक स्वास्थ्य स्थितियों का ट्रैक रखता है।



देखभाल का कर्तव्य

एक बार जब मौखिक इतिहास, चेकअप और व्यक्ति के साथ चर्चा हो जाती है, तो प्राप्त ज्ञान का उपयोग शिक्षा योजना और रेफरल मार्ग तैयार करने के लिए किया जाना चाहिए। बातचीत के दौरान सभी मरीज़ों को तम्बाकू का सेवन शुरू न करने और तम्बाकू के सभी रूपों (धुआं रहित या धूम्रपान), सुपारी और इस तरह के किसी भी नियमित चबाने की आदत के उपयोग को छोड़ने की सलाह दें।

शोध से पता चला है कि निम्नलिखित तरीके से सलाह देना लोगों को तंबाकू का उपयोग छोड़ने में मदद करने में प्रभावी साबित हुआ है।

तम्बाकू समाप्ति के लिए बहुत संक्षिप्त सलाह देना

तम्बाकू समाप्ति के लिए संक्षिप्त सलाह देने के लिए 3 मुख्य चरण हैं।

पूछें - की मरीज़ किन प्रकार के तम्बाकू का सेवन करता है

सलाह- तम्बाकू के उपयोग को रोकने पर सलाह दिए

कार्य- बात करिये और तम्बाकू छोड़ने के लिए स्वयं सहायता सामग्री प्रदान करिये

1. पूछें

- कई प्रतिभागी / मरीज़ तंबाकू उपयोगकर्ता होंगे
- उनके द्वारा उपयोग किए जाने वाले उत्पाद विभिन्न प्रकार के धूम्रपान से लेकर धूम्रपान रहित तंबाकू उत्पादों तक भिन्न हो सकते हैं।
- प्रतिभागी से उनके द्वारा उपयोग किए जाने वाले उत्पाद (उत्पादों) के प्रकार के बारे में पूछें.
- इसे तालमेल बनाने, बातचीत शुरू करने के अवसर के रूप में उपयोग करें।

2. सलाह दें

- मरीज़ के ज्ञान के निर्माण / प्रबलन पर ध्यान केंद्रित करें - छोड़ने पर जोर देने के लिए तंबाकू से संबंधित नुकसान पर चर्चा करें।
- फिर मरीज़ को निम्नलिखित तरीके से बात करके तम्बाकू का उपयोग बंद करने की सलाह दें।

"तम्बाकू का उपयोग स्वास्थ्य के लिए हानिकारक है; इसलिए, यह महत्वपूर्ण है कि आप इसे तुरंत इस्तेमाल बंद करने की कोशिश करें। तम्बाकू के सेवन से कई बीमारियों होती हैं जैसे की कैंसर, हृदय रोग, फेफड़ों की बीमारी, स्ट्रोक आदि से जुड़ा हुआ है।"

3. कार्य

- स्वीकार करें कि तम्बाकू शोध्न के लिए मरीज़ विभिन्न तरीकों का उपयोग कर सकते हैं

- मरीज़ के साथ तम्बाकू छोड़ने की तारीख की योजना बनाने पर जोर दिए और स्वयं सहायता सामग्री देकर तम्बाकू छोड़ने में मदद करिये। आप उनसे ये कह सकते हैं -

"तंबाकू छोड़ना कई लोगों के लिए मुश्किल हो सकता है, और अलग-अलग लोग इसे अलग-अलग तरीकों से करने की कोशिश कर सकते हैं। तम्बाकू छोड़ने का एक तरीका छोड़ने की तारीख निर्धारित करना है; इसका मतलब है कि एक तारीख की पहचान करना जब आप तंबाकू का पूरी तरह से उपयोग करना बंद कर देते हैं।"

शराब छोड़ने की सलाह

जो मरीज़ शराब का सेवन करते हैं उन्हें शराब छोड़ने के लिए प्रेरित करिये। उन्हें सलाह दिए की सेहत को ग़ौर में रखते हुए उन्हें शराब का सेवन कम करना चाहिए। जो लोग धूम्रपान करते हैं और पीते हैं, उन्हें संयुक्त खतरों के बारे में बताया जाना चाहिए। ये सभी विशेष रूप से उन लोगों पर लागू होते हैं जो मध्यम आयु या बुढ़ापे में हैं।

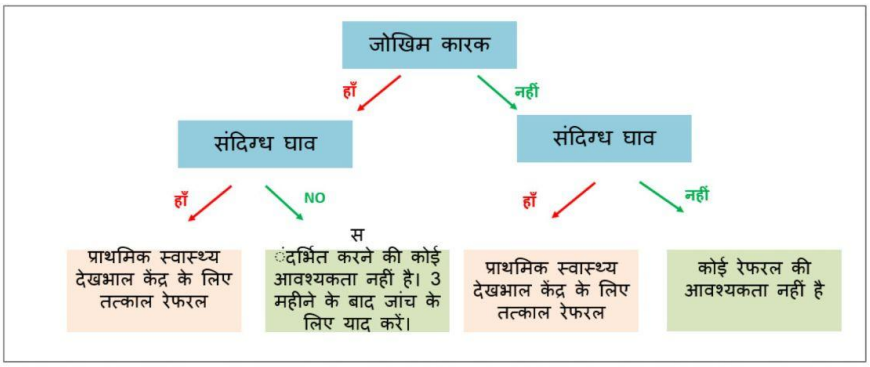
स्वस्थ आहार खाना और व्यायाम करना

मरीज़ों को स्वस्थ खाने और व्यायाम करने की सलाह देनी चाहिए| उन्हे पोष्टिक आहार के सीवन के लाभ के बारे में बताइये जिसमे सब्जी, फल और अनाज शामिल हो। जिन मारेजों में मुख कैंसर की संभावना है उन्हें मिर्च और मसाले वाला खाने से बचने की सलाह दिए ताकि उन्हें खाने में तकलीफ न हो।

मारेज़ों को उनकी जीवनशैली में व्यायाम शामिल करने के लिए प्रोतसाहित करना चाहिए। अक्सर अगर व्यक्ति का सामान्य स्वस्थ अच्छा है तो उनकेमौखिक स्वास्थ्य के अच्छे होने की संभावना होती है।

रेफरल मार्ग

यदि आप घाव का पता लगाते हैं, तो रोगी को आगे के निदान के लिए निकटतम प्राथमिक स्वास्थ्य देखभाल केंद्र में संदर्भित करें। किस मरीज़ को कब आगे जांच के लिए भेजना है, ये जानकारी आपको निम्नलिखित डिब्बे में मिलेगी-



मुख कैंसर के बारे में सामान्य मिथक और तथ्य

मिथक ✘	तथ्य ✓
तंबाकू दांत दर्द से राहत में मदद करता है।	तम्बाकू को दांतों के दर्द के उपाय के रूप में नहीं इस्तेमाल किया जाना चाहिए। अगर मरीज़ के दांत में दर्द है तो उसे जल्द से जल्द दन्त चिकित्सक को दिखाना चाहिए। उनकी सलाह से गरम नमक पानी का कुल्ला करना चाहिए और दर्द के लिए दवा लेनी चाहिए।
तंबाकू आधारित पाउडर जैसे गुल मंजन, कोयला, लाल टूथपाउडर दांतों की सफाई के लिए अच्छे हैं।	इन चीज़ों को इस्तेमाल करने से आपके दांत जल्दी घिस सकते हैं और ख़राब हो सकते हैं। गुल मंजन का प्रयोग अत्यधिक हानिकारक है। इसमें मौजूद रसायनों से इस्तेमाल करने की लत लग सकती है।
युवाओं को मुख कैंसर के विकास का खतरा नहीं है	युवाओं की बढ़ती संख्या सिगरेट और चबाने वाले तंबाकू के बढ़ते उपयोग के कारण मुख कैंसर विकसित कर रही है।
केवल धूम्रपान करने वालों को मुख कैंसर होता है	मुख कैंसर किसी भी प्रकार के तम्बाकू के उपयोग से हो सकता है। यह धुंआ रहित तंबाकू जैसे गुटखा, खैनी, जर्दा, मावा आदि के प्रयोग से मजबूती से जुड़ा हुआ है। अन्य कारकों में धूमपान, शराब का सेवन , खराब आहार, नुकीले दांत और मानव पैपिलोमावायरस के साथ संक्रमण शामिल हैं।
यदि मुझे मुख कैंसर है, तो मुझे पता चल जाएगा क्योंकि मेरे पास लक्षण होंगे।	मुख कैंसर अक्सर दर्द या अन्य लक्षणों के बिना भी हो सकता है ख़ास कर शुरुवाती दिनों में। आमतौर पर ये मुंह में लाल या सफेद चकत्ते या घाव के रूप में शुरू होता है। इसलिए, विशेष रूप से उच्च जोखिम वाले लोगों में नियमित रूप से कैंसर स्क्रीनिंग करना महत्वपूर्ण है।

APPENDIX 21

CONSENT FORM

Title of Study: Feasibility and acceptability of remotely training non-specialist health workers for screening Oral Potentially Malignant Disorders due to tobacco use.

[Note: For participants who are unable to read, the researcher will be required to read out the full consent form once the Participant information sheet has been read to them. Following this, the researcher will collect signatures from the participant on this consent form. If the participant is also unable to write, the researcher will record a thumb impression of the participant in the presence of a witness, who will also sign off on this consent form in the space provided]

Dear Sir/Miss,

If you have decided to take part in this study, please go through the following and provide your signatures/thumb prints along with your full name at the bottom. The researcher will collect these forms once you have provided your consent. Please note that a separate copy of this form will be provided to you for your records.

Please tick (√) the box to indicate the agreement

1. I confirm that I have read and understood the information sheet (version 1 dated 3.12.20)/ I have had the information sheet (version 1 dated 3.12.20) read out to me by a research officer, which explains what the study is about and how my information will be used.

2. I have had the opportunity to ask questions by discussing the details of this study with the research team and have received satisfactory answers to all my questions.

3. I understand my participation in the study is voluntary and that I am free to withdraw from the study:

- At any time
- Without having to give a reason for withdrawing

4. I agree to fill out a questionnaire and I will be helped with this if I need it.

5. I understand that during the study, I may be invited to take part in an interview with a researcher which will be audiotaped, and notes taken. I agree for you to contact me to invite me to take part in the group discussion.

6. I understand that relevant sections of data collected during the study may be looked at by the researcher (Dr Zainab Kidwai) for permission for her to have access to my records.

7. I understand that any information I provide, including personal data, will be kept confidential, stored securely and only accessed by those carrying out the study.

8. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in any reports that result from the research.

9. I agree to take part in this study

_____	_____
Participant's full name	**Participant's signature**

_____	_____	_____
Research officer's name	**Research officer's signature**	**Date of consent**

APPENDIX 22

PARTICIPANT INFORMATION SHEET

Title of Study

Feasibility and acceptability of remotely training non-specialist health workers for screening Oral Potentially Malignant Disorders due to tobacco use.

We would like to invite you to participate in a research study about online training for screening of Oral Potentially Malignant Disorders in tobacco users. You are requested to take a few minutes and read this leaflet, which will provide you the relevant information to help you make your decision. You can take time to decide whether or not you wish to take part and discuss it with your friends and relatives if you wish. Feel free to ask us if there is anything that is not clear or if you would like more information. We will answer any questions that you may have after reading this document. If you decide to take part, our research officer will provide you a consent form. You are requested to read and sign the consent letter and return it to him/her. A copy of the signed consent form will also be given to you for your records.

What is the purpose of this study?

Oral cancer is a big problem in Bangladesh, Pakistan and India, mainly because of high tobacco use. Oral cancer presents with early warning signs in the mouth in the form of diseases called 'Oral Potentially Malignant Disorders' which can be identified with an oral exam or screening. The purpose of this study is to understand if non- healthcare professionals (Community Health Workers in this case) can be trained to screen for these diseases in the community and whether it is feasible to incorporate this programme into the current work routine of the Community Health Workers.

Who is doing the study?

This study is being undertaken by Dr Zainab Kidwai as part of her PhD research in Health Sciences department at the University of York, UK. The research is funded by the Department of Health Sciences in this University.

Why have I been asked to participate?

We are currently recruiting Community Health Workers who have access to a laptop/tablet or mobile phone and who are interested in taking part in a 1-day training workshop on screening for Oral Potentially Malignant Disorders.

You have been asked to consider taking part in this study to understand whether it's possible to train clinical skills like oral screening to Community Health Workers via web-based platform.

Taking part in the study is entirely voluntary and your decision not to participate will not affect you in any way.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you would be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect you in any way.

What will be involved if I take part in this study?

If you are happy to proceed with the study, we will ask you some basic questions about you and your current work and skillset. We will provide a 1-day online training to you to examine the mouth and identify oral lesions, following which you will be invited to take part in a survey. Please note, you may also be invited to take part in an interview at the end of the study. The purpose of the interview will be to obtain your views on your participation in the online workshop and understand how well the training was delivered. The discussion will last around 1 hour and will be audiotaped for research purpose.

What are the advantages/benefits and disadvantages/risks of taking part?

Possible benefits: As a participant, you will have the opportunity to enhance your skillset and learn to do oral screening. As an incentive to take part you will also be provided with a workshop completion certificate.

Possible disadvantages: There are no health risks of participating in this study. Taking part in the study, however, will take some of your time.

Can I withdraw from the study at any time?

Participation in the study is voluntary and you are free to withdraw anytime during the study by contacting Dr Zainab Kidwai. You will not be required to give any reason should you wish to withdraw. In case you withdraw from the study, with your consent, we may still use data collected from you for the purpose of research. Any data that you provide will be made anonymous and cannot be linked to you.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

Will my taking part in this study be kept confidential?

All information which is collected about you during the research will be kept strictly confidential. The data obtained from the audio recording shall be transferred securely to a software for the purpose of analysis and all identifying information of participants such as their names will be removed and given an ID instead.

How will the information and personal data I give be handled?

All information that you provide us, will be treated as confidential information. This means that we will not share the information with anyone outside the research team. Your name and details will be kept separate from any information that you give us. This is to avoid any other person accidently finding your details on the information that you provide.

The information you provide will be stored in an electronic format in a password protected computer at the University of York, in the UK. We will keep the information for 10 years and then destroy it according to the University of York policy. Audio recordings will also be handled in the strictest confidence and will only be listened to by members of the research team. The recordings will be destroyed after 10 years. Data shall be handled and stored in accordance with the University of York data management guidelines which can be accessed at:

https://www.york.ac.uk/records-management/dp/

What will happen to the results of the study?

All data collected from research participants will be analysed collectively and results will be generated. We will also publish the results of this study in a scientific journal, and present findings in meetings to people who work in this area of research. We will prepare brief reports to share with health authorities, NGOs, and healthcare providers, and hold seminars and events to engage the general public. Neither the presentations nor publications will identify individuals or families who participated in the study.

Who has reviewed and approved this study?

This study has been reviewed and approved by the University of York's Health Sciences Research Governance Committee and the Institutional Review Board of the collaborating institution in (India/Pakistan/Bangladesh). The function of these committees is to make sure that the planned research is carried out in an ethical way that ensures your safety and well-being.

Who do I contact for more information about the study?

Please contact Dr Zainab Kidwai for further details at: zk623@york.ac.uk

You will be given a copy of the information sheet and a signed consent form to keep.

Who do I contact in the event of a complaint?

If you are unhappy with the way your personal data has been handled, you have a right to complain to the University's Data Protection Officer at dataprotection@york.ac.uk.

Thank you for taking the time to read this information sheet.

APPENDIX 23

SAMPLE SIZE CALCULATION

Using the estimates of mean difference (2.320) and standard deviation (2.155) reported in this study, the effect size of 1.076 was calculated, which was further input in the G*Power 3.1.9.4 software to give the relevant sample size for 95% power and 99% confidence interval. The sample size was adjusted for the non-response rate by inflating it by 15%.

Table 64: Sample size calculated using the mean difference of -2.32, standard deviation of 2.55 and effect size of -1.07.

Power	90% CI			95% CI			99% CI		
	G1	G2	Total	G1	G2	Total	G1	G2	Total
80%	7	7	14	9	9	18	14	14	28
90%	9	9	18	12	12	24	17	17	34
95%	11	11	22	14	14	28	19	19	38

APPENDIX 24

PARTICIPANT PRE- AND POST-TRAINING QUESTIONNAIRE

This form is to be administered by a researcher for each participant enrolled in the study.

Please note:
To be used only for those study participants who are eligible and have given consent to participate in the study. Please note when answering each question, insert a tick mark in the space provided and tick in all spaces that apply unless you are given other instructions. The instructions for the Researcher completing the questionnaire, are provided in parentheses (italicised) below each question.

Information to be completed by the Researcher:

a. Form completed:	Day / Month / Year	b. Researcher: (Initials only)	
c. Study site			

Section 1: Socio-demographic and baseline information *This is the first section of the questionnaire; the questions are about your background, level of education and service as a Community Health Worker*	
1.1	How old are you? *[record age in completed years]* Years
1.2	Participant's sex Female Male
1.3	What is the highest level of education you have completed? No formal education Primary (class 1-5) Middle (class 6-8) Secondary (class 9-10) Higher (class 11 & above) Others, please specify: _____
1.4	How many years have you worked as a Community Health Worker? Less than 12 months Between 1-3 years Between 4-5 years More than 5 years
1.5	Have you attended an oral cancer training programme or oral cancer awareness/education session before? *[If "no" then go to Question 1.7]* Yes No
1.6	When was your most recent training or awareness programme on oral cancer? In the last 12 months 13-24 months ago >24 months ago This is my first time attending
1.7	What is your self-assessment of your current: A. Knowledge of **risk factors** of oral cancer? Excellent Good Fair Poor

	B. Knowledge of **clinical signs and symptoms** of oral cancer? Excellent Good Fair Poor C. Knowledge of **early detection and screening** process? Excellent Good Fair Poor D. Knowledge of **diagnosis, referral and treatment** modalities? Excellent Good Fair Poor
1.8	Would you be interested in attending an oral cancer screening workshop in the future? *[If "no" then go to Question 1.10 -if "yes", proceed to next Q]* Yes No I am not sure.
1.9	What format would you prefer for the workshop? Online Face to face Hybrid Other: _____
1.10	In your opinion, what is the level of importance of Community Health Workers in the prevention and diagnosis of early signs of oral cancer? High Medium Fair Low

Section 2: Knowledge about Oral Cancer and Oral Potentially Malignant Disorders *The next few questions ask details about your knowledge of suspicious oral lesions. Please give your best answer.*	
2.1	What are the common sites for developing oral cancer and Oral Potentially Malignant Disorders? *[Tick all that apply]* Tongue Floor of the mouth Buccal mucosa All of the above
2.2	What is the predominant age-group in which these lesions occur? Less than 18 years 18 to 39 years More than 40 years None of the above
2.3	Which of the following is **NOT** an early sign of oral cancer and Oral Potentially Malignant Disorders? White patch in the mouth Red patch in the mouth A non-healing ulcer Pain in the abdomen
2.4	Which of the following is **NOT** the risk factor for oral cancer and Oral Potentially Malignant Disorders? *[Tick all that apply]* Alcohol Tobacco Areca nut Consumption of fruits and vegetables
2.5	Which of the following potentially malignant lesion has the highest rate of malignant transformation? Oral submucous fibrosis Erythroplakia Leukoplakia Oral lichen planus

Section 3: Knowledge and attitude regarding oral cancer screening *The next few questions ask details about knowledge (Q 3.1- Q 3.7) and attitude (Q 3.8- Q 3.11) regarding oral cancer screening*	
3.1	Which of the following is the most affordable, feasible, and effective method for population-based screening of oral cancer? Biopsy Oral Visual Examination Vital staining Cytology
3.2	Which of the following instruments should be used for conducting thorough oral screening? Mouth mirror Gauze Tongue blade All of the above
3.3	Which of these should be the first step in conducting oral screening? Taking oral history. Performing intra-oral examination. Performing extra-oral examination. Charting lesion on a mouth map.
3.4	Which of these will you observe during the extra- oral examination? Enlarged lymph nodes Swelling of face and jaws Ulceration and sores on head and neck All of the above
3.5	When observing a suspicious lesion, which of these will you note? Colour of the lesion Location of the lesion Size of the lesion All of the above
3.6	What should be the first step when examining the lips? Reverting the lip and inspecting the inner surface. Inspecting the gingivolabial sulcus, the gingival mucosa, and the teeth. Palpating the lip with your thumb and index finger. None of the above.
3.7	If you detect a suspicious lesion, where should you first refer the case?

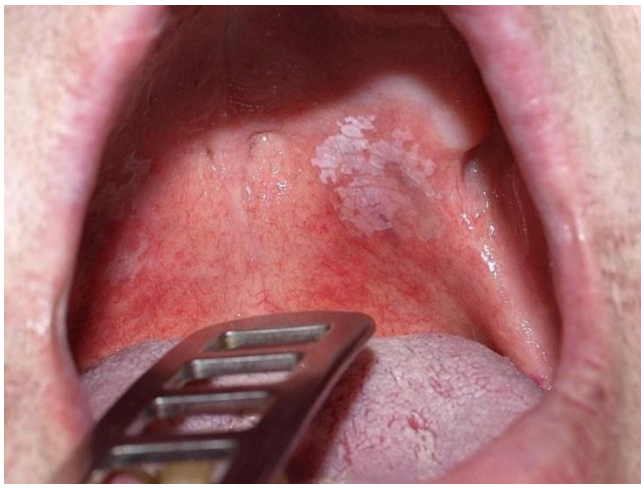
	Ask the patient to visit later for follow up Primary Health Centre Ask the patient to visit a private dentist None of the above
3.8	How useful would you say early detection of oral cancer and Oral Potentially Malignant Disorders is in improving disease prognosis? Not at all useful Slightly useful Moderately useful Very useful Extremely useful
3.9	How informed are you about prevention and early detection of oral cancer and Oral Potentially Malignant Disorders? Not informed at all Somewhat informed Informed Very Informed
3.10	How confident are you in performing screening procedures to detect oral cancer and pre-cancers? Not at all confident Slightly confident Somewhat confident Fairly confident Completely confident
3.11	How confident are you in taking medical and dental history of a patient? a. Not at all confident Slightly confident Somewhat confident Fairly confident Completely confident
3.12	How confident are you in talking to a patient and telling them the results of screening? Not at all confident Slightly confident Somewhat confident Fairly confident Completely confident
3.13	How confident are you in referring a patient to the healthcare services?

	Not at all confident Slightly confident Somewhat confident Fairly confident Completely confident
3.14	How confident are you in delivering any kind of educational advice to the patient following screening? Not at all confident Slightly confident Somewhat confident Fairly confident Completely confident

Section 4: Case Presentation (To be administered post-training)

In this section, you will be presented with photographs and oral history of various patients. Kindly read the case details and look at the photographs carefully, following which you will be asked questions about identification of suspected lesions (Oral cancer and Oral Potentially Malignant Disorders).

4.1 This is a case of a 64 year old man who gave a history of pan masala and gutkha chewing, at least 4-5 times a day since the past 20 years. Look at the photograph below and answer the following questions:



A. Does the patient give history of any risk factors?
[If "no" then go to PART C -if "yes", proceed to next Q]

Yes

No

B. Record information on risk factors below:

Type: _____
Frequency: _____

Duration: _____

C. Is there a lesion present?
[If "no" then go to PART J -if "yes", proceed to next Q]

Yes

No

I am not sure

D. What is the location of the lesion?

Tongue

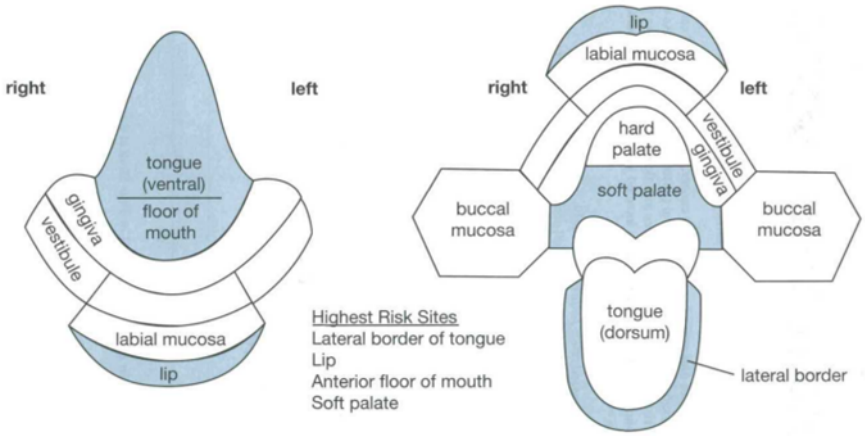
Lips

Palate

Buccal Mucosa

Floor of the mouth

Other: _____



E. What is the colour of the lesion?

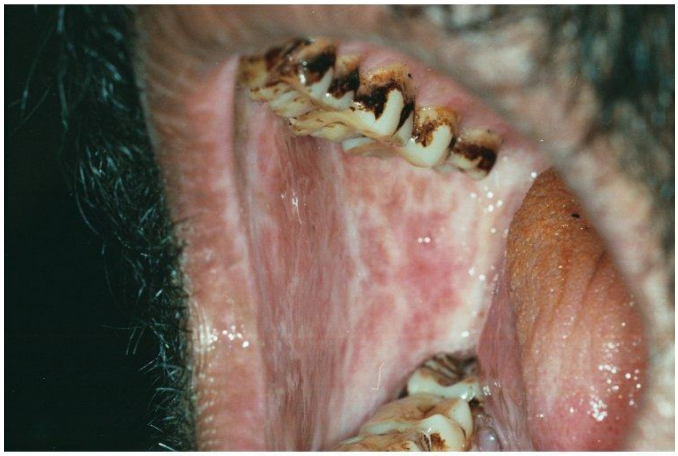
White

Red

Mixed

Other: _____

	F. What is the approximate size of the lesion? Up to 5 mm Between 5-20 mm More than 20 mm Other: _____ G. What is the shape of the lesion? Round Rectangular Other: _____ H. What is the distribution and definition of the lesion? [*Tick one from each row)* Localized OR Generalized Single OR Multiple Well-defined OR Poorly-defined I. Based on the above information, how will you classify the lesion? Non-suspicious oral lesion Suspicious Oral Potentially Malignant Lesion Oral Cancer Other: _____ J: Based on the result of oral screening, what should you do next? [*Tick mark all that apply*] Routine follow-up of patient. Refer patient for further head and neck evaluation. Refer to counselling and support services. Give brief advice on tobacco cessation. Other: _____
4.2	This is a case of a 48 year old man who presented with a chief complaint of burning sensation in mouth while eating and difficulty opening the mouth. He gave a history of chewing gutkha and smoking cigarettes, at least 4-5 times a day since the past 23 years. Look at the photograph below and answer the following questions:



A. Does the patient give history of any risk factors?
[If "no" then go to PART C -if "yes", proceed to next Q]

Yes

No

B. Record information on risk factors below:

Type: _____
Frequency: _____
Duration: _____

C. Is there a lesion present?
[If "no" then go to PART H -if "yes", proceed to next Q]

Yes

No

I am not sure

D. What is the location of the lesion?

Tongue

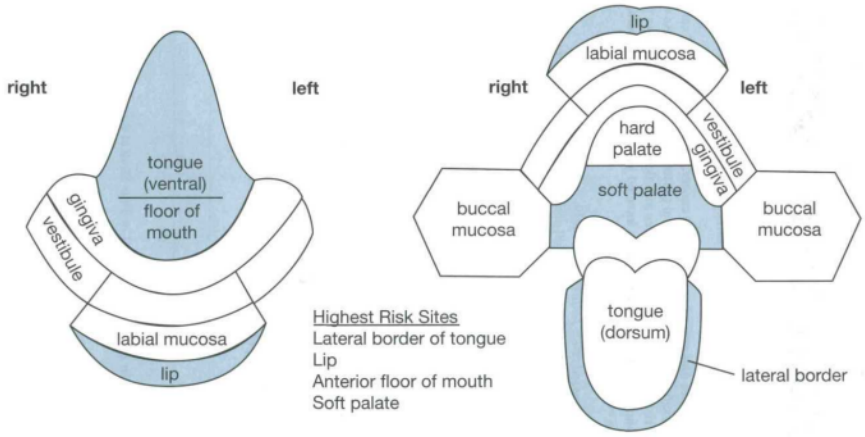
Lips

Palate

Buccal Mucosa

Floor of the mouth

Other: _____



E. What is the colour of the lesion?

White

Red

Mixed

Other: _____

F. What is the approximate size of the lesion?

Up to 5 mm

Between 5-20 mm

More than 20 mm

Other: _____

G. What is the shape of the lesion?

Round

Rectangular

Other: _____

H. What is the distribution and definition of the lesion?

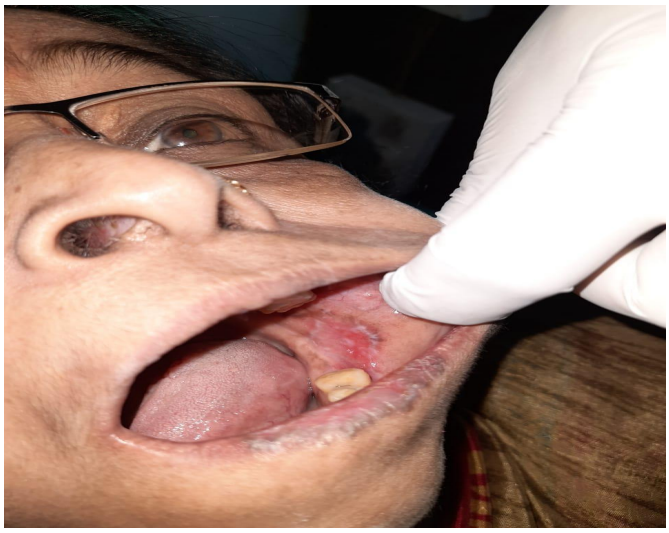
[*Tick one from each row)*

Localized	OR	Generalized
Single	OR	Multiple
Well-defined	OR	Poorly-defined

I. Based on the above information, how will you classify the lesion?

Non-suspicious oral lesion

Suspicious Oral Potentially Malignant Lesion

	Oral Cancer Other: _____ J: Based on the result of oral screening, what should you do next? [*Tick mark all that apply*] Routine follow-up of patient. Refer patient for further head and neck evaluation. Refer to counselling and support services. Give brief advice on tobacco cessation. Other: _____
4.3	This is a case of a 52 year old woman who presented with a chief complaint of pain and redness in mouth. She gave a history of chewing paan with tobacco at least 2-3 times a day since the past 15 years. Look at the photograph below and answer the following questions:  A. Does the patient give history of any risk factors? *[If "no" then go to PART C -if "yes", proceed to next Q]* Yes No B. Record information on risk factors below: Type: _____ Frequency: _____ Duration: _____ C. Is there a lesion present? *[If "no" then go to PART J -if "yes", proceed to next Q]* Yes

No

I am not sure

D. What is the location of the lesion?

Tongue

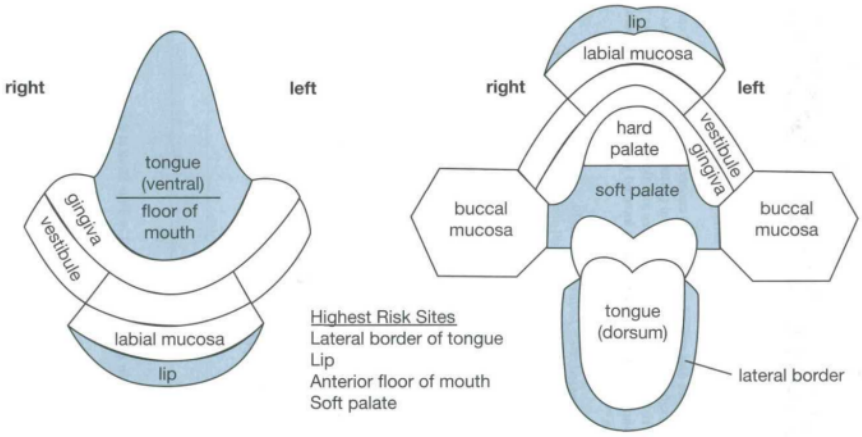
Lips

Palate

Buccal Mucosa

Floor of the mouth

Other: _____



E. What is the colour of the lesion?

White

Red

Mixed

Other: _____

F. What is the approximate size of the lesion?

Up to 5 mm

Between 5-20 mm

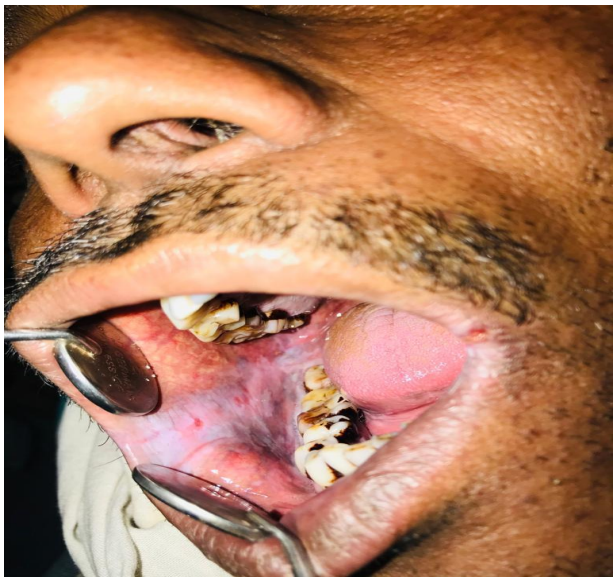
More than 20 mm

Other: _____

G. What is the shape of the lesion?

Round

Rectangular

	Other: _____ H. What is the distribution and definition of the lesion? [*Tick one from each row)* Localized OR Generalized Single OR Multiple Well-defined OR Poorly-defined I. Based on the above information, how will you classify the lesion? Non-suspicious oral lesion Suspicious Oral Potentially Malignant Lesion Oral Cancer Other: _____ J: Based on the result of oral screening, what should you do next? [*Tick mark all that apply*] Routine follow-up of patient. Refer patient for further head and neck evaluation. Refer to counselling and support services. Give brief advice on tobacco cessation. Other: _____
4.4	This is a case of a 44 year old man who came in for a regular check-up with no chief complaint. He gave a history of chewing khaini and zarda, at least 2-3 times a day since the past 15 years. Look at the photograph below and answer the following questions:  A. Does the patient give history of any risk factors?

[If "no" then go to PART C -if "yes", proceed to next Q]

Yes

No

B. Record information on risk factors below:

Type: _____
Frequency: _____
Duration: _____

C. Is there a lesion present?
[If "no" then go to PART J -if "yes", proceed to next Q]

Yes

No

I am not sure

D. What is the location of the lesion?

Tongue

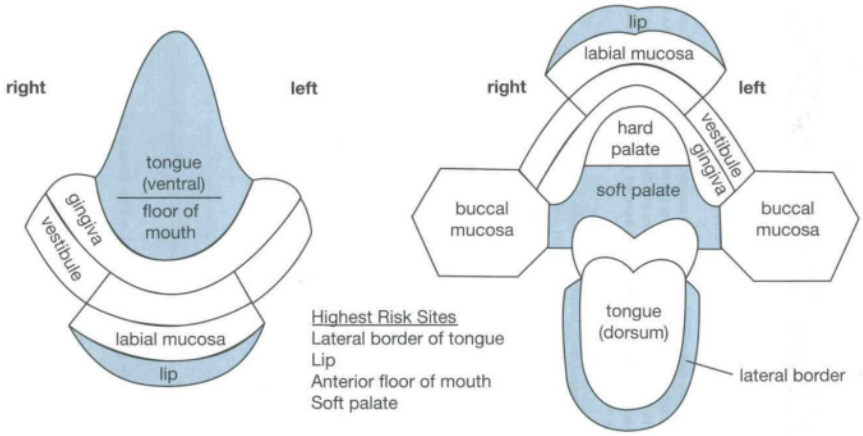
Lips

Palate

Buccal Mucosa

Floor of the mouth

Other: _____



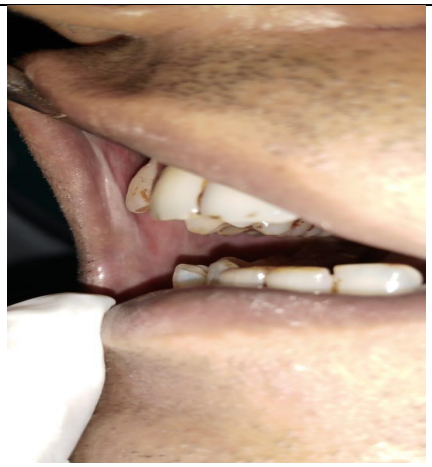
E. What is the colour of the lesion?

White

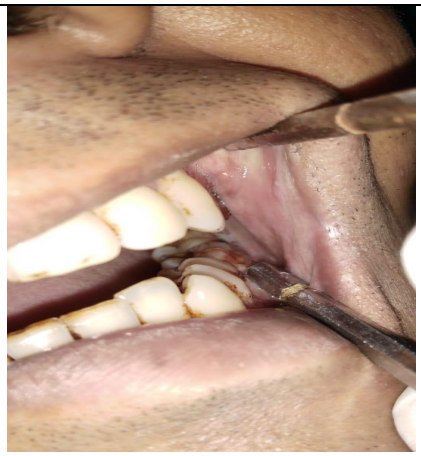
Red

Mixed

	Other: _____ F. What is the approximate size of the lesion? Up to 5 mm Between 5-20 mm More than 20 mm Other: _____ G. What is the shape of the lesion? Round Rectangular Other: _____ H. What is the distribution and definition of the lesion? [*Tick one from each row)* Localized OR Generalized Single OR Multiple Well-defined OR Poorly-defined I. Based on the above information, how will you classify the lesion? Non-suspicious oral lesion Suspicious Oral Potentially Malignant Lesion Oral Cancer Other: _____ J: Based on the result of oral screening, what should you do next? [*Tick mark all that apply*] Routine follow-up of patient. Refer patient for further head and neck evaluation. Refer to counselling and support services. Give brief advice on tobacco cessation. Other: _____
4.5	This is a case of a 26 year old man who presented with a chief complaint of reduced mouth opening since the past 1 year. He gave a history of chewing paan with areca nut and smoking bidi, at least 3-4 times a day since the past 8 years. Look at the photograph below and answer the following questions:



Right



Left

A. Does the patient give history of any risk factors?
[If "no" then go to PART C -if "yes", proceed to next Q]

Yes

No

B. Record information on risk factors below:

Type: _____
Frequency: _____
Duration: _____

C. Is there a lesion present?
[If "no" then go to PART H -if "yes", proceed to next Q]

Yes

No

I am not sure

D. What is the location of the lesion?

Tongue

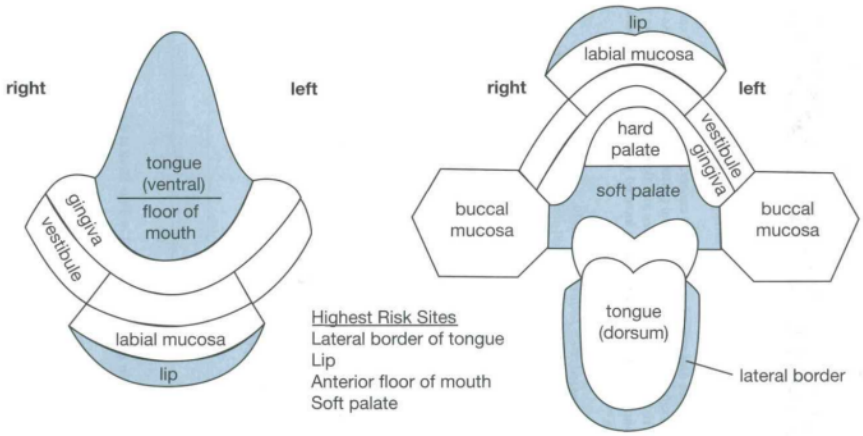
Lips

Palate

Buccal Mucosa

Floor of the mouth

Other: _____



E. What is the colour of the lesion?

White

Red

Mixed

Other: _____

F. What is the approximate size of the lesion?

Up to 5 mm

Between 5-20 mm

More than 20 mm

Other: _____

G. What is the shape of the lesion?

Round

Rectangular

Other: _____

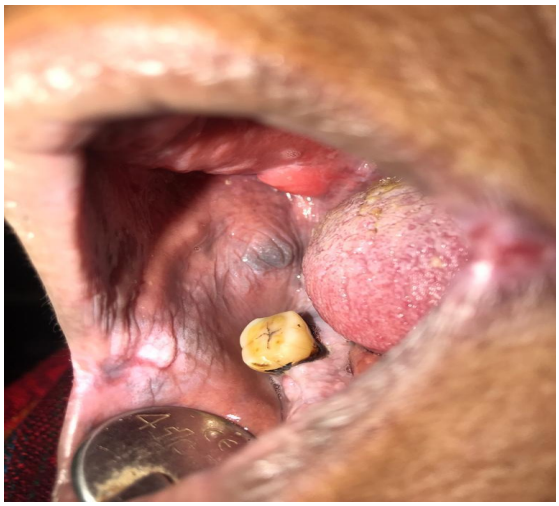
H. What is the distribution and definition of the lesion?

[*Tick one from each row)*

Localized	OR	Generalized
Single	OR	Multiple
Well-defined	OR	Poorly-defined

I. Based on the above information, how will you classify the lesion?

Non-suspicious oral lesion

	Suspicious Oral Potentially Malignant Lesion Oral Cancer Other: _____ J: Based on the result of oral screening, what should you do next? [*Tick mark all that apply*] Routine follow-up of patient. Refer patient for further head and neck evaluation. Refer to counselling and support services. Give brief advice on tobacco cessation. Other: _____
4.6	This is a case of a 74 years old man who came in for a regular check-up. He gave a history of chewing gutkha and tambakoo, at least 4-5 times a day since the past 40 years. Look at the photograph below and answer the following questions:  A. Does the patient give history of any risk factors? *[If "no" then go to PART C -if "yes", proceed to next Q]* Yes No B. Record information on risk factors below: Type: _____ Frequency: _____ Duration: _____ C. Is there a lesion present? *[If "no" then go to PART J -if "yes", proceed to next Q]* Yes

No

I am not sure

D. What is the location of the lesion?

Tongue

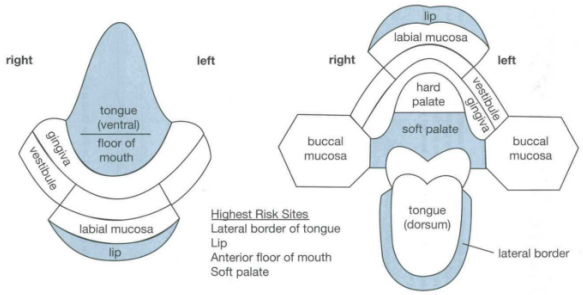
Lips

Palate

Buccal Mucosa

Floor of the mouth

Other: _____



E. What is the colour of the lesion?

White

Red

Mixed

Other: _____

F. What is the approximate size of the lesion?

Up to 5 mm

Between 5-20 mm

More than 20 mm

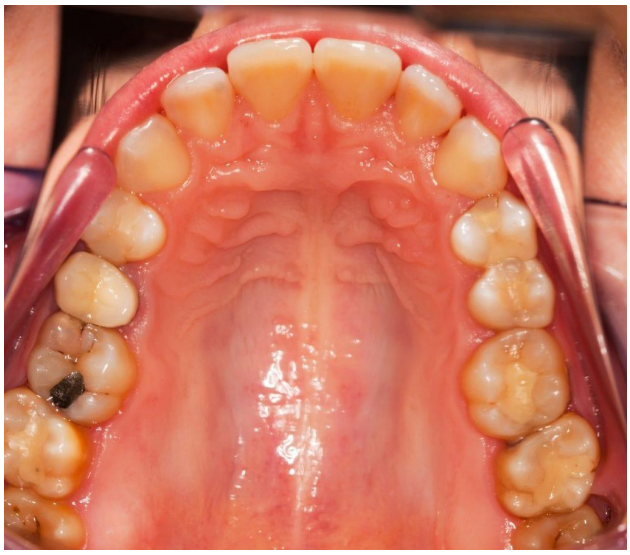
Other: _____

G. What is the shape of the lesion?

Round

Rectangular

Other: _____

	H. What is the distribution and definition of the lesion? [*Tick one from each row)* Localized OR Generalized Single OR Multiple Well-defined OR Poorly-defined I. Based on the above information, how will you classify the lesion? Non-suspicious oral lesion Suspicious Oral Potentially Malignant Lesion Oral Cancer Other: _____ J: Based on the result of oral screening, what should you do next? [*Tick mark all that apply*] Routine follow-up of patient. Refer patient for further head and neck evaluation. Refer to counselling and support services. Give brief advice on tobacco cessation. Other: _____
4.7	This is a case of a 24 years old man who came in for a regular check-up. He gave a history of dental fillings in 3 upper teeth. The patient gave no history of smoking or chewing tobacco. Look at the photograph below and answer the following questions:  A. Does the patient give history of any risk factors? *[If "no" then go to PART C -if "yes", proceed to next Q]* Yes

No

B. Record information on risk factors below:

Type: _____
Frequency: _____
Duration: _____

C. Is there a lesion present?
[If "no" then go to PART J -if "yes", proceed to next Q]

Yes

No

I am not sure

D. What is the location of the lesion?

Tongue

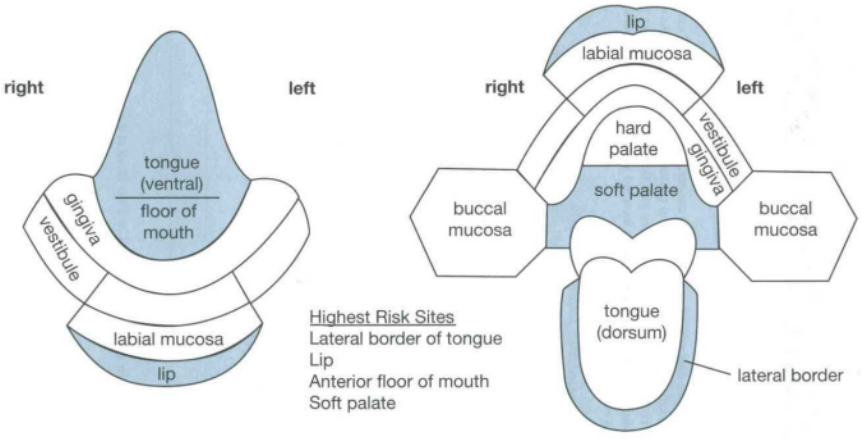
Lips

Palate

Buccal Mucosa

Floor of the mouth

Other: _____



E. What is the colour of the lesion?

White

Red

Mixed

Other: _____

F. What is the approximate size of the lesion?

Up to 5 mm

Between 5-20 mm

More than 20 mm

Other: _____

G. What is the shape of the lesion?

Round

Rectangular

Other: _____

H. What is the distribution and definition of the lesion?

[*Tick one from each row)*

Localized	OR	Generalized
Single	OR	Multiple
Well-defined	OR	Poorly-defined

I. Based on the above information, how will you classify the lesion?

Non-suspicious oral lesion

Suspicious Oral Potentially Malignant Lesion

Oral Cancer

Other: _____

J: Based on the result of oral screening, what should you do next?

[*Tick mark all that apply*]

Routine follow-up of patient.

Refer patient for further head and neck evaluation.

Refer to counselling and support services.

Give brief advice on tobacco cessation.

Other: _____

Thank you for taking part in this survey.

प्रतिभागी प्रशिक्षण पूर्व और प्रशिक्षण पश्चात की प्रश्नावली

यह प्रपत्र अध्ययन में नामांकित प्रत्येक प्रतिभागी के लिए शोधकर्ता द्वारा नामांकित किया जाना है.

कृपया ध्यान दें:

यह प्रश्नावली केवल अध्ययन में पात्र नामांकित प्रतिभागियों के लिए उपयोग की जानी हैं और जिन्होंने अध्ययन में भाग लेने के लिए सहमति दी है। कृपया ध्यान दें कि प्रत्येक प्रश्न का उत्तर देते समय दिए गए स्थान में सही का निशान लगाएं और जब तक आपको अन्य निर्देश न दिए जाएं, तब तक लागू होने वाले सभी स्थानों पर सही का निशान लगाएं। प्रश्नावली को पूरा करने वाले शोधकर्ता के लिए निर्देश प्रत्येक प्रश्न के नीचे कोष्ठक (इटैलिकाइज्ड) में दिए गए हैं।

शोधकर्ता द्वारा पूर्ण की जाने वाली जानकारी:

a. पूर्ण प्रपत्र :	☐☐ ☐☐ ☐☐☐☐ दिन/ महीने / वर्ष	b. शोधकर्ता: (केवल संक्षिप्त हस्ताक्षर)	
c. अध्ययन स्थल			

खंड 1: सामाजिक-जनसांख्यिकीय और आधारभूत जानकारी *यह प्रश्नावली का पहला खंड है; प्रश्न आपकी पृष्ठभूमि, शिक्षा के स्तर और सामुदायिक स्वास्थ्य कार्यकर्ता के रूप में सेवा के बारे में हैं*	
1.1	आप की उम्र क्या है? *[पूर्ण वर्षों में अभिलिखित आयु]* ☐☐ वर्ष
1.2	लिंग ☐ महिला ☐ पुरुष
1.3	आपने किस उच्चतम स्तर की शिक्षा पूरी की है? ☐ कोई औपचारिक शिक्षा नहीं ☐ प्राथमिक (कक्षा 1-5) ☐ मध्य (कक्षा 6-8) ☐ माध्यमिक (कक्षा 9-10) ☐ उच्च (कक्षा 11 और ऊपर) ☐ अन्य, कृपया निर्दिष्ट करें: _____
1.4	आपने सामुदायिक स्वास्थ्य कार्यकर्ता के रूप में कितने वर्षों तक काम किया है? ☐ 12 महीने से कम ☐ 1-3 साल के बीच ☐ 4-5 साल के बीच ☐ 5 साल से अधिक
1.5	क्या आपने पहले मुंह के कैंसर प्रशिक्षण कार्यक्रम या मुंह के कैंसर जागरूकता/ शिक्षण सत्र में भाग लिया है? [*यदि "नहीं" तो प्रश्न 1.7 पर जाएं*] ☐ हाँ ☐ नही
1.6	मुंह के कैंसर पर आपका सबसे हाल ही का प्रशिक्षण या जागरूकता कार्यक्रम कब था? ☐ पिछले 12 महीनों में ☐ 13-24 महीने पहले ☐ >24 महीने पहले ☐ मैं पहली बार भाग ले रहा/ रही हूँ
1.7	वर्तमान में आपके कार्य का स्व-मूल्यांकन क्या है: क. मुंह के कैंसर के जोखिम कारकों की जानकारी? ☐ अति उत्कृष्ट ☐ अच्छा ☐ निष्पक्ष

	☐ खराब B. मुंह के कैंसर के चिक्तिस्य संकेत और लक्षणों की जानकारी? ☐ अति उत्कृष्ट ☐ अच्छा ☐ निष्पक्ष ☐ खराब C. प्रारंभिक पहचान और जांच प्रक्रिया का ज्ञान? ☐ अति उत्कृष्ट ☐ अच्छा ☐ निष्पक्ष ☐ खराब D. निदान, रेफरल और उपचार के तौर-तरीकों का ज्ञान? ☐ अति उत्कृष्ट ☐ अच्छा ☐ निष्पक्ष ☐ खराब
1.8	क्या आप भविष्य में मुंह के कैंसर स्क्रीनिंग कार्यशाला में भाग लेने के इच्छुक होंगे/ होंगी? *[यदि "नहीं" तो प्रश्न 1.10 पर जाएं- यदि "हां", तो अगले प्रश्न पर जाएं]* ☐ हाँ ☐ नही ☐ मैं ठीक से नहीं कह सकता/ सकती ।
1.9	कार्यशाला के लिए आप कौन सा प्रारूप पसंद करेंगे? ☐ ऑनलाइन ☐ आमने - सामने ☐ मिश्रित ☐ अन्य: _____
1.10	आपकी राय में, मुंह के कैंसर के शुरुआती लक्षणों की रोकथाम और निदान में सामुदायिक स्वास्थ्य कार्यकर्ताओं के महत्व का स्तर क्या है? ☐ उच्च ☐ मध्यम ☐ निष्पक्ष ☐ निम्न

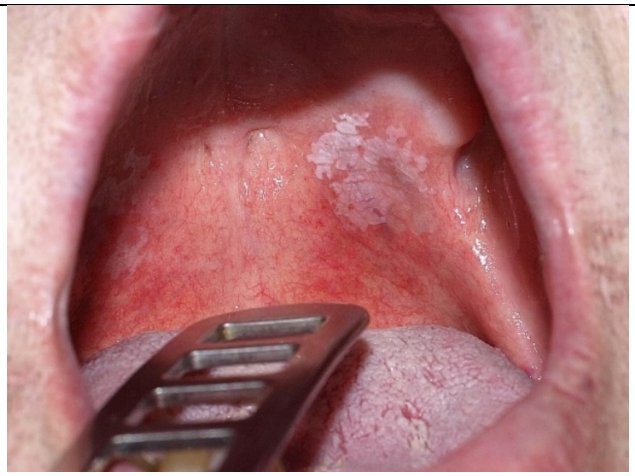
खंड 2: मुंह के कैंसर और मुँह के कैंसर के प्रारंभिक घाव के बारे में ज्ञान *अगले कुछ प्रश्न संदिग्ध मुँह के घावों के बारे में आपके ज्ञान के बारे में विवरण पूछते हैं। कृपया अपना सर्वश्रेष्ठ उत्तर दें।*	
2.1	मुंह के कैंसर और मुँह के कैंसर के प्रारंभिक घाव के विकास के लिए सामान्य स्थल कौन से हैं? *[जो लागू हो उस पर सही का निशान लगाएं]* ☐ जीभ ☐ मुँह का तल ☐ गाल के अंदर की तरफ ☐ उपर्युक्त सभी
2.2	प्रमुख आयु वर्ग कौन सा है जिसमें ये मौखिक घाव होते हैं? ☐ 18 साल से कम ☐ 18 से 39 वर्ष ☐ 40 साल से अधिक ☐ इनमे से कोई भी नहीं
2.3	निम्नलिखित में से कौन मुंह के कैंसर और मुँह के कैंसर के प्रारंभिक घाव का प्रारंभिक संकेत **नहीं** है? ☐ मुंह में सफेद दाग ☐ मुंह में लाल धब्बे ☐ न भरने वाला घाव ☐ पेट में दर्द
2.4	निम्नलिखित में से कौन मुंह के कैंसर और मुँह के कैंसर के प्रारंभिक घाव के लिए जोखिम कारक **नहीं** है? *[जो लागू हो उस पर सही का निशान लगाएं]* ☐ शराब ☐ तंबाकू ☐ सुपारी ☐ फलों और सब्जियों का सेवन
2.5	निम्नलिखित में से किस मुँह के कैंसर के प्रारंभिक घाव में घातक परिवर्तन की दर उच्चतम है? ☐ ओरल सबम्यूकस फाइब्रोसिस (मुख अवश्लेष्म फाइब्रोसिस) ☐ एरिथ्रोपालकिया (मुंह के अंदर लाल चकत्ते) ☐ ल्यूकोप्लाकिया (मुंह में सफेद दाग) ☐ ओरल लाइकेन प्लानस (मुंह का लाइकेन प्लानस)

खंड 3: मुंह के कैंसर की जांच के संबंध में ज्ञान और दृष्टिकोण *अगले कुछ प्रश्न मुख के कैंसर स्क्रीनिंग के संबंध में ज्ञान (Q 3.1- Q 3.7) और दृष्टिकोण (Q 3.8- Q 3.11) के बारे में विवरण पूछते हैं*	
3.1	मुंह के कैंसर की जनसंख्या आधारित जांच के लिए निम्नलिखित में से कौन सा सबसे सस्ता, व्यवहार्य और प्रभावी तरीका है? ☐ बायोप्सी ☐ मौखिक दृश्य परीक्षा ☐ जैव अभिरंजन ☐ कोशिका विज्ञान
3.2	मौखिक जांच के लिए निम्नलिखित में से किस उपकरण का उपयोग किया जाना चाहिए? ☐ मुख दर्पण ☐ पट्टी या गौज ☐ जीभ कष्टकारक या जीभ ब्लेड ☐ उपर्युक्त सभी
3.3	इनमें से कौन मौखिक जांच करने में पहला कदम होना चाहिए? ☐ मौखिक इतिहास लेना ☐ अंतर्मुख परीक्षण करना ☐ बाह्य मुख परीक्षण करना ☐ मुख नक्शे पर घाव चिन्हित करना
3.4	अतिरिक्त मौखिक परीक्षण के दौरान आप इनमें से किसका निरीक्षण करेंगे? ☐ बढ़े हुए लिम्फ नोड्स ☐ चेहरे और जबड़ों की सूजन ☐ सिर और गर्दन पर छाले और घाव ☐ उपर्युक्त सभी
3.5	एक संदिग्ध घाव को देखते समय, आप इनमें से किसका ध्यान रखेंगे? ☐ घाव का रंग ☐ घाव का स्थान ☐ घाव का आकार ☐ उपर्युक्त सभी
3.6	होठों की जांच करते समय पहला कदम क्या होना चाहिए? ☐ होंठ को उल्टा करना और आंतरिक सतह का निरीक्षण करना. ☐ जिंजीवोलैबियल सल्कस, सतह, मसूड़ों और दांतों का निरीक्षण करना. ☐ अपने अंगूठे और पहली अंगुली से होंठों को टटोलना.

	☐ इनमे से कोई भी नहीं.
3.7	यदि आप एक संदिग्ध घाव का पता लगाते हैं, तो आपको सबसे पहले मामले को कहां रेफर करना चाहिए? ☐ अनुवर्ती कार्रवाई के लिए रोगी को बाद में आने के लिए कहें ☐ प्राथमिक स्वास्थ्य केंद्र ☐ रोगी को एक निजी दंत चिकित्सक के पास जाने के लिए कहें ☐ इनमे से कोई भी नहीं
3.8	आप क्या कहेंगे कि मुंह के कैंसर और मुँह के कैंसर के प्रारंभिक घाव का जल्दी पता लगाना रोग के निदान में सुधार लाने में कितना उपयोगी है? ☐ कतई उपयोगी नहीं ☐ थोड़ा उपयोगी ☐ मध्यम उपयोगी ☐ बहुत उपयोगी ☐ अत्यंत उपयोगी
3.9	मुंह के कैंसर और मुँह के कैंसर के प्रारंभिक घाव की रोकथाम और जल्दी पता लगाने के बारे में आप कितने जागरूक हैं? ☐ बिल्कुल नहीं ☐ कुछ हद तक सूचित ☐ सूचित ☐ बहुत सूचित
3.10	आप मुंह के कैंसर और मुँह के कैंसर के प्रारंभिक घाव का पता लगाने के लिए स्क्रीनिंग प्रक्रियाओं को करने में कितने आश्वस्त हैं? ☐ कतई आश्वस्त नहीं ☐ थोड़ा आश्वस्त ☐ कुछ हद तक आश्वस्त ☐ काफी आश्वस्त ☐ पूरी तरह से आश्वस्त
3.11	आप एक रोगी के चिकित्सा और दंत इतिहास लेने में कितने आश्वस्त हैं? ☐ कतई आश्वस्त नहीं ☐ थोड़ा आश्वस्त ☐ कुछ हद तक आश्वस्त ☐ काफी आश्वस्त ☐ पूरी तरह से आश्वस्त
3.12	आप एक मरीज से बात करने और उन्हें स्क्रीनिंग के परिणाम बताने में कितने आश्वस्त हैं? ☐ कतई आश्वस्त नहीं

	☐ थोड़ा आश्वस्त ☐ कुछ हद तक आश्वस्त ☐ काफी आश्वस्त ☐ पूरी तरह से आश्वस्त
3.13	आप एक मरीज को स्वास्थ्य सेवाओं के लिए संदर्भित करने में कितने आश्वस्त हैं? ☐ कतई आश्वस्त नहीं ☐ थोड़ा आश्वस्त ☐ कुछ हद तक आश्वस्त ☐ काफी आश्वस्त ☐ पूरी तरह से आश्वस्त
3.14	स्क्रीनिंग के बाद रोगी को किसी भी प्रकार की शैक्षिक सलाह देने में आप कितने आश्वस्त हैं? ☐ कतई आश्वस्त नहीं ☐ थोड़ा आश्वस्त ☐ कुछ हद तक आश्वस्त ☐ काफी आश्वस्त ☐ पूरी तरह से आश्वस्त

खंड 4: केस प्रस्तुतिकरण (प्रशिक्षण के बाद प्रशासित किया जाना) *इस खंड में, आपको विभिन्न रोगियों की तस्वीरें और मौखिक इतिहास प्रस्तुत किया जाएगा। कृपया मामले का विवरण पढ़ें और तस्वीरों को ध्यान से देखें, जिसके बाद आपसे संदिग्ध घावों (मुंह के कैंसर और मुँह के कैंसर के प्रारंभिक घाव) की पहचान के बारे में प्रश्न पूछे जाएंगे।.*	
4.1	यह मामला एक 64 वर्षीय व्यक्ति का है जिसने पिछले 20 वर्षों से दिन में कम से कम 4-5 बार पान मसाला और गुटखा चबाने का इतिहास दिया है। नीचे दी गई तस्वीर को देखें और निम्नलिखित प्रश्नों के उत्तर दें:



A. क्या रोगी किसी जोखिम कारक का इतिहास देता है?
[यदि "नहीं" तो भाग सी पर जाएं- यदि "हां", तो अगले प्रश्न पर जाएं]

☐ हां

☐ नहीं

B. नीचे जोखिम कारकों पर जानकारी अभिलिखित करें:

प्रकार: _____
आवृत्ति: _____

- अवधि: _____

C. क्या कोई घाव मौजूद है?
[यदि "नहीं" तो भाग J पर जाएँ- यदि "हाँ", तो अगले प्रश्न पर जाएँ]

☐ हाँ

☐ नहीं

☐ कुछ निश्चित नहीं है

D. घाव का स्थान क्या है?

☐ जीभ

☐ होंठ

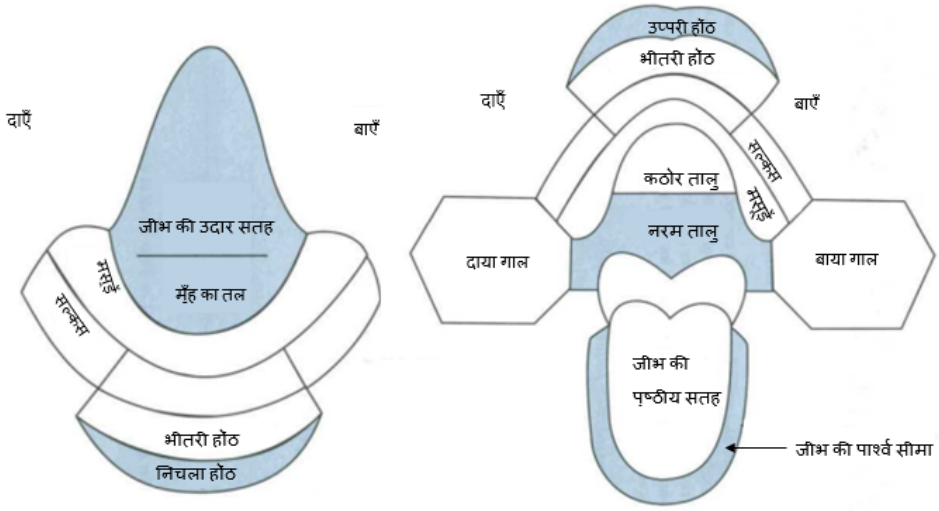
☐ तालु

☐ गाल के अंदर

☐ मुंह का तल

☐ अन्य: _____

इसे मानचित्र पर भी अंकित करें



E. घाव का रंग क्या है?

☐ सफेद

☐ लाल

☐ मिश्रित

☐ अन्य: _____

F. घाव का अनुमानित आकार क्या है?

☐ 5 मिमी. तक

☐ 5-20 मिमी. के बीच

☐ 20 मिमी. से अधिक

☐ अन्य: _____

G. घाव का आकार क्या है?

☐ गोल

☐ आयताकार

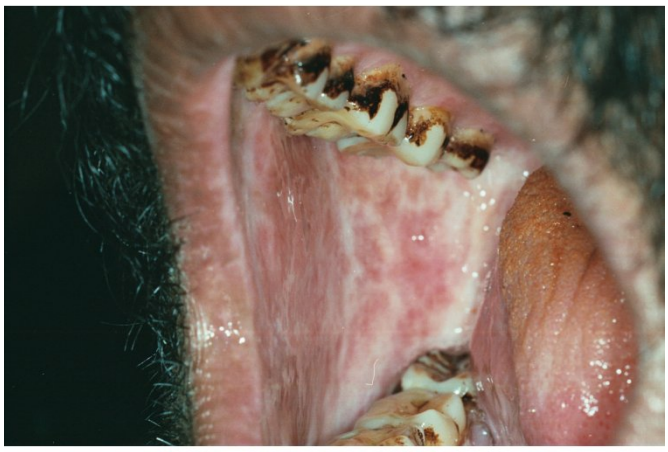
☐ अन्य: _____

H. घाव का वितरण और परिभाषा क्या है?

[*प्रत्येक पंक्ति में से एक पर निशान लगाएं)*

☐ स्थानीय या सामान्यीकृत

☐ एक या विभिन्न

	☐ अच्छी तरह से परिभाषित या खराब रूप से परिभाषित I. उपरोक्त जानकारी के आधार पर आप घाव का वर्गीकरण कैसे करेंगे? ☐ गैर-संदिग्ध मौखिक घाव ☐ संदिग्ध मुँह के कैंसर के प्रारंभिक घाव ☐ मुंह का कैंसर ☐ अन्य: _____ J: मौखिक जांच के परिणाम के आधार पर, आपको आगे क्या करना चाहिए? [*जो लागू हो उस पर सही का निशान लगाएं*] ☐ रोगी की नियमित जाँच। ☐ सिर और गर्दन की जांच के लिए रेफर करें। ☐ परामर्श और सहायता सेवाओं का संदर्भ लें। ☐ तंबाकू छुड़वाने पर संक्षिप्त सलाह दें। ☐ अन्य: _____
4.2	यह मामला एक 48 वर्षीय व्यक्ति का है, जिसे खाने के दौरान मुंह में जलन और मुंह खोलने में कठिनाई की मुख्य शिकायत थी। उन्होंने पिछले 23 वर्षों से दिन में कम से कम 4-5 बार गुटखा चबाने और सिगरेट पीने का इतिहास दिया। नीचे दी गई तस्वीर को देखें और निम्नलिखित प्रश्नों के उत्तर दें:  A. क्या रोगी किसी जोखिम कारक का इतिहास देता है? *[यदि "नहीं" तो भाग सी पर जाएं- यदि "हां", तो अगले प्रश्न पर जाएं]* ☐ हां ☐ नहीं

B. नीचे जोखिम कारकों पर जानकारी अभिलिखित करें:

प्रकार: _____
आवृत्ति: _____
अवधि: _____

C. क्या कोई घाव मौजूद है?
[यदि "नहीं" तो भाग एच पर जाएं - यदि "हां", तो अगले प्रश्न पर जाएं]

☐ हां

☐ नहीं

☐ कुछ निश्चित नहीं है

D. घाव किस स्थान पर है?

☐ जीभ

☐ होंठ

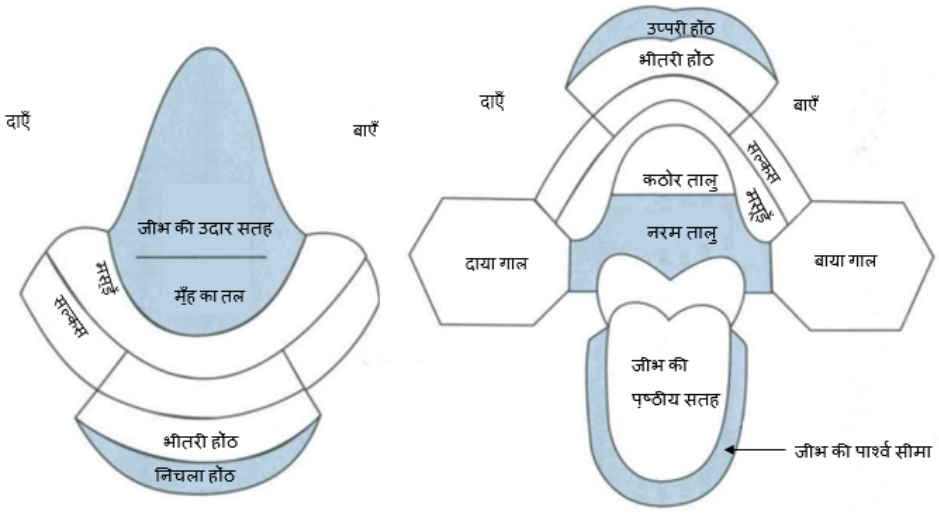
☐ तालु

☐ गाल के अंदर

☐ मुंह का तल

☐ अन्य: _____

इसे मानचित्र पर भी अंकित करें



E. घाव का रंग क्या है?

☐ सफेद

☐ लाल

☐ मिश्रित

☐ अन्य: _____

F. घाव का अनुमानित आकार क्या है?

☐ 5 मिमी . तक

☐ 5-20 मिमी . के बीच

☐ 20 मिमी . से अधिक

☐ अन्य: _____

G. घाव का आकार क्या है?

☐ गोल

☐ आयताकार

☐ अन्य: _____

H. घाव का फैलाव और व्याख्या क्या है?

[प्रत्येक पंक्ति में से एक पर निशान लगाएं]

☐ अवस्थिति या ☐ सामान्यीकृत

☐ एक या ☐ विभिन्न

☐ अच्छी तरह से परिभाषित या ☐ खराब परिभाषित

I. उपरोक्त जानकारी के आधार पर आप घाव का वर्गीकरण कैसे करेंगे?

☐ गैर-संदिग्ध मौखिक घाव

☐ संदिग्ध मुँह के कैंसर के प्रारंभिक घाव

☐ मुंह का कैंसर

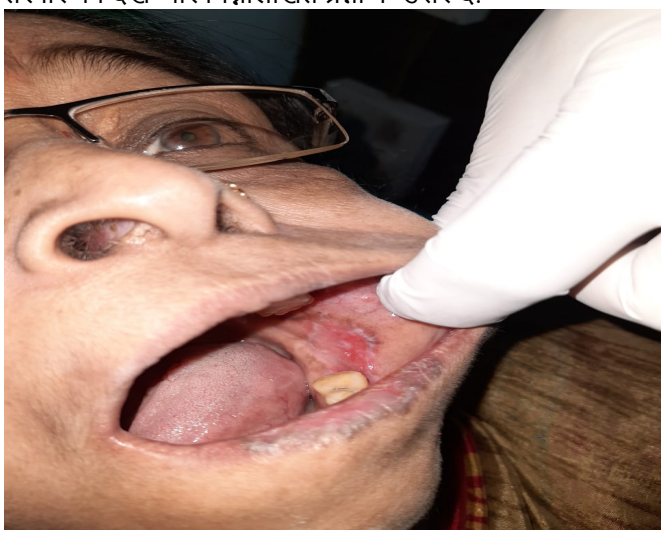
☐ अन्य: _____

J: मौखिक जांच के परिणाम के आधार पर, आपको आगे क्या करना चाहिए?

[*जो लागू हो उस पर सही का निशान लगाएं*]

☐ रोगी की नियमित जाँच करना.

☐ सिर और गर्दन की जांच के लिए रेफर करें।

	☐ परामर्श और सहायता सेवाओं का संदर्भ लें. ☐ तंबाकू बंद करने पर संक्षिप्त सलाह दें. ☐ अन्य: _____
4.3	यह एक 52 वर्षीय महिला का मामला है, जिसने मुंह में दर्द और लाली की मुख्य शिकायत पेश की। उन्होंने पिछले 15 सालों से दिन में कम से कम 2-3 बार तंबाकू के साथ पान चबाने का इतिहास दिया है। नीचे दी गई तस्वीर को देखें और निम्नलिखित प्रश्नों के उत्तर दें:  A. क्या रोगी किसी जोखिम कारक का इतिहास देता है? *[यदि "नहीं" तो भाग सी पर जाएं- यदि "हां", तो अगले प्रश्न पर जाएं]* ☐ हां ☐ नहीं B. नीचे जोखिम कारकों पर जानकारी अभिलिखित करें: प्रकार: _____ आवृत्ति: _____ अवधि: _____ C. क्या कोई घाव मौजूद है? *[यदि "नहीं" तो भाग D पर जाएँ- यदि "हाँ", तो अगले प्रश्न पर जाएँ]* ☐ हाँ ☐ नहीं ☐ कुछ निश्चित नहीं है D. घाव का स्थान क्या है? ☐ जीभ ☐ होंठ

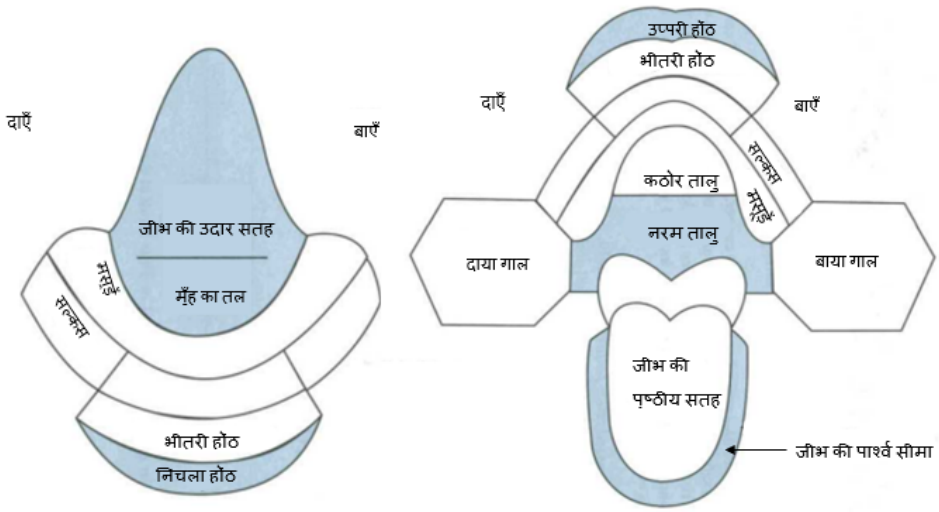
☐ तालु

☐ गाल के अंदर

☐ मुख का तल

☐ अन्य: _____

इसे मानचित्र पर भी अंकित करें



E. घाव का रंग क्या है?

☐ सफेद

☐ लाल

☐ मिश्रित

☐ अन्य: _____

F. घाव का अनुमानित आकार क्या है?

☐ 5 मिमी . तक

☐ 5-20 मिमी . के बीच

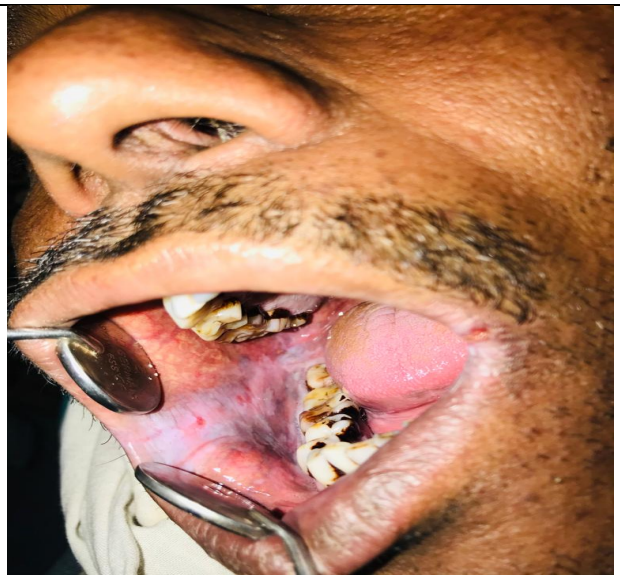
☐ 20 मिमी . से अधिक

☐ अन्य: _____

G. घाव का आकार क्या है?

☐ गोल

	☐ आयताकार ☐ अन्य: _____ H. घाव का वितरण और परिभाषा क्या है? *प्रत्येक पंक्ति में से एक पर निशान लगाएं)* ☐ स्थानीय या ☐ सामान्यीकृत ☐ एक या ☐ विभिन्न ☐ अच्छी तरह से परिभाषित या ☐ खराब परिभाषित I उपरोक्त जानकारी के आधार पर आप घाव का वर्गीकरण कैसे करेंगे? ☐ गैर-संदिग्ध मौखिक घाव ☐ संदिग्ध मुँह के कैंसर के प्रारंभिक घाव ☐ मुंह का कैंसर ☐ अन्य: _____ J: मौखिक जांच के परिणाम के आधार पर, आपको आगे क्या करना चाहिए? [*जो लागू हो उस पर सही का निशान लगाएं*] ☐ रोगी की नियमित जाँच करना। ☐ सिर और गर्दन की जांच के लिए रेफर करें। ☐ परामर्श और सहायता सेवाओं का संदर्भ लें। ☐ तंबाकू छुड़वाने पर संक्षिप्त सलाह दें। ☐ अन्य: _____
4.4	यह एक 44 वर्षीय व्यक्ति का मामला है जो बिना किसी मुख्य शिकायत के नियमित जांच के लिए आया था। उन्होंने पिछले 15 वर्षों से दिन में कम से कम 2-3 बार खैनी और जर्दा चबाने का इतिहास दिया। नीचे दी गई तस्वीर को देखें और निम्नलिखित प्रश्नों के उत्तर दें:



A. क्या रोगी किसी जोखिम कारक का इतिहास देता है?
[यदि "नहीं" तो भाग सी पर जाएं- यदि "हां", तो अगले प्रश्न पर जाएं]

☐ हां

☐ नहीं

B. नीचे जोखिम कारकों पर जानकारी अभिलिखित करें:

प्रकार: _____
आवृत्ति: _____
अवधि: _____

C. क्या कोई घाव मौजूद है?
[यदि "नहीं" तो भाग J पर जाएँ- यदि "हाँ", तो अगले प्रश्न पर जाएँ]

☐ हाँ

☐ नहीं

☐ कुछ निश्चित नहीं है

D. घाव किस स्थान पर है?

☐ जीभ

☐ होंठ

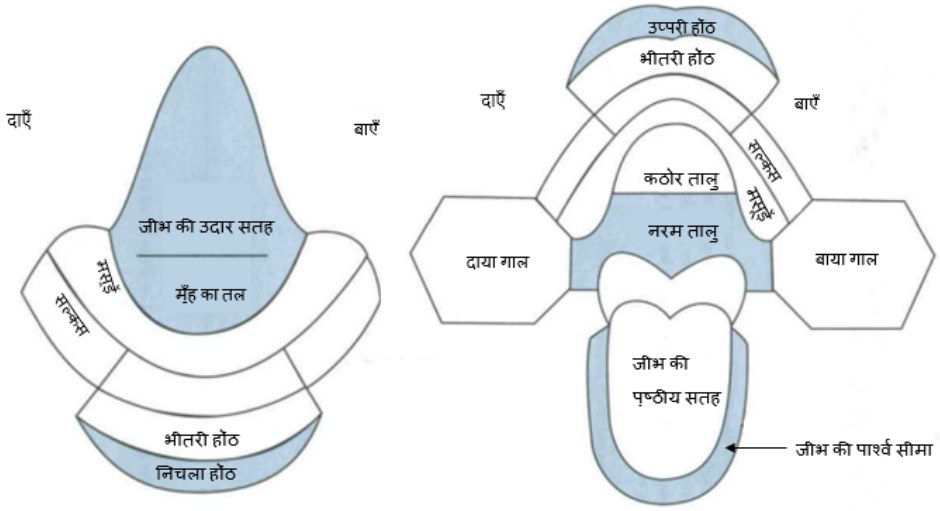
☐ तालु

☐ गाल के अंदर

☐ मुख का तल

☐ अन्य: _____

इसे मानचित्र पर भी अंकित करें



E. घाव का रंग क्या है?

☐ सफेद

☐ लाल

☐ मिश्रित

☐ अन्य: _____

F. घाव का अनुमानित आकार क्या है?

☐ 5 मिमी . तक

☐ 5-20 मिमी . के बीच

☐ 20 मिमी . से अधिक

☐ अन्य: _____

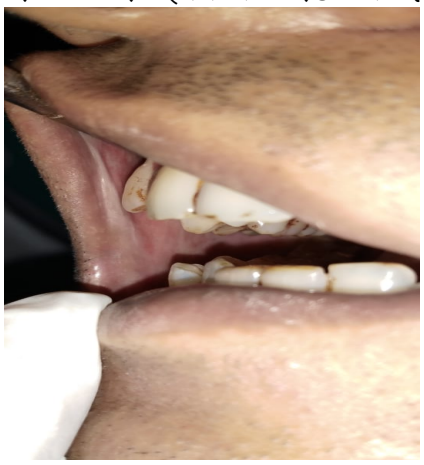
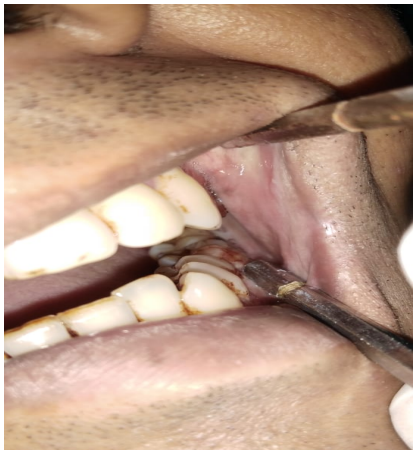
G. घाव का आकार क्या है?

☐ गोल

☐ आयताकार

☐ अन्य: _____

H. घाव का वितरण और परिभाषा क्या है?

	प्रत्येक पंक्ति में से एक पर निशान लगाएं) ☐ स्थानीय या ☐ सामान्यीकृत ☐ एक या ☐ विभिन्न ☐ अच्छी तरह से परिभाषित या ☐ खराब परिभाषित I उपरोक्त जानकारी के आधार पर आप घाव का वर्गीकरण कैसे करेंगे? ☐ गैर-संदिग्ध मौखिक घाव ☐ संदिग्ध मुँह के कैंसर के प्रारंभिक घाव ☐ मुंह का कैंसर ☐ अन्य: _____ J: मौखिक जांच के परिणाम के आधार पर, आपको आगे क्या करना चाहिए? [*जो लागू हो उस पर सही का निशान लगाएं*] ☐ रोगी की नियमित जाँच करना। ☐ सिर और गर्दन की जांच के लिए रेफर करें। ☐ परामर्श और सहायता सेवाओं का संदर्भ लें। ☐ तंबाकू छुड़वाने पर संक्षिप्त सलाह दें। ☐ अन्य: _____
4.5	यह एक 26 वर्षीय व्यक्ति का मामला है जिसने पिछले 1 वर्ष से मुंह कम खुलने की मुख्य शिकायत प्रस्तुत की। उन्होंने पिछले 8 वर्षों से दिन में कम से कम 3-4 बार सुपारी के साथ पान चबाने और बीड़ी पीने का इतिहास दिया। नीचे दी गई तस्वीर को देखें और निम्नलिखित प्रश्नों के उत्तर दें:   दायां बाएं A. क्या रोगी किसी जोखिम कारक का इतिहास देता है? *[यदि "नहीं" तो भाग सी पर जाएं- यदि "हां", तो अगले प्रश्न पर जाएं]*

☐ हां

☐ नहीं

B. नीचे जोखिम कारकों पर जानकारी अभिलिखित करें:

प्रकार: _____
आवृत्ति: _____
अवधि: _____

C. क्या कोई घाव मौजूद है?
[यदि "नहीं" तो भाग J पर जाएँ - यदि "हाँ", तो अगले प्रश्न पर जाएँ]

☐ हाँ

☐ नहीं

☐ कुछ निश्चित नहीं है

D. घाव किस स्थान पर है?

☐ जीभ

☐ होंठ

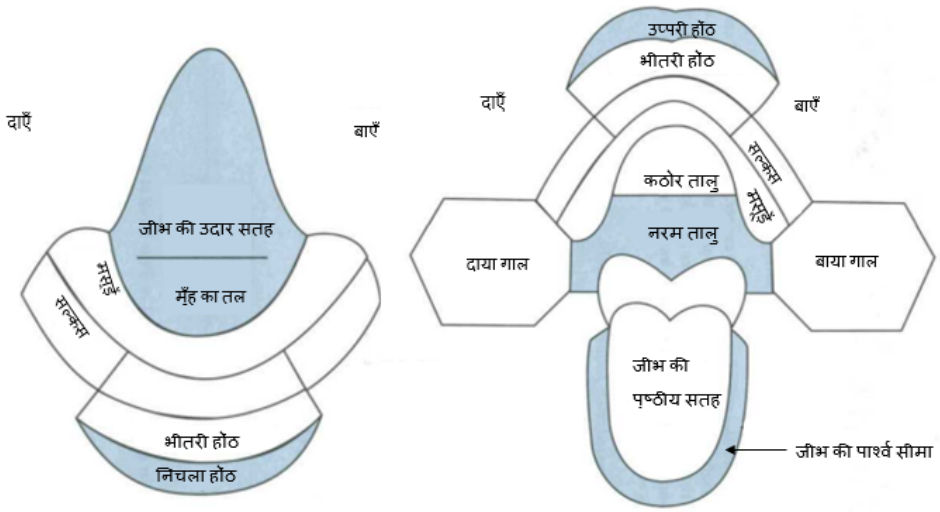
☐ तालु

☐ गाल के अंदर

☐ मुख का तल

☐ अन्य: _____

इसे मानचित्र पर भी अंकित करें



E. घाव का रंग क्या है?

☐ सफेद

☐ लाल

☐ मिश्रित

☐ अन्य: _____

F. घाव का अनुमानित आकार क्या है?

☐ 5 मिमी . तक

☐ 5-20 मिमी . के बीच

☐ 20 मिमी . से अधिक

☐ अन्य: _____

G. घाव का आकार क्या है?

☐ गोल

☐ आयताकार

☐ अन्य: _____

H. घाव का वितरण और परिभाषा क्या है?

प्रत्येक पंक्ति में से एक पर निशान लगाएं)

☐ स्थानीय	या	☐	सामान्यीकृत
☐ एक	या	☐	विभिन्न
☐ अच्छी तरह से परिभाषित	या	☐	खराब परिभाषित

I उपरोक्त जानकारी के आधार पर आप घाव का वर्गीकरण कैसे करेंगे?

☐ गैर-संदिग्ध मौखिक घाव

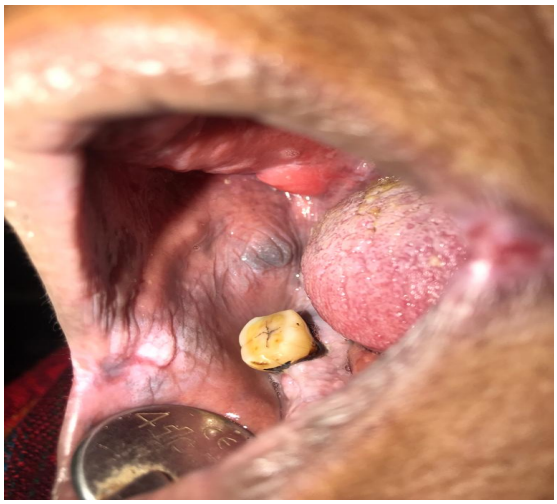
☐ संदिग्ध मुँह के कैंसर के प्रारंभिक घाव

☐ मुंह का कैंसर

☐ अन्य: _____

J: मौखिक जांच के परिणाम के आधार पर, आपको आगे क्या करना चाहिए?

[*जो लागू हो उस पर सही का निशान लगाएं*]

	☐ रोगी की नियमित जाँच करना। ☐ सिर और गर्दन की जांच के लिए रेफर करें। ☐ परामर्श और सहायता सेवाओं का संदर्भ लें। ☐ तंबाकू छुड़वाने पर संक्षिप्त सलाह दें। ☐ अन्य: _____
4.6	यह मामला एक 74 वर्षीय व्यक्ति का है जो नियमित जांच के लिए आया था। उन्होंने पिछले 40 वर्षों से दिन में कम से कम 4-5 बार गुटखा और तंबाकू चबाने का इतिहास दिया। नीचे दी गई तस्वीर को देखें और निम्नलिखित प्रश्नों के उत्तर दें:  A. क्या रोगी किसी जोखिम कारक का इतिहास देता है? *[यदि "नहीं" तो भाग सी पर जाएं- यदि "हां", तो अगले प्रश्न पर जाएं]* ☐ हां ☐ नहीं B. नीचे जोखिम कारकों पर जानकारी अभिलिखित करें: प्रकार: _____ आवृत्ति: _____ अवधि: _____ C. क्या कोई घाव मौजूद है? *[यदि "नहीं" तो भाग J पर जाएँ- यदि "हाँ", तो अगले प्रश्न पर जाएँ]* ☐ हाँ ☐ नहीं ☐ कुछ निश्चित नहीं है D.घाव किस स्थान पर है?

☐ जीभ

☐ होंठ

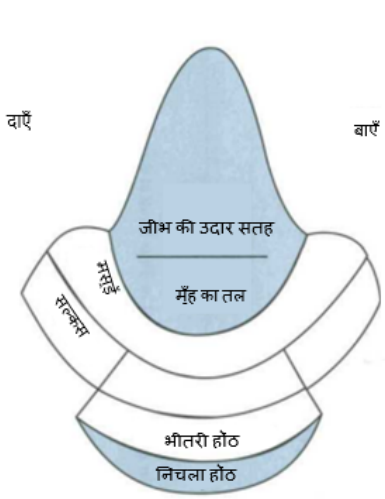
☐ तालु

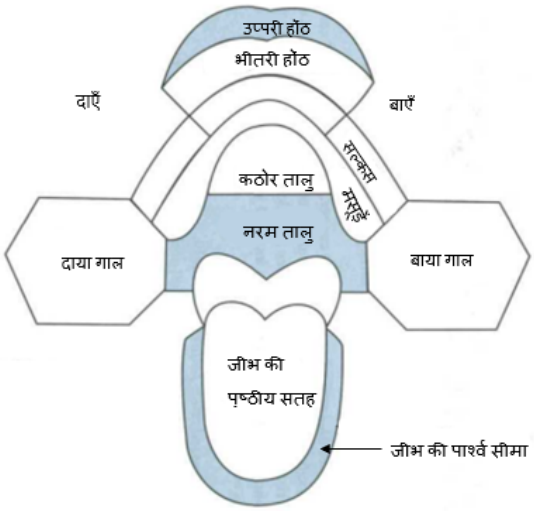
☐ गाल के अंदर

☐ मुख का तल

☐ अन्य: _____

इसे मानचित्र पर भी अंकित करें





E. घाव का रंग क्या है?

☐ सफेद

☐ लाल

☐ मिश्रित

☐ अन्य: _____

F. घाव का अनुमानित आकार क्या है?

☐ 5 मिमी . तक

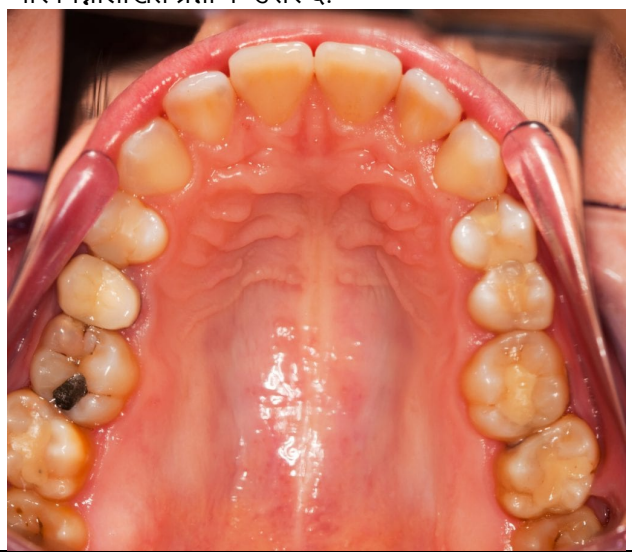
☐ 5-20 मिमी . के बीच

☐ 20 मिमी . से अधिक

☐ अन्य: _____

G. घाव का आकार क्या है?

☐ गोल

	☐ आयताकार ☐ अन्य: _____ H. घाव का वितरण और परिभाषा क्या है? *प्रत्येक पंक्ति में से एक पर निशान लगाएं)* ☐ स्थानीय या ☐ सामान्यीकृत ☐ एक या ☐ विभिन्न ☐ अच्छी तरह से परिभाषित या ☐ खराब परिभाषित I उपरोक्त जानकारी के आधार पर आप घाव का वर्गीकरण कैसे करेंगे? ☐ गैर-संदिग्ध मौखिक घाव ☐ संदिग्ध मुँह के कैंसर के प्रारंभिक घाव ☐ मुंह का कैंसर ☐ अन्य: _____ J: मौखिक जांच के परिणाम के आधार पर, आपको आगे क्या करना चाहिए? [*जो लागू हो उस पर सही का निशान लगाएं*] ☐ रोगी की नियमित जाँच करना। ☐ सिर और गर्दन की जांच के लिए रेफर करें। ☐ परामर्श और सहायता सेवाओं का संदर्भ लें। ☐ तंबाकू छुड़वाने पर संक्षिप्त सलाह दें। ☐ अन्य: _____
4.7	यह मामला 24 साल के एक युवक का है जो नियमित जांच के लिए आया था। उन्होंने 3 ऊपरी दांतों में दंत भरने का इतिहास दिया। रोगी ने धूम्रपान या तंबाकू चबाने का कोई इतिहास नहीं दिया। नीचे दी गई तस्वीर को देखें और निम्नलिखित प्रश्नों के उत्तर दें: 

A. क्या रोगी किसी जोखिम कारक का इतिहास देता है?
[यदि "नहीं" तो भाग सी पर जाएं- यदि "हां", तो अगले प्रश्न पर जाएं]

☐ हां

☐ नहीं

B. नीचे जोखिम कारकों पर जानकारी अभिलिखित करें:

प्रकार: _____
आवृत्ति: _____
अवधि: _____

C. क्या कोई घाव मौजूद है?
[यदि "नहीं" तो भाग J पर जाएँ- यदि "हाँ", तो अगले प्रश्न पर जाएँ]

☐ हाँ

☐ नहीं

☐ कुछ निश्चित नहीं है

D. घाव का स्थान क्या है?

☐ जीभ

☐ होंठ

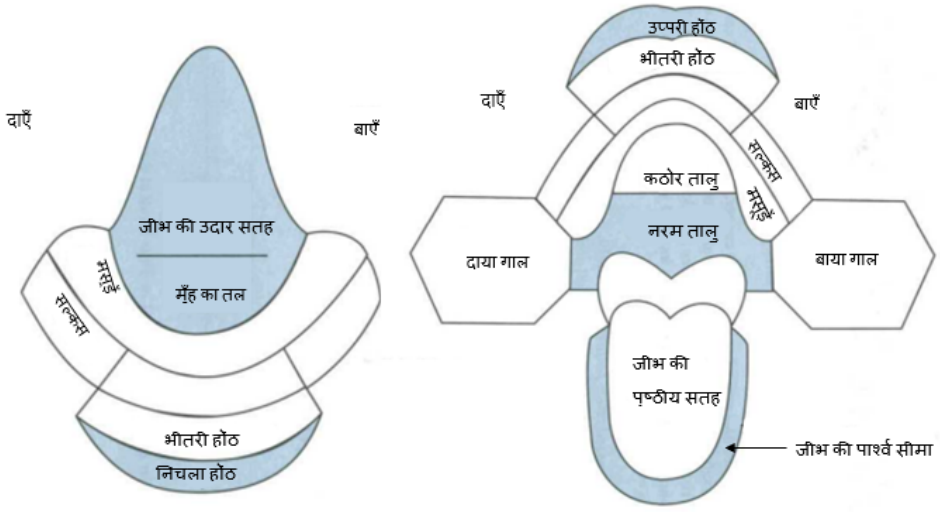
☐ तालु

☐ गाल के अंदर

☐ मुख का तल

☐ अन्य: _____

इसे मानचित्र पर भी अंकित करें



E. घाव का रंग क्या है?

☐ सफेद

☐ लाल

☐ मिश्रित

☐ अन्य: _____

F. घाव का अनुमानित आकार क्या है?

☐ 5 मिमी . तक

☐ 5-20 मिमी . के बीच

☐ 20 मिमी . से अधिक

☐ अन्य: _____

G. घाव का आकार क्या है?

☐ गोल

☐ आयताकार

☐ अन्य: _____

H. घाव का वितरण और परिभाषा क्या है?

प्रत्येक पंक्ति में से एक पर निशान लगाएं)

☐ स्थानीय या ☐ सामान्यीकृत

☐ एक या ☐ विभिन्न

☐ अच्छी तरह से परिभाषित या ☐ खराब परिभाषित

I उपरोक्त जानकारी के आधार पर आप घाव का वर्गीकरण कैसे करेंगे?

☐ गैर-संदिग्ध मौखिक घाव

☐ संदिग्ध मुँह के कैंसर के प्रारंभिक घाव

☐ मुंह का कैंसर

☐ अन्य: _____

J: मौखिक जांच के परिणाम के आधार पर, आपको आगे क्या करना चाहिए?

[*जो लागू हो उस पर सही का निशान लगाएं*]

	☐ रोगी की नियमित जाँच करना। ☐ सिर और गर्दन की जांच के लिए रेफर करें। ☐ परामर्श और सहायता सेवाओं का संदर्भ लें। ☐ तंबाकू छुड़वाने पर संक्षिप्त सलाह दें। ☐ अन्य: _____

इस सर्वेक्षण में भाग लेने के लिए धन्यवाद

প্রশিক্ষণ-পূর্ব এবং প্রশিক্ষণ পরবর্তী প্রশ্নসমূহ

একজন গবেষক দ্বারা এই ফর্মটি গবেষণায় অংশগ্রহনকারী প্রত্যেককে সরবরাহ করা হবে।

লক্ষ্য করুনঃ

এই ফর্মটি শুধুমাত্র তাঁদের ক্ষেত্রে ব্যবহার করা হবে যাঁরা গবেষণায় অংশগ্রহনের উপযুক্ত বলে বিবেচিত হয়েছেন এবং গবেষণায় অংশগ্রহন করতে সম্মতি জ্ঞাপন করেছেন। লক্ষ্য রাখবেন যে, প্রশ্নের উত্তরগুলো নির্ধারিত প্রদত্ত স্থানে টিক চিহ্ন দেওয়ার মাধ্যমে প্রদান করা হবে এবং যতগুলো উত্তর সঠিক বলে মনে হবে— ততোগুলোতেই টিক চিহ্ন প্রদান করতে হবে (যদি না এ বিষয়ে অন্য কোনো নির্দেশনা দেওয়া থাকে)। প্রতিটি প্রশ্নের নীচে বাঁকানো (ইটালিক ফর্ম্যাট)-এর অক্ষরে গবেষকদের জন্য নির্দেশনা প্রদান করা থাকবে।

গবেষকদের দ্বারা পূরণ/সম্পন্ন করার জন্য তথ্যসমূহঃ

a. ফর্ম পূরণ করার তারিখঃ	☐☐ ☐☐ ☐☐☐☐ দিন / মাস / বছর	b. গবেষকঃ (কেবল নামের আদ্যক্ষর / ইনিশিয়াল সমূহ)	
c. গবেষণার এলাকাঃ			

Section 1: জন-সামাজিক এবং **প্রশিক্ষণ-পূর্ব** তথ্যসমূহ

এটি হচ্ছে এই প্রশ্নাবলীর প্রথম অংশ; এই প্রশ্নগুলো হচ্ছে আপনার সম্পর্কে প্রাথমিক তথ্যসমূহ, আপনার শিক্ষাগত যোগ্যতা এবং কমিউনিটি স্বাস্থ্যকর্মী হিসেবে আপনার কর্মকাণ্ড

1.1	আপনার বয়স কত? [বয়সটি পূর্ণ হওয়া বছরের ভিত্তিতে উল্লেখ করুন] ☐☐ বছর
1.2	অংশগ্রহনকারী কি নারী কিংবা পুরুষ? ☐ নারী ☐ পুরুষ
1.3	আপনার শিক্ষাগত যোগ্যতা (সম্পন্নকৃত সর্বশেষ ডিগ্রী) নির্বাচন করুন। ☐ কোনো প্রাতিষ্ঠানিক শিক্ষা গ্রহন করা হয়নি ☐ প্রাথমিক (১ম শ্রেণী থেকে ৫ম শ্রেণী) ☐ নিম্ন মাধ্যমিক (৬ষ্ঠ শ্রেণী থেকে ৮ম শ্রেণী) ☐ মাধ্যমিক (৯ম ও ১০ম শ্রেণী) ☐ উচ্চতর পর্যায় (একাদশ শ্রেণী বা এর উপরে) ☐ অন্যান্য, অনুগ্রহ করে উল্লেখ **করুনঃ** _____
1.4	আপনি কমিউনিটি স্বাস্থ্যকর্মী হিসেবে কত বছর কাজ করেছেন? ☐ ১২ মাসের কম ☐ ১-৩ বছর ☐ ৪-৫ বছর ☐ ৫ বছরের বেশি
1.5	**পূর্বে আপনি কি কখনো মুখগহ্বরের ক্যান্সারের উপর কোনো প্রশিক্ষণ/ট্রেনিং-এ অংশ নিয়েছেন; কিংবা মুখের ক্যান্সারের উপর কোনো সচেতনতামূলক কিংবা শিক্ষামূলক কার্যক্রমে অংশ নিয়েছেন?** *[যদি এই প্রশ্নের উত্তর "না" হয়, তবে প্রশ্ন নং 1.7 -তে চলে যান]* ☐ হ্যাঁ ☐ না
1.6	মুখগহ্বরের ক্যান্সার বিষয়ক প্রশিক্ষণ/ট্রেনিং বা সচেতনতামূলক কার্যক্রমে আপনি সর্বশেষ কবে অংশ নিয়েছিলেন? ☐ বিগত ১২ মাসের মধ্যে ☐ ১৩-১৪ মাস আগে ☐ ২৪ মাসেরও আগে ☐ আমি এবারেই সর্বপ্রথম অংশগ্রহন করেছি
1.7	নিম্নোক্ত প্রশ্নসমূহের ক্ষেত্রে বর্তমানে আপনার নিজ অবস্থাকে মূল্যায়ন করুনঃ A. ওরাল/মুখগহ্বরের ক্যান্সার–এর ঝুঁকি সমূহের বিষয়ে আপনার কতটুকু জ্ঞান রয়েছে / কতোটুকু জানেন? ☐ খুব ভালো ☐ ভালো ☐ মোটামুটি ☐ ভালো নয় B. ওরাল/মুখগহ্বরের ক্যান্সার–এর লক্ষণ ও উপসর্গ সমূহের বিষয়ে আপনার কতটুকু জ্ঞান রয়েছে / কতোটুকু জানেন?

	☐ খুব ভালো ☐ ভালো ☐ মোটামুটি ☐ ভালো নয় C. ওরাল/মুখগহ্বরের ক্যান্সার–এর দ্রুত সনাক্তকরণ বা রোগ-নির্ণয়ের বিষয়ে আপনার কতটুকু জ্ঞান রয়েছে / কতোটুকু জানেন? ☐ খুব ভালো ☐ ভালো ☐ মোটামুটি ☐ ভালো নয় D. ওরাল/ মুখগহ্বরের ক্যান্সার–এর রোগ নির্ণয়, রোগী রেফার করা এবং এর চিকিৎসার বিষয়ে আপনার কতটুকু জ্ঞান রয়েছে / কতোটুকু জানেন? ☐ খুব ভালো ☐ ভালো ☐ মোটামুটি ☐ ভালো নয়
1.8	আপনি কি ওরাল/ মুখগহ্বরের ক্যান্সার সনাক্তকরণ বিষয়ক ওয়ার্কশপে/কর্মশালায় ভবিষ্যতে অংশগ্রহন করতে ইচ্ছুক? *[যদি উত্তর ''না'' হয়ে থাকে, তবে প্রশ্ন নং 1.10 –এ চলে যান। আর যদি উত্তর ''হ্যাঁ'' হয়ে থাকে, তবে পরবর্তী প্রশ্নে চলে যান।* ☐ হ্যাঁ ☐ না ☐ নিশ্চিত নই
1.9	আপনি এই ওয়ার্কশপের কোন ধরনের মাধ্যম ব্যবহার করে অংশগ্রহন করতে স্বাচ্ছন্দ্যবোধ করবেন? ☐ অনলাইন ☐ মুখোমুখি / সরাসরি ☐ অনলাইন এবং সরাসরি ওয়ার্কশপের একটি সমন্বিত মিশ্রণ (হাইব্রিড) ☐ অন্যান্যঃ _____
1.10	আপনার মতে, ওরাল/ মুখগহ্বরের ক্যান্সারের প্রতিরোধ এবং দ্রুত সনাক্তকরনের ক্ষেত্রে কমিউনিটি স্বাস্থ্যকর্মীদের গুরুত্ব কতটুকু? ☐ অনেক বেশি ☐ মাঝামাঝি ☐ কিছুটা ☐ খুব কম

Section 2: মুখগহ্বরের ক্যান্সার এবং মুখগহ্বরের সম্ভাব্য ম্যালিগন্যান্ট (ক্যান্সার জাতীয়) ক্ষত বা সমস্যাসমূহ

মুখগহ্বরের সন্দেহজনক ক্ষত বা সমস্যা–এর বিস্তারিত বিষয়ে পরবর্তী কিছু প্রশ্ন করা হবে। আপনার কাছে যেসকল উত্তর সঠিক মনে হবে, সেগুলোতে টিক চিহ্ন দিন।

2.1	ওরাল/মুখগহ্বরের ক্যান্সার এবং মুখগহ্বরের সম্ভাব্য ম্যালিগন্যান্ট (ক্যান্সার জাতীয়) সমস্যাসমূহ কোন কোন স্থানে সবচেয়ে বেশি পরিলক্ষিত হয়? [প্রযোজ্য সবগুলো উত্তরে টিক চিহ্ন দিন] ☐ জিহ্বা

	☐ মুখের নীচের তালু (জিহ্বার নীচে) ☐ গালের ঝিল্লী (মুখের ভিতরে গালের মাংসল অংশ) ☐ উপরোক্ত সবগুলো
2.2	সাধারণত কোন বয়সের রোগীদের মুখে এই ক্ষত বা সমস্যাগুলো গুলো বেশি দেখা যায়? ☐ ১৮ বছরের কম বয়সে ☐ ১৮ থেকে ৩৯ বছর বয়সে ☐ ৪০ বছরের বেশি বয়সে ☐ উপরোক্ত কোনোটিই নয়
2.3	নিম্নোল্লেখিত কোনটি ওরাল/মুখগহ্বরের ক্যান্সার এবং মুখগহ্বরের সম্ভাব্য ম্যালিগন্যান্ট (ক্যান্সার জাতীয়) সমস্যাসমূহের লক্ষণ **নয়**? ☐ মুখগহ্বরের ভেতর কোনো সাদাটে অংশ ☐ মুখগহ্বরের ভেতর কোনো লালচে অংশ ☐ ভালো হচ্ছেনা বা সেরে যাচ্ছেনা এমন কোনো ক্ষত ☐ পেটে ব্যাথা
2.4	নিম্নোল্লেখিত কোনটি ওরাল/মুখগহ্বরের ক্যান্সার এবং মুখগহ্বরের সম্ভাব্য ম্যালিগন্যান্ট (ক্যান্সার জাতীয়) সমস্যাসমূহের ঝুঁকি বা কারন **নয়**? [প্রযোজ্য সবগুলো উত্তরে টিক চিহ্ন দিন] ☐ মদ্যপান ☐ তামাক ☐ সুপারী ☐ ফল এবং সবজী খাওয়া
2.5	মুখগহ্বরের সম্ভাব্য ম্যালিগন্যান্ট (ক্যান্সার জাতীয়) ক্ষত বা সমস্যা সমূহের মধ্যে কোনগুলো পরবর্তীতে সত্যিকারের ম্যালিগন্যান্ট (ক্যান্সার জাতীয়) রোগসমূহে পরিবর্তিত হয়ে যাওয়ার হার বেশি? ☐ ওরাল সাবমিউকাস ফাইব্রোসিস ☐ ইরাইথ্রোপ্লাকিয়া ☐ লিউকোপ্লাকিয়া ☐ ওরাল লাইকেন প্ল্যানাস

Section 3: ওরাল/মুখগহ্বরের ক্যান্সারের সনাক্তকরণ (স্ক্রীনিং)-এর বিষয়ে জ্ঞান/ধারনা এবং মনোভাব

পরবর্তী কিছু প্রশ্নের মাধ্যমে ওরাল/ মুখগহ্বরের ক্যান্সারের সনাক্তকরণ (স্ক্রীনিং)- এর বিষয়ক জ্ঞান/ধারনা (Q 3.1- Q 3.7) এবং মনোভাব (Q 3.8- Q 3.11) –এর বিষয়ে জানতে চাওয়া হবে।

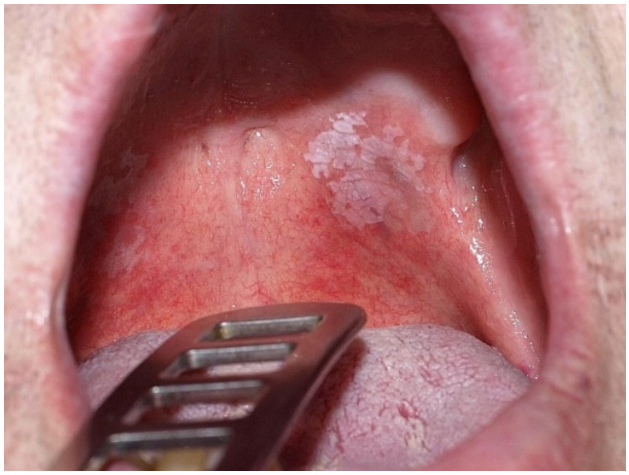
3.1	জনসংখ্যার ওরাল/মুখগহ্বরের ক্যান্সার সনাক্তকরণ/স্ক্রীনিং এর জন্য নিম্নোক্ত কোনটি সবচেয়ে বেশি সাশ্রয়ী, উপযুক্ত এবং কার্যকরী পদ্ধতি? ☐ বায়োপসি ☐ মুখগহ্বরের চাক্ষুস পরীক্ষা ☐ ভাইটাল স্টেইনিং ☐ সাইটোলজি বা কোষবিদ্যা
3.2	মুখগহ্বরের যথাযথ স্ক্রীনিং এর ক্ষেত্রে নিম্নোক্ত কোন উপকরণটি আবশ্যক? ☐ মাউথ মিরর বা মুখের ভেতরে দেখবার আয়না ☐ গজ ☐ টাং-ব্লেড ☐ উপরোক্ত সবগুলোই
3.3	নিম্নোক্ত কোনটি মুখগহ্বরের স্ক্রীনিং-এর ক্ষেত্রে প্রথম ধাপ হওয়া উচিৎ? ☐ মুখগহ্বর সম্পর্কিত পূর্ব ইতিহাস/হিস্ট্রি জেনে নেওয়া ☐ মুখগহ্বরের ভেতরে নীরিক্ষন বা পর্যবেক্ষণ ☐ মুখগহ্বরের বাইরে নীরিক্ষন বা পর্যবেক্ষণ ☐ মুখগহ্বরের ক্ষত বা সমস্যাটির অবস্থান চিহ্নিতকরণ (মাউথম্যাপে চার্টিং-এর মাধ্যমে)
3.4	মুখগহ্বরের বাইরে নীরিক্ষন বা পর্যবেক্ষণের সময়ে আপনি নিম্নোক্ত কোন কোন অংশ পরীক্ষা করে দেখবেন? ☐ বর্ধিত (এনলার্জড) লিম্ফ-নোড ☐ মুখগহ্বর এবং চোয়ালে ফুলে যাওয়া অংশ ☐ মুখমণ্ডল ও ঘাড়ের আলসার/ক্ষত এবং ব্যাথাযুক্ত স্থান ☐ উপরোক্ত সবগুলোই
3.5	যখন একটি সন্দেহজনক ক্ষত বা সমস্যা চোখে পড়বে, তখন কোন কোন বিষয়গুলো পর্যবেক্ষণ করে লিপিবদ্ধ করবেন? ☐ ক্ষত বা সমস্যাটির রং ☐ ক্ষত বা সমস্যাটি মুখের কোন স্থানে অবস্থিত ☐ ক্ষত বা সমস্যাটি আকারে কতটুকু ☐ উপরোক্ত সবগুলোই
3.6	ঠোঁট নীরিক্ষন বা পর্যবেক্ষণের সময়ে আপনি কোন অংশটি পরীক্ষা সর্বপ্রথম দেখবেন? ☐ ঠোঁট উল্টে নিয়ে এর ভেতরের অংশ নীরিক্ষণ করা ☐ ‘জিনজাইভো-ল্যাবিয়াল সালকাস’ অর্থাৎ ঠোঁট ও এর লাগোয়া মাড়ির মধ্যবর্তী অংশ, ‘জিনজাইভাল মিউকোসা’ অর্থাৎ ঠোঁটের লাগোয়া মাড়ি এবং দাঁত ☐ বৃদ্ধাঙ্গুলি এবং তর্জনীর সাহায্যে ঠোঁট পালপেট বা পরীক্ষা করা ☐ উপরোক্ত কোনোটিই নয়
3.7	আপনি যদি একটি সন্দেহজনক ক্ষত বা সমস্যা চিহ্নিত করেন, তবে রোগীকে সর্বপ্রথম কোথায় পাঠাবেন / রেফার করবেন? ☐ রোগীকে ফলোআপ বা পরবর্তী ভিজিটে আসবার জন্য বলুন ☐ প্রাথমিক স্বাস্থ্যসেবা কেন্দ্র ☐ একজন প্রাইভেট প্র্যাক্টিস করা ডেন্টিস্ট/দন্ত-চিকিৎসক এর নিকট দেখাতে বলবো ☐ উপরোক্ত কোনোটিই নয়
3.8	ওরাল/মুখগহ্বরের ক্যান্সার এবং সম্ভাব্য ক্যান্সারজনিত সমস্যাসমূহ দ্রুত নির্নয় করাটা রোগের অবস্থার উন্নতির ক্ষেত্রে কতোটা গুরুত্বপূর্ণ? ☐ একেবারেই গুরুত্বপূর্ণ নয় ☐ সামান্য গুরুত্বপূর্ণ ☐ মোটামুটিভাবে গুরুত্বপূর্ণ

	☐ বেশ গুরুত্বপূর্ণ ☐ অত্যন্ত গুরুত্বপূর্ণ
3.9	ওরাল/মুখগহ্বরের ক্যান্সার এবং সম্ভাব্য ক্যান্সারজনিত সমস্যাসমূহের প্রতিরোধ কিংবা এর দ্রুত নির্নয় করার বিষয়ে আপনি কতটুকু জ্ঞাত রয়েছেন / জানেন? ☐ একেবারেই জানা নেই ☐ সামান্য জানা আছে ☐ জানা আছে ☐ ভালোভাবে জানা আছে
3.10	ওরাল/মুখগহ্বরের ক্যান্সার এবং ক্যান্সারপূর্ব (প্রি-ক্যান্সার) সমস্যা সনাক্তকরণ/স্ক্রীনিং করার ক্ষেত্রে আপনি কতটুকু আত্মবিশ্বাসী? ☐ একেবারেই আত্মবিশ্বাসী নই ☐ সামান্য আত্মবিশ্বাসী ☐ কিছুটা আত্মবিশ্বাসী ☐ মোটামুটি আত্মবিশ্বাসী ☐ সম্পূর্ণরূপে আত্মবিশ্বাসী

Section 4: কেস প্রেজেন্টেশন (ট্রেনিং পরবর্তী সময়ের জন্য)

এই সেকশনে আপনাকে বিভিন্ন রোগীদের মুখগহ্বরের সমস্যার সঙ্গে সম্পর্কিত ফটোগ্রাফ এবং অতীত বিবরণ (হিস্ট্রি) প্রদান করা হবে। অনুগ্রহ করে কেস-ডিটেলস (বিবরণী)-টি ভালোভাবে পড়ুন এবং প্রদত্ত ফটোগ্রাফগুলো দেখুন। উক্ত বিবরণী এবং ছবির বিষয়ে আপনাকে প্রশ্ন করা হবে এবং উক্ত (ওরাল/মুখগহ্বরের ক্যান্সার এবং মুখগহ্বরের সম্ভাব্য ম্যালিগন্যান্ট ক্ষত বা সমস্যা সংবলিত) ছবি তে প্রদত্ত সন্দেহজনক ক্ষত বা সমস্যাটি কোন রোগের কারনে হয়েছে – সেটি নির্ণয় করতে বলা হবে।

4.1 এটি ৬৪ বছর বয়সী একজন পুরুষ রোগীর মুখগহ্বরের ছবি, তিনি বিগত ২০ বছর যাবৎ প্রতিদিন ৪-৫ বার করে পান-মশলা এবং গুটখা চিবানোর অতীত বিবরণী (হিস্ট্রি) দিয়েছেন। প্রদত্ত ছবিটি দেখুন, এবং নিম্নোক্ত প্রশ্নসমূহের উত্তর দিনঃ



A. এই রোগী কি রোগের জন্য দায়ী কোনো ঝুঁকি/কারন-এর কথা উল্লেখ করেছেন?
[যদি উত্তর "না" হয়, তবে PART C-তে চলে যান। যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান।]

☐ হ্যাঁ
☐ না

B. রোগীর ইতিহাসের ভিত্তিতে নীচে ঝুঁকির কারণগুলির উপর তথ্য রেকর্ড করুন
ধরনঃ _____
কতবার **করেঃ** _____
কত সময় যাবৎ (দিন/মাস/বছর): _____

C. ছবিতে কি কোনো ক্ষত বা অন্য সমস্যা দেখা যাচ্ছে?

[যদি উত্তর "না" হয়, তবে PART J-তে চলে যান/ যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান/]

☐ হ্যাঁ
☐ না
☐ নিশ্চিত নই

D. উক্ত ক্ষত বা সমস্যাটি মুখের কোন জায়গায় হয়েছে?

☐ জিহ্বা
☐ ঠোঁট
☐ তালু
☐ **গালের ভেতরের দিকে**

☐ জিহ্বার নীচে (ফ্লোর অফ দ্য মাউথ)

☐ অন্যান্যঃ _____

E. ক্ষত বা সমস্যাটির রং কী?

☐ সাদা
☐ লাল
☐ মিশ্র রং
☐ অন্যান্যঃ _____

F. এই ক্ষত বা সমস্যাটির আনুমানিক আকার কতটুকু?

☐ ৫ মিলিমিটার পর্যন্ত
☐ ৫ – ২০ মিলিমিটারের মধ্যে
☐ ২০ মিলিমিটারের বেশি
☐ অন্যান্যঃ _____

G. ক্ষত বা সমস্যাটির আকৃতি কেমন?

☐ গোল
☐ চারকোনা
☐ অন্যান্যঃ _____

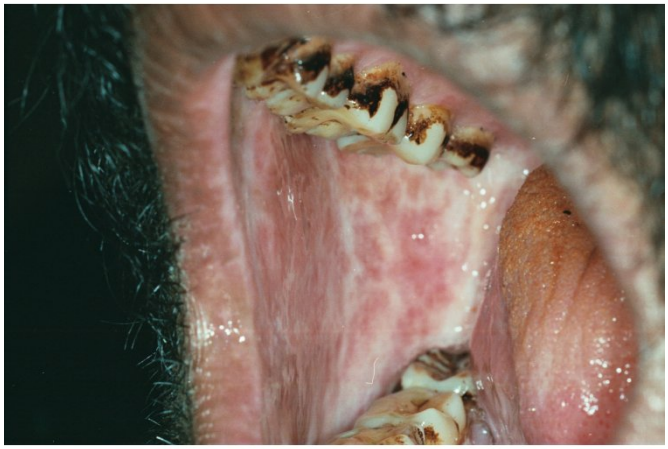
H. ক্ষত বা সমস্যাটির পরিধি (ডিসট্রিবিউশন) কতটুকু এবং এর কিনারা/প্রান্ত (ডেফিনিশন, অর্থাৎ কীরূপে ডিফাইন্ড) কী ধরনের?

[প্রতিটি সারি থেকে একটি উত্তর নির্বাচন করে টিক চিহ্ন দিন]

☐ লোকালাইজড (একটি স্থানেই রয়েছে)	কিংবা	জেনারালাইজড (অন্যান্য স্থানে ছড়িয়ে গেছে)
☐ সিঙ্গেল (একটি ক্ষত বা সমস্যা)	কিংবা	একাধিক ক্ষত বা সমস্যা
☐ ওয়েল ডিফাইন্ড (কিনারা বা বর্ডার স্পষ্ট)	কিংবা	পুওরলি ডিফাইন্ড (কিনারা বা বর্ডার অস্পষ্ট)

I. উপরোক্ত সকল তথ্যের ভিত্তিতে, আপনি ক্ষত বা সমস্যাটিকে কোন শ্রেণীভুক্ত করবেন?

☐ সন্দেহজনক নয়, বরং মুখের একটি সাধারণ ক্ষত বা সমস্যা
☐ সন্দেহজনক এবং সম্ভাব্য ম্যালিগনেন্ট (ক্যান্সার জাতীয়) সমস্যা

	☐ ওরাল/মুখগহ্বরের ক্যান্সার ☐ অন্যান্যঃ _____ J: উক্ত রোগীর ওরাল/মুখগহ্বরের স্ক্রীনিং/রোগ-নির্ণয় –এর উপর ভিত্তি করে, আপনার পরবর্তী পদক্ষেপ কী হবে? *[প্রযোজ্য সকল উত্তরে টিক চিহ্ন দিন]* ☐ রোগীকে নিয়মিতভাবে ফলোআপ করা ☐ রোগীর মাথা এবং ঘাড়ের স্বাস্থ্যগত অবস্থার বিষয়ে আরো বিস্তারিত অনুসন্ধানের জন্য তাকে রেফার করা ☐ কাউন্সিলিং (পরামর্শ প্রদান) এবং সাপোর্ট সার্ভিস (সহায়তামূলক সেবা) প্রাপ্তির জন্য রোগীকে রেফার করা ☐ তামাকগ্রহন বন্ধ করার জন্য রোগীকে সংক্ষিপ্ত আকারে পরামর্শ প্রদান ☐ অন্যান্যঃ _____
4.2	এটি ৪৮ বছর বয়সী একজন পুরুষ রোগীর মুখগহ্বরের ছবি। মূল সমস্যা হিসেবে তিনি জানিয়েছেন যে, খাদ্যগ্রহনের সময়ে তাঁর মুখে জ্বালাপোড়ার অনুভূতি হয়ে থাকে, এবং মুখ খুলতে গেলে অর্থাৎ হা করতে গেলে তাঁর সমস্যা হয়। অতীতের বিবরণী (হিস্ট্রি) হিসেবে তিনি বিগত ২৩ বছর যাবৎ প্রতিদিন কমপক্ষে ৪-৫ বার করে গুটখা চিবানো এবং ধূমপান করার কথা জানিয়েছেন। প্রদত্ত ছবিটি দেখুন, এবং নিম্নোক্ত প্রশ্নসমূহের উত্তর দিনঃ  A. এই রোগী কি রোগের জন্য দায়ী কোনো ঝুঁকি/কারন-এর কথা উল্লেখ করেছেন? *[যদি উত্তর "না" হয়, তবে PART C-তে চলে যান। যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান।]* ☐ হ্যাঁ ☐ না B. **রোগীর ইতিহাসের ভিত্তিতে নীচে ঝুঁকির কারণগুলির উপর তথ্য রেকর্ড করুন** **ধরনঃ** _____ কতবার **করেঃ** _____ কত সময় যাবৎ (দিন/মাস/বছর): _____ C. ছবিতে কি কোনো ক্ষত বা অন্য সমস্যা দেখা যাচ্ছে? *[যদি উত্তর "না" হয়, তবে PART J-তে চলে যান। যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান।]* ☐ হ্যাঁ ☐ না

☐ নিশ্চিত নই

D. উক্ত ক্ষত বা সমস্যাটি মুখের কোন জায়গায় হয়েছে?

☐ জিহ্বা
☐ ঠোঁট
☐ তালু
☐ গালের ভেতরের দিকে

☐ জিহ্বার নীচে (ফ্লোর অফ দ্য মাউথ)

☐ অন্যান্যঃ _____

E. ক্ষত বা সমস্যাটির রং কী?

☐ সাদা
☐ লাল
☐ মিশ্র রং
☐ অন্যান্যঃ _____

F. এই ক্ষত বা সমস্যাটির আনুমানিক আকার কতটুকু?

☐ ৫ মিলিমিটার পর্যন্ত
☐ ৫ – ২০ মিলিমিটারের মধ্যে
☐ ২০ মিলিমিটারের বেশি
☐ অন্যান্যঃ _____

G. ক্ষত বা সমস্যাটির আকৃতি কেমন?

☐ গোল
☐ চারকোনা
☐ অন্যান্যঃ _____

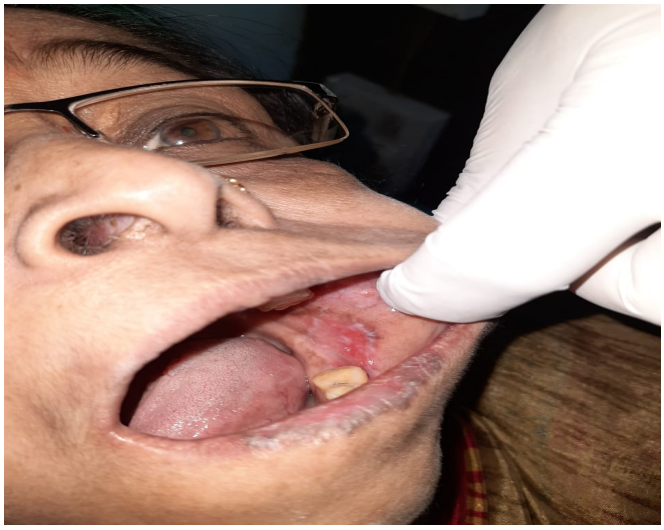
H. ক্ষত বা সমস্যাটির পরিধি (ডিসট্রিবিউশন) কতটুকু এবং এর কিনারা/প্রান্ত (ডেফিনিশন, অর্থাৎ কীরূপে ডিফাইন্ড) কী ধরনের?

[প্রতিটি সারি থেকে একটি উত্তর নির্বাচন করে টিক চিহ্ন দিন]

☐ লোকালাইজড (একটি স্থানেই রয়েছে) কিংবা জেনারালাইজড (অন্যান্য স্থানে ছড়িয়ে গেছে)
☐ সিঙ্গেল (একটি ক্ষত বা সমস্যা) কিংবা একাধিক ক্ষত বা সমস্যা
☐ ওয়েল ডিফাইন্ড (কিনারা বা বর্ডার স্পষ্ট) কিংবা পুওরলি ডিফাইন্ড (কিনারা বা বর্ডার অস্পষ্ট)

I. উপরোক্ত সকল তথ্যের ভিত্তিতে, আপনি ক্ষত বা সমস্যাটিকে কোন শ্রেণীভুক্ত করবেন?

☐ সন্দেহজনক নয়, বরং মুখের একটি সাধারণ ক্ষত বা সমস্যা
☐ সন্দেহজনক এবং সম্ভাব্য ম্যালিগনেন্ট (ক্যান্সার জাতীয়) সমস্যা
☐ ওরাল/মুখগহ্বরের ক্যান্সার
☐ অন্যান্যঃ _____

	J: উক্ত রোগীর ওরাল/মুখগহ্বরের স্ক্রীনিং/রোগ-নির্ণয় –এর উপর ভিত্তি করে, আপনার পরবর্তী পদক্ষেপ কী হবে? *[প্রযোজ্য সকল উত্তরে টিক চিহ্ন দিন]* ☐ রোগীকে নিয়মিতভাবে ফলোআপ করা ☐ রোগীর মাথা এবং ঘাড়ের স্বাস্থ্যগত অবস্থার বিষয়ে আরো বিস্তারিত অনুসন্ধানের জন্য তাকে রেফার করা ☐ কাউন্সিলিং (পরামর্শ প্রদান) এবং সাপোর্ট সার্ভিস (সহায়তামূলক সেবা) প্রাপ্তির জন্য রোগীকে রেফার করা ☐ তামাকগ্রহন বন্ধ করার জন্য রোগীকে সংক্ষিপ্ত আকারে পরামর্শ প্রদান ☐ অন্যান্যঃ _____
4.3	একজন ৫২ বছর বয়সী নারী রোগীর মুখগহ্বরের ছবি। মূল সমস্যা হিসেবে তিনি জানিয়েছেন যে, তাঁর মুখের ভেতরে ব্যাথা এবং লালচে ভাব রয়েছে। অতীতের বিবরণী (হিস্ট্রি) হিসেবে তিনি বিগত ১৫ বছর যাবৎ প্রতিদিন কমপক্ষে ২-৩ বার তামাক সহ পান চিবানোর কথা জানিয়েছেন। প্রদত্ত ছবিটি দেখুন, এবং নিম্নোক্ত প্রশ্নসমূহের উত্তর দিনঃ  A. এই রোগী কি রোগের জন্য দায়ী কোনো ঝুঁকি/কারন-এর কথা উল্লেখ করেছেন? *[যদি উত্তর "না" হয়, তবে PART C-তে চলে যান। যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান।]* ☐ হ্যাঁ ☐ না B. **রোগীর ইতিহাসের ভিত্তিতে নীচে ঝুঁকির কারণগুলির উপর তথ্য রেকর্ড করুন** **ধরনঃ** _____ কতবার **করেঃ** _____ কত সময় যাবৎ (দিন/মাস/বছর): _____ C. ছবিতে কি কোনো ক্ষত বা অন্য সমস্যা দেখা যাচ্ছে? *[যদি উত্তর "না" হয়, তবে PART J-তে চলে যান। যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান।]* ☐ হ্যাঁ ☐ না ☐ নিশ্চিত নই D. উক্ত ক্ষত বা সমস্যাটি মুখের কোন জায়গায় হয়েছে? ☐ জিহ্বা ☐ ঠোঁট

☐ তালু

☐ গালের ভেতরের দিকে

☐ জিহ্বার নীচে (ফ্লোর অফ দ্য মাউথ)

☐ অন্যান্যঃ _____

E. ক্ষত বা সমস্যাটির রং কী?

☐ সাদা

☐ লাল

☐ মিশ্র রং

☐ অন্যান্যঃ _____

F. এই ক্ষত বা সমস্যাটির আনুমানিক আকার কতটুকু?

☐ ৫ মিলিমিটার পর্যন্ত

☐ ৫ – ২০ মিলিমিটারের মধ্যে

☐ ২০ মিলিমিটারের বেশি

☐ অন্যান্যঃ _____

G. ক্ষত বা সমস্যাটির আকৃতি কেমন?

☐ গোল

☐ চারকোনা

☐ অন্যান্যঃ _____

H. ক্ষত বা সমস্যাটির পরিধি (ডিসট্রিবিউশন) কতটুকু এবং এর কিনারা/প্রান্ত (ডেফিনিশন, অর্থাৎ কীরূপে ডিফাইন্ড) কী ধরনের?

[প্রতিটি সারি থেকে একটি উত্তর নির্বাচন করে টিক চিহ্ন দিন]

☐ লোকালাইজড (একটি স্থানেই রয়েছে) কিংবা জেনারালাইজড (অন্যান্য স্থানে ছড়িয়ে গেছে)

☐ সিঙ্গেল (একটি ক্ষত বা সমস্যা) কিংবা একাধিক ক্ষত বা সমস্যা

☐ ওয়েল ডিফাইন্ড (কিনারা বা বর্ডার স্পষ্ট) কিংবা পুওরলি ডিফাইন্ড (কিনারা বা বর্ডার অস্পষ্ট)

I. উপরোক্ত সকল তথ্যের ভিত্তিতে, আপনি ক্ষত বা সমস্যাটিকে কোন শ্রেণীভুক্ত করবেন?

☐ সন্দেহজনক নয়, বরং মুখের একটি সাধারণ ক্ষত বা সমস্যা

☐ সন্দেহজনক এবং সম্ভাব্য ম্যালিগনেন্ট (ক্যান্সার জাতীয়) সমস্যা

☐ ওরাল/মুখগহ্বরের ক্যান্সার

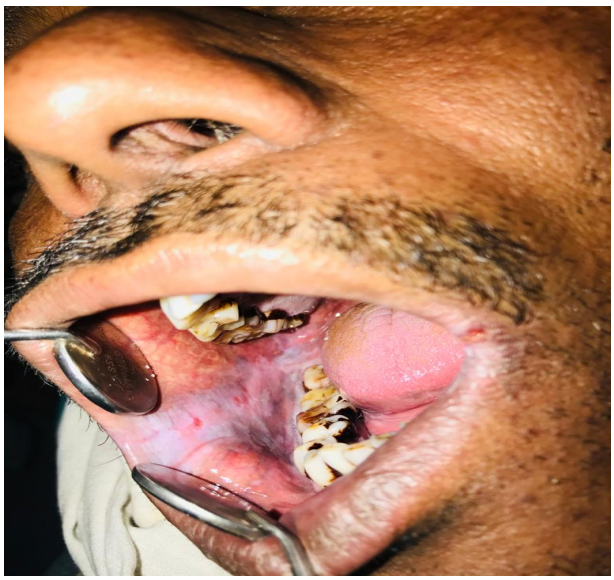
☐ অন্যান্যঃ _____

J: উক্ত রোগীর ওরাল/মুখগহ্বরের স্ক্রীনিং/রোগ-নির্ণয় –এর উপর ভিত্তি করে, আপনার পরবর্তী পদক্ষেপ কী হবে?

[প্রযোজ্য সকল উত্তরে টিক চিহ্ন দিন]

☐ রোগীকে নিয়মিতভাবে ফলোআপ করা

☐ রোগীর মাথা এবং ঘাড়ের স্বাস্থ্যগত অবস্থার বিষয়ে আরো বিস্তারিত অনুসন্ধানের জন্য তাকে রেফার করা

	☐ কাউন্সিলিং (পরামর্শ প্রদান) এবং সাপোর্ট সার্ভিস (সহায়তামূলক সেবা) প্রাপ্তির জন্য রোগীকে রেফার করা ☐ তামাকগ্রহন বন্ধ করার জন্য রোগীকে সংক্ষিপ্ত আকারে পরামর্শ প্রদান ☐ অন্যান্যঃ _____
4.4	এটি হচ্ছে একজন ৪৪ বছর বয়সী পুরুষ রোগীর মুখগহ্বরের ছবি, যিনি কোনো সমস্যা বোধ করছেন না, কেবলমাত্র রেগুলার চেকআপ করাতে এসেছেন। অতীতের বিবরণী (হিস্ট্রি) হিসেবে তিনি বিগত ১৫ বছর যাবৎ প্রতিদিন কমপক্ষে ২-৩ বার খৈনী এবং জর্দা চিবানোর কথা জানিয়েছেন। প্রদত্ত ছবিটি দেখুন, এবং নিম্নোক্ত প্রশ্নসমূহের উত্তর দিনঃ  A. এই রোগী কি রোগের জন্য দায়ী কোনো ঝুঁকি/কারন-এর কথা উল্লেখ করেছেন? *[যদি উত্তর "না" হয়, তবে PART C-তে চলে যান। যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান।]* ☐ হ্যাঁ ☐ না B. রোগীর ইতিহাসের ভিত্তিতে নীচে ঝুঁকির কারণগুলির উপর তথ্য রেকর্ড করুন **ধরনঃ** _____ কতবার **করেঃ** _____ কত সময় যাবৎ (দিন/মাস/বছর): _____ C. ছবিতে কি কোনো ক্ষত বা অন্য সমস্যা দেখা যাচ্ছে? *[যদি উত্তর "না" হয়, তবে PART J-তে চলে যান। যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান।]* ☐ হ্যাঁ ☐ না ☐ নিশ্চিত নই D. উক্ত ক্ষত বা সমস্যাটি মুখের কোন জায়গায় হয়েছে? ☐ জিহ্বা ☐ ঠোঁট ☐ তালু ☐ গালের ভেতরের দিকে

☐ জিহ্বার নীচে (ফ্লোর অফ দ্য মাউথ)

☐ অন্যান্যঃ _____

E. ক্ষত বা সমস্যাটির রং কী?

☐ সাদা
☐ লাল
☐ মিশ্র রং
☐ অন্যান্যঃ _____

F. এই ক্ষত বা সমস্যাটির আনুমানিক আকার কতটুকু?

☐ ৫ মিলিমিটার পর্যন্ত
☐ ৫ – ২০ মিলিমিটারের মধ্যে
☐ ২০ মিলিমিটারের বেশি
☐ অন্যান্যঃ _____

G. ক্ষত বা সমস্যাটির আকৃতি কেমন?

☐ গোল
☐ চারকোনা
☐ অন্যান্যঃ _____

H. ক্ষত বা সমস্যাটির পরিধি (ডিসট্রিবিউশন) কতটুকু এবং এর কিনারা/প্রান্ত (ডেফিনিশন, অর্থাৎ কীরূপে ডিফাইন্ড) কী ধরনের?

[প্রতিটি সারি থেকে একটি উত্তর নির্বাচন করে টিক চিহ্ন দিন]

☐ লোকালাইজড (একটি স্থানেই রয়েছে)	কিংবা	জেনারালাইজড (অন্যান্য স্থানে ছড়িয়ে গেছে)
☐ সিঙ্গেল (একটি ক্ষত বা সমস্যা)	কিংবা	একাধিক ক্ষত বা সমস্যা
☐ ওয়েল ডিফাইন্ড (কিনারা বা বর্ডার স্পষ্ট)	কিংবা	পুওরলি ডিফাইন্ড (কিনারা বা বর্ডার অস্পষ্ট)

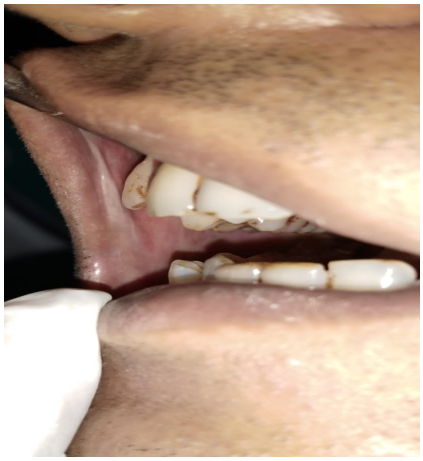
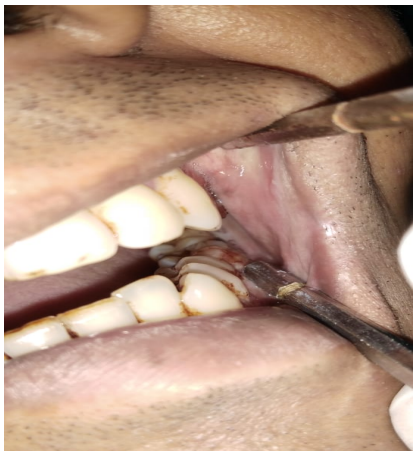
I. উপরোক্ত সকল তথ্যের ভিত্তিতে, আপনি ক্ষত বা সমস্যাটিকে কোন শ্রেণীভুক্ত করবেন?

☐ সন্দেহজনক নয়, বরং মুখের একটি সাধারণ ক্ষত বা সমস্যা
☐ সন্দেহজনক এবং সম্ভাব্য ম্যালিগনেন্ট (ক্যান্সার জাতীয়) সমস্যা
☐ ওরাল/মুখগহ্বরের ক্যান্সার
☐ অন্যান্যঃ _____

J: উক্ত রোগীর ওরাল/মুখগহ্বরের স্ক্রীনিং/রোগ-নির্ণয় –এর উপর ভিত্তি করে, আপনার পরবর্তী পদক্ষেপ কী হবে?

[প্রযোজ্য সকল উত্তরে টিক চিহ্ন দিন]

☐ রোগীকে নিয়মিতভাবে ফলোআপ করা
☐ রোগীর মাথা এবং ঘাড়ের স্বাস্থ্যগত অবস্থার বিষয়ে আরো বিস্তারিত অনুসন্ধানের জন্য তাকে রেফার করা
☐ কাউন্সিলিং (পরামর্শ প্রদান) এবং সাপোর্ট সার্ভিস (সহায়তামূলক সেবা) প্রাপ্তির জন্য রোগীকে রেফার করা
☐ তামাকগ্রহন বন্ধ করার জন্য রোগীকে সংক্ষিপ্ত আকারে পরামর্শ প্রদান
☐ অন্যান্যঃ _____

4.5	এটি ২৬ বছর বয়সী একজন পুরুষ রোগীর মুখগহ্বরের ছবি। মূল সমস্যা হিসেবে তিনি জানিয়েছেন যে, বিগত ১ বছর যাবৎ মুখের চেরা কমে এসেছে, অর্থাৎ হা করতে সমস্যা হয় অর্থাৎ অল্প হা করতে পারেন। অতীতের বিবরণী (হিস্ট্রি) হিসেবে তিনি বিগত ৮ বছর যাবৎ প্রতিদিন কমপক্ষে ৩-৪ বার করে পান-সুপারী এবং বিড়ি খাওয়ার কথা জানিয়েছেন। প্রদত্ত ছবিটি দেখুন, এবং নিম্নোক্ত প্রশ্নসমূহের উত্তর দিনঃ   ডান বাম A. এই রোগী কি রোগের জন্য দায়ী কোনো ঝুঁকি/কারন-এর কথা উল্লেখ করেছেন? *[যদি উত্তর "না" হয়, তবে PART C-তে চলে যান। যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান।]* ☐ হ্যাঁ ☐ না B. রোগীর ইতিহাসের ভিত্তিতে নীচে ঝুঁকির কারণগুলির উপর তথ্য রেকর্ড করুন **ধরনঃ** _____ কতবার **করেঃ** _____ কত সময় যাবৎ (দিন/মাস/বছর): _____ C. ছবিতে কি কোনো ক্ষত বা অন্য সমস্যা দেখা যাচ্ছে? *[যদি উত্তর "না" হয়, তবে PART J-তে চলে যান। যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান।]* ☐ হ্যাঁ ☐ না ☐ নিশ্চিত নই D. উক্ত ক্ষত বা সমস্যাটি মুখের কোন জায়গায় হয়েছে? ☐ জিহ্বা ☐ ঠোঁট ☐ তালু ☐ **গালের ভেতরের দিকে** ☐ জিহ্বার নীচে (ফ্লোর অফ দ্য মাউথ)

☐ অন্যান্যঃ _____

E. ক্ষত বা সমস্যাটির রং কী?

☐ সাদা
☐ লাল
☐ মিশ্র রং
☐ অন্যান্যঃ _____

F. এই ক্ষত বা সমস্যাটির আনুমানিক আকার কতটুকু?

☐ ৫ মিলিমিটার পর্যন্ত
☐ ৫ – ২০ মিলিমিটারের মধ্যে
☐ ২০ মিলিমিটারের বেশি
☐ অন্যান্যঃ _____

G. ক্ষত বা সমস্যাটির আকৃতি কেমন?

☐ গোল
☐ চারকোনা
☐ অন্যান্যঃ _____

H. ক্ষত বা সমস্যাটির পরিধি (ডিসট্রিবিউশন) কতটুকু এবং এর কিনারা/প্রান্ত (ডেফিনিশন, অর্থাৎ কীরূপে ডিফাইন্ড) কী ধরনের?

[প্রতিটি সারি থেকে একটি উত্তর নির্বাচন করে টিক চিহ্ন দিন]

☐ লোকালাইজড (একটি স্থানেই রয়েছে) কিংবা জেনারালাইজড (অন্যান্য স্থানে ছড়িয়ে গেছে)
☐ সিঙ্গেল (একটি ক্ষত বা সমস্যা) কিংবা একাধিক ক্ষত বা সমস্যা
☐ ওয়েল ডিফাইন্ড (কিনারা বা বর্ডার স্পষ্ট) কিংবা পুওরলি ডিফাইন্ড (কিনারা বা বর্ডার অস্পষ্ট)

I. উপরোক্ত সকল তথ্যের ভিত্তিতে, আপনি ক্ষত বা সমস্যাটিকে কোন শ্রেণীভুক্ত করবেন?

☐ সন্দেহজনক নয়, বরং মুখের একটি সাধারণ ক্ষত বা সমস্যা
☐ সন্দেহজনক এবং সম্ভাব্য ম্যালিগনেন্ট (ক্যান্সার জাতীয়) সমস্যা
☐ ওরাল/মুখগহ্বরের ক্যান্সার
☐ অন্যান্যঃ _____

J: উক্ত রোগীর ওরাল/মুখগহ্বরের স্ক্রীনিং/রোগ-নির্ণয় –এর উপর ভিত্তি করে, আপনার পরবর্তী পদক্ষেপ কী হবে?

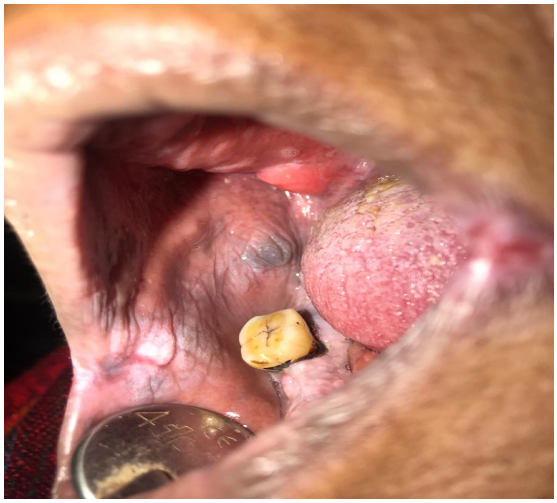
[প্রযোজ্য সকল উত্তরে টিক চিহ্ন দিন]

☐ রোগীকে নিয়মিতভাবে ফলোআপ করা
☐ রোগীর মাথা এবং ঘাড়ের স্বাস্থ্যগত অবস্থার বিষয়ে আরো বিস্তারিত অনুসন্ধানের জন্য তাকে রেফার করা
☐ কাউন্সিলিং (পরামর্শ প্রদান) এবং সাপোর্ট সার্ভিস (সহায়তামূলক সেবা) প্রাপ্তির জন্য রোগীকে রেফার করা
☐ তামাকগ্রহন বন্ধ করার জন্য রোগীকে সংক্ষিপ্ত আকারে পরামর্শ প্রদান

☐ অন্যান্যঃ _____

4.6

এটি ৭৪ বছর বয়সী একজন পুরুষ রোগীর মুখগহ্বরের ছবি, যিনি রেগুলার চেকআপ করাতে এসেছেন। অতীতের বিবরণী (হিস্ট্রি) হিসেবে তিনি বিগত ৪০ বছর যাবৎ প্রতিদিন কমপক্ষে ৪-৫ বার করে গুটখা এবং তামাক চিবানোর কথা জানিয়েছেন। প্রদত্ত ছবিটি দেখুন, এবং নিম্নোক্ত প্রশ্নসমূহের উত্তর দিনঃ



A. এই রোগী কি রোগের জন্য দায়ী কোনো ঝুঁকি/কারন-এর কথা উল্লেখ করেছেন?
[যদি উত্তর "না" হয়, তবে PART C-তে চলে যান। যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান।]

☐ হ্যাঁ
☐ না

B. রোগীর ইতিহাসের ভিত্তিতে নীচে ঝুঁকির কারণগুলির উপর তথ্য রেকর্ড করুন
ধরনঃ _____
কতবার **করেঃ** _____
কত সময় যাবৎ (দিন/মাস/বছর): _____

C. ছবিতে কি কোনো ক্ষত বা অন্য সমস্যা দেখা যাচ্ছে?
[যদি উত্তর "না" হয়, তবে PART J-তে চলে যান। যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান।]

☐ হ্যাঁ
☐ না
☐ নিশ্চিত নই

D. উক্ত ক্ষত বা সমস্যাটি মুখের কোন জায়গায় হয়েছে?

☐ জিহ্বা
☐ ঠোঁট
☐ তালু
☐ **গালের ভেতরের দিকে**

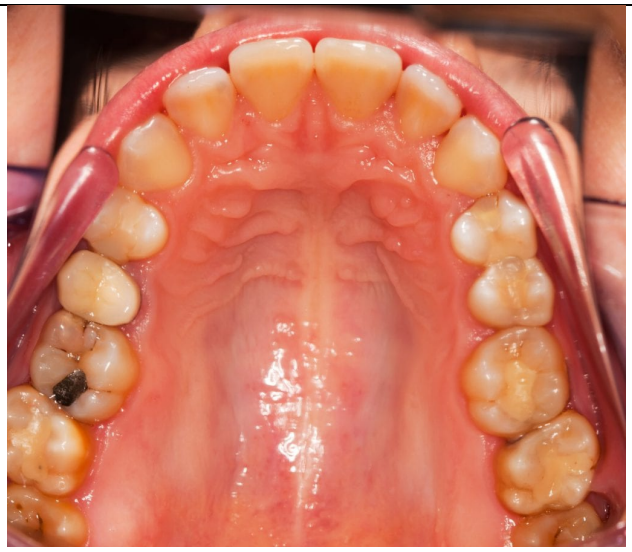
☐ জিহ্বার নীচে (ফ্লোর অফ দ্য মাউথ)

☐ অন্যান্যঃ _____

E. ক্ষত বা সমস্যাটির রং কী?

☐ সাদা
☐ লাল

	☐ মিশ্র রং ☐ অন্যান্যঃ _____ F. এই ক্ষত বা সমস্যাটির আনুমানিক আকার কতটুকু? ☐ ৫ মিলিমিটার পর্যন্ত ☐ ৫ – ২০ মিলিমিটারের মধ্যে ☐ ২০ মিলিমিটারের বেশি ☐ অন্যান্যঃ _____ G. ক্ষত বা সমস্যাটির আকৃতি কেমন? ☐ গোল ☐ চারকোনা ☐ অন্যান্যঃ _____ H. ক্ষত বা সমস্যাটির পরিধি (ডিসট্রিবিউশন) কতটুকু এবং এর কিনারা/প্রান্ত (ডেফিনিশন, অর্থাৎ কীরূপে ডিফাইন্ড) কী ধরনের? *[প্রতিটি সারি থেকে একটি উত্তর নির্বাচন করে টিক চিহ্ন দিন]* ☐ লোকালাইজড (একটি স্থানেই রয়েছে) কিংবা ☐ জেনারালাইজড (অন্যান্য স্থানে ছড়িয়ে গেছে) ☐ সিঙ্গেল (একটি ক্ষত বা সমস্যা) কিংবা ☐ একাধিক ক্ষত বা সমস্যা ☐ ওয়েল ডিফাইন্ড (কিনারা বা বর্ডার স্পষ্ট) কিংবা ☐ পুওরলি ডিফাইন্ড (কিনারা বা বর্ডার অস্পষ্ট) I. উপরোক্ত সকল তথ্যের ভিত্তিতে, আপনি ক্ষত বা সমস্যাটিকে কোন শ্রেণীভুক্ত করবেন? ☐ সন্দেহজনক নয়, বরং মুখের একটি সাধারণ ক্ষত বা সমস্যা ☐ সন্দেহজনক এবং সম্ভাব্য ম্যালিগনেন্ট (ক্যান্সার জাতীয়) সমস্যা ☐ ওরাল/মুখগহ্বরের ক্যান্সার ☐ অন্যান্যঃ _____ J: উক্ত রোগীর ওরাল/মুখগহ্বরের স্ক্রীনিং/রোগ-নির্ণয় –এর উপর ভিত্তি করে, আপনার পরবর্তী পদক্ষেপ কী হবে? *[প্রযোজ্য সকল উত্তরে টিক চিহ্ন দিন]* ☐ রোগীকে নিয়মিতভাবে ফলোআপ করা ☐ রোগীর মাথা এবং ঘাড়ের স্বাস্থ্যগত অবস্থার বিষয়ে আরো বিস্তারিত অনুসন্ধানের জন্য তাকে রেফার করা ☐ কাউন্সিলিং (পরামর্শ প্রদান) এবং সাপোর্ট সার্ভিস (সহায়তামূলক সেবা) প্রাপ্তির জন্য রোগীকে রেফার করা ☐ তামাকগ্রহন বন্ধ করার জন্য রোগীকে সংক্ষিপ্ত আকারে পরামর্শ প্রদান ☐ অন্যান্যঃ _____
4.7	এটি ২৪ বছর বয়সী একজন পুরুষ রোগীর মুখগহ্বরের ছবি, যিনি রেগুলার চেকআপ করাতে এসেছেন। তাঁর উপরের পাটির ৩টি দাঁতে ফিলিং করানো আছে। তাঁর কোনোরূপ ধূমপান বা তামাকপণ্য চিবানোর অতীত ইতিহাস (হিস্ট্রি) নেই। প্রদত্ত ছবিটি দেখুন, এবং নিম্নোক্ত প্রশ্নসমূহের উত্তর দিনঃ



A. এই রোগী কি রোগের জন্য দায়ী কোনো ঝুঁকি/কারন-এর কথা উল্লেখ করেছেন?
[যদি উত্তর "না" হয়, তবে PART C-তে চলে যান/ যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান/]

☐ হ্যাঁ
☐ না

B. রোগের জন্য দায়ী কোনো ঝুঁকি/কারন বিষয়ক তথ্য নিম্নে লিপিবদ্ধ করুনঃ

ধরনঃ _____
কতবার করেঃ _____
কত সময় যাবৎ (দিন/মাস/বছর): _____

C. ছবিতে কি কোনো ক্ষত বা অন্য সমস্যা দেখা যাচ্ছে?
[যদি উত্তর "না" হয়, তবে PART J-তে চলে যান/ যদি উত্তর "হ্যাঁ" হয়, তবে পরবর্তী প্রশ্নে চলে যান/]

☐ হ্যাঁ
☐ না
☐ নিশ্চিত নই

D. উক্ত ক্ষত বা সমস্যাটি মুখের কোন জায়গায় হয়েছে?

☐ জিহ্বা
☐ ঠোঁট
☐ তালু
☐ **গালের ভেতরের দিকে**

☐ জিহ্বার নীচে (ফ্লোর অফ দ্য মাউথ)

☐ অন্যান্যঃ _____

E. ক্ষত বা সমস্যাটির রং কী?

☐ সাদা
☐ লাল
☐ মিশ্র রং

☐ অন্যান্যঃ _____

F. এই ক্ষত বা সমস্যাটির আনুমানিক আকার কতটুকু?

☐ ৫ মিলিমিটার পর্যন্ত
☐ ৫ – ২০ মিলিমিটারের মধ্যে
☐ ২০ মিলিমিটারের বেশি
☐ অন্যান্যঃ _____

G. ক্ষত বা সমস্যাটির আকৃতি কেমন?

☐ গোল
☐ চারকোনা
☐ অন্যান্যঃ _____

H. ক্ষত বা সমস্যাটির পরিধি (ডিসট্রিবিউশন) কতটুকু এবং এর কিনারা/প্রান্ত (ডেফিনিশন, অর্থাৎ কীরূপে ডিফাইন্ড) কী ধরনের?

[প্রতিটি সারি থেকে একটি উত্তর নির্বাচন করে টিক চিহ্ন দিন]

☐ লোকালাইজড (একটি স্থানেই রয়েছে) কিংবা ☐ জেনারালাইজড (অন্যান্য স্থানে ছড়িয়ে গেছে)
☐ সিঙ্গেল (একটি ক্ষত বা সমস্যা) কিংবা ☐ একাধিক ক্ষত বা সমস্যা
☐ ওয়েল ডিফাইন্ড (কিনারা বা বর্ডার স্পষ্ট) কিংবা ☐ পুওরলি ডিফাইন্ড (কিনারা বা বর্ডার অস্পষ্ট)

I. উপরোক্ত সকল তথ্যের ভিত্তিতে, আপনি ক্ষত বা সমস্যাটিকে কোন শ্রেণীভুক্ত করবেন?

☐ সন্দেহজনক নয়, বরং মুখের একটি সাধারণ ক্ষত বা সমস্যা
☐ সন্দেহজনক এবং সম্ভাব্য ম্যালিগনেন্ট (ক্যান্সার জাতীয়) সমস্যা
☐ ওরাল/মুখগহ্বরের ক্যান্সার
☐ অন্যান্যঃ _____

J: উক্ত রোগীর ওরাল/মুখগহ্বরের স্ক্রীনিং/রোগ-নির্ণয় –এর উপর ভিত্তি করে, আপনার পরবর্তী পদক্ষেপ কী হবে?

[প্রযোজ্য সকল উত্তরে টিক চিহ্ন দিন]

☐ রোগীকে নিয়মিতভাবে ফলোআপ করা
☐ রোগীর মাথা এবং ঘাড়ের স্বাস্থ্যগত অবস্থার বিষয়ে আরো বিস্তারিত অনুসন্ধানের জন্য তাকে রেফার করা
☐ কাউন্সিলিং (পরামর্শ প্রদান) এবং সাপোর্ট সার্ভিস (সহায়তামূলক সেবা) প্রাপ্তির জন্য রোগীকে রেফার করা
☐ তামাকগ্রহন বন্ধ করার জন্য রোগীকে সংক্ষিপ্ত আকারে পরামর্শ প্রদান

☐ অন্যান্যঃ _____

জরিপে অংশগ্রহন করার জন্য আপনাকে আন্তরিক ধন্যবাদ।

APPENDIX 25

INTERVIEW WITH THE COMMUNITY HEALTH WORKERS

TOPIC GUIDE

INTRODUCTION

Thank you for taking part in this study. My name is Zainab Kidwai, and I am a research student at the University of York, United Kingdom. I am carrying out a research study to understand the attitudes and experiences of Community Health Workers on attending online training for oral cancer screening. The interview is very informal and completely confidential. Your name will not appear on anything I write. With your permission, I would like to record the interview. The digital recording will be stored securely and will only be shared with colleagues in the research team. The interview should take approximately 45 minutes to an hour. Can I just confirm that you are still willing to participate in this interview and that you are aware and happy for the interview to be recorded?

ICEBREAKER

- Can I start by asking you to tell me a bit about yourself?
    - Why did you decide to become a Community Health Worker?
    - How long have you been in this profession?
    - How has your experience as a CHW been overall?
    - What are your current title and responsibilities?
    - How does being a CHW fit into the rest of your life?

SECTION: ACCESS TO RESOURCES

- Talk me through the registration process. How was your experience registering for this workshop?
    - Was it easy or difficult?
    - Why do you think it was so?
    - What can be done to improve it?
- Let's talk about the technology--How did you access the training course and course materials?
    - What equipment did you use to access it? E.g., a laptop, a computer, or a smartphone.
    - Did this equipment belong to you?
- How did you access the online web-based internet?
    - Was it free or did you have to pay for the internet?
- How did technology affect your uptake of the course?
    - Did it make it easy or difficult?
    - Did you find it engaging?
    - What can be done to improve it?
- Let's talk about the environment
    - Where did you attend the training from? E.g., Workplace, home, other.
    - What was the time?
    - Did you have any prior commitments during that time?
    - How did the commitments affect the uptake of the course?
    - Did you like the settings of the environment? What can be done to improve it?

SECTION 1: EXPERIENCE IN USING A WEB-BASED TRAINING PLATFORM FOR ORAL CANCER SCREENING

- Have you previously participated in an online workshop? If yes, when?
    - What was this training on?

    - How would you compare today's training to the previous one you attended?
- Overall, what has been your experience of getting trained remotely?
    - Were you able to follow what was taught?
    - Were you able to ask questions and interact with the tutor?
    - How confident are you in using web resources?
- How did you feel about filling out the online survey?
    - How well did it go?
    - How long did it take to fill it? Was the time enough? Did you need more time?
    - Was the language appropriate or not?
    - Was the length of the questionnaire okay?
    - Was it relevant to the training programme or not?
    - Overall, what worked well?
    - What worked less well?
    - How can we improve it?

SECTION 2: CONTENT OF THE TRAINING

- Describe for me the overall training in terms of knowledge and skill improvement.
    - Do you feel this course gave you the required knowledge for the task?
    - What was the most important part of the course?
    - Is there anything which was too complicated for you to understand?
    - Was there information that was already known to you?
    - Was the information given enough?
    - If not, what else should be included in the training?
- Have you received training on this topic before or have you read about this topic before?
    - If yes, then where did you hear it from?
    - Was there any difference between the content?
    - If yes, what was different?
- We used PowerPoint, video and PDF to deliver this course. How did you feel about it?
    - Do you think it was helpful?
    - If yes, what was helpful about it?
    - How well did the resources work? Why is that?
    - What worked well?
    - What worked less well?
    - How can we improve these resources? What can we change? (*Prompts: Add or remove pictures, words etc.)*

SECTION 3: TRAINING SESSIONS

- Let's talk about the training sessions now. Were the number of sessions sufficient?
    - Would you have preferred more (how many?) or fewer sessions?
- Was the duration of each session sufficient?
    - Would you have preferred a longer or shorter duration?
- Were the breaks sufficient?
    - How many breaks would you prefer?
    - Would you prefer a longer or shorter break?
    - How did you utilise the break time?

SECTION 4: THE SCREENING PROCESS

- How useful do you think this is in detecting oral cancer and Oral Potentially Malignant Disorders?

- Have you done anything similar before in the role you are currently in?
- How well do you think patients would receive this?
- Who could support you in doing this better?
- What do you think would be the challenges?
    - How do you think we can plan ahead for them?
- Has the training improved your confidence in performing oral screening?
    - On a scale of 1 to 5, with 1 being least confident and 5 being most confident, how would you rate your oral screening skills?
    - How do you think the training has improved your understanding of the disease itself?
    - How do you think it has improved the application of your ability to perform oral screening?
- If you spot a suspicious lesion, what will be your next course of action?
    - How will you reassure the patient?
    - Do you know if there are any counselling services or psychological support available?
    - How would you make a referral?
    - Where would you refer them?
    - Do you know of existing services where you can refer to such cases?
- Usually, do you advise people on quitting tobacco?
    - If you do, what strategy do you use?
    - If not, how would you advise them on quitting tobacco?
    - In your opinion, how will people receive the advice given?
    - Do you think people will follow this?

<u>SECTION 5: FIELDWORK DURING THE PANDEMIC</u>

- Thinking about the current pandemic, how has it impacted the way you conduct fieldwork?
- What are the challenges of undertaking your responsibilities in these times?
    - What support would you need to do this in the field?

<u>SECTION 7: RECOMMENDATIONS FOR FUTURE</u>

- How do you feel about the training being included in the current Community Health Worker programme?
    - Can you tell us a few positives and issues of concern regarding this?
    - How can this be made more viable?
- Would you like to take part in a future trial of this research?
    - If yes, why?
    - If not, why not?

<u>CLOSING REMARKS</u>

Is there anything else, you think we should be thinking about the training?

APPENDIX 26

Table 65: List of variables

Index	name	type	label	Variable label
1	PrePart_ID	int		Participant_ID
2	Pre_a	string		Form completed
3	Pre_b	string		Research officer
4	Pre_c	string	study_site	Study Site
5	Pre_Q1_1	byte	age	How old are you?
6	Pre_Q1_2	byte	gender	Participant's gender
7	Pre_Q1_3	byte	level_of_edu	What is the highest level of education you have completed?
8	Pre_Q1_3_1	string		Others, please specify:
9	Pre_Q1_4	byte	work_exp	How many years have you worked as a Community Health Worker?
10	Pre_Q1_5	byte	prev_training	Have you attended an oral cancer training programme or oral cancer awareness/education session before?
11	Pre_Q1_6	byte	most_rec_training	When was your most recent training or awareness programme on oral cancer?
12	Pre_Q1_7a	byte	knowledge_rf	What is your self-assessment of your current Knowledge of risk factors of oral cancer?
13	Pre_Q1_7b	byte	knowledge_ss	What is your self-assessment of your current Knowledge of clinical signs and symptoms of oral cancer?
14	Pre_Q1_7c	byte	knowledge_ed	What is your self-assessment of your current Knowledge of early detection and screening process?
15	Pre_Q1_7d	byte	knowledge_diag	What is your self-assessment of your current Knowledge of diagnosis, referral and treatment modalities?

16	Pre_Q1_8	byte	future_int	Would you be interested in attending an oral cancer screening workshop in the future?
17	Pre_Q1_9	byte	workshop_format	What format would you prefer for the workshop?
18	Pre_Q1_9_1	string		Other:
19	Pre_Q1_10	byte	level_of_imp	In your opinion, what is the level of importance of Community Health Workers in the prevention and diagnosis of early signs of oral cancer?
20	Pre_Q2_1	byte	common_site	What are the common sites for developing oral cancer and Oral Potentially Malignant Disorders?
21	Pre_Q2_2	byte	pred_agegroup	What is the predominant age-group in which these lesions occur?
22	Pre_Q2_3	byte	not_earlysign	Which of the following is NOT an early sign of oral cancer and Oral Potentially Malignant Disorders?
23	Pre_Q2_4	byte	not_riskfactor	Which of the following is NOT the risk factor for oral cancer and Oral Potentially Malignant Disorders?
24	Pre_Q2_5	byte	malig_trans	Which of the following potentially malignant lesion has the highest rate of malignant transformation?
25	Pre_Q3_1	byte	pop_screening	Which of the following is the most affordable, feasible, and effective method for population-based screening of oral cancer?
26	Pre_Q3_2	byte	instruments	Which of the following instruments should be used for conducting thorough oral screening?
27	Pre_Q3_3	byte	first_step_screening	Which of these should be the first step in conducting oral screening?
28	Pre_Q3_4	byte	extra_oral	Which of these will you observe during the extra- oral examination?

29	Pre_Q3_5	byte	susp_lesion	When observing a suspicious lesion, which of these will you note?
30	Pre_Q3_6	byte	first_step_lips	What should be the first step when examining the lips?
31	Pre_Q3_7	byte	refer_case	If you detect a suspicious lesion, where should you first refer the case?
32	Pre_Q3_8	byte	disease_prog	How useful would you say early detection of oral cancer and Oral Potentially Malignant Disorders is in improving disease prognosis?
33	Pre_Q3_9	byte	info_prevention	How informed are you about prevention and early detection of oral cancer and Oral Potentially Malignant Disorders?
34	Pre_Q3_10	byte	conf_screening	How confident are you in performing screening procedures to detect oral cancer and pre-cancers?
35	Pre_Q3_11	byte	conf_history	How confident are you in taking medical and dental history of a patient?
36	Pre_Q3_12	byte	conf_talking	How confident are you in talking to a patient and telling them the results of screening?
37	Pre_Q3_13	byte	conf_referring	How confident are you in referring a patient to the healthcare services?
38	Pre_Q3_14	byte	conf_advise	How confident are you in delivering any kind of educational advice to the patient following screening?
39				
40	PostPart_ID	int		Participant_ID
41	Post_a	string		Form completed
42	Post_b	string		Research officer
43	Post_c	string	study_site	Study Site

44	Post_Q1_1	byte	age	How old are you?
45	Post_Q1_2	byte	gender	Participant's gender
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71	Post_Q3_8	byte	disease_prog	How useful would you say early detection of oral cancer and Oral Potentially Malignant Disorders is in improving disease prognosis?
72	Post_Q3_9	byte	info_prevention	How informed are you about prevention and early detection of oral cancer and Oral Potentially Malignant Disorders?
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74	Post_Q3_11	byte	conf_history	How confident are you in taking medical and dental history of a patient?
75	Post_Q3_12	byte	conf_talking	How confident are you in talking to a patient and telling them the results of screening?
76	Post_Q3_13	byte	conf_referring	How confident are you in referring a patient to the healthcare services?
77	Post_Q3_14	byte	conf_advise	How confident are you in delivering any kind of educational advice to the patient following screening?
78	Post_Q4_1a	byte	history_rf	Does the patient give history of any risk factors?
79	Post_Q4_1b_a	byte	info_type	Record information on risk factors_Type
80	Post_Q4_1b_b	byte	info_frequency	Record information on risk factors_Frequency
81	Post_Q4_1b_c	byte	info_duration	Record information on risk factors_Duration
82	Post_Q4_1c	byte	lesion_present	Is there a lesion present?
83	Post_Q4_1d	byte	lesion_location	What is the location of the lesion?
84	Post_Q4_1d_1	string		Other
85	Post_Q4_1d_2	byte	mouth_map	Mouth Map

86	Post_Q4_1e	byte	lesion_colour	What is the colour of the lesion?
87	Post_Q4_1e_1	string		Other
88	Post_Q4_1f	byte	lesion_size	What is the approximate size of the lesion?
89	Post_Q4_1f_1	string		Other
90	Post_Q4_1g	byte	lesion_shape	What is the shape of the lesion?
91	Post_Q4_1g_1	string		Other
92	Post_Q4_1h_a	byte	lesion_lg	What is the distribution and definition of the lesion (Localised/Generalised)?
93	Post_Q4_1h_b	byte	lesion_sm	What is the distribution and definition of the lesion (Single/Multiple)?
94	Post_Q4_1h_c	byte	lesion_wp	What is the distribution and definition of the lesion (Well-defined/Poorly defined?
95	Post_Q4_1i	byte	lesion_classification	Based on the above information, how will you classify the lesion?
96	Post_Q4_1i_1	string		Other
97	Post_Q4_1j	byte	next_steps	Based on the result of oral screening, what should you do next?
98	Post_Q4_1j_1	string		Other
99	Post_Q4_2a	byte	history_rf	Does the patient give history of any risk factors?
100	Post_Q4_2b_a	byte	info_type	Record information on risk factors_Type
101	Post_Q4_2b_b	byte	info_frequency	Record information on risk factors_Frequency
102	Post_Q4_2b_c	byte	info_duration	Record information on risk factors_Duration
103	Post_Q4_2c	byte	lesion_present	Is there a lesion present?
104	Post_Q4_2d	byte	lesion_location	What is the location of the lesion?
105	Post_Q4_2d_1	string		Other

106	Post_Q4_2d_2	byte	mouth_map	Mouth Map
107	Post_Q4_2e	byte	lesion_colour	What is the colour of the lesion?
108	Post_Q4_2e_1	string		Other
109	Post_Q4_2f	byte	lesion_size	What is the approximate size of the lesion?
110	Post_Q4_2f_1	string		Other
111	Post_Q4_2g	byte	lesion_shape	What is the shape of the lesion?
112	Post_Q4_2g_1	string		Other
113	Post_Q4_2h_a	byte	lesion_lg	What is the distribution and definition of the lesion (Localised/Generalised)?
114	Post_Q4_2h_b	byte	lesion_sm	What is the distribution and definition of the lesion (Single/Multiple)?
115	Post_Q4_2h_c	byte	lesion_wp	What is the distribution and definition of the lesion (Well-defined/Poorly defined?
116	Post_Q4_2i	byte	lesion_classification	Based on the above information, how will you classify the lesion?
117	Post_Q4_2i_1	string		Other
118	Post_Q4_2j	byte	next_steps	Based on the result of oral screening, what should you do next?
119	Post_Q4_2j_1	string		Other
120	Post_Q4_3a	byte	history_rf	Does the patient give history of any risk factors?
121	Post_Q4_3b_a	byte	info_type	Record information on risk factors_Type
122	Post_Q4_3b_b	byte	info_frequency	Record information on risk factors_Frequency
123	Post_Q4_3b_c	byte	info_duration	Record information on risk factors_Duration
124	Post_Q4_3c	byte	lesion_present	Is there a lesion present?
125	Post_Q4_3d	byte	lesion_location	What is the location of the lesion?

126	Post_Q4_3d_1	string		Other
127	Post_Q4_3d_2	byte	mouth_map	Mouth Map
128	Post_Q4_3e	byte	lesion_colour	What is the colour of the lesion?
129	Post_Q4_3e_1	string		Other
130	Post_Q4_3f	byte	lesion_size	What is the approximate size of the lesion?
131	Post_Q4_3f_1	string		Other
132	Post_Q4_3g	byte	lesion_shape	What is the shape of the lesion?
133	Post_Q4_3g_1	string		Other
134	Post_Q4_3h_a	byte	lesion_lg	What is the distribution and definition of the lesion (Localised/Generalised)?
135	Post_Q4_3h_b	byte	lesion_sm	What is the distribution and definition of the lesion (Single/Multiple)?
136	Post_Q4_3h_c	byte	lesion_wp	What is the distribution and definition of the lesion (Well-defined/Poorly defined?
137	Post_Q4_3i	byte	lesion_classification	Based on the above information, how will you classify the lesion?
138	Post_Q4_3i_1	string		Other
139	Post_Q4_3j	byte	next_steps	Based on the result of oral screening, what should you do next?
140	Post_Q4_3j_1	string		Other
141	Post_Q4_4a	byte	history_rf	Does the patient give history of any risk factors?
142	Post_Q4_4b_a	byte	info_type	Record information on risk factors_Type
143	Post_Q4_4b_b	byte	info_frequency	Record information on risk factors_Frequency
144	Post_Q4_4b_c	byte	info_duration	Record information on risk factors_Duration
145	Post_Q4_4c	byte	lesion_present	Is there a lesion present?

146	Post_Q4_4d	byte	lesion_location	What is the location of the lesion?
147	Post_Q4_4d_1	string		Other
148	Post_Q4_4d_2	byte	mouth_map	Mouth Map
149	Post_Q4_4e	byte	lesion_colour	What is the colour of the lesion?
150	Post_Q4_4e_1	string		Other
151	Post_Q4_4f	byte	lesion_size	What is the approximate size of the lesion?
152	Post_Q4_4f_1	string		Other
153	Post_Q4_4g	byte	lesion_shape	What is the shape of the lesion?
154	Post_Q4_4g_1	string		Other
155	Post_Q4_4h_a	byte	lesion_lg	What is the distribution and definition of the lesion (Localised/Generalised)?
156	Post_Q4_4h_b	byte	lesion_sm	What is the distribution and definition of the lesion (Single/Multiple)?
157	Post_Q4_4h_c	byte	lesion_wp	What is the distribution and definition of the lesion (Well-defined/Poorly defined?
158	Post_Q4_4i	byte	lesion_classification	Based on the above information, how will you classify the lesion?
159	Post_Q4_4i_1	string		Other
160	Post_Q4_4j	byte	next_steps	Based on the result of oral screening, what should you do next?
161	Post_Q4_4j_1	string		Other
162	Post_Q4_5a	byte	history_rf	Does the patient give history of any risk factors?
163	Post_Q4_5b_a	byte	info_type	Record information on risk factors_Type
164	Post_Q4_5b_b	byte	info_frequency	Record information on risk factors_Frequency
165	Post_Q4_5b_c	byte	info_duration	Record information on risk factors_Duration

166	Post_Q4_5c	byte	lesion_present	Is there a lesion present?
167	Post_Q4_5d	byte	lesion_location	What is the location of the lesion?
168	Post_Q4_5d_1	string		Other
169	Post_Q4_5d_2	byte	mouth_map	Mouth Map
170	Post_Q4_5e	byte	lesion_colour	What is the colour of the lesion?
171	Post_Q4_5e_1	string		Other
172	Post_Q4_5f	byte	lesion_size	What is the approximate size of the lesion?
173	Post_Q4_5f_1	string		Other
174	Post_Q4_5g	byte	lesion_shape	What is the shape of the lesion?
175	Post_Q4_5g_1	string		Other
176	Post_Q4_5h_a	byte	lesion_lg	What is the distribution and definition of the lesion (Localised/Generalised)?
177	Post_Q4_5h_b	byte	lesion_sm	What is the distribution and definition of the lesion (Single/Multiple)?
178	Post_Q4_5h_c	byte	lesion_wp	What is the distribution and definition of the lesion (Well-defined/Poorly defined?
179	Post_Q4_5i	byte	lesion_classification	Based on the above information, how will you classify the lesion?
180	Post_Q4_5i_1	string		Other
181	Post_Q4_5j	byte	next_steps	Based on the result of oral screening, what should you do next?
182	Post_Q4_5j_1	string		Other
183	Post_Q4_6a	byte	history_rf	Does the patient give history of any risk factors?
184	Post_Q4_6b_a	byte	info_type	Record information on risk factors_Type
185	Post_Q4_6b_b	byte	info_frequency	Record information on risk factors_Frequency

186	Post_Q4_6b_c	byte	info_duration	Record information on risk factors_Duration
187	Post_Q4_6c	byte	lesion_present	Is there a lesion present?
188	Post_Q4_6d	byte	lesion_location	What is the location of the lesion?
189	Post_Q4_6d_1	string		Other
190	Post_Q4_6d_2	byte	mouth_map	Mouth Map
191	Post_Q4_6e	byte	lesion_colour	What is the colour of the lesion?
192	Post_Q4_6e_1	string		Other
193	Post_Q4_6f	byte	lesion_size	What is the approximate size of the lesion?
194	Post_Q4_6f_1	string		Other
195	Post_Q4_6g	byte	lesion_shape	What is the shape of the lesion?
196	Post_Q4_5g_1	string		Other
197	Post_Q4_6h_a	byte	lesion_lg	What is the distribution and definition of the lesion (Localised/Generalised)?
198	Post_Q4_6h_b	byte	lesion_sm	What is the distribution and definition of the lesion (Single/Multiple)?
199	Post_Q4_6h_c	byte	lesion_wp	What is the distribution and definition of the lesion (Well-defined/Poorly defined?
200	Post_Q4_6i	byte	lesion_classification	Based on the above information, how will you classify the lesion?
201	Post_Q4_6i_1	string		Other
202	Post_Q4_6j	byte	next_steps	Based on the result of oral screening, what should you do next?
203	Post_Q4_6j_1	string		Other
204	Post_Q4_7a	byte	history_rf	Does the patient give history of any risk factors?
205	Post_Q4_7b_a	byte	info_type	Record information on risk factors_Type

206	Post_Q4_7b_b	byte	info_frequency	Record information on risk factors_Frequency
207	Post_Q4_7b_c	byte	info_duration	Record information on risk factors_Duration
208	Post_Q4_7c	byte	lesion_present	Is there a lesion present?
209	Post_Q4_7d	byte	lesion_location	What is the location of the lesion?
210	Post_Q4_7d_1	string		Other
211	Post_Q4_7d_2	byte	mouth_map	Mouth Map
212	Post_Q4_7e	byte	lesion_colour	What is the colour of the lesion?
213	Post_Q4_7e_1	string		Other
214	Post_Q4_7f	byte	lesion_size	What is the approximate size of the lesion?
215	Post_Q4_7f_1	string		Other
216	Post_Q4_7g	byte	lesion_shape	What is the shape of the lesion?
217	Post_Q4_7g_1	string		Other
218	Post_Q4_7h_a	byte	lesion_lg	What is the distribution and definition of the lesion (Localised/Generalised)?
219	Post_Q4_7h_b	byte	lesion_sm	What is the distribution and definition of the lesion (Single/Multiple)?
220	Post_Q4_7h_c	byte	lesion_wp	What is the distribution and definition of the lesion (Well-defined/Poorly defined?
221	Post_Q4_7i	byte	lesion_classification	Based on the above information, how will you classify the lesion?
222	Post_Q4_7i_1	string		Other
223	Post_Q4_7j	byte	next_steps	Based on the result of oral screening, what should you do next?
224	Post_Q4_7j_1	string		Other

label	list		Value label
study_site	1	Bangladesh	
	2	India	
gender	1	male	mf
	2	female	
			npmsh
level_of_edu	1	No formal education	
	2	Primary (class 1-5)	
	3	Middle (class 6-8)	
	4	Secondary (class 9-10)	
	5	Higher (class 11 & above)	
work_exp	1	Less than 12 months	lbbm
	2	Between 1-3 years	
	3	Between 4-5 years	
	4	More than 5 years	
prev_training	1	Yes	yn
	2	No	
most_rec_training	1	In the last 12 months	i12t
	2	13-24 months ago	
	3	>24 months ago	
	4	This is my first time attending	
knowledge_rf	1	Excellent	egfp
	2	Good	
	3	Fair	
	4	Poor	

knowledge_ss	1	Excellent	egfp
	2	Good	
	3	Fair	
	4	Poor	
knowledge_ed	1	Excellent	egfp
	2	Good	
	3	Fair	
	4	Poor	
knowledge_diag	1	Excellent	egfp
	2	Good	
	3	Fair	
	4	Poor	
future_int	1	Yes	yni
	2	No	
	3	I am not sure	
workshop_format	1	Online	ofh
	2	Face to face	
	3	Hybrid	
level_of_imp	1	High	hmfl
	2	Medium	
	3	Fair	
	4	Low	
common_site	1	Tongue	tfba
	2	Floor of the mouth	
	3	Buccal mucosa	

	4	All of the above	
pred_agegroup	1	Less than 18 years	l1mn
	2	18 to 39 years	
	3	More than 40 years	
	4	None of the above	
not_earlysign	1	White patch in the mouth	wrap
	2	Red patch in the mouth	
	3	A non-healing ulcer	
	4	Pain in the abdomen	
not_riskfactor	1	Alcohol	atac
	2	Tobacco	
	3	Areca nut	
	4	Consumption of fruits and vegetables	
malig_trans	1	Oral submucous fibrosis	oelo
	2	Erythroplakia	
	3	Leukoplakia	
	4	Oral lichen planus	
pop_screening	1	Biopsy	bovc
	2	Oral Visual Examination	
	3	Vital staining	
	4	Cytology	
instruments	1	Mouth mirror	mgta
	2	Gauze	
	3	Tongue blade	
	4	All of the above	

first_step_screening	1	Taking oral history	tppc
	2	Performing intra-oral examination	
	3	Performing extra-oral examination	
	4	Charting lesion on a mouth map	
extra_oral	1	Enlarged lymph nodes	esua
	2	Swelling of face and jaws	
	3	Ulceration and sores on head and neck	
	4	All of the above	
susp_lesion	1	Colour of the lesion	clsa
	2	Location of the lesion	
	3	Size of the lesion	
	4	All of the above	
first_step_lips	1	Reverting the lip and inspecting the inner surface	ripn
	2	Inspecting the gingivolabial sulcus, the gingival mucosa, and the teeth	
	3	Palpating the lip with your thumb and index finger	
	4	None of the above	
refer_case	1	Ask the patient to visit later for follow up	apan
	2	Primary Health Centre	
	3	Ask the patient to visit a private dentist	
	4	None of the above	
disease_prog	1	Not at all useful	nsmve
	2	Slightly useful	
	3	Moderately useful	
	4	Very useful	
	5	Extremely useful	

info_prevention	1	Not informed at all	nsiv
	2	Somewhat informed	
	3	Informed	
	4	Very Informed	
conf_screening	1	Not at all confident	nssfc
	2	Slightly confident	
	3	Somewhat confident	
	4	Fairly confident	
	5	Completely confident	
conf_history	1	Not at all confident	nssfc
	2	Slightly confident	
	3	Somewhat confident	
	4	Fairly confident	
	5	Completely confident	
conf_talking	1	Not at all confident	nssfc
	2	Slightly confident	
	3	Somewhat confident	
	4	Fairly confident	
	5	Completely confident	
conf_referring	1	Not at all confident	nssfc
	2	Slightly confident	
	3	Somewhat confident	
	4	Fairly confident	
	5	Completely confident	
conf_advise	1	Not at all confident	nssfc
	2	Slightly confident	

	3	Somewhat confident	
	4	Fairly confident	
	5	Completely confident	
history_rf	1	Yes	yn
	2	No	
lesion_present	1	Yes	yni
	2	No	
	3	I am not sure	
lesion_location	1	Tongue	tlpbf
	2	Lips	
	3	Palate	
	4	Buccal Mucosa	
	5	Floor of the mouth	
mouth_map	1	Upper lip	
	2	Upper labial mucosa	
	3	Upper vestibule	
	4	Upper gingiva	
	5	Hard palate	
	6	Soft palate	
	7	Right buccal mucosa	
	8	Left buccal mucosa	
	9	Dorsal tongue	
	10	Lateral border of tongue	
	11	Lower lip	
	12	Lower labial mucosa	
	13	Lower vestibule	
	14	Lower gingiva	

	15	Ventral surface of tongue	
	16	Floor of mouth	
lesion_colour	1	White	wrm
	2	Red	
	3	Mixed	
lesion_size	1	Up to 5 mm	ubm
	2	Between 5-20 mm	
	3	More than 20 mm	
lesion_shape	1	Round	rr
	2	Rectangular	
lesion_lg	1	Localized	lg
	2	Generalized	
lesion_sm	1	Single	sm
	2	Multiple	
lesion_wp	1	Well-defined	wp
	2	Poorly-defined	
lesion_classification	1	Non-suspicious oral lesion	nso
	2	Suspicious Oral Potentially Malignant Lesion	
	3	Oral Cancer	
next_steps	1	Routine follow-up of patient	rrrg
	2	Refer patient for further head and neck evaluation	
	3	Refer to counselling and support services	
	4	Give brief advice on tobacco cessation	

APPENDIX 27

ETHICS APPLICATION AND APPROVAL

DEPARTMENT OF HEALTH SCIENCES

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17 December 2019

Miss Z Kidwai

University of York

Department of Health Sciences

York YO10 5DD

Dear Zainab

HSRGC/2019/355/D: **Early detection of Oral Potentially Malignant Disorders by Community Health Workers in India**

Thank you for your email of 17 December, including responses to the remaining issues with your study, which I raised in my Chair's Action letter of 30 November.

Having reviewed your responses, I am pleased to approve the project by Chair's Action. I had two feedback points:

- I would suggest you include a few more details in the Information Sheets under, 'What will be involved if I take part in this study?' In particular, you should state where the FGDs will take place (participants will be reimbursed travel expenses, but I couldn't see where they are informed as to how far they will have to travel).
- The Information Sheet equivocates over confidentiality: 'Participant confidentiality means that any data that you provide shall be made anonymous and cannot be linked to you' *versus* 'confidential information […] means that we will not share the information with anyone outside the research team'. There is no problem here, because data are clearly well managed, but it is important to get terms such as 'confidential', 'anonymous' and 'linked' clear in order to avoid misleading participants.

If you have any queries about this Chair's Action, or make any substantial changes to the study, please contact me. In the meantime, many thanks to you and your supervisors for engaging so positively with the HSRGC.

Yours sincerely

Stephen Holland
Chair: HSRGC

cc. Prof K Siddiqi, Dr M Kanaan, Dr N Mdege

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30 September 2021

Zainab Kidwai
PhD Candidate, Department of Health Sciences,
University of York, UK
Email: zainab.kidwai@york.ac.uk

Title: Feasibility and acceptability of remotely training non-specialist health workers for screening of Oral Potentially Malignant Disorders due to tobacco use.

Dear Zainab Kidwai,

The Institutional Review Board of the Institute of Health Economics (IHE-IRB), which is approved by the U.S. Department of Health and Human Services Federalwide Assurance (FWA), No. FWA00026031 had reviewed your submissions, both the initial and the subsequent in response to the IHE-IRB's comments for the ethical approval of the proposal "Feasibility and acceptability of remotely training non-specialist health workers for screening of Oral Potentially Malignant Disorders due to tobacco use."

IHE-IRB is providing the ethical approval of the proposal.

With thanks and regards,

Dr. Muhammod Abdus Sabur
Chair
Institutional Review Board

ICMR-NATIONAL INSTITUTE OF CANCER PREVENTION AND RESEARCH
I-7, SECTOR-39, NOIDA

icmr NICPR

Suggestions to be included: **To sign a formal MOU with the EZIPREP company and vet it through ITR division, ICMR, HQ** **To increase the sample size of the study.**			
3	Medical professionals' perspective on the relevance of bibliometric indices and metrics: A questionnaire-based survey"	NICPR/IEC/2021/007	Dr.Ruchika Gupta
Decision: Approved from ethics point of view **Suggestions to be included:** **Include participants from different levels of seniority/ different cadres/teaching and non-teaching institutions**			
4	AI-assisted classification of conventional cervical smears using Google's Tensorflow artificial neural network	NICPR/IEC/2021/008	Dr.Ruchika Gupta
Decision: Approved from ethics point of view **Suggestions to be included:** Considering the important nature of the studies and the required commitment for each study, committee suggests that Dr.Ruchika Gupta not to conduct all the studies that were presented on 24-09-21 for approval simultaneously			
5	Development and Evaluation of CRISPR/Cas13 based diagnostic system for HPV detection	NICPR/IEC/2021/009	Dr.Anita Kumari
Decision: Approved from ethics point of view **Suggestions to be included:** **To include diabetic patients in the study** **To clarify/ justify the exclusion criteria for cardiac patients** **To add more information on cost effectiveness of the test** **To include information on the impact of ease of doing this test** **The justification for the use of CRISPER CAS** **To take expert opinion from biomedical engineering experts from IIT Delhi**			
6	Feasibility and acceptability of remotely training non-specialist health workers for screening oral lesions due to tobacco use	NICPR/IEC/2021/010	Dr.Zainab Kidwai

Anurag Srivastava

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