Behavioural risk factors associated with oral cancer: assessment and prevention in primary care dental practices in Scotland

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Abstract

The incidence of oral cancer continues to rise in the UK and in Scotland, with a steady increase in oral cavity cancer rates and a rapid increase in oropharyngeal cancer rates in the last decade. These rates are projected to increase further over the next decade, so there is a pressing need to optimise oral cancer prevention strategies. Tobacco and alcohol use are recognised as the major modifiable risk factors for developing oral cancer (both oral cavity and oropharyngeal). In addition, there is a significant increased risk for oral cancer among lower socioeconomic groups, males, and older age groups. Recently there has been recognition of the role of human papillomavirus in the aetiology of oropharyngeal cancers. The major behavioural risk factors (tobacco and alcohol) implicated in oral cancer risk are also associated with a wide range of diseases affecting oral and general health and are thus termed 'common risk factors', increasing the public health benefit should they be tackled.

Given the pivotal role in oral cancer and wider disease prevention of reducing tobacco and alcohol use, there is a clear need to optimise the role of primary care dental professionals in delivering behavioural interventions. However, there are uncertainties about the best evidence for particular strategies and approaches to assess risk factors, advise and/or refer in the dental practice setting, with a particular lack of clarity in terms of the specific form and content of such interventions (for example: duration, tailoring to need, who delivers). In addition, the barriers and facilitators to implementation in primary care dental practice - from both the dental professional and patient perspectives - is relatively under-explored.

This thesis describes studies undertaken to address these gaps in the knowledge and evidence-base. First a systematic overview was undertaken of systematic reviews and published (international) clinical guidelines. This aimed to identify the evidence on the best practice for the assessment of the major behavioural risk factors associated with oral cancer and for delivering effective behaviour change preventive interventions (in relation to, for example: advice, counselling, signposting/referral to preventive services) by dental professionals in primary care dental practice setting. This evidence was then explored via a

study in primary care dental practices in Scotland utilising qualitative in-depth interviews with dental professionals, to identify barriers and facilitators to implementation, and to gather suggestions to inform the development of interventions to support dental professionals in delivering prevention. Finally, a small qualitative survey of patients attending primary care dental practice was conducted to explore barriers, facilitators, and acceptability of risk factor assessment and preventive interventions from the patients' perspective.

The overview shows a lack of direct evidence from the dental practice setting (one high-quality systematic review relating to tobacco prevention and none relating to alcohol). However, relatively strong evidence and recommendations from other primary care (medical/pharmacy) settings were identified and synthesised, which could potentially be adapted and adopted by dental professionals. Overall the findings show that robust risk factor assessment is an important first step in any prevention intervention. There is a clear indication of the effectiveness of a "brief", in-person, motivational intervention for sustained tobacco abstinence and reduced alcohol consumption. The lack of detail particularly in relation to duration made it difficult to make a conclusion regarding precise specification of the duration of element of the "brief" interventions. For tobacco users, though longer (10-20 minutes) and intensive (more than 20 minutes, with follow-up visits) interventions have shown to be effective in increasing quit rates compared to no intervention, very brief (less than 5 minutes) interventions in a single session also showed comparable effectiveness to the longer brief or intensive interventions. While, for alcohol users, 10-15 minutes multi-contact interventions were most effective, compared to no intervention or very brief intervention or intensive intervention; brief interventions of 5 minutes duration were also reported to be equally effective. Thus, very brief or brief advice of up to 5 minutes, should be trialled for tobacco and alcohol respectively in a dental practice setting, tailored to patient motivational status. Exploring use of the dental team is supported, as effectiveness was generally independent of primary care provider (i.e. general practice physician or nurse).

The qualitative studies on feasibility showed time and resources to be the major barriers from the dental professional perspective. Dental professionals also

reported social barriers for a) using cancer as a term to frame preventive consultations and b) in delivering alcohol advice which may not be welcome by patients. Professionals were willing to receive training to overcome confidence issues in approaching behavioural aspects of both main risk factors. Patients however generally supported explicit conversations on oral cancer, and were amenable to alcohol as well as smoking advice, provided their stage-of-change (motivational readiness) was incorporated. The use of formal risk assessment tools to frame discussions was broadly supported by patients and professionals alike.

Recommendations are made for testing a model of preventive consultation that draws from this best available evidence and addresses barriers for professionals and patients alike to help shape practice and support this important area of public health going forward.

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– Albert Schweitzer

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Author's Declaration

Parts of the research work included in this thesis have been presented in national and international conferences, and have also been published with co-authors.

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I declare that, except where explicit reference is made, that this thesis is the result of my own work and has not been submitted, partly or in whole, for any other degree at the University of Glasgow or any other institution.

SWETA MATHUR
Glasgow, November 2018

Abbreviations

ADAPTE	Resource Toolkit for guideline adaptation
AGREE II	Appraisal of Guidelines for REsearch & Evaluation II
AMSTAR	A Measurement Tool to Assess systematic Reviews
ASH	Action on Smoking and Health
AUDIT	Alcohol Use Disorders Identification Test
AUDIT-C	Alcohol Use Disorders Identification Test-Concise
AUDIT-PC	Alcohol Use Disorders Identification Test-Primary Care
BCW	Behaviour Change Wheel
BDA	British Dental Association
BMC	BioMed Central
CAGE	4-item alcohol screening questionnaire
CG	Clinical Guideline
CI	Confidence Interval
COGS	Conference on Guideline Standardization
COM-B	Capability, Opportunity, Motivation and Behaviour
CoMeTS	Comparative Method for Themes Saturation
CPD	Continuing Professional Development
CRD	Centre for Reviews and Dissemination
DART	Dental Alcohol Reduction Trial
EMBASE	Excerpta Medica dataBASE
ESRC	Economic and Social Research Council
FAST	Fast Alcohol Screening Test
FCTC	Framework Convention on Tobacco Control
FRAMES	Feedback, Responsibility, Advice, Menu, Empathy, Self-efficacy
GDC	General Dental Council
GG&C	Greater Glasgow & Clyde
GLOBOCAN	Global Cancer Observatory
GP	General Practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HPV	Human Papilloma Virus
IADR	International Association for Dental Research
IARC	International Agency for Research on Cancer
ICD	International Classification of Diseases
ICSI	Institute for Clinical Systems Improvement
INHANCE	International Head and Neck Cancer Epidemiology Consortium
INVOLVE	Public involvement in research by National Institute for Health Research
IPCRG	International Primary Care Respiratory Group
IRAS	Integrated Research Application System
ISSG	Information Specialists' Sub-Group
MAST	Michigan Alcoholism Screening Test
MECC	Making Every Contact Count
MEDLINE	Medical Literature Analysis and Retrieval System Online
MeSH	Medical Subject Headings

MI	Motivational Interviewing
MQIC	Michigan Quality Improvement Consortium
N.S.S.R.	Narrative Synthesis in Systematic Reviews
NCD	Non-Communicable Diseases
NCSCT	National Centre for Smoking Cessation and Training
NHS	National Health Services
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NRT	Nicotine Replacement Therapy
OR	Odds Ratio
PHE	Public Health England
PICOS	Participants, Intervention, Comparator, Outcomes, and Setting
PICOTS	Populations, Interventions, Comparators, Outcomes, Timing, Settings
PRISMA	Preferred reporting items for systematic review and meta-analysis
PRISMA-P	Preferred reporting items for systematic review and meta-analysis protocols
PROSPERO	International prospective register of systematic reviews
QSR	Qualitative Analysis Software
R&D	Research & Development
RACGP	Royal Australian College of General Practitioners
RATs	Risk Assessment Tools
RCT	Randomized Control Trial
REC	Research Ethics Committee
ROBIS	Risk Of Bias In Systematic reviews
RR	Relative Risk
SDCEP	Scottish Dental Clinical Effectiveness Programme
SIGN	Scottish Intercollegiate Guidelines Network
SIMD	Scottish Index of Multiple Deprivation
SMART	Specific, Measurable, Attainable, Realistic, and Timely
SR	Systemic Review
TRIP	Turning Research Into Practice
UK	United Kingdom
USPSTF	United States Preventive Services Task Force
VT	Vocational Trainees
WCPD	World Congress on Preventive Dentistry
WMD	Weighted Mean Difference
WHA	World Health Assembly
WHO	World Health Organisation
WOSRES	West of Scotland Research Ethics Service

Chapter 1 Introduction

"It is better to put out the fire while it is still small" (Stewart and Wild, 2014; Saracci and Wild, 2015). This saying from the "Kalenjin" tribe in Kenya has been used to greet patients arriving at the Tenwek Mission Hospital in the Western Highlands, and has been adopted as "an idiom for cancer prevention" by the *World Health Organization's International Agency for Research on Cancer (WHO IARC's) World Cancer Report 2014* (Stewart and Wild, 2014). This phrase was further highlighted in the recent publication to mark the 50th anniversary of the establishment of *IARC*, and was featured as one of its missions/visions for the second 50 years of *IARC* to reduce the burden of cancer globally (Saracci and Wild, 2015). In order to address this mission, *IARC* is promoting international collaboration in research for cancer prevention in three important areas, which are: "describing the occurrence of cancer; identifying / understanding the causes of cancer; and evaluating preventive interventions and their implementation" (Stewart and Wild, 2014). Addressing each of these areas is described by the *WHO IARC* as "a vital contribution to the spectrum of cancer prevention" (Stewart and Wild, 2014).

The understanding of underlying causes of a specific cancer, and the subsequent development of preventive strategies, is not complete without a description of the occurrence of the disease (i.e. incidence and mortality rates). According to the *World Health Organisation's Global Health Observatory* data (WHO, 2016a), in 2016, of 56.9 million worldwide deaths, there were an estimated 40.5 million deaths due to all major non-communicable diseases (NCDs), including cardiovascular disease, diabetes, chronic respiratory disease, and cancer. Cancer is the second leading cause of death (after cardiovascular diseases), with 22% (9.0 million) of all non-communicable disease deaths (Ferlay et al., 2015; WHO, 2016a). A global transition was witnessed between 1990 and 2010, where deaths from communicable diseases decreased by 17% and those from non-communicable diseases increased by 30%. A large proportion (about 80%) of these non-communicable disease-related deaths occurred in low- and middle-income countries, while the majority of those occurring in high-income countries were attributed to cancer (Bray and Soerjomataram, 2015; WHO, 2016a). Moreover, the *World Cancer Report 2014 (WHO IARC)* presents head and neck

cancers (oral cavity and oropharyngeal cancers combined) as the seventh most commonly occurring cancer, and as ninth-ranked in the world in terms of mortality for the year 2012 (Stewart and Wild, 2014). It has been estimated that more than half (50%) of all deaths due to cancer could be prevented by avoiding exposure to specific carcinogens, which follows from understanding the underlying causes. The idiom for cancer prevention reported above thus represents an "understandable desire to do better for patients by complementing the efforts to avoid the development of cancer in the first place".

This thesis focuses on evaluating the effective preventive interventions for oral cancer and understanding how best to support their implementation in a dental practice setting. This chapter provides background relevant to this thesis and context for the research undertaken. First, it sets out to identify and summarise the scientific literature related to this thesis, specifically the definitions, epidemiology, and aetiology of oral cancer. The chapter will then set the foundation to explore various behavioural preventive interventions that could be implemented in a primary care dental practice setting relevant to oral cancer. Lastly, it will identify uncertainties and gaps in the literature, and then provide the rationale for this thesis.

1.1 Oral cancer: background

1.1.1 Definition

Oral cancer has been defined in various ways based on discussions about the coding of various anatomical sites for the classification of the disease. There has been debate among clinicians and researchers around the definitions of "the oral cavity", "the mouth", and "the oropharynx", as their boundaries cannot be clearly defined (Moore et al., 2000; Tapia and Goldberg, 2011). One of the broadly accepted anatomical texts, *Gray's Anatomy* (Bannister, 1995) describes these areas as follows: "the boundaries of the oral cavity (or mouth) extends from the mucosal surface of lips to the palatoglossal folds; covered superiorly by the hard palate; inferiorly by the floor of the mouth and the anterior two-thirds of the tongue; and the soft tissue mucosa in the oral cavity is described as

squamous cell epithelium". *Gray's Anatomy* describes the "oropharynx as being situated behind the oral cavity and extending from the posterior aspect of the soft palate to the superior border of the epiglottis (but not including the epiglottis itself)" (Bannister, 1995). Within the oropharynx, "the posterior third of the tongue and the isthmus of fauces are anterior, the oropharyngeal wall is posterior, and the palatopharyngeal arches and the tonsils are lateral" (Bannister, 1995). According to *Gray's Anatomy*, "the palatoglossal folds" mark the boundary between the oral cavity and the oropharynx (Bannister, 1995). However, there is a variation in the defined boundaries between the oral cavity and the oropharynx among anatomical texts. *Cunningham's Textbook of Anatomy* (Cunningham and Robinson, 1918) defines the isthmus of fauces as the boundary between the oral cavity and the oropharynx, while *Hollinshead's Textbook of Anatomy* (Rosse and Gaddum-Rosse, 1997) has no clear depiction, describing the soft palate to be the posterior boundary.

Conway and colleagues (2018), in their recently published narrative review, explored oral cancer definitions and stated that: "the debate over definitions is encapsulated and exemplified by the variation in routine publication of oral cancer statistics in the UK Cancer Registries" (Conway et al., 2018). The review further studied definitions from each of the UK Cancer Registries. It stated that, according to the Cancer Registration statistics for England (Statistics, 2018) and the Northern Ireland Cancer Registry (Registry, 2018a), the oral cancer has been defined as a single group "lip, oral cavity, and pharynx", with the pharynx including oropharynx as well as nasopharynx and hypopharynx sites. The Cancer Registry for Wales (Unit, 2018), combines "oral and oropharynx cancer" together in their publication reporting cancer incidence, while the Scottish Cancer Registry (Registry, 2018b) reports several subgroupings of head and neck cancer including "oral cavity cancer" and "oropharyngeal cancer" (Conway et al., 2018).

More recently the differing aetiology, based on the role of human papilloma virus (HPV) infections which is mainly associated with oropharyngeal cancer, is driving the importance of defining "oral cavity" and "oropharyngeal" cancer distinctly (Chaturvedi et al., 2008; Conway et al., 2018). Oral cancer broadly includes oral cavity (mouth) and oropharyngeal (throat) cancers, and a

consensus on the definition is beginning to emerge (Chaturvedi et al., 2013). There are a number of *International Classification of Diseases (ICD)* codes included in both "oral cavity" and "oropharynx" definitions. Based on the *World Health Organization's (WHO) International Statistical Classification of Diseases and Related Health Problems 10th revision* (ICD-10) and *International Classification of Diseases for Oncology (ICD-O)* coding: oral cavity cancer includes cancers of the lip (excluding external surface) (C00.3-C00.9), other and unspecified parts of the tongue (C02, excluding C02.4), the gum (C03), the floor of the mouth (C04), the palate (C05), other and unspecified parts of the mouth (C06), but not cancers of the salivary glands. Oropharyngeal cancer includes cancers of the base of the tongue (C01), the lingual tonsil (C02.4), the tonsils (C9.0-9.9), the oropharynx (C10.0-10.9), areas of the pharynx not otherwise specified (C14.0) and the Waldeyer ring (C14.2) (WHO, 2011; WHO, 2013).

Despite being anatomically diverse, oral cavity and oropharyngeal cancers are mostly consistent with regards to clinical manifestations and descriptive epidemiology, and are often clinically managed and treated together. Moreover, the major etiologic factors (detailed in Section 1.2), i.e. tobacco and alcohol, still dominate oropharyngeal cancer risk besides human papilloma virus infections. Hence, most clinical guidelines have clinically combined/clustered these subsites together as "oral cancer", or included them under a broader heading "head and neck cancers" (SIGN, 2006; NICE, 2015). However, they can be separable in terms of some aspects of early detection and prevention (Chaturvedi et al., 2013). For this thesis, both oral cavity and oropharyngeal cancers combined will be referred to as "oral cancer". However, they will be discussed distinctly, where needed, to describe specific aspects of prevention.

1.1.2 Incidence burden and trends

1.1.2.1 Global burden and trends

The *World Cancer Report 2014 (WHO IARC)* presents oral cavity and oropharyngeal cancers combined as the seventh most commonly occurring cancer, and as ninth-ranked in the world in terms of mortality for the year 2012 (Stewart and Wild, 2014). It was reported that in 2012, there were approximately 529,000 new cases and 292,000 deaths from oral cavity and

pharyngeal cancers worldwide (Stewart and Wild, 2014). More recently, a report by Shield et al. (2017) provided the best peer-reviewed analyses of global data for new cases of lip, oral cavity, and pharyngeal cancers by subsite, country, sex, and age for the year 2012 based on data from the IARC's *Cancer Incidence in 5 Continents Volume X* (2003 to 2007) and *GLOBOCAN* (Forman et al., 2013). For both sexes combined, Shield et al. (2017) reported that in 2012 (by subsite), cancer of the oral cavity presented the highest number of incidences (202,000 cases), followed by oropharyngeal cancer (100,500 cases). Among other subsites, the newly diagnosed cases that year were: nasopharynx (86,700 cases); hypopharynx (60,800 cases); parotid gland and other and unspecified major salivary gland (40,100 cases); lip (23,700 cases); and other and ill-defined cancers of the lip, oral cavity, and pharynx (15,800 cases) (Shield et al., 2017).

The *WHO IARC's* global estimates identified considerable differences in the incidence of oral cavity and oropharyngeal cancer in different sex and age groups. In 2012, 70.8% of newly diagnosed cancer cases (375,000 cases) of the lip, oral cavity, and pharynx occurred in men, while only 29.2% (154,400 cases) of newly diagnosed cases occurred in women; with the majority of cases occurring among people aged 50 and above (Shield et al., 2017). The global estimated age-standardised rate for oral cavity cancer was 2.7 per 100,000, incidence being reliably higher in men than women (Male:Female rate ratio being 2:1); while for oropharyngeal cancer it was lower at 1.4 per 100,000, though with a considerably higher Male:Female rate ratio of 4.8:1 (Shield et al., 2017).

Conway and co-workers (2018) in their recent narrative review summarised the findings from a number of detailed peer-reviewed epidemiological studies on the worldwide trends (between 1975 and 2012) of oral cavity and oropharyngeal cancer incidence (Schottenfeld and Fraumeni Jr, 2006; Chaturvedi et al., 2011; Gillison et al., 2012; Chaturvedi et al., 2013; Simard et al., 2014; Gillison et al., 2015; Shield et al., 2017). The authors reported that, in recent decades, oropharyngeal cancer has among the most rapidly increasing incidence rates in both men and women, and in younger age groups (people under 60 years of age) (Chaturvedi et al., 2013; Conway et al., 2018). The authors further showed that the trends of HPV-associated oropharyngeal cancer cases show a dramatic

increase, especially in high-income or developed countries (particularly in the North America and Europe), while patterns are still unclear in less developed countries (Gillison et al., 2012; Hashibe and Sturgis, 2013; Conway et al., 2018). On the other hand, the incidence rates for oral cavity cancer were reported to be "flat-lining" or marginally increasing in women and decreasing in men (Chaturvedi et al., 2013; Conway et al., 2018). The authors suggested that, "these changing trends are a global phenomenon and have been related to changing population risk factors" (Conway et al., 2018). Hashibe and Sturgis (2013) further depicts this changing tend as "controlling a tobacco epidemic while a human papillomavirus epidemic emerges".

1.1.2.2 UK burden and trends

A recent study by Louie and co-workers (2015) used data from "population-based cancer registries in England", and reported trends and burden of head and neck cancers (with specific subsites) between 1995 and 2011, and further projected trends from 2011 to 2025. The authors reported that between 1995 and 2011, there was an annual increase of oral cavity cancer cases by 2.8% for men and 3.0% for women, while oropharyngeal cancer cases increased by 7.3% for men and 6.5% for women; and projected a further annual increase from 2011 to 2025 (Louie et al., 2015).

More recently, a detailed descriptive epidemiology study by Purkayastha and co-workers (2016) analysed the Scottish Cancer Registry data and reported that between 2001 and 2012 there was a dramatic increase in oropharyngeal cancer cases (85%) in Scotland, while incidence rates remained relatively unchanged for oral cavity cancer (only 10% increase) (Purkayastha et al., 2016). The rates were again higher among men than women. The authors further examined the trends by socioeconomic status (deprivation) across all subsites, and reported a socioeconomic inequality in incidence rates, with rates being higher in people from more deprived backgrounds (Purkayastha et al., 2016). Moreover, oropharyngeal cancer rates are now markedly higher than those of cervical cancer, melanoma of the skin, and adenocarcinoma of the oesophagus in Scotland (Junor et al., 2010). The recent review by Conway and co-workers (2018) further explored the incidence burden and trends of oral cancer (oral

cavity and oropharyngeal) from region to region in the UK, and reported that Scotland, Wales, and Northern Ireland have higher oral cancer (oral cavity and oropharyngeal) incidence rates than England.

1.1.2.3 Summary - incidence burden and trends

In summary, similar to the studies reporting changing oral cancer trends globally (Shield et al., 2017; Conway et al., 2018), the studies in the UK show a rapid increase in oropharyngeal cancer incidence rates in all four countries in the last decade (Louie et al., 2015; Purkayastha et al., 2016; Conway et al., 2018). In comparison, oral cavity cancer incidence rates were relatively stable or steadily increasing over the period (Louie et al., 2015; Purkayastha et al., 2016; Shield et al., 2017; Conway et al., 2018). The rates are further projected to increase over the next decade for both oral cavity and oropharyngeal cancers (Louie et al., 2015; Purkayastha et al., 2016; Shield et al., 2017; Conway et al., 2018). Therefore, this projected heavy burden warrants a need to take steps to devise more effective oral cancer prevention and control strategies. Gathering accurate global data on oral cancer incidence and mortality from population-based cancer registries (as discussed above) is a fundamental component to cancer prevention and control, as is the need to elucidate oral cancer causes. This will facilitate a better understanding of this important disease and help prioritize and plan appropriate prevention and control strategies (Stewart and Wild, 2014).

1.2 Oral cancer: risk factors

The most up to date and comprehensive data on oral cancer risk factors can be found from research by the *International Head and Neck Cancer Epidemiology* (INHANCE) consortium (INHANCE, 2018). INHANCE is a consortium of research groups which pools individual patient data from large epidemiological studies (mostly case-control studies) involving cases (patients) with head and neck cancer (including oral cavity and oropharyngeal cancers), and controls (comparisons) without head and neck cancers. To-date INHANCE includes over 35 original analyses/studies from across the world (including United States, Europe, Brazil, Latin America, and Asia), and investigators of these studies have pooled data from 25,500 cases and 37,100 controls in order to expand the understanding of the aetiology of head and neck cancer (including cancers of oral cavity,

oropharynx, hypopharynx, and larynx), focusing on behavioural, social, environmental and genetic risk factors and interactions among these risk factors (Conway et al., 2009; Winn et al., 2015). The major strength of this large INHANCE dataset is that it provides more precise estimates (including individual patient data) of risk by controlling for potential confounding factors and examining factors that may interact with each other (Conway et al., 2009; Winn et al., 2015). However, currently the consortium does not include any studies reporting data from South-East Asia (including Bangladesh and India) and Africa, where there are many areas with very high head and neck cancer rates (Conway et al., 2009; Winn et al., 2015).

The findings of these INHANCE studies have been reviewed, with a particular focus on the major behavioural risk factors (tobacco smoking and alcohol drinking) taking into consideration various sociodemographic factors. The other key and emerging risk factors have also been presented. The data from other published observational studies or systematic reviews have been reviewed, where there were gaps in the INHANCE analyses.

1.2.1 Major risk factors

1.2.1.1 Tobacco smoking and alcohol drinking

There is explicit evidence establishing tobacco smoking (IARC, 2004) and alcohol drinking (IARC, 2007) as the major risk factors in oral cancer development. In the UK, over two-thirds of oral cancers in men and over half in women are linked to smoking, while over a third of oral cancers in men and around a sixth in women are associated with alcohol consumption (Cancer Research, 2014). The "population-attributable risks" of smoking and alcohol consumption combined have been estimated to be 80% for males, 61% for females, and 74% overall, i.e. approximately three-fourths of all oral and pharyngeal cancers (Blot et al., 1988; Petersen, 2009).

Using INHANCE data, where there were sufficient numbers of study participants (oral cavity and oropharyngeal cases) who were never smokers or alcohol drinkers, the issue of confounding could be fully examined (Conway et al., 2009; INHANCE, 2018). Hashibe and colleagues (2007) provided a true and precise risk

estimate by projecting the effects of alcohol drinking in never users of tobacco, and the effects of cigarette smoking in never drinkers of alcohol (Hashibe et al., 2007). They reported that cigarette smoking was associated with a two-fold increased risk of oral cancer among never alcohol drinkers, and the risk increased with frequency, duration, and pack-years of cigarette smoking. Heavy alcohol drinking (three or more drinks per day) among persons who never used tobacco was also linked to a similar two-fold increased risk (Hashibe et al., 2007).

Pooled data analysis from INHANCE found that the combined effects of tobacco and alcohol use are greater than the multiple of their individual effects on the risk of developing oral cancer, i.e. the risks are highest among individuals who both smoked tobacco and consumed alcohol heavily, showing a five-fold increased risk (Hashibe et al., 2009). The majority of oral cavity (64%), pharyngeal (72%), and laryngeal cancers (89%) are associated with these behaviours combined (Hashibe et al., 2009).

The INHANCE analyses have also established a dose-response relationship; the risk of developing oral cancer increases with increased frequency (i.e. numbers of cigarettes or drinks per day or week) and duration (i.e. years of smoking or drinking) of tobacco and alcohol use (Lubin et al., 2009). This study found, as per the lung cancer risk (Peto, 2012), that smoking fewer cigarettes per day over a longer period of time is more harmful for oral cancer risk than smoking more cigarettes per day over a shorter period of time (i.e. duration more important than frequency) (Lubin et al., 2009). On the contrary, for alcohol-associated oral cancer risks, frequency is more important than duration, i.e. higher alcohol consumption (three or more drinks per day) for a shorter period of time led to greater harm than fewer drinks over a longer time period (Lubin et al., 2009). Furthermore, there are no safe low limits for either smoking or alcohol consumption, i.e. low intake of cigarettes and alcohol drinking increased the risk of oral cancer (Berthiller et al., 2015). Differences were also observed by anatomic sites for head and neck cancer; smoking risks were mostly greater for laryngeal cancer, and alcohol drinking for oral cavity and pharyngeal cancers (Lubin et al., 2009).

Similar results were obtained for different types of tobacco smoking products, i.e. increased risks of oral cancer for cigarettes, cigars, or pipes (Wyss et al., 2013). Another INHANCE study investigated the independent associations with different measures of beverage consumption of beer, wine, and liquor (Purdue et al., 2008). Findings suggested the relative risks of oral cancer are equivalent for consumption of beer, liquor and, high consumption levels of wine. A comparatively weaker risk was observed at low consumption levels for wine, however, the authors were not able to rule out confounding from diet and other lifestyle factors (Purdue et al., 2008).

INHANCE analyses further established that a beneficial effect on reducing oral cancer risk was observed following smoking cessation and quitting alcohol drinking. This study showed a benefit appearing within 1-4 years of smoking cessation, though the risk level of "never users" of tobacco may not be attained until 20 or more years post-cessation (Marron et al., 2010). In contrast, the benefit emerged much later, after 20 years of quitting alcohol drinking (Marron et al., 2010).

1.2.1.2 Socioeconomic status

Increased oral cancer risk is also observed in cases of lower socioeconomic status than controls, independent of tobacco smoking and alcohol drinking (Conway et al., 2008; Conway et al., 2015). According to a large INHANCE pooled data analysis (involving 31 studies in 27 countries), lower education status and lower income have been implicated as important oral cancer risk factors, showing more than a two-fold increased risk, even in a subgroup who neither smoked nor drank alcohol (Conway et al., 2015). This large data analyses by Conway and co-workers (2015) further reported that the higher risk associated with lower socioeconomic status was not confined to men, nor to older people and was not fully explained by other behavioural risk factors (for example, diet or other tobacco use), although residual confounding could not be ruled out.

1.2.2 Other risk factors

1.2.2.1 Smokeless tobacco

In 2004, a Working Group at the *IARC*, established that smokeless tobacco is "carcinogenic to humans", and evidenced that oral cancer risk (in particular oral cavity cancer) is increased by using smokeless tobacco (powdered snuff, chewing betel quid with or without tobacco) (Cogliano et al., 2004). The INHANCE analyses showed that the risk increases with the quantity consumed, duration of consumption, and consumption from an early age; with a nearly two-fold increased risk association, even among never cigarette smokers (Winn et al., 2015; Wyss et al., 2016).

A systematic review and meta-analysis of 15 case-control studies by Gupta and Johnson (2014) showed that betel quid (or "paan") without tobacco has a near three-fold increased risk association with oral cancer. Various large case–control studies conducted in Asia further suggest that chewing tobacco and/or betel may have an increased risk for oral cavity cancer compared with smoked tobacco and alcohol. Women appeared to be more susceptible to the carcinogenic effect of betel than men, at the same level of consumption (Radoï and Luce, 2013).

1.2.2.2 Marijuana

Marijuana (Cannabis sativa) is the most widely used illegal drug worldwide, which is mainly consumed by smoking and is often smoked together with tobacco and/or used with alcohol (UN, 2007). Most of the carcinogens in the marijuana smoke are the same as in tobacco smoke, which raises concerns that marijuana smoking may be a risk factor for tobacco-related cancers (Hashibe et al., 2005; Radoï and Luce, 2013). However, it is difficult to exclude the possibility of residual confounding by tobacco and alcohol consumption (Radoï and Luce, 2013). As tobacco and alcohol are major risk factors for oral cancer, the association of marijuana and oral cancer risk has been reviewed in some studies. One of the INHANCE studies by Berthiller and co-workers (2009) analysed the effects of marijuana use among never tobacco and alcohol users, and found no increased risks associated with the increase in frequency, duration or cumulative consumption of marijuana smoking. Several other studies also evaluated the

association of marijuana smoking and oral cancer. However, at present, sufficient evidence is not available to evaluate the influence of marijuana on oral cancer risk (Hashibe et al., 2005; Berthiller et al., 2009).

1.2.2.3 Human papillomavirus

Human papillomavirus (HPV) is mainly associated with increased risk of oropharyngeal (rather than oral cavity) cancer. Recent epidemiological studies (case-control studies) conducted in the United States show increased oropharyngeal cancer rates, which are thought to be partly attributable to the human papillomavirus and especially HPV16 (risks as high as 15 times greater), which is sexually transmitted (D'Souza et al., 2007; Gillison et al., 2015). INHANCE analyses found a slightly increased oropharyngeal cancer risk associated with certain sexual behaviours, i.e. history of having six or more lifetime sexual partners, four or more lifetime oral sex partners, an earlier age (<18 years) at sexual debut, and same-sex sexual contact (Heck et al., 2009).

A review by Gillison and co-workers (2015), of recent data on the epidemiology of HPV-associated oropharyngeal cancer concluded that, despite the increased incidence rates or changing trends (Section 1.1.2), little is known about the natural history (i.e. prevalence, persistence, and determinants) and factors associated with oral human papillomavirus infections (Conway et al., 2018). A large cross-sectional survey by Gillison and co-workers (2012) investigated the prevalence of oral human papillomavirus infection among the United States population, and found an overall prevalence of 6.9% among men and women aged 14 to 69 years, with significantly higher prevalence among men than women (10.1% v/s 3.6%).The study identified some risk factors associated with oral human papillomavirus infections, which were: smoking, alcohol, number of sexual partners, number of oral sex partners, and open mouth (deep) kissing (Gillison et al., 2012). However, the authors recommended the need for further research to understand the effects of sexual behaviours on the incidence of oral human papillomavirus infections and their subsequent risk associations with oropharyngeal cancer, which are not well understood (Gillison et al., 2012). These prevalence findings were largely replicated in a small feasibility study in Scotland (Conway et al., 2016).

Furthermore, given the growing acceptance of the role of human papillomavirus in the aetiology (and HPV testing in the management) of oropharyngeal cancers, the implications for patient/social history taking in oral health assessment and for patient counselling needs to be considered (Chu et al., 2013). In theory, HPV-associated oropharyngeal cancer could be prevented through behavioural modification / safer sexual practices, i.e. use of condom or dental (rubber) dam during oral sex (NHS, 2018a). However, there is a lack of evidence on the effectiveness of sexual behaviour advice within the primary care setting and opportunities are being explored for the prevention of human papillomavirus infections through vaccinations (Kreimer, 2014). This latter approach, i.e. HPV-related vaccine prevention is beyond the scope of this thesis.

1.2.2.4 Age and gender

Oral cancer is more common in males than in females, with two-thirds of oral cavity cancer cases occurring in men worldwide. There is also an increased risk for oral cancer among older age groups, with the majority of cases occurring in people aged 50 or over (Ferlay et al., 2015). A further INHANCE study compared the role of major oral cancer risk factors (tobacco smoking and alcohol drinking) in younger adults and older adults, and found similar major risk factors in young and in older groups, i.e. a positive association with oral cancer and these major risk factors independent of age (Toporcov et al., 2015).

1.2.2.5 Diet

Incidence of oral cancer among individuals who do not drink or smoke, indicates the involvement of other risk factors in oral cancer development. There is some evidence showing a positive relationship between inadequate fruit and vegetable intake and higher risk of oral cancer (Warnakulasuriya, 2009; Radoï and Luce, 2013). Indeed, dietary intake of fresh fruits and vegetables, vitamin C, vitamin E and beta-carotene have been established as protective factors for oral cancer. Studies have shown a 50% lower oral cancer risk among those consuming approximately five or more fresh fruit and vegetable portions per day compared with those consuming low levels (Edefonti et al., 2011; Chuang et al., 2012). It is noteworthy that obesity was not linked with an increased oral cancer risk, unlike for many cancers (for example, cancer of the gallbladder, pancreas, liver,

breast) (Arnold et al., 2016). In contrast, there is some data to suggest that oral cancer may be more prone in those with low body mass index (Gaudet et al., 2010).

1.2.2.6 Genetics

Genetic predispositions have also been identified as an aetiologic factor for the onset of oral cancer, however, at present their effects are likely to be underestimated (van Monsjou et al., 2013; Winn et al., 2015). There is some limited evidence showing associations of certain genetic loci associated with alcohol and nicotine metabolism, and DNA repair pathways - thus demonstrating the likely "genetic-environmental risk interactions" (Winn et al., 2015). Another INHANCE study demonstrated a relatively strong family history (hereditary) head and neck cancer risk. There was an increased risk associated with having a first degree relative with head and neck cancer (Negri et al., 2009).

1.2.2.7 Oral health

The INHANCE analyses further shows the links between poor oral health and increased oral cancer risk, independent of tobacco smoking and alcohol drinking. Good oral health indicated by few missing teeth and no gum disease, and good dental care indicated by annual dentist visits and daily tooth brushing, were found to modestly reduce the risk of oral cavity and oropharyngeal cancer (Ahrens et al., 2014; Hashim et al., 2016). Having two or less indicators of good oral health or dental care was found to add an estimated 8.9% of oral cavity cancers. There was no association observed for wearing dentures (Ahrens et al., 2014; Hashim et al., 2016).

A potential role for mouthwash use in the risk of oral cancer was suggested from the INHANCE research, given the alcohol content in many types of mouthwash. For example, 26.9% alcohol content in Listerine and around 22% alcohol in many of the mint flavoured mouthwashes. There was a modestly elevated risk associated with mouthwash use over a prolonged period (35 years or more) and for use greater than once per day; although it was not possible to completely assess risks in the non-users of tobacco and alcohol in this analysis (Boffetta et

al., 2016). A non-significant increased risk association for regular mouthwash use was also reported in an earlier systematic review (Gandini et al., 2012).

1.2.3 Summary - oral cancer risk factors

Oral cancer (oral cavity and oropharyngeal cancer) risk factor data analyses have established the clear role of tobacco smoking and alcohol drinking in its aetiology. Moreover, strengthening evidence on the benefits of quitting tobacco (smoking and other forms) and alcohol use, and the role of lower socioeconomic status, are crucial in planning and managing both individual and population risk reduction or preventive strategies. This understanding provides enhanced opportunities to help develop more effective tailored prevention strategies, including effective history taking, communication of risk, and adherence to advice given for oral cancer in a dental practice setting (detailed in following sections). For example, the more general risk associated with tobacco and alcohol means that risk prediction tools, available from other health contexts (for example, cardiovascular disease, lung cancer), might be of interest (Usher-Smith et al., 2015). However, so far, they have been largely ignored in relation to oral cancer (Speight et al., 2006).

The other key and emerging risk factors (for example, human papillomavirus infection) also need to be considered. However, the initial literature search showed a lack of evidence to demonstrate the effectiveness of sexual behavioural advice in a primary care setting, including the dental practice. This topic (sexual behavioural advice), was therefore considered beyond the remit of this thesis.

The focus for this thesis, regarding delivering preventive interventions, was based on the two major risk factors, i.e. tobacco and alcohol, given the fact that tobacco and alcohol are the major etiologic factors that dominate both oral cavity and oropharyngeal cancer risk.

1.3 Oral cancer: prevention

"Since the middle of the last century, enormous progress has been made in identifying the causes of cancer, so that more than 50% of cases could be prevented based on current knowledge" (Stewart and Wild, 2014). This important message emerging from the recent "*WHO IARC's World Cancer Report 2014*" (Stewart and Wild, 2014), and also from other global cancer control documents, including prevention module of the "*Cancer Control: Knowledge into Action, WHO's Guide for Effective Programs*" (WHO, 2007a), emphasises that cancer prevention via risk assessment is an essential component for all cancer control policies. Moreover, the current successes in identifying cancer causes/risks necessitates an evaluation of the most effective preventive approaches, and consideration of how best to support their implementation into particular healthcare settings (Stewart and Wild, 2014).

1.3.1 Prevention strategies

The prevention of oral cancer may be applied using a primary, secondary or tertiary approach (Reichart, 2001; BDA, 2010). Primary prevention refers to strategies to prevent the onset of disease by removing causative risk factors (risk reduction), and thus aims to reduce the incidence of disease. Primary prevention has the potential to defeat the condition, as it involves interventions that are applied before there is any evidence of disease (for example, changes to behaviours such as tobacco smoking or alcohol drinking). However, it is also recognized that such lifestyles or behaviours are resistant to change, and thus secondary prevention through the early detection of malignant or potentially malignant lesions is essential (Brocklehurst et al., 2013a).

The overall staging of cancer, based on TNM (tumour, node, metastasis) system, has four main stages which are defined as:
Stage I – tumour less than two centimetres in size and not spread to the neighbouring tissues, lymph nodes, or organs;
Stage II – tumours that are greater than two centimetres but less than four centimetres in size and have not spread to the neighbouring lymph nodes or organs;

Stage III - a) tumours that are greater than four centimetres but have not spread to the lymph nodes or other parts of the body, or b) cancers that are of any size but have spread to one lymph node on the same side of the neck (no bigger than three centimetres);
Stage IV - is the advanced stage of cancer and is further divided into categories IVa, IVb, and IVc based on the extent of metastasis and the size of the lesion (IARC, 2017; Cancer Research, 2018).
The five-year survival rate is projected to be 80% when oral cancer is detected early (or for localised disease). However, over 50% of cases are detected after metastasis and thus five year survival is less than 50% for certain types (Ragin et al., 2007; Goy et al., 2009; IARC, 2017). Rusthoven and colleagues (2010) reported that the survival rates of patients with advanced stage (III-IV) cancer was significantly lower than that of those with early stage (I-II) cancer. Moreover, as the stage of cancer advanced, the five-year survival rates decreased extensively (from 90% at Stage I to 60% at Stage III and 4% at Stage IVc) (Iro and Waldfahrer, 1998; Carvalho et al., 2005).

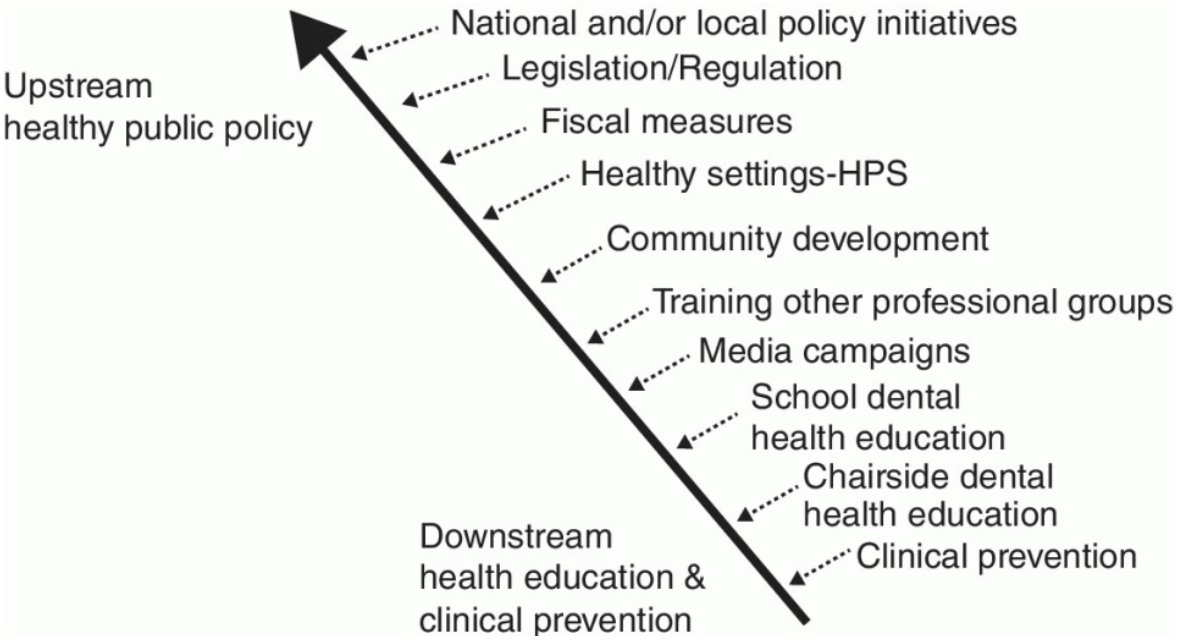
This illustrates the important role of the General Dental Practitioner, as a primary healthcare professional, in early detection and prevention through regular patient contact and pre-symptomatic screening. Where oral cancer is suspected, the dental healthcare team plays a vital role in the early management of oral cancer through referral and sympathetic discussion, thus helping early diagnosis and definitive treatment (Conway et al., 2002). Tertiary prevention refers to preventing recurrence and further spread of disease in patients already treated for oral cancer and minimising morbidity (Reichart, 2001; Joseph, 2002; BDA, 2010).

Secondary and tertiary prevention are beyond the scope of this thesis, and the evidence has been considered to be much clearer in these area (Petersen, 2009). Moreover, a sister PhD project (in the University of Glasgow Dental School) is undertaking a study to assess best practice evidence for oral cancer early detection, screening and examination (Al Bulushi et al., 2016). The main focus of this thesis relates to primary prevention approaches, which are now discussed.

1.3.2 Upstream to downstream approaches

The public health interventions for disease prevention and improving health often occur at multiple levels or metrics, leading to differences in individual-level and population-level approaches (McKinlay, 1998; Brownson et al., 2010). Brownson and colleagues (2010) conducted a review to better understand the use of policy metrics that can affect these approaches at upstream, midstream, or downstream levels. The authors described that, upstream interventions involve "policy approaches that can affect large populations through regulation, increased access, or economic incentives", i.e. changes happening at the macro policy level (national and international) in order to diminish the "causes-of-the-causes" (Brownson et al., 2010). With midstream interventions, changes generally occur at the micro policy level (regional, local, community or organizational) and are about changing the causes (Brownson et al., 2010). Downstream interventions involve "individual-level behavioural approaches for prevention or disease management", i.e. changes happening at the service or access to service level and are about changing the "effects of the causes" (Brownson et al., 2010). Figure 1.1 below presents a range of options for oral disease prevention – upstream to downstream approaches, as adapted from a review paper by Watt RG (2007).

Figure 1.1: Upstream to downstream: options for oral disease prevention (adapted from (Watt, 2007))



It is clear from these multiple level approaches that it is crucial to identify and understand the underlying root causes of the problem in order to develop an effective action to promote health (including oral health) and in turn tackle health inequalities (Watt, 2007; Brownson et al., 2010). Much of clinical and recent epidemiological research has concentrated on the "downstream" factors in disease aetiology, which involves behaviour change interventions targeted at the individual "lifestyle or behavioural" and biological risk factors (Pearce, 1996; Sprod et al., 1996; Kay and Locker, 1998; Ostlin et al., 2005). It comprises of several actions or interventions for tobacco cessation or alcohol reduction delivered directly to individuals, such as counselling, tailored advice, health education, self-help programmes, and pharmacologic treatments.

This downstream approach has guided the development of leading oral health preventive models. For example, *Scotland's Oral Health Improvement Plan* focuses "to encourage a more prevention-based provision recognising the benefits of anticipatory care" (Scottish Government, 2018b). It recommends providing each patient with a "personalized care plan based on an assessment of the level of risk to their oral health". In addition, some progress has been achieved in improving oral health via implementing the *"Ottawa Charter"* 20-years since its first publication with a goal of "Health For All" (WHO, 1986). For example, significant success has been achieved in the field of tobacco control in many parts of the developed world, which in turn has led to oral health improvements (Watt, 2007). One of the good examples of coordinated global action is the *"WHO Framework Convention on Tobacco Control (FCTC)"* (WHO, 2004). Various policies have been implemented linked to this framework, which are: banning tobacco advertising, sponsorship and promotion; health warnings; combatting illicit trade; plain packaging; taxation; smoke-free public places; and offering people help to end their addictions to tobacco (i.e. cessation) (WHO, 2004). Article 14 of the *WHO FCTC* states that the key cessation support could include various approaches such as telephone quit lines, brief advice from health workers, internet support, or even more intensive behavioural support delivered by trained specialists (WHO, 2004). Similar progress has been made via implementing "*WHO's Global strategy to reduce harmful use of alcohol"* (WHO,

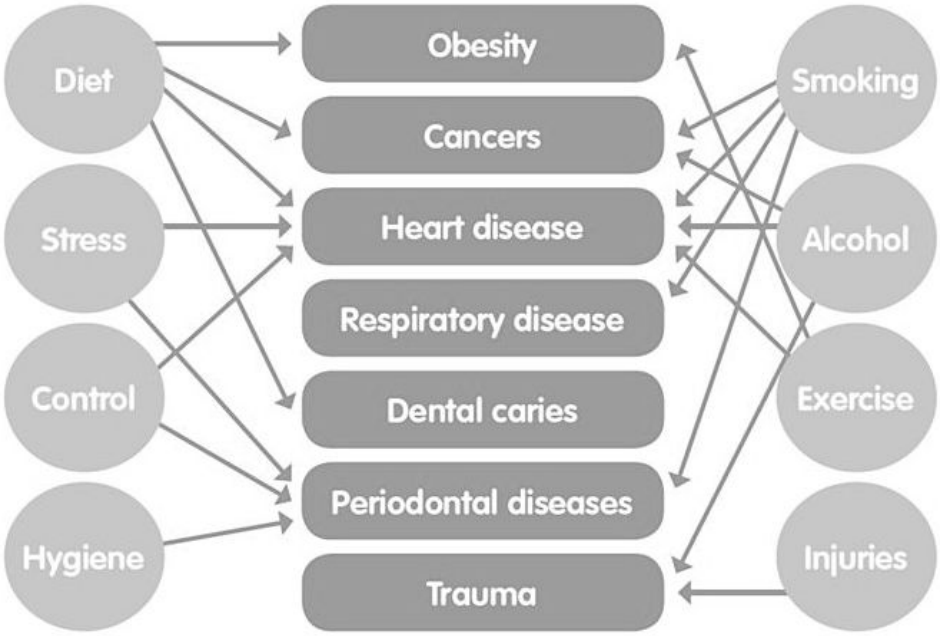
2010), which includes various policy actions such as: community action; drink-driving policies and countermeasures; availability of alcohol; marketing of alcoholic beverages; pricing policies (including the Scottish Government's Minimum Unit Pricing for alcohol); and health services' response (which includes identification and brief advice programmes and referral to specialist services) (WHO, 2010; Scottish Government, 2018a). Indeed, delivering alcohol brief interventions was found to be among the most effective alcohol policies in a *WHO* review of 32 alcohol strategies and interventions (WHO, 2005a).

The evidence for the effectiveness of tobacco cessation and alcohol reduction policies and interventions is extensive and comes from a large international body of research from a variety of health-care settings (WHO, 2004; WHO, 2010). Although more still needs to be known in many areas, notably in approaches to assess risk factors and effective components of preventive interventions (WHO, 1986; Petersen, 2009).

1.3.3 Common and multiple risk factors

The risk factors implicated in oral cancer risk are also associated with a wide range of diseases (such as periodontal disease, cardiovascular disease, cancer, diabetes, stroke and other oral diseases); hence tobacco, alcohol and socioeconomic status in particular are known as common or shared risk factors (Sheiham and Watt, 2000). Therefore adopting a shared approach is more rational than a disease specific approach (Sheiham and Watt, 2000). The common risk factor approach is an important element to be considered in terms of preventing oral cancer, and has been presented in Figure 1.2, as described by Sheiham and Watt (2000).

Figure 1.2: Common risk factor approach (adapted from (Sheiham and Watt, 2000))



The associated common risk factor approach recognises that dental professionals can contribute to improve not only oral health but also general health. More recently, the WHO has supported this approach at a global level in their agenda "*Global action* plan *for the prevention and control of non-communicable diseases (NCDs) 2013-2020*" (WHO, 2016b), which includes nine global targets in order to address prevention and management of four major non-communicable diseases (including cardiovascular disease, diabetes, chronic respiratory disease, and cancer) and on four shared behavioural risk factors - tobacco use, unhealthy diet, physical inactivity and harmful use of alcohol (WHO, 2016b). Reducing these common or shared risk factors is a major strategic priority for the WHO going forward for the prevention and management of non-communicable diseases (WHO, 2016b). This action plan has a specific mention of oral diseases including oral cancer, and states that an effective oral cancer prevention strategy may have benefits that are not limited to this particular condition alone (Sheiham and Watt, 2000; Watt, 2005; WHO, 2016b).

The *World Health Organization (WHO)* and the *International Agency for Research on Cancer (IARC)* are conducting further research in order to develop effective strategies for oral cancer prevention and control (Petersen, 2009; Stewart and Wild, 2014). These reports also highlight that primary preventive

approaches are the most cost effective long-term strategies for oral cancer control and are valuable as they can help in preventing various non-communicable diseases that share the same risk factors (Petersen, 2009; WHO, 2016b). In the recent *World Congress on Preventive Dentistry (WCPD)* (2017), which was organized jointly by the *WHO* and *IADR*, the *WHO* non-communicable disease global action plan was discussed extensively, and participants from different parts of the world debated the role of the oral health community in relation to this action plan (WHO, 2016b; WCPD, 2017). One of the key note speakers, Dr. Thamarangsi (Director, Department of Noncommunicable Diseases and Environmental Health, WHO Regional Office for South-East Asia), highlighted the importance of promoting oral health through controlling common risk factors for non-communicable diseases by using three key words:
1) “Be connected - join the non-communicable disease movement and support WHO strategies and recommendations”
2) “Be strategized - develop and implement oral health strategy integrated to non-communicable disease agenda towards Sustainable Development Goals”, and
3) “Be strong - building comprehensive capacity at all levels” (Thamarangsi, 2017).

This common risk approach is now widely supported. However, there remains a challenge for many oral healthcare or dental professionals for changing from the isolated and individualistic pattern of working to this approach, due to many organizational and administrative constraints (Petersen, 2003).

Consideration also needs to be given to focusing on the presence of multiple risk factors in individuals, i.e. clustering of unhealthy behaviours and socioeconomic factors. Research has shown that risk factors (for example, tobacco, alcohol, poor diet and physical inactivity) occur in combinations and show multiplicative interactions and are strongly associated with poorer socioeconomic environments (Lawder et al., 2010). This is particularly relevant to oral cancer prevention where there is a synergistic relationship between multiple risk factors, with tobacco and alcohol in combination magnifying the risk for oral cancer (Hashibe et al., 2009).

1.3.4 Risk communication

Communicating risks associated with oral cancer is a key challenge for dental professionals and can help in changing behaviour and/or improving patient decision-making (Ahmed et al., 2012). One of the strategies for effective risk communication and to promote positive health behaviour change is to identify/create a "teachable moment", which is an opportunity to implement preventive interventions (Lawson and Flocke, 2009). Moreover, the *National Health Services (NHS)* campaign "Making Every Contact Count (MECC)" states that all healthcare professionals are in the position to utilise and make the most of day-to-day interactions that they have with every patient in order to encourage and help people to make healthier choices to achieve positive long-term behaviour change (Varley and Murfin, 2014). Here "risk" is the probability or chance that a disease will occur over a period of time. Risk communication can be defined as a two-way open exchange of views and information about harms and benefits, in order to promote patient involvement, improve the understanding of risks and lead to more informed decision-making about managing risks. If risk is communicated effectively, it can also trigger changes in patient's beliefs and behaviours (French et al., 2017).

There exists a good state of knowledge regarding non-personalised risk communication which is not specific to an individual, for example, general information on the harmful effects of smoking (Sheeran et al., 2014). A recent systematic review evaluating the effect sizes across 93 risk communication studies, found a mean increase of 'd=0.23' on subsequent behaviour change, where interventions produced a significant increase in risk appraisals/assessment relative to control participants (Sheeran et al., 2014). Additionally, in line with theory (Maddux and Rogers, 1983), effect sizes were much larger (d=0.45) on subsequent behaviour when "response-efficacy and self-efficacy" were also increased (Sheeran et al., 2014). Response-efficacy refers to "a person's belief that changing their behaviour (for example, smoking cessation) will reduce risk", and self-efficacy refers to "a person's belief that they are capable of changing the relevant behaviour" (Maddux and Rogers, 1983).

Despite this current knowledge in terms of the most effective ways of non-personalised risk communication for behaviour change, there is a lack of information regarding the extent to which response-efficacy and self-efficacy have been targeted in interventions involving personalised risk information (French et al., 2017). Moreover, there is a lack of clarity regarding behaviour change techniques used in such interventions to address risk assessments and efficacy assessments (Michie et al., 2013). More recently, a systematic review of systematic reviews by French and co-workers (2017) investigated a wide range of personalised approaches of assessing and communicating risk information, and found little evidence of strong or steady effects of personalised risk information on health-related behaviours. The quality of the included reviews was judged to be good, however, the quality of most of the primary studies was criticised. The reviews using imaging/visual techniques to provide risk feedback on smoking behaviours showed the most promising effects, although there were more null findings than significant ones and little evidence of sustained change (French et al., 2017). The effects of other methods of personalised risk communication for smoking cessation, for example, providing numerical risk information, were not promising (French et al., 2017). Overall, the authors showed that there is limited to no evidence from the existing reviews regarding stronger effects of personalised risk communications than non-personalised communications (French et al., 2017). One of the likely reasons is that personalised risk communications did not generally target response-efficacy and self-efficacy, which could increase the impact of risk communication on health-related behaviours (Peters et al., 2013; Sheeran et al., 2014). Moreover, work is required to compare various risk communication strategies to find out whether they promote uptake of evidence-based behaviour change programmes, because it seems unlikely that merely communicating personalised risk would bring about sustained behaviour change (French et al., 2017).

1.4 Oral cancer: primary prevention (behaviour change) approaches

The primary prevention of oral cancers in or via dental practice setting is important (Watt, 2007). Again, the principles of prevention should reflect the evidence of major oral cancer risks. For example, there is reduction in oral cancer risk when behaviours stop (i.e. tobacco cessation and reduced alcohol consumption). Primary preventive interventions for the major behavioural oral cancer risk factors of tobacco and alcohol can be either non-pharmacologic/ behavioural, or pharmacologic, or a combination of these. The primary focus of this thesis is behavioural preventive interventions, with or without pharmacotherapy, or referral to specialist cessation services - that could be implemented in a primary care dental practice setting.

1.4.1 Primary preventive interventions

1.4.1.1 Behavioural interventions

Behavioural science and strategies play an important role and inform, to a large extent, various approaches to behaviour change such as tobacco cessation and reducing alcohol consumption in patients in primary care practices. There are many theoretical approaches that could be used to deliver a behavioural preventive intervention, for example, *"Motivational Interviewing (MI)"* developed by Miller and Rollnick (Miller, 1983), the *"Stages-of-Change or Transtheoretical Model of Change"* by Prochaska and DiClemente (1983), and the *"Cognitive Behavioural Technique"* developed by Sanchez-Craig (1990). These models have been the basis for developing effective interventions to promote health behaviour change, by modifying a problem behaviour or acquiring a positive behaviour. Moreover, these models have been widely applied in behaviour modification techniques in various healthcare settings. Indeed, much of the core principles of behavioural science models that are effective for other health-related areas are equally relevant to and can complement the strategies to change behaviours associated with oral cancer. For example, *Stages-of-Change* in "*Promoting nonpharmacologic interventions to treat elevated blood pressure"* are relevant to the patients who attempt to

quit smoking and reduce alcohol consumption for oral cancer prevention as well (Stuart et al., 1993; Goldberg et al., 1994; Walsh and Sanson-Fisher, 2001).

The first step in any behaviour modification intervention is the assessment of individual risk factors in clinical practice in order to inform decisions about risk factor management. This involves assessing a patient's readiness to make changes in their lifestyle and also assessing their health literacy (Harris and Lloyd, 2012; Harris et al., 2017). The *Stages-of-Change* model by Prochaska and DiClemente (1983), which is "an integrative model of change to conceptualize the process of intended behaviour change", describes essential stages of a patient's readiness to make changes in their lifestyle or behaviours (Prochaska and DiClemente, 1983; Prochaska et al., 2008). These includes:

1) Pre-contemplation (not ready to change)
2) Contemplation (thinking of changing)
3) Preparation (ready to change)
4) Action (making change)
5) Maintenance (staying on track)
6) Relapse (fall from grace)

Prochaska and DiClemente (1983) have provided a useful summary of these stages for smoking cessation interventions. They reported that the vast majority of smokers are in the pre-contemplation or contemplation stages. This model emphasizes the need to identify such patients and convince those who have never considered quitting smoking to do so effectively by advancing from one stage to the next (Prochaska and DiClemente, 1983; Walsh and Sanson-Fisher, 2001). The *Stages-of-Change* model has also been applied successfully to assess a wide variety of behaviours beyond smoking cessation such as alcohol abuse, physical activity, diet, weight loss, chronic pain, safer sex, condom use and many other problem behaviours (O'Connell and Velicer, 1988; DiClemente and Hughes, 1990; Marcus et al., 1992; Prochaska et al., 1994; Greene et al., 1999; Kerns and Rosenberg, 2000). This approach allows healthcare professionals to tailor (personalise) their advice - which has been demonstrated to be effective in supporting behaviour change (Wanyonyi et al., 2011).

Subsequent to assessment of individual risk factors, *Motivational Interviewing* is the most commonly used approach for the behavioural management of disorders, and has been defined as "a collaborative conversation style for strengthening a person's own motivation and commitment to change" (Miller, 1983; Miller and Rollnick, 2013). Motivational interviewing is a "patient-centred" psychotherapeutic approach that attempts to alter a patient's harmful behaviour – by relying on personality or engaging style of a person. It may occur with an individual or in a group format and in a range of settings, gaining particular interest in healthcare settings (for example: general medical or dental practice, general hospital wards, and emergency departments) (Britt et al., 2004; Rollnick et al., 2008). A number of systematic reviews have shown over a period of time the effectiveness of motivational interviewing for alcohol abuse, drug addiction, diet, physical activity, diabetes, oral health, and smoking cessation (Miller, 1983; Burke et al., 2003; Knight et al., 2006; Martins and McNeil, 2009; Lindson-Hawley et al., 2015).

In primary care, one of the key behaviour change frameworks for understanding the implementation of preventive interventions targeting behavioural risk factors (for example, tobacco and alcohol) is the "5A's Behaviour Change Model" (Whitlock et al., 2002; Glasgow et al., 2003; Glasgow et al., 2004; Goldstein et al., 2004; Dosh et al., 2005). This approach has been widely accepted for addressing behavioural risk factors and includes the following behaviour change "techniques" delivered by healthcare professionals:
1) Ask/Assess: systematic identification, assess behavioural risk factors, multiple risks, readiness to change, health literacy, inform decisions
2) Advise: tailored information, motivational interviewing
3) Agree: goal setting, shared decision making
4) Assist: referral to intensive interventions
5) Arrange: schedule follow up, maintenance (Glasgow et al., 2004; Goldstein et al., 2004; Dosh et al., 2005; Harris and Lloyd, 2012).

This patient-centred model of care demonstrates that an increase in patient motivation and behaviour change are associated with the progress along the pathway from assessment and advice to goal setting, referral, and follow-up. The 5 A's model has been used as a framework for understanding prevention and

for formulating recommendations in most of the current clinical guidelines in primary care medical practices (Fiore et al., 2008; RACGP, 2016), and has also been adapted in many dental practice guidelines (SDCEP, 2012; SDCEP, 2014).

In addition to assessing readiness for change, it is important to assess patient's health literacy in order to tailor appropriate messages and preventive approaches (Harris and Lloyd, 2012; Harris et al., 2017). Health literacy is defined as the "cognitive and social skills which determine the motivation and the ability of individuals to gain access to, understand, and use information in ways which promote and maintain good health" (Nutbeam, 2000). Studies have shown that patients with low health literacy are less likely to receive preventive interventions, as these patients are less likely to ask questions and leading to provider assumptions that these patients are not interested in preventive care (Beach et al., 2006). Patients with low health literacy could be supported by primary care professionals through provision, for example, of specific advice including 2-3 key points, repeating key points, demonstrating points using models or graphics, and at the end of the consultation confirming patients understand what they need to know (DeWalt et al., 2010; Harris and Lloyd, 2012; Harris et al., 2017).

The preventive advice (Advise/Agree) should then be tailored to a patient's readiness to change and health literacy. Where patients are uncertain as to whether they want to take action to improve their health or change harmful behaviours, motivational interviewing should be offered to help them. The main current focus of preventive behavioural strategies is the delivery of a "Brief Intervention", which involves "oral discussion, negotiation or encouragement, with or without written or other support; delivered by anyone who is trained in the necessary skills and knowledge; and are often carried out when the opportunity arises, typically taking no more than a few minutes for basic advice" (Bien et al., 1993; NICE, 2014). A brief intervention may also involve signposting/referral for further interventions, i.e. directing people to more intensive support, and follow-up visits (Assist/Arrange). Referrals to intensive preventive services could be delivered in a number of ways, for example, as group and individual programs, telephone and internet/web based interventions, or delivered by private provider or healthcare professional (including general

practitioner, practice nurse, psychologists, health educators) (Harris and Lloyd, 2012; Harris et al., 2017). Primary care professionals, at an individual patient level, can influence tobacco use or alcohol drinking levels by systematically providing opportunistic advice and offering support to all tobacco users or alcohol drinkers who attend primary care practices.

Despite the preponderance of guidelines, recommendations, and evidence on behavioural preventive interventions, it is difficult to establish precisely what they should involve and which components of interventions are most effective, particularly in primary care dental practice settings (Carr and Ebbert, 2012; Ramseier and Suvan, 2015).

1.4.1.2 Pharmacotherapy

Rigorous scientific research has shown that medical interventions or pharmacotherapies, delivered along with behavioural preventive interventions, are efficacious in promoting the cessation of major risk factors associated with oral cancer, in particular smoking cessation (Kottke et al., 1988; Cahill et al., 2013). There is limited evidence relating to the impact of medications or pharmacotherapy in the treatment of non-dependent alcohol abuse (Johnson et al., 2011). However, effectiveness has been reported for the use of medications to treat alcohol dependence (Ernst et al., 2008). The main focus of this thesis is the primary prevention of risk factors and not the secondary/tertiary prevention of addiction or dependence treatment, which is beyond the scope of this thesis. Thus, these approaches have not been discussed, and only pharmacotherapy, as part of primary prevention, is detailed below.

There are three standard smoking cessation medications which are licensed for this purpose in Europe and the Unites States - nicotine replacement therapy (NRT), bupropion and varenicline (Cahill et al., 2013). These medications have been shown to be more effective than placebo in helping patients to stop smoking (Kottke et al., 1988; Cahill et al., 2013). In addition, varenicline has been shown to be effective in helping people to stop using smokeless tobacco, while NRT and bupropion have not been shown to help smokeless tobacco users to quit (Ebbert et al., 2011). NRT has been a major element of programmes to stop smoking. Other critical components of treatment include proper assessment

of the patient, appropriate advice or counselling, and support and follow-up to ensure compliance (Kottke et al., 1988; Cahill et al., 2013).

One of the evolving technologies to help smokers who want to reduce the risks of smoking is the use of "Electronic Cigarettes" (McRobbie et al., 2014). Electronic cigarettes are electronic devices that produce a vapour or smoke-like aerosol for inhalation, with or without nicotine (the total level of nicotine in vapor generated by 20 series of 15 puffs varied from 0.5 to 15.4 mg) (Goniewicz et al., 2012). Some electronic cigarettes look like regular cigarettes, cigars, or pipes; while others look like USB flash drives, pens, and other everyday items. They lack most of the toxins from cigarette smoke. A recent Cochrane review examined the effectiveness of electronic cigarettes to help smokers quit over the long-term (McRobbie et al., 2014). This review showed a reduction in cigarette consumption in electronic cigarette users compared with placebo (reported in 2 trials) and NRT or nicotine patches (reported in one trial). However, the small number of effectiveness trials limits the certainty of these findings. The electronic cigarette has been a topic of interest among smokers, healthcare professionals and policy makers to know if these devices could help in smoking harm reduction. Thus, further research is needed to confirm this (McRobbie et al., 2014).

1.4.2 Role of primary care dental team in delivering behaviour change interventions

A series of current narrative reviews, systematic reviews, and even randomised controlled trials have established that the dental team can play a potentially important role in disseminating oral health promotion advice (Conway et al., 2002; Macpherson et al., 2003; Binnie et al., 2007; Watt et al., 2014; Ramseier and Suvan, 2015). In the UK, primary prevention aimed at changing behaviours (i.e. avoidance of tobacco use, controlled use of alcohol) is viewed as a priority by the *Department of Health*, *National Institute for Health and Care Excellence (NICE)*, and the *General Dental Council (GDC)*, and dental team members are encouraged to advise proactively against risky behaviour and are expected to deliver oral cancer prevention as appropriate (PHE, 2014a; NICE, 2015; GDC, 2017). Moreover, the implementation of prevention and cessation counselling for tobacco and alcohol use in a dental practice has been recommended by the

WHO's "*Global Oral Health Programme"* and "*Oral health action plan"* as one of the priority goals, and has also been recommended by many current clinical guidelines worldwide (WHO, 2007b; Petersen, 2008; SDCEP, 2014; SIGN, 2014; RACGP, 2016).

It has been recommended that in order to contribute to the prevention of oral cancer effectively, dental professional roles may include: understanding the aetiology of oral cancer; recognising increased-risk patients as a result of lifestyle/behaviours; recording social and medical history; effectively communicating risks to patients to reduce risk levels; delivering appropriate prevention (providing motivational counselling, education, goal setting, arranging referral/signposting, and follow up), taking into account the patient's sociodemographic context, and promoting behaviour change (Petersen, 2008; BDA, 2010). Research has shown that dental professionals are in a key position to identify the apparent first signs of tobacco and alcohol use, for example, tooth discoloration, bad breath, soft tissue changes and tooth wear, and thus provide an excellent platform for delivering tobacco cessation and alcohol reduction counselling to their patients (Petersen, 2008; Shepherd et al., 2010; Amemori et al., 2011; SDCEP, 2014).

The *General Dental Council* has recently identified improved oral cancer detection as a recommended area for the Continuing Professional Development (CPD) of dental professionals. Moreover, the *General Dental Council* has an expectation that practitioners deliver oral cancer prevention, and it is now a professional duty that dental professionals provide up-to-date evidence-based preventive care to patients for behavioural risk factors in dental practice settings. In a recent hearing, a dentist was placed under supervision for failing to ensure that a patient with ulceration was urgently referred to a specialist, and was also cited on a charge that the dentist had "failed to ensure that Patient A [who smoked 10-15 cigarettes a day] was provided with smoking cessation advice" (GDC, 2017). However, it is still not quite defined or specified as to what this advice might involve or how this could/should be delivered in a primary care dental practice setting.

Moreover, it is crucial for all primary care professionals (medical and dental) to encourage patients to become aware of the harmful effects and benefits of tobacco cessation and reducing alcohol consumption, tailor advice to the needs of the patient, and thus aim to prevent oral diseases and promote general health (Watt et al., 2014). One study investigated the role of primary care health professionals in the prevention and detection of oral cancer by conducting a questionnaire and focus group interview study among medical and dental professionals in Scotland (Macpherson et al., 2003). The findings indicated that over half (58%) of dentists reported examining regularly for signs of oral cancer while for medical practitioners, examining the mouth was usually in response to symptoms being reported by patients. Although most general medical practitioners indicated they considered they should have a role in oral cancer detection, many felt that opportunistic screening should primarily be the remit of dental professionals (Macpherson et al., 2003).

Most of the existing literature on preventive interventions in a dental practice setting has reported only a small proportion of dental professionals being involved routinely in enquiring about a patient's tobacco and alcohol use (Conway et al., 2002; Macpherson et al., 2003). For example, in the study by Macpherson et al. (2003), only 19% of dental professionals reported asking about a patient's smoking status, while only 3% asked about a patient's alcohol use. However, a recent survey study in the UK, reported relatively higher proportion of dental professionals providing smoking cessation advice (76.7%) and alcohol advice (38%); though the dentists in this study reported a lack preventive knowledge, but showed positive attitudes towards delivering prevention (Yusuf et al., 2015). Moreover, these studies identified a need for further training for primary care dental professionals to strengthen their abilities to diagnose oral cancer and promote oral cancer prevention activities, i.e. advice on smoking and alcohol (Conway et al., 2002; Macpherson et al., 2003; Yusuf et al., 2015). Moreover, it was emphasised that members of the primary care dental team should receive information on various services or groups to which patients could be referred for counselling (Conway et al., 2002; Macpherson et al., 2003).

Although, the current evidence and guidelines highlights the increased involvement of dental professionals in preventive activities (for example, advice

or counselling) (Watt et al., 2014; Yusuf et al., 2015), there is limited evidence for the effectiveness of these activities in a dental practice setting (Carr and Ebbert, 2012; Ramseier and Suvan, 2015). A key element of supporting behaviour change preventive interventions in a dental practice setting is to understand the process and barriers (and facilitators) involved in changing health-related behaviours (Watt et al., 2014). In addition, it is fundamental to recognise the assistance and support patients need to achieve sustained behaviour change (Watt et al., 2014). The various barriers reported in the literature to implement behaviour change interventions in a primary care dental practice setting are presented below.

1.4.3 Evidence-based practice and implementation of behaviour change interventions in a primary care dental practice

"Implementation Science" is a new and developing area which focuses effort on the factors (barriers and facilitators) than affect or promote the systematic uptake of evidence-based practice by healthcare professionals in routine clinical and organisational settings. This helps to improve the quality and effectiveness of healthcare services (Eccles and Mittman, 2006; Bauer et al., 2015). The field has developed due to known issues, involving staff, patient and organisational aspects, which affect the reliable adoption of evidence-based practices (Bauer et al., 2015). Exploring such issues is a vital and necessary step in supporting healthcare teams in implementation (Bauer et al., 2015). In order to understand the complex settings or contexts in which implementation efforts occur (due to the multiple interaction levels, for example, healthcare providers, teams, patients), this field needs a solid grounding in theory. That is, the implementation effort requires "clear, collective, consistent use of theory to build knowledge about what works, where, and why" (Grol and Grimshaw, 2003; Damschroder and Hagedorn, 2011; Bauer et al., 2015).

Previous implementation attempts have usually taken the form of interventions or trials which seek to identify barriers and facilitators to adoption (rates and quality of use) of evidence-based practice by employing specific implementation strategies in controlled trials. For example, implementation trials to test a theory-driven implementation strategy for delivering smoking cessation advice by general practitioners, or to increase access to alcohol use disorder

pharmacotherapy in primary care settings (Michie et al., 2011; Bauer et al., 2015). Other implementation studies enhance evidence-based practice adoption under naturalistic conditions. However, practice-based uptake remains variable and there are concerns about long-term sustainability and clinical effectiveness (Bauer et al., 2015).

Despite dental practice being identified as an ideal setting to deliver health promotion activities to prevent oral cancer, i.e. tobacco cessation and alcohol reduction advice, there have been barriers identified in the successful implementation of these activities in a dental practice setting (Macpherson et al., 2003; Shepherd et al., 2010; Amemori et al., 2011; Watt et al., 2014). Research has shown that despite being aware of the harmful effects of tobacco and alcohol use, dental professionals report barriers in assisting patients to quit. Various barriers being reported are lack of knowledge, skills, confidence, and time, and even doubts about the effectiveness of counselling (Macpherson et al., 2003; Shepherd et al., 2010; Amemori et al., 2011; Yusuf et al., 2015). These barriers have resulted in a widening gap between evidence-based clinical preventive care (including guideline recommendations) and their implementation. Thus, there is a need to design interventions to enhance the implementation of evidence-based preventive care in a dental practice setting (Amemori et al., 2011; Watt et al., 2014).

1.5 Rationale and gaps identified

There is a plethora of evidence and guidance available for dental professionals regarding the causes of oral cancer worldwide (WHO, 2007b; Petersen, 2009; Winn et al., 2015). The current evidence also shows the potential importance of dental professionals in delivering preventive interventions. However, this literature review has identified uncertainties within the dental setting environment about the best approaches or strategies to assess risk factors associated with oral cancer (Petersen, 2009), and the effective components of preventive interventions for behaviour change. This includes questions about what are the “active ingredients”/mechanisms (Petersen, 2009; Carr and Ebbert, 2012; Ramseier and Suvan, 2015) and implementation strategies (i.e.

"how to do" rather than "what to do") (Grol and Grimshaw, 2003; Damschroder and Hagedorn, 2011; Bauer et al., 2015).

The literature shows that specific preventive interventions are often absent or only cursorily described in oral cancer prevention/early detection clinical guidelines (SIGN, 2006; Petersen, 2009; NCC-C, 2016). There is much policy and guidance regarding tobacco and alcohol interventions more generally (WHO, 2004; WHO, 2005b), however, practical detailed advice applicable to the dental practice setting is more limited. There is a need to determine the potential role of teachable moments related to oral cancer (which could be created, for example, through risk factor assessment or clinical examination) to facilitate dental professionals deliver more effective risk communication (Lawson and Flocke, 2009; Ahmed et al., 2012). It is often still hard to establish what these preventive interventions should involve, and which components of interventions are most effective, particularly in a primary care dental practice setting (Carr and Ebbert, 2012; Ramseier and Suvan, 2015). In addition, there are implementation gaps in relation to evidence-based preventive practice targeting the behavioural risk factors. These include gaps in: assessment, advice, referral, and maintenance (Amemori et al., 2011; Harris and Lloyd, 2012).

Thus, there is a need to more clearly present details of evidence-based approaches for risk factor assessment and prevention for dental professionals for effective behaviour change to benefit those at risk of oral cancer (for example, tobacco cessation, reduced alcohol consumption). Thus, this thesis involves identifying and appraising evidence for the best practice in oral cancer risk factor assessment and the delivery of preventive interventions for effective behaviour change by conducting a systematic overview of systematic reviews and clinical guidelines. The barriers and facilitators to implementation of this synthesised evidence in primary care dental practices were then identified by conducting face-to-face interviews with dental professionals. In order to maximize the impact of the systematic overview and dental professional interviews, finally, interviews with patients attending primary care dental practices were conducted to gather their perceptions, compare them with dental professional views, and to make recommendations for the development of an oral cancer prevention intervention package.

The reason to focus on tobacco and alcohol (taking into consideration various sociodemographic factors) in this thesis was that these are the major oral cancer risk factors, with high population-attributable risks. Additionally, they are implicated in a wide range of diseases beyond oral cancer, thus integrating oral and the wider public health agenda by improving not only oral health but also general health (Sheiham and Watt, 2000; WHO, 2016b). The "*WHO global action plan for the prevention and control of non-communicable diseases 2013-2020*" calls on the need to focus on reducing these common or shared risk factors and this is a major strategic priority for the WHO going forward for the prevention and management of all leading non-communicable diseases (WHO, 2016b).

The "dental professionals" in this thesis included: dentists, dental hygienists, dental therapists, dental nurses, and oral health educators in primary care dental practice setting.

Chapter 2 Aims and overview

This chapter sets out the overarching aims and objectives of the research, and gives a brief overview of the thesis.

2.1 Aims and objectives

The overall aims of the research were:

a) to synthesise best practice evidence (from current systematic reviews and clinical guidelines) in relation to undertaking assessment of behavioural risk factors for oral cancer and delivering preventive interventions (for example, advice, counselling, and/or referral) in the primary care dental practice setting, via a systematic overview (Chapter 3);

b) to identify barriers and facilitators to implementation of the synthesised best practice evidence for behavioural risk factor assessment and subsequent preventive interventions for oral cancer, via interviews with dental professionals in Scotland (Chapter 4);

c) to examine the views of patients attending primary care dental practices in Scotland on the acceptability of behavioural risk factor assessment and subsequent preventive interventions for oral cancer, via short patient interviews/survey (Chapter 5); and

d) to make recommendations to inform the development of interventions to support evidence-based oral cancer prevention delivered by dental professionals in the primary care dental practice setting in Scotland and beyond (Chapter 6).

Specific objectives included:

a) identify data sources for systematic review evidence and clinical guidelines; determine scope of overview via inclusion and exclusion criteria; specify search terms for systematic review evidence and clinical guidelines; collate initial dataset; screen for inclusion, including cross-coding comparisons; appraise strength of evidence in systematic reviews and clinical guidelines via validated

appraisal tools (also including cross-coding); extract main findings; synthesise high-quality evidence/guidance; assess the applicability of high-quality findings from medical/pharmacy settings to dental practice setting;

b) target dental professionals for recruitment, stratified by area-based deprivation codes; obtain university ethical approval for methods; develop and pilot in-depth interview schedules; contact practices and arrange interviews; obtain consent and conduct in-depth interviews; transcribe and analyse qualitative data;

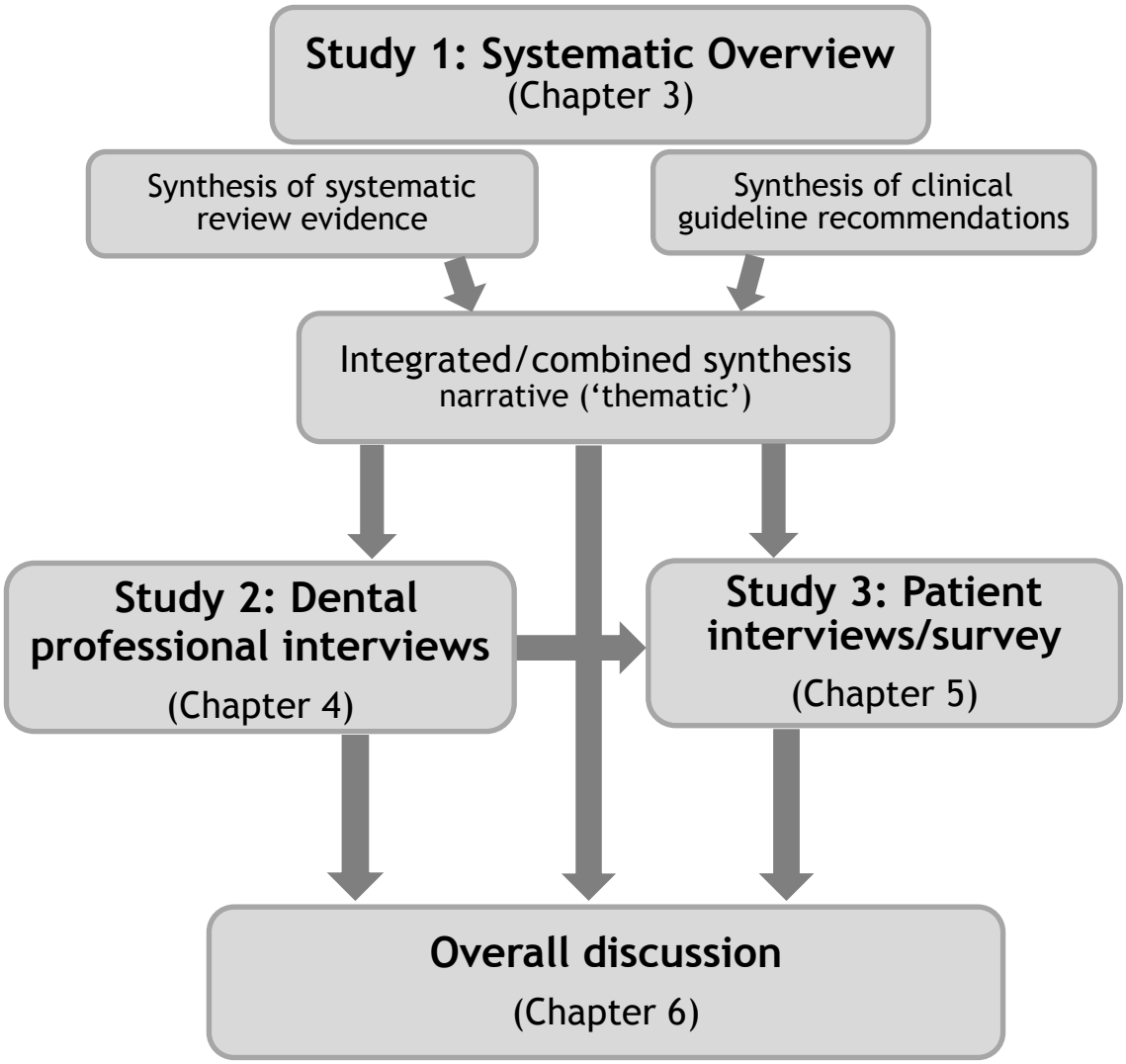
c) target dental practices for access to patient recruitment, stratified by area-based deprivation codes; obtain NHS ethical approval for methods; develop and pilot short semi-structured interview schedules; contact practices and arrange times; obtain consent and conduct short interviews; transcribe and analyse qualitative data; collate quantitative (short survey) data;

d) synthesise evidence-base and professional and patient views; make recommendations for intervention; discuss wider policy implications; set out future research directions.

2.2 Overview of the thesis

Figure 2.1 gives an overview of the following Chapters 3-6.

Figure 2.1: Overview of the chapters in this thesis



It can be seen from Figure 2.1 that Chapter 3 proceeds via an overview of systematic reviews and clinical guidelines in parallel, then bringing these strands together in a narrative synthesis. This feeds (denoted by arrows) into the design of research questions for both Chapter 4 (dental professional perspective on evidence) and Chapter 5 (patient perspective, which builds also on the professional viewpoint).

Considering the aims and objectives stated above, it was decided that adoption of a pragmatic approach was appropriate for this research. The pragmatic approach links methods directly to the research questions, paying less attention to a philosophical commitment to a particular view of data (epistemology) or the world/reality (ontology); i.e. the design and methods are best suited to the purpose (Darlington and Scott, 2002; Creswell and Creswell, 2017). Rather than simple practicality, pragmatism has been seen as a philosophical paradigm in its own right (Teddlie and Tashakkori, 2009). Pragmatism is often adopted in applied health services research to guide researchers, as it avoids inherent bias in particular belief systems, such as constructivism (qualitative / inductive) or positivism (quantitative / deductive) (Teddlie and Tashakkori, 2009; Creswell and Creswell, 2017). Thus, here each method (i.e. systematic overview, qualitative interview, and qualitative survey) was chosen to fit particular research questions. A detailed description and justification for the specific methods chosen for each study in this thesis will be given in the respective chapter; however, a brief overview of the chosen methods for each study/chapter is outlined here.

2.2.1 Study 1: Systematic overview study (Chapter 3)

First, a ‘systematic overview’ of systematic reviews and clinical guidelines was conducted to establish best practice for addressing the major behavioural risk factors associated with oral cancer in primary care dental practice setting. Chapter 3 details the rationale for the search scope, which was across primary care more generally, and not restricted to oral cancer interventions. Firstly, the best practice, high-quality, evidence-base (reviews) and recommendations (guidelines) were synthesised in separate ‘streams’ using rigorous selection, screening and appraisal / risk of bias techniques; then a novel integrated comparison of both streams was provided.

2.2.2 Study 2: Qualitative in-depth interview study (Chapter 4)

Chapter 4 shows how qualitative in-depth interviews were conducted with dental professionals in Scotland, including dentists, dental hygienists, and dental therapists. Theory-based analysis aimed to describe the feasibility of translating the best practice evidence (from Chapter 3) into dental practice setting, and

examining potential oral cancer prevention interventions to support dental professionals in daily preventive care.

2.2.3 Study 3: Qualitative survey study (Chapter 5)

Then a small qualitative survey (individual interviews with a mixture of open-ended and closed-ended (scale) questions) was conducted with patients (who are the target population of oral cancer prevention) attending primary care dental practices in Scotland. The aim was to assess patient views on the acceptability of the evidence-based preventive interventions (from Chapter 3) in the dental practice setting, and to compare/contrast the patient perspective with that of the dental professionals (from Chapter 4).

2.2.4 Overall discussion of findings (Chapter 6)

Finally, the three studies described above are then discussed in Chapter 6 in terms of potential future interventions to improve the entire 'end-to-end' preventive consultation in a primary care dental practice. A high-level discussion of findings from all these studies helped to make recommendations for the development of an oral cancer prevention intervention delivered by dental professionals, and for associated future research. Strengths and limitations of the work are also outlined in this final chapter.

Chapter 3 Systematic overview of systematic reviews and clinical guidelines: assessment and prevention of behavioural risk factors associated with oral cancer to inform dental professionals in primary care dental practices

3.1 Introduction

Oral cancer aetiology is multifactorial, and tobacco and alcohol are recognised as the major risk factors for both oral cavity and oropharyngeal cancers. Primary care dental professionals have a potential role in delivering preventive interventions (for example, tobacco cessation and reducing alcohol-related harm). In order to contribute to the prevention of oral cancer effectively, dental professionals need to assess patients in relation to the major risk factors (tobacco and alcohol), and deliver appropriate prevention, taking into account the patient's sociodemographic background. However, there are uncertainties about the best approaches/strategies to assess risk factors associated with oral cancer, effective components of preventive interventions for behaviour change, and implementation strategies in primary care dental practices. Moreover, there is a raft of systematic review literature and international clinical guidelines, some focused in primary dental care, but the majority from across primary care settings. Thus, to address these research gaps and to distil this body of literature a systematic overview of both the systematic review literature and clinical guidelines was undertaken. This involved systematically searching, identifying and quality appraising the international literature (and grey literature for clinical guidelines), followed by synthesis of the evidence for best practice in delivering oral cancer preventive interventions (including risk factor assessment, behavioural advice, and/or signposting/referral) for effective behaviour change (for example, tobacco cessation and reduced alcohol consumption) to benefit those at risk of oral cancer. A systematic overview is the commonly used term used for systematic reviews of systematic reviews and systematic reviews of clinical guidelines (Koes et al., 2010; Silva et al., 2012; Lee et al., 2014; Alvarez-Bueno et al., 2015; Roque and Esteves, 2016). Silva et al. (2012) reported that "overviews of systematic reviews" are suited especially for

healthcare decision-makers, and are developed to provide a synthesis and incorporate information from multiple studies in order to reduce the uncertainties in decision-making; especially when the amount of "evidence" or studies has reached the stage where there are multiple systematic reviews covering either updates with recent randomised controlled trials, or in different contexts or settings. Overviews have a similar structure to intervention or trial reviews, but include systematic reviews (rather than primary studies); and are conducted in priority areas where a number of intervention systematic reviews already exist (Silva et al., 2012). More recently this methodology has also been applied to clinical guidelines to utilise these sources of evidence, where randomised controlled trials or systematic reviews perhaps do not exist, or cover areas of practice not suited to randomised trial methodology (Koes et al., 2010; Lee et al., 2014). Researchers have also reported that this new type of study (i.e. overviews) could generate a new hierarchy in the pyramid of evidence (Becker and Oxman, 2011).

Hence, it was decided to conduct a systematic overview to identify the best practice in delivering oral cancer preventive interventions (including risk factor assessment, behavioural advice, and/or signposting/referral).

3.2 Aims and research questions

The main aim of this systematic overview was to collate, appraise, and synthesise evidence from systematic reviews and clinical guidelines on the best practice for a) undertaking an assessment of the major behavioural risk factors (tobacco smoking and alcohol drinking) associated with oral cancer, and b) delivering preventive interventions for major behavioural risk factors associated with oral cancer (for example, behavioural advice, signposting/referral to preventive services) by dental professionals in primary care dental practices.

Specific objectives were to:

- identify data sources for systematic reviews and clinical guidelines;
- determine scope of overview via inclusion and exclusion criteria;

- specify search terms for systematic reviews and clinical guidelines; collate initial dataset; and screen for inclusion including cross-coding comparisons;

- appraise strength of evidence in systematic reviews and clinical guidelines via validated appraisal tools (also including cross-coding);

- extract main findings; synthesise high quality evidence/guidance; assess the applicability of high-quality findings from medical/pharmacy settings to dental practice;

- compare and contrast between evidence synthesised from current systematic reviews and clinical guidelines;

- finally synthesise systematic reviews and clinical guidelines together.

These objectives were set in order to address the following broad research questions for this study, developed in accordance with the PICOS (Population, Intervention, Comparator, Outcomes, and Setting) format (Moher et al., 2015; Shamseer et al., 2015):

a) What methods are considered best practice for assessing the major behavioural risk factors associated with oral cancer delivered by dental professionals on patients visiting primary care dental practices?

b) What methods are considered best practice for effective behaviour change in relation to delivering preventive interventions for major behavioural risk factors associated with oral cancer by dental professionals on patients visiting primary care dental practices?

c) What is the commonality and/or divergence in recommended practice (on oral cancer risk factor assessment and delivering preventive interventions) between evidence synthesised from current systematic reviews and clinical guidelines currently available to primary care dental professionals, and to synthesise systematic reviews and clinical guidelines together?

3.3 Methods

The methodology for this overview was registered with PROSPERO (registration number CRD42015025289). The protocol was published in the journal *BMC Systematic Reviews* (Mathur et al., 2015). The PRISMA-P 2015 statement and checklist for systematic review protocols was consulted for developing this protocol (Moher et al., 2015; Shamseer et al., 2015). The PRISMA-P 2015 checklist is provided in Appendix 1. Other similar systematic reviews of reviews and/or guidelines were also referred to for convention, for example: Koes et al. (2010); Al-Ansary et al. (2013); Álvarez-Bueno et al. (2015); and Damery et al. (2015).

Portions of this "Methods" section have been extracted from the following published protocol: (Mathur et al., 2015).

Ethical approval was not required for this study as it reports a systematic overview that involved no primary data collection.

3.3.1 Eligibility criteria

3.3.1.1 Types of studies

Systematic reviews or meta-analyses (of randomised and non-randomised studies) and clinical guidelines (published/e-learning) available worldwide were included in this systematic overview. The included systematic reviews comprised evidence for the effectiveness of interventions for addressing risk factors associated with oral cancer and/or for relevant preventive interventions delivered in a primary care setting. The included clinical guidelines were all recognized by a national, governmental or provider organization, and comprised of recommendations or best practice related to risk factors associated with oral cancer, history taking, delivery of preventive interventions in a primary care setting and/or referral to preventive services.

3.3.1.2 Types of population

The study population/ target groups included in the overview were: for risk factor assessment - all adult patients (18 years and above) attending primary

care practices (dental/medical/pharmacy); while for preventive interventions - adults who were at high risk of developing oral cancers, i.e. tobacco users, alcohol drinkers.

3.3.1.3 Types of interventions

The overview included primary preventive interventions to assess risk factors and/or promote behaviour change. Interventions included behavioural advice, counselling, brief interventions, motivational interviewing and signposting/referral to preventive services, or any combination of these. Secondary prevention screening interventions for the early detection of oral cancer (for example: visual screening, visual staining using toluidine blue, oral cytology using brush biopsies, fluorescence imaging and light-based techniques) were excluded from this overview.

3.3.1.4 Types of outcome measures

The main outcomes of interest were:

1) The best practice (effective) evidence in oral cancer risk factor assessment (for example, how best to ask about behaviour / assess risk / communicate risk).

2) The best practice (effective) evidence in preventive interventions:
a) Effectiveness or significant effects of interventions, i.e. changes in behaviours (for example, decrease in tobacco consumption or smoking cessation, reduction in alcohol consumption - from baseline to follow-up)
b) Description of evidence-based preventive interventions (for example, duration and content of preventive interventions, number of follow-up sessions, referral pathways)
c) Role of specific aspects, such as combination interventions (addressing multiple risks).

3.3.1.5 Types of setting

A major decision in undertaking the overview was whether to restrict the setting to primary care dental practices (i.e. the first point of contact in the health care system, for example, general dental practice and the public dental service), or

to include interventions delivered in other primary care settings, such as, general medical practice and community pharmacy services. It was decided that evidence would only be restricted to the dental practice setting if literature of sufficient quality and quantity could be identified. After scoping the initial literature (Chapter 1), it was decided that all primary care settings (dental and medical/pharmacy) would be included, and best practice identified elsewhere would be separately appraised for its applicability/feasibility of implementation by dental professionals. Prevention interventions and guidelines for secondary or tertiary settings were excluded from this study.

Professionals involved in reviewed studies or targeted by included guidelines were thus:

- dentists, dental therapists, dental hygienists, dental nurses, and oral health educators in primary care dental practices:
- primary care physicians, general practitioners, family physicians, and practice nurses in primary care medical practices;
- pharmacists, community pharmacists, and pharmacy assistants in primary care pharmacy practices.

3.3.2 Search strategy

A dedicated University Librarian (HW-A) helped develop the search strategy for identifying systematic reviews and clinical guidelines. The search terms were identified from scoping the initial literature and from MeSH subject headings. In order to find all relevant data, the search terms included were broad, drawing from across primary care (both dental and medical practice setting). In addition it was decided not to limit the search to “oral cancer”, because of not wanting to rule out good evidence and/or guidelines on how to assess risk and deliver oral cancer prevention that could be extracted from systematic reviews and/or clinical guidelines aimed at another clinical condition (for example, smoking cessation strategies targeting periodontal disease) (SDCEP, 2014).

3.3.3 Information sources

The literature search for systematic reviews and clinical guidelines was carried out in August 2015 in the following health and psychological electronic databases: *Cochrane Library, Ovid MEDLINE, EMBASE, Web of Science, PsychINFO, PubMed, TRIP,* and *Google Scholar*.

An internet search of the websites of health boards and relevant (professional, medical, dental, public health, scientific) organizations/agencies was also carried out in August 2015. A list of organizations/databases for searching clinical guidelines has been provided in Appendix 2. A dedicated University Librarian (HW-A) helped to develop a bespoke protocol to allow identification of clinical guidelines (published/e-learning) via websites of relevant organizations/agencies and an Internet Search Engine (Google). The bibliographies or reference lists of identified documents were also hand-searched for additional references. Experts in the area were contacted to help locate any unpublished and ongoing research as the overview proceeded to minimise publication bias.

3.3.4 Literature search

The principal researcher or author (SM) conducted all of the literature searches (systematic reviews and clinical guidelines). The *Ovid MEDLINE* search strategy is provided in Appendix 3. The *MEDLINE* search strategy was finalised first and then it was adapted for other databases.

Key terms were organised according to three subsets:

- Prevention (for example: advice, cessation, harm reduction, brief intervention, counselling);
- Primary care (for example: general dental practice, general medical practice, pharmacy);
- Risk factors (for example: tobacco, alcohol)

Various truncation symbols (for example: *, ?, $) and Boolean operators (for example: AND, OR, proximity) were used to refine the search.

The *InterTASC Information Specialists' Sub-Group (ISSG)* search filter resource provides easy access to published and unpublished search filters designed to retrieve records by study design or focus (ISSG, 2015). Thus, in order to retrieve systematic reviews in *Ovid MEDLINE* and *EMBASE*, the *Scottish Intercollegiate Guidelines Network (SIGN)* search filters were used; whereas to retrieve clinical guidelines in *Ovid MEDLINE*, the *University of Texas School of Public Health* search filters were used (ISSG, 2015). The search was limited to systematic reviews and clinical guidelines by using the filters provided in the databases: *Cochrane Library, PsychINFO, PubMed and TRIP*. In the *Web of Science* database, the search was limited to "Reviews" (including literature reviews and systematic reviews), as there was no filter for systematic review only. Using search filters helped to reduce the number of articles to be screened while identifying higher quality evidence and maximising specificity (Lee et al., 2012). The *SIGN* search filters and the *University of Texas School of Public Health* search filters have been provided in Appendix 4.

No language restrictions were applied for identifying systematic reviews and clinical guidelines. The non-English papers were translated to English with the help of the Google Translate and private translation services. Clinical guidelines were limited to the last 10 years (2006 to 2015). There were no date restrictions for systematic reviews. Narrative/literature reviews and systematic review protocols were excluded.

3.3.5 Data management

In accordance with Cochrane review group guidance, all steps in data management (review of titles and abstracts, inclusion and exclusion decisions, data extraction, quality appraisal, assessing risk of bias, collating themes for final synthesis) were carried out independently by two members of the multidisciplinary review team (author (SM) + one of three supervisors (AJR/DIC/LMDM)), and discrepancies discussed with the wider team (Higgins and Green, 2008). It was decided if, after discussions between the review team,

uncertainties persisted, authors of the original studies would be contacted to resolve disagreements. However, this was not required as discrepancies were resolved by discussion between the author and supervisors.

Records from all searches were combined, imported into *EndNote X7* bibliographic software (Reuters, 2013) and duplicate records were removed.

3.3.6 Data screening

Two investigators, the principal researcher (SM) and principal supervisor (AJR), independently reviewed the title and abstract of all records against the eligibility criteria (inclusion/exclusion criteria) to select for full text review. Disputed papers were included at this stage. Full text copies of selected systematic reviews and clinical guidelines were obtained and used to assess the eligibility of the records to be included in the final systematic overview. Reasons for exclusion were recorded and reported (Appendix 5). Where more than one eligible systematic review or clinical guideline of the same research data existed, the most recent publication was included. Discrepancies were discussed among the two reviewers (SM and AJR) and a few discrepancies were also discussed with the wider team (DIC and LMDM).

To summarize, a PRISMA four-phase flow diagram was completed at the end of the study screening and selection process (Figures 3.1 and 3.3 in the Results section).

The next steps were to extract data from the systematic review and clinical guidelines for separate systematic quality assessment / risk of bias exercises and synthesis, and finally to compare, contrast, and synthesise systematic reviews and clinical guidelines together.

3.3.7 Data extraction

Data were extracted independently by the author and checked for accuracy by one of the supervisors (AJR and DIC). The data extraction template was adapted from the *Cochrane Collaboration* (Higgins and Green, 2008) and the *Centre for Reviews and Dissemination (CRD) at the University of York* (CRD, 2009) data

extraction checklist. The data extraction form was pilot-tested on a small set of papers (three systematic reviews and three clinical guidelines) and refined to ensure the correct sensitivity and specificity.

The following review or guideline characteristics were extracted: number and type of included studies, target population, setting or provider (for example: general practitioner, dentist, nurse, pharmacy), risk factors assessed, type of intervention (content, duration and number of sessions), type of control/comparison group, how professionals communicated risks or assessed risk factors, advice provided (whether tailored or not), training of providers, any referral to preventive services or any follow-up, main findings/outcomes for abstinence or behaviour change, and overall conclusion of study.

All but one of the included clinical guidelines were published in English; one guideline was published in Czech (Kralikova et al., 2015). This guideline was translated to English with the help of the Google Translate and private translation services.

3.3.8 Quality assessment and risk of bias

3.3.8.1 Systematic reviews

In order to assess the methodological quality of included systematic reviews, the AMSTAR (**A** **M**ea**S**urement **T**ool to **A**ssess systematic **R**eviews) instrument was used (Shea et al., 2007). The AMSTAR checklist consisted of 11 key items designed to help systematically rate the quality of various methodological aspects (for example: an 'a priori' design, comprehensive literature search, data extraction by at least two independent reviewers, at least two electronic sources searched, duplicate study selection, list of included and excluded studies, quality of included studies assessed, quality considered while formulating conclusions, assessment of publication bias, conflict of interest stated) (Shea et al., 2007). AMSTAR categorizes quality as: 8-11 high quality, 4-7 medium quality, and 0-3 as low quality, as per previous studies (Shea et al., 2007; Sharif et al., 2013).

In addition, the ROBIS (**R**isk **O**f **B**ias **I**n **S**ystematic reviews) tool was used for assessing the risk of bias in included systematic reviews (Whiting et al., 2016). This is a new tool which is completed by assessing relevance, identifying concerns with the review process and finally judging risk of bias (high, low, or unclear). Both AMSTAR and ROBIS assessments of included systematic reviews were assessed independently by two reviewers (SM and AJR/DIC/LMDM). The final score was determined, if different between two reviewers, by discussion among the wider team.

3.3.8.2 Clinical guidelines

The quality of the included clinical guidelines was appraised using the AGREE II (**A**ppraisal of **G**uidelines for **RE**search & **E**valuation **II**) instrument by two reviewers (SM and AJR/DIC/LMDM) (Consortium, 2009). The final score was determined, if different between two reviewers, by discussion among the wider team. The Conference on Guideline Standardization (COGS) checklist (Shiffman et al., 2003) to assess the validity of a clinical practice guideline was also consulted, but it was decided to proceed with AGREE II. As AGREE II is the better validated (and more recently updated and widely supported) measure and covers substantially the same ground (Bouwmeester et al., 2009; Sabharwal et al., 2014).

AGREE II consists of 23 key items in 6 domains, and was used to assess the methodological rigor and transparency in the development of the included clinical guidelines (Consortium, 2009). Each domain helped to appraise the quality of clinical guidelines in a unique dimension, i.e. scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability and editorial independence. This instrument also allows researchers to assign to each clinical guideline an overall quality rating between 1 (lowest possible quality) and 7 (highest possible quality), and to indicate whether the user would recommend the guideline for use in practice or not.

Some researchers have been critical of AGREE II stating that it does not provide a clear distinction between high- and low-quality guidelines (Hoffmann-Eßer et al., 2017). Many researchers have therefore used a priori cut-offs to distinguish between high- and low-quality guidelines (Lee et al., 2014; Hoffmann-Eßer et

al., 2017). Thus, the principal researcher and the supervisors decided a priori that an overall AGREE II score of 6 or 7 would be considered a high-quality guideline and would be recommended for use in practice, guidelines that scored 3 to 5 would be medium quality and recommended with modifications, and a score of 1 or 2 would be low-quality and not recommended for use in practice. Other similar texts were also referred to for convention (Lee et al., 2014).

3.3.9 Data synthesis

The general frameworks for conducting narrative ('thematic') synthesis developed by the *Economic and Social Research Council (ESRC) Methods Programme* (Popay et al., 2006), along with guidance from the *Centre for Reviews and Dissemination* (CRD, 2009), and Petticrew and Roberts (2008) text book were adopted for conducting a narrative synthesis in "systematic overviews". A final "integrated/combined synthesis" then compared and contrasted evidence from the reviews and guidelines streams.

The best practice evidence was assessed via a narrative synthesis of extracted data, taking quality and recency of evidence into account. Systematic reviews and clinical guidelines were initially kept as separate 'streams', and each was synthesised rigorously according to the guidance on conducting narrative synthesis in the context of systematic reviews (Popay et al., 2006; CRD, 2009). Popay and co-workers (2006) described this approach as the "Narrative Synthesis in Systematic Reviews (N.S.S.R.)". These frameworks were developed for answering a wide a range of review questions. The guidance by Popay et al. (2006), for practical reasons, focuses on the conduct of mainly two types of systematic reviews which have particular salience for those who want their work to inform 'policy and practice'; for example, systematic reviews addressing the effects of an intervention and implementation of an intervention in primary trial studies (Popay et al., 2006). As this overview aimed to assess the best practice evidence for an effective behaviour change intervention in the primary care practice, this framework was deemed appropriate and was thus adopted for conducting narrative synthesis in this study (for both the systematic reviews and clinical guidelines). Moreover, for narrative synthesis of clinical guidelines,

besides adapting these frameworks, other similar texts (reviews of guidelines) were also consulted (Koes et al., 2010; Polus et al., 2012).

The main steps (as adapted from above frameworks) in synthesis involved initially keeping systematic reviews and clinical guidelines as separate 'streams' and included:

a) Developing a theory: the implicit theory underlying most preventive interventions was that assessing risk factors associated with oral cancer (i.e. tobacco use status and alcohol consumption) and providing behavioural advice can increase knowledge of potential risks, change perceptions and lead to behaviour change (i.e. tobacco cessation and reduction in alcohol consumption).

b) Developing a preliminary synthesis: extraction and organization of data in tabular form separately for systematic reviews and clinical guidelines. This was used to provide details of study design or type of guideline, quality assessment scores, outcome measures for effective intervention, and other findings / recommendations.

c) Assessing the robustness of evidence-base and recommendations: the overall weight or strength of the evidence-base and recommendations was determined using validated tools to appraise each systematic review and clinical guideline (AMSTAR / ROBIS for reviews; AGREE II for guidelines). As an integral component of each narrative synthesis, data were related to the quality assessment in order to illustrate the strongest evidence among included systematic reviews and clinical guidelines. Thus, the synthesis included reviews and guidelines receiving an overall weighting of "high"; i.e. Low ROBIS, AMSTAR score of 8-11, and AGREE II score of 6 or 7 (Section 3.3.8). The levels of evidence within systematic reviews and clinical guidelines with same quality scores were further synthesised considering the recency of publication. The trials within both the systematic reviews and clinical guidelines were compared to check for and assess data duplication, this is conventional (or expected) in overviews, and thus needs to be considered to ensure that the syntheses add weight to findings based on trials being included in more than one review or guideline (Silva et al., 2012).

d) Exploring relationships in the data: analyses within and between reviews / guidelines, and within and between risk factors and professional groups/settings (dental and medical/pharmacy) were conducted. As stated above, the relationship was also explored considering the recency of the publication and data duplication. The relationships between characteristics and effectiveness of various components of preventive interventions (based on 5A's model- as described in Chapter 1) were reported. The patterns across the results identified various factors that explained differences in direction and size of effect across the included reviews or guidelines (as separate streams). This further helped to understand "how and why interventions have or do not have an effect". Exploring the influence of heterogeneity showed that there was much heterogeneity among the included systematic reviews and clinical guidelines in relation to the interventions covered, the target populations, and the methods employed. The synthesis therefore took a narrative 'thematic' approach to describing each stream, in line with study objectives. The heterogeneity or sources of variability among study populations, settings, or outcomes were explored as an integral part of data synthesis, but as this work was not meta-analytic (decided a priori, considering heterogeneity based on initial literature search), the narrative synthesis approach was used to address the applicability of findings across: primary care setting, professional groups, and/or patient behaviours.

The initial literature search revealed a much greater body of research in the primary care medical practice setting compared to that in the dental practice setting. Therefore, informed by the ADAPTE framework (Collaboration, 2009), which provides a systematic approach to adapting guidance developed in one setting for use in another setting, the high-quality evidence and recommendations in the primary care medical/pharmacy setting in this overview were adapted for use in the dental practice setting.

The within-stream synthesis has been presented (Section 3.4) separately for dental and other primary care settings (medical/pharmacy), considering review quality, recency, and trial duplication.

Integrated / combined synthesis

After this within-stream synthesis, the final integration of findings and comparison between evidence-base in systematic reviews and clinical guidelines (i.e. both 'streams' together) included systematic consideration to all the steps or elements in the framework discussed above (Popay et al., 2006). The patterns identified and analysed within the systematic reviews and clinical guidelines were compared and contrasted across both streams to give an overview of effective intervention. That is, the final synthesis included the analysis of relationships within and between evidence-base and guidelines, which lead to an overall assessment of the strength of the evidence available for drawing conclusions on the basis of a narrative synthesis. This helped to answer specific questions about whether evidence from reviews was reflected in current guidance or whether collated guidance showed areas where better evidence was required (i.e. highlighting gaps).

Similar to 'within-stream' synthesis, the integral component of this 'combined synthesis' was to relate data to the quality assessment (high-quality systematic reviews and clinical guidelines), followed by recency of the publication, and data duplication, in order to illustrate the strongest evidence which could be reflected in a primary care dental practice. In other words, the overall hierarchy of integrated/combined synthesis considered in this overview was: high-quality evidence and recommendations from dental practice setting followed by other primary care settings (medical/pharmacy), recency of the publication, and data duplication. Thus, the final integrated synthesis examined carefully the link between the systematic review evidence and clinical guideline recommendations. This allowed recommendations to be made where a) gaps in guidance were identified or b) guidance showed areas where more evidence was required.

3.4 Results

3.4.1 Systematic Reviews

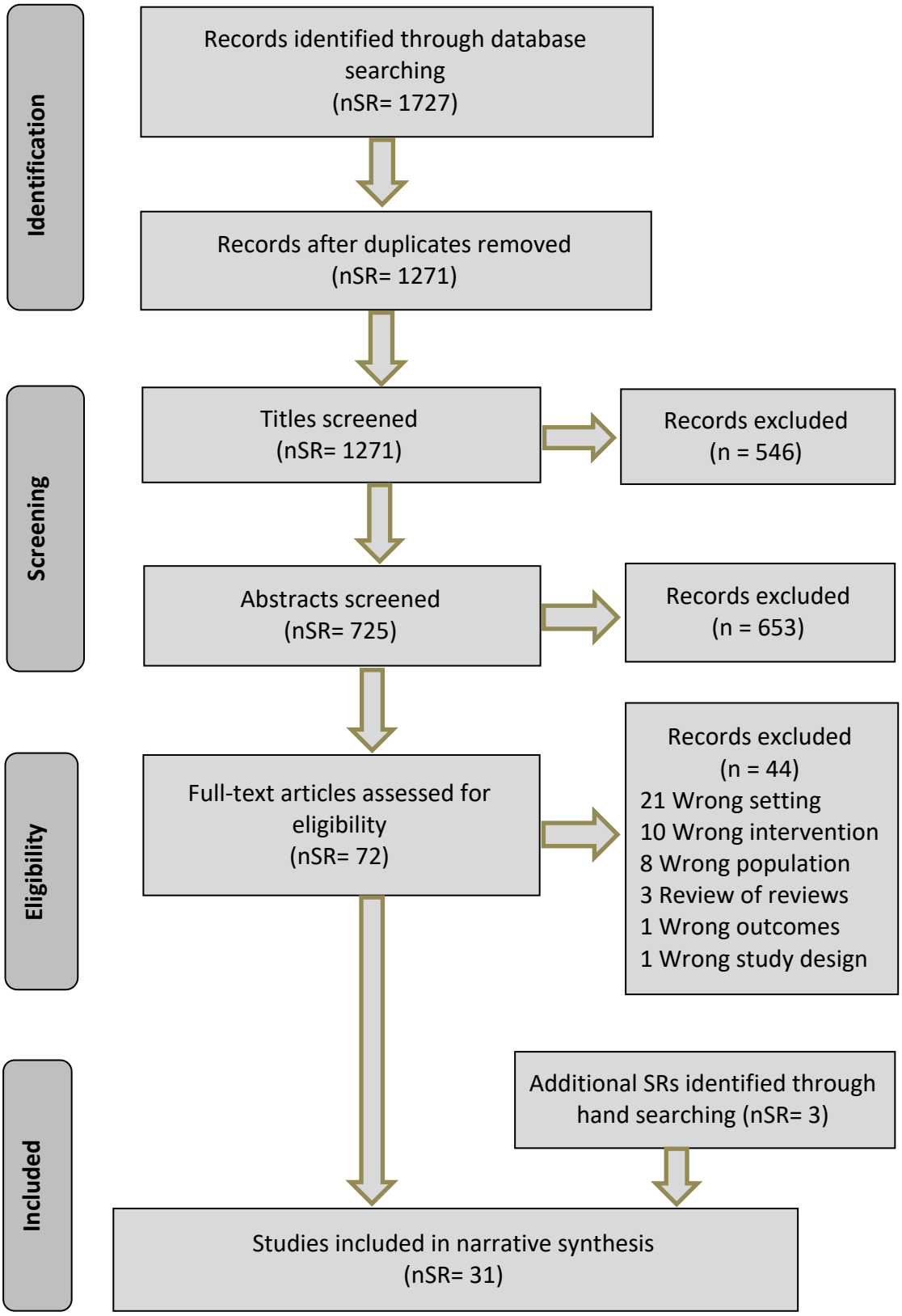
This section details the data/study selection, characteristics, quality assessment, and synthesis for the identified systematic reviews as a separate "stream".

3.4.1.1 Study selection

The search strategy retrieved 1727 potentially relevant records. All included records were screened (title and abstract) independently by two reviewers (SM and AJR) and of these, 72 records were selected for full text review. 28 systematic reviews were included after discussion among the two reviewers (SM and AJR) and a few discrepancies were discussed with the wider team (DIC and LMDM). Three additional systematic reviews were included through hand searching of the reference lists of the 28 included systematic reviews. Thus, finally 31 systematic reviews (nSR=31) were included in this overview (Figure 3.1).

A list of excluded studies (n=44) is presented with the reasons for exclusion in Appendix 5.

Figure 3.1: PRISMA four-phase flow diagram - for included systematic reviews



3.4.1.2 Trial duplication

All systematic reviews included randomised control trials; one systematic review included before and after studies (non-RCTs) along with clinical trials (Blenkinsopp et al., 2003), while another included economic evaluations only (Angus et al., 2014). As might be expected there was trial duplication or overlap in the included systematic reviews, i.e. reviews included some trials in common. To address this, a list of all authors of all primary studies/trials referenced by all included systematic reviews was created, sorted, and labelled to identify publications which appeared two or more times on the list (Dijkers, 2018). The findings were synthesised considering the quality scores and recency of the systematic reviews. For example, there were seven systematic reviews (Kahan et al., 1995; Poikolainen, 1999; Blenkinsopp et al., 2003; Sinclair et al., 2004; Ballesteros et al., 2004; Hyman, 2006; Huibers et al., 2007) in which all included trials were found in more recent systematic reviews. The synthesis focused on the newer reviews in these cases, unless the older reviews were of higher quality. For example, trials in Sinclair et al. (2004) were found in Brown et al (2012), but findings from Sinclair et al. (2004) were included in the final synthesis as this review was of higher quality. In other systematic reviews (where not all trials were duplicate), synthesis focused on effects reported in the higher quality and recent publications, considering quality of the primary trials within systematic reviews, and even analysing the full text of each trial publication where findings were not clear. This avoided counting findings more than once if repeated in multiple systematic reviews, which would falsely inflate the effect or weight of findings. The steps have been detailed in the Section 3.4.1.5 - best practice findings.

There was a total of 171 original trials (after removing duplicates) included in all 31 systematic reviews, which delivered face-to-face preventive interventions in a primary care setting. Appendix 6 provides a list of trials included in all 31 systematic reviews. The included trials were labelled as T1-171; red coloured labels in Appendix 6 shows duplicate trials.

3.4.1.3 Study characteristics

The main characteristics and findings of the included 31 systematic reviews are presented in Table 3.1 (for example: ID assigned to each systematic review, risk factors reviewed, included preventive interventions, intervention provider, study quality, type of synthesis and outcomes). Only the characteristics and findings of primary care, face-to-face interventions targeting adult populations (18 years and above) included in all 31 systematic reviews have been reported in Table 3.1.

Table 3.1: Characteristics and main findings from all included systematic reviews (n=31)

Study ID (Author, year)	Risk factors and number of primary care trials/ studies	Intervention provider	Preventive interventions (Ask/Assess/Advise/Referral)	Type of synthesis and Main findings	Quality score (AMSTAR/ ROBIS)
SR1 (Lindson-Hawley et al., 2015)	Smoking (n=3 RCTs)	General practitioners	Motivational interviewing (MI)- 1-6 sessions, duration of each session ranging from 10-60 minutes Training ranged from 2-40 hours (usually in the form of workshops) Follow-up telephone calls (1-4 calls) and around 10 minutes each, every 6 months (n=2 RCTs)	Meta-analysis <u>Tobacco abstinence</u>: MI > brief advice or usual care Shorter sessions (< 20 minutes) > longer sessions (> 20 minutes) Single sessions > multiple sessions Face-to-face MI = telephone MI 1 or 2 follow-up calls > more than 2 follow-up calls General practitioner > nurses or counsellors (n=1)	AMSTAR= 11 ROBIS= Low
SR2 (Bully et al., 2015)	Smoking (n=7 RCTs)	Primary care-nurses, doctors, psychologists, and nutritionists	Brief motivational interview or counselling, self-help manuals, written prescriptions, emails, and financial incentives. Theoretical approaches: transtheoretical model (TTM), theory of planned behaviour (TPB), health belief model (HBM)	Narrative synthesis <u>Smoking cessation</u>: Brief intervention (TTM based) > usual care HBM or TPB based = usual care Long term effectiveness of interventions (>12 months follow-up)- (n=4 RCTs)	AMSTAR= 8 ROBIS= Low

			Duration: few minutes to a number of months (not clearly reported)		
SR3 (Morton et al., 2015)	Alcohol (n=11 RCTs)	Primary care practitioners	Motivational interviewing (MI)- with or without additional intervention components. Face-to-face MI (n=8): 1-8 sessions, 11 to 20 min. Both face-to-face and phone MI sessions (n=3)	Narrative synthesis <u>Alcohol reduction</u>: MI > usual care or minimal intervention (n=6). 'Low' intervention (one face-to-face session and 5 follow-up calls) > 'High' intervention group (6 face-to-face sessions) (n=1)	AMSTAR= 6 ROBIS= Unclear
SR4 (Angus et al., 2014)	Alcohol (n=22 economic or modeling evaluations)	General practitioner and practice nurse	Screening and brief interventions (SBI), supportive written materials, follow-up telephone call (5 min.) or follow-up consultations with further advice (if necessary). BIs of 10 min or less (n=12); over 10 min (maximum 45 min) (n=11). "stepped care"- 20 min. advice + referral to motivational enhancement therapy and/or specialist alcohol services. "minimal intervention"- 5 min. advice	<u>Cost-effectiveness (alcohol interventions)</u>: SBIs > no advice General practitioner (n=15) = nurse (n=5) interventions Shorter BIs (10 min or less) = longer BIs (over 10 min) Longer BIs > shorter BIs (n=5) "stepped care" > "minimal intervention" (nurse-led) (n=2)	AMSTAR= 7 ROBIS= High
SR5 (Gebara et al., 2013)	Alcohol (n=1 RCT)	Primary care provider	Brief intervention (BI) -face-to-face intervention in a single session, with the session length varying between 10 and 30 minutes.	Thematic and structural content analysis <u>Alcohol reduction</u>: BI (single session, 10-30 min)- not effective	AMSTAR= 3 ROBIS= High

				(controls not reported) Males > Females (female consumption increasing following the BI, more defensive reactions- result being classified as negative)	
SR6 (Rice et al., 2013)	Smoking (n=24 RCTs)	Nurses	High intensity intervention- more than 10 minutes, additional materials and/or strategies other than simple leaflets, follow-up visits (n=19). Low intensity intervention- advice provided (with or without a leaflet), 10 minutes or less, with up to one follow-up visit (n=5). Use of NRT (n=2) Intervention was a core component of nurse's role (n=4); other studies nurses trained (using the '5 As' framework).	Meta-analysis (n=18) and narrative synthesis (n=6) <u>Smoking cessation</u>: Nursing intervention > no intervention or usual care (at 6 months or longer) High intensity intervention = low intensity intervention	AMSTAR= 10 ROBIS= Low
SR7 (VanBuskirk and Wetherell, 2013)	Smoking (n=3 RCTs) Alcohol (n=3 RCTs) Substance use (Marijuana) (n=1 RCT)	Physicians, nurse practitioners, or other trained professionals (e.g. therapist, health educator,	Motivational interviewing (MI)- in-person MI sessions with phone calls as ''booster'' or follow-up sessions. MI-specific training: 8 hours to 4 weeks (n=5) Use of AUDIT tool (n=1)	Meta-analysis <u>Smoking cessation</u>: Three 20-min sessions > usual care (7 times more quitting) (n=1) In-person MI session plus follow-up phone calls (four 15-min calls) = in-person MI session only (n=1) <u>Alcohol reduction</u>:	AMSTAR= 7 ROBIS= Low

		counsellor, interventionist, research assistant)		2 MI sessions (20 min. each) or 1 MI session (45–60 min) > usual care; 12-month follow-up Substance use: One 15–20 min in-person MI session followed by one 10-min booster phone call > usual care	
SR8 (Stead et al., 2013a)	Smoking (n=42 RCTs)	Physicians, or physicians supported by another healthcare worker	Minimal intervention: advice (with or without a leaflet), single consultation lasting less than 20 minutes plus up to one follow-up visit. Intensive intervention: greater time at the initial consultation, additional materials other than a leaflet (e.g. demonstration of expired carbon monoxide or pulmonary function tests, self-help manuals), or more than one follow-up visit or referral to a cessation clinic. Follow-up: typically one year, the longest being three years.	Meta-analysis Smoking cessation: Brief advice > no advice/ usual care (n=17) (RR 1.66, 95% CI 1.42 to 1.94; I^2=31%). Intensive advice > no advice/ usual care (n=11) (RR 1.86, 95% CI 1.60 to 2.15; I^2=50%). Intensive advice > minimal advice (small difference- RR 1.37, 95% CI 1.20 to 1.56; I^2=32%). Follow-up visits – more effective (n=5) Use of additional aids (n=10) = no additional aids (n=17) Combination of brief advice and computer-generated tailored letters > advice or letter alone (n=1)	AMSTAR= 10 ROBIS= Low
SR9 (Noordman et al., 2012)	Smoking (n=6) Alcohol (n=6) Combined lifestyle	General practitioners (or physicians), nurses or both (in	Face-to-face communication-related behaviour change techniques (BCTs)- behavioural counselling or motivational interviewing or education and advice. 1 to 15 sessions, lasted from 30s to	'Best Evidence Synthesis' Single or combined interventions significantly effective. Physicians = nurses or both or in combination with other providers - provide effective BCTs.	AMSTAR= 5 ROBIS= High

	behaviours (n=25)	combination with other health care providers)	60 min. Most studies combined techniques such as advice and education or goal setting, self-monitoring and motivational interviewing.	Simple advice > intensive advice (simple advice as effective as motivational interviewing). Feedback, risk-assessment, goal-setting, cognitive behaviour therapy and self-monitoring- showed significant effects.	
SR10 (Willis et al., 2012)	Smoking (n=5 RCTs)	Health care professional. Nurse-led (n=5), with behavioural scientists, nutritionists and health councillors providing care.	Multifactorial (lifestyle) interventions- tailored intervention based on individual risk profile, goal setting, supporting materials. Duration- not reported. Follow-up: mean 3 years, ranging from 1 to 7 years. Screening: sessions to record smoking status (also cholesterol, blood glucose, activity level and dietary habits)- calculate cardiovascular disease risk scores.	Narrative synthesis <u>Smoking cessation</u>: Multifactorial lifestyle interventions- strong evidence for the success of smoking cessation (no change in cardiovascular disease risk score) More intensive interventions > lower intensity interventions (n=2)	AMSTAR= 7 ROBIS= Low
SR11 (Jonas et al., 2012)	Alcohol (n=23 RCTs)	Primary care physician - alone or with a health educator, nurse, psychologist or researcher	Behavioural counselling, with or without referral (brief advice, feedback, motivational interviews, or cognitive behavioural strategies). Very brief (≤ 5 minutes, single-contact); brief (6 to 15 minutes, single-contact); extended (>15 minutes, single-contact); brief multi-contact (each contact ≤15 minutes); or extended multi-contact (some	Meta-analyses (n=19) and qualitative synthesis (n=23) <u>Alcohol reduction</u>: Brief (10 to 15-minute) multicontact interventions- most effective (effect remains for several years). Brief multicontact interventions > extended multicontact interventions. Very brief interventions and brief interventions	AMSTAR= 10 ROBIS= Low

			contacts >15 minutes). Screening assessments: multistep processes, interviews with research personnel up to 30 minutes.	are less effective or ineffective. Men = women Delivered by primary care providers > research personnel	
SR12 (Carr and Ebbert, 2012)	Smoking (n=8 RCTs- 6 RCTs involved adult smokers); Smokeless tobacco (n=6 RCTs)	Dentists and dental hygienists	Behavioural interventions involved either: 1) brief advice plus quitline referral, brief advice plus motivational interviewing, brief advice plus video-based cessation program with phone follow-up, or 2) counselling using the 5 A's plus NRT, 5 A's plus NRT and population-specific printed material, 3 A's plus pharmacotherapy and referral as needed. Duration: 10-15-minute advice in single session (n=3). BIs also included combinations of an oral examination, feedback from the examination as to oral effects of tobacco use and involved team effort. Tobacco use status was determined from the patient's chart and health questionnaire.	Meta-analysis Tobacco abstinence: Behavioural interventions > usual care (n=14) (OR 1.71, 95% CI 1.44 to 2.03 - at 6 to 24 months, I2=61%) (among both cigarette smokers and smokeless tobacco users) Subgroup of adult smokers (n=5), effect was stronger (OR=2.38, 95%CI 1.70, 3.35) Brief intervention > extended intervention (n=1)	AMSTAR= 9 ROBIS= Low
SR13	Smoking (n=16 RCTs)	General practitioners,	Counselling interventions- classified by intensity of contact with the	Narrative synthesis	AMSTAR= 5

(Taggart et al., 2012)	Alcohol (n=2 RCTs)	physician or nurse	subjects (High ≥ 8 points of contact hours; Moderate >3 and <8; Low ≤ 3 points of contact hours).	Smoking cessation: Individual counselling and written materials > group education Low intensity interventions > high intensity interventions Primary health care settings > community settings Alcohol reduction: Interventions- not effective Health literacy: Low intensity interventions = high intensity interventions	ROBIS= High
SR14 (Brown et al., 2012)	Smoking (n=35 RCTs); substance abuse including alcohol (n=25 RCTs); sexual health (n=27 RCTs)	Community pharmacists	Interventions promoting changes to a healthier lifestyle Structured interventions, using NRT & counselling	Narrative synthesis Smoking cessation: Structured interventions > opportunistic intervention Pharmacists training > no training Substance abuse including alcohol and sexual health: Weak evidence for effectiveness	AMSTAR= 5 ROBIS= High
SR15 (Zbikowski et al., 2012)	Smoking (n=4 RCTs)	Physicians, general practitioners and nurses	Behavioural counselling- moderate level (2-5 sessions), tailored to older smokers or stage-based, with self-help materials and follow-up advice or phone calls. 11min advice followed by 2 phone	Descriptive/ narrative synthesis Smoking cessation: Physician delivered interventions > no intervention (n=4) Physician/nurse counselling with	AMSTAR= 2 ROBIS= High

			calls 7 min. each (n=1)	pharmacotherapy and brief follow-up > no counselling (n=2)	
SR16 (Cahill et al., 2010)	Smoking (n=2 RCTs)	Primary care physician	Individual counselling or brief advice- 10-minute, tailored to the participant's perceived stage of change, tailored self-help materials, one or more follow-up phone calls or letters, use NRT gum if appropriate. Training of physicians in the stages of change model; one trial used MI-based counselling.	Meta-analysis <u>Smoking cessation</u>: Evidence not clear for primary care staged intervention, and training of physicians. Advice + NRT = usual care (n=1) Training = no training (n=2)	AMSTAR= 11 ROBIS= Low
SR17 (Kaner et al., 2009)	Alcohol (n=24 RCTs)	General practitioners, nurse practitioners or psychologists	Motivational interviews or cognitive behavioural therapy approaches. Brief intervention (BI): 1-5 sessions, 1 to 50 minutes each. Treatment duration ranged from 5-10 minutes to 60 minutes advice. Extended interventions: 2-7 sessions, initial and booster sessions ranged from 15 to 50 minutes. Screening- general health questionnaires, or alcohol screening tools such as CAGE, AUDIT or MAST, or variations on these. Administered by telephone or in the clinic (at registration).	Meta-analysis <u>Alcohol reduction</u>: Brief intervention > control group (n=22), follow-up of one year or longer (mean difference: -38 grams/week, 95% CI: -54 to -23, I^2=57%) Men > Women (at one year of follow up) Extended interventions > Brief intervention (n=5) (non-significant)	AMSTAR= 10 ROBIS= Low

SR18 (Halcomb et al., 2007)	Smoking (n= 9 RCTs) Alcohol (n= 3 RCTs)	General practice nurse- all trials Doctor (n=2)	Individual or one-to-one interventions Multifaceted interventions- involved a range of individualised health assessment, lifestyle counselling, motivational interviewing, health education and protocol driven management of various risk factors. Targeted interventions- involved a baseline health check followed by the delivery of various forms of health education, focused on modification of a single lifestyle risk factor.	Narrative synthesis Smoking cessation: Multifaceted interventions interventions > no interventions Nurse interventions = doctor interventions (n=1) Targeted interventions interventions > no interventions (n=1) interventions = no interventions (n=2) number of those who stopped smoking decreased with increasing age Alcohol reduction: Low intervention group (one appointment and five 15-min telephone follow ups and education manual) > control group (n=1) High intervention group (six 45-min appointments and education manual) = control group (n=1) High & low intervention group > control group (n=1)	AMSTAR= 7 ROBIS= Unclear
SR19 (Wilhelmsson and Lindberg, 2007)	Alcohol (n=1 RCT and 1 before-after study)	Clinicians, physician- and nurse practitioners	Brief intervention/ counselling Staff received training (2.5 hr. in RCT) in an alcohol preventive programme	Narrative synthesis Alcohol reduction: Very short counselling or BI > usual care alcohol-related discussions were longer among	AMSTAR= 4 ROBIS= High

				the clinicians who received training	
SR20 (Huibers et al., 2007)	Smoking (n=2 RCTs & CCTs) Alcohol (n=2 RCTs & CCTs)	General practitioners (or family physician or family doctor)	Psychosocial interventions (including counselling, or more structured approaches, like cognitive behavioural interventions (CBI) or problem-solving therapy) Intervention consisted of a standardised number of at least 2 face-to-face contacts between patient and general practitioner. Timing of interventions not reported	Meta-analysis (results from smoking and alcohol studies were not pooled due to heterogeneity) Smoking cessation: 1 high quality RCT: Five-session 'repeated counselling' (RC) = one-session minimal intervention (MI) = RC+gum = RC+spirometry - overall cessation in all groups at 12 months Alcohol reduction: 1 high quality RCT: Two-session CBI by research GP = CBI by nurse = one-session brief advice by regular GP - overall reduction in all groups at 12 months	AMSTAR= 9 ROBIS= Low
SR21 (Hyman, 2006)	Alcohol (n=2 RCTs)	Staff or clinic nurse (1 trial compared nurse delivered to physician delivered BI)	Brief interventions (Two 30 min. sessions included in one study, another study included 2 or more consultation sessions over 12 months)	Review of clinical trials (summarized results from all included studies, no synthesis) Alcohol reduction: Limited evidence Nurse delivered BI > non-intervention or control group Equal effectiveness at 3, 6 and 12 months (no difference for follow-up)	AMSTAR= 6 ROBIS= High

SR22 (Bertholet et al., 2005)	Alcohol (n= 19 RCTs)	Primary care provider: GP (most studies), physician, nurse, trained interventionist or researchers	Brief Alcohol Intervention (BAI)- advice, motivational interviewing or cognitive behavioural techniques, feedback regarding alcohol consumption levels and/or adverse effects of alcohol consumption. Length of intervention ranged from 5 to 45 minutes, a booster session or follow-up visit. AUDIT or CAGE scores	Qualitative synthesis and Meta-analysis Alcohol reduction: BI (5-15 min.) > no intervention/usual care/less than 5 min. of intervention BI accompanied by written material and repeated intervention (follow-up visits) - more effective (n=6) Men = women Follow-up: 6 months = 12 months	AMSTAR= 7 ROBIS= Low
SR23 (Gorin and Heck, 2004)	Smoking (n= 16 RCTs and quasi-experimental studies)	Primary care physicians, dentists, nurse or healthcare team	In-person cessation advice or counselling Intensity ranged from brief (3-5 min.) over single health visit, to structured behavioural change interventions lasting an hour delivered over multiple visits. Average duration of interventions was 76.5 days, no. of sessions was 4, with mean duration per session of 22.7 min.	Descriptive analyses and Metaregression (meta-analyses) Smoking cessation: Cessation effects: Physicians > multiprovider teams = dentists > nurses Cessation effects: More health care providers > fewer providers Measured clinical components- assess, assist, or arrange had no statistically significant influence on cessation.	AMSTAR= 5 ROBIS= High
SR24	Smoking	General	Stages-of-change–based	Qualitative (best-evidence synthesis) and	AMSTAR= 6

(van Sluijs et al., 2004)	(n=14 RCTs/CTs)	practitioner (GP) or primary care physician	interventions; differed from a mailed letter to a possible six contact moments with individual counselling. Provider training- one study provided 1.5hr group session + 1/2hr individual session with role play; another study included manuals and training incorporated in a 10-week lecture series	quantitative synthesis (odds ratios) Smoking cessation: Stages-of-change–based interventions > Usual care or brief standard advice or no provider training Personal advice from the primary care physician, with follow-up advice during subsequent visits (mostly not planned for smoking cessation) - most effective strategy Medium-term follow-up (limited evidence) > short and long-term follow-up (no evidence for effect)	ROBIS= Low
SR25 (Whitlock et al., 2004)	Alcohol (n= 11 RCTs and 1 CT)	Primary care physicians (additionally, research staff or health educators, counsellors or clinic nurses delivered some or all of the intervention)	Very brief interventions (n=2)- 1 session, up to 5 minutes long Brief interventions (n=6)- 1 session, up to 15 minutes long Brief multicontact interventions (n=7)- an initial session up to 15 minutes long, plus follow-up contacts Training: sessions, ranged from 15 minutes to 2.5 hours (n=7)	Qualitative or narrative synthesis Alcohol reduction: Brief multicontact interventions > usual care (13% to 34% reduction per week) Very BIs & BIs ≥ usual care (limited evidence, n=3) Effective interventions (any intensity) included at least 2 of 3 key elements- feedback, advice, and goal-setting. 2 studies also reported tailoring intervention.	AMSTAR= 7 ROBIS= Low

			Screening: involved self-administered questionnaires or brief interviews. Conducted outside the routine care encounter, approx. 30 minutes. Many of the trials used CAGE and AUDIT instruments.	Men = women (Brief multicontact interventions) Older adults ≥ younger adults (n=1) Outcomes- at least 12 months follow-up	
SR26 (Ballesteros et al., 2004)	Alcohol (n= 13 RCTs)	Primary care providers	Brief interventions (BIs) lasting ~10–15 minutes in one session, with reinforcing visits through follow-up of ~3–5 min each Minimal interventions (MI) lasting ~3–5 minutes Extended brief interventions (EBI)- BI plus several specific reinforcement sessions through follow-up, ~10–15 min each.	Meta-analysis Alcohol reduction: BIs > minimal interventions/usual care BIs to heavy drinkers > moderate drinkers EBI- limited evidence for effectiveness	AMSTAR= 7 ROBIS= Unclear
SR27 (Sinclair et al., 2004)	Smoking (n=2 RCTs)	Pharmacists and/or members of pharmacy staff	Advice or more intensive behavioural therapy, with or without the use of any form of NRT or other pharmacotherapy. Involved training interventions which included the Stages of Change Model- 2-3-hour workshop for pharmacists and pharmacy assistants	Narrative synthesis Smoking cessation: Pharmacist interventions > usual pharmacy support or any less intensive programme The strength of evidence is limited because only one of the trials showed a statistically significant effect.	AMSTAR= 9 ROBIS= Low

			Follow-up points were not identical (3, 6 and 12 months in one, and 1, 4 and 9 months in the other study). In both studies, follow- up was by postal questionnaire and depended on self-reported smoking status.		
SR28 (Blenkinsopp et al., 2003)	Smoking (n=2 RCTs, 3 non-RCTs)	Community pharmacists and pharmacy assistants	2 RCTs: Structured or tailored counselling, an information leaflet, weekly follow-up for the first 4 weeks and monthly thereafter as needed up to 12 months. Training based on 'stages of change' model, which included self-study and attending a 3hr. workshop or one evening training session and subsequently supported by a researcher visit (n=2 RCTs). 1 non-RCT: intervention included six 1.5hr. meetings in each pharmacy. 2 days intensive training (with lectures, role plays and discussions with other smoking cessation professional).	Qualitative synthesis Smoking cessation: Advice/counselling > usual care (n=2 RCTs) Training > no training	AMSTAR= 6 ROBIS= High
SR29 (Poikolainen, 1999)	Alcohol (n=7)	Family or general practitioners	Very brief (5-20 min) interventions and extended (2-5 sessions or several visit) brief interventions (BIs)	Meta-analysis <u>Alcohol reduction</u>: Extended BIs > Very BIs	AMSTAR= 3 ROBIS= High

				Women > men (Significant statistical heterogeneity)	
SR30 (Ashenden et al., 1997)	Smoking (n=23 RCTs) Alcohol (n=6 RCTs)	General practitioner, nurse or counsellor	Lifestyle advice- verbal advice plus written materials Brief advice- single consultation; Intensive advice- more than a single consultation and follow-up by appointment, telephone or letter. Multifactorial advice (n=3)	Meta-analysis <u>Smoking cessation</u>: Brief or intensive advice > no advice (n=16) Brief advice = intensive advice (n=7) <u>Alcohol reduction</u>: Brief or intensive advice > no advice (n=3) advice = no advice (n=3) men > women (n=2)	AMSTAR= 6 ROBIS= Unclear
SR31 (Kahan et al., 1995)	Alcohol (n=6 RCTs)	Primary care physicians	Brief interventions, sessions with patients lasted 30 minutes or less Training sessions: 1 hour or less	Narrative/ descriptive synthesis <u>Alcohol reduction</u>: Intervention group > control group (n=3) - among men Intervention group < control group (n=2) - among women (negative results) 15-minute counselling session = 5-minutes of advice (n=2)	AMSTAR= 4 ROBIS= High

It can be seen from Table 3.1 that all included systematic reviews were published between 1995 and 2015, and included preventive interventions for tobacco and/or alcohol, in a primary care setting (medical, dental, or community pharmacy). Of 31 systematic reviews, 11 reviews provided quantitative or meta-analyses, 15 reviews provided qualitative or narrative analyses, while four included both narrative and meta-analyses, and one was a cost-effectiveness review. Study IDs (from Table 3.1) will now be used to represent/reference a particular systematic review in the following sections.

As can be seen from Table 3.1, the included systematic reviews were relatively heterogeneous in that they covered different primary care settings (dental/medical/pharmacy), risk factors (tobacco/alcohol) and behavioural preventive interventions (motivational/stage-based). The systematic reviews varied in the types of preventive interventions in areas such as: duration of individual sessions, total number of sessions, follow-up visits and provider training (Table 3.1). All 31 systematic reviews included individual or face-to-face interventions, which provided behavioural advice focused on modification of a single or multiple lifestyle risk factor (tobacco or alcohol). The various behavioural preventive interventions included verbal advice from primary care providers in the form of: brief advice to quit, motivational interviewing, cognitive behavioural techniques, behavioural counselling, structured or tailored counselling programme and stages-of-change–based interventions. These approaches have been defined in Chapter 1 (Section 1.4.1.1). Most systematic reviews included “brief interventions” - advice or counselling, however definitions varied a lot among the included systematic reviews.

3.4.1.3.1 Dental practice setting

There were only two systematic reviews out of 31 which included preventive interventions (including risk factor assessment, behavioural advice, and/or signposting/referral) delivered in a primary care dental practice setting: one of these reviews (SR 23) included studies in both primary care medical and dental practices, interventions delivered by physicians, nurses, and/or dentists; while the other review (SR 12) focused exclusively in a primary care dental practice,

with interventions delivered by dental professionals only - dentists and/or dental hygienists.

Both systematic reviews in the dental practice setting focused on providing advice for smoking (SR: 12, 23), one of these also included smokeless tobacco advice (SR 12). None of the dental reviews included advice for alcohol reduction.

3.4.1.3.2 Medical or community pharmacy setting

The majority, i.e. 29 out of the 31 systematic reviews, included studies which provided preventive interventions (including risk factor assessment, behavioural advice, and/or signposting/referral) in a primary care medical practice setting. Of these, 22 reviews (SR: 1, 2, 3, 4, 5, 7, 8, 9, 11, 13, 15, 16, 17, 19, 20, 22, 24, 25, 26, 29, 30, 31) included interventions delivered by various primary care providers, for example: physicians or general practitioners, and non-physicians like nurses, counsellor, health educator, psychologists, nutritionists, trained interventionist, researchers or healthcare teams; four reviews (SR: 6, 10, 18, 21) included interventions delivered or led by primary care nurses only; while in three reviews (SR: 14, 27, 28) interventions were delivered by community pharmacists or pharmacy assistants/staff.

Of these 29 systematic reviews: smoking cessation interventions or advice were included in ten reviews (SR: 1, 2, 6, 8, 10, 15, 16, 24, 27, 28); alcohol reduction interventions were included in 12 reviews (SR: 3, 4, 5, 11, 17, 19, 21, 22, 25, 26, 29, 31); while seven systematic reviews (SR: 7, 9, 13, 14, 18, 20, 30) included interventions for both smoking and alcohol. All 29 reviews included single/isolated interventions for smoking and/or alcohol (unifactorial), none of the studies included combined interventions targeting both smoking and alcohol (multifactorial).

3.4.1.4 Quality assessment (AMSTAR) and Risk of Bias (ROBIS)

The AMSTAR scores for all systematic reviews are included in Table 3.2; only two reviews met all 11 criteria in AMSTAR (SR: 1, 16). Included systematic reviews were considered high-quality if the AMSTAR score ranged from 8 to 11, medium quality if score ranged 4 to 7, and low-quality if score ranged 0 to 3 (as stated earlier in Section 3.3.8.1). Thus, this overview included ten high-quality systematic reviews, 18 mid-quality, and three low-quality reviews. The ROBIS scores for all systematic reviews are included in Table 3.3. Figure 3.2 depicts a graphical representation of both AMSTAR and ROBIS scores. Blue vertical bars in the figure represent the AMSTAR scores (which ranges from 1-11) and low/high/unclear written in boxes are ROBIS scores. It can be seen that all ten systematic reviews with high AMSTAR score had low risk of bias in ROBIS, three reviews with low AMSTAR score had high risk of bias, while risk of bias varied in reviews with mid AMSTAR score. Of 18 medium AMSTAR quality systematic reviews, nine had high risk of bias, five reviews had low risk of bias and four reviews were unclear.

Table 3.2: AMSTAR scores for included systematic reviews (n=31) (Shea et al., 2007)

Study ID (Author, year)	Was an " a priori" design provided?	Was there duplicate study selection and data extraction?	Was a comprehensive literature search performed?	Was the status of publication (i.e. grey literature) used as an inclusion criterion?	Was a list of studies (included and excluded) provided?	Were the characteristics of the included studies provided?	Was the scientific quality of the included studies assessed and documented?	Was the scientific quality of the included studies used appropriately in formulating conclusions?	Were the methods used to combine the findings of studies appropriate?	Was the likelihood of publication bias assessed?	Was the conflict of interest included?	AMSTAR score
SR1 (Lindson-Hawley 2015)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11
SR2 (Bully 2015)	✓	✓	✓	✓	×	✓	✓	✓	✓	×	×	8
SR3 (Morton 2015)	✓	✓	×	×	×	✓	✓	✓	✓	×	×	6
SR4 (Angus 2014)	✓	×	✓	✓	×	✓	✓	✓	✓	×	×	7
SR5 (Gebara 2013)	×	✓	×	×	×	✓	×	×	✓	×	×	3
SR6 (Rice 2013)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	10

SR7 (VanBuskirk 2013)	×	×	✓	✓	×	✓	✓	✓	✓	✓	×	7
SR8 (Stead 2013)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	10
SR9 (Noordman 2012)	×	✓	×	×	×	✓	✓	✓	✓	×	×	5
SR10 (Willis 2012)	×	✓	✓	✓	×	✓	✓	✓	✓	×	×	7
SR11 (Jonas 2012)	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓	10
SR12 (Carr 2012)	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	×	9
SR13 (Taggart 2012)	×	✓	✓	×	×	✓	✓	✓	×	×	×	5
SR14 (Brown 2012)	✓	×	✓	✓	×	✓	✓	×	×	×	×	5
SR15 (Zbikowski 2012)	×	×	✓	×	×	✓	×	×	×	×	×	2
SR16 (Cahill 2010)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11
SR17 (Kaner 2009)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	10
SR18 (Halcomb 2007)	×	✓	✓	✓	✓	✓	✓	×	✓	×	×	7
SR19 (Wilhelmsson 2007)	×	✓	×	×	×	✓	✓	✓	×	×	×	4
SR20 (Huibers 2007)	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	×	9

SR21 (Hyman 2006)	×	×	✓	✓	×	✓	✓	✓	✓	×	×	6
SR22 (Bertholet 2005)	×	✓	✓	×	×	✓	✓	✓	✓	✓	×	7
SR23 (Gorin 2004)	×	×	✓	✓	×	×	×	✓	✓	✓	×	5
SR24 (van Sluijs 2004)	×	✓	✓	×	×	✓	✓	✓	✓	×	×	6
SR25 (Whitlock 2004)	×	✓	✓	✓	✓	✓	✓	✓	×	×	×	7
SR26 (Ballesteros 2004)	?	×	✓	×	✓	✓	✓	✓	✓	✓	×	7
SR27 (Sinclair 2004)	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	×	9
SR28 (Blenkinsopp 2003)	✓	×	✓	✓	×	✓	✓	✓	×	×	×	6
SR29 (Poikolainen 1999)	×	×	✓	×	×	✓	×	×	✓	×	×	3
SR30 (Ashenden 1997)	×	×	✓	×	×	✓	✓	✓	✓	✓	×	6
SR31 (Kahan 1995)	×	×	✓	×	×	✓	✓	✓	×	×	×	4

✓ = Yes; × = No; ? = Can't answer

Table 3.3: ROBIS scores (notation as per (Whiting et al., 2016))

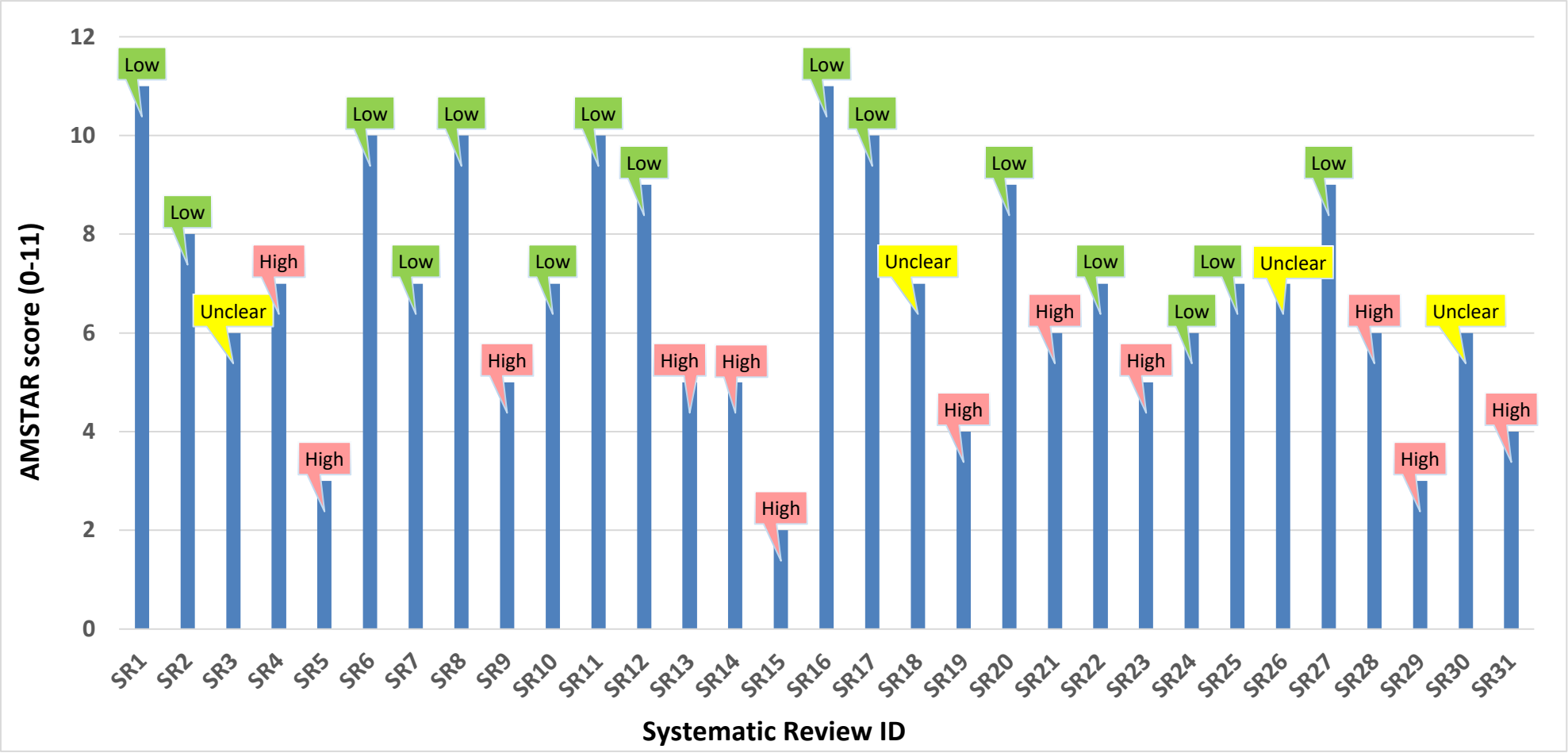
	Phase 2				Phase 3
Study ID (Author, year)	**1. Study eligibility criteria**	**2. Identification and selection of studies**	**3. Data collection and study appraisal**	**4. Synthesis and findings**	**Risk of bias in the review**
SR1 (Lindson-Hawley 2015)	☺	☺	☺	☺	☺
SR2 (Bully 2015)	?	☺	☺	?	☺
SR3 (Morton 2015)	?	?	☺	?	?
SR4 (Angus 2014)	☺	?	☹	?	☹
SR5 (Gebara 2013)	☹	☹	☹	☹	☹
SR6 (Rice 2013)	☺	☺	☺	☺	☺
SR7 (VanBuskirk 2013)	?	?	☺	☺	☺
SR8 (Stead 2013)	?	☺	☺	☺	☺
SR9 (Noordman 2012)	☺	☺	☹	☹	☹
SR10 (Willis 2012)	☺	☺	☺	☺	☺

SR11 (Jonas 2012)	☺	☺	☺	☺	☺
SR12 (Carr 2012)	☺	☺	☺	☺	☺
SR13 (Taggart 2012)	?	?	?	?	☹
SR14 (Brown 2012)	?	☹	☹	?	☹
SR15 (Zbikowski 2012)	☹	☹	?	☹	☹
SR16 (Cahill 2010)	☺	☺	☺	☺	☺
SR17 (Kaner 2009)	☺	☺	☺	☺	☺
SR18 (Halcomb 2007)	☺	☺	☺	☹	?
SR19 (Wilhelmsson 2007)	☹	?	☹	☹	☹
SR20 (Huibers 2007)	?	☺	☺	☺	☺
SR21 (Hyman 2006)	?	☹	☹	☺	☹
SR22 (Bertholet 2005)	☺	☺	☺	☺	☺
SR23 (Gorin 2004)	☹	☹	☹	☹	☹
SR24 (van Sluijs 2004)	☺	?	☺	☺	☺

SR25 (Whitlock 2004)	☺	☺	☺	☹	☺
SR26 (Ballesteros 2004)	☺	?	?	☺	?
SR27 (Sinclair 2004)	?	☺	☺	☺	☺
SR28 (Blenkinsopp 2003)	☹	☺	?	☹	☹
SR29 (Poikolainen 1999)	☹	☹	☹	☺	☹
SR30 (Ashenden 1997)	☺	?	☺	☺	?
SR31 (Kahan 1995)	?	?	?	?	☹

☺ = low risk; ☹ = high risk; ? = unclear risk (use of characters- suggested tabular presentation for ROBIS results) (Whiting et al., 2016)

Figure 3.2: Graphical representation of both AMSTAR and ROBIS scores



3.4.1.5 Best practice (high-quality) systematic review evidence

The high-quality evidence/findings were presented from all low risk of bias (low ROBIS) reviews, giving priority in the narrative data synthesis to: firstly, high-quality AMSTAR scores with low risk of bias in ROBIS (n=10); and secondly to mid-quality AMSTAR scores but with low risk of bias in ROBIS (n=5).

Trial data duplication assessment identified that in the ten reviews with high AMSTAR and low ROBIS: one of the reviews (SR 20) had all trials duplicate with more recent reviews (SR: 8, 17) which were also of higher quality, thus findings from SR 20 were not included in this synthesis; while for another review (SR 27), which also had duplicate trials with a more recent review (SR 14), findings were included in the synthesis, as it was of higher quality. For the remaining high-quality reviews, some of the included trials were duplicate (Appendix 6), which are discussed while synthesising findings.

Thus, the findings synthesised in this overview were from 14 systematic reviews which had:
1) High AMSTAR and low ROBIS (n=9) (SR: 1, 2, 6, 8, 11, 12, 16, 17, 27)
2) Mid AMSTAR and low ROBIS (n=5) (SR: 7, 10, 22, 24, 25)

The details of the other main findings from these high-quality reviews and all remaining systematic reviews with lower quality scores (i.e. mid AMSTAR with high/unclear ROBIS, and low AMSTAR with high ROBIS) were recorded in Table 3.1.

As this is a systematic overview, the synthesis focused on the results of the included systematic reviews and not results of individual trials/studies within these systematic reviews. However, the results from individual trials/studies have been presented where the included systematic reviews had not reported combined results for all primary care studies in that review. The number of the included trials/studies and other features (such as, effect sizes) have also been mentioned in order to depict the nature and strength of the evidence. The results have now been presented separately for dental and other primary care settings (medical/pharmacy), considering review quality, recency, and trial duplication. Furthermore, as all high-quality reviews focused on interventions /

outcomes in terms of tobacco and/or alcohol, the results have been organised under these two headings.

3.4.1.5.1 Dental practice setting

Of the 14 high-quality systematic reviews, there was only one review (SR 12) which investigated behavioural preventive interventions (including risk factor assessment, behavioural advice and/or referral) delivered exclusively in a primary care dental practice setting. This high-quality Cochrane review (SR 12) included preventive interventions for smoking and smokeless tobacco. This review (SR 12) included 14 randomised controlled trials, and the interventions were delivered by dentists and/or dental hygienists to smokers or tobacco users of any age exclusively in a dental practice setting. Eight trials targeted smokers and six trials targeted smokeless tobacco users.

Risk factor assessment (Ask/ Assess)

There was limited description of risk factors assessment of smoking behaviour in this dental review (SR 12). Most of the included trials did not provide information on how they assessed a patient's smoking or tobacco use status. Only one of the trials reported that patient charts, medical records or health questionnaires were used to determine tobacco use status and to identify at risk groups. All the other studies simply mentioned determining tobacco use status but provided no details.

A significant component of behavioural preventive interventions in all included trials was to identify and record findings from the patient's oral examination, and then incorporating it as an integral part of advice/counselling by relating it to the patient's tobacco use.

Behavioural preventive intervention (Advise/ Arrange)

This high-quality Cochrane review (SR 12) investigated the effectiveness of smoking and smokeless tobacco cessation interventions in a dental practice setting. Following meta-analyses, it found that, in general, tobacco cessation interventions delivered by dental professionals are likely to be effective at increasing tobacco abstinence for at least 6 months (OR=1.71, 95%CI 1.44, 2.03;

n=14 trials). In the subgroup of adult smokers (n=5 trials), the effect was stronger (OR=2.38, 95%CI 1.70, 3.35). The review concluded that: “Differences between the studies limit the ability to make conclusive recommendations regarding the intervention components that should be incorporated into clinical practice, however, behavioural counselling (typically brief) in conjunction with an oral examination was a consistent intervention component that was also provided in some control groups”. The review further stated that results need to be viewed with caution due to a lack of biochemical validation of self-reported tobacco abstinence (only two trials reported it).

Exploring the interventions employed in the trials further, there was high heterogeneity, including: brief tailored advice, or motivational interviewing using printed educational materials or self-help aids, or counselling using the 5 A’s (brief) or 3 A’s (very brief), or quit-line referral (as needed). All trials employed brief behavioural interventions (advice or counselling) and only one needed pharmacotherapy as part of the intervention. All trials included an oral examination as an interventional component, and provided personalized (tailored) feedback to patients from the examination as to the oral effects of tobacco use. The trials further incorporated a training component for dental professionals to deliver effective interventions (brief or intensive), however the details of training (duration, number of sessions) were not reported. In addition, the effects were not reported to compare interventions delivered by professionals ‘with’ versus ‘without’ training.

There were differences in the definition of ‘brief’ intervention amongst the 14 trials. Most of the trials did not report the duration and number of sessions of tobacco cessation interventions. Two of the trials with smokeless tobacco users reported effectiveness of 3-5-minutes very brief advice to stop, following an oral examination, and an offer of 10-15-minutes brief motivational counselling session and pharmacotherapy (if needed - in the case of addiction). Another trial included ‘intensive’ interventions for smokers including eight 40-minute counselling sessions over four months, while ‘brief’ interventions in this trial included one 30-minute counselling session to explain an 8-week self-help programme. Thus, there was wide inconsistency in the reporting of the duration and definition of brief behavioural interventions.

The other trials (which did not report duration) considered an intervention as brief or very brief if it included an advice or message to quit, plus educational materials or self-help guide, and an offer of quit-line referrals. On the other hand, intensive interventions were described as: brief intervention plus motivational counselling (or video), setting a quit date (within 2 weeks or more), including a follow-up appointment to see if the patient has quit, and developing a plan or training to prevent relapse. Where compared, one trial found benefit of intensive intervention over brief intervention for smokeless tobacco users. Other trials reported similar quit rates for 'brief' and 'intensive' interventions for smokers (or smokeless tobacco users), showing no additional benefit of intensive intervention (gauged by number of personal contact) over brief intervention. One of the trials reported 3.3% quit rates (27/817) for both brief and intensive interventions. The results for intensive interventions were not included in the meta-analysis in this review (SR 12), as results were similar.

Overall, the review reported that interventions in all included trials were a team effort involving brief dental encounters and behavioural interventions which differed in intensity "as measured by number of planned contacts but there was no clear indication of a dose-response relationship" (SR 12).

Referral to cessation services (Assist)

Most of the included trials reported brief interventions as tailored advice plus an offer of quit-line referral, as needed. However, outcomes for referral were not reported in the majority trials. Only one trial reported that a brief advice plus quit-line referral resulted in a 3.3% quit rate compared to usual care (simple advice). Largely, in most other trials, it was not clear whether the effective adult brief interventions included additional support from signposting/referral to smoking cessation services.

Summary

Table 3.4 summarises the reviewed best practice evidence for tobacco cessation interventions in a primary care dental practice setting. Overall this dental review (SR 12) demonstrated an effectiveness of brief (or very brief) interventions delivered by trained dental professionals incorporating an oral examination component, compared to no intervention or usual care in increasing

tobacco abstinence rates for at least 6 months (OR=1.71, 95%CI 1.44, 2.03; n=14 trials) among cigarette smokers and smokeless tobacco users. The effect was stronger (OR=2.38, 95%CI 1.70, 3.35) in the subgroup of adult smokers (n=5 trials). Though the review showed no additional benefit of intensive intervention (gauged by number of personal contact) over brief intervention, the results were not synthesised here due to lack of reporting of effect sizes comparing both.

The dental review (SR 12) concluded that: "Differences between the studies limit the ability to make conclusive recommendations regarding the intervention components that should be incorporated into clinical practice, however, behavioural counselling (typically brief) in conjunction with an oral examination was a consistent intervention component that was also provided in some control groups."

Table 3.4: Dental practice - best practice (high-quality) evidence for smoking cessation interventions in the systematic review (SR)

Preventive interventions for smoking		Strength of evidence (based on effect size)	SR supporting evidence
Ask/ Assess	Use patient's charts, medical records or health questionnaires to determine tobacco use status and at-risk groups	Weak	SR 12
	Record findings from oral examination and relate to patient's tobacco use	Strong	
Advise/ Arrange	Brief (or very brief) behavioural advice > No intervention	Strong	SR 12
	Personalised (tailored) feedback from the oral examination as to the oral effects of tobacco use	Strong	
	Intensive intervention > brief intervention	Weak	
	Effectiveness of interventions delivered by trained professionals (effect sizes not reported)	None	
Assist/ Referral	Brief advice plus quit-line referral > simple brief advice to quit (only one trial reported 3.3% quit rate)	Weak	SR 12

"**>**" greater-than sign – used to show greater effects

As reported previously (Section 3.4.1.3.1), there were no systematic reviews of alcohol interventions in the dental practice setting.

In the next section, the evidence from the primary care medical or community pharmacy setting will be synthesised, which constitutes the majority of evidence found in this overview study.

3.4.1.5.2 Medical or community pharmacy setting

While there was only one systematic review in the dental practice setting (SR 12), the remaining 13 high-quality reviews (SR: 1, 2, 6, 7, 8, 10, 11, 16, 17, 22, 24, 25, 27) investigated tobacco cessation interventions delivered in a primary care medical or community pharmacy setting (Table 3.1). Of these, eight systematic reviews included trials/studies with preventive interventions solely for smoking (SR: 1, 2, 6, 8, 10, 16, 24, 27), four reviews included studies with preventive interventions for alcohol only (SR: 11, 17, 22, 25), while one review (SR 7) included studies delivering preventive interventions for both smoking and alcohol (as separate interventions). Thus, there were nine systematic reviews with smoking interventions (SR: 1, 2, 6, 7, 8, 10, 16, 24, 27), and five reviews with alcohol interventions (SR: 7, 11, 17, 22, 25).

The results have now been organised in relation to the two major risk factors – smoking and alcohol. As mentioned earlier, the main findings from these high-quality systematic reviews (and other reviews with lower quality) has been summarised in Table 3.1.

SMOKING

Risk factor assessment (Ask/ Assess)

The majority of the included trials in the nine systematic reviews with smoking cessation interventions reported providing personalised feedback or tailored advice based on assessment of patient's smoking status (effectiveness detailed in next section). However, trials did not provide information on how they assessed people at risk or how a patient's smoking status was determined. Only one review (SR 10) reported that included trials involved screening sessions to record smoking status along with cholesterol, blood glucose, activity level, and

dietary habits - to calculate cardiovascular disease risk scores. The results from these screening sessions informed the treatment given, i.e. patients were provided tailored interventions based on individual risk profiles. However, none of the trials/studies reported how a patient's self-reported smoking status was confirmed - in terms of duration, frequency, or type (cigarette, cigar, pipe).

Behavioural preventive interventions (Advise/ Arrange)

The nine high-quality systematic reviews (SR: 1, 2, 6, 7, 8, 10, 16, 24, 27) included smoking cessation interventions delivered by primary care professionals to adult smokers, and all reported cessation interventions (advice or counselling) to be more effective in helping smokers to quit compared to no intervention or usual care. These reviews reported strong strength of evidence for the effectiveness of smoking cessation interventions in a primary care setting (for example, effect sizes ranged from (RR 1.66, 95% CI 1.42 to 1.94) to (OR 6.91, 95% CI 1.98–24.15) – detailed below.

Type of interventions

The behavioural preventive interventions included in these nine high-quality reviews were heterogeneous and comprised of various treatment approaches. There was quite a lot variation in the definitions, terminologies, and characteristics of behavioural interventions among these reviews. The most commonly used theoretical techniques for delivering smoking interventions were: motivational interviewing (SR: 1, 7, 8) and stages-of-change-based interventions (SR: 2, 16, 24, 27), which were included in most trials/studies within seven of the high-quality reviews. The other two reviews (SR: 6, 10) did not describe any theoretical model underpinning smoking cessation interventions - interventions were simply referred as structured advice/counselling (some based on 5A's), with varying intensities (brief or intensive). The control groups in all included reviews consisted of either no intervention or simple (non-structured) advice or interventions of lower intensities. The specific theory-based interventions, for example, motivational interviewing and stages-of-change-based interventions (explained in Chapter 1; Section 1.4.1.1), reported higher quit rates than simple advice or usual care (SR: 1, 2, 7, 8, 16, 24, 27). The findings from these reviews, with effect sizes (where reported), are now discussed.

The three most recent reviews (SR: 1, 7, 8) included trials/studies delivering a smoking cessation intervention involving *Motivational Interviewing* techniques, describing it as an approach in which smokers were given personalised feedback to help them build commitment and reach a decision to change in a non-threatening manner (Miller and Rollnick, 2013). The majority of trials in these recent reviews described 'brief' motivational interventions as a tailored advice lasting 5-20 minutes, delivered by a primary care professional, with up to one follow-up visit. The 'intensive' motivational interventions, on the other hand, were described as tailored advice of more than 20 minutes in a single consultation (in-person), with more than one follow-up sessions (in-person or telephone). In the one high-quality Cochrane systematic review (SR 8), investigating the effectiveness of smoking cessation interventions delivered by primary care physicians (or medical practitioners), 42 trials were included. Following meta-analyses (effect sizes reported as relative risks (RR)), it found that amongst 17 trials comparing brief or very brief advice (which included face-to-face advice plus printed materials) versus no advice (or usual care) there was a significant increase in the rate of quitting (RR 1.66, 95% CI 1.42 to 1.94) – additional 1 to 3% quit rates than control group. The duration of brief or very brief interventions were not reported in all included trials - one trial reported it as 2 minutes, while another reported 10 minutes advice. The estimated effects were detected to be higher (RR 1.84, 95% CI 1.60 to 2.13) amongst 11 trials where the interventions were more intensive (face-to-face advice plus self-help manuals and offering additional follow-up visits), however, there was no statistical difference between the intensive and brief (or very brief) subgroups. Direct comparison between brief and intensive smoking cessation interventions amongst 15 trials showed that, overall, there was a small but significant advantage of more intensive advice (RR 1.37, 95% CI 1.20 to 1.56), with a small benefit of follow-up visits. Overall, the Cochrane review (SR 8) concluded / indicated: "the potential benefit from brief simple advice given by physicians to their smoking patients. The challenge as to whether or not this benefit will be realised depends on the extent to which physicians are prepared to systematically identify their smoking patients and offer them advice as a matter of routine. Providing follow-up, if possible, is likely to produce additional benefit. However, the marginal benefits of more intensive interventions, including use of aids, are small, and cannot be justified as a routine intervention

in unselected smokers. They may, however, be of benefit for individual, motivated smokers."

The other two systematic reviews (SR 1, 7) lend support to these findings, where brief motivational interventions were effective in shorter duration and over one or two sessions. The Cochrane review (SR 1) amongst these two reviews, investigated whether motivational interviewing interventions help people to quit more than simple advice or usual care in a range of settings, including primary care, outpatient clinics and hospital settings. Only the findings from primary care trials have been synthesized here. The review reported that the effect size associated with brief motivational interventions (mostly 10-20 minutes, but also included some trials with less than 5-minutes advice) seem to be higher than that for intensive interventions (more than 20 minutes advice). The effect for brief intervention versus control was - RR of 1.69 (95% CI 1.34 to 2.12; 9 trials; N = 3651). This review further detected an increased probability of quitting with single brief sessions over multiple sessions – with both treatments (single and multiple sessions) producing positive outcomes. However, the review (SR 1) concluded that: "the results should be interpreted with caution, due to variations in study quality, treatment fidelity, between-study heterogeneity and the possibility of publication or selective reporting bias." Two smoking cessation trials in the other high-quality review (SR 7) reported that intensive motivational interventions were more likely to increase quit rates compared to control groups (which received either simple advice or self-help didactic materials). Patients in one of these trials showed seven times greater odds of quitting in the motivational interviewing group, involving three in-person 20 minutes session, after 12 months (OR 6.91, 95 % CI 1.98–24.15); than in the control group which involved simple anti-smoking advice. The review (SR 7) however, concluded that: "as few as one motivational interviewing session may be effective in enhancing readiness to change and action directed towards reaching health behaviour-change goals."

The smoking cessation interventions based on *Stages-of-Change* (SR: 2, 16, 24, 27) showed weaker evidence (limited to no evidence for effectiveness) compared to motivational interviewing interventions in a primary care setting. Not all the included trials/studies reported duration and number of sessions of

interventions which utilized a stages-of-change-based approach. The trials in one of the recent reviews (SR 2) established superiority of interventions based on stages-of-change in promoting smoking cessation in primary care over the long-term, compared to interventions based on other theories (for example, social cognitive theory or theory of planned behaviour). None of the trials, however, compared stages-of-change with motivational interviewing interventions. Only two trials in the review (SR 2) reported duration of the stage-based interventions, which ranged from 10-20 minutes each plus 2-3 follow-up sessions and found positive results in the long-term (outcomes measured one year or longer post-intervention). However, effect sizes were not reported.

Another Cochrane review included in this overview (SR 16), which had the highest quality score (AMSTAR=11), investigated the effectiveness of stages-of-change-based interventions in helping smokers to quit in a range of healthcare settings. The review included three primary care trials of which one trial was a duplicate with the more recent review described above (SR 2). The evidence was not clear in this older review (SR 16) for primary care interventions, where two trials found no advantage for the stage-based smoking cessation interventions (face-to-face advice and/or tailored materials, pharmacotherapy for dependence) against usual care (simple advice or self-help materials). The effect sizes for primary care trials were not synthesised separately. Overall the review (SR 16) concluded that: “based on four trials using direct comparisons, stage-based self-help interventions (expert systems and/or tailored materials) and individual counselling were neither more nor less effective than their non-stage-based equivalents. Thirty-one trials of stage-based self-help or counselling interventions versus any control condition demonstrated levels of effectiveness which were comparable with their non-stage-based counterparts. Providing these forms of practical support to those trying to quit appears to be more productive than not intervening. However, the additional value of adapting the intervention to the smoker’s stage of change is uncertain”. The findings were further supported by another high-quality systematic review (SR 24) which included ten primary care trials, of which six trials were duplicates with those in the more recent reviews (SR 1, 2, 6, 16). The remaining four trials (which were not duplicate) found limited to no evidence for an effect at short and long-term

follow-up on stages-of-change for smoking and smoking quit rates, based on the strength of the evidence (a rating system developed based on previously used best-evidence syntheses and odds ratios). However, the odds ratios for quitting smoking showed a positive trend at all follow-up measurements. The duration and number of sessions (dose response / intensity data) was not reported in any of these trials.

The other high-quality systematic review (SR 10), which did not describe incorporating any theoretical model in the smoking cessation interventions, demonstrated the potential of a multifactorial lifestyle intervention, including five primary care trials. The smoking cessation advice was included as part of a healthy lifestyle advice intervention (along with dietary and physical activity advice), which aimed to lower cardiovascular disease risk and mortality. However, none of these trials included alcohol advice along with smoking cessation advice. The main outcome measures used in the included trials were changes in the validated cardiovascular disease risk score and mortality. A meta-analysis was not conducted in this review (SR 10) due to a lack of homogeneity in outcomes and risk scores used. The review found strong evidence for the success of smoking cessation following multifactorial interventions; one of the trials even reported significant differences in smoking cessation at a 7-year follow-up. The significant benefits were associated with an intensive intervention, however, details of the nature of the intensive interventions were not provided by all included trials. Only one of the trials described intensive interventions as: two initial screening sessions for high risk individuals (cardiovascular risk); assessment of smoking status (along with blood pressure, dietary assessment and lipid profiling) at 4 and 8 months; and 10 weekly group sessions. Although there were significant benefits associated with smoking cessation, the trials did not report statistically significant change in cardiovascular disease risk score, compared to the control group.

In the majority of trials/studies in all high-quality reviews, the behavioural advice was reinforced by providing or involving one or more of the following supportive strategies: written materials, self-help manuals or videos, or tailored feedback letters (SR: 1, 2, 6, 7, 8, 10, 16, 24, 27). However, none of these trials

assessed the effectiveness of interventions 'with' versus 'without' supporting materials or strategies.

Intervention providers and training to deliver preventive interventions

The smoking cessation interventions were effective irrespective of the intervention provider, for example, interventions delivered by a primary care physician, nurse or pharmacist resulted in positive results (increased quit rates). However, one of the reviews (SR 1) reported that motivational interviewing interventions, delivered by general medical practitioners, confer greater benefit (RR 3.49; 95% CI 1.53 to 7.94: 2 trials, N = 736) than those delivered by nurses (RR 1.24; 95%CI 0.91 to 1.68; 5 trials, N= 2256) or counsellors (RR 1.25; 95% CI 1.15 to 1.36; 22 trials, N = 13,593). The review (SR 1), however, stated that this evidence should not be "overstated", as it was based on findings from only two small trials. The nurse-delivered interventions had a non-significant effect on quit rates, which was supported by findings from another systematic review (SR 6), where weaker evidence was found for an effect of smoking cessation interventions delivered by nurses when health promotion or smoking cessation was not a core component of their role. The other high-quality systematic reviews did not compare effects of interventions delivered by different primary care providers, the interventions were reported to be effective if delivered by any member of the primary care team, who received training on how to deliver behavioural preventive interventions (irrespective of care provider). However, the effects were not reported to compare interventions delivered by professionals 'with' versus 'without' training. The evidence was not clear in one high-quality Cochrane review (SR 16), where two of the primary care trials found no advantage for the training of physicians to deliver stage-based smoking cessation advice against usual care.

The training characteristics were not reported in all trials/studies. Where reported, provider training involved workshops based on motivational interviewing or stages-of-change-based interventions. However, heterogeneity between training duration and number of sessions limit the ability to make recommendations in a primary care setting. Trials in one review (SR 1) reported motivational interviewing specific training, with training time ranging from 2 to 40 hours workshop; another review (SR 7) reported training time ranging from 8

hours to 4 weeks; while trials in a further review (SR 24) reported 1.5-hour group session with role play to 1 or 2 half day trainings, or a 10-week lecture series. However, the longest training reported (10-week lecture series) was from a low-quality trial and reported non-significant results, thus the findings need to be considered with caution. The provider training was reinforced by inclusion of manuals or booklets and discussions with other professionals.

There was only one high-quality systematic review which reported smoking cessation interventions delivered by community pharmacists (SR 27). Both trials in this review included a large number of pharmacies in the UK: 51 pharmacies in one trial and 60 in the other, with a total of 976 smokers. The trials recruited pharmacy customers who expressed a wish to stop smoking. The interventions involved stages-of-change based training interventions (2-3 hours workshops) for pharmacists and pharmacy assistants, followed by a support programme involving counselling and record keeping, which were compared with the usual pharmacy support. One of the trials showed a statistically significant difference in self-reported cessation rates at 12 months: 14.3% versus 2.7% ($p < 0.001$); while the other trial showed a positive trend (not statistically significant) at each follow-up, with 12.0% versus 7.4% ($p = 0.09$) at nine months. Moreover, at the end of the intervention in both trials, a significant proportion of participants started using nicotine replacement therapy (87% and 98%). The review, however, concluded that: “the strength of evidence is limited because only one of the trials showed a statistically significant effect.”

Referral to cessation services (Assist)

Two reviews (SR 1, 8) included trials/studies which included referral to more intensive interventions/therapy, or local cessation services, or quit-lines as part of the smoking cessation interventions. The results were quite variable in the trials included in both these high-quality reviews regarding effectiveness of referral. One of the trials in one review (SR 1) had a control group where smokers were provided with simple advice based on the 5A’s (duration not reported) and referral to a state quit-line. The findings were compared to an additional 45-minute motivational counselling session with a health educator and two follow-up telephone calls. The intensive motivational interventions were more effective compared to the control group, however, controls also showed a

significant benefit. One of the trials in the other review (SR 8) found structured physician advice of 3-5 minutes plus referral to group therapy to be more effective than structured advice only. The effect sizes for these trials were not reported in these reviews (showing a weaker evidence), thus making it difficult to make comparisons with other intervention components.

Summary

Table 3.5 summarises the reviewed best practice evidence for smoking cessation interventions in a primary care medical practice setting. Overall nine high-quality medical practice reviews demonstrated an effectiveness of theory-based 'brief' interventions (motivational interviewing in particular) delivered by primary care professionals in a single session, following an assessment of a patient's smoking status, compared to no intervention or simple advice in increasing smoking cessation rates. The lack of precise reporting of intervention duration and number of sessions (brief intervention described as 5-20 minutes; wide range), somewhat limited the inferences (regarding duration of sessions) that can be drawn from the review findings. It was reported that although longer interventions (10-20 minutes) were more effective in increasing quit rates, even very brief interventions of as little as 2 minutes have also been shown to be effective (RR 1.66, 95% CI 1.42 to 1.94). There was a small additional benefit of more intensive interventions (more than 20 minutes, and more than one follow-up visits) compared to brief (or very) interventions (RR 1.37, 95% CI 1.20 to 1.56). Interventions were reported to be effective if delivered by a primary care professional with minimal training in theory-based approaches, however, effect sizes were not reported to compare interventions delivered by professionals without training. Moreover, the exact training characteristics to deliver the intervention require better reporting and clarification by future researchers. Additional components (i.e. written materials, self-help aids) were reported to support behavioural advice, however, again, effect sizes were not reported to compare interventions 'with' versus 'without' supporting materials. Furthermore, this overview showed a lack of trials reporting effect sizes for referral pathway compared with behavioural advice for smoking cessation in primary care settings.

Table 3.5: Medical practice - best practice (high-quality) evidence for smoking cessation interventions in the systematic reviews (SRs)

Preventive interventions for smoking		Strength of evidence (based on effect size)	SRs supporting evidence
Ask/ Assess	Assess and record patient's smoking status	Strong	SR: 1, 2, 6, 7, 8, 10, 16, 24, 27
	Details of smoking assessment, for example, duration, frequency, or type (cigarette, cigar, pipe).	None	
Advise/ Arrange	Theory-based or structured interventions > Simple advice or message to quit	Strong	SR: 1, 2, 7, 8, 16, 24, 27
	Brief (or very brief) motivational interventions > No intervention	Strong	SR: 1, 2, 6, 7, 8, 10, 16, 24, 27
	Intensive interventions (more than 20 minutes) > Brief interventions (small but significant benefit)	Moderate	SR: 1, 6, 7, 8
	Single sessions > multiple sessions	Strong	SR: 1, 7, 8
	Physician > nurses or counsellors (reported in only two small trials)	Weak	SR: 1
	Training received by providers > no training (effects not reported)	None	
	Effectiveness of additional components: written materials or self-help aids (effect sizes not reported)	None	
Assist (Referral)	Brief advice (3-5minutes) plus referral to cessation services > Brief advice only (effect sizes not reported)	Weak	SR 8

"**>**" greater-than sign – used to show greater effects

ALCOHOL

Risk factor assessment (Ask/ Assess)

All five high-quality systematic reviews which included alcohol interventions (SR: 7, 11, 17, 22, 25), reported the use of alcohol screening tools such as AUDIT, CAGE or another screening questionnaire to establish the level of alcohol consumption (low, moderate, or heavy drinkers). These questionnaires were either self-administered, or administered by research personnel in a clinic, or over the telephone before a patient's appointment. The preventive interventions were later determined based on different levels of alcohol consumption. For example, patients with heavy alcohol consumption or dependence were more likely to need referral to specialist services or treatment, while for at-risk or moderate drinker, behavioural preventive interventions in primary care may be effective. The time taken to administer these screening tools in a primary care practice was not reported in these reviews.

Two of the reviews (SR: 11, 25) included studies which used a multistep process for screening assessments, involving up to 30-minute interviews with research staff in order to assess whether individuals had heavy alcohol consumption or dependence (and should probably be referred for specialized treatment) as opposed to risky or moderate drinking (provided with behavioural interventions).

Behavioural preventive interventions (Advise/ Arrange)

Five high-quality systematic reviews (SR: 7, 11, 17, 22, 25) included behavioural preventive interventions to adult drinkers or alcohol users delivered by primary care providers. All these reviews reported behavioural advice or counselling to be more effective in reducing alcohol consumption compared to no intervention or usual care. There was strong evidence for effectiveness of alcohol interventions in the primary care settings for improving drinking behaviour outcomes, such as alcohol consumption, heavy drinking episodes, and drinking above recommended levels – effect sizes detailed below.

Type of interventions

The most commonly used approaches for delivering a behavioural preventive intervention for reducing alcohol consumption were: simple advice/counselling to reduce consumption, motivational interviewing or cognitive behavioural therapy, with or without referral to specialist services. These interventions included various strategies to reinforce behavioural advice, such as: self-completed action plans, written materials or educational leaflets specifically on alcohol or general health issues, written personalised feedback about alcohol consumption levels and adverse effects of alcohol consumption, follow-up visits or telephone counselling, drinking diaries, problem-solving exercises to complete at home, or goal setting.

The most recent alcohol review (SR 7) included three trials which included individuals with at-risk (moderate) drinking. The effect sizes of meta-analyses of primary care alcohol trials were not synthesised separately, therefore the findings from individual trials are reported here. One of these trials was a smaller study (26 individuals) and included one 45-60 minutes in-person motivational interviewing session delivered by a nurse practitioner to hazardous alcohol drinkers. This trial resulted in a significant reduction in daily alcohol use at 6-weeks and a significant reduction in gamma-glutamyltransferase levels in the blood (a marker of alcohol consumption), versus no treatment (no advice) group. Another trial in this review (SR 7) supported these findings, however, instead of one long session, this trial included two motivational interviewing sessions of 20 minutes each. The third large trial (897 individuals) in this review (SR 7) included six motivational interviewing sessions delivered entirely over the telephone, with no face-to-face behavioural session. The trial showed significantly lower drinking days and amounts compared to control groups who received a mailed pamphlet (which also showed some positive effects).

The second high-quality alcohol review (SR 11) included 23 trials, of which only one trial was duplicate with the more recent review (SR 7). The remaining 22 trials in the review (SR 11) included behavioural counselling interventions of varying duration and number. The ‘brief’ interventions included in this review consisted of single or multiple sessions of motivational discussions without any underpinning theory (for example, advice, counselling, feedback); while

‘intensive’ interventions included various theoretical approaches (for example, motivational interviewing or cognitive behavioural strategies). The review (SR 11) concluded that the evidence for the effectiveness in adult drinkers is strongest for brief (10-15-minutes) multi-contact interventions, compared to no intervention or very brief intervention (less than 5 minutes) or intensive interventions (more than 20 minutes). Among adults receiving interventions, the consumption decreased by 3.6 drinks per week from baseline (95% CI, 2.4 to 4.8 drinks/wk; 10 trials; 4332 participants). The overall strength of evidence was judged to be moderate. The review showed that very brief interventions (less than 5 minutes) compared with brief interventions (5-20 minutes) were less effective in reducing alcohol consumption (5-8% increased abstinence in very brief versus 7-12% in brief intervention); however, based on only one head-to-head study, it concluded that there was “insufficient evidence to determine how very brief and brief intensity interventions compare for improving intermediate outcomes”. The review (SR 11) also provided comparison between brief multi-contact and intensive multi-contact interventions and found both to be effective in reducing alcohol consumption. However, brief multi-contact interventions were found to be the most effective and their effect lasted for several years. The reported benefits were similar for men and women in a subgroup analysis.

The third high-quality alcohol review (a Cochrane review) (SR 17) included in total 24 trials, of which 11 trials were duplicates of those in the more recent review (SR 11) and the results of which have been discussed in the previous paragraph. Of the remaining 13 trials, six trials were excluded in the more recent review (SR 11), the main reasons reported for exclusions being poor quality and wrong PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings). Thus, the findings of these poor-quality trials had not been synthesised in this overview study, as the target was to get the best quality evidence. The remaining seven trials (not duplicate with recent reviews) compared a brief intervention with a control intervention (no intervention or usual care or simple advice), and showed that individuals receiving a brief intervention drank less alcohol per week than those receiving a control intervention after follow-up of one year or longer (mean difference: -38 grams/week, 95% CI: -54 to -23). However, there was considerable heterogeneity between the findings of the trials. The duration of effective brief

interventions ranged from 5-10 minutes, with 2-5 visits over a year; and the advice was supported by written materials or self-help manuals. However, the evidence needs to be considered with caution as five of these seven trials were reported in this review to have unclear or inadequate risk of bias (concealment of allocation). While only two trials had adequate risk of bias. Where compared, intensive interventions (more than 20 minutes) showed a little evidence (non-significant) of greater reduction in alcohol consumption than brief intervention (mean difference = -28, 95%CI: -62 to 6 grams/week). The review (SR 17) concluded that future trials should focus on defining the most effective components of interventions.

The review (SR 22) had in total 18 alcohol trials (face-to-face interventions), of which the majority (15 trials) were duplicate with those in recent reviews (SR 11, 17): six trials duplicate with SR 11; and ten trials duplicate with SR 17 (one trial common in both SR 11 and 17). The remaining three trials had methodological quality assessed in the review (SR 22) as: two trials with low quality and the other trial with a high-quality score. The high-quality trial included a brief intervention of 10-15-minutes duration in the first session, followed by a booster session of 90-minutes with no written materials provided to the patients. The two low-quality trials included a brief intervention of 5 minutes duration in the first session, followed by a booster session of 15-20 minutes, with written materials provided to patients at both visits. The interventions were delivered by psychologists, social workers, and advanced medical students in one trial, and by nurses in another trial. All three trials reported no positive/significant effects of the alcohol brief interventions compared to usual care or no interventions.

The final high-quality alcohol review (SR 25) had in total 12 trials, of which 11 trials were duplicate with those in the more recent reviews (SR 11 and 17), and the remaining trial was excluded from the recent reviews (SR 11 and 17) as it had wrong PICOTS, no pre-specified outcomes and quality of this trial was judged to be fair. The findings from this trial showed that brief multi-contact interventions significantly reduced average daily alcohol consumption compared with no intervention. However, the details of the intervention were not clearly reported, for example, duration, number of sessions, and intervention provider.

Intervention provider and training to deliver preventive interventions

Overall, the alcohol preventive interventions were found to be effective irrespective of the intervention provider in a primary care setting (physician or non-physician). The interventions were delivered by a general practitioner, nurse practitioner, health educator, or counsellor; there were no pharmacist delivered alcohol interventions. One of the reviews (SR 11) compared interventions delivered by a primary care provider and research personnel, and found greater reduction for interventions delivered by primary care providers (WMD, -4.0 drinks per week, 95% CI, -5.4 to -2.6) compared to those delivered primarily by research personnel (WMD, -3.0, 95% CI, -5.0 to -1.0).

Alcohol interventions were more effective when primary care providers received training on how to deliver behavioural preventive interventions; however, effect sizes were not reported to compare interventions delivered by a professional 'with' versus 'without' training. Again, not all the included trials/studies reported details of the training received by healthcare professionals (for example, duration and number of training sessions). There was only one high-quality review (SR 11) in which most of the included trials/studies reported details of training a primary care provider to deliver effective screening and behavioural interventions for alcohol misuse. Where reported, training duration ranged from as little as 15 minutes to as long as 6 to 8 hours, full-day workshops, or a 4-week training in motivational interviewing principles. One of the trials in another review (SR 7) reported that intensive interventions included training primary care providers in motivational interviewing or cognitive-behavioural skills.

Referral to specialist services (Assist)

Referral to more intensive interventions/therapy or specialized treatment services was mentioned in only one alcohol review (SR 11). Some of the trials/studies in this review reported assessing patients at the screening stage as to whether they had alcohol abuse or dependence, in which case they referred them for specialized treatment. However, none of these trials reported outcomes for referral, i.e. evaluating the number/proportion of individuals who followed up with referrals and whether it worked when individuals got there.

Summary

Table 3.6 summarises the reviewed best practice evidence for alcohol interventions in a primary care medical practice. Overall, it could be concluded from all high-quality systematic reviews for reducing alcohol consumption that brief (10-15 minutes) multi-contact (two or more follow-up visits over a year) motivational interventions were most effective (consumption decreased by 3.6 drinks per week from baseline; 95% CI, 2.4 to 4.8 drinks/wk) (SR 11); interventions of 5 minutes duration were also reported to be effective in equally higher quality review (mean difference: -38 grams/week, 95% CI: -54 to -23) (SR 17). Intensive interventions were also reported to be effective, however, where compared, the reported effect rates were smaller for intensive compared to brief interventions (non-significant) (SR 11). There was little or insufficient evidence for the effectiveness of very brief (less than 5 minutes) interventions in reducing alcohol consumption (5-8% increased abstinence in very brief versus 7-12% in brief intervention) (SR 11). The effective brief advice was further supported by written materials or self-help manuals, however, effect sizes were not reported to compare intervention 'with' and 'without' supporting materials. This overview showed an overall lack of studies reporting local referral pathway for reducing alcohol consumption and its effectiveness compared to brief interventions or usual care.

Table 3.6: Medical practice - best practice (high-quality) evidence for alcohol reduction interventions in the systematic reviews (SRs)

Preventive interventions for alcohol		Strength of evidence (based on effect size)	SRs supporting evidence
Ask/ Assess	Assess and record patient's alcohol consumption levels (moderate or dependence), using validated screening tools – to determine treatment options	Strong	SR: 7, 11, 17, 22, 25
Advise/ Arrange	Behavioural interventions (face-to-face tailored advice/counselling) > No intervention or usual care	Strong	SR: 7, 11, 17, 22, 25
	Brief (5-20 minutes) interventions > no intervention or very brief or intensive intervention	Strong	SR: 11, 17, 22
	Multiple sessions > single sessions	Strong	SR: 11, 17
	Intensive (more than 20 minutes) > brief intervention	Weak	SR 11
	Very brief (less than 5-minutes) > brief intervention	Weak	SR 11
	Primary care providers (physician, nurses, health educator) > research personnel	Strong	SR: 11
	Training received by providers > no training (effects not reported)	None	
	Additional components to support: written materials or self-help manuals (effects not reported)	None	
Assist (Referral)	Referral to specialized treatment services (outcomes for effectiveness not reported)	None	

"**>**" greater-than sign – used to show greater effects

3.4.1.6 Summary of systematic overview of systematic reviews

This overview study aimed to identify best practice evidence emerging from all primary care settings (dental/medical/pharmacy), primarily from the dental perspective, i.e. giving higher weighting to dental review findings, and considering higher quality and more recent medical/pharmacy findings applicable in a dental practice setting. The key findings from high-quality systematic reviews that constitute this systematic overview had been presented in respective tables at the end of each section (Tables: 3.4, 3.5 and 3.6).

There was only one high-quality systematic review in the dental practice setting relating to smoking cessation and no high-quality reviews on alcohol reduction (not even mid- or low-quality reviews) in a dental practice setting were available. However, best practice has been developed from synthesising and drawing from the best evidence from other primary care (medical/pharmacy) settings, which could be adapted / adopted to dental practice, along with synthesising with the recommendations (evidence) within dental clinical guidelines (Section 3.4.2).

Overall, for smoking cessation interventions this systematic overview showed strong evidence for the effectiveness of brief, in-person, motivational interventions in a single session, delivered by primary care professionals (irrespective of provider type – physician, nurse, or pharmacist), following an assessment of a patient's smoking status, in comparison with no intervention or usual care in a primary care setting for adults. Though, longer brief interventions (10-20 minutes) and intensive interventions (more than 20 minutes, with follow-up visits) have shown to be effective in increasing quit rates (marginal additional benefit over shorter duration), very brief interventions (less than 5 minutes) have also shown a significant and comparable effect, and thus should be trialled in a dental practice setting. The lack of detail particularly in relation to duration made it difficult to make a conclusion regarding precise specification of the duration of element of the "brief" interventions. The effect sizes showing the effectiveness of training primary care providers, including referral to the smoking cessation services, and

supporting materials along with brief intervention were not reported, thus showing a weaker evidence.

For reducing alcohol consumption, overall it could be concluded that: after assessing/recording patient's alcohol consumption levels, a 'brief' in-person motivational intervention delivered by primary care professional (physician or nurse) with one or more follow-up visits over a year are likely to have a greater effect for sustained alcohol reduction compared to no intervention or very brief intervention or intensive interventions. Though, 10-15 minutes multi-contact interventions were reported most effective, brief interventions of 5 minutes duration were also reported to be equally effective, and thus should be trialled in a dental practice setting. Again, the duration of the effective 'brief' intervention ranged from 5-20 minutes (wide range) in the high-quality reviews, thus making it difficult to make a conclusion regarding precise specification of the duration of element of the "brief" interventions. Referral to specialist services was suggested in cases of alcohol dependence, however, again, outcomes for effectiveness of referral were not reported. Similarly, the effect sizes showing the effectiveness of training primary care providers and including supporting materials along with brief intervention were not reported, thus showing a weaker evidence.

Lastly, this overview showed a lack of combined interventions for smoking and alcohol (only isolated interventions were reported).

3.4.2 Clinical Guidelines

The recommendations from the high-quality clinical guidelines regarding assessment of major oral cancer risk factors and various components of behavioural preventive interventions (advice, signposting/referral) that could be delivered in a primary care practice setting (dental/medical/pharmacy) will now be reviewed in this section. The section outlines the clinical guideline selection, characteristics, quality assessment and synthesis of the identified clinical guidelines as a separate 'stream'.

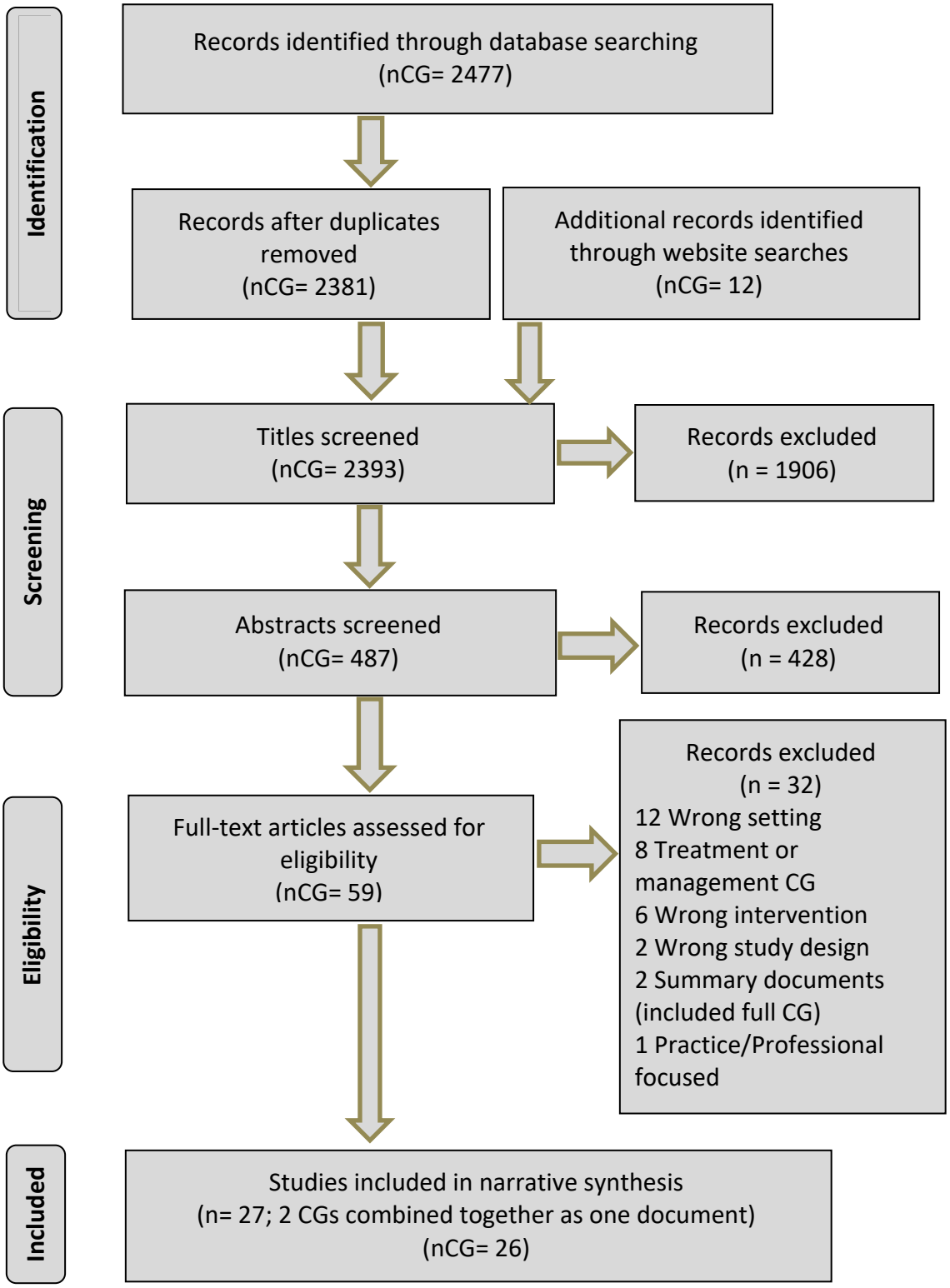
3.4.2.1 Guideline selection

The search strategy retrieved 2477 potentially relevant records through database searches and 12 additional records were identified through organization or health board website searches. All included records were screened (title and abstract) and of these, 59 records were selected for full text review. Finally, 27 clinical guidelines were included in this overview. One of the included guidelines (MQIC, 2015) was presented as a summary document and was based on another large/detailed guideline document (Fiore et al., 2008). Thus, both guidelines were considered as a single document in this overview, and referred to as CG 23 (Table 3.7). Thus, in total, there were 26 clinical guidelines (nCG= 26) included in this overview (Figure 3.3).

The reference lists of the included clinical guidelines were hand searched for any relevant clinical guidelines (and systematic reviews) to be included in this overview. Some of the referenced systematic reviews (which met our inclusion criteria) in the included guidelines were already included in this overview (SR: 1, 6, 8, 12, 16, 27). Thus, showing that a comprehensive search strategy was followed in this overview to promote inclusion of all relevant systematic reviews and clinical guidelines.

A list of excluded guidelines (n=32) is presented, with the reasons for exclusion, in Appendix 5.

Figure 3.3: PRISMA four-phase flow diagram - for included clinical guidelines



3.4.2.2 Guideline characteristics

This overview included clinical guidelines from different countries/regions across the world: Australia, Europe, India, New Zealand, United Kingdom, and United States. As mentioned in Section 3.3.3, the clinical guideline search was limited to the last ten years, thus all included clinical guidelines were published between 2006 and 2015 (guideline search was carried out in August 2015). During data extraction, published updates of three included guidelines were found. Thus, it was decided to include the updated versions of these clinical guidelines in this overview, which were CG: 1, 2, 3 (Kottke et al., 2016; Piepoli et al., 2016; RACGP, 2016).

The 26 clinical guidelines included recommendations based, or drawn from, the other existing (older) guidelines, relevant systematic reviews, research/trial evidence, and the opinion of experts and experienced practitioners. The majority of the guidelines provided details of the strategy used to search for the evidence-base to develop the guideline, e.g. search terms used, sources consulted, and dates of the literature covered, thus showing rigour in the development of the guideline (which was reflected in their quality scores – high AGREE II scores). However, a few guidelines did not provide details of the strategy used to search for the evidence-base to develop the guideline, and thus scored low on AGREE II (Section 3.4.2.3).

The various guideline characteristics have now been presented for dental and medical (or pharmacy) settings as separate sub-sections.

3.4.2.2.1 Dental practice setting

Of the 26 clinical guidelines, five included recommendations exclusively for a primary care dental practice (CG: 6, 8, 9, 11, 16); while of the other 21 clinical guidelines (medical/pharmacy), some included dental professionals along with a range of primary care medical professionals as their target users (see Table 3.7 at the end of section 3.4.2.2.2). The dental clinical guidelines (CG: 6, 8, 9, 11, 16) were designed for use by the whole primary care dental team, including dentists, dental therapists, dental hygienists, dental nurses, and oral health

educators. Directors of public health, dental public health consultants and strategic leads who plan local dental services were also reported as target users of these dental clinical guidelines (CG: 6, 8, 9, 11, 16).

All five dental guidelines mentioned oral cancer as one of the target health conditions together with other oral health conditions (for example, periodontal diseases, tooth loss, tooth wear, halitosis, stained teeth). Four guidelines included recommendations for delivering preventive interventions (including risk factor assessment, behavioural advice and/or referral) for smoking, smokeless tobacco, and/or alcohol, along with advice on diet, oral hygiene practices, and the use of fluoride (CG: 6, 8, 11, 16). One dental guideline included advice for tobacco use only (smoking and smokeless tobacco) (CG 9).

3.4.2.2.2 Medical or community pharmacy setting

The majority, 21 out of the 26 clinical guidelines, included recommendations for delivering preventive interventions (including risk factor assessment, behavioural advice and/or referral) in a primary care medical or pharmacy setting. The clinical guidelines aimed to help tackle a range of major behaviours including smoking, smokeless tobacco, and alcohol misuse. Similar to the systematic reviews (Section 3.4.1), the main risk factors discussed were smoking and alcohol in all included guidelines. These behaviours were linked to a range of health problems and chronic diseases, such as cardiovascular disease, type 2 diabetes, and cancer. The medical guidelines were designed for use by the whole primary care medical (or pharmacy) team and included a range of health care professionals (target users) who could deliver a preventive intervention, targeting various health conditions. Some of the guidelines also reported dental professionals as their target users (Table 3.7). Three of the primary care medical guidelines mentioned preventing oral cancer along with other chronic diseases (CG: 3, 17, 23).

A summary of the type of interventions within the 21 medical guidelines is shown below:

- Smoking cessation interventions were included in the majority of the guidelines - 17 guidelines (CG: 1, 2, 3, 4, 5, 7, 12, 13, 14, 18, 19, 20, 22, 23, 24, 25, 26);

- Smokeless tobacco interventions were included in three guidelines (CG: 17, 19, 23), one of these guidelines (CG 17) included advice exclusively for smokeless tobacco use;

- Alcohol reduction interventions were included in nine guidelines (CG: 1, 2, 3, 4, 10, 14, 15, 21, 25).

Table 3.7 presents the various recommendations made about the assessment of major risk factors and delivering behavioural preventive interventions for each of the included clinical guidelines (n=26), along with target risk factors, and target users for these guidelines.

Table 3.7: Recommendations from all included clinical guidelines (n=26) about oral cancer risk factor assessment and delivering preventive interventions

Clinical Guideline (CG) ID	Target users	Risk factors (target population)	Ask/ Assess	Advise/ Arrange	Assist/ Referral
CG1 (Kottke et al., 2016)	Health care professionals- all clinicians, clinics and health care delivery systems, and other expert audiences	Tobacco and alcohol (Adults aged 18 years or more)	Tobacco: All adults to be screened for tobacco use. Record a patient's smoking status as a vital sign or list tobacco use or exposure as a specific problem in the medical records. Alcohol: Screen individuals using validated tool for risky/hazardous drinking. Ask a single question about heavy drinking, or administer a written self-report instrument (AUDIT, AUDIT-C).	Tobacco: Clinicians should advise patients who smoke to quit. Offer behavioural (motivational) or pharmacologic interventions. Agree upon one or more SMART goals. Alcohol: Offer a brief behavioural intervention for individuals who screen positive; 10-15 minutes, multi-contacts. Agree upon one or more SMART goals.	Tobacco: Offer more intensive counselling or referrals Alcohol: For alcohol dependence refer to chemical dependency counsellor or program
CG2 (Piepoli et al., 2016)	Healthcare professionals in their clinical practice: primary	Smoking Alcohol- as part of recommendations	Smoking: (5A's) Ask: Systematically inquire about smoking status at every opportunity.	Smoking: Advise: Unequivocally urge all smokers to quit. Arrange: Arrange a schedule of	Smoking: Assist: Agree on a smoking cessation strategy, including setting

	care, acute hospital settings and cardiac rehabilitation centre	on nutrition	Assess: Determine the person's degree of addiction and readiness to quit. Alcohol: not reported	follow-up. Alcohol: Consumption of alcoholic beverages should be limited to 2 glasses per day (20 g/d of alcohol) for men and 1 glass per day (10 g/d of alcohol) for women.	a quit date, behavioural counselling, and pharmacological support. Alcohol: not reported
CG3 (RACGP, 2016)	General practitioner, clinicians and practice nurses	Smoking, alcohol and sexual behaviours	Smoking: Ask about patient's interest in quitting. Assess nicotine dependence Alcohol: All patients should be asked about the quantity and frequency of alcohol intake from age 15 years.	Smoking: Advise to stop smoking, agree on quit goals and offer pharmacotherapy if appropriate. Follow-up to support maintenance and prevent relapse using self-help or pharmacotherapy. Alcohol: Those with at-risk patterns of alcohol consumption should be offered brief advice to reduce their intake. Provide interventions using brief motivational interviewing targeted at high-risk use; 5-15 minute advice. Training for clinicians and practice nurses.	Smoking: Offer referral to a proactive telephone call-back cessation service (e.g. the Quitline 13 7848), or motivational interviewing. Alcohol: not reported

CG4 (RACGP, 2015)	General practitioners (GPs) and practice staff (the GP practice team)	Lifestyle risk factors of smoking, nutrition, alcohol and physical activity (SNAP)	Smoking: (5 A's) Ask- identify patients with smoking Assess: Amount smoked, dependence, readiness to change. Smoking status should be assessed for every patient aged 10 years and older. Alcohol: All patients aged 15 years and older should be asked about the quantity and frequency of their alcohol intake. Assess: Alcohol intake and readiness to change; AUDIT and AUDIT-C	Smoking: Advise/agree: Brief advice and motivational interviewing, set a quit date (quit-plan). Arrange: Quit-line, follow-up visit Alcohol: Advise/agree: Information and motivational interviewing Arrange: Drug and alcohol services, follow-up visit	Smoking: Assist: Quit-line, consider pharmacotherapy Alcohol: Assist: Drug and alcohol services, pharmacotherapy
CG5 (Siu, 2015)	Primary care providers, including clinicians, physicians, nurses, psychologists, social workers, and cessation counsellors	Tobacco smoking	Smoking: (5 A's) Asking every patient (all adults) about tobacco use Assessing the willingness of all tobacco users to make an attempt to quit	Smoking: Behavioural interventions alone (in-person behavioural support and counselling, telephone counselling, and self-help materials) or combined with pharmacotherapy substantially improve achievement of tobacco cessation. Brief sessions (<10 min)	Smoking: Assist all tobacco users with their attempt to quit Arrange follow-up

				effectively increase the proportion of adults who successfully quit smoking and remain abstinent for 1 year. Although less effective than longer interventions, even minimal interventions (<3 min) have been found to increase cessation rates in some studies	
CG6 (NICE, 2015)	Dental care professionals, e.g. dental hygienists, dental nurses, dental therapists, dental technicians and orthodontic therapists. Directors of public health, dental public health consultants, educators	Smoking and alcohol	Smoking: Ask and record whether the person uses tobacco. Alcohol: Consider asking people about their alcohol use	Smoking: Offer brief advice and follow recommendations from CG 22 (NICE ph10 guideline). Alcohol: Follow recommendations from CG 21. Consider delivering oral health improvement messages in a variety of formats and using different media to meet the needs of different groups. Trained professionals	Smoking: Offer to refer them to the local stop smoking service
CG7 (Kralikova et	All professions in clinical medicine – as recommended	Tobacco	Document for each patient identified and selected as smoker; and encourage to	From brief intervention (10-minute) at each clinical contact with patients up to intensive	Not reported

al., 2015)	by WHO mainly doctors, nurses, pharmacists and dentists		stop	treatment. It includes psycho-socio-behavioural support and pharmacotherapy.	
CG8 (PHE, 2014a)	Primary dental care teams	Smoking (or tobacco use) Alcohol	Smoking (or tobacco): Ask – establish and record smoking status Alcohol: Ask – establish and record if the patient is drinking above low risk (recommended) levels	Smoking (or tobacco): Advise – advise on benefits of stopping and that evidence shows the best way is with a combination of support and treatment Alcohol: Advise – offer brief advice to those drinking above recommended levels Training: in undergraduate or dental setting; in line with national training standards. The minimum standard that every dental practice member should achieve is 'Very brief advice, just 30 seconds to ask, advise and act'.	Smoking (or tobacco): Act – offer help referring to local stop smoking services Alcohol: Act – refer or signpost high risk drinkers to their GP or local alcohol support services
CG9 (PHE, 2014b)	Dental professionals or dental teams, commissioners and	Tobacco (refers to PHE 2014a, and NICE guidelines)	Establish and record smoking status (ASK)- at least once a year. Is the patient a smoker, ex-smoker or a non-smoker?	Very brief advice Advise on the personal benefits of quitting (ADVISE)	Offer help (ACT) Refer to local stop smoking services

	educators				
CG10 (CDC, 2014)	For alcohol screening: receptionists, medical assistants, nurses To deliver the brief interventions: primary care practitioners/physicians, physician assistants, nurse practitioners, nurses, health educators, or other allied health professionals	Alcohol use	Patients should be screened at least annually The 'Single Question Alcohol Screen' or AUDIT (1–3) Ask if they would like your medical advice	Patients who screen positive for risky drinking need a brief intervention (5-15 minutes). Tailoring the plan for alcohol brief interventions to your practice; establish a goal and develop an action plan. Provide feedback about screening results. Establish a follow-up system to monitor patients' drinking, provide encouragement and support. Determine who needs training- since every primary care practice is different.	For dependence: Offer the patient a referral to further treatment A qualified clinician in the practice to manage dependent patients. Offering medications for alcohol dependence, particularly if patients refuse to go to traditional alcohol treatment.
CG11 (SDCEP, 2014)	Clinicians who are involved in the prevention and treatment of periodontal diseases e.g. dentists, dental therapists, dental hygienists and oral health educators	Smoking and Alcohol (patients both at risk of and with periodontal diseases)	Smoking: Ask the patient if he/she (still) smokes (or uses smokeless tobacco) and record the response. Ask if the patient is interested in stopping smoking. Alcohol: Assess patient's alcohol consumption. Ask about his/her daily/weekly alcohol	Smoking: Discuss effect smoking has on his/her oral health and general health and the benefits of stopping. Inform the patient that stopping smoking is the single most important thing he/she can do to improve not only oral health but general health as well. Offer relevant health promotion material (e.g. 'Aspire' magazine)	Smoking: Refer to smoking cessation services if necessary Alcohol: Advise the patient to see his/ her general medical practitioner for further advice and help.

			consumption and convert into units. Ask patient's willingness to discuss this.	Alcohol: Outline the possible harmful effects of excessive alcohol consumption. Advise them to visit the Alcohol Focus Scotland website (www.alcohol-focus-scotland.org.uk) for further advice and help.	
CG12 (New Zealand Health, 2014)	All health care workers, managers of health care services, practitioners in stop-smoking services	Smoking (or tobacco)	The ABC pathway Ask about and document every person's smoking status.	Give brief advice (face-to-face) to stop to all patients who smoke at every opportunity. Can give this advice in 30 seconds. Tailored brief advice and self-help materials. Seek appropriate training	Strongly encourage every person who smokes to use Cessation support (a combination of behavioural support and stop-smoking medicine works best) and offer them help to access it. Refer to, or provide, cessation support to everyone who accepts the offer.
CG13 (Zwar et al., 2014)	General practice team (GP or practice nurse)	Smoking	<u>5As approach</u> Ask- regularly ask all patients if they smoke and record the information in the medical record. Assess- interest in quitting, to help tailor advice to each smoker's needs and stage of	Advise- all smokers to quit in a clear, unambiguous way such as 'the best thing you can do for your health is to stop smoking'. Arrange: follow-up visits to increase the likelihood of long-term abstinence.	Assist: all smokers should be offered help to quit.

			change. Nicotine dependence should also be assessed as this helps to guide treatment. Assessment of other relevant problems, such as mental health conditions, other drug dependencies and comorbidities.	When time is short, use the approach of 'very brief advice'- Ask, Advise and Refer.	
CG14 (NICE, 2014)	Practitioners, policy makers, researchers, individuals, health and social care organisations and other service providers	Range of behaviours including smoking, alcohol misuse	Assess participants' health in relation to the behaviour and the type of actions needed	Use a very brief or brief intervention to motivate people to change behaviours that may damage their health. The interventions should also be used to inform people about services or interventions that can help them improve their general health and wellbeing. Tailor interventions to meet participants' needs. Train professionals	Direct and refer people to specialist support services
CG15 (Moyer and Preventive Services Task, 2013)	Primary care practices or primary care clinicians	Alcohol misuse	Clinicians should screen adults aged 18 years or older for alcohol misuse AUDIT, AUDIT-C, or Single-question screening, such as asking, "How many times in the past year have	Provide persons engaged in risky or hazardous drinking with brief behavioural counselling interventions to reduce alcohol misuse. Interventions may be delivered by face-to-face sessions, written self-help materials, computer- or	Not reported

			you had 5 (for men) or 4 (for women and all adults older than 65 y) or more drinks in a day?"	Web-based programs, or telephone counselling. Brief multi-contact (each contact is 6 to 15 minutes) behavioural counselling seems to have the best evidence of effectiveness; very brief (≤ 5 minutes) behavioural counselling has limited effect.	
CG16 (SDCEP, 2012)	Primary care dental team	Tobacco and alcohol	Tobacco: Assess the patient's smoking habits: follow the 'ask' and 'assess' elements of the 5 'A' protocol Alcohol: Ask each patient about their weekly alcohol consumption in units and the largest number of units consumed in the past week. Consider using a validated alcohol screening tool to gain an objective measure of alcohol consumption.	Tobacco: After 'ask' and 'assess', either 'refer' the patient or carry out the remaining 'advise', 'assist' and 'arrange follow-up' elements of the 5 'A' protocol. Alcohol: Advise high-risk drinkers about possible harmful effects of excessive alcohol consumption	Tobacco: After 'ask' and 'assess', refer the patient to a smoking cessation service Alcohol: Advise to see their general medical practitioner and/or to visit the Alcohol Focus Scotland website if they have concerns.
CG17 (NICE, 2012)	Primary healthcare teams: GPs, nurses, dentists, dental	Smokeless tobacco (people of South Asian origin are the	Ask people if they use smokeless tobacco, using the names that the various	Ensure smokeless tobacco users are aware of the health risks. Use a brief intervention to	In addition to delivering a brief intervention, refer people who want to quit to

	nurses, dental hygienists, community pharmacists	focus of this guidance as they are the predominant users of smokeless tobacco products in England)	products are known by locally. If necessary, show them a picture of what the products look like, using visual aids. (This may be necessary if the person does not speak English well or does not understand the terms being used.) Record the outcome in the patient notes.	advise them to stop. Record the response to any attempts to encourage or help them to stop using smokeless tobacco in the patient notes (as well as recording whether they smoke). Training for practitioners	local specialist tobacco cessation services (see NICE guidance ph10). This includes services specifically for South Asian groups, where they are available.
CG18 (RACGP, 2011)	All health professionals, including dental professionals	Smoking	A system for identifying all smokers and documenting tobacco use should be used in every practice or healthcare service. Assessment of readiness to quit is a valuable step in planning treatment	All smokers should be offered brief advice to quit. Offer brief cessation advice in routine consultations and appointments whenever possible (at least annually). All smokers attempting to quit should be offered follow-up. Pharmacotherapy should be offered in case of nicotine dependence	Telephone call-back counselling services are effective in assisting cessation for smokers who are ready to quit. Referral to such services should be considered for this group of smokers.
CG19 (NTCP, 2011)	Physician or other health care providers	Tobacco	(5 A's) Systematically identify all tobacco users at every visit. It should be an essential part of evaluation that for every tobacco user at every consultation, tobacco-use status be queried and	All tobacco users should be firmly advised to quit in a way that is supportive and nonconfrontational. Tell them about benefits of quitting. Brief advice (few minutes) should have a clear, strong, and personalized message.	Not reported

			documented. Determine willingness to make a quit attempt. Assess nicotine dependence	Pharmacotherapy where needed. Schedule a follow-up contact.	
CG20 (NHG, 2011)	Primary care professionals, general practitioner	Smoking	A risk questionnaire is completed (calculate risk score) before the Prevention Consultation, which can be used to deduce whether there is an increased risk of the listed cardiometabolic conditions. Individuals with a score on the questionnaire below the threshold value but with risk factors (smoking, etc.) receive targeted lifestyle advice.	Tailored or targeted lifestyle advice, and patients are informed of the option to make an appointment with the GP or the practice support employee for risk communication and targeted lifestyle advice according to the NHG Guidelines on Smoking Cessation (only summary document available online) – which recommends that it is important to offer smokers, who are motivated to stop, intensive support at the right moment. Medicinal support in the way of nicotine replacement therapy, nortriptyline or bupropion is, if possible, recommended in motivated smokers who smoke at least 10 cigarettes daily.	Not reported
CG21 (NICE, 2010)	Trained primary healthcare; other healthcare services	Alcohol (Adult drinkers-hazardous or	Complete a validated alcohol questionnaire, e.g. AUDIT, or abbreviated version (such as	Offer a session of structured brief advice on alcohol for 5–15 minutes, based on FRAMES	Referral to a specialist alcohol treatment service for alcohol dependence or

	(outpatient departments, sexual health, pharmacies, dental surgeries)	harmful amount of alcohol)	AUDIT-C, AUDIT-PC, or FAST)	principles (feedback, responsibility, advice, menu, empathy, self-efficacy). Offer an extended intervention (motivational interviewing or motivational-enhancement therapy), from 20 to 30 minutes. Follow up or offer up to four additional sessions (if needed).	have failed to benefit from structured brief advice and an extended brief intervention.
CG22 (NICE, 2008)	NHS and other professionals responsible for smoking cessation services. e.g. Doctors, nurses, pharmacists, dentists, quit-line counsellors	Smoking or tobacco use (everyone who smokes or uses tobacco in any other form)	Identify and record the smoking and/or tobacco use status of all their patients	Healthcare professionals should be trained to give brief advice (less than 10 minutes) on stopping tobacco use. Remind at every suitable opportunity of the health benefits of stopping. Pharmacotherapy as appropriate. Train all healthcare staff to offer brief advice and to make referrals	Offer referral to the NHS Stop Smoking Service, to help people in their attempt to quit
CG23 (Fiore et al., 2008)	Physician or other clinician (e.g., nurse, psychologist, dentist, or counsellor)	Smoker or tobacco user	Identify and document tobacco use status for every patient at every visit as a 'vital sign'. Assess willingness to make a quit attempt.	Advise in a clear, strong, and personalized manner, urge every tobacco user to quit (3-10-minutes). Or offer intense counselling of four or more sessions that are 10 minutes or more in length. Arrange follow-up contacts, self-help material, or offer medication.	Provide or refer for counselling or additional treatment to help the patient quit. E.g. Quit-lines, smoking cessation program, or patient's health plan program. Alternative programs such as acupuncture or

					hypnotism.
CG24 (IPCRG, 2008)	Primary care health professionals or clinicians including doctors, GPs, nurses and other health workers	Smoking	Ask smokers and ex-smokers about smoking status on at least an annual basis: All members of the practice team should ask about smoking status at all opportunities. - Assess desire to quit, dependence and barriers to quitting	a) Brief intervention: opportunistic advice in less than a minute- ask, assess, provide self- help materials, and refer. b) Moderate intervention: advice in 2-5-minutes- ask, assess, advise on strategies to overcome barriers, provide self-help materials, set a quit date, assist by offering pharmacotherapy, arrange follow-up (or refer). c) Intense intervention: advice if more than 5 minutes available- ask, assess, advise, assist, arrange follow-up consultation (or refer), and address issues of dependence, habit, triggers, negative emotions. Brainstorm solutions and develop a quit plan.	Refer to available smoking cessation services. Promote self-help materials, leaflets, quitline numbers in the waiting room, display no smoking posters.
CG25 (RACGP, 2006)	General practitioners, general practice nurses and other practice staff, and divisions of general practice	Smoking Hazardous alcohol drinking	One-minute interventions using the 5A framework Smoking: Ask- Do you smoke? Assess- Interest in quitting; Barriers to quitting; Nicotine dependence	Smoking: Advise- Provide brief, non-judgmental personalised and clear advice to aid quitting Alcohol: Advise- Provide brief, personalised and non-	Smoking: Assist- Offer relevant pamphlets Arrange- Follow up or referral Alcohol: Assist- Enlist support

			Alcohol: Ask- Do you drink? How much on a typical day? How many days a week? Assess- Concern about drinking; Interest in cutting down; Barriers to cutting down	judgmental clear advice to cut down; Highlight other benefits of cutting down	Arrange- Offer relevant pamphlets on safe drinking levels and ideas to help reduce intake; Follow up soon after
CG26 (NICE, 2006a)	GPs, nurses in primary and community care, other health professionals, such as hospital clinicians, pharmacists and dentists	Smoking	Ask people who smoke how interested they are in quitting, i.e. an assessment of the patient's commitment to quit	Brief intervention, 5-10-minutes; involving simple opportunistic advice to stop, an offer of pharmacotherapy and/or behavioural support, provision of self-help material	If they want to stop, refer them to an intensive support service such as NHS Stop Smoking Services. If they are unwilling or unable to accept a referral, offer a stop smoking aid (pharmacotherapy).

3.4.2.3 Quality assessment (AGREE II)

The quality of all included clinical guidelines was assessed using the AGREE II instrument. The AGREE II scores of all the clinical guidelines are included in Table 3.8. Figure 3.4 depicts a graphical representation of AGREE II scores. Blue vertical bars in the figure represent the AGREE II scores (which range from 0-7).

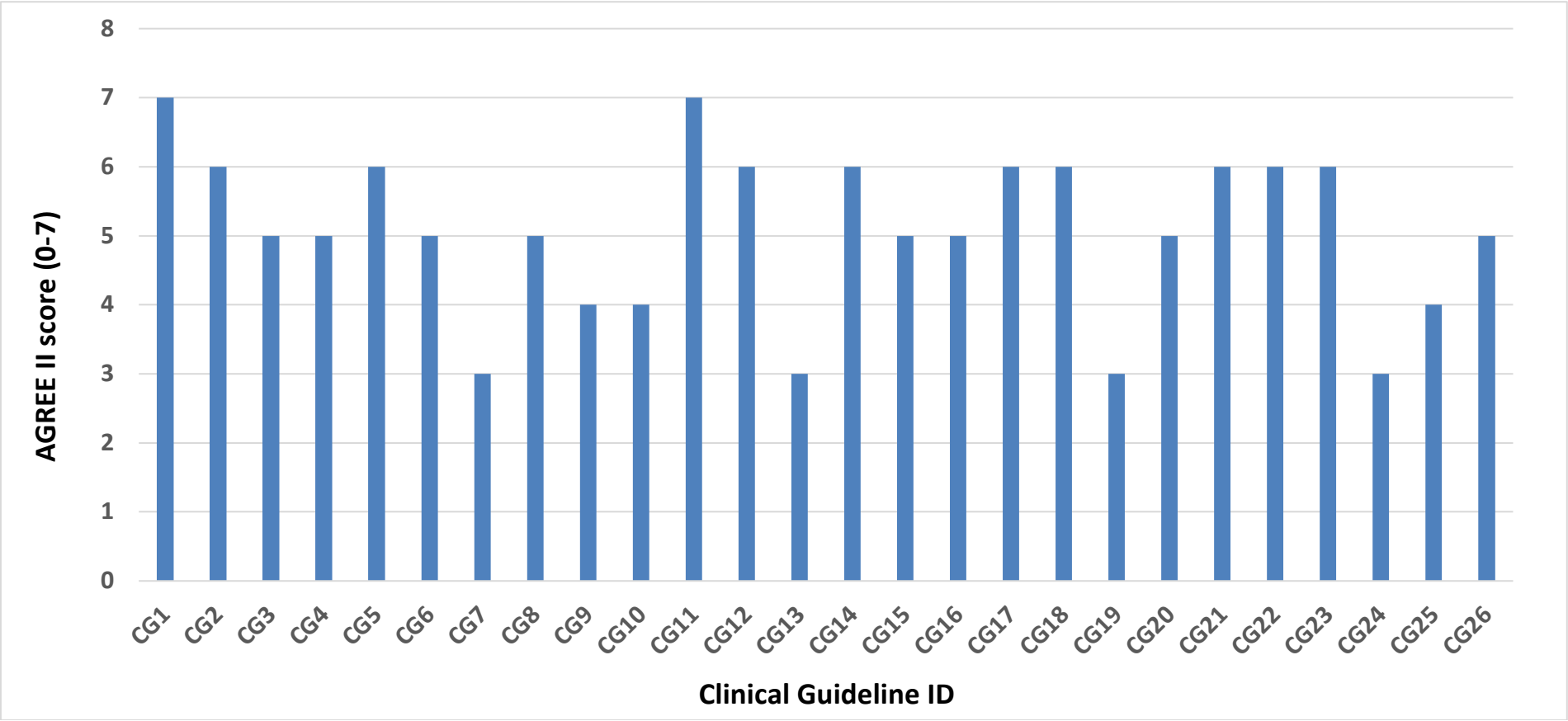
The guidelines were considered high-quality if the AGREE II score was 6 or 7; medium or mid-quality if the score ranged from 3 to 5; and a score of 1 or 2 indicated a low-quality guideline (Section 3.3.8.2). It can be seen from Table 3.8 that this overview included 11 high-quality guidelines and 15 mid-quality guidelines; there were no low-quality guidelines. The 11 clinical guidelines with high quality score were: CG 1, 2, 5, 11, 12, 14, 17, 18, 21, 22, 23; and two of these high quality guidelines met all the criteria in AGREE II and scored 7 (CG: 1, 11) (SDCEP, 2014; Kottke et al., 2016).

Table 3.8: Quality scores of clinical guidelines for the six domains of the AGREE II Instrument (D 1–D 6) and the overall quality

Clinical Guideline (CG) ID	D 1			D 2			D 3								D 4			D 5				D 6		Overall quality of CG	Recommend CG for use
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23		
CG1 (Kottke 2016)	6	6	6	6	2	6	6	5	7	6	7	7	6	7	7	6	7	6	6	4	1	7	7	7	Yes
CG2 (Piepoli 2016)	7	7	7	7	2	7	2	3	7	7	6	7	7	4	7	7	7	6	7	5	2	2	7	6	Yes
CG3 (RACGP 2016)	6	6	6	7	4	7	2	2	6	4	5	6	6	5	6	6	6	6	6	5	2	2	2	5	Yes, with modifications
CG4 (RACGP 2015)	6	6	6	6	4	7	2	2	7	2	6	7	6	3	7	7	7	7	7	6	6	2	2	5	Yes, with modifications
CG5 (Siu 2015)	7	7	7	6	5	6	7	7	7	4	7	7	5	2	3	6	6	7	6	6	2	6	7	6	Yes
CG6 (NICE 2015)	6	6	6	6	6	6	6	6	4	5	5	4	6	6	4	4	5	3	4	3	2	6	4	5	Yes, with modifications
CG7 (Kralikova 2015)	3	4	3	4	2	4	3	3	3	2	3	3	2	2	3	4	4	5	4	5	2	3	2	3	No
CG8 (PHE 2014a)	6	6	6	5	1	6	3	3	6	6	5	6	5	3	6	6	6	4	5	1	1	1	1	5	Yes, with modifications
CG9 (PHE 2014b)	6	6	6	6	1	7	1	1	1	1	3	4	2	2	4	5	6	6	6	1	1	1	1	4	Yes, with modifications
CG10 (CDC 2014)	6	6	6	2	2	6	2	1	2	2	2	2	2	2	6	6	6	6	7	4	5	1	2	4	Yes, with modifications
CG11 (SDCEP 2014)	7	7	7	7	6	7	7	6	7	7	6	7	7	7	7	7	7	6	7	1	4	2	4	7	Yes
CG12 (NZHealth 2014)	6	7	5	7	2	7	7	7	7	7	7	7	5	6	7	6	7	7	7	4	6	2	7	6	Yes

CG13 (Zwar 2014)	6	6	7	2	1	5	1	1	1	1	4	4	4	1	6	6	6	4	4	1	1	1	6	3	No
CG14 (NICE 2014)	6	6	6	6	6	6	6	6	4	5	5	4	6	6	5	6	5	4	5	4	3	6	5	6	Yes
CG15 (Moyer 2013)	5	6	5	5	4	5	6	6	6	3	5	6	4	2	3	5	5	6	5	5	2	5	6	5	Yes, with modifications
CG16 (SDCEP 2012)	6	7	7	7	1	5	2	2	1	5	5	2	6	5	4	6	5	5	5	2	6	2	4	5	Yes, with modifications
CG17 (NICE 2012)	6	7	7	6	3	5	4	4	3	6	6	4	6	6	5	6	6	5	5	4	6	5	5	6	Yes
CG18 (RACGP 2011)	7	7	6	6	2	7	2	2	7	3	6	7	6	5	7	7	7	6	7	2	2	4	7	6	Yes
CG19 (NTCP 2011)	5	5	6	5	2	4	2	2	2	2	6	3	4	2	5	6	4	5	3	2	2	2	2	3	No
CG20 (NHG 2011)	5	6	6	5	2	3	3	4	4	5	5	3	5	6	5	6	5	5	5	3	5	3	4	5	Yes, with modifications
CG21 (NICE 2010)	6	5	6	6	2	7	5	5	6	7	6	7	6	5	7	6	5	6	6	6	4	2	2	6	Yes
CG22 (NICE 2008)	6	6	6	6	6	6	6	6	6	6	5	6	6	6	5	5	5	5	5	5	6	5	4	6	Yes
CG23 (Fiore 2008)	6	6	6	5	4	6	6	7	7	7	6	7	6	6	5	6	6	5	6	5	5	5	6	6	Yes
CG24 (IPCRG 2008)	3	4	4	4	2	4	3	3	3	2	3	3	2	2	5	5	5	5	5	5	2	3	2	3	No
CG25 (RACGP 2006)	6	7	5	5	3	7	2	2	3	2	5	4	3	2	5	6	4	6	7	5	6	3	2	4	Yes, with modifications
CG26 (NICE 2006a)	6	6	6	5	5	6	5	5	5	5	6	6	6	6	5	5	5	4	4	5	6	6	4	5	Yes, with modifications

Figure 3.4: Graphical representation of AGREE II scores



3.4.2.4 Best practice (high-quality) recommendations

Table 3.7 presents the main recommendations reported in all included clinical guidelines (n=26) for risk factor assessment and delivering a preventive intervention for smoking cessation and reducing alcohol use (for example, risk factors, recommended interventions, target users and population). The recommendations for a face-to-face behavioural preventive intervention, targeting adult populations (18 years and above) and in a primary care setting, (dental/medical/pharmacy) were reported.

Similar to the systematic review synthesis (Section 3.4.1.5), the best practice, high-quality, guideline recommendations were synthesised here. Thus, the recommendations presented and discussed in this overview are for the 11 clinical guidelines with high AGREE II scores (CG: 1, 2, 5, 11, 12, 14, 17, 18, 21, 22, 23) (Section 3.4.2.3).

To deal with levels of recommendation quality within the "high-quality" clinical guidelines, so that all statements within the guidelines were not all given the same weight, the preference for synthesis within the high-quality guidelines was given to the higher quality (AGREE II) score, recency of publication, and the level of evidence for particular recommendations within high-quality guidelines. Data duplication, i.e. previous guidelines or systematic reviews (used for developing guidelines) was also considered while presenting recommendations from all high-quality guidelines. The main recommendations from all remaining guidelines are summarised in Table 3.7.

The guideline recommendations have been presented separately for dental and for other primary care settings (medical/pharmacy). Furthermore, as all high-quality guidelines focused on preventive interventions in terms of smoking and/or alcohol, the recommendations have been organised under these two major headings.

3.4.2.4.1 Dental practice setting

Of the 11 high-quality guidelines, there was only one guideline (CG 11) which provided recommendations for delivering behavioural preventive interventions (including risk factor assessment, behavioural advice and/or referral) delivered exclusively in a primary care dental setting. This guideline was developed by the *Scottish Dental Clinical Effectiveness Programme* (SDCEP), and met all criteria in AGREE II. The guideline included recommendations on best practice for the prevention and treatment of periodontal diseases in a primary care setting. This guidance presented clear and consistent advice to support dental professionals to deliver preventive interventions for both smoking (or smokeless tobacco) and alcohol. The guidance emphasised that these risk factors (tobacco and alcohol) are not only associated with periodontal diseases, but also cancers of the mouth, other oral diseases, and many other chronic diseases (i.e. common risk factors). The guideline reported that it was based on existing guidelines (for example, British Society of Periodontology), relevant systematic reviews, research evidence and the opinion of experts and experienced practitioners (discussed in detail later under relevant sections - for smoking and alcohol).

TOBACCO

The smoking cessation interventions in this dental guideline (CG 11) were based on another existing guideline: the *NHS Health Scotland* publication "*A Guide to Smoking Cessation in Scotland 2010*" (NHS, 2017), which in turn included recommendations drawn from the *National Institute for Health and Care Excellence (NICE)* Public Health Guidance on smoking cessation (NICE, 2006a; NICE, 2008) which were also included in this overview study under medical practice guidelines (CG: 22, 26) (Table 3.7).

It was stated that dental practices were well placed to provide smoking cessation support given the large proportion of the population who visit a dentist (or dental care professionals) for regular check-ups, including teenagers and pregnant women who are entitled to free dental care (NHS, 2017). Many of the recommendations for smoking cessation in this guideline were based on the research evidence reported in a Cochrane review (Carr and Ebbert, 2012), which reported the effectiveness of smoking cessation interventions in a dental

practice setting, and was the only dental review included in this overview study under systematic review evidence (SR 12) (Section 3.4.1.5.1).

The main recommendation regarding smoking cessation stated that (CG 11): "All health and health-related staff should raise the issue of stopping smoking in their day-to-day work with patients and clients and, where appropriate, refer them on to local services to help them stop".

Risk factor assessment (Ask/Assess)

The high-quality dental guideline (CG 11) recommended to ask a patient if they smoked (or used smokeless tobacco) and to record the response (i.e. patient's smoking/tobacco use status) as part of a social history. It was also recommended to ask if the patient had considered the effect smoking (or smokeless tobacco) had on their oral health and general health and the benefits of stopping, and to ask if the patient was interested in stopping smoking (or tobacco use), and then deliver a preventive intervention accordingly. This recommendation was in line with the only high-quality dental systematic review (SR 12) included in this overview, also referenced in this guideline.

Behavioural preventive interventions (Advise/ Arrange)

The guideline (CG 11) recommended providing a 'brief' intervention to encourage smoking cessation, which was defined as "opportunistic discussions where healthcare professionals deliver advice, encouragement, and referral to more intensive treatment where appropriate". It was recommended to offer a brief or very brief advice to stop smoking, tailored or adapted to suit the circumstances of each individual (i.e. patient's preferences and needs). It was mentioned that spending a few minutes to raise the issue of smoking (or tobacco use) with patients might trigger a successful attempt at quitting, i.e. very brief advice in a single visit was effective in increasing smoking cessation rates. This recommendation reflects the evidence from the dental Cochrane review (SR 12) included in this overview (Section 3.4.1.5.1), suggesting strong strength of recommendation.

It was further recommended that dental professionals were not expected to provide comprehensive specialist support, i.e. intensive or structured (theory-

based) interventions, as this could be best delivered by trained smoking cessation counsellors. The guideline highlighted that the dental professionals should: “Ask if the patient has considered the effect smoking has on his/her oral health and general health and the benefits of stopping and inform the patient that stopping smoking is the single most important thing he/she can do to improve not only their oral health but their general health as well”. It was also recommended that dental professionals should provide patients with various smoking cessation resources, for example: relevant educational or health promotion materials, and online support (strength of recommendation not supported with research evidence).

Referral to specialist services (Assist)

With a very brief intervention, dental professionals were required to direct patients who expressed an interest in stopping smoking to local smoking cessation services or provide ‘Smokeline’ numbers (if necessary), in order to increase their chances of a successful quit attempt. The guideline (CG 11) further mentioned that smoking cessation services were available from every community pharmacy in Scotland and specialist services were also offered by smoking cessation advisors (trained) throughout Scottish health board areas. However, there was no review or research evidence reported in this guideline to support smoking referrals.

Summary

Table 3.9 summarises recommendations from the high-quality guideline on smoking cessation interventions in a primary care dental practice. Overall, it was recommended to record a patient’s smoking (or tobacco use) status as part of social history, assess patient’s risk levels, and offer a very brief opportunistic advice (for few minutes) to stop smoking (or tobacco use). It was further recommended to offer information on referrals to quit-line or local stop smoking services. However, not all recommendations made were supported by research evidence.

Table 3.9: Dental practice - best practice (high-quality) recommendations for smoking cessation interventions in the clinical guideline (CG)

Preventive interventions for smoking		Strength of recommendations (based on supported evidence)	CG supporting recommendations
Ask/ Assess	Ask and record patient's smoking (or tobacco use) status as part of social history	Strong	CG 11
	Assess patient's risk levels, and their interest in stopping smoking	Strong	
Advise/ Arrange	Offer brief or very brief opportunistic interventions	Strong	CG 11
	Brief interventions should be tailored to meet individual needs	Strong	
	Advice supported with educational materials or online support	Weak	
Assist/ Referral	Offer smokers (or tobacco users) 'Smokeline' numbers or information on local smoking cessation services	Weak	CG 11

ALCOHOL

The interventions for reducing alcohol consumption in this dental guideline (CG 11) were based on two existing guidelines: the *Scottish Intercollegiate Guidelines Network Guideline 74* (SIGN, 2003) and a brief guidance by *NHS Health Scotland* on the link between alcohol and oral health (NHS, 2012). The NHS guidance in turn included recommendations drawn from the other SDCEP guidance *"Oral Health Assessment and Review"* document (SDCEP, 2012) and the NICE Public Health Guidance on behaviour change (NICE, 2014). Both of these guidelines were already included in this overview study (CG: 14, 16) (Table 3.7); the recommendations from CG 16 were not synthesised here as it had a lower quality score, while CG 14 is synthesised under medical practice guidelines.

Similar to providing smoking cessation support in a dental practice, it was recommended to include preventive interventions to reduce alcohol consumption in a dental practice setting, given the large proportion of the population who visit a dentist (or dental care professionals) for regular check-ups, including teenagers (NHS, 2017). The research evidence reported in these guidelines also suggested that raising the issue of alcohol with patients in a dental practice was feasible and quite acceptable to patients (McAuley et al., 2011). The evidence for the effectiveness of alcohol reduction interventions in this dental guideline were adapted from the review of trial evidence in the medical practice settings. There was no dental research evidence referenced in this guideline – which was reflected in the systematic review synthesis in this overview study, where there were no dental reviews identified.

Risk factor assessment (Ask/Assess)

The high-quality dental guideline (CG 11) recommended assessment of a patient's alcohol consumption by asking about average weekly alcohol consumption and maximum daily consumption in the last week and to convert this into units. The guideline stated: "The recommended limit for men is 21 units of alcohol per week, with no more than 4 units in any one day; the recommended limit for women is 14 units of alcohol per week, with no more than 3 units in any one day."

The guideline recommended that a patient's alcohol consumption should be recorded as part of a social history, and that the dental professional should then ask and assess if the patient is interested in reducing alcohol consumption and in seeking further help. It was further recommended to use various screening tools to assess a patient's alcohol consumption, for example AUDIT-PC (Alcohol Use Disorders Identification Test – Primary Care) and FAST (Fast Alcohol Screening Test) – which are shorter versions (taking only a couple of minutes to administer the tool) of other alcohol screening tools (for example, AUDIT) to identify risky drinkers in primary care settings.

Behavioural preventive interventions and referral to specialist services (Advise/ Arrange/ Assist)

The dental guideline (CG 11) recommended that: "If a patient is drinking alcohol excessively and is willing to discuss this with you, outline the possible harmful effects of excessive alcohol consumption and advise the patient to see his/ her general medical practitioner and/or to visit the Alcohol Focus Scotland website (www.alcohol-focus-scotland.org.uk) for further advice and help." It stated that the alcohol issue must be addressed with sensitivity and that it might be useful to deliver advice in the context of improving a patient's oral tissues (or oral health) as a result of changes to their alcohol consumption. No further details were provided in this dental guideline (CG 11) regarding delivering behavioural preventive interventions for alcohol reduction, for example, exact duration of advice, follow-up visits, or training of dental professionals. However, similar to smoking interventions, it was mentioned that spending a few minutes i.e. very brief advice in a single visit was effective in reducing alcohol consumption. However, there was no research evidence to support this recommendation. There were no details provided in this dental guideline regarding making referrals for specialist alcohol treatment services.

Summary

Table 3.10 summarises recommendations from the high-quality guideline on alcohol reduction interventions in a primary care dental practice. Overall, it was recommended to assess a patient's alcohol consumption (using screening tools), followed by very brief advice/discussion to outline and discuss the possible harmful effects of excessive alcohol consumption, and then recommend that patients visit their general medical practitioner for further advice and help. However, there were no research evidence reported to support these recommendations. Thus, further guidance is required (with evidence to support recommendations) regarding delivering effective behavioural alcohol intervention in a dental practice setting.

Table 3.10: Dental practice - best practice (high-quality) recommendations for alcohol reduction interventions in the clinical guideline (CG)

Preventive interventions for alcohol		Strength of recommendations (based on supported evidence)	CG supporting recommendations
Ask/ Assess	Ask, assess and record patient's average daily/weekly alcohol consumption as part of social history	Weak	CG 11
	Use shorter versions of validated screening tools (AUDIT-PC, FAST)	Weak	
Advise/ Arrange	Very brief advice - outline the possible harmful effects of excessive alcohol consumption (no details provided, e.g. duration, number of sessions, training)	Weak	CG 11
Assist/ Referral	Refer patients to general medical practitioner for further advice and help	Weak	CG 11
	Provide online support (e.g. visit "Alcohol Focus Scotland" website)	Weak	

3.4.2.4.2 Medical or community pharmacy setting

As reported in the previous section, there was only one high-quality guideline (CG 11) in the dental practice setting. The remaining 10 high-quality guidelines (CG: 1, 2, 5, 12, 14, 17, 18, 21, 22, 23) related to interventions delivered in a primary care medical or community pharmacy setting (Table 3.7). There were no separate recommendations provided to be delivered particularly in a pharmacy setting; recommendations were in general for all primary care practices including pharmacy. Five guidelines (CG: 17, 18, 21, 22, 23) also included dental professionals as their target users.

It can be seen from Table 3.7 that, of these 10 high-quality guidelines, nine guidelines included recommendations for smoking (or smokeless tobacco) cessation (CG: 1, 2, 5, 12, 14, 17, 18, 22, 23), while alcohol reduction interventions were included in four guidelines (CG: 1, 2, 14, 21). The recommendations have now been organised under two major risk factors - tobacco and alcohol. The main recommendations from these high-quality guidelines (and other guidelines with lower quality) has been summarised in Table 3.7.

TOBACCO

Risk factor assessment (Ask/Assess)

In line with the systematic reviews, all nine high-quality clinical guidelines which included smoking (or smokeless tobacco) interventions (CG: 1, 2, 5, 12, 14, 17, 18, 22, 23) recommended that clinicians should ask and document/record every patient's smoking (or tobacco use) status: i.e., ask all individuals if they (still) smoke (or use smokeless tobacco), ask if the patient is interested in stopping smoking (or tobacco use) and record the response, even those who are not ready to stop and review with the individual once a year, where possible. The strength of these recommendations was evaluated as strong in these guidelines, as evaluated by various evaluation/grading methods in these guidelines; for example, CG 1 used the "Grading of Recommendations Assessment, Development and Evaluation (GRADE)" methodology system (Guyatt et al., 2008).

One of the guidelines (CG 17; a NICE guideline) included recommendations exclusively for reducing smokeless tobacco use. It was recommended in this guideline to ask individuals at their regular patient visits if they used smokeless tobacco (for example, ghukta, paan, betel quid with tobacco, areca nut). If the person did not understand the terms used or did not understand English, it was suggested to use local names of the various smokeless tobacco products or show the product image (CG 17).

It was further recommended in all high-quality guidelines that records should be updated regularly at every admission to hospital and at least annually in primary care (CG: 1, 2, 5, 12, 14, 17, 18, 22, 23). Two of the high-quality guidelines (CG:

1, 12) even recommended that a patient's smoking status should be recorded as a "vital sign" or as a specific medical problem in the patient's clinical records, in order to remind healthcare professionals to ask about and record smoking status. Recording a patient's smoking (or tobacco use) status this way might increase rates of referral for smoking cessation counselling (CG: 1, 12).

Three of the high-quality guidelines (CG: 12, 18, 23) recommended assessing the nicotine dependence by asking about the time to first cigarette and the number of cigarettes smoked a day: for example, ask patients, "How soon after you wake up do you usually have your first cigarette?" or "Number of cigarettes per day?" These guidelines mentioned that there was a high likelihood of nicotine dependence if the person smokes within 30 to 60 minutes of waking, and smokes more than ten cigarettes a day. If the patient had previously attempted to quit, it was recommended to investigate whether the patient had withdrawal symptoms (CG: 12, 18, 23). The strength of this recommendation (assessing nicotine dependence) was judged to be strong, however, there was no research evidence reported to support this.

Thus, this first step in the smoking (or tobacco) cessation intervention, i.e. asking, identifying, and assessing tobacco use status helped to divide patients into three treatment categories: (1) those who are willing to quit should receive interventions to help in their quit attempt; (2) those who are unwilling to quit should receive motivational interventions to encourage them to quit; and (3) those who recently quit using tobacco should be provided relapse prevention treatment (Fiore et al., 2008).

Behavioural preventive interventions (Advise/ Arrange)

The smoking (or tobacco use) cessation recommendations included in the most recent guideline (CG 1) were based on another older guideline included in this overview (CG 5), which in turn included recommendations based on a large document/guideline developed by the Department of Health and Human Services in the United States (CG 23). These three guidelines were all developed in the United States. Another high-quality guideline (CG 18) which was developed by the "Royal Australian College of General Practitioners (RACGP), included recommendations based on two recent guidelines included in this overview: the

U.S. Department of Health and Human Services guideline (CG 23), and the New Zealand Smoking Cessation Guideline (CG 12).

The recommendations from these high-quality guidelines (CG: 1, 5, 12, 18, 23) have been presented together, considering higher AGREE II score, recency, and duplication. The recommendations were evidence based: produced from a review of good quality systematic reviews, and a literature search or systematic review of randomized controlled trials conducted by the guideline development team. Some of the referenced systematic reviews in these guidelines (on which recommendations were based) were also included in this overview study, for example, SR: 1, 6, 8, 12, 16, 27 (Section 3.4.1.5.2); thus, showing strength of the evidence in this overview study.

The recommendations in these guidelines (CG: 1, 5, 12, 18, 23) were organised around the "5A's behaviour change model" for delivering smoking cessation interventions in a primary care setting. After asking and assessing a patient's smoking (or tobacco use) status and their willingness to quit, these high-quality guidelines recommended offering face-to-face behavioural interventions to patients if acceptable to them. It was recommended to offer smoking cessation advice to all patients who smoke, regardless of the amount they smoke, in routine consultations and appointments whenever possible (at least annually). The guidelines also recommended that all smokers should also be offered follow-up interventions, as it further increases the quit rates. The strength of these recommendations was strong, as they were based on evidence obtained from systematic reviews of relevant randomized controlled trials.

In line with the systematic reviews, either brief (5-20 minutes) or intensive (more than 20 minutes) interventions were recommended to increase the quit rates; a small dose response relationship was reported to be effective to improve quit rates (i.e., longer sessions or more follow-up support). The strength of the recommendation was graded as strong for providing 'brief' advice to all smokers at every opportunity and recording this in patient records. It was reported that although longer interventions were more effective in increasing quit rates, even very brief interventions (less than 3-minutes) have been found to be effective. Overall, it was emphasised in these guidelines (CG:

1, 5, 12, 18, 23) that every smoker (or tobacco user) should first be offered at least a very brief intervention; that is, firstly advised in a clear, strong and personalized manner to quit. If patients were unwilling to quit after this very brief advice, primary care professionals should provide motivational interventions designed to increase future quit attempts.

Three of the remaining high-quality smoking (or smokeless tobacco) guidelines were developed by the "National Institute for Health and Care Excellence (NICE)" in England (CG: 14, 17, 22), and had similar quality (AGREE II) scores. The more recent NICE guideline (CG 14) on "Individual approaches for Behaviour Change" aimed to help tackle a range of behaviours including smoking, alcohol misuse, poor eating patterns, lack of physical activity, and unsafe sexual behaviour. The recommendations for smoking cessation in this recent NICE guideline (CG 14) were based on another older NICE guideline exclusively on "Smoking Cessation Services" (CG 22). The third NICE guideline (CG 17) included recommendations exclusively for reducing smokeless tobacco use, and people of South Asian origin were the main target population for this guidance, as they were the predominant users of smokeless tobacco products in England.

The recommendations in these NICE guidelines (CG: 14, 17, 22) were similar to the guidelines reported above (CG: 1, 5, 12, 18, 23), i.e. for patients who smoke (or use smokeless tobacco), primary care professionals were recommended to consider offering a brief behavioural intervention in routine consultations and appointments whenever possible (at least annually). The brief interventions should involve: opportunistic advice, encouragement, and referral. Additionally, these NICE guidelines defined a measure of success as "not having smoked in the third and fourth week after the quit date" (CG 22). Furthermore, the success should be validated by carbon monoxide monitoring, with a reading of less than 10 ppm at the 4-week point.

Based on an expert paper, the recent NICE guideline (CG 14) also recommended offering a very brief intervention, which involved 30 seconds to a couple of minutes advice following an "ask, advise, assist" structure. For example, very brief advice on smoking would involve recording the individual's smoking status and advising them that stop smoking services offer effective help to quit. If the

patient agrees, the patient could be directed to these services for additional support. However, the strength of the evidence for the effectiveness of such a very brief (30 seconds advice) intervention for smoking cessation was weak; the recommendation was based on an expert paper and descriptive studies; however, no systematic reviews or randomized controlled trials were reported supporting this evidence. Thus, the main recommendation, with higher strength of evidence, was to offer brief, rather than very brief advice (CG 14).

A similar approach of providing a very brief intervention was recommended by the other high-quality guideline, which was the New Zealand guideline for "Helping People to Stop Smoking" (CG 12). This updated version of the guideline replaced the "5A's advice" with the simpler "ABC pathway". This pathway includes 'Asking' about and documenting every patient's smoking status; providing 'Brief advice' to stop smoking; and finally referring to services, or providing, 'Cessation support' to smokers who are willing to stop smoking. It was recommended that such advice could be delivered in 30 seconds and the "ABC pathway" should take less than two-minutes. The recommendation (30 seconds advice) was based on a consensus statement by Jackson and colleagues (2001) with special reference to primary care, and considering various studies reporting lack of time as a major barrier by most professionals in providing such interventions (New Zealand Health, 2014). Thus, presenting moderate or weak strength of recommendation (a grading system developed by the Australian National Health and Medical Research Council (NHMRC, 2009)).

The majority of these high-quality guidelines recommended that clinicians should tailor or personalize brief advice to the individual patient to meet their needs by assessing and then addressing them. In addition, they stated that consideration needs to be given to personal, cultural, social, environmental and economic barriers to an individual's health. For an intensive intervention (if required), professionals should agree on quit goals (SMART goals, i.e. Specific, Measurable, Attainable, Relevant, and Timely) and targets with their patients by developing action plans to prioritise actions and coping plans to prevent and manage relapses. Patients should be encouraged and supported to self-monitor behaviour and its outcomes and be provided with regular feedback on behaviour and its outcomes.

Intervention providers and training to deliver preventive interventions

It was recommended that smoking (or tobacco use) cessation interventions were effective if delivered by any member of the primary care team, including physicians, nurses, psychologists, social workers, cessation counsellors, pharmacists, or dental professionals (CG: 17, 18, 22, 23) - who were trained to offer advice. It was strongly recommended for healthcare professionals to receive appropriate training to provide brief (or very brief) advice effectively. Training should include how to support people to quit smoking by providing brief advice and also on how to make referrals, where needed. In addition, it was recommended in one of the NICE guidelines (CG 22) that training to provide smoking cessation interventions should be included as part of the core curriculum for healthcare undergraduates and postgraduates.

However, the guidelines reported a lack of evidence reporting effect size between practitioner training, subsequent competencies and behaviour change interventions (CG 14). It was further recommended to have future research to determine: "what characteristics of behaviour change training influence the effectiveness of behaviour change practitioners?"

Additional support

Providing educational or self-help materials, tailored to the individual patient, also had a small effect in improving smoking abstinence rates (CG: 1, 5, 12, 18, 23). An offer of pharmacotherapy, including nicotine replacement therapy (NRT), where appropriate (for dependence), was also recommended to increase the smoking (or tobacco) abstinence rates. Moreover, a combination of brief behavioural intervention and pharmacotherapy was recommended to work best (CG: 1, 5, 12, 18, 23). A similar combined approach was strongly recommended in another high-quality guideline (CG 2) which was a "European Guideline on cardiovascular disease prevention". This guideline, along with offering repeated 5 A's advice, recommended offering pharmacological support (including nicotine replacement therapies, varenicline, and/or bupropion) to increase quit rates. The level of evidence was strong as it was derived from multiple randomized clinical trials or meta-analyses (Cahill et al., 2012; Cahill et al., 2013).

Referral to specialist services (Assist)

Besides offering brief behavioural support within the practice, it was recommended to refer individuals who agree to quit to more intensive external support such as quit-lines or telephone counselling, an accredited tobacco treatment specialist, or other local cessation programmes or services (CG: 1, 2, 5, 12, 14, 17, 18, 22, 23). It was reported that more people will make a quit attempt if the very brief advice is followed by an offer of cessation support (lack of evidence reported in the systematic reviews; Table 3.5). Moreover, referral was reported to be most effective when it included a brief description of the recommended service or treatment. The strength of the recommendations was graded as strong to moderate in most guidelines, i.e. "body of evidence can be trusted to guide practice in most situations", as it was based on one or two randomised controlled trials or on expert opinions. One of the high-quality guidelines (CG: 12) also reported evidence based on one systematic review of trials from the four Cochrane reviews (one of these Cochrane reviews included this overview study - SR 8; Section 3.4.1.5.2; other reviews were not included in this overview study as they had the wrong setting or had no face-to-face intervention, see Appendix 5).

Telephone call-back counselling services, also known as "quit-lines", were reported in most high-quality guidelines to be effective in assisting cessation for smokers who were ready to quit. It was reported that quit-lines have broad reach and thus are effective in diverse populations. Thus, it was strongly recommended that referral to such services should be considered for smokers who are willing to quit or who have recently quit. The strength of the recommendation was graded as strong in three of the high-quality guidelines (CG: 12, 18, 23), as it was based on Cochrane reviews, randomized controlled trials, cost-effectiveness studies, and expert opinions; these studies reported that adding quit-line counselling to brief intervention and pharmacotherapy increases abstinence rates (RR 1.29; 95% CI: 1.20–1.38) (Shearer and Shanahan, 2006; Borland et al., 2008; Stead et al., 2013b). Moreover, it was recommended in these guidelines to have a proactive form of support from these quit-line services, as it was reported that most smokers (or tobacco users) do not make/initiate the calls to a quit-line to get the full benefit. However, they readily accept proactive calls from these services (CG: 12, 18, 23).

Furthermore, the NICE guideline on "Smokeless tobacco cessation for South Asian communities" (CG 17) and the New Zealand guideline for "Helping People to Stop Smoking" (CG 12) recommended referring Asian people to services specifically for their groups, where available. It was recommended that the stop-smoking practitioners who provide support to Asian people should obtain training so that they are technically and culturally skilled in this role. However, the strength of this recommendation was not strong, as there was limited evidence available for effectiveness, and it was based mostly on clinical experience and expert opinions.

Summary

Table 3.11 now summarises the recommendations from all nine high-quality clinical guidelines on smoking cessation interventions in primary care practices. It was recommended to ask, assess, and record a patient's tobacco use status in the clinical records, and offer an opportunistic 'brief' tailored intervention to all smokers (or tobacco users) by a trained primary care provider (although no evidence to support effectiveness of training), to increase abstinence rates; with some guidelines recommending very brief intervention – but this had little evidence base. Intensive interventions (more than 20 minutes) were likely to have a small additional effect on quit rates (in line with systematic review evidence in this study; Table 3.5). Again, the duration of effective interventions recommended ranged from as little as 3 minutes to 20 minutes or even more, thus making it difficult to determine a precise specification of the intervention duration. It was further recommended, if the patient is willing to quit, to make referral to quit-line services (proactive support) for further help which were reported to be effective along with brief intervention and pharmacotherapy to increase abstinence rates (RR 1.29; 95% CI: 1.20–1.38). The recommendations seem to be much strong from clinical guidelines regarding referral to cessation services than came through from systematic reviews in medical practice setting in this overview study. In addition, it was recommended for primary care providers to support advice with feedback, written materials, and follow-up support, however, no evidence to support its effectiveness.

Table 3.11: Medical practice - best practice (high-quality) recommendations for smoking cessation interventions in the clinical guidelines (CGs)

Preventive interventions for smoking		Strength of recommendations (based on supported evidence)	CGs supporting recommendations
Ask/ Assess	Ask and record every patient's smoking (or tobacco use) status, and update regularly (at every visit or at least annually)	Strong	CG: 1, 2, 5, 12, 14, 17, 18, 22, 23
	Assess nicotine dependence (by asking amount smoked)	Weak	CG: 12, 18, 23
	Assess readiness to change and their interest in receiving further help	Strong	CG: 1, 2, 5, 12, 14, 17, 18, 22, 23
Advise/ Arrange	Offer brief or very brief tailored intervention to increase tobacco abstinence rates	Strong	CG: 1, 5, 12, 14, 17, 18, 22, 23
	Intensive interventions (over multiple sessions) more effective than brief intervention (small additional effect)	Moderate	CG: 1, 5, 12, 18, 23
	Educational materials to support advice	Weak	CG: 1, 5, 12, 18, 23
	Intervention delivered by any member of the primary care team	Strong	CG: 1, 2, 5, 12, 14, 17, 18, 22, 23
	Training received by providers to deliver effective intervention	Weak	CG: 14, 17, 18, 22, 23
	Behavioural advice plus pharmacotherapy effective to increase abstinence rates	Strong	CG: 1, 5, 12, 18, 23
Assist/ Referral	Make referral to quit-line services (proactive support), as part of brief intervention	Strong	CG: 12, 18, 23

ALCOHOL

Risk factor assessment (Ask/Assess)

Again, in line with the systematic reviews, three of the high-quality clinical guidelines comprising alcohol interventions (CG: 1, 14, 21) recommended that clinicians should screen adult patients aged 18 years or older for excessive alcohol use by asking questions about heavy drinking. For example, asking a single question as: for men - "How many times in the past year have you had five or more drinks in a day?"; for women - "How many times in the past year have you had four or more drinks in a day?" If the patient reports one or more heavy drinking days, they screen positive for alcohol misuse. In addition, it was recommended administering a written self-report instrument or validated screening tool (for example, AUDIT, AUDIT-C, AUDIT-PC, CAGE, or FAST) for assessing alcohol risk levels. These high-quality guidelines (CG: 1, 14, 21) suggested using validated screening tools to decide whether to offer patients a brief intervention (for moderate drinkers) or whether to make a referral for specialist treatment (if patient is dependent on alcohol). It was further recommended to record/document the patient's alcohol use and any diagnosis of alcohol dependence in clinical records, and to update records regularly at every admission to hospital and at least annually in primary care. The strength of recommendations graded in these guidelines was strong (CG: 1, 14, 21), as they were based on relevant systematic reviews, randomised controlled trials, and expert papers/opinions.

Behavioural preventive interventions (Advise/ Arrange)

There were four high-quality guidelines which included alcohol reduction interventions in a primary care setting (CG: 1, 2, 14, 21). Of these, the recommendations in the most recent and higher quality guideline (CG 1), which was developed by the *Institute for Clinical Systems Improvement (ICSI)* in the United States, were based on another older mid-quality guideline (which was also included in this overview study - CG 15; Table 3.7). The other two high-quality guidelines were developed by the "National Institute for Health and Care Excellence (NICE)" in England (CG: 14, 21). The more recent NICE guideline (CG 14) on "Individual approaches for Behaviour Change" included recommendations for alcohol reduction based on another older NICE guideline (CG 21) which included recommendations exclusively on "Alcohol-use disorders". While the

fourth high-quality guideline (CG 2), which was “European Guideline on cardiovascular disease prevention (ESC)”, included alcohol reduction interventions as part of recommendations on nutrition. This guideline also included some recommendations based on the NICE guideline on “Alcohol-use disorders” (CG 21). However, the guideline (CG 2) did not provide any details on the components of the behavioural intervention for alcohol reduction (for example, duration and number of sessions).

The recommendations from these high-quality alcohol guidelines (CG: 1, 2, 14, 21) have been presented together, considering higher quality (AGREE II) score, recency, and duplication. The recommendations were evidence based: produced from a review of good quality systematic reviews, and a literature search or systematic review of randomized controlled trials conducted by the guideline development team. Some of the referenced systematic reviews in these guidelines (on which recommendations were based) were also included in this overview study, SR: 11, 17, 22 (Section 3.4.1.5.2); thus, showing strength of the evidence in this overview study.

All four high-quality guidelines recommended providing face-to-face behavioural interventions (structured advice) to help address a patient’s alcohol use after assessing their alcohol consumption (CG: 1, 2, 14, 21). It was recommended that the behavioural intervention should be tailored or personalized to the individual patient to meet their needs by assessing and then addressing them (for example, based on severity of alcohol use, comorbidities) (CG: 1, 14, 21). It was further recommended in the NICE guidelines (CG: 14, 21) that the intervention should aim to reduce the amount an individual drinks to low-risk levels, reduce risk-taking behaviours as a result of drinking alcohol, or to consider moderation. Like smoking interventions, recommendations in the most recent high-quality guideline - ICSI guideline (CG 1) were based on the “5A’s behaviour change model” for delivering alcohol interventions in a primary care setting. Clinicians were recommended to consider offering a brief behavioural intervention for individuals who screen positive on a validated tool for risky/hazardous drinking. Interventions could be delivered in the form of brief advice or motivational interviewing (including action plans, drinking diaries, stress management, or problem solving). The duration of the brief intervention was recommended as

10-15 minutes for effective behaviour change in this guideline (CG 1). It was further recommended to deliver intervention in two or more sessions, i.e. multi-contact interventions. The strength of recommendations was strong, as evaluated by the GRADE system (Guyatt et al., 2008). Very brief (less than five minutes) and single-contact interventions were reported to be ineffective or less effective than multi-contact interventions; there was a weak evidence to support this (CG 1). These recommendations were in line with the systematic review evidence identified in this overview study (Section 3.4.1.5.2; Table 3.6).

The NICE guideline on "Alcohol-use disorders" (CG 21), instead of using the 5 A's approach, recommended using an evidence-based resource based on the "FRAMES principles (i.e. feedback, responsibility, advice, menu, empathy, self-efficacy)" for delivering a brief intervention. It was recommended that the intervention should last from 5–15 minutes and include: "feedback (on the client's risk of having alcohol problems), responsibility (change is the client's responsibility), advice (provision of clear advice when requested), menu (what are the options for change?), empathy (an approach that is warm, reflective and understanding) and self-efficacy (optimism about the behaviour change)". It was further recommended to routinely monitor a patient's progress in reducing their alcohol consumption to a low-risk level and to offer an additional session of structured brief advice (where required). If the patient does not respond to the brief advice, offer an intensive intervention (in the form of motivational interviewing or motivational-enhancement therapy) to motivate them to address their alcohol misuse. An intensive intervention could last from 20-30 minutes, and it was recommended to set up a follow-up appointment in order to support the behaviour change and re-evaluate drinking behaviours. The other NICE guideline (CG 14), besides offering a brief intervention as mentioned in the guideline (CG 21), recommended offering a very brief intervention, which involved 30 seconds to a couple of minutes of advice following an "ask, advise, assist" structure. However, the strength of the evidence for the effectiveness of a very brief intervention for alcohol reduction was weak; the recommendation was based on expert papers and descriptive studies, however no systematic reviews or randomized controlled trials were reported supporting this evidence. Thus, the main recommendation, with higher strength of evidence, was to offer brief, rather than very brief advice (CG 14).

Similar to smoking interventions, alcohol reduction interventions were recommended to be effective if delivered by any member of the primary care team, including physicians, nurses, psychologists, social workers, cessation counsellors, pharmacists, or dental professional (CG: 21) - who were trained to offer advice (CG: 1, 2, 14, 21). It was strongly recommended for healthcare professionals to receive appropriate training to provide brief advice effectively. However, the duration of training was not reported in any high-quality alcohol guideline, and research evidence supporting effectiveness were not reported.

It was further recommended that brief advice should be supported by providing written information or self-help materials (CG: 1, 2, 14, 21). However, again, there was no research evidence to support this.

Referral to specialist services (Assist)

It was recommended in three of the high-quality alcohol guidelines (CG: 1, 14, 21) that healthcare professionals should consider making a referral for specialist alcohol treatment services under these circumstances:

a) if the patient is diagnosed with alcohol dependence;

b) if the patient fails to benefit from the structured advice (brief and intensive interventions); and

c) if the patient is willing to receive further help for his/her alcohol problem.

However, the strength of this recommendation was not reported in these guidelines, due to lack of supporting evidence.

Summary

Table 3.12 summarises the recommendations from all four high-quality clinical guidelines on alcohol reduction interventions in a primary care medical practice. It was recommended to ask, assess, and record an adult patient's alcohol use in the clinical records. Use of validated screening tools (for example, AUDIT, AUDIT-C, CAGE) was recommended for assessing alcohol risk levels. Following alcohol risk assessment, a brief (10-15 minutes) multi-contact intervention (two or more sessions) delivered by a trained provider was recommended to be the most effective in a primary care setting. Very brief interventions of less than 5 minutes were also recommended, but the evidence reported was weaker

compared to the longer interventions to support this recommendation. Where needed, for example if patient is dependent on alcohol, it was recommended to make a referral to specialist alcohol treatment services. In addition, it was recommended to support advice with written materials, self-help materials, and/or goal-setting. However, research evidence was not reported to support the recommendations for referral and supporting materials.

Table 3.12: Medical practice - best practice (high-quality) recommendations for alcohol reduction interventions in the clinical guidelines (CGs)

Preventive interventions for alcohol		Strength of recommendations (based on supported evidence)	CGs supporting recommendations
Ask/ Assess	Ask, assess, and record patient's alcohol consumption levels (moderate or dependence), using validated screening tools – to determine treatment options	Strong	CG: 1, 14, 21
Advise/ Arrange	Offer behavioural (face-to-face) structured interventions to all patients with excessive alcohol consumption	Strong	CG: 1, 2, 14, 21
	Brief (10-15-minutes) multi-contact (two or more sessions) interventions were recommended to be most effective	Strong	CG: 1, 14, 21
	Very brief intervention (less than 5 minutes) or intensive interventions (more than 20 minutes)	Weak	CG: 1, 14
	Additional components to support advice: written information or self-help materials, goal-setting	Weak	CG: 1, 2, 14, 21
	Intervention delivered by any member of the primary care team	Strong	CG: 1, 2, 14, 21
	Training received by primary care providers (evidence not reported to support effectiveness)	Weak	CG: 1, 2, 14, 21
Assist/ Referral	Make referral to specialist alcohol treatment services (for alcohol dependence)	Weak	CG: 1, 14, 21

3.4.2.5 Summary of systematic overview of clinical guidelines

Similar to the systematic review synthesis, this clinical guideline synthesis aimed to identify best practice recommendations emerging from all primary care practices (dental/medical/pharmacy), primarily from the dental perspective, i.e. giving higher weighting to dental guideline recommendations and considering higher quality and more recent medical recommendations applicable in a dental practice setting. The key recommendations from the high-quality clinical guidelines in a primary care setting that constitute this systematic overview have been presented in respective tables at the end of each section (Tables: 3.9, 3.10, 3.11, and 3.12).

There was only one high-quality clinical guideline relating to smoking cessation and alcohol reduction in a dental practice setting. However, best practice was developed from synthesising and drawing from the recommendations from other primary care (medical/pharmacy) settings, which could be adapted / adopted to dental practice.

Overall recommended intervention for smoking cessation included: ask, assess, and record a patient's smoking (or tobacco use) status in the clinical records (along with other "vital signs"); offer a brief or very brief smoking cessation advice (tailored based on individual needs) to all smokers, regardless of the amount they smoke, in routine consultations whenever possible; if the patient is willing to quit, make referral to quit-line services (proactive support) for further help. Interventions to be delivered by any member of the primary care team (physician, nurse, pharmacist, or dental professional). It was further recommended that intensive (or longer) interventions were likely to have a greater (but marginal) effect on quit rates compared to brief interventions. Overall, guidelines recommended to start with brief advice (plus quit-line referral) and then offer intensive advice depending on patient needs or addiction.

For reducing alcohol consumption, it was recommended to assess patient's alcohol consumption (using validated screening tools), followed by a brief tailored intervention with one or more follow-up visits, delivered by primary care professional (physician, nurse, pharmacist, or dental professional) to

outline the possible harmful effects of excessive alcohol consumption. A brief (10-15-minutes) intervention was best recommended in medical practice guidelines for helping alcohol users to reduce consumption, though 5 minutes advice was also reported to be effective (supported with research evidence). Referral to specialist services was suggested in cases of alcohol dependence, however, again, outcomes for effectiveness of referral were not reported.

Again, similar to systematic reviews, none of the clinical guidelines recommended offering combined interventions for tobacco and alcohol.

3.4.3 Integrated or combined synthesis (systematic review evidence and clinical guideline recommendations)

The results from Section 3.4.1.5 (high-quality systematic review evidence synthesis) and Section 3.4.2.4 (high-quality clinical guideline recommendation synthesis) helped to answer research questions 1 and 2 (Section 3.2), which were to identify the evidence-based best practice for assessing major behavioural risk factors associated with oral cancer and associated behaviour change preventive interventions delivered by dental professionals in primary care dental practices. In order to answer research question 3 (Section 3.2), the results from current systematic review evidence and clinical guideline recommendations were compared and contrasted to provide an integrated/combined overview that is relevant to primary care dental professionals. As mentioned in the data synthesis section (Section 3.3.9), after the within-stream synthesis (Section 3.4.1.5 and 3.4.2.4) an integrated synthesis was conducted in order to answer specific questions about whether evidence from reviews were reflected in current guidance or whether collated guidance showed areas where better evidence was required.

The behavioural preventive interventions included in all high-quality systematic reviews and clinical guidelines were heterogeneous and comprised of various treatment approaches. There was quite a lot variation in the definitions, terminologies, and characteristics of behavioural interventions among these reviews. After detailed analysis of all included interventions within high-quality reviews and guidelines (even primary studies or trials within them), it was decided that the following definitions would be used: a “very brief” intervention

would last for less than 5-minutes (including as little as 30 seconds to a couple of minutes advice), involving a message to highlight benefits of quitting/moderating and providing information for further help; a "brief" intervention would last 5-20 minutes, usually involving theory-based advice to motivate individuals for behaviour change and could involve 1 or 2 follow-up visits; while an "intensive" intervention is similar in content to a brief intervention, but would last more than 20-minutes and involve multiple sessions (NICE, 2014). All these interventions involve (within that duration) other components such as: asking, assessing, and recording an individual's tobacco/alcohol use status; providing supporting materials; or referral to local support services – as discussed previously in the overview findings. The relative effectiveness of each intervention for tobacco cessation and alcohol reduction has been reported earlier in the within-stream synthesis (Section 3.4.1.5 and 3.4.2.4); the effect sizes are further reported below to give a combined synthesis of both systematic review evidence and clinical guideline recommendations.

3.4.3.1 Areas where evidence-base and guidance match (strong strength of evidence / recommendations)

Most of the high-quality systematic review evidence and clinical guideline recommendations were in accordance with each other, i.e. guidelines were based on the review evidence. However, there were some areas where evidence and guidance were lacking, and these will be discussed in Section 3.4.3.2.

All high-quality reviews and guidelines were consistent in recommending offering behavioural intervention delivered by primary care professionals (irrespective of provider type) to adult smokers (or tobacco users) or alcohol drinkers, following an assessment of a patient's tobacco use status or alcohol levels, for effective behaviour change (tobacco cessation and reducing alcohol consumption). Furthermore, review evidence and guideline recommendations were synchronous with regards to assessing and recording a patient's alcohol use status. It was reported in both reviews and guidelines that validated screening tools (for example, AUDIT, AUDIT-C, CAGE, FAST) should be used for assessing alcohol risk levels (or dependence), to recognise the high-risk drinkers who are at higher risk of developing oral cancer or other chronic diseases. However, there were

differences with regards to assessment of a patient's smoking status (discussed in Section 3.4.3.2).

The lack of precise reporting of duration and number of sessions of behavioural interventions for both tobacco and alcohol (for example, brief intervention described as 5-20 minutes; quite a wide range), somewhat limited the inferences (regarding duration of sessions) that can be drawn from the overview findings. The overall conclusions drawn from the systematic review evidence and clinical guideline recommendations for smoking cessation interventions were similar: it was recommended to offer in-person brief motivational (and tailored) interventions to all smokers (or tobacco users) to increase quit rates (RR 1.66, 95% CI 1.42 to 1.94) (SR 8). It was reported that although longer interventions (10-20 minutes) were more effective in increasing quit rates, even very brief interventions of as little as 2-3 minutes have also been shown to be effective. There was a small additional benefit of intensive interventions (more than 20 minutes) compared to brief interventions (RR 1.37, 95% CI 1.20 to 1.56) (SR 8). Evidence-base reviews and guidelines on reducing alcohol consumption were also similar. These were drawn largely from the medical practice setting (there were no dental alcohol systematic reviews). A brief motivational (10-15 minutes), multi-contact (two or more follow-up visits) tailored intervention, following risk assessment, was most effective for helping alcohol users to reduce consumption (decreased by 3.6 drinks per week from baseline; 95% CI, 2.4 to 4.8 drinks/wk) (SR 11); interventions of 5 minutes duration were also reported to be effective (mean difference: -38 grams/week, 95% CI: -54 to -23) (SR 17). The reported effect rates (where compared) were smaller for intensive and very brief interventions compared to brief interventions (5-8% increased abstinence in very brief versus 7-12% in brief intervention) (SR 11).

The high-quality guidelines (dental and medical) went beyond the review evidence, and recommended more practical advice (i.e. very brief - for couple of minutes) based on some descriptive studies, and expert papers or opinions. Moreover, it was recommended in high-quality dental practice guideline that dental professionals were not expected to provide intensive interventions for tobacco and alcohol, instead they should refer patients to a trained counsellor.

The lack of trial evidence for smoking and alcohol referrals (in systematic reviews) will be discussed in Section 3.4.3.2.

3.4.3.2 Areas where evidence-base is weak

The majority of the included trials/studies in the high-quality systematic reviews did not provide information on how they assessed high-risk smokers (or tobacco users). The high-quality reviews mentioned about asking and recording a patient's tobacco use status in the clinical records. The high-quality dental review further reported recording findings from a patient's oral examination and relating it to their tobacco use. None of the high-quality reviews reported how a patient's self-reported tobacco use status was confirmed. In addition, details of a tobacco risk assessment, including that of nicotine dependency, were not provided in the review evidence (for example, duration, frequency, or type (cigarette, cigar, pipe)). On the other hand, clinical guidelines (medical practice) went beyond the review evidence and were clearer in their recommendations for a smoking (or tobacco) risk assessment. It was strongly recommended to systematically ask and record every patient's tobacco use status at every opportunity in clinical records as a "vital sign". Guidelines further recommended assessment of nicotine dependence by asking about the time to first cigarette, number of cigarettes smoked a day, and withdrawal symptoms (if the patient previously attempted to quit). Although the strength of this recommendation was judged to be strong, the source of these recommendations was not clear in terms of any trial or review evidence. In addition, there were no validated screening tools reported for assessing a patient's tobacco use status in all high-quality reviews and guidelines. This has implications for the use of tobacco risk assessment tools in a primary care practice.

Although very brief interventions (less than 5 minutes) were reported to be effective in promoting smoking cessation, there was limited trial evidence, reported in both systematic reviews and clinical guidelines, compared to brief or intensive interventions for increasing tobacco abstinence rates. The clinical guidelines (dental and medical practice) considered this very brief advice as a more pragmatic/practical approach, that is easier to implement in a dental

practice setting (for both smoking and alcohol). Thus, considering the large number of trials supporting relatively longer intervention sessions, more trials would be helpful to study the effectiveness of very brief advice in a dental practice setting.

Furthermore, high-quality reviews and guidelines in the dental practice setting were lacking with regard to evidence of effectiveness of interventions for reducing alcohol consumption. All the high-quality advice for alcohol came from the primary care medical practice settings. Thus, there is a need for more studies to evaluate the effectiveness of behavioural alcohol interventions in a primary care dental practice setting. In addition, there was a lack of studies evaluating combined interventions for smoking and alcohol (only isolated interventions were reported).

Patient referrals to cessation services were an important part of the brief interventions recommended in all high-quality reviews and guidelines. However, the high-quality systematic reviews (dental and medical) reported a lack of evidence (no effect sizes) for the effectiveness of smoking (or tobacco use) cessation referrals. Guidelines on the other hand, seem to have much stronger recommendations regarding referral to cessation services than came through from systematic reviews in this overview study. Based on some trial evidence (in the medical practice) and expert papers, it was strongly recommended to refer or signpost all tobacco users (who agree to quit following brief advice) to quit-lines services (proactive support). While for high risk drinkers (alcohol dependence), referral to a general medical practitioner or to specialist alcohol treatment services was recommended in high-quality guidelines, there was, however, no evidence reported to support alcohol referrals in this overview. Thus, there is a need for more trial evidence reporting the effectiveness of local referral pathways for both tobacco and alcohol in primary care dental practices.

Both systematic reviews and clinical guidelines stressed the importance of the training of healthcare professionals to deliver behavioural interventions (for tobacco and alcohol). It was noteworthy that most of the effective behavioural interventions (for tobacco and alcohol) in the majority high-quality reviews were delivered by a trained primary care provider (for example: dentists, clinicians,

nurses, pharmacists, health educators); clinical guidelines also recommended training primary care professionals to deliver behavioural interventions. However, effect sizes were not reported (in both reviews and guidelines) to compare effectiveness of interventions delivered by professionals 'with' versus 'without' training. Thus, making it difficult to make any conclusions regarding effectiveness of offering training to primary care professionals to deliver behavioural interventions. Moreover, reviews and guidelines failed to describe the nature of the provider training that would be sufficient to deliver an effective intervention, including duration and number of training sessions. Although some high-quality reviews reported training duration, it was quite varied and difficult to make a conclusion. Thus, there is a need for more evidence and recommendations in this regard, although it is recognised that the content and duration of any training programme will be related to the type of intervention planned.

Moreover, reviews and guidelines were in agreement regarding supporting behavioural advice (for tobacco and alcohol) with: educational or self-help materials, or online support. However, there was no evidence-base with effect sizes regarding effectiveness of interventions delivered 'with' versus 'without' supporting materials. Thus, again, making it difficult to make conclusions regarding effectiveness of supporting materials provided along with behavioural interventions.

3.5 Discussion and conclusions

The present overview study is, to the best of the author's knowledge, the first to synthesise the evidence-base from current systematic reviews and clinical guidelines, which are relevant to primary care dental professionals, with regard to undertaking a patient assessment of the major behavioural risk factors associated with oral cancer (tobacco and alcohol), and delivering preventive interventions (for example, behavioural advice, signposting/referral to preventive services). While the quality appraisal and synthesis methods followed validated protocols and frameworks (Section 3.3.8 and 3.3.9), the "higher level" synthesis of these two "streams" together in this way was innovative and is believed to be a good contribution to knowledge.

3.5.1 Comparison with literature

The findings of this overview are consistent with the implicit theory developed as part of the narrative synthesis (Section 3.3.9), i.e. assessing risk factors associated with oral cancer (tobacco and alcohol) and providing behavioural preventive advice can increase a patient's knowledge of potential risks, motivate them, and eventually lead to behaviour change (i.e. smoking cessation and reduction in alcohol consumption). The preventive interventions conducted in a primary care setting (dental/medical/pharmacy) were more effective than usual care or no intervention for promoting smoking cessation in adult smokers and reducing alcohol consumption in high-risk drinkers.

Current findings were based on a much greater body of research in the primary care medical practice setting compared to the limited research undertaken in the dental practice setting. Informed by the ADAPTE framework (Collaboration, 2009), which provides a systematic approach to adapting guideline developed in one setting for use in another setting, the high-quality evidence and recommendations in the primary care medical/pharmacy setting in this overview were adapted to develop recommendations relevant to the dental practice setting.

3.5.1.1 Tobacco cessation interventions

This overview, based on the findings from the systematic reviews and clinical guidelines in medical practice settings, suggested that the same can be expected from dental professionals who interact with smokers (or tobacco users) in clinical setting. The results from another overview study by Ramseier and Suvan (2015), that aimed to improve periodontal health, supported these findings and showed the effectiveness of tobacco use cessation interventions in the primary care dental practice. The study (Ramseier and Suvan, 2015) included five systematic reviews: one of these reviews (Carr and Ebbert, 2012) was included in this overview study (only high-quality review in the dental practice setting (SR 12)); other four reviews were not included in this overview - due to wrong study design (overviews or literature reviews) (Dyer and Robinson, 2006a; Nasser, 2011), wrong population (adolescent) (Gao et al., 2014), while other review (Needleman et al., 2010) was an update of the older version of Cochrane

systematic review included in this overview study (SR 12). The effect size reported in the study by Ramseier and Suvan (2015) were similar to that reported in this overview (OR 2.38; 95% CI 1.70–3.35), to increase the odds of quitting tobacco. However, it failed to report the type of intervention, optimal length and frequency of interventions for effective tobacco cessation; and showed a need for further research in this field (Ramseier and Suvan, 2015). A similar lack of dental evidence was reported in reviews and guidelines included in this overview study, i.e. insufficient number of studies to determine the specific support measures delivered by dental professionals to provide an increased effectiveness beyond brief advice (Carr and Ebbert, 2012; SDCEP, 2014).

The current clinical guidelines in this overview study reported that an offer of assistance/support (referral to cessation services) to quit smoking was more motivating than simple advice to do so; i.e. a very brief intervention adopting "ask, assess and assist" approach (with lack of trial evidence). This has been supported by findings from another overview by Aveyard and co-workers (2012), which reviewed trials included in four Cochrane reviews of physician advice and pharmacotherapy for smoking cessation. It reported strong statistical evidence that offering assistance (referral or pharmacotherapy) for smoking cessation motivates an additional 40–60% smokers to attempt cessation compared to being advised to quit on medical grounds (Aveyard et al., 2012). The interventions were based in a range of healthcare settings (including primary care, hospital settings). However, it is worth noting that offering assistance in the included interventions was confined to offering pharmacotherapy (nicotine replacement therapy) along with a brief advice to quit, and effects for referral to quit-line or local support services were not reported. Thus, findings were in line with this overview study, showing a lack of evidence for effectiveness of referral services. Pharmacotherapy or medical interventions delivered along with behavioural preventive interventions have been shown to be effective in this overview study and a number of other studies for promoting tobacco use cessation, particularly in case of dependence (Kottke et al., 1988; Stead and Lancaster, 2012; Cahill et al., 2013).

Moreover, as was found in this overview study, a more “proactive” approach to quit-line support or telephone call-back counselling services was recommended by high-quality guidelines (medical practice) and were reported to be more effective than signposting or expecting patients to contact these services. However, there was a lack of systematic review or trial evidence reported in this overview study. A recent large smoking cessation trial (42,277 patients) conducted in ten family practice clinics in the United States further reinforced this guideline recommendation (Vidrine et al., 2013). This trial compared the “Ask-Advise-Connect” and “Ask-Advise-Refer” approaches, and reported that there was a 13-fold increase in the cessation treatment enrolment when smokers were directly connected to quit-line services (telephone call-back), compared to the nationally recommended method of referrals to the quit-line (i.e. providing referral cards rather than connections) (Vidrine et al., 2013). There is a need for trials to study the effectiveness of connecting and referring approaches in a dental practice setting.

Some of the high-quality guidelines in this overview study recommended a similar approach to the “Ask-Advise-Connect”, to be delivered as a very brief opportunistic intervention of 30 seconds to a couple of minutes for reducing tobacco use (CG 12, 14). However, review or trial evidence was relatively lacking for this very brief advice. The very brief approach has, however, been recently reported to have a dramatic impact for motivating weight loss by primary care physicians in England (Aveyard et al., 2016). This prospective randomised trial showed that patients who received a 30-seconds physician-delivered opportunistic intervention (behaviourally-informed advice and support) had 1.43 kg more weight loss compared to those who received simple advice (Aveyard et al., 2016). The procedures in this trial drew on the findings of the smoking cessation trial reported in the previous paragraph (Vidrine et al., 2013). The applicability of this very brief approach (30 seconds chat) for smoking cessation in the primary care settings, particularly dental practice settings, is therefore worthy of further consideration.

3.5.1.2 Alcohol reduction interventions

As discussed in the introduction (Chapter 1), dental professionals are in an ideal position to provide brief alcohol advice to their patients. Despite, this opportunity, there is a lack of studies developing and evaluating alcohol brief interventions in a dental practice setting. Moreover, studies have reported various barriers to the successful implementation of these brief interventions in a dental practice, some of the barriers reported in previous feasibility studies being: lack of knowledge, skills, confidence, and time, and even doubts about the effectiveness of counselling (Macpherson et al., 2003; Shepherd et al., 2010; Amemori et al., 2011; Yusuf et al., 2015).

None of the systematic reviews in this overview reported alcohol reduction interventions in the primary care dental practice setting. The dental guideline (CG 11) also lacked detailed recommendations regarding the required content of the brief intervention. This lack of evidence supporting the effectiveness of brief alcohol reduction interventions in primary care dental practices, in comparison to other primary care medical practice settings, has been reported in other existing literature (Dyer and Robinson, 2006a; McAuley et al., 2011; Ramseier and Suvan, 2015). Another overview study by Ramseier and Suvan (2015), agreed with these findings, showing insufficient evidence to make conclusions about the effectiveness of interventions to reduce alcohol consumption in a dental practice setting, aiming to improve periodontal health. As reported in this overview, the dental guideline recommended that dental professionals should provide very brief tailored advice of a couple of minutes (weak trial evidence) to motivate alcohol users to reduce consumption. The medical guidelines and systematic reviews, however, recommended providing a brief intervention lasting 10-15 minutes (strong trial evidence) with follow-up sessions in a primary care setting to reduce alcohol consumption. These results (10-15 minutes advice) were in agreement with two other overviews in a medical practice setting, which supported the effectiveness of brief alcohol interventions (O'donnell et al., 2013; Alvarez-Bueno et al., 2015). The overview conducted by Alvarez-Bueno and co-workers (2015) reported similar findings (for example, duration and number of sessions) to those reported in the majority of reviews and guidelines in this overview, i.e. 5-15-minutes intervention with follow-up

sessions had more effectiveness than intensive interventions or usual care. The study by O'donnell and co-workers (2013), on the other hand, failed to report the components of an effective brief intervention required to maintain longer-term effects, for example, optimum length and frequency. There is a need for further research to find out whether the 10-15 minutes advice could be applied to alcohol interventions delivered in a dental practice setting. Moreover, considering the comparable effectiveness of shorter 5 minutes advice and feasibility, this need to be tested in a dental practice setting. The feasibility issues of implementing brief alcohol interventions in dental practice settings, i.e. transferability of findings or recommendations from medical to dental practice setting will be explored in the next chapters in this thesis (Chapter 4 and 5).

Similar to smoking cessation interventions, some of the high-quality guidelines in this overview study recommended very brief opportunistic intervention of 30 seconds to a couple of minutes for reducing alcohol consumption. However, the strength of the recommendations was weak, due to lack of reviews or trial evidence for this very brief alcohol advice. Thus, there is a need for further research to find whether the very brief approach could be applied to opportunistic alcohol interventions in primary care, including the dental practice.

3.5.1.3 Combined interventions (for tobacco and alcohol)

As discussed earlier in the introduction (Chapter 1), multiple risk factors need to be considered for oral cancer prevention, as tobacco and alcohol in combination magnifies the risk for oral cancer. However, combined interventions were almost completely lacking in this overview. Other existing reviews and guidelines have also reported a similar lack of evidence focusing on the most effective approach to deal with multiple behaviours (for example, if someone smokes, and consumes alcohol above recommended limits) (Goldstein et al., 2004; NICE, 2014). The question thus remains: whether these behaviours should be approached in sequence or in combination, and how this should be decided? Hence, further investigation is needed to address this large gap in knowledge about the effectiveness of multifactorial or combined interventions,

incorporating both smoking and alcohol advice in a primary care setting, including dental practice.

3.5.2 Strengths and limitations

3.5.2.1 Strengths

This study was novel in synthesising evidence from both systematic reviews and clinical guidelines. After conventional synthesis of each stream, a robust framework was developed for evidence synthesis (narrative 'thematic' synthesis) across these information sources, addressing review/guideline quality, recency and duplication. A detailed methodology was provided in Section 3.3, which was registered with PROSPERO, and published in the journal *BMC Systematic Reviews* (Mathur et al., 2015).

One of the major strengths of this overview study was the extensive, systematic literature search; i.e. international literature, with no language restriction, and involving the grey literature search (for clinical guidelines). The systematic search was not limited to "oral cancer", thus the overview did not rule out good guidelines and/or evidence on how to assess risk and deliver prevention for the risk factors (tobacco and alcohol) that may be aimed at another oral condition (for example, periodontal disease) (SDCEP, 2014). Furthermore, the systematic search was not limited to the dental practice setting. Preventive interventions delivered in all primary care settings (dental/medical/pharmacy) were included in this overview, in order to again not rule out any good guidelines and/or evidence on how to assess risk and deliver prevention for the risk factors (smoking and alcohol) that may be aimed at another clinical/medical condition (for example, cardiovascular disease, lung cancer) (Fiore et al., 2008; NICE, 2010). Thus, despite a lack of reviews and guidelines in dental practice settings, best practice was developed (Section 3.4.3 and summarised in Section 3.5.3) from synthesising and drawing from the best evidence and recommendations from other primary care (medical/pharmacy) settings, which could be adapted / adopted to dental practice. Moreover, a number of referenced reviews in the high-quality guidelines (on which recommendations were based) were also included in this overview study, for example, SR: 1, 6, 8, 11, 12, 16, 17, 22, 27;

thus, showing that a comprehensive search strategy was followed in this overview to include all relevant systematic reviews and clinical guidelines.

This overview was carried out in accordance with the PRISMA statement (Moher et al., 2009) (Appendix 1), and using the well-established quality instruments (AMSTAR, ROBIS, and AGREE II) to evaluate the quality of the included reviews and guidelines. As the overview aimed to synthesise the best practice or high-quality evidence and recommendations, a robust quality appraisal was carried out to assess the methodological quality of included systematic reviews (AMSTAR and ROBIS instruments), and clinical guidelines (AGREE II instrument). Moreover, the quality was assessed independently by two reviewers, and discrepancies discussed with the wider team. This helped to ensure the rigour of findings.

The duplication of trials in all included systematic reviews, and duplication of guidelines and reviews within all included clinical guidelines was addressed, i.e. none of the findings were synthesised twice, thus strengthening the robustness of the overview synthesis. Moreover, as the individual trials from included systematic reviews have been isolated (to address duplication; Appendix 6), it might be possible to conduct a meta-analysis in future, subject to statistical requirements.

3.5.2.2 Limitations

One of the main limitations of this study concerned the limited number of systematic reviews in the dental practice setting relating to smoking advice (only one high-quality review) and the fact that there were no systematic reviews regarding providing alcohol advice in a dental practice setting. This resulted in restrictions and in extrapolating findings from other settings (medical/pharmacy) to the dental practice setting.

The heterogeneity or sources of variability among study populations, settings and outcomes were explored as an integral part of data synthesis, but as this work was not meta-analytic, a narrative synthesis approach was used to address the applicability of findings across, professional groups and/or patient behaviours. Moreover, there was heterogeneity among the reviews and guidelines included in terms of the preventive interventions covered: type,

duration, number of sessions, methods employed (for example: simple advice, motivational interviewing, feedback, follow-ups, and use of educational materials). This again influenced the decision to undertake a narrative review rather than a meta-analysis.

Another limitation was related to the fact that there was no consensus about the use of the terminologies in terms of the definitions of “brief, very brief, and intensive interventions” – which led to a difficulty in interpreting these terminologies. Additionally, there was limited information provided on many occasions regarding details of interventions covered. Furthermore, there was very limited evidence available in terms of effect sizes for some interventions that both the systematic reviews and clinical guidelines were to some extent recommending. This included referral to specialist services and the use of patient educational materials such as posters and leaflets. Thus, this heterogeneity (and limited information) constrained the ability to make conclusive recommendations regarding which components of behavioural preventive interventions should be incorporated into primary care practices.

Another limitation could be the synthesis of only high-quality systematic reviews and clinical guidelines. Initial synthesis from data extraction of all findings (including medium- and low-quality), however, did not report any meaningful or definitive results. Therefore, after careful consideration of all the included reviews and guidelines, it was decided to use the current framework (synthesising high-quality reviews), particularly as the aim of this overview was to synthesise the “best practice evidence-base”.

3.5.3 Chapter conclusions

In conclusion, this overview study adopted a novel robust framework to synthesise best practice evidence from both systematic reviews and clinical guidelines for undertaking a risk factor assessment and delivering preventive interventions for major behavioural risk factors associated with oral cancer (tobacco and alcohol). The overview went beyond the review and trial evidence, and contributed to the knowledge by suggesting interventions based on an

integrated or combined synthesis of current high-quality systematic reviews and clinical guidelines.

Overall, the findings from this overview identified that risk factor assessment is an important first step in any prevention intervention (i.e. questions must be asked to assess the risk levels or dependence). Regarding tobacco cessation intervention, it was found that an appropriate intervention would be to offer an in-person brief motivational, tailored intervention, delivered by dental professionals, in a single session, following an assessment of a patient's tobacco use status (risk levels) and incorporating an oral examination component. Although longer (10-20 minutes) and intensive (more than 20 minutes, with follow-up visits) interventions have shown to be effective in increasing quit rates compared to shorter interventions, very brief (less than 5 minutes) interventions also showed comparable effectiveness to the longer brief or intensive interventions. For alcohol drinkers, after assessing the patient's alcohol use or dependence (using validated screening tools), a brief motivational, tailored intervention, delivered by dental professionals, could be offered to motivate alcohol users to reduce consumption in a dental practice setting. A brief 10-15 minutes multi-contact intervention was the best recommended intervention in medical practice reviews and guidelines for helping alcohol users to reduce consumption; brief interventions of 5 minutes duration were also reported to be equally effective. Thus, very brief (less than 5 minutes) or brief advice (of up to 5 minutes), should be trialled for tobacco and alcohol respectively in a dental practice setting (considering feasibility and effectiveness as reported in reviews and guidelines), tailored to patient motivational status.

The next step was to investigate the feasibility of implementing these techniques in the primary care dental practice, and to make recommendations for pilot trials of such implementation (Chapter 4 and 5).

Chapter 4 A theoretically-informed exploration of dental teams' views on implementing best practice oral cancer prevention in primary care dental practices in Scotland

This chapter focuses on gauging the dental teams' views on the practical barriers and facilitators to implementing behaviour change interventions in NHS primary care dental practices (in Scotland).

4.1 Introduction

Implementation research (Section 1.4.3) focuses effort on the factors (barriers or facilitators) that inhibit or promote the systematic uptake of evidence-based practice, by healthcare professionals in routine clinical and organisational settings (Eccles and Mittman, 2006; Bauer et al., 2015). The field has developed due to a number of recognised issues, involving staff, patient, and organisational aspects, which affect the reliable adoption of evidence-based practices (Bauer et al., 2015). Exploring such issues is a vital and necessary step in supporting healthcare teams and systems in implementation (Bauer et al., 2015).

The introduction (Section 1.4.3) discussed previous studies of general barriers, both personal and organisational, affecting the adoption of tobacco and alcohol-related interventions in dental practice. For example, some of the barriers reported were lack of knowledge, skills, confidence, and time, and there are reported doubts about the effectiveness of counselling (Macpherson et al., 2003; Shepherd et al., 2010; Amemori et al., 2011; Yusuf et al., 2015).

Importantly, the Behaviour Change Wheel methodology employed in this study (detailed in Section 4.3.9), is based on the theory of enhancing opportunities, capabilities and motivation, and advantages identified in particular settings (termed 'facilitators'), as well as identifying and overcoming barriers (Michie et al., 2011). For example, it has been argued that dental professionals are in a key position to identify patients at high risk for developing oral cancer because patients visit for routine preventive appointments where they may not be aware of any health problems or symptoms (Petersen, 2008; Shepherd et al., 2010;

Amemori et al., 2011; SDCEP, 2014). There may be opportunities for implementation of interventions associated with the prevention of oral cancer due to the fact that aspects of the dental "check-up" consultation are already orientated towards risk factors, for example routine use of patient history questionnaires. Additionally, preventive advice can be linked to the clinical examination (for example, where this shows periodontal disease, tooth discoloration, halitosis, soft tissue changes) (Edwards et al., 2006; Petersen, 2008; Shepherd et al., 2010; Amemori et al., 2011; SDCEP, 2014).

Further opportunities may exist because tobacco and alcohol form common risk factors not just for oral cancer but for a range of other health conditions, and is in line with moves to an integrated oral and wider public health agenda (Sheiham and Watt, 2000). The policy context also comes with opportunity regarding enhancing the role of the dental team (Steele, 2014; WHO, 2016b; Scottish Government, 2018b). For example, *"Scotland's Oral Health Improvement Plan"* focuses on introducing a preventive care pathway and an oral health risk assessment for all adult patients on a regular basis, followed by a personalized care plan based on the assessment of the risk level to their oral health (Scottish Government, 2018b). It also focuses on increasing the role and nature of preventive interventions within the primary care dental contract (Scottish Government, 2018b). Moreover, the *"WHO's Global strategy for prevention and control of non-communicable diseases"* integrates the common risk factor approach into global policy for oral diseases (Petersen, 2008; WHO, 2016b).

This study now takes this implementation landscape for oral cancer prevention further by: a) focusing quite specifically on individual components of behaviour change interventions (some of which are evidenced from other settings such as primary care medical practice); and b) employing a dedicated implementation framework (the Behaviour Change Wheel) which allows for the exploring different types of barriers and facilitators with a view of identifying optimal targets for further implementation / feasibility testing.

Finally, the more general risks associated with tobacco and alcohol mean that risk prediction tools, available from other health contexts, could be adopted and

adapted (Usher-Smith et al., 2015). These risk prediction tools are used in primary care medical practice in asymptomatic individuals who are at higher risk of developing disease, and might help facilitate effective history taking, communication of risk, and adherence to advice, as well as supporting clinical decision making, thus improving patient outcomes. There are tools specifically for primary care use relating to breast, lung, prostate, and colorectal cancer, and for cardiovascular disease (Usher-Smith et al., 2015). However, there is a lack of such a personalised risk tool, with potential to guide opportunistic assessment and behavioural interventions specifically targeted at oral cancer reduction.

In summary, conducting high quality studies, and producing clear clinical guidelines and recommendations for professionals, is a necessary first step *but not in itself sufficient* to ensure patients receive the best possible preventive care. Implementation can be inhibited or enhanced by a range of factors, and targeted interventions, based on sound behavioural and organisational theory, are necessary to support improvement. This study now proceeds to apply such theory in a rigorous fashion to the international evidential synthesis produced in Chapter 3.

4.2 Aims and research questions

The main aims of this study were:

a) to identify barriers and facilitators to implementation of the synthesised best practice evidence for oral cancer risk factor assessment and prevention in primary care dental practice in Scotland;

b) to make recommendations for developing and testing interventions to support evidence-based oral cancer prevention in primary care dental practice in Scotland and beyond.

A supplementary aim was to explore the views of dental professionals on the specific merits/demerits of oral cancer risk prediction tools in primary care dental practice.

Specific objectives were to:

- Recruit members of the dental team to participate in an interview
- Develop a theory-based, semi-structured interview schedule
- Explore dental professionals' history, knowledge and awareness of oral cancer risk factor assessment and prevention
- Gather views on the feasibility (barriers and facilitators) of implementing the synthesised evidence-base, and on potential interventions to support dental professionals
- Gather views on risk prediction tools

These objectives were developed in order to address the following broad research questions for this study:

a) What are the current barriers and/or facilitators to oral cancer risk factor assessment and prevention in primary care dental practices in Scotland?

b) What aspects of best practice/evidence-based risk factor assessment and preventive advice, taken from medical and pharmacy settings, are transferrable to primary care dental practices in Scotland?

c) What are the recommendations for conducting a pilot intervention in primary care dental practices in Scotland?

d) What are the views of the dental team on utilising an oral cancer risk prediction tool in primary care dental practices in Scotland?

4.3 Methods

4.3.1 Choice of method

A qualitative cross-sectional study, using semi-structured interviews, was undertaken to explore the views of dental professionals.

Qualitative methodology was considered most appropriate as the aims of this study were to explore the perceptions, understandings and preferences of the individuals (Ritchie et al., 2013). As described in Chapter 2, a pragmatic approach was adopted for this thesis. This approach does not start from a "disinterested" position, i.e. is not fully exploratory, but nor does it test a specific hypothesis and thus prescribe exactly what the response set should be (Creswell and Creswell, 2017). Rather, a flexible semi-structured method is employed which is directly linked to research questions or aims in order to understand the problem, but allows for some freedom of expression of related views (Creswell and Creswell, 2017). A phenomenological approach was not deemed appropriate for this study, as this focuses primarily on experience, i.e. the essence of dental professionals' experiences of the topic and how they reflect on them (Moustakas, 1994; Creswell and Creswell, 2017). Similarly, a grounded theory approach was not embraced as the aim of this study was not to develop a general, conceptual theory of implementation of oral cancer risk factor assessment and prevention grounded in the views of dental professionals (Glaser and Strauss, 1967). Instead, the aim was to gather a rich description of dental professionals' views on the practical application of the identified best practice evidence (from Chapter 3) on oral cancer risk factor assessment and prevention. This was deemed amenable to a pragmatic approach which combines an 'a priori' framework of specific questions (with a dedicated practical purpose) with full exploration of views and inductive coding of responses.

An in-depth, semi-structured interview approach was the method used for data collection in this exploratory qualitative study (Longhurst, 2009). This is a structured research process in which a well-trained interviewer/researcher asks a set of semi-structured probing questions, establishes good rapport, listens and records the responses, in order to obtain particular information from individuals

(Hennink et al., 2010; Ritchie et al., 2013; Silverman, 2013). In-depth interviews are usually conducted in a face-to-face setting, to allow the researcher to respond better to non-verbal cues, which may lead to specific prompts. These interviews allow for an in-depth exploration of meaning and language, and as these interviews are interactive, flexible and generative in nature, the face-to-face encounter is an essential context of these interviews (Ritchie et al., 2013). Therefore, face-to-face, individual interviews were conducted with dental professionals, in order to explore and gain detailed insight.

4.3.2 Ethical approval

4.3.2.1 NHS

Formal confirmation was received from the West of Scotland Research Ethics Service (WOSRES) that no NHS Research Ethics Committee (REC) approval was required for this study, as the project involved only NHS staff and dental practitioners in their professional capacity. The advice was received on March 20th, 2015 (Appendix 7).

4.3.2.2 University of Glasgow

Ethical approval was sought from the College of Medicine, Veterinary and Life Sciences ethics committee at the University of Glasgow. Initial approval was received on June 12th, 2015. Further approval was obtained on June 16th, 2016 due to a change to the interview method and removal of a survey component from the study (Appendix 8).

A study proposal form was also submitted to the Glasgow Dental Hospital and School Research Management Committee at the University of Glasgow. Approval from this committee was received on February 11th, 2015.

4.3.3 Ethical considerations

No conflicts of interest were identified in relation to this study. The information gathered was obtained, processed and retained in keeping with the Community Oral Health (COH) Section Data Security Protocol. The unit's Data Security Protocol is in keeping with the University of Glasgow's Data Protection and

Records Management Policies and was recently audited by the University. The principal researcher and supervisors with access to data were required to sign the Research Data Security and Confidentiality Agreement.

4.3.4 Sampling and participant recruitment

Sampling

This study involved a non-probabilistic, purposive sample with participants chosen based on their ability to inform the aims of the research, i.e. to allow exploration of barriers and facilitators to a comprehensive preventive approach in practice. Purposive (non-probabilistic) stratified sampling, as is common in qualitative research, is a trade-off between efficiency (recruiting people who can provide great detail of interest) and thoroughness (obtaining representation from those with different length of experience, professional roles etc.) (Oliver and Jupp, 2006).

The choice was both pragmatic (target staff who can respond in time and to subject matter) and analytic (those providing routine care tend to be the ones who best reflect the system under observation). It has been argued that for small sample sizes (typically in studies using intensive qualitative methods), the bias from sampling based on selected criteria is less dangerous than the lack of precision introduced by probability samples (Deville, 1991).

Selection criteria

The research focused on NHS dental practitioners and professionals in their professional capacity across Scotland. The dental professionals were recruited from a range of dental practices, in order to cover different geographical locations. Stratification ensured a mix of participants to give a range of responses across:

a) General dental practitioners and other dental care professionals in the team (dental hygienists/therapists) providing preventive care

b) Range of socioeconomic backgrounds (Scottish Index of Multiple Deprivation - SIMD quintile) of the location of their dental practice

c) Years of experience (experienced dental professionals to current dental trainees)

Recruitment

A list of accessible dental practices (based on selection criteria) was drawn up in consultation with specialists in Dental Public Health at the University of Glasgow Dental School. These practices were also who had either previously participated in research projects or had expressed an interest in participating. All potential participants (dental professionals) were approached by sending an invitation email, and participants were asked to give approval to be contacted for the semi-structured interview by replying to that email. The information sheet outlining the aims and objectives of the study was sent along with the invitation email and an opportunity was given to the potential participants to discuss the project verbally prior to taking part in the study, to ensure that they were fully informed about the study. A reminder email was sent after two weeks to those who did not reply to the first email. The potential participants were not contacted again if they did not respond to the second email. For participants who gave approval to be contacted, face-to-face interview appointments were arranged at a mutually convenient time.

The target was to recruit and conduct 12 interviews in this study, but the planned number of interviews undertaken was open to change in relation to the research questions (Guest et al., 2006). As is common in qualitative work, the final set was determined under principles of data saturation. Here, a point is reached when no new themes emerge from analysis, and exhaustiveness in relation to the research questions can be assumed (Sandelowski, 2001; Fusch and Ness, 2015). Many qualitative researchers in their studies have showed that 7 to 12 interviews are usually enough to achieve a desired research objective, however, this may not be the case with a relatively heterogenous study group (Guest et al., 2006; Fusch and Ness, 2015; Hennink et al., 2017). For this study, as the aim was to understand common perceptions and experiences among dental professionals in Scotland (a group of relatively homogeneous individuals), it was believed that 12 interviews would suffice. In total 13 dental professionals agreed to participate, so they were all interviewed (n=13) as part of this study, and data saturation was achieved after seven interviews (data saturation detailed in Section 4.3.8).

4.3.5 Topic guide preparation

A semi-structured topic guide addressing the study aims and objectives was developed (Appendix 9). The questions were based on practical application of the best practice evidence identified from the systematic overview of primary care prevention in Chapter 3. The topic guide or interview schedule was developed based on initial synthesis of the overview findings, however, the detailed overview synthesis continued even after the dental professional interviews were conducted. This somewhat restricted further in-depth exploration of dental professional views based on the findings from robust overview synthesis (discussed in Section 4.5.3.2).

Interviews followed the topic guide, but discussions were revised in situ to follow emerging topics of interest, thus not restricting interviews completely to pre-determined questions. For example, some dental professionals talked about differences between private and NHS dental practices - this topic was then explored in following interviews. During data collection the topic guide was modified further to address topics of interest that emerged during earlier interviews.

4.3.6 Data collection

The data were collected between August and October 2016. The interviews were carried out at dental practices or offices at participants' discretion within office hours. Prior to beginning the interview, participants were assured that their participation was entirely voluntary, and they were free to withdraw from the study at any time without giving any reason. The participants were also assured that the interview data would be anonymised and all the information which could identify the participants would be removed from the transcripts. Participants were assigned a unique code identifier at the onset of the interviews that was logged on a contact information sheet and stored separately. Participants were reassured that all personal information would be destroyed at the end of the study, and records would not be retained for longer than necessary (retained until completion of the study and submission of the thesis).

At the start of the interview, participants were told about the purpose of the study, and participants were provided with a paper copy of the participant information sheet and the consent form and were allowed to ask any questions about them (Appendix 10 and 11). When a participant agreed to participate in the study, he/she was asked to sign the written consent form prior to interview. Participant's permission (written consent) was also taken to audio record the interviews.

The interviews were conducted in English. During the interview, a supportive environment was created, so that participants could express their views freely. Discussions were facilitated by asking for more information or explanations where needed on topics, by trying to direct the discussions back on topic and also by managing the pace of the discussions. An opportunity was given to participants at the end of the interview to add or discuss any additional points or issues, and participants were also asked to offer any feedback about the interview.

Written field notes were made immediately after each interview covering the main points that emerged during interviews, for example, general impression or personal reflections on the interview process; any inferences for future interviews or analysis; and what it added to the body of the data.

4.3.7 Pilot interviews

Practice interviews (and training) were conducted with two supervisors (AJR and DIC) in order to get feedback on the interview process, and iterate the topic guide in response to any difficulties or omissions. A pilot interview was then conducted, with an experienced dental practitioner (not directly involved in the research study) taking the role of participant, prior to commencement of the fieldwork. The author of this thesis (principal researcher) had previous experience in conducting qualitative research (from master's research project); thus, the main purpose was for the author to gain experience of this particular topic guide / piece of work, and gain further valuable interview experience. One of the supervisors (AJR) observed the pilot interview and gave feedback. Subsequent reflections and feedback from the dental practitioner and supervisor

guided some valuable changes to the topic guide for succeeding interviews. Moreover, feedback from the dental practitioner was that the questions would be acceptable, and were relevant to dental professionals working in Scotland.

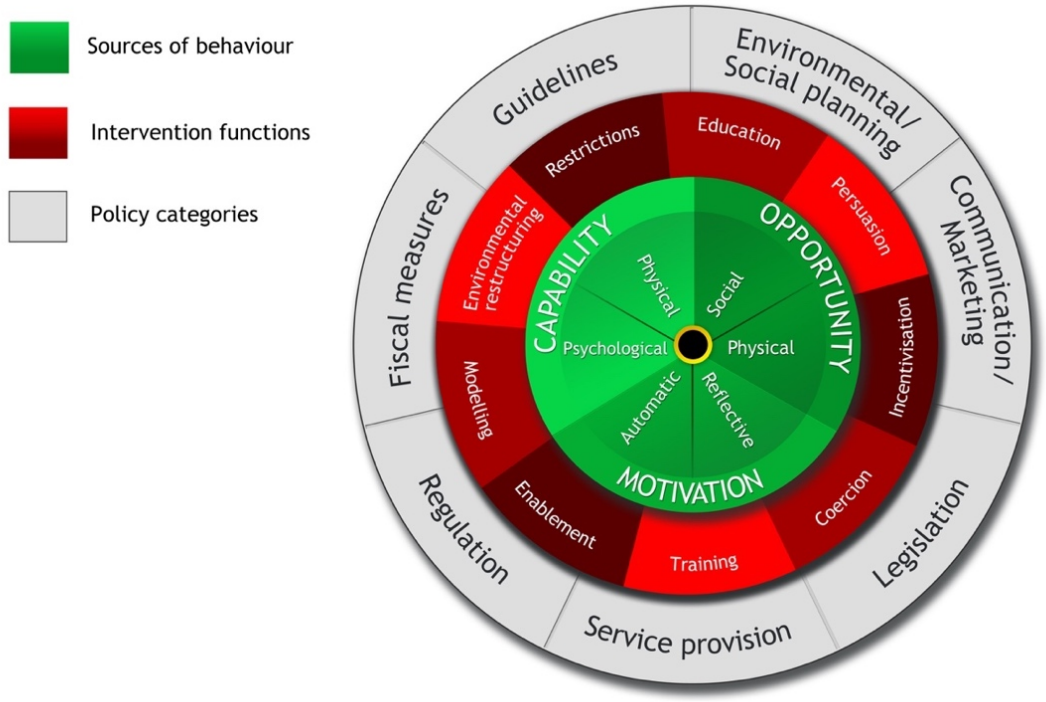
4.3.8 Data analysis

4.3.8.1 Implementation analysis

An advantage of the dedicated 'Implementation Science' approach employed in this study is that it allows the researcher doing empirical qualitative work to go beyond a set or list of generic themes (Creswell and Creswell, 2017) by imposing a structure to examine barriers and facilitators (framed in terms of capability, opportunity and motivation) to specific practices (termed behaviours) to identify specific recommendations for intervention (Boyatzis, 1998; Michie et al., 2011).

This approach is facilitated by a visual representation of the model called the Behaviour Change Wheel (BCW) (Michie et al., 2011). Starting with the behaviours in question, the centre of the wheel involves identifying categories of determinants which can help or hinder implementation (hence barriers or facilitators). Each behaviour is seen as emerging from the interaction of three aspects: capability (C), opportunity (O) and motivation (M). Hence the relation between these factors and behaviour is called COM-B (Michie et al., 2011). Capability has been defined as the "individual's psychological and physical capacity to engage in the activity concerned. It includes having the necessary knowledge and skills". Opportunity is defined as "all the factors that lie outside the individual that make the behaviour possible or prompt it" and includes time and other resources. Motivation is defined as "all those brain processes that energize and direct behaviour, not just goals and conscious decision-making. It includes habitual processes, emotional responding, as well as analytical decision-making" (Michie et al., 2011). Figure 4.1 shows the 'wheel', with the COM-B framework in the centre.

Figure 4.1: The Behaviour Change Wheel (Michie et al., 2011)



It can be seen from Figure 4.1 that the COM-B model is framed by: a) intervention functions or possibilities and b) higher level policy categories. The present study had a focus on developing intervention recommendations for each of a set of evidence-based practices or behaviours. Policy implications are included in the final discussion in Chapter 6.

The method for intervention recommendations is underpinned by previous work synthesising approaches to the specific barrier types (to be addressed) or facilitator types (to be enhanced and reinforced) identified in relation to the target behaviours (Michie et al., 2011). For example, the Behaviour Change Wheel had been used to illustrate to Members of the UK Parliament that the current UK Government is disregarding important evidence-based interventions to change behaviour concerning public health (for example, tobacco control) (West and Michie, 2010; Featherstone et al., 2010). As advocated by the popular book “Nudge” (Thaler and Sunstein, 2008), to influence behaviour, the UK Government focused on environmental restructuring, some incentivisation and

subtle persuasion, while eschewing the other important intervention functions from the Behaviour Change Wheel that one might use (Michie et al., 2011).

Table 4.1 below shows the general theory-based interventions that are linked to each subcategory under the COM-B framework, i.e. the table can be used to identify intervention functions most likely to be effective in changing a particular target behaviour (addressing identified COM barriers and facilitators). The greyed (shaded) squares highlight where “evidence or consensus suggests that a function may be effective for addressing a particular behavioural determinant” (Michie et al., 2011; Barker et al., 2016).

Table 4.1: Intervention functions from COM-B model and Behaviour Change Wheel (activities designed to change behaviours) (Michie et al., 2011)

		Intervention functions								
		Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
COM-B components	Physical capability					■				■
	Psychological capability	■				■				■
	Physical opportunity						■	■		■
	Social opportunity						■	■		■
	Automatic motivation		■	■	■			■	■	■
	Reflective motivation	■	■	■	■					

The greyed (shaded) squares highlight where "evidence or consensus suggests that a function may be effective for addressing a particular behavioural determinant" (Michie et al., 2011; Barker et al., 2016).

It can be seen from Table 4.1 that some intervention types have potential for addressing multiple determinants (COM barriers and facilitators) and all determinants can be addressed in various potential ways. The results in this chapter are based on: a) identifying the determinants for each component of the best practice evidence synthesis and b) discussing these in terms of the recommended intervention possibilities.

Michie et al. (2011) have defined various COM-B components/determinants as:

Psychological capability	The capacity to engage in the necessary thought processes, e.g. reasoning, comprehension, etc. It can be achieved through imparting knowledge or understanding, training emotional, cognitive and/or behavioural skills or through enabling interventions such as medication.
Physical capability	It relates to the skill and technique issues.
Physical opportunity	Includes time and other resources. These issues point to a need for environmental or organisational change.
Social opportunity	It is afforded by the cultural milieu that dictates the way that we think about things (e.g., the words and concepts that make up our language). Also point to a need for environmental or organisational change.
Reflective motivation	Involves evaluations and plans, i.e. beliefs about what is good and bad, conscious intentions, decisions and plans.
Automatic motivation	Involves emotions and impulses that arise from associative learning and/or innate dispositions.

While the various intervention functions from the Behaviour Change Wheel (Figure 4.1 and Table 4.1) are defined as (Michie et al., 2011):

Education	Increasing knowledge or understanding
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivization	Creating an expectation of reward
Coercion	Creating an expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing barriers to increase capability (beyond education and training) or opportunity (beyond environmental restructuring).

4.3.8.2 Coding the data

The semi-structured interviews were audio-recorded with consent from all participants, transcribed and transferred to computer files (as Microsoft Word 2016 documents). Two interviews were transcribed first for the purposes of familiarisation with the data, and the remaining interviews were transcribed using a contracted transcription service. All interviews were transcribed verbatim. The transcripts were imported into the Qualitative Analysis Software (QSR) NVivo version 11.0 (QSR, 2017) and were read over repetitively and at the same time the interview recordings were listened to again, in order to ensure accuracy and consistency of all transcripts. This also helped in becoming acquainted with the depth of content of the dataset as a whole.

The anonymized transcripts of the interviews were then coded and organised into an initial set of determinants for evidence-based practice associated with the research aims (and topic guide from the systematic overview) using thematic analysis techniques (Braun and Clarke, 2006) and facilitated by the NVivo 11.0 qualitative analysis software (QSR, 2017). This broad initial coding determined the final set of interviews (n=13) using the principle of data saturation via absence of newly emergent themes/data (Guest et al., 2006). A robust method was used to achieve data saturation as described by Constantinou and colleagues (2017), which they term "Comparative Method for Themes Saturation (CoMeTS)". This method involves compiling all themes and then reordering the sequence of interviews several times for examination in order to confirm new interviews have stopped adding to the coverage (Constantinou et al., 2017). Reaching data saturation this way ensures the validity and robustness of the study results (Fusch and Ness, 2015; Constantinou et al., 2017).

Determinants were then collated for each of the set of specific synthesised evidence-based practices ('behaviours'), which broadly take the form of a chronological consultation flow from ask/assess, through give advice, to refer (Chapter 3). The final determinants, targeted at specific aspects of the consultation, were then matched to interventions for consideration to improve and support implementation. Interpretation was in line with the project aims to produce recommendations for implementation of best practice and a future intervention to support preventive care.

All coded determinants were cross checked between two coders and disagreements discussed by the author and all supervisors to ensure robust categorisation. The verbatim quotations or segments of the coded data from interview transcripts were extracted as instances from the data, in order to:
a) illustrate key points;
b) provide evidence of identified themes within the data;
c) express the essence of the point being discussed.

All quotations were anonymised and any names identifying persons, dental practices, and locations were removed. A pause in the conversation was indicated in the verbatim quotations as "ellipsis" (three dots ...), while material

omitted in the quotations was indicated as “ellipsis” in a square bracket and italicized (*[...]*).

4.4 Results

13 individual interviews were conducted with dental professionals from 11 primary care dental practices within ‘West of Scotland’ between August and October 2016. The principal researcher (author) conducted all interviews.

Participant characteristics

Table 4.2 provides general information about the participants: gender of the participants, professional role, experience in dentistry, socioeconomic status of the location of the dental practice, and ID assigned to them for this study.

Table 4.2: General characteristics of the participants (n=13)

ID	Gender	Dental professional role	Years or months of experience	NHS or private or mixed dental practice	SIMD16 Quintile (dental practice)
D1	Female	Dentist	36 years	NHS	1
D2	Female	Dentist	17 years	Mixed	5
D3	Male	Dentist	31 years	NHS	5
D4	Male	Dentist	18 years	Mixed	1
D5	Male	Dentist	33 years	Mixed	2
D6	Female	Dentist	23 years	Mixed	1
D7	Female	Dentist (VT)	1 month	NHS	2
D8	Female	Dentist	33 years	NHS	2
D9	Female	Dentist	16 years	NHS	2
D10	Female	Dental Hygienist	32 years	NHS	3
D11	Female	Hygienist/ Therapist (VT)	2 months	NHS	5
D12	Female	Hygienist/ Therapist (VT)	2 months	Mixed	2
D13	Female	Dentist	14 years	NHS	1

VT: Vocational Trainees; SIMD16: Scottish Index of Multiple Deprivation 2016

The mean duration of the interviews was 37 minutes (range 25-51). It can be seen from Table 4.2 that the male: female ratio of participants in interviews was 3:10 (three male dentists, seven female dentists and rest female hygienist/therapist), which showed less involvement of male dental professionals in this study.

Most of the dental professionals participating in this study had an experience of over 10 years in dentistry. There were three dental professionals who were undergoing their vocational training (VT). The average length of dental professional experience was 19.5 years, ranging from 1 month to 36 years. In addition, there was a range of SIMD (deprivation score) for locations of dental practices in the study, i.e. from least deprived (score of 5) to most deprived (score of 1) locations.

In the following sections, the main findings from the dental professional interviews have been presented under various determinants (COM-B barriers and facilitators) for each component of the best practice evidence synthesis.

4.4.1 Tobacco

4.4.1.1 Risk factor assessment (Ask/ Assess)

With regards to asking about and assessing the patient's tobacco use status, synthesis of high-quality systematic reviews and clinical guidelines (Chapter 3) identified that it is best practice for dental professionals to systematically inquire about and record every patient's smoking (or tobacco use) status in clinical records (to be updated regularly). It was further recommended to assess the patient's readiness to change and their interest in receiving further help for quitting smoking (or tobacco use).

The various barriers and facilitators (in terms of capability, opportunity and motivation) to implementation of this evidence for oral cancer risk factor assessment are presented below. The examples (quotes) of each theme from dental professional interviews have been presented in Table 4.3 (at the end of section).

Psychological capability (knowledge and confidence)

This section includes data coded under "psychological capability" in the Behaviour Change Wheel (Figure 4.1).

The best practice of inquiring about and recording every patient's smoking (or tobacco use) status in clinical records was done routinely by dental professionals. This was underpinned by a facilitator in terms of psychological capability - all dental professionals interviewed in this study demonstrated a good knowledge of oral cancer risk factors and talked about a range of factors, including tobacco use, alcohol misuse, HPV, diet, lifestyle, precancerous lesions, and even talked about sociodemographic factors. All professionals believed that smoking increased the risk of oral cancer and had an impact on oral health as well as general health. Moreover, they acknowledged that smoking combined with alcohol increased the risk more, compared to individual factors.

Regarding risk factor assessment, all professionals mentioned taking patients' social and medical histories (including questions about tobacco use) on a paper 'checklist' or questionnaire which patients self-complete each time they visit for a dental check-up. Most professionals mentioned that the completed questionnaires were uploaded onto their computer clinical IT record system by a dental nurse or receptionist; they checked, compared and contrasted forms regularly, and flagged up any changes or issues to dentists for discussion with patients. In addition, all professionals reported conducting a thorough oral examination in order to look for any changes in the oral cavity relating to smoking (for example, tooth discoloration/staining, foul smell, soft tissue changes, or periodontal disease).

There were no barriers reported to dental professional's psychological capability in terms of risk factor assessment for smoking (or other forms of tobacco).

Social opportunity (norms/attitudes/culture)

This section includes data coded under "social opportunity" in the Behaviour Change Wheel (Figure 4.1).

Patient attitudes, adverse behaviour, causing offence and awkwardness were the major social barriers, and were reported to some extent in most dental professional interviews. When dental professionals were asked specifically about verbalising the term "oral cancer" while discussing oral cancer risks with their patients, a lack of consensus was observed. Some dental professionals reported avoiding the term "cancer" as they believe it "terrifies patients". They reported that using the term is not routine, but can only be justified or appropriate when the professional deems the patient to be at high risk. Others said that they do not mind using the term, as they believe the people who are at risk (smokers or tobacco users) have already heard all the warnings about every other type of cancer anyway (albeit they may be ignoring such warnings and be resistant to behaviour change).

Automatic and reflective motivation (professional role, beliefs and considered motivation)

Taking patients' medical and social histories was deeply embedded in dental practice. Thus, asking patients about their smoking behaviours (regardless of patient's age and gender) at regular intervals was seen as something dentists were fairly automatically motivated to do. There were no reflective motivational factors reported for risk factor assessment for smoking; motivation was more reflective in relation to providing behavioural preventive advice for smoking cessation, which are now discussed.

4.4.1.2 Behavioural preventive intervention (Advise/ Arrange)

The synthesis of high-quality systematic reviews and clinical guidelines (Chapter 3) identified that offering a brief tailored intervention up to 5-minutes by dental professionals was best practice in promoting smoking (or tobacco use) cessation. The intervention could be supported with educational materials, feedback from the oral examination, pharmacotherapy (where needed), and follow-up visits to check success of quit attempts.

The various barriers and facilitators (in terms of capability, opportunity and motivation) to implementation of this evidence is now presented. The examples (quotes) of each theme from dental professional interviews have been presented in Table 4.3.

Psychological capability (knowledge and confidence)

It was apparent in all dental professional interviews that, unlike assessing risk itself, "psychological capability" played an important role in delivering behavioural preventive interventions by dental professionals in primary care dental practices. Skill and technique ("physical capability") was less of a factor.

When asked about providing behavioural advice to patients about smoking (or other forms of tobacco) cessation, most professionals reported providing advice for smoking cessation in their regular patient appointments. Some also stated that they look for smokeless tobacco use in certain communities (for example, South Asians), but they reported that this was not commonly seen in their practices. Professionals admitted that they were more confident in talking to patients about the harmful effects of smoking on their oral health and general health, and benefits of quitting, compared to alcohol reduction advice which was seen as a major issue by most dental professionals (Section 4.4.2). Moreover, it was acknowledged in most interviews (by both senior and younger dental professionals) that younger dental professionals (VTs), who recently graduated, address smoking (and alcohol) issues really well as they had been trained to provide a more preventive service.

However, regarding smoking cessation interventions in primary care dental practices, most professionals (particularly senior professionals) reported that a preventive consultation was somewhat limited to asking patients about their smoking status and providing them quit-line numbers, rather than other aspects, for example, goal setting, tailoring advice, follow-up phone calls, and formal referral to cessation services. The structured advice (i.e. motivational interviewing or stages-of-change-based counselling) was only reported to be delivered by younger professionals, who talked with their patients about harmful effects of smoking and the benefits of quitting, gave tailored advice relevant to personal needs and then provided quit-line numbers or asked patients to contact

a local pharmacy as considered appropriate. There was limited structured advice provided by senior dental professionals to help patients stop smoking. The main reasons reported for not delivering smoking cessation best practice were physical opportunity related (i.e. lack of time, and associated funding implications), which are discussed next.

Physical opportunity (time, remuneration, and resources)

Time and funding available to deliver best practice preventive interventions, and lack of formal training to deliver these interventions, are major barriers (physical opportunity). Other barriers reported were lack of good quality educational materials or posters for oral health promotion in primary care dental practices. Among facilitators for physical opportunity were getting remuneration for including preventive interventions in primary care dental practices, and receiving training to deliver preventive interventions.

Time, remuneration or funding:

Dental professionals were asked about the feasibility of providing best practice preventive interventions - i.e. brief advice of up to five minutes for smoking during regular dental appointments. An important barrier reported by all dental professionals was time available to provide such advice, related to lack of funding or payment for providing advice. These two factors (time and money) were linked to each other in most conversations. Professionals reported that compressing more and more things (e.g. preventive advice with dental examinations and procedures) into the same time period of regular dental check-ups or treatment appointments was not feasible until the funding increases. One of the dental professionals mentioned that this could even lead to loss of money for their dental practice, as instead of spending time providing preventive advice, they would want to see new patients for dental treatment (main priority).

The professionals reported that if they were being paid for providing smoking cessation advice and allowed more time for each patient appointment (i.e. see less patients in a day), behavioural preventive interventions could be a part of regular patient appointments in primary care dental practices. Some professionals also added that time was more of an issue in the NHS dental

practices compared to private practices, as NHS practices often have strict timelines for dental appointments, i.e. 15-20 minutes for each patient, during which period dental professionals need to examine patients and perform dental procedures as well. Thus, incorporating up to 5 minutes of advice on smoking (and alcohol) was not reported as a feasible option in NHS dental practices. However, professionals from private practices also reported time being a major barrier in providing preventive advice.

On the other hand, providing very brief advice (1-2 minutes) was seen as a more feasible option in primary care (both NHS and private). Providing a very short message for a couple of minutes and referring patients to local support groups or cessation services was considered a feasible option that could be incorporated in all dental practices - i.e. “ask and assist/refer” structure compared to the best practice “ask and advise” structure. Furthermore, younger dental professionals (receiving their vocational training) reported that even though they had longer appointment times compared to senior dental professionals, they would prefer to incorporate a very brief advice into their appointments compared to longer counselling sessions – i.e. asking patients about their smoking status and referring them to cessation services or other trained professionals.

Some dental professionals also emphasised that these short messages were quite effective compared to hour long support or counselling. As mentioned under “psychological capability”, most dental professionals were already employing this in their practices, i.e. asking patients about their smoking status and providing them with quit-line numbers. This very brief advice of 30 seconds to a couple of minutes was supported by some high-quality guidelines in the systematic overview study (Chapter 3), where they reported that although longer interventions were more effective to increase quit rates, even very brief interventions had been found to be effective for increasing smoking abstinence rates.

Resources (training and education materials):

Another major barrier under "physical opportunity" reported by most dental professionals was a lack of training for delivering behavioural preventive interventions. Attending training is a resource which is an important factor in professional motivation, engagement, and positive morale or confidence; and is recommended for delivering effective behavioural preventive interventions (lack of trial evidence for effectiveness) (Chapter 3). There was some mention of training for smoking advice provision during undergraduate studies and continuing professional development courses. One of the dental professionals mentioned that there was a lack of training in particular for dentists compared to other healthcare professionals (for example, general medical practitioners, pharmacists) and training courses available were designed in particular for the medical profession. Thus, it was emphasised that training designed specifically for dental professionals is required, partially as they are seeing patients much more regularly.

On asking about what duration or intensity of training would be sufficient to learn how to counsel or advise patients on smoking, the majority agreed that one or two sessions (half days) would be good, which could be repeated after a few years (the evidence in equivocal about the specific duration or number of training sessions that could be recommended as best practice). Dental professionals in this interview study suggested that the first training session could include details about various behavioural interventions and encourage dental professionals to start including them in regular patient appointments; and then the second session could "touch base" to see how professionals got on and to reflect upon whether what they did worked, or to find out what further barriers and/or facilitators were encountered. For example, if dental professionals found difficulties speaking to patients about risks, the specialized trainer helping with the counselling could help guide them on how to deal with these awkward conversations they have with their patients.

Besides remuneration and training, having good educational resources (materials or posters) in the waiting room in dental practices was seen in all dental professional interviews to have a big influence on changing patients' behaviour. This had been recommended in the systematic overview study (Chapter 3),

where most behavioural interventions were supported with stop smoking educational materials which could be tailored or personalised to patient needs (however, there was a lack of trial evidence for effectiveness). Most dental professionals in this study reported a lack of posters or leaflets for advising patients of oral cancer risks in their dental practices. Some professionals mentioned that there needs to be more initiatives to make patients aware of oral cancer and associated risk, because they believe people are not aware of the risk of oral cancer (or are in denial of the risks). It was emphasised that there is a "big hole" in terms of giving people information on oral cancer. People get screening for breast, bowel, cervical, prostate and other health contexts; thus, there was a reported need to make the same sort of publicity and awareness gains for coming to the dentist for oral cancer screening too, and it was felt that good posters or leaflets are the best way to make people aware of or remind them of such things when they visit their dental professional.

Social opportunity (norms/attitudes/culture)

Most dental professionals believed that social influences or attitudes were more of an issue while discussing patient's drinking behaviours (Section 4.4.2) compared to raising their smoking habits. However, "social opportunity" issues for providing smoking advice were reported to some extent in some dental professional interviews. Some dental professionals mentioned that discussing an individual patient's smoking behaviour was quite a "sensitive" topic, and that they needed to take care to convey messages in a non-confrontational way. They further added that it is important to maintain a good dentist-patient relationship. A related barrier cited by some dental professionals was the perception that most patients do not consider receiving smoking advice (to some extent) to be related to oral health or dental issues.

Automatic and reflective motivation (professional role, beliefs and considered motivation)

As mentioned earlier in risk factor assessment (Section 4.4.1.1), asking patients about their smoking behaviours (regardless of patient's age and gender) at regular intervals was seen as something dental professionals were fairly automatically motivated to do. Most dental professionals were clearly motivated to address smoking in regular patient visits, and some also reported giving brief

advice to patients about their smoking. However, some dental professionals did indicate reluctance to include structured behavioural interventions for smoking cessation in regular patient appointments in their practice, but more for resources reasons.

As outlined under “social opportunity”, the social aspect of perceived patient wishes or needs was another supposed barrier affecting reflective motivation for some dental professionals. It was presumed that patients will consider discussing smoking (to some extent), irrelevant to dentistry or their oral health. It was reported that to ask about such aspects is less than useful sometimes because patients may not self-report such behaviours accurately or honestly.

4.4.1.3 Referral to cessation services (Assist)

The synthesis of high-quality systematic reviews and clinical guidelines (Chapter 3) identified that there was a lack of trial evidence in dental practices for the effectiveness of offering referral to ‘quit-lines’ or local cessation services along with some brief advice to quit. However, a referral to telephone ‘call-back’ counselling services or proactive support was recommended in clinical guidelines to increase abstinence rates. That is, simply providing quit-line numbers (signposting) to patients and expecting them to call these services was not recommended; a more proactive support (telephone call-back) was identified best practice in guidelines.

The various barriers and facilitators for referral are presented here. The examples (quotes) of each theme from dental professional interviews have been presented in Table 4.3.

Psychological capability (knowledge and confidence)

A lack of knowledge of local referral pathways for smoking cessation was seen a further barrier in terms of psychological capability. However, dental professionals acknowledged that referral services would be a good support to help patients quit smoking. Most professionals reported providing a card or leaflet containing quit-line numbers to smokers. However, professionals were

unaware whether patients were contacting these services and how helpful these services were to patients.

Most dental professionals recognised their lack of knowledge and showed an interest in learning about the routine way of referring patients to cessation services and reported a need for more information or guidelines on local referral pathways for smoking. This presented a facilitator to participant's reflective motivation, which will be discussed later.

Physical opportunity (time, remuneration and resources)

As mentioned earlier under "physical opportunity", providing a very short message for a couple of minutes, and referring patients to local support groups or cessation services, was considered a feasible option that could be incorporated in all primary care dental practices. Most dental professionals were already employing this in their practices, i.e. asking patients about their smoking status and providing them with quit-line numbers.

Automatic and reflective motivation (professional role, beliefs and considered motivation)

As discussed under "psychological capability", most dental professionals recognised their lack of knowledge and showed an interest in learning about the routine way of referring patients to cessation services and reported a need for more information or guidelines on local referral pathways for smoking. Moreover, it was emphasised that formal training, designed specifically for dental professionals, is required, particularly as they are seeing patients much more regularly than other professional groups.

Table 4.3 presents examples of each theme, i.e. barriers and facilitators (in terms of capability, opportunity and motivation) for delivering smoking cessation interventions by presenting quotes from dental professional interviews. The various determinants (barriers and facilitators) are then discussed in terms of the recommended intervention possibilities (from the Behaviour Change Wheel) for smoking cessation evidence-based practices or behaviours - presented in Section 4.5.2.

Table 4.3: COM-B barriers and facilitators related to delivering smoking cessation interventions

Psychological Capability		
	Barriers (with examples)	**Facilitators (with examples)**
Ask/Assess	None reported	**Risk factor assessment (social and medical history) done routinely** D1: We have to do social history for every patient and we need to ask whether they are doing smoking habits, drug using… and also medical histories updated on every appointment. So, then we have got background, right, and later obviously patient complaints but also it is…if it is careful examination which we are doing, always while checking soft tissue. D4: They're (patients) given a medical history questionnaire which includes questions about alcohol and smoking… and whether they want help to stop, smoking *[...]* there's a range of questions about whether or not their medical history has changed.
Advise/ Arrange	**Lack of knowledge: structured behavioural interventions** D2: I mean, we do some smoking cessation here as well but we don't do anything apart from advice, discuss if they're interested to stop smoking and give them leaflets. D11: If I was to come across a patient with that I probably wouldn't really know what to advise but I would advise to see their GP and	None reported

	then maybe we could refer them on to counselling or from there.	
Referral (Assist)	**Lack of knowledge: local referral pathways** D2: What we do is we get… in the leaflet which has the numbers on it, so… we don't refer to them… just signposting. D7: I'm not actually completely familiar with the referral pathway D8: Well, if I knew who they were. I mean, the people that do it, it would be much easier. And where they were. I mean, the card we have is a phone number. And I tell the people to phone that number. But I haven't phoned that number, I don't know who's at the other end of that phone [laughing] D12: I'm not sure what it is, what the smoke line is here in Glasgow, so I just advise them to look into it *[...]* but I just need to find out who it is I need to refer to.	None reported
Physical Opportunity		
	Barriers (with examples)	**Facilitators (with examples)**
Ask/Assess	None reported	None reported
Advise/ Arrange	**Lack of time: delivering preventive interventions in dental practices (up to five minutes)** D1: We have limited time. So, we need to choose.	**Very brief advice (ask and refer) is routine** D1: We need to send sometimes very short messages… what I'm doing…just…I'm giving short message.

	D7: I don't think if he (principal dentist) had five minutes of smoking… I think that would be kind of too much time spent on it, just feasibly *[...]* because you don't have a lot of time with each patient in the NHS dentistry. D11: well because we're quite strict to appointment times…especially it's NHS as well…you probably only maybe three minutes for your clerking in *[...]* you would probably have to try and cut that appointment down… in some other aspects. I think maybe in private practice it would be a lot easier but within NHS like scale appointments are only 15 minutes and you don't know what you're going to be faced with. **Lack of funding or remuneration: delivering preventive interventions in dental practices** D2: basically, they would need to remunerate for that extra time… D3: the fee for what we do would have to be increased. There would have to be some kind of, change in the way that we're funding it. D4: It comes down to time and money. You only get paid so much for what you do *[...]* you can set all the guidelines in the world, but people won't do it if there's no way of funding it… that's the biggest issue. D5: Unless you can charge the patient, I don't know, maybe thirty or forty pounds, you don't have thirty or forty minutes. I've got	D5: I think a good deal can be done…general practitioners are pretty effective communicators… and they can deliver a lot in a minute. And five minutes is a long time to…for me to talk to you about your smoking, to be honest. I mean, if I've not delivered the message in a minute, then I'm not very effective, I don't think. D7: I think similarly smoking, giving them a brief outline, written information, support network to phone, and maybe writing a referral letter *[...]* a very short kind of advice, and then we can refer on to like say there's pharmacy support groups for smoking, so we don't actually sit and provide say an hour long support *[...]* I think that's probably the best way.

	twenty minutes and, I lose money. It is actually financial suicide. I've got a practice that loses money. D6: I think in the NHS… we get paid very little for an examination. In that time… I think I have to address their pain and their toothache and things like that… I don't have time for five minutes consultation on smoking and drinking *[...]* Well, the golden thing is money. --- **Lack of training: preventive interventions (advice and referral)** D1: Dentist…we as a profession, as a group, we should also be useful to have any, professional, like psychological training how to speak to the patient about risks, especially risk of oral cancer *[...]* with actors or somebody else, that somebody pretends to be a patient or my colleague. D2: because we're not formally trained *[...]* There wasn't really that training available. It was more available for the pharmacists and the GPs. It wasn't…didn't seem to be available for the dentists. --- **Lack of educational materials** D1: I would like to have any good leaflets because personally I was looking for in the Google from long, long time… The only one what I could find it is from British Dental Health Foundation. It's actually action is wonderful. The materials are horrible…the graphic is unacceptable. D11: I definitely think information leaflets with graphic pictures	

	would be really good *[…]* sometimes maybe if oral cancer was to develop in a patient might not think anything of it, of a lesion, or just like it's just something. Whereas if they've (patients) seen these information leaflets it might make them more, alert or wary to the fact, oh, I've seen that leaflet, what's best, sort of and then get themselves in for an appointment to be checked a lot quicker than maybe	
Referral (Assist)	None reported	**Signposting (ask and refer) is routine** D7: I think similarly smoking, giving them a brief outline, written information, support network to phone, and maybe writing a referral letter *[…]* a very short kind of advice, and then we can refer on to like say there's pharmacy support groups for smoking or there's say like alcohol organisations, so we don't actually sit and provide say an hour long support *[…]* I think that's probably the best way.
Social Opportunity		
	Barriers (with examples)	**Facilitators (with examples)**
Ask/Assess	**Patient attitudes: using term "oral cancer"** D7: I think the word cancer scares people a lot… because I find patients get a bit nervous the minute you mention those kinds of words. D9: I think a lot of patients prefer you to avoid directly talking about the word cancer. It's not a nice word to a lot of people.	None reported

Advise/ Arrange	**"Sensitive" topic** D4: One of the things which is, important is that we don't lose a relationship...from a dental point of view by setting up an antagonistic relationship over somebody smoking (or drinking). You know, if you push too hard then they may decide that actually they don't want to see you again, and then that's a detriment to their oral health. D11: I feel that they are quite sensitive subjects (smoking and alcohol) because it is personal *[...]* It is a really sensitive when it comes to personal things like that, especially with patients it can be quite a sensitive subject when they feel you're trying to force somebody to do something that they want to do. **Patient attitudes** D4: It depends on the individual. If somebody's interested, then they'll let you talk. If they're not interested by and large... they'll tell you pretty quickly. D6: We just say, you know, yes, see you're still smoking and most people…some people get quite defensive about it. D7: …they also don't think it's a dental issue, so maybe just…	None reported

Referral (Assist)	None reported	None reported

Automatic and Reflective Motivation		
	Barriers (with examples)	**Facilitators (with examples)**
Ask/Assess	None reported	**Consider their role/job: ask and assess smoking status** D12: I feel like you have to ask because you know the importance of asking. D13: I feel my role is just there, they already know everything, I'm just there to prick their conscience and if they seem interested then I'm ready with all the help and advice they need to try and stop.
Advise/ Arrange	**Reluctance to include behavioural interventions (not considered their role)** D3: I'm not sure that it's a dentist's job to be then checking up on them and calling them back and saying, you know, get them to fill in data about how much they smoke and how much they drank *[...]* advice up to five minutes I don't think is practicable, personally *[...]* I would attend… I mean training to provide advice as to… where to go or how to then seek more help but not training to provide the smoking cessation itself… and to get involved in the follow-up phone calls… and goal setting and things like that. D5: And then by the time you get to all the end of that (oral	**Consider their role/job: provide advice** D11: I am comfortable with it to be honest, because at the end of the day it's my role to do it and… like doctors and dentistry… as well as we would see patients a lot more than what those other services would see them. Therefore, it's our job to inform them. **Considered motivation: always provide behavioural advice** D1: We advise patient... always. If somebody's a smoker, always I advise *[...]* have you ever thought to

	examination and charting), to spend five minutes on alcohol and five minutes on smoking is just not going to happen. It's not realistic… five minutes is a lot *[...]* I probably don't ask them about their sexual habits… I perhaps don't want to have that discussion [laugh] either. **Perceived patient wishes and needs** D1: confidential but in this way… we start to interfere, as in totally private life. D6: I think some people are maybe not expecting to hear that from me, I don't know. I'm old school. D7: They (patients) also don't think it's a dental issue, so maybe just…	give up smoking...it is unhealthy for you and... for the gums and everything altogether. D2: We'll ask them (how much they're drinking and) how much they're smoking and then we would bring it up… I would say that to everybody… everybody would be getting the same message *[...]* And I did think that we're seeing the patients so much more regularly…you know, and it would make more sense if were doing it… D12: Every single patient gets it… they all wonder why I ask all these questions… but I have to explain, it's important *[...]* I tailor it to each person, so it depends what they're moaning about when they come in *[...]* I always mention cancer as one, definitely… **Receiving formal training to provide behavioural advice would work** D3: I think it would be interesting to… I would attend that kind of thing… I mean training to provide advice as where to go or how to then seek more help… D7: So, I think maybe just a, a short course like a morning or something, part of a CPD training, because oral cancer obviously is a big issue. D13: I think we should learn about the research that's been done and also be told about the developments for healthcare for improved care for cancers and things. So,

		it would be good to get that once every five years I think.
Referral (Assist)	None reported	**More information or guidelines on referral** D1: Every practitioner should, have any like instruction. I think maybe supplied by the health board, exactly pathway where to refer the patient… but how to get consultant. D2: Set something up more like Childsmile where there was a referral thing. The thing with that is… where we were, kind of, connecting with the pharmacists and the doctors. D8: Well, maybe more knowledge of where the smoking cessation services are located. That means the professional ones are located... **Receiving formal training to provide referral would work** D2: if the dentists were trained in that, to be able to refer… to be able to prescribe any (intensive counselling or pharmacological treatments)

4.4.2 Alcohol

In most of the dental professional interviews smoking and alcohol tended to be talked about in combination. Most of the barriers and facilitators reported were thus common for both risk factors, but there were some differences.

The various barriers and facilitators to implementation are presented below. The examples (quotes) of each theme from dental professional interviews have been presented in Table 4.4 (at the end of section).

4.4.2.1 Risk factor assessment (Ask/Assess)

The synthesis of high-quality systematic reviews and clinical guidelines (Chapter 3) identified that it was a best practice for dental professionals to screen all adult patients for alcohol misuse, administer a validated screening tool (for example, AUDIT, CAGE, or FAST) for assessing risk levels, and record status in clinical records (to be updated regularly). However, some barriers and facilitators were apparent, and these are described in the following sections.

Psychological capability (knowledge and confidence)

As reported under smoking (Section 4.4.1.1), all dental professionals interviewed in this study demonstrated a good knowledge of oral cancer risk factors and talked about a range of factors, including alcohol misuse. They emphasised that smoking combined with alcohol increased the risk more compared to individual factors. Regarding risk factor assessment, all professionals mentioned taking patients' social and medical histories (including questions about alcohol use) on a paper checklist questionnaire which patients self-complete each time they visit for a dental check-up. Most professionals mentioned that the completed questionnaires were uploaded onto the computers by dental nurse or receptionist, who checked, compared and contrasted forms regularly, and flagged up any changes or issues to dentists for discussion with patients. However, none of the professionals reported using any screening tool for assessing alcohol misuse and most professionals admitted that they were not aware of these tools at all.

Automatic and reflective motivation (professional role, beliefs and considered motivation)

As reported under smoking (Section 4.4.1.1), taking patients' medical and social history was deeply embedded in dental practice. Thus, asking patients about their drinking behaviours (regardless of patient's age and gender) at regular intervals was seen as something dental professionals were fairly automatically motivated to do. There were no reflective motivational factors reported for risk factor assessment for alcohol; motivation was more reflective in relation to providing behavioural preventive advice for alcohol reduction, which are discussed next.

4.4.2.2 Behavioural preventive intervention (Advise/ Arrange)

The synthesis of high-quality systematic reviews and clinical guidelines (Chapter 3) identified that offering a brief tailored intervention of up to 5 minutes by dental professionals could be considered best practice in reducing alcohol consumption, with this intervention to be supported with educational materials, and feedback from the oral examination. A brief (10-15-minutes) multi-contact intervention is, however, recommended as best practice in medical practice guidelines (strong trial evidence) for helping alcohol users to reduce consumption. The various barriers and facilitators to this synthesised evidence are now discussed.

Psychological capability (knowledge and confidence)

As reported under smoking (Section 4.4.1.1), dental professionals admitted that they were more confident in talking to patients about the harmful effects of smoking on their oral health and general health, and the benefits of quitting, compared to alcohol reduction advice which was seen as a major issue by most dental professionals. They showed a lack of knowledge and confidence in providing alcohol advice, and also regarding referrals (Section 4.4.2.3). However, younger dental professionals (VTs) felt more comfortable and confident talking to patients about their drinking behaviours compared to senior professionals. One of the senior professionals even acknowledged that younger dentists, who recently graduated, address these issues really well as they had been trained to provide advice for both smoking and alcohol.

Physical opportunity (time, remuneration and resources)

Once again, time and funding available to deliver best practice preventive interventions, and lack of formal training to deliver alcohol interventions were the major barriers ("physical opportunity") in most dental professional interviews. Other barriers reported were lack of good quality educational materials or posters for oral health promotion. Among facilitators for physical opportunity were getting remuneration for including preventive interventions in primary care dental practices, experience delivering very brief interventions, and receiving training to deliver preventive interventions.

Dental professionals reported that incorporating 5 minutes or more of advice on alcohol was not a feasible option in their dental practices, as they have got strict timelines for dental appointments, i.e. 15-20 minutes for each patient, during which period dental professionals need to examine patients and perform dental procedures as well. As reported under smoking (Section 4.4.1.1), dental professionals were motivated to provide a very short message to all smokers to quit and considered it as a more feasible option to be included in their regular patient appointments (most dental professionals were already employing this in their practices). However, none of them reported asking about alcohol. Some professionals were happy to include very brief advice (couple of minutes) for alcohol along with smoking, while other professionals reported barriers to asking about alcohol, which will be discussed under "social opportunity".

Another major barrier was a lack of training for delivering behavioural interventions for alcohol misuse. As mentioned earlier under "psychological capability", dental professionals reported lack of confidence in providing behavioural advice (in particular for alcohol misuse). This was linked in most interviews to a lack of training on delivering behavioural interventions. Thus, it can be seen here that factors in COM-B affect each other, especially capabilities and opportunities go hand in hand. Moreover, it was emphasised that training designed specifically for dental professionals is required.

Again, similar to smoking, a lack of posters or leaflets for advising patients of oral cancer risks was reported. It was pointed out that there were some materials available addressing smoking cessation, while there were very few

advising on alcohol drinking or other oral cancer risk factors. Some participants mentioned that there needs to be more initiatives to make patients aware of oral cancer and associated risk, because they believe people are not aware of the risk of oral cancer (or are in denial of the risks).

Social opportunity (norms/attitudes/culture)

Patient attitudes, adverse behaviour, causing offence and awkwardness were the major social barriers, and were reported to some extent in most dental professional interviews; an important finding is that professionals believed that social influences or attitudes were more of an issue while discussing patient's drinking behaviours compared to smoking.

Dental professionals mentioned that discussing an individual patient's drinking behaviours was quite a "sensitive" topic, and that they needed to take care while talking to patients and ensure they conveyed messages in a non-confrontational way. They further added that it is important to maintain a good dentist-patient relationship. Some professionals called it an "awkward" topic, as they felt in a sense as if they were "prying". However, they also acknowledged that when professionals practise asking patients about their drinking habits, they get used to it and it just becomes part of the routine check-up.

A related barrier cited by most dental professionals was the perception that most patients don't consider receiving alcohol advice to be related to oral health or dental issues. Dental professionals mentioned patients were not comfortable discussing their drinking behaviour and some professionals felt it would offend or upset their patients. Professionals reported that they would provide alcohol advice only if a patient admits their excessive drinking to the health professional and are ready to talk about it. A further barrier was that some dental professionals mentioned that they would not ask about alcohol to patients from certain ethnic or religious groups, because they think that people might get offended.

Automatic and reflective motivation (professional role, beliefs and considered motivation)

Motivation to discuss alcohol was more reflective, for the social reasons discussed above. Some younger professionals cited discussing a patient's drinking behaviours on a regular basis and considered providing behavioural advice to reduce alcohol consumption as their job/role. They mentioned they considered it to be their responsibility to inform the patients about various risks and if patients make the decision against it, then it's their choice, but at least patients have got the right information. However, most dental professionals did not consider providing alcohol advice as part of their role, as they consider it to be interfering in a patient's personal life.

As outlined under "social opportunity", the social aspect of perceived patient wishes or needs was another supposed barrier affecting reflective motivation for some dental professionals. It was presumed that patients will consider discussing drinking behaviours irrelevant to dentistry or their oral health. It was reported that to ask about such aspects is less than useful sometimes because patients may not self-report such behaviours accurately or honestly.

4.4.2.3 Referral to cessation services (Assist)

The synthesis of high-quality systematic reviews and clinical guidelines (Chapter 3) identified a lack of evidence for the effectiveness of alcohol referrals, however, guidelines recommended making referral for patients with alcohol dependence to a general medical practitioner or a specialist alcohol treatment service. The various barriers and facilitators for referral are now discussed.

Psychological capability (knowledge and confidence)

A lack of knowledge of local referral pathways for alcohol is the main capability barrier. All dental professionals admitted that they have no knowledge about referring patients to any specialist alcohol services, but some professionals admitted that they would simply think about referring a patient with alcohol dependence to their general practitioner (which was recommended in guidelines in the overview study). They mentioned that most training and educational materials available target smoking rather than alcohol (discussed under

"physical opportunity" in Section 4.4.2.2). However, dental professionals acknowledged that referral services would be a good support to help patients address moderate alcohol consumption or alcohol dependence.

Most dental professionals recognised their lack of knowledge and showed an interest in learning about the routine way of referring patients to cessation services and reported a need for more information or guidelines on local referral pathways for alcohol.

Physical opportunity (time, remuneration and resources)

As mentioned earlier under "physical opportunity" to delivering behavioural preventive interventions (Section 4.4.2.2), providing a very short message for alcohol (couple of minutes) similar to smoking advice, and referring patients to local support groups or specialist services, was considered a feasible option that could be incorporated in all primary care dental practices. Longer interventions where not deemed feasible in time and resource terms, thus there is a real need to consider how best to facilitate advice (see discussion).

Automatic and reflective motivation (professional role, beliefs and considered motivation)

As discussed under "psychological capability", most dental professionals recognised their lack of knowledge and showed an interest in learning about the routine way of referring patients to cessation services and reported a need for more information or guidelines on local referral pathways for alcohol. Moreover, it was emphasised that formal training designed specifically for dental professionals is required, partially as they are seeing patients much more regularly. This reflection offers possibilities of such training being effective.

Table 4.4 presents examples of each theme, i.e. barriers and facilitators (in terms of capability, opportunity and motivation) for delivering interventions for reducing alcohol consumption by presenting quotes from dental professional interviews. The various determinants (barriers and facilitators) are then discussed in terms of the recommended intervention possibilities (from the Behaviour Change Wheel) for alcohol reduction evidence-based practices or behaviours - presented in Section 4.5.2.

Table 4.4: COM-B barriers and facilitators related to delivering alcohol reduction interventions

Psychological Capability		
	Barriers (with examples)	**Facilitators (with examples)**
Ask/Assess	**Lack of knowledge: risk assessment tools** D2: No, I've not used this (AUDIT/CAGE tools) D13: No, we just use the medical history form and ask them about their drinking habit.	**Risk factor assessment (social and medical history) done routinely** D1: We have to do social history for every patient and we need to ask whether they are doing smoking habits, drug, using alcohol… and also medical histories updated on every appointment. So, then we have got background, right, and later obviously patient complaints but also it is…if it is careful examination which we are doing, always while checking soft tissue. D4: They're (patients) given a medical history questionnaire which includes questions about alcohol and smoking… and whether they want help to stop *[...]* there's a range of questions about whether or not their medical history has changed.
Advise/ Arrange	**Lack of knowledge: structured behavioural interventions** D11: If I was to come across a patient with that I probably wouldn't really know what to advise but I would advise to see their GP and then maybe we could refer them on to counselling or from there.	**Younger professionals: more confident to provide alcohol advice** D6: I know the younger dentists do and I've had a few VTs who have addressed it (alcohol advice) quite well. D7: We've just come from uni. so, I feel quite comfortable talking about it, but maybe people who've

	Lack of knowledge: alcohol advice D2: I wouldn't know how to deal with somebody who you thought had an alcohol problem *[...]* advice on how to reduce their intake, I wouldn't know where to start with that one, to be quite honest. I would just advise, you know, you're at risk. D12: Because I just started this, so I'm not sure who it is, but definitely, I think some people need it, I think that's the only way that they can quit and cut down and things, with that support, I think it's important. **Lack of confidence: alcohol advice** D9: I wouldn't feel trained enough to and it wouldn't be possibly appropriate to... start challenging someone and saying, oh, I actually think you drink twice as much as you're admitting [laugh]. I don't think I'd feel comfortable with that, no. D12: I would feel comfortable, if I knew who it was and knew who to refer to…	been out of university for a long time maybe don't know how to approach it as much because we've just had fresh teaching of it.
Referral (Assist)	**Lack of knowledge: local referral pathways for alcohol** D7: I'm not actually completely familiar with the referral pathway D8: Well, if I knew who they were. I mean, the people that do it, it would be much easier. And where they were. D12: That's the other thing, I don't know who it (alcohol referral services) is here in this area, but I think it's important to, definitely, just because they need support sometimes.	None reported

Physical Opportunity		
	Barriers (with examples)	**Facilitators (with examples)**
Ask/Assess	None reported	None reported
Advise/ Arrange	**Lack of time: delivering preventive interventions in primary care dental practices (five minutes or more)** D1: We have limited time. So, we need to choose. D7: I don't think if he (principal dentist) had five minutes of smoking, five minutes alcohol… I think that would be kind of too much time spent on it, just feasibly *[...]* because you don't have a lot of time with each patient in the NHS dentistry. D11: well because we're quite strict to appointment times…especially it's NHS as well…you probably only maybe three minutes for your clerking in *[...]* you would probably have to try and cut that appointment down… in some other aspects. I think maybe in private practice it would be a lot easier but within NHS like scale appointments are only 15 minutes and you don't know what you're going to be faced with. **Lack of funding or remuneration: delivering preventive interventions in primary care dental practices** D2: basically, they would need to remunerate for that extra time…	**Very brief advice (ask and refer) could be routine** D1: We need to send sometimes very short messages… what I'm doing…just…I'm giving short message. D7: giving them a brief outline, written information, support network to phone, and maybe writing a referral letter *[...]* a very short kind of advice, and then we can refer on to like… there's say like alcohol organisations, so we don't actually sit and provide say an hour long support *[...]* I think that's probably the best way.

	D3: the fee for what we do would have to be increased. There would have to be some kind of, change in the way that we're funding it. D4: It comes down to time and money. You only get paid so much for what you do *[...]* you can set all the guidelines in the world, but people won't do it if there's no way of funding it… that's the biggest issue. D5: Unless you can charge the patient, I don't know, maybe thirty or forty pounds, you don't have thirty or forty minutes. I've got twenty minutes and, I lose money. It is actually financial suicide. I've got a practice that loses money. D6: I think in the NHS… we get paid very little for an examination. In that time… I think I have to address their pain and their toothache and things like that… I don't have time for five minutes consultation on smoking and drinking *[...]* Well, the golden thing is money. --- **Lack of training: preventive interventions (advice and referral)** D1: Dentist…we as a profession, as a group, we should also be useful to have any, professional, like psychological training how to speak to the patient about risks, especially risk of oral cancer *[...]* with actors or somebody else, that somebody pretends to be a patient or my colleague. D2: It's a bit of the training (for alcohol) would be more… if that could be incorporated with smoking *[...]* because we're not	

	formally trained *[...]* There wasn't really that training available. It was more available for the pharmacists and the GPs. It wasn't…didn't seem to be available for the dentists. D9: Well, we're trained to do a certain level of smoking cessation advice *[...]* I wouldn't feel trained enough to and it wouldn't be possibly appropriate to start challenging someone and saying, oh, I actually think you drink twice as much as you're admitting. --- **Lack of educational materials (in particular for alcohol)** D1: I would like to have any good leaflets because personally I was looking for in the Google from long, long time… The only one what I could find it is from British Dental Health Foundation. It's actually action is wonderful. The materials are horrible…the graphic is unacceptable. D13: Well, need more posters. We need posters like the smoking ones. The posters for stop smoking is everywhere and the advice and helplines are up and about. But they don't the same kind of posters for drinking alcohol. It's the same going into my local GP surgery. I don't see any posters about alcoholism on the walls. But you see loads of smoking things *[...]* it would be good to have posters up like on oral cancer health week or whatever.	
Referral (Assist)	None reported	**"Ask/Assess and Refer" could be routine** D7: a very short kind of advice, and then we can refer on to like there's say like alcohol organisations, so we don't actually sit and provide say an hour long support *[...]* I think that's probably the best way.

Social Opportunity		
	Barriers (with examples)	**Facilitators (with examples)**
Ask/Assess	**Patient attitudes: using term "oral cancer"** D7: I think the word cancer scares people a lot… because I find patients get a bit nervous the minute you mention those kinds of words. D9: I think a lot of patients prefer you to avoid directly talking about the word cancer. It's not a nice word to a lot of people.	None reported
Advise/ Arrange	**"Sensitive" topic** D4: One of the things which is, important is that we don't lose a relationship...from a dental point of view by setting up an antagonistic relationship over somebody drinking. You know, if you push too hard then they may decide that actually they don't want to see you again, and then that's a detriment to their oral health. D11: I feel that they are quite sensitive subjects (smoking and alcohol) because it is personal *[...]* It is a really sensitive when it comes to personal things like that, especially with patients it can be quite a sensitive subject when they feel you're trying to force somebody to do something that they want to do. **"Awkward" topic: alcohol advice** D7: It's always a bit of an awkward topic asking about someone's drinking…	None reported

	D9: There seems to be more of a stigma putting a high alcohol intake down than a high smoking… it's difficult to question that without, you know, seeming to be, making the patient uncomfortable and almost accusatory then [laugh]. So, in my experience I wouldn't feel comfortable to challenge the patient about it. D12: Because I think some people feel awkward going to talk about it and things *[...]* Smoking was fine, it was more the alcohol that I felt awkward asking about. D13: There's more of a stigma attached to alcoholism than there is smoking, because smoking has been talked about so much; it's in adverts, it's in posters… But alcohol's a bit different because you're allowed to drink a little bit, and everybody's idea of how much is a little bit is different. --- **Patient attitudes: alcohol advice** D4: It depends on the individual. If somebody's interested, then they'll let you talk. If they're not interested by and large... they'll tell you pretty quickly. D7: …they also don't think it's a dental issue, so maybe just… D13: Some are in denial of the risks *[...]* and some people don't want to discuss their alcoholism. I mean I have quite a lot of patients who I know are functioning alcoholics. You can smell it on their breath… and they've got the red oral mucosa and stuff like	

	that. And they don't talk about it or bring it up and I just feel… I just wouldn't like to upset them by mentioning they smell of booze.	
Referral (Assist)	None reported	None reported
Automatic and Reflective Motivation		
	Barriers (with examples)	**Facilitators (with examples)**
Ask/Assess	None reported	**Consider their role/job: ask and assess alcohol consumption** D12: I feel like you have to ask because you know the importance of asking. D13: I feel my role is just there, they already know everything, I'm just there to prick their conscience and if they seem interested then I'm ready with all the help and advice they need to try and stop.
Advise/ Arrange	**Reluctance to include behavioural interventions (not considered their role)** D1: Drinking habits actually… as a dentist I don't think that it is my role. I think it is coming too far, because it just looks like that I judge somebody *[...]* I don't think that it is my position to tell him what he's doing, because the next step will be how many partners you have got and what are you doing after eight o'clock? D3: I'm not sure that it's a dentist's job to be then checking up on	**Consider their role/job: provide advice** D11: I am comfortable with it to be honest, because at the end of the day it's my role to do it and… like doctors and dentistry… as well as we would see patients a lot more than what those other services would see them. Therefore, it's our job to inform them.

	them and calling them back and saying, you know, get them to fill in data about how much they smoke and how much they drank *[...]* advice up to five minutes I don't think is practicable, personally. D5: And then by the time you get to all the end of that (oral examination and charting), to spend five minutes on alcohol and five minutes on smoking is just not going to happen. It's not realistic… five minutes is a lot *[...]* I probably don't ask them about their sexual habits… I perhaps don't want to have that discussion [laugh] either. D8: Usually it's just smoking. I would think. I don't ask them (hygienists) to provide alcohol advice. **Perceived patient wishes and needs** D1: confidential but in this way… we start to interfere, as in totally private life. D6: I think some people are maybe not expecting to hear that from me, I don't know. I'm old school. D7: They (patients) also don't think it's a dental issue, so maybe just… D9: I think it's (alcohol) something that people like to keep hidden... and if they're not going to admit it to the health professional then it's quite hard.	**Considered motivation: always provide behavioural advice** D2: We'll ask them how much they're drinking and how much they're smoking and then we would bring it up… I would say that to everybody… everybody would be getting the same message *[...]* And I did think that we're seeing the patients so much more regularly…you know, and it would make more sense if were doing it… D12: Every single patient gets it… they all wonder why I ask all these questions… but I have to explain, it's important *[...]* I tailor it to each person, so it depends what they're moaning about when they come in *[...]* I always mention cancer as one, definitely… **Receiving formal training to provide behavioural advice would work** D3: I think it would be interesting to… I would attend that kind of thing… I mean training to provide advice as where to go or how to then seek more help… D7: So I think maybe just a, a short course like a morning or something, part of a CPD training, because oral cancer obviously is a big issue. D13: I think we should learn about the research that's been done and also be told about the developments for healthcare for improved care for cancers and things. So it would be good to get that once every five years I

	Perceived lack of benefit D8: I would need some proof that it actually did any good. I mean, I'm not convinced that if I said to somebody to stop drinking alcohol, it would make a lot of difference to them...if they wanted to drink alcohol.	think.
Referral (Assist)	None reported	**More information or guidelines on referral** D1: Every practitioner should, have any like instruction. I think maybe supplied by the health board, exactly pathway where to refer the patient… but how to get consultant. D2: Set something up more like Childsmile where there was a referral thing. The thing with that is… where we were, kind of, connecting with the pharmacists and the doctors. D8: Well, maybe more knowledge of where the alcohol cessation is in. That means the professional ones are located... **Receiving formal training to provide referral would work** D2: if the dentists were trained in that, to be able to refer… to be able to prescribe any (intensive counselling or pharmacological treatments)

4.4.3 Risk prediction tool

A supplementary aim of this study was to explore dental professionals' views on having a dedicated oral cancer risk prediction tool in primary care dental practices, to help facilitate the best practice behaviours and processes discussed above and in the previous chapter. Some dental professionals were not sure if having such tools would have any additional benefit in their clinical practice, as they believe the medical and social history forms in use in their practice already cover most of the questions to identify individuals' characteristics and behaviours. Dental professionals also said they were following a similar process, albeit calculating risk "in their head" via thorough oral examination/screening along with patient history. In terms of affecting change to patient behaviours and/or lifestyle, mixed responses were observed. Some professionals believed there would be no effect, while others considered that having such a risk tool would be beneficial for a) identifying a high-risk patient and b) tailoring specific advice for them. In other words, it was felt that such a risk tool would help facilitate the best practice of providing a tailored intervention to high-risk individuals.

As outlined earlier under "physical opportunity", the major opportunity barriers to prevention were time and money, and these same barriers were reported in most interviews for having a risk tool in primary care dental practices. Professionals emphasised that unless funding increases, they cannot allow more time for using new tools in their practice. They have limited time slots, and they cannot compress more and more things into that same time slot. Another major barrier cited for having such a risk tool (online or paper version) was concern over data storage and data protection; one of the professionals even called this record keeping a "storage nightmare" for the dental practices.

One of the possible benefits reported was that patients would know, through the derivation of an outcome score, if they are at either high or low risk and thus this might facilitate them being amenable to professional intervention. However, it was also acknowledged that low risk does not mean patients are not going to get disease. Another benefit reported for having such a risk tool was for professionals who have less confidence in dealing with these issues, such a tool

could help those professionals to discuss these risks more efficiently, thus addressing barriers to dental professional's "psychological capability" and also "social opportunity" by making discussions less awkward and more comfortable.

Training to implement a risk tool

Some stated that for such risk tools there needs to be more information and training sessions for implementation with a wider range of practices, so all professionals are doing similar types of things. In particular, professionals should be trained to advise those patients who got a high-risk score without frightening them (i.e. effective risk communication). Professionals should also be prepared to answer questions like: how this risk score is going to affect their patient?; where patients go from there?; what they do with that written score?, etc. One of the professionals further added that such a tool should be implemented with professional help and counselling, and there should be a "before and after" session to assess effectiveness.

Practicable approaches to implement a risk tool

Professionals were asked about the best way such tools would work in the dental practice, for example: self-completion in waiting room by patients; dental professionals administer to patients during an oral health assessment; filled in as an online tool or as a mobile application (app.); or as a paper questionnaire. Self-completion by patients on computers or tablets in waiting room was considered the best option by most dental professionals, the reason being patients should not feel under pressure in the dental practice with the dentist looking at what they are answering, or prompting them when completing fields. Patients were thought to feel more comfortable providing such information confidentially. Another option suggested was a mobile 'app.' where patients can check their score themselves; information of this app. could be put on posters in the waiting areas in dental practices. Some professionals suggested implementation through including a few more questions in the current patient history form/ questionnaire in the practice, as most of the lifestyle and sociodemographic questions are already included in these forms. Primarily, there was agreement that the way in which such a tool is implemented should be easy, quick and convenient, and should be incorporated into the practice

management system in order to save dental professionals time - addressing "physical opportunity" barriers.

Team effort

Some dental professionals suggested that for such tools to be effective, not only dental professionals, but medical professionals, pharmacists or other providers (e.g. retail, advice centres etc.) should be involved in this. One of the professionals even called it a "multi-directed action", where dentists perform standard examination for detecting any suspicious lesions and provide advice for high risk patients. An idea put forward was that such advice could be reinforced or repeated by a general medical practitioner, general nurse, or social worker, so patients receive consistent and coherent reminders. If the patients agree, dentists could co-operate with pharmacies or cessation services for further support. This supports the evidence-based best practice (Chapter 3) where team effort was considered more effective in achieving desired behaviour change among high-risk individuals. Moreover, one of the dental professionals suggested that all information should be made available for patients on the mobile app, so it becomes a "do it yourself tool kit".

Table 4.5 presents examples of each theme, under the question of acceptability of a risk prediction tool, by presenting quotes from dental professional interviews.

Table 4.5: Barriers and facilitators related to having risk prediction tool in primary care dental practices

Barriers (with examples)	Facilitators (with examples)
Perceived lack of benefits of having oral cancer risk prediction tool D4: From my point of view I don't know that it's going to change the...what I do particularly and... make me look differently at anybody. D5: Not sure. But, I mean, well you didn't need a computer to tell you that. I'm sitting right here and you're a doctor, you could have told me that [laugh] without the computer. I think…you've got the brains to tell me that. D6: I don't think it's going to help people to say I think you're at high risk of oral cancer. I don't think so [laughing]. I think it might frighten them. D7: I mean, we tend to do that anyway, but it's not…it's more in your head, like you think, okay, this person's over a certain age, they could have had something in the past, medication they're on or if they're smoking, if their alcohol…that kind of thing, so you do have that calculate a risk in your head. D13: I don't think it would help my clinical practice any… The only benefit from this is the patient knowing they're either high or low risk.	**Perceived benefits for communicating oral cancer risks** D2: I think that if you were using a tool like this, it definitely highlights in the patient, why are they (dentists) talking about this (smoking and alcohol)? You know, this is obviously important. D9: That might be useful and you could then…receive that information and have their classification and discuss it further with them. They're asked how much they smoke and drink and they're maybe not aware of why they're being asked that and they don't really want to answer it, whereas if they knew, you know, if it's explained it was part of a way of assessing how much at risk they were of oral cancers…to help dentists detect, that might encourage them to be more truthful and raise their awareness and care of their oral cavity basically. D12: I think people would use it and find it beneficial, because then at least you know you're not missing anything. I think that's the benefit of it, you're not missing anything, it keeps you on top of things like that
Lack of funding for risk tool D2: I think the practices need to be remunerated for their time, you know… if everything's put in then it just becomes part of it… we try to encompass everything and we do everything here, but it's tough to do it all. D4: if somebody is willing to fund us to have, you know, a couple of hundred tablets so that... but I think that the feasibility of that is quite low […] and constantly every time something else comes out you're adding onto it, but funding doesn't increase in any way, shape or form. So, if you've got	**Self-completion as an online tool/ an app** D1: It could be mobile app, like, are you risk of cancer, check yourself *[...]* Could be poster, do you want to check, if…are you under risk of a cancer, go to the apps and then…nice, very, very colourful picture, not to be frightened. D11: Like if we had like a practice iPad, or something like that, that they could complete it on themselves *[...]* Something online would be good. D13: I think it would be better giving them an iPad and allow them to do it in their own quiet space while they're sitting in the waiting room or whatever.

an admin process and a clinical process how do you pay for that?	
Lack of time D4: how do you allot the time… that's the biggest issue is... that you're compressing more and more things into the same time, and if the funding doesn't increase then you can't allow more time. D7: I think the main thing with dentistry is… it needs to be kind of easy to access… because you don't have a lot of time with each patient in the NHS dentistry. D8: That is the sort of thing that you probably need to increase your appointment time for, isn't it? Because it already takes them five or six minutes to fill up the medical questionnaire.	**Incorporated with patient history forms** D2: Possibly incorporated in to the end of the medical history. That would be okay *[…]* I think here…again very similar to the Childsmile, if it was incorporated in to the computer system we're doing, it was picking all of this up for you, you know, that was doing that automatically for you…then that would be very helpful *[…]* we were doing a social and medical history, we could be clicking that through while the patient talks and then at the end of it, I suppose we could be delivering the verdict. D7: I think that would be… because they fill out forms anyway, fill in medical history, so I think having that included…maybe just a wee…
Data or record storage and protection D4: then again you're talking about how that (paper or online tool) interacts with patient management software *[…]* then where do you store the record? How do you store it safely, look at it from a data protection point of view? That then becomes very difficult. And if you're talking about paper where do you store the paper?	**Implemented as a team approach** D1: I think it must be multi-directed action. So everybody from every site *[…]* information from every corner, from dental professional, medical professional, from society, apps, as much as possible. D13: I would be more comfortable doing it in an audit with a wider range of practices within [area name] so we're all doing similar types of things.

4.4.4 Summary of findings

The main themes developing from this study using in-depth dental professional interviews were developed according to a dedicated framework in terms of capability, opportunity and motivation to reveal barriers and facilitators faced by dental professionals in primary care dental practices to delivering evidence-based best practice oral cancer risk factor assessment and prevention in Scotland. The main findings can be summarised as follows:

- All dental professionals reported good knowledge of oral cancer risk factors and identified smoking and alcohol as the major risk factors for oral cancer and other chronic diseases. It was reported that all patients were asked about their smoking and alcohol habits in the patient history forms or questionnaires, irrespective of patient's age and gender.

- However, there was a lack of knowledge of formal risk assessment tools for alcohol, for example, AUDIT or CAGE tools.

- Advice and prevention related to smoking was more common compared to alcohol with patients in primary care dental practice. However, this was mainly limited to simply asking smokers about their willingness to stop smoking, and "signposting" such as providing them with quit-line numbers or leaflets.

- There was a lack of knowledge of local referral pathways for smoking cessation services, which was seen a barrier to their psychological capability.

- Providing behavioural interventions for reducing alcohol consumption was seen as a problematic issue by most dental professionals. They reported a lack of knowledge and confidence in providing alcohol advice. In most conversations, alcohol came out as the topic/issue which was least talked about in primary care dental practices.

- None of the professionals reported signposting or referring patients to specialist alcohol services, and all were unaware of local alcohol referral pathways.

- Opportunities – both physical (resource centred) and social (e.g. cultural or normative) were raised as major themes/issues for implementing evidence-based best practice for oral cancer behavioural preventive interventions in almost all dental professional interviews. Lack of time and funding were the resource (physical) barriers reported by most dental professionals for providing behavioural interventions in primary care

dental practice. Incorporating 5 minutes of advice on smoking and alcohol was not reported as a feasible option in primary care dental practice until professionals were remunerated for this.

- Providing very brief advice for less than 2-minutes and referring patients to local support groups or cessation services (i.e. simply "ask and refer") was seen as feasible in physical opportunity terms and was therefore considered a possible option that could be incorporated in all primary care dental practices - and including the brief interventions if resourced.

- Among other facilitators to physical opportunity reported were: receiving training to deliver behavioural interventions (advice and referral) and having good education materials or posters in the waiting room in primary care dental practice.

- Social opportunity and reflective motivation of dental professionals created a further major barrier to delivering preventive interventions in primary care dental practice; most dental professionals do not see providing alcohol advice as their role and cited this as an "awkward" topic to discuss.

- Younger dental professionals reported more confidence in discussing patients' smoking and drinking behaviours compared to more senior professionals, and were more likely to see it as part of their core role.

- Patient attitude was perceived to be the major barrier reported in terms of social opportunity; in particular patients were not seen as happy for dental professionals to discuss alcohol drinking behaviours (as most patients were thought not to consider this to be related to oral health or dental issues). This in turn affects dental motivation to engage in these discussions. Patients' viewpoints were further explored as part of this thesis, in order to examine if their perspectives match those of dental professionals (Chapter 5).

- Furthermore, discussing an individual's smoking or drinking behaviours was considered quite a "sensitive" topic, and it was recognised that professionals need to convey messages in a way that maintains a good dentist-patient relationship.

- Mixed responses were received regarding having an oral cancer risk prediction tool. Some dental professionals considered having such a risk tool to be beneficial for identifying a high-risk patient and tailoring advice for them. However, once more, time and funding were the major barriers to implementing such a tool in primary care dental practices.

4.5 Discussion and conclusions

There now follows a short discussion of the main findings from the dental professional interviews, in the context of existing literature. The strengths and limitations of this study will also be discussed, and suggestions for implementing these findings in practice by using various intervention functions from the Behaviour Change Wheel framework will be provided.

4.5.1 Comparison with literature

This qualitative study with theoretically-based thematic analysis explored current views on delivering evidence-based behavioural preventive interventions for oral cancer risk factors (smoking and alcohol) in a primary care dental practice. This is the first study, to the best of author's knowledge, to systematically isolate synthesis of best practice via a systematic overview, then assess theory-based barriers and facilitators to each component of the evidence-base, and to take this approach specifically in relation to oral cancer.

As reported in the results, there was a less involvement of male dental professionals in this interview study. Similar gender differences or male non-participation has been reported in many other studies in a range of health contexts (Markanday et al., 2013; Techau et al., 2014; Slauson-Blevins and Johnson, 2016). Reasons for non-participation in these studies varied depending on the research areas or topics. A few common reasons reported by men were time constraints, inability to understand or cope with the study, and an

uncertainty over health examinations/studies. There was no particular study (to the best of the author's knowledge) reporting gender differences for non-participation among dental professional studies.

4.5.1.1 Oral cancer risk factor assessment and preventive interventions

As behaviour change is essential for the prevention of a disease and health promotion, the Behaviour Change Wheel's COM-B model is significant to all healthcare professionals. This model was used in this study to identify barriers (and facilitators) to implementing best practice preventive intervention in dental practices. The reliability of the Behaviour Change Wheel was examined by Michie et al. (2011) in two important public health domains of behaviour change: tobacco control and obesity. This was tested to describe interventions within the *English Department of Health's 2010* tobacco control strategy (DoH, 2010) and the *National Institute of Health and Clinical Excellence's* guidance on reducing obesity (NICE, 2006b). Another study by Cane et al. (2012) refined and tested the validity of the "Theoretical Domains Framework" and provided a system for theoretically assessing implementation problems, along with other health-related behaviours in order to inform intervention development. The 14 theoretical domains were independently mapped against the COM-B components in order to assist intervention designers in designing effective behaviour change interventions (Cane et al., 2012). In this study, the Behaviour Change Wheel was used systematically to determine intervention functions necessary to best overcome existing barriers (Michie et al., 2011; Cane et al., 2012) (Section 4.5.2).

The findings from this study are that there are fewer barriers in giving smoking (or tobacco use) advice relative to alcohol advice. This concurs with previous studies where advice against tobacco use was considered appropriate in a dental setting, while dental professionals were reluctant to enquire about alcohol use and give advice on alcohol moderation (Warnakulasuriya and Johnson, 1999; Cruz et al., 2005; Shepherd et al., 2010; McAuley et al., 2011).

Lack of knowledge or confidence for providing face-to-face behavioural preventive interventions for reducing alcohol consumption was reported by most dental professionals in this study. This finding is consistent with other studies,

which also reported a lack of knowledge regarding best approaches (advice and referral) to help patients reduce heavy drinking (Dyer and Robinson, 2006b; Neff et al., 2013), and lack of confidence when discussing alcohol (Dyer and Robinson, 2006b; Shepherd et al., 2010). These studies also reported insufficient personal skills in delivering alcohol interventions by dental professionals in primary care dental practices.

The results from this study confirm the link between knowledge or confidence to inadequate training, perception of poor efficiency, disruption of the dentist-patient relationship, and awkwardness or perceived problems with relevance to the clinical situation (Macpherson et al., 2003; Dyer and Robinson, 2006b; Shepherd et al., 2010; McAuley et al., 2011). However, regarding smoking cessation, a lack of knowledge of local referral system and low perceived efficacy has been reported in few studies (Edwards et al., 2006).

Younger dental professionals in this study were more confident in discussing patients' smoking and drinking behaviours compared to more senior professionals and even recognised it as their job or role. However, again a lack of knowledge was reported regarding local referral pathways (for both smoking and alcohol). These findings have been supported elsewhere, where newer dental graduates reported recording patients' smoking status more routinely and believed that clinicians' advice and NRT were effective in promoting smoking cessation (John et al., 1997). A further study reported that undergraduate dental students felt that they had sufficient knowledge regarding oral cancer prevention and early detection, and that they reported providing advice to patients regarding oral cancer risk factors after graduation (Carter and Ogden, 2007).

Physical (resource) opportunity was raised as a major issue in all dental professional interviews in delivering preventive interventions in primary care dental practices. The results are in agreement with several other studies, where lack of time and lack of incentive/remuneration were reported as important barriers to providing preventive advice in dental practices. Lack of time was an important concern regarding implementation of preventive interventions in primary care dental practice that has been reported in many studies

(Macpherson et al., 2003; Dyer and Robinson, 2006b; McAuley et al., 2011; Neff et al., 2013). Lack of proper reimbursement or funding to offer these services has been an important issue reported in several dental studies (Cruz et al., 2005; Dyer and Robinson, 2006b; McAuley et al., 2011).

The findings from this study suggested that lack of time was more of an issue in NHS dental practices compared to private practices. Similar findings had been reported in another study by Csikar et al. (2009), which explored the differences in the health promotion and smoking cessation activities between NHS-orientated and more privately-orientated dental practices. They reported that dental practitioners from the NHS-orientated practices were more likely to cite 'lack of time', 'no incentive' and 'lack of expertise' as potential barriers to providing health promotion advice (Csikar et al., 2009). However, results in this study differed in terms of lack of incentive/funding and lack of training, which were cited as potential barriers by both NHS and private practice dental professionals. Moreover, remuneration to include preventive interventions was more of an issue reported by private practitioners, and lack of training to deliver preventive interventions was reported by both NHS and private practice practitioners.

Lack of training to assist patients in quitting tobacco use (smoking and smokeless tobacco) has been reported by dental professionals in various studies in the last two to three decades (Schroeder and Heisel, 1992; Hastreiter et al., 1994; Warnakulasuriya and Johnson, 1999; Macpherson et al., 2003; Cruz et al., 2005). Again, lack of training was the main barrier limiting dental professionals' involvement in providing alcohol advice which has been reported in number of studies (Warnakulasuriya and Johnson, 1999; Macpherson et al., 2003; Cruz et al., 2005; Shepherd et al., 2010; McAuley et al., 2011). As reported in findings from this study, most dental professionals were motivated towards receiving training to provide preventive interventions (brief advice and referral) for smoking cessation and reducing alcohol consumption in patients attending primary care dental practices. Studies have shown the effectiveness of training dental professionals to deliver effective smoking cessation interventions (Wood et al., 1997; Gould et al., 1998; Binnie et al., 2007). These studies showed that after receiving training a significant increase was reported in the number of

dental professionals who started assisting patients with stopping tobacco use. In addition, dental professionals also reported a significant improvement in their confidence after training. Similar positive impact of training dental professionals had been reported in a pilot study by Awojobi et al. (2016), by reducing perceived barriers, increasing self-efficacy, and increasing oral cancer discussions between dentists and patients (Awojobi et al., 2016).

Regarding training to deliver alcohol interventions in primary care dental practices, Ntouva and colleagues (2018) recently assessed a brief alcohol advice training programme designed and tailored specifically to the needs of NHS general dental practitioners. The programme comprised of two half-day (a total of 8 hour) highly interactive sessions, including exercises, role-plays, training manuals and other resources for use in the practice. The results were encouraging, showing a significant improvement in knowledge, attitudes and confidence of NHS dentists towards alcohol screening and delivering brief advice. The study established that dental professionals can be trained with the relevant knowledge, attitudes and confidence needed to deliver alcohol screening and brief advice to patients (Ntouva et al., 2018). However, future research is needed to evaluate its effectiveness and cost-effectiveness. This training programme was part of a feasibility randomised controlled trial (Dental Alcohol Reduction Trial – DART) which aimed to "assess the acceptability and practicality of an alcohol brief advice intervention delivered in primary dental practices across North London, UK" (Ntouva et al., 2015). The trial was successfully completed, though results are yet to be published (Cato, 2016).

Moreover, a study by Roked and colleagues (2014) suggested replacing the alcohol units question on the medical history form in a dental setting with a single item screening instrument - Modified-Single Alcohol Screening Question (M-SASQ): "How often do you have eight or more standard drinks if male, or six or more standard drinks if female, on one occasion?" This screening instrument has demonstrated to be an effective, reliable and valid tool that could be used quickly in busy healthcare settings (Roked et al., 2014).

4.5.1.2 Oral cancer risk prediction tool

Risk prediction tools are available to predict risk of future cancer incidence for a range of cancer sites (for example: breast, lung, prostate, colorectal cancer, etc.), for effective risk communication, and to identify asymptomatic individuals who are at higher risk of developing cancer (Usher-Smith et al., 2015). The development of cancer risk assessment tools (RATs) is one of the initiatives in England that aims to support primary care professionals to identify and quantify the risk of cancer in primary care patients (Green et al., 2014). The tool is currently available for fifteen cancer sites (common cancers that are presented to primary care). The RATs were perceived as beneficial by general medical practitioners in a study by Green et al. (2014), exploring their views for incorporating the RATs for lung and bowel cancers into their clinical practice. The tools were perceived by general practitioners as additive to their skills sets and appreciated as an instructive tool, but not to supersede their clinical judgement. Moreover, offering adequate training and support packages was highlighted as a key factor for successful implementation of the RATs (Green et al., 2014). This thesis, albeit a small study with dental professionals and patients (Chapter 5), explored the barriers/facilitators and feasible options for having an oral cancer risk assessment/prediction tool in primary care dental practice and found these not insurmountable; future research is needed to establish an intervention/tool adapting suggestions from dental professional interviews, and further research to assess its effectiveness and cost-effectiveness.

4.5.2 Implications for practice

Table 4.6 shows how the identification of specific barriers and facilitators is theoretically mapped to a set of intervention functions to explore each target behaviour (based on general theory-based intervention - Table 4.1 in the Section 4.3.8). For example, what needs to be addressed or changed (barriers) and what needs to be enhanced or reinforced (facilitators) at the personal level and/or in the environment to attain the desired change in behaviour.

Table 4.6: Identifying intervention functions from COM-B Model and Behaviour Change Wheel (activities designed to change behaviours)

		Intervention functions								
		Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
COM-B components	Physical capability									
	Psychological capability					■				
	Physical opportunity									■
	Social opportunity							■		■
	Automatic motivation									
	Reflective motivation	■		■						

The greyed (shaded) squares highlight where "evidence or consensus suggests that a function may be effective for addressing a particular behavioural determinant" (Michie et al., 2011; Barker et al., 2016).

From the dental professional interviews, it was identified that: physical opportunity, social opportunity, and reflective motivation were raised as having most potential for addressing in order to implement best practice for oral cancer risk factor assessment and prevention. The intervention functions which are potentially relevant in bringing about the desired behaviour change based on issues identified by dental professionals are greyed (or shaded) in Table 4.6 and are:

- Incentivisation in the form of CPD credits or "Quality and Outcomes Framework" payments (Leech, 2009) linked to "good practice" in delivering preventive interventions in dental practices. This would address the most fundamental issue, i.e. resources, and in turn dental professional motivation. The "Quality and Outcomes Framework" was a general practitioner payment model for delivering interventions such as smoking. It was criticised in general medical practice as being more process than outcome driven and has since been changed (Gillam, 2010; Gillam et al., 2012). But this model might work better in a dental practice setting which is more driven by activity (DoH, 2016).

- Educate dental professionals by providing more information on the best approaches of brief advice (in particular motivational or structured brief interventions for alcohol) and referrals (local referral pathways for both smoking and alcohol services). This would help to increase capability and overcome barriers in dental professionals' knowledge and understanding.

- Training dental professionals in delivering brief interventions for smoking and alcohol and overcoming social barriers. Training is recommended in evidence; modelling, for example, using actors to roleplay and showing examples of good practice could also be incorporated in training.

- Change the environment or context in which the preventive interventions are delivered, for example, assessing risk factors in the waiting room; considering which staff could deliver; use of online or e-assessment tools.

- Enablement strategies might include providing clear materials for enhancing referrals.

4.5.3 Strengths and limitations

4.5.3.1 Strengths

This study was based on a rigorous overview of the best practice evidence synthesised from systematic reviews and clinical guidelines (Chapter 3). Interview topic guides were created based on systematic overview findings. The study results will be valuable in informing and improving further the current practice on oral cancer risk factor assessment and prevention among dental professionals in primary care dental practices in Scotland and beyond. This would further help to design a pilot/trial to inform the development of an oral cancer prevention intervention package delivered by dental professionals in a primary care dental practice.

In-depth, semi-structured interviews used for data collection in this exploratory qualitative study, are interactive and tend to be flexible in nature, thus allowing for questions to be asked in an order most suited to the respondent, permitting responses to be fully explored and allowing the researcher to be receptive to significant issues raised spontaneously by the respondent (Ritchie et al., 2013). However, in-depth interviews are difficult to replicate and there are chances of interviews being subjective, i.e. there are concerns about impact of researcher's views and close relationship with respondents. Thus, researcher/interviewer needs to be skilled in order to avoid any influence on topic/data collection, as researcher is the main instrument of data collection (Kvale and Brinkmann, 2009). The principal researcher (author) in this study, had prior experience of conducting qualitative interviews, and received further training, conducted pilot interviews (Section 4.3.7) to gain valuable interview experience for succeeding dental professional interviews.

The principal researcher was able to reflect on each interview, as the data were collected over a period of time. A semi-structured topic guide was used, so interviews were guided by the principal researcher in real time and were not restricted to specific questions, and were quickly revised as new information

emerged. The principal researcher spent time after each interview reflecting on how well they have been conducted; personal reflections on the process; what it added to the body of the data; and any implications for future discussions, interviews, or analysis.

In-depth semi-structured interviews explored views of dental professionals from a range of dental practices. A range of views were obtained from: dental team members including dentists, dental hygienists/therapists, VTs; with a wide range of years of experience (younger and more experienced professionals); and range of socioeconomic status (SIMD) of the location of their dental practice. Thus, the knowledge generated might be transferable to other professionals or other settings, for example, findings replicable to primary care medical practice addressing these common risk factors (smoking and alcohol) for other major non-communicable diseases.

The coded data were double checked by one of the supervisors (AJR) and any coding discrepancies identified were solved by discussion among the principal researcher and supervisors. This ensured that a robust coding frame was developed in order to enrich qualitative analysis in this study, further ensuring accuracy, reliability and consistency of analysis. Moreover, reaching data saturation after seven interviews using a novel method (as described in Section 4.3.8.2) ensured the validity and robustness of study results.

4.5.3.2 Limitations

One of the key limitations of this study was that the topic guide was developed based on initial synthesis of the overview findings, however, the detailed overview synthesis continued even after the dental professional interviews were conducted. The interviews were conducted after initial overview synthesis due to the time constraints, considering this was a PhD project. This somewhat restricted further in-depth exploration of dental professional views based on the findings from robust overview synthesis. For example, assessing feasibility of longer brief or intensive interventions for smoking cessation in case of patients with tobacco dependence or for those patients who were not willing to go to cessation services. Future work would thus involve incorporating the in-depth

overview findings and exploring these in detail, again using the Behaviour Change Wheel.

Selection bias was another limitation, only professionals who agreed to participate in the interview and who could inform the aims of the research had a chance of being included in this study. The dental professionals included were only from the dental practices in the West of Scotland - due to the time and financial constraints it was not possible to spread across different locations in Scotland (out with West of Scotland). Moreover, dental nurses could have been included in the study, considering 'Extended Duty Dental Nurses' are taking important prevention role in patient care, for example in Childsmile (a national oral health improvement programme for children in Scotland) (O'Keefe, 2015). Although, as discussed earlier (Section 4.3.4), for small sample sizes (typically in studies using intensive qualitative methods), the bias from sampling based on selected criteria is less dangerous than the lack of precision introduced by probability samples (Deville, 1991).

This was a cross-sectional study, thus views expressed by dental professional were on that particular day. Thus, revisiting professionals at different time point to see if they express the same views would significantly strengthen the internal validity of the findings. Secondly, the participants were mostly experienced dental professionals (more than ten years of experience) and also there was a female domination (gender issues). Whilst this is not uncommon in studies of this type, it may limit the generalizability of the findings.

4.5.4 Chapter conclusions

Dental professional perspectives on barriers and facilitator in relation to implementing tobacco and alcohol behaviour change interventions in primary care were captured. The implementation barriers include lack of time and funding/remuneration for providing behavioural preventive interventions in primary care dental practice setting. The facilitators reported included: defining and specifying the content and approach of very brief / brief interventions, receiving training to deliver behavioural interventions, and having good supportive information resources. The dental team reported that patient

attitudes, the perception of causing offence, and awkwardness / embarrassment, and relevance to topic were more of an issue while discussing alcohol drinking behaviour rather than smoking. Although this qualitative study focused on Scotland, the arguments made, and principles described can be applied to other parts of the UK and beyond.

In addition to these dental professional perspectives, the patient views are required to more fully understand the implementation and feasibility challenges.

Chapter 5 Patient views on implementation of best practice oral cancer prevention in primary care dental practices in Scotland

5.1 Introduction

A short qualitative survey, utilising both open and closed questions, was conducted with patients attending primary care dental practices in Scotland, with the aim of exploring patient's views on the acceptability of receiving oral cancer preventive interventions (including risk factor assessment, advice, and/or referral) delivered by dental professionals, and comparing / contrasting views with the dental professionals' responses.

The burden of treatment costs means that preventive measures, including primary prevention, are likely to be of considerable global interest going forward (D'souza and Addepalli, 2018). Involving patient perspectives is vital; it is known for example that there are barriers in terms of the connections patients make between smoking, cancer and health, and up to a third of patients smoke even after a head and neck cancer diagnosis (Abdelrahim et al., 2018). Prior studies have explored patient/public knowledge and awareness of oral cancer, including its causes, early signs, screening or examinations (Warnakulasuriya et al., 1999; Humphris and Field, 2004; West et al., 2006; Awojobi et al., 2012). These studies reported a general lack of awareness about oral cancer, associated risks and early signs of oral cancer. Awareness was found to be even lower in individuals who were at higher risk as a result of their behaviour (for example, smokers and those with excessive alcohol consumption) (Humphris and Field, 2004; West et al., 2006). However, none of the studies, to the best of the author's knowledge, have explored patient perceptions, attitudes, and experiences in relation to preventive interventions (including assessment, advice, and/or referral) in a primary care dental practice setting. Thus, this study aimed to address this issue by ensuring the patient perspective is considered in any future evidence-based preventive intervention.

5.2 Aims and research questions

The main aims of this study were:

a) to examine the views of patients attending primary care dental practices in Scotland on the acceptability of oral cancer risk factor assessment and subsequent behavioural preventive interventions delivered by dental professionals in practice;

b) to compare and contrast the views of patients and dental professionals (Chapter 4) in relation to implementing oral cancer risk factor assessment and prevention in primary care dental practice in Scotland; and

c) to make recommendations to inform the development of an evidence-based oral cancer prevention intervention delivered by dental professionals in primary care dental practice.

As with the dental professional interview study (Chapter 4), a supplementary aim under the above was to explore the views of patients on the specific merits/demerits of oral cancer risk prediction tools.

Specific objectives were to:

- Recruit patients attending primary care dental practices to participate in an interview
- Develop a theory-based, survey instrument (incorporating open-ended and closed-ended (scale) questions)
- Explore patients' history, knowledge and awareness of oral cancer risk factor assessment and prevention
- Gather views on the feasibility (barriers and facilitators) of implementing the synthesised evidence-base, and on potential interventions to support patient care

- Compare and contrast views reported by patients and dental professionals
- Gather views on risk prediction tools

These objectives were developed in order to address the following broad research questions for this study:

a) What are patients' experiences of previous and current practices in relation to oral cancer risk factor assessment and behavioural prevention (advice and/or referrals) in primary care dental practices in Scotland?

b) What are patients' level of knowledge and understanding in relation to oral cancer risks and prevention?

c) What are the patient-related barriers and facilitators (for example: views, attitudes, expectations, motivations, practical concerns) to implementing oral cancer risk factor assessment and prevention in primary care dental practices?

d) What are the differences and similarities in barriers/ facilitators to implementing oral cancer risk factor assessment and prevention reported by patients and dental professionals?

e) What are the suggestions/recommendations from patients to inform the development of prevention interventions for oral cancer to be delivered by dental professionals in primary care?

f) What are patients' preferences in regard to having an oral cancer risk prediction tool in primary care dental practices?

5.3 Methods

5.3.1 Choice of method

This study was a short qualitative survey of patients, undertaken to further explore the feasibility of translating the best practice evidence on oral cancer risk factor assessment to applied preventive interventions. The study design was exploratory and cross-sectional.

A short mixed survey method, incorporating fixed response and open ended questions, was deemed appropriate for this study as it allows for a) collection of broad information to get an overview about people's knowledge, attitudes, beliefs, and behaviour (Boynton and Greenhalgh, 2004) and b) exploration of views in a little more detail where necessary to further the aims and answer the research questions. Thus, a flexible, in-depth mode of interviewing (semi-structured face-to-face individual interview) was adopted alongside collection of structured data as in a more traditional questionnaire (Johnson and Turner, 2003; Kelley et al., 2003); the survey instrument contained both open-ended and closed-ended or scale questions (Appendix 12). Studies have shown that collecting quantitative data alongside qualitative responses is feasible and acceptable. Various studies have referred to this approach as "qualitative survey", "mixed methods data collection" or "mixed methods interview study" (Johnson and Turner, 2003; Teddlie and Tashakkori, 2009; Frels and Onwuegbuzie, 2013)(Jansen 2010). A study by Brannen (2005) provided several examples of research found in the literature and demonstrated how researchers developed, utilized and enhanced the different aspects of the research process (e.g. research plan; data collection; and data interpretation and contextualization) by incorporating such a multiple or mixed-method strategy. This mixed-method interviewing design provides pragmatic benefits when exploring complex research questions. For example, the qualitative responses help to explain or justify any contradictions in the structured survey responses and provide a check on understanding of the topic, while the aggregated or quantified overview indicates the general pattern of responses (Brannen, 2005).

An important practical consideration in this study was the sampling strategy and setting (see Section 5.3.4). Patients were recruited at the time of attendance at primary care dental practice. This meant that the window of opportunity for eliciting views was relatively short. In-depth interviewing would have meant a (smaller) group of patients being recruited and separate interview dates / locations being drawn up. It was decided that a slightly bigger sample, giving brief information open to some exploration, was optimal given tight financial and time restraints. It has been argued that this mixed-method design is most appropriate for studies that do not require either comprehensive/extensive analysis of qualitative data or multivariate analysis of quantitative data (Brannen, 2005; Driscoll et al., 2007).

5.3.2 Survey instrument

A mixed-methods survey instrument or topic guide was developed for conducting interviews with patients attending primary care dental practices in Scotland. There were no existing validated instruments that could have been employed directly for this study, so the instrument was developed (Appendix 12), guided by the research questions, and incorporating open-ended and closed-ended (scale) response items pragmatically (Johnson and Turner, 2003; Boynton and Greenhalgh, 2004). Fixed response answers were collated, and free-range responses were transcribed and coded after the fact. Both sets were then described in a narrative (thematic) analysis. The survey instrument was developed in consultation with experts in the field of behavioural science, dental public health and oral medicine, and the instrument was pilot tested before starting fieldwork. Oral cancer was referred to as “mouth cancer” in all patient interviews to facilitate lay understanding.

As established earlier in this thesis, tobacco and alcohol are the major risk factors for oral cancer (and also for other non-communicable diseases), and these two risk factors characterise the target population of the evidence-based interventions. Thus, patients were asked questions regarding preventive interventions under these two major headings (tobacco and alcohol).

5.3.3 Ethical approval

5.3.3.1 NHS

Full ethical approval was obtained from the National Health Service (NHS) Research Ethics Committee (REC) and the NHS Greater Glasgow & Clyde Research & Development (R&D) department for conducting patient interviews in Scotland.

Research Ethics Committee (REC) approval

The NHS REC application form, research protocol and supporting documentation were submitted for review through the Integrated Research Application System (IRAS). The Proportionate Review Sub-committee of the South Central - Berkshire B Research Ethics Committee reviewed the application and gave a favourable ethical opinion of the research on January 24th, 2017 (Appendix 13).

Research & Development (R&D) approval

NHS Research & Development (R&D) approval was also obtained from the Greater Glasgow & Clyde (GG&C) Health Board for conducting patient interviews in Scotland. It was decided that other health board approvals would be obtained if sufficient participants were not recruited from GG&C health board. R&D Management approval was obtained on January 26th, 2017, and the approval letter is appended in Appendix 14.

Site Setup workshop/training was received by the principal researcher on November 14th, 2017. This was required by NHS GG&C for researchers to maintain a study file for the research study requiring ethical and board approval. All the study documents were organised in a Site Setup Folder: soft copies in a "e-Site Setup Folder" on the University of Glasgow J drive, while all hard copies were kept in a secure filing drawer in the university office. It was agreed that all data would be stored anonymously, any identifiable data would not be stored on a laptop and all data would be stored for 10 years and then destroyed.

Research Passport

A site-specific form was also submitted to obtain "Letter of Access for Research", this was required as patient interviews were taking place on NHS premises. This was obtained on January 26th, 2017 (Appendix 15).

5.3.3.2 University of Glasgow

In addition to NHS REC and R&D approval, approvals were obtained from: University of Glasgow College of Medicine, Veterinary and Life Sciences ethics committee on January 25th, 2017 (Appendix 16), and Glasgow Dental Hospital and School Research Management Committee on February 2nd, 2017.

5.3.3.3 Ethical considerations

No conflicts of interest were identified in relation to this study. Data access and storage processes were as previously outlined in Section 4.3.3.

5.3.4 Sampling and participant recruitment

Sampling

This study was an exploratory study and involved a non-probabilistic, purposive sample with participants chosen based on their ability to inform the aims of the research, i.e. to allow barriers and facilitators to be explored to a comprehensive preventive approach in practice. The purposive sampling technique applied at the dental practice level was convenience sampling, while at the patient level opportunistic sampling was employed (Kemper et al., 2003; Palinkas et al., 2015).

Purposive (non-probabilistic) stratified sampling, as is common when qualitative methods (e.g. interviews) are used for data collection, is a trade-off between efficiency (recruiting people who can provide great detail of interest) and thoroughness (obtaining representation from those with different experiences, cultural backgrounds etc.) (Kelley et al., 2003). The convenience sampling to recruit dental practices (from where patients were accessed) helped to collect information from a range of settings that were easily accessible by the principal researcher. Patients from these dental practices were then recruited

opportunistically, a formal approach which takes advantage of circumstances, events and opportunities for data collection as they arise (Kemper et al., 2003; Palinkas et al., 2015).

Selection criteria (inclusion / exclusion)

All dental practices were NHS dental practices (two from the Public Dental Service and two from the General Dental Service) within the NHS GG&C health board area in Scotland. Inclusion criteria were: adult patients (18 years and above) attending dental practice; ability to understand information relevant to making an informed, voluntary decision to participate in research (i.e. provide written informed consent to take part in the interview on the same day of their dental appointment). Patients who could not speak or understand English, and those with significant oral disease (i.e. dental emergency appointment for pain, trauma, bleeding, etc.) or incapacity issues were not included in this study. One single included patient could not speak and understand English but was accompanied by her son who agreed to translate the discussion and thus facilitate the interview.

Patients were recruited opportunistically, but via a stratification frame to cover a range of participant characteristics (where possible) via screening of patient lists in the dental practices and/or asking screening questions (including asking if patients were happy to answer questions about tobacco and alcohol) to ascertain eligibility for the study:

a) Age- 18-60 years, and 60 and above (60+ years)
b) Gender- Male/Female
c) Range of tobacco/alcohol users
d) Range of area-based socioeconomic deprivation (SIMD) of the location of their dental practice
e) Range of patients' socioeconomic circumstances, i.e. SIMD of the location of their home residence.

Recruitment

Patients were approached through the practices of the dental professionals interviewed as part of the second study in this thesis (Chapter 4). Four dental practices were included in the NHS GG&C area in Scotland (which were located

across the range of SIMDs) and the aim was to interview 5-6 patients in each dental practice. Thus, in total 20-24 patient interviews were aimed for, to ensure a mix of participants in the final cohort, whilst being flexible in relation to the research questions under principles of data saturation. Here, a point is reached when no new themes emerge from analysis, and exhaustiveness in relation to the research questions can be assumed (Sandelowski, 2001; Guest et al., 2006). As the survey adopted a broadly qualitative mode of interviewing (i.e. using open-ended questions), the sample size needed was smaller than for a standard survey method with fixed responses. Sample size considerations did not apply as the aim was not to determine statistically significant differences, for example, between smokers and non-smokers; only descriptive statistics were collated to describe in narrative terms the participants pattern of scale responses (Section 5.3.7) (Kelley et al., 2003).

The dental practices were recruited where there was a separate private room available to interview patients. Dental teams were provided with the patient selection criteria, and were asked to screen lists of patients who had appointments on a selected day. Once patients met the selection criteria and agreed to be approached, staff introduced patients to the principal researcher in the waiting area.

All eligible patients were then approached and advised about the study and provided with the study information sheet outlining the aims and objectives of the study (Appendix 17). Patients were given 10 minutes to read the information sheet (this amount of time was decided in consultation with experts in the field and referring to previous approved projects with similar time to make a decision) and ask questions / discuss the project prior to taking part to ensure that they were fully informed about the study. Only the patient's approval to participate in the study was discussed in the waiting area, no other sensitive information was discussed here.

5.3.5 Data collection

The data were collected between February and March 2017. The study involved 15-20 minute semi-structured face-to-face individual interviews, with a number of closed-ended (scale) questions for descriptive purposes. All interviews were carried out before or after each patient's dental appointment time, in a separate private room at their dental practice. Participant's permission (written consent; Appendix 18) was taken to audio record the interviews. Participants recorded their responses for the closed-ended (scale) questions on a paper copy of the survey instrument.

Prior to beginning the interview, participants were assured by the principal researcher that their participation was entirely voluntary, and they were free to withdraw from the study at any time without giving any reason. Participants were informed that their responses would be confidential, and would not be shared with their dentist or any other health care professionals. The participants were also assured that the interview data would be anonymised and all the information which could identify the participants would be removed from the transcripts and survey instruments. Participants were assigned a unique code identifier at the onset of the interviews that was stored on a separate participant log. Participants were reassured that all personal information would be destroyed at the end of the study, and records would not be retained for longer than necessary.

During the interview, a supportive environment was created, so that participants could express their views freely. Interviews followed the survey instrument to ensure all the topics of interest were covered. Further questioning and discussions of emerging topics raised by patients was also employed where applicable. Discussions were facilitated by following the schedule, prompting for clarity or to facilitate understanding, directing responses back on topic, and by managing the pace of the discussions to fit the timescale. All patients had the opportunity at the end of the interview to add or discuss any additional points or issues not covered and participants were also asked to offer feedback about the interview. The principal researcher made written field notes immediately after each interview covering the main points that emerged during interviews, e.g.

general impression or personal reflections on the interview process; any inferences for future interviews or analysis; and what it added to the body of the data.

5.3.6 Pilot interviews

Practice interviews (and training) were conducted with two supervisors (AJR and DIC) in order to get feedback on the interview process, and to further develop/fine-tune the topic guide in response to any difficulties or omissions. Two pilot interviews were conducted prior to commencement of the fieldwork with: a) an experienced staff member working at the University of Glasgow Dental School; and with b) a dental student at the University of Glasgow Dental School (both of whom were registered as patients with a NHS General Dental Practitioner in Scotland). One of the participants was a 'smoker and regular alcohol drinker', while the other was a 'non-smoker and occasional alcohol drinker'; one of the participants was 50-60 years old, and the second between 20-30 years. The aim was to get feedback on the questions asked and to test the survey instrument. Subsequent reflections and feedback from the pilot participants and supervisor further guided some valuable changes to the survey instrument for succeeding interviews. For example, the sequence or order of questions asked was changed based on suggestions from the participants, who generally felt that the questions were acceptable, and were relevant to patients attending dental practices in Scotland.

5.3.7 Data analysis

The semi-structured interviews were audio-recorded, transcribed verbatim and transferred to computer files (as Microsoft Word 2016 documents) where they were dis-identified. The anonymized transcripts of the responses to the open-ended questions were then coded and organised into broad themes using thematic analysis techniques (Braun and Clarke, 2006) and facilitated by Qualitative Analysis Software NVivo version 11.0 (QSR, 2017). The responses to closed-ended (scale) questions were coded and added onto a Microsoft Excel 2016 workbook. Descriptive statistics (frequencies of responses), along with the simple graphics (bar charts/graphs) were used to present and describe the basic

features of the data. This included describing the sample, their knowledge, and their views and experiences of current/previous dental visits.

The transcripts were imported into the NVivo 11 software and were read over repetitively and at the same time the interview recordings were listened to again, in order to ensure accuracy and consistency of all transcripts. This also helped in becoming acquainted with the depth of the entire content in the data.

Tabulated responses to scale items are appended (Appendix 19). These are useful for illustration of patterned responses but due to small numbers should not be interpreted as conventional survey data. Results below are in thematic narrative form, drawing for illustration from either description of scale responses and/or quotations from the coded text data.

These themes were developed from the research questions and following analysis of the dental professional interviews, as well as allowing for emergent, data-driven themes which appeared inductively through the data (Braun and Clarke, 2006). As with the dental professional interviews, verbatim quotations were extracted and are included in the results as instances from the data, in order to:

a) illustrate key points;
b) provide evidence of identified themes within the data;
c) express the essence of the point being discussed.

5.4 Results

24 individual patient interviews were conducted across GG&C health board in Scotland between February and March 2017. The duration of the interviews ranged from 8 minutes to 22 minutes, with a mean duration of 14 minutes (which is slightly less than the 15-20-minute time that was proposed in the study protocol – Section 5.3.5).

5.4.1 Participant characteristics

Table 5.1 provides general information about the participants: age, gender, Scottish Index of Multiple Deprivation (SIMD) quintile of the location of their dental practice and of their home residence, occupation, ethnicity, tobacco/alcohol use and ID assigned to them for this study.

Table 5.1: Characteristics of study participants and coding used (n=24)

ID	Gender	Age (years)	SIMD16 Quintile (dental practice)	SIMD16 Quintile (patient residence)	Occupation (manual/ non-manual)	Ethnicity	Tobacco use	Alcohol use
P1	Male	27	1	1	manual	White Scottish	current smoker	drinker
P2	Female	36	1	2	not working	Asian Other (Arab)	non-smoker	non-drinker
P3	Male	41	1	2	not working	Asian Other (Arab)	non-smoker	non-drinker
P4	Male	37	1	5	non-manual	Asian Indian	ex-smoker	non-drinker
P5	Male	57	1	1	manual	White Scottish	ex-smoker	drinker
P6	Female	56	1	1	manual	White Other (Czech)	current smoker	non-drinker
P7	Female	72	1	1	not working	White Scottish	ex-smoker	non-drinker
P8	Female	27	1	1	manual	White Scottish	non-smoker	drinker
P9	Male	46	1	4	manual	White Scottish	ex-smoker	drinker
P10	Female	40	1	1	not working	Black Other (Italian)	ex-smoker	drinker
P11	Female	28	1	1	not working	White Scottish	current smoker	drinker
P12	Male	54	1	4	manual	White Scottish	ex-smoker	drinker
P13	Female	67	1	2	not working	White Scottish	current smoker	non-drinker
P14	Male	67	1	2	not working	White Scottish	ex-smoker	drinker

P15	Female	65	1	1	not working	White Irish	non-smoker	drinker
P16	Male	69	1	3	not working	White Scottish	non-smoker	non-drinker
P17	Female	44	5	3	not working	White Scottish	non-smoker	drinker
P18	Female	44	5	5	non-manual	White Other (Dutch)	non-smoker	drinker
P19	Male	34	5	5	non-manual	White Scottish	non-smoker	drinker
P20	Female	32	5	1	non-manual	African British	non-smoker	non-drinker
P21	Female	72	5	1	not working	White Scottish	non-smoker	non-drinker
P22	Female	32	5	2	non-manual	White Scottish	non-smoker	non-drinker
P23	Female	49	5	1	non-manual	White British	ex-smoker	drinker
P24	Female	65	5	4	not working	White Scottish	current smoker	drinker

It can be seen from the Table 5.1 that there was a mix of participants in this study, with a range of socio-demographic and behavioural characteristics. The male: female ratio of participants in this study was 3:5, while the ratio of participants based on age groups (18-60 years and 60+ years) was 17:7.

Number of visits to dental practices in the last five years

Most patients were regular attenders, reporting visiting dental practices at least twice a year in the last five years (specific responses are appended in Appendix 19).

Females reported visiting dental practices more often compared to male patients. All patients aged 60+ years reported visiting dental practices twice a year or more, while the number of visits for patients aged 18-60 years was more variable. The main reasons reported for visiting dental practice were: receiving basic dental services such as check-up; pain or emergency; scaling/polishing; cavity fillings; tooth extractions; and follow-up appointments. Some patients also reported visiting dental practice for major dental services such as root canal treatment and dental implants.

5.4.2 Patient awareness and knowledge of oral cancer and its causes

The main theme that emerged with regards to the background knowledge and awareness of the sample is that patients are aware of oral cancer, but do not generally consider themselves knowledgeable on the topic.

Almost all patients (22/24; 92%) said that they had heard (or were aware) of oral cancer, while only two patients (2/24; 8%) stated that they had not heard of it at all (Appendix 19). When asked how much knowledge they had about oral cancer and its causes, the majority of the patients (20/24; 83%) reported having a “slight/little” or “some knowledge”. Only two patients (2/24; 8%) reported having a “good knowledge” of the causes for oral cancer (one male and one female; both aged 18-60 years), while, on the other hand, two patients (2/24; 8%) reported having “no knowledge” at all (both female; 18-60 years; see Appendix 19). There was little difference in the knowledge levels reported across gender and age groups.

With respect to causes, coded responses showed smoking had a much higher profile than other risk factors:

> "Would it be smoking that would be something to do with it? But, that's all, that's all I would know" (P15)

> "Smoking, maybe" (P16)

> "Well I thought a risk, you know, was smoking." (P18)

Beyond smoking, there was a tendency to be uncertain:

> "Is it basically just your oral hygiene, I'm guessing maybe, or part of that? I'm not too sure, to be honest" (P8)

Importantly, none of the patients reported that their dental team had ever spoken to them about oral cancer or mentioned it in any of their conversations:

> "No I've never, I don't think so not that I can recall." (P1)

The general awareness seems to stem from exposure to media sources (for example: newspapers, television, magazines) and friends/family members having the disease:

> "Two people I know have, somebody had it on their tongue and somebody had it at the back of their throat" (P15)

> "Just probably social media, I suppose; the newspapers" (P16)

> "Media… well usually famous actors who died from it *[…]* And a neighbour a few doors down recently died of throat cancer." (P18)

5.4.3 Patient views and experiences of oral cancer risk factor assessment and preventive interventions

The main aim of this study was to gather information from patients on primary prevention in practice, with research questions targeting their previous experiences, barriers and enablers to engagement with prevention, concordance with dental professional views, and suggestions for implementation of the evidence-base.

Four major thematic narratives emerged from this patient survey after analysis:

1) Patients are open to being asked questions, and to exploring ways to give information to dental professionals using various assessment tools, times and locations, which may potentially overcome some resource barriers to the preventive consultation in practice

2) Patients are generally happier to receive advice on risk factors than professionals may assume; this applies in particular to alcohol assessment and advice where professionals felt a strong socially normative barrier

3) Advice must be tailored to patient need and motivational stage, as is recognised in evidence; professionals are not necessarily trained and confident in this regard

4) Patients on the whole are happy to discuss risk specifically in relation to oral cancer; again this offers a perspective on professional interviews, where using direct cancer terminology was deemed more problematic

5) Patients reported very little experience of referral or signposting to other services.

5.4.3.1 Asking and assessing risk

Dental professionals (Chapter 4) saw smoking and alcohol questions as equally embedded in the medical/social history forms that patients self-complete at the time of their first visit to the dental practice. Some patients outlined this:

> "Just from the medical history, so that mentions about it" (P4)

> "Yeah, again, it was more when I first registered… they just asked me, how often and how many units would you drink each time" (P8)

Most patients (19/24; 79%) recalled being asked about their smoking status by the dental team. Patients said they were asked questions about their smoking in the medical/social history form they filled in at the time of their first visit to the dental practice (which is best practice - Chapter 3; and also reported by dental professionals to be done routinely - Chapter 4). However, on being asked if the dental team ever asked patients about their alcohol drinking, only half of the patients (12/24; 50%) reported being asked questions about their drinking habit in the medical/social history form they filled in at the time of their first visit to the dental practice.

As previously outlined, one aim of this study was to explore patients' views on having a dedicated oral cancer risk prediction tool in primary care that would make the combined risk of smoking and alcohol explicit (the details of such scoring have been presented in Chapter 4 together with views of dental professionals; Section 4.4.3).

On being asked for their views on having a risk score / categorisation for predicting oral cancer risk, based on their personal information (for example: smoking, alcohol, age, years of education, family history) - most patients thought this might be helpful in increasing awareness among people and helping people at high-risk to take early steps to prevent the condition. On a happiness scale (Appendix 19), the majority of patients (20/24; 83%) were happy (or very happy) to receive such a score. The remainder said:

> "I wouldn't say that I would be happy, but I wouldn't be like not happy. I wouldn't be over sure either because it is a good thing. I would say in between not sure and happy." (P1)

> "I don't want to know so I am not happy about it." (P6)

Some of the barriers reported to receiving an oral cancer risk score (as high, medium or low) were: they did not want to receive any "bad news"; did not

want their insurance companies to know about their risk scores; or uncertainty as to what would be done with that risk score.

> "Oh no… if they say I may (high risk), then I don't want any bad news." (P10)

> "Well, yeah, risk scores, I would want to know if it's just for your awareness, but I wouldn't want the insurance companies to know. What gets done with this information if you get the risk score and it gets written down in your…does that mean that…?" (P18)

Similar ambiguity had been raised by some dental professionals, where they suggested that they would require formal training to answer questions like: how this risk score is going to affect their patient?; where patients go from there?; what they do with that written score? Dental professionals also cited that they need to be prepared (or trained) to advise those patients who got a high-risk score "without frightening them" (Section 4.4.3).

Patients were asked for their preferences for how they might provide the personal information to calculate the oral cancer risk score. Examples included: self-completion in waiting room, dental professionals going over with patients during their oral health assessment, an online tool or as a mobile application (app.), or as a paper questionnaire. Mixed responses were received. Some patients were happy for their dental professionals to ask these details, as they were "fed up" with filling out forms or questionnaires:

> "Yeah, just the dental team to ask it, yeah… Well, you fill forms out for everything. People get fed up with it." (P24)

> "It's probably dentist. It would be easier and quicker for me than…'cause I've got little time as it is." (P12)

But most patients were happy to self-complete on computer or a paper form in the waiting room, or were happy both ways:

> "I think I'd be alright doing it myself *[…]* you can be more honest when you're sitting writing yourself. You've not got anyone watching you." (P1)

> "Yes, that's better (self-completion), because I can read it two times or three times and understand everything" (P3)

> "I'm open to both of them, no preference." (P4)

Self-completing information was desirable for some because they would feel under pressure if the dental team was watching them; having a personal space to provide information would help them to understand questions properly and provide "honest" answers. This finding coincides with dental professional interviews (Section 4.4.3), where self-completion of information by patients was considered the best option by most professionals, and perhaps surprisingly almost identical reasons were reported by dental professionals as well, i.e. patients feeling under pressure with the dentist looking at what they were answering or more comfortable providing such information confidentially.

When patients were further asked about their preference on the mode of presentation of a risk score, for example: traffic light (red/amber/green) or high/medium/low or as a number or percentage score - again mixed responses were received. There was a slight preference (10/24; 42%) towards receiving a risk score as "high, medium and low"; the reason reported was that it was much easier to understand compared to a number or percentage or traffic light system:

> "I think high, medium low is better, I think that's (number/percentage) more difficult to calculate." (P4)

> "I would think high, medium or low would be better. I think it's simplified. You're either high, medium or you're low based on this… as well but that's the way I'd prefer it I think." (P12)

> "if they give you a red card…I don't know if I'm getting the traffic light, but I understand high, medium and low." (P18)

Some patients (8/24; 33%) preferred to receive the score as a number or percentage, as it would provide an "accurate view" of how close people are to developing a condition or how serious their present situation is:

> "I'd say the number… Aye because high, medium and low that's just three options it's not giving you an accurate view of how close you are but if they give you a number say you have sixteen percent chance or something." (P1)

> "It is better giving me percentage... Because sometimes maybe by using red, yellow, you will not understand exactly what is really there." (P10)

While the remaining patients (6/24; 25%) preferred to receive risk score as a traffic light (red/amber/green):

> "Traffic lights, aye. I don't know, just it's easier." (P11)

> "The traffic light is better probably. It just, it's in your face, you can see it." (P15)

Overall, as with dental professional responses (Section 4.4.3), there was agreement that the way in which any such risk score is provided should be easy to understand by the patients and quick to calculate in order to save patients time. Finally, both professionals and patients mentioned accuracy/ reliability of behavioural risk factor reporting or assessment. Research would be needed as to whether a more formal scoring type tool might help in this regard.

5.4.3.2 Advising and referring

Smoking

In terms of smoking advice, current and ex-smokers (n=13) were prompted as to whether their dental team ever offered advice/counselling on quitting smoking (including context, for example, mouth cancer, gum disease, staining, or other). In a perhaps surprisingly low level, about a third (4/13; 31%) of patients said that their dental team had encouraged quitting and/or talked about the harmful effects of smoking on their oral health. Advice was said to be brief (lasted a couple of minutes):

> "Aye we spoke about it while they were doing the work. They told me that my gums were due to the smoking as well as the Irn Bru." (P1)

> "It was just basically to stop smoking, that it's not good for you, type thing… just general advice […] it was only a couple of minutes. When he was doing the check-up he basically said, you know, I need to stop smoking." (P12)

> "because I smoke, and they're (dentists) always on your back…to stop smoking." (P24)

This finding that most current smokers did not report receiving brief advice, contrasts with the dental professional interviews (Section 4.4.1) where most dental professionals reported asking smokers about their willingness to stop smoking and undertook "signposting", such as providing them with quit-line

numbers. The very fact that this picture is inconsistent (patient did not recall advice and signposting), might be indicative of the somewhat variable approach to oral cancer prevention in practice.

Patients were further asked for their views in terms of how happy they would be receiving brief advice (up to 5 minutes duration) from their dental team about quitting smoking (Appendix 19). Mixed responses were received from the small number of current smokers, making it difficult to come to any firm conclusion. Three out of five were happy to receive advice from their dental team, and reported no barrier to this advice:

> "I would say as part of the consultation and it saves you going somewhere else… Well they're (dental team) doing everything else to your teeth why not that as well." (P1)

> "I would be happy with that… I just think anything…like, a professional person giving you advice, you should listen to it, no matter if it's a dentist or a doctor or whatever. If they're going to give you the advice, you should listen." (P12)

> "'cause obviously if it's affecting your mouth they (dentist) should be telling you" (P13).

The other two current smokers were either not sure or not happy to receive such advice from their dental team:

> "Not happy at all, no… And I would consider it disturbing because I know the risks of smoking, but I am not going to give up." (P6)

> "Not sure… Well, I prefer my GP, to talk to my GP about it." (P24)

Patients in general showed slightly more inclination towards receiving smoking advice from their general medical practitioner or pharmacist compared to from the dental team (Appendix 19). Trust emerged as an issue - one patient said that as they had known their general medical practitioner or pharmacist for a long time, they would be more comfortable sharing personal information with them:

> "My GP or pharmacist… Well, I prefer my GP *[…]* I've known him for years, and I trust him" (P24)

These patients reported more regular visits to medical practices and pharmacies compared to dental check-up frequencies:

> "Chemist… I don't know, because I'm usually at the chemist back and forward for my gran, medication and that, aye, health *[…]* and I just feel as if, I don't know, I don't wait as long" (P11)

A related finding was reported in some dental professional interviews (Section 4.4.1), where it was presumed that patients will consider discussing smoking (to some extent) irrelevant to dentistry or their oral health, and thus prefer discussing it with their general medical practitioner or pharmacists. However, patients were happy to receive advice from their dental team as well; they acknowledged that if smoking is affecting their oral health then the dental team should be advising about it.

Patients were generally sceptical about the effect brief intervention could have. The evidence-base is that they do work, but patients took an individualistic, self-motivational view:

> "It's up to yourself if you're going to stop or not and nobody else can make you, it's all to do with you." (P1)

> "It's up to the person themselves, do you know what I mean? It's a lot of willpower, you know, it's your own willpower *[…]* So you've got to be determined, you've got to want to do it." (P7)

> "I decided it's because my first daughter was born 2005, so before she was born I decided to stop and I stopped myself, nobody advised." (P10)

> "No, when I stopped smoking I did it myself." (P14)

This probably reflects a societal discourse that views smoking in particular as an addiction and persistent relapse as inevitable:

> "I have quit quite a few times. I stopped for six months once and then I just walked by somebody smoking and the smell got to me and that was it, I was smoking again." (P1)

Again, discussing patients' smoking was considered quite a "sensitive" topic by most dental professionals, but this was not echoed by patients. The thematic narrative in this study was more that patients already had knowledge of smoking

being undesirable (risk of continuing, benefit of stopping) and that dental professionals couldn't add much to this:

> "Well I already know the benefits and all that and you see it everywhere." (P1)

> "I probably know it all anyway, 'cause you see it on the TV all the time." (P5)

> "I know the risks of smoking…" (P6)

In terms of adjunct materials and referrals, patients as might be expected, were favourably disposed to receiving informational or educational materials such as posters or leaflets. These are evidenced weak (no effect sizes reported) as adjunctive to brief tailored advice/ counselling. There does not appear to be any downside to this, however, one smoker mentioned not fully engaging with the material:

> "Oh aye, not last week but the week before I ended up walking out with a book full of stuff on stopping smoking, the effects of pH that stuff through water and all that. There was quite a few things, I didn't actually read through it all to be honest." (P1)

None of this small group of patients had any experience of being referred to specialist services via their dental team regarding smoking cessation. Dental teams, on the other hand, did mention "signposting" via quit-line numbers - it may simply be that the small number of patients in this study with smoking experience do not see this as "being referred".

Alcohol

Current alcohol drinkers were further probed by being asked if their dental team ever offered advice/counselling on reducing alcohol consumption (including context, for example, mouth cancer, gum disease, trauma, or other). This finding was clearer - no patients (one patient was 'not sure') reported that they were ever offered any advice (or referral) on alcohol by their dental team.

> "No, they just asked, do you drink?" (P1)

> "No… they didn't ask anything" (P3)

"No, not really." (P12)

These findings synchronize with the dental professional interviews where providing preventive interventions (advice and referral) for reducing alcohol consumption was seen as a problematic issue by most dental professionals (Section 4.4.2).

Most patients said they were happy to receive brief advice of up to 5 minutes from their dental team about reducing alcohol consumption. In fact, the overall impression from most patients was that they were happy to receive advice from any healthcare professional, and especially if drinking more than recommended levels and advice helps to improve their health. Patients were further probed on a happiness scale to assess their acceptance for receiving brief alcohol advice (up to 5 minutes duration) from the dental team (Appendix 19). Most current drinkers (11/14; 79%) were happy (or very happy) to receive brief advice up to 5 minutes from their dental team about reducing alcohol consumption:

"I would say as part of the consultation (dental) and it saves you going somewhere else… Well they're doing everything else to your teeth why not that as well." (P1)

"Aye, I wouldn't have a problem with that… I'd be happy" (P5)

"I've not got a problem with the dental team." (P9)

"I prefer anyone that can give me good advice for my health is okay by me." (P10)

This contrasts with the dental professional view that patients are less happy or comfortable overall in discussing their drinking behaviour with the dental team (Section 4.4.2). This acceptance of the norm by patients seems, in part, to be due to exposure to safe drinking messages:

"Well I already know the benefits and all that and you see it everywhere." (P1)

"I probably know it all anyway, 'cause you see it on the TV all the time. So many units you're allowed each day…sorry, each week, a man or a woman or whatever." (P5)

However, the barriers that dentists alluded to were certainly present. Dental professionals felt that patients would consider discussing alcohol to be irrelevant in the context of oral health, and thus might prefer discussing it with their general medical practitioner or pharmacists. Some patients seemed to echo the dentists' concern about whether this was part of their professional role:

> "I don't know if that sounds silly but with your dentist you just think your teeth, you don't think alcohol and things like that." (P8)

> "I wouldn't personally go and speak to a dentist about any problems I had, kind of, thing." (P5)

Again, as with smoking, there was slightly more patient inclination (8/14; 57%) towards receiving alcohol advice from their general medical practitioner or pharmacists compared to the dental team. When asked the reason for their preference for receiving advice from a medical practitioner, as with smoking, patients said that they were more comfortable talking about such personal topics with their general medical practitioner. Some patients also mentioned that they don't relate discussing alcohol with their dental or oral health.

> "Probably your GP would probably…the best person to tell you more or less, not the dentist I think… it's more a personal thing. Not your dentist, kind of thing. 'Cause you can go to your GP and tell them things." (P5)

> "I don't know if that sounds silly but with your dentist you just think your teeth, you don't think alcohol and things like that." (P8)

Dental professionals were also aware of the sensitivity of discussing patients' behaviours on common risk factors and the effect it may have on the dentist-patient relationship. Patients independently talked about this rapport, and how it could be damaged, especially with generally "responsible" patients:

> "You know, because certain sections of society, they need to be told over and over and over again. But… within people who are more responsible, if it's at a manageable level, there's…I don't think there's any point. I think they would lose the rapport with the patient. They could damage that even if they were to impress it too much […] it doesn't sound like the dentist cares. It would more sound like they're just having to read it because it's part of their job." (P19)

Cultural barriers were reported to a lesser extent. One patient (self-reported Arab ethnicity) reported not being asked questions about alcohol, because the dental team understands that alcohol is "forbidden" in their country.

> "No, they don't ask this (alcohol) question, because it is forbidden… in our country." (P2)

This cultural sensitivity needs to be incorporated in any generic guidance (Chapter 6).

In general, patient views endorse the evidence-based principle that advice should be 'tailored' to individuals and their needs and/or motivational stages. Patients are unlikely to accept advice, for example, until their self-perception is that they are at risk (a more formal assessment tool may help in this regard):

> "I don't really drink that much to tell you the truth" (P12)

5.4.3.3 Making oral cancer the focus

Importantly, patients were happy for their dental professionals to discuss oral cancer risks with them, in particular, verbalising or using the term "oral cancer" in discussions. There was a motivation to learn about oral cancer risks and signs/symptoms (see above section on risk prediction); this can be contrasted with how most dental professionals reported avoiding the term "cancer" due to the view that this 'scares' patients:

> "No it wouldn't scare me I would just think that at least they are double checking for you and making sure that you're alright. It wouldn't scare me, no." (P1)

> "I'd be happy with it *[…]* I'm open to, I'd rather know as not know what's going on in my body." (P15)

> "It wouldn't terrify me *[…]* I am happy… If there were any signs that they would…of it, they would make me aware of it." (P18)

5.4.4 Summary of the thematic comparison between patient and dental professional views

The main findings from the patient interviews regarding receiving preventive interventions (including risk factor assessment, advice, and/or referral) in primary care dental practice setting and comparison with the dental professional interviews (i.e. where their views matched or were different) are summarised in Table 5.2.

Table 5.2: Comparison of views of patients attending primary care dental practice with dental professional views (from Chapter 4)

Thematic narrative	Sub-theme	Dental professional view	Patient view (concurring with professionals; contrasting; mixed)	Implication
Patient openness to assessment	Alcohol assessment	Alcohol (as well as smoking) routinely asked about/ assessed as part of medical/social history forms or questionnaires	Contrasting: only 50% reported being asked about their drinking by the dental team in the medical/social history form.	Alcohol risk/ history taking visibility to be increased
	Formal risk tool	Open to exploring a formal risk assessment tool for oral cancer	Concurring: also open to exploring if no extra time/ cost	Best tool to be feasibility tested
	Self-completion of assessment tool	Desirable to give patients privacy and save time in consultation	Concurring: also felt less pressure if completing score alone	Form of tool administration to be tested
Patient reception of advice	Smoking advice	Structurally inhibited to very brief plus referral leaflets	Mixed: did not all recall such advice; were happy to receive brief advice; sceptical of effect	Explore optimal level of brief/very brief advice re evidence base
	Alcohol advice	Socially inhibited regarding sensitivity, cultural norms, professional role etc.	Mixed: most less inhibited than expected; some cultural sensitivity	Explore optimal level of brief/very brief advice re evidence base; incorporate cultural

				diversity
	Provider of advice	Feeling not professional role; some risk to relationship	Mixed: some felt general medical practitioner or pharmacist more suited	Explore multi-disciplinary cohesion
	Tailoring	Generally, a universal advice model	Contrasting: highly sensitive to individual motivation	Explore best way of tailored, motivationally nuanced advice
	Adjuncts	Barrier was lack of good supporting materials	Concurring: materials seen as welcome	Design best supporting materials
Focus on oral cancer	Using the term	Barrier was avoidance of the term due to perceived effect on patients.	Contrasting: most patients happy for dental team specifically verbalising the term "oral cancer" while discussing oral cancer risks.	Ask, advise, refer re major risk factors specifically in relation to cancer risk (see formal risk tool above)

5.4.5 Summary of findings

In summary, patients were successfully and ethically recruited to ascertain their views, in line with the study aims to produce recommendations for implementation of best practice and future interventions supporting preventive care. It could be seen from patient interviews that awareness of oral cancer in patients was high, but knowledge was reportedly low. Overall, patients were happy to talk specifically about oral cancer, and to be asked about the risk factors prior to receiving support and/or referral from their dental team (and/or general medical practitioner/pharmacists). Formal risk assessment was generally supported. However, they were still sceptical about the effect on some patients due to individual factors, perhaps because an evidence-based preventive

consultation, involving targeted assessment, tailored brief advice, adjunct materials, and referral, has not been their experience.

5.5 Discussion and conclusions

There now follows a short discussion of the main findings from the patient interviews, in the context of existing literature. The strengths and limitations of this study will also be discussed, and brief suggestions for implementing these findings in practice (see also Chapter 6).

5.5.1 Comparison with literature

This exploration of themes from 24 interviews with patients attending primary care dental practices in Scotland, examining their views and experiences on the acceptability of oral cancer preventive interventions (risk factor assessment, behavioural advice, and referral) delivered by dental professionals in primary care dental practices, would appear to be the most in-depth study to take this approach, specifically in relation to oral cancer prevention for both tobacco and alcohol. There is a plethora of evidence exploring patient awareness and knowledge levels in relation to oral cancer, early signs/symptoms and associated risk factors. However, only a few studies have reported the patient perspective towards receiving tobacco cessation or alcohol moderation advice in a primary care dental practice setting.

5.5.1.1 Knowledge and awareness of oral cancer

The findings from this study highlighted that, overall, patients were aware of oral cancer; however, knowledge of its risk factors was reportedly low. The level of awareness of oral cancer in this study is in agreement with the existing literature in the UK (and other countries) over the past two decades (Tomar and Logan, 2005; West et al., 2006; Choi et al., 2008; Amarasinghe et al., 2010; Awojobi et al., 2012). This increased awareness had been mainly linked to the mass media promotions or campaigns, for example, oral cancer awareness week. Prior studies have shown the importance of media campaigns along with messages from healthcare professionals (dentists or general medical practitioner) to be an important source to inform public about oral cancer and

its risks (Warnakulasuriya et al., 1999; West et al., 2006). Here, media (for example, newspapers, television, radio, magazines) was reported to be a major source for knowing about oral cancer and its causes. However, only one patient recalled their dentist or medical practitioner having mentioned oral cancer. This matches evidence from other studies in the UK and other countries (for example: United States, India) where mass media was cited as the most common source of information about oral cancer, and the contribution of dentists and other healthcare professionals to awareness levels was considered to be very low (West et al., 2006; Srikanth Reddy et al., 2012; Babiker et al., 2017).

Moreover, findings had been comparable in all prior studies (older and more recent) with respect to lower level of knowledge of risk factors associated with oral cancer. While smoking was recognized as a major risk by some patients in this study, the association between alcohol (and other factors) and oral cancer was known to only a few. Remarkably similar results have been reported in other studies in the UK (Bhatti et al., 1995; Warnakulasuriya et al., 1999; West et al., 2006; Awojobi et al., 2012), as well as studies conducted in other countries (for example: United States, India, Germany, Poland) where smoking was recognised by most patients as a risk factor for oral cancer (Horowitz et al., 1995; Raczkowska et al., 1997; Patton et al., 2004; Choi et al., 2008; Hertrampf et al., 2012; Srikanth Reddy et al., 2012; Formosa et al., 2015; Hassona et al., 2015; Shimpi et al., 2018). For example, West et al. (2006) reported that 84.7% of participants identified smoking as a risk factor, with the corresponding value for alcohol being 19.4%. Additionally the values reported by Hertrampf et al. (2012) were 75% for smoking and 40% for alcohol. This general lack of knowledge of alcohol as a risk factor in this thesis study and most other studies shows a clear need to engage directly with patients in: a) assessing risk; b) tying advice specifically to oral cancer; and c) providing good adjunctive materials (in particular for alcohol which was less associated with cancer than smoking).

5.5.1.2 Acceptability of oral cancer risk factor assessment and preventive interventions

The findings from this study showed that, patients were acceptable to learning about the role of smoking and alcohol as risk factors for oral cancer and were open to support from their dental team to reduce their risk of developing oral

cancer. However, patients were sceptical regarding the effectiveness of brief interventions due to individual differences, i.e. they did not expect intervention to be equally successful for all patients. This is not surprising, and may part explain why reported effect sizes (Chapter 3) are variable even when more intensive interventions are used, i.e. interventions only work for some patients. Moreover, the view from patients can be explained by the *Stages-of-Change* model (Chapter 1; Section 1.4.1.1), which recognises patients' individual factors and their readiness to make changes in lifestyle as important mediators (Prochaska and DiClemente, 1983; Walsh and Sanson-Fisher, 2001). This approach encourages dental professionals to provide targeted and tailored advice to meet individual needs and/or motivational stages, which is evidence-based and also endorsed by patients. Therefore, the views from patients in this study, drawing from a small sample, fit with literature and are considered broadly in line with the population perspective.

In this study, patients did not recall use of the phrase "oral cancer" by dentists or other members of the dental team in any of their conversations during dental visits. However, they were generally amenable to this. Similar findings have been reported in a study by West et al. (2006), where only 7.1% reported that their dentist or general practitioner had spoken to them about oral cancer. Comparable findings were reported in other studies where less than 15% of patients reported having received oral cancer advice/counselling by a dentist or a general medical practitioner (Villa et al., 2011; Srikanth Reddy et al., 2012). Although such activity is perceived to be infrequent, patients in principle appear to be in favour of discussing oral cancer with their dental team (West et al., 2006; Awojobi et al., 2012; Srikanth Reddy et al., 2012; Babiker et al., 2017).

Tobacco

There was only one previous study (Campbell et al., 1999) found which reported on patients' perspectives and attitudes towards receiving tobacco cessation advice from dental professionals. Most studies have focussed on the viewpoint of dental professionals toward cessation interventions. This warrants a need for further studies exploring the views of patients regarding receiving tobacco cessation advice from dental professionals.

Most patients in this study reported being asked about their smoking status in the medical/social history form they filled in at the time of their first visit to the dental practice. However, only a few current smokers reported that they were offered advice to quit smoking by their dental team in previous dental visits, which included talking about the harmful effects of smoking on a patient's oral health and lasted a couple of minutes (Section 5.4.3.2). Whilst giving smoking cessation advice was considered acceptable by most dental professionals, mixed responses were received from patients (few current smokers in this study) regarding receiving advice for smoking cessation from the dental team. Most patients were open to receiving brief smoking advice from their dental team, however, they reported low estimates of efficacy.

In this study, discussing such issues was still viewed as more normalised in the primary care medical setting. A related finding had been reported from focus group discussions among US adults where participants were more comfortable discussing oral cancer with their physicians than with their dentists (Horowitz et al., 2002); this focus group study did not further explore participants views or attitudes towards receiving smoking cessation advice or referral from their dentists. The large study by Campbell et al. (1999) reported that most patients (58.5%) believed that dental professionals should provide tobacco cessation services to patients. However, most dental professionals (61.5%) believed patients did not expect tobacco cessation services (Campbell et al., 1999).

Having good adjunctive materials was reported by both dental professionals and patients in this study as a way to inform patients. Humphris and Field (2004) conducted two randomized controlled trials in primary care practices (medical and dental) in the UK, to investigate whether smokers gained greater benefits (increased knowledge levels) on receiving an oral cancer brief patient information leaflet than non-smokers. Findings showed that smokers who did not read the patient information leaflet reported less knowledge about oral cancer compared to non-smokers, while knowledge levels were similar for those having read the information leaflet (Humphris and Field, 2004).

Alcohol

As with smoking, there was limited existing literature which reported patient perspectives and attitudes towards receiving alcohol moderation advice from dental professionals in a primary care dental practice (Miller et al., 2006; Goodall and McAuley, 2012). As seen in Chapter 4 (Section 4.4.2), dental professionals were reportedly reluctant to enquire about patients' alcohol use and give advice on alcohol moderation and reported a range of barriers, which was persistent in some existing studies (Warnakulasuriya and Johnson, 1999; Cruz et al., 2005; Shepherd et al., 2010; McAuley et al., 2011). Conversely, most patients in this study specified that they were supportive of their dental team asking about their alcohol drinking and, where appropriate, advising them to reduce their consumption. However, there was some cultural sensitivity reported to receiving alcohol advice.

This further concurs with previous studies where advice against alcohol moderation was considered appropriate in a dental practice setting (Miller et al., 2006; McAuley et al., 2011; Goodall and McAuley, 2012). A survey study by Miller et al. (2006) in the United States, reported that a majority of dental patients (more than 75%) were in support of being screened for alcohol use by their dentists with regards to oral cancer (use of AUDIT-C, a three-item alcohol screening test). Furthermore, regardless of their age, sex or drinking status, patients were in approval of dentists' providing them with alcohol advice/counselling (Miller et al., 2006).

5.5.1.3 Oral cancer risk score/categorization

As discussed in Chapter 4 (Section 4.5.1.2), there is a lack of tools to predict risk of future oral cancer incidence (Green et al., 2014; Usher-Smith et al., 2015). Risk prediction tools are currently available for fifteen cancer sites (for example: breast, lung, prostate, colorectal, and other common cancers that are presented to primary care), not including oral cancer, suggesting a need for development. This thesis, albeit a small study with patients (and dental professionals; Chapter 4), explored the barriers/facilitators and feasible options for having an oral cancer risk assessment/prediction tool in a primary care dental practice setting. In general, both patients and professionals reacted fairly

favourably to the possibilities. Future research is needed to explore this further with the potential to develop an intervention/tool, in part informed by responses from patient and dental professional interviews. Further research is also required to assess the effectiveness and cost-effectiveness of such tools.

5.5.2 Implications for practice

The results from this patient interview study and other existing studies (Section 5.5.1), showed that most patients would accept a formal risk assessment, framing using cancer terms, and brief advice for smoking and alcohol specifically in relation to oral cancer from their dental team. This may have implications for this intervention in practice (final discussion Chapter 6).

5.5.3 Strengths and limitations

5.5.3.1 Strengths

This was a short survey but nevertheless was based on theory, ethically approved and targeted at illuminating patients views on both the best practice evidence synthesised from systematic reviews and clinical guidelines (Chapter 3) and barriers and facilitators reported by dental professionals in primary care dental practices (Chapter 4). The qualitative survey instrument was created based on findings from these previous studies in this thesis so that patient interviews were directed to specific aspects which might be important for applied interventions in practice. Results will be valuable in informing and improving further the current practice on oral cancer risk factor assessment and prevention among dental professionals in primary care dental practices in Scotland and beyond, for example by helping to design a pilot/trial to inform the development of an oral cancer prevention intervention package for primary care.

A pragmatic approach to suit study purposes was adopted to develop a mixed-methods qualitative survey instrument (containing both open-ended and closed-ended questions); this approach endeavoured to resolve the breadth versus depth trade-off between traditional quantitative survey and qualitative interviews respectively.

Interviews were guided by the principal researcher in real time and were not restricted to specific questions, and were quickly revised as new information emerged. The principal researcher spent time after each interview reflecting on how well they had been conducted; personal reflections on the process; what it added to the body of the data; and any implications for future discussions, interviews or analysis.

Coded data were cross checked to develop narrative themes, and any coding discrepancies identified were solved by discussion among the principal researcher and supervisors. This ensured that a robust coding frame was developed in order to enrich data analysis in this study, ensuring consensus in themes reported.

5.5.3.2 Limitations

Selection bias or sampling error might be a limitation (Kelley et al., 2003). The participant group (patients) included in this study were regular attenders at practice. This study targeted patients in waiting rooms in primary care dental practices in the largest health board in Scotland. The principal researcher did not go to individual households to select participants for this study. Studies have shown that individuals with oral cancer risks (smokers and excessive alcohol drinkers) usually do not turn up for these preventive consultations in primary care dental practice setting (Purkayastha et al., 2018). One recent paper (Purkayastha et al., 2018) showed that less than 50% of those diagnosed with cancer had attended anytime in the last five years. So, this study had in part a lower risk group. This might lead to reduced opportunities for providing preventive advice to those at high-risk (target population for preventive interventions in a primary care dental practice setting). Though this sampling error could not be disregarded entirely, the selection criteria endeavoured to recruit a mix of participant characteristics (Section 5.3.4).

Another limitation was that there was no patient and public involvement (PPI) in the design of this study. Patients were included in this study as participants, i.e. patients were interviewed, but were not actively involved in setting the terms of the research. Studies have reported that patient and public involvement at all stages of the research process can help to improve the research quality, make

positive impact and enhance the appropriateness of research, as patients/lay people can often bring to a research study their unique insights and expertise that adds-on to those of researchers and health care professionals. Moreover, patient and public involvement is believed to improve the way the research is recognised, prioritised, designed, commissioned, disseminated and implemented (WHO, 1978; Entwistle et al., 1998; Mockford et al., 2011; Brett et al., 2014; INVOLVE, 2018). Thus, future research should include patient and public involvement so that patient input contributes to the research development, such as setting questions.

The relatively small sample size (n=24) is a limitation for scaled items but less so for coded data or for a survey where no inferential test is involved (Kelley et al., 2003). For "qualitative survey" studies using individual interviews, like this study, the sample size required would usually be smaller. Moreover, the sample size was determined pragmatically based on: the aims of the study, resources available, and statistical analysis needed (only descriptive statistics) (Kelley et al., 2003).

This was a cross-sectional study, gathering views expressed by patients on a particular day. Thus, revisiting patients at different time point to see if they express the same views would significantly strengthen the internal validity of the findings.

5.5.4 Chapter conclusions

In conclusion, this chapter studied the views of patients attending primary care dental practices in Scotland on evidence-based oral cancer prevention and compared them with the dental professional perspective. Some identified barriers, as reported by patients and dental professionals, would need to be addressed before successful implementation of preventive intervention programmes for oral cancer risk factors (tobacco and alcohol). However, a number of ways forward are suggested in the next synthesis chapter. Patients in general are: open to being asked questions, and to exploring ways to give information to dental professionals using various assessment tools; happy to

receive alcohol advice if culturally appropriate; need advice tailored to their motivational profile; and are happy to frame discussions in terms of oral cancer.

As reported, there was a lack of previous evidence on this patient perspective on receiving preventive interventions for oral cancer from dental professionals. Thus, this study will be a good contribution to the knowledge. Although this short survey study focused on Scotland, the arguments made, and principles described can be applied to other parts of the UK and beyond. The next stage would be to actively involve patients/public in the planning and implementation of an evidence-based preventive intervention delivered in primary care dental practices to improve outcomes for patients.

Chapter 6 Discussion and conclusions

This chapter highlights the collective findings of the research in the context of the overarching aims of this thesis; describes the contribution to the literature by comparing the thesis findings to existing work, and provides possible explanations for the findings drawing on existing literature. It then identifies some of the methodological strengths and limitations of the thesis. Recommendations for practice and policy are made, and finally the chapter discusses some of the future work that can be undertaken.

6.1 Summary of thesis findings

This thesis integrates three studies (Chapters 3, 4, and 5) which constitute a comprehensive approach. First the evidence-base on best practice for undertaking an assessment of major behavioural risk factors associated with oral cancer (tobacco and alcohol) and delivering effective behaviour change preventive interventions by dental professionals in a primary care dental practice was synthesised. Then the feasibility (barriers and facilitators) to implementation and acceptability of the synthesised evidence-base relevant to a dental practice setting was investigated from both the professional and patient perspectives using a theory-based approach (as postulated by the 'Behaviour Change Wheel'). This helped to make recommendations to inform the development and implementation of interventions to support evidence-based (and feasible) oral cancer prevention delivery.

The systematic overview study found that there was a limited evidence-base directly from dental practice relating to delivering tobacco cessation and alcohol reduction interventions. However, best practice was developed from synthesising and drawing from the best evidence and recommendations from other primary care (medical/ pharmacy) settings, which could be adapted / adopted to dental practice setting. Combining the review evidence and guideline recommendations (following a novel robust synthesis framework), overall, the findings recognised that risk factor assessment is an important first step in any preventive intervention (i.e. questions must be asked to assess the risk levels or dependence). Regarding tobacco cessation and alcohol reduction interventions,

it was found that an appropriate intervention would be to offer an in-person brief motivational, tailored intervention, delivered by dental professionals, following an assessment of a patient's tobacco and alcohol use status (risk levels) and incorporating an oral examination component. For tobacco users, although longer interventions (10-20 minutes) were more effective in increasing quit rates, even very brief interventions (less than 5 minutes) have also shown comparable effectiveness. It is also acknowledged that there was a small additional benefit of intensive interventions (more than 20 minutes, with follow-up visits) compared to brief interventions. The guidelines also recommended making a referral to a telephone "quit-line" service for further help (proactive support) if the patient is willing to quit, however, this did not reflect in the systematic reviews in this overview – thus further consideration is required for including referral along with a brief intervention. For alcohol users, a brief 10-15 minutes multi-contact intervention was the "best recommended" intervention in medical practice reviews and guidelines for helping alcohol users to reduce consumption; even 5 minutes advice was also found to be equally effective. Thus, very brief (less than 5 minutes) or brief advice (of up to 5 minutes), should be trialled for tobacco and alcohol respectively in a dental practice setting (considering feasibility and effectiveness as reported in reviews and guidelines), tailored to patient motivational status.

The lack of precise reporting of duration (and number) of sessions of behavioural interventions for both tobacco and alcohol, somewhat limited the inferences regarding effective components that can be drawn from the findings. The clinical guidelines (dental and medical practice) went beyond the review evidence, and recommended offering a more pragmatic/practical approach, i.e. very brief advice for a couple of minutes, that is easier to implement in a dental practice setting. However, more trials would be helpful to study the effectiveness of very brief advice in a dental practice setting. Overall, behavioural preventive interventions were effective, irrespective of the primary care provider (for example, general practice physicians or practice nurses). In addition, there is a read across to primary care dental practices such that members of the dental team – hygienists, nurses, as well as dentists could be involved in delivering these prevention interventions.

On exploring the feasibility of implementation of the synthesised evidence-base via dental professional interviews, it was identified that it was more common for dentists to deliver smoking preventive interventions compared to alcohol interventions to their patients in primary care dental practice. Lack of time and funding/remuneration were the major resource (physical) barriers reported by most dental professionals. Providing very brief advice for less than 2-minutes and referring patients to local support groups or cessation services (i.e. simply "ask and refer") was seen as feasible in physical opportunity terms and was therefore considered a possible option that could be incorporated in all primary care dental practices, and including the brief interventions (up to 5 minutes) if resourced. Other feasible opportunities were: receiving training to deliver behavioural interventions (advice and referral) and having good education materials or posters in the waiting room in primary care dental practices (although the evidence-base does not support these). Dental professionals reported that patient attitudes, causing offence and awkwardness were the major social barriers to implementing preventive interventions. These barriers were more of an issue while discussing patients' drinking behaviours compared to smoking. The proposal of having an oral cancer risk prediction tool was considered to be somewhat beneficial for assessing behavioural risk factors - identifying a high-risk patient and tailoring advice for them. However, once more, time and funding were the major barriers to implementing such a tool in primary care dental practices, and receiving appropriate training was seen as a feasible opportunity so that professionals knew how to use information gained from such a tool.

On exploring the views of patients attending primary care dental practices, smoking was identified as the major risk factor by most patients, and alcohol was recognised as a risk factor less often. Media (for example, newspapers, television, magazines) was cited as the major source for knowing about oral cancer and its causes. None of the patients reported learning about oral cancer and associated risks from their dental team. Overall, patients were happy to learn about the risk factors associated with oral cancer and were open to receiving support from their dental team (as well as medical/pharmacy professionals) to reduce their risk of developing oral cancer. However, patient readiness for change (denial/unwillingness) were seen as a barrier to quitting

smoking and reducing alcohol consumption in some patient interviews, even among those aware of the risks associated with smoking and alcohol consumption, and the benefits of quitting. Receiving a risk score/ categorisation was considered to be beneficial in a) increasing awareness and b) framing risk directly in relation to oral cancer terminology. Some concern was raised as to what would be done with that risk information.

6.2 Contributions to the literature

The findings from the studies outlined in this thesis are important because they highlight the potential for delivering tobacco and alcohol behavioural preventive interventions in the primary care dental practice setting. The findings will be valuable in informing and improving further the current practice on oral cancer prevention in Scotland and beyond - contributing to some of the existing literature on cancer control and prevention.

As discussed in Chapter 1, the *World Health Organization's International Agency for Research on Cancer (WHO IARC)* is promoting international collaboration in research for cancer prevention in three important areas in order to reduce the cancer burden worldwide (Stewart and Wild, 2014). These areas are: "describing the occurrence of cancer; identifying / understanding the causes of cancer; and evaluating preventive interventions and their implementation" (Stewart and Wild, 2014). Addressing each of these areas is described by the *WHO IARC* as "a vital contribution to the spectrum of cancer prevention". In addition, the prevention module of the *World Health Organisation's (WHO) "Cancer Control: Knowledge into Action, WHO Guide for Effective Programs"* was developed to help "implement effective cancer prevention by controlling major avoidable cancer risk factors" (WHO, 2007a). This *WHO Cancer Control* guide further suggested three key planning steps followed by policy implementation steps to help develop an effective cancer prevention program, which are: 1) "where are we now?; 2) where do we want to be?; and 3) how do we get there?" This guide helps to provide practical advice for policy-makers and programme managers to make recommendations with regard to taking actions that could help accomplish these steps (WHO, 2007a). The relevant issues recommended by the WHO are: firstly, to systematically assess cancer risk factors at the country and individual

levels, in order to set priorities for evidence-based actions to prevent cancer; secondly, to focus interventions on the individuals most likely to benefit from them because they are at highest risk; thirdly, to acquire knowledge about the effectiveness of interventions, considering the acceptability of the interventions at the social, cultural or political levels. The guide gives practical advice, taking into account available financial resources and other potential barriers and constraints for the planning and implementation of the interventions. A combination of individual and population-based approaches were recommended for tobacco cessation and to reduce alcohol consumption in this guide (WHO, 2007a). The population level approaches are included in various policy documentations, for example, the "*WHO Framework Convention on Tobacco Control*" (WHO, 2004) and the "*World Health Assembly's Public-health problems caused by harmful use of alcohol*" (WHO, 2005b). This thesis is focused on downstream, individual level clinical prevention delivered in healthcare settings. However, to deliver this – some upstream / policy changes are required, for example, a change to the primary care contract (Section 6.5.2).

The findings reported in the systematic overview study (Chapter 3) contribute to the key research areas highlighted by the *WHO IARC* and the planning phases suggested by *WHO's Cancer Control* guide by presenting the best practice evidence for "individual level" approaches, i.e. to identify individuals at high-risk of developing oral cancer and delivering effective evidence-based behavioural preventive interventions. The overview went beyond the review and trial evidence, and contributed to the knowledge by suggesting interventions based on an integrated or combined synthesis (using a novel robust framework) of current high-quality reviews and guidelines. The thesis further contributed by identifying the immediately feasible options, based on professional and patient views, for delivering effective tobacco cessation and alcohol reduction interventions in primary care dental practices, which would have the greatest impact on patients' oral health. Moreover, the findings are significant in that preventive interventions delivered by dental professionals can contribute to the improvement of not only oral health, but also general health, as tobacco and alcohol are the common risk factors. Reducing these common risk factors is a major strategic priority for the *"WHO's Global action plan for the prevention and control of non-communicable diseases (NCDs) 2013-2020*" (WHO, 2016b).

This action plan has a specific mention of oral diseases including oral cancer, and states that an effective oral cancer prevention strategy may have benefits that are not limited to this particular condition alone (Sheiham and Watt, 2000; Watt, 2005; WHO, 2016b).

The *"Implementation Guide and Toolkit for Making Every Contact Count (MECC)"* recognizes MECC as the first stage of the Behaviour Change Pathway that individuals might take in order for them to make and maintain a behaviour change (for example, stop smoking and drink alcohol within the recommended daily limits) (Varley and Murfin, 2014). Three core components for the effective implementation of MECC are: "organizational readiness, staff readiness, and enabling and empowering the public" (Varley and Murfin, 2014). This public health policy in the UK, requires healthcare professionals to deliver opportunistic health behaviour change interventions to patients during routine medical consultations (Varley and Murfin, 2014). Keyworth and co-workers (2018), in a recent cross-sectional national survey with NHS staff in the UK, reported that these opportunities are often missed during routine clinical interactions; some of the implementation barriers being lack of training, lack of time, workload, organisational barriers, and healthcare professionals' beliefs/viewpoints about patient motivation to change their behaviour (Keyworth et al., 2018). The barriers reported by dental professionals in this thesis (Chapter 4) were in agreement with these barriers. The findings from this thesis further contributed to the knowledge by recommending implementation strategies which draw upon recognized behaviour change theory (the 'Behaviour Change Wheel'), aimed at enhancing dental professionals' capability, opportunities and motivation to deliver behaviour change interventions (Michie et al., 2011; Varley and Murfin, 2014; Keyworth et al., 2018). The dental professional interview study identified the intervention functions and policy categories (Section 6.5) from the 'Behaviour Change Wheel' to support changes in dental professional behaviour and increase implementation of public health policies by translating evidence into practice (Michie et al., 2011; Keyworth et al., 2018).

There is a lack of literature examining the patient perspective and attitudes towards receiving opportunistic health behaviour change interventions (for

tobacco and alcohol) in a primary care setting. Keyworth and co-workers (2018) have highlighted a need for further research to examine patients' perspectives in relation to MECC, and particularly their views regarding receiving behaviour change interventions during routine consultations. This thesis contributes to the knowledge in this area, by presenting patient views and specific barriers (and some facilitators) in relation to translating the evidence-base to practice (Chapter 5). Moreover, this thesis compared and contrasted the views of patients and dental professionals, in order to capture the most relevant barriers and facilitators to dental practice. Addressing these barriers/facilitators will be an important step towards prevention and control of oral cancer (and other chronic conditions). Triangulation (Table 5.2) showed patients in general were amenable to most evidence-based approaches; opportunity barriers on the professional side are stronger. However, it is recognised that these were patients attending practice regularly.

Previous studies in the UK, using data from large national surveys, reported that the probability of regular dental attendance was low among individuals who are at higher risk of developing oral cancer (i.e. smokers and heavy drinkers) compared to those who are at lower risk (Netuveli et al., 2006; Yusof et al., 2006). Thus, opportunities are reduced for both screening and providing preventive advice to those at high-risk. This suggests a need to have interventions targeted at practice and at policy levels for services to reach out to those communities at highest risk, in order to encourage high-risk individuals to take preventive actions, such as regular dental visiting (Netuveli et al., 2006; Yusof et al., 2006). Moreover, despite this low attendance of high-risk individuals, dental professionals should continue assessing all patients and deliver preventive interventions as needed, which could contribute to prevention of oral cancer as well as other oral diseases and non-communicable diseases (via common risk factors).

6.3 Explanation of findings

There is emerging policy proposals for delivering tobacco and alcohol interventions in dental practice settings (WHO, 2007b; Scottish Government, 2018b). With reference to ethical principles (Tannahill, 2008), the common risk factor approach (Sheiham and Watt, 2000), and *WHO's Global Action Plan* for the prevention and control of non-communicable diseases (WHO, 2016b) - tobacco and alcohol brief interventions can not only improve oral health, but can improve health in general. The tobacco and alcohol preventive interventions, as identified from the findings of this thesis, are reasonable in that every dental patient who attends can be assessed for risk behaviours and offered a brief intervention. They are sustainable because of their quick delivery, and low implementation costs after initial training is completed (although practitioners would need payment to deliver brief intervention; Section 6.5.2), and they also have the potential to impact on inequalities in oral health (McAuley et al., 2011; NICE, 2014; Varley and Murfin, 2014; WHO, 2016b).

The findings from the overview study showed that there was a lack of systematic reviews and trials regarding delivering tobacco cessation interventions (only one review) and there were no reviews reporting alcohol reduction interventions in a dental practice setting. Moreover, the dental review concluded that there were differences between the studies that limit the ability to make conclusive recommendations regarding the intervention components that should be incorporated into the dental practice setting. These results were in line with a recent systematic review by Kay and co-workers (2016), which included 44 studies (including randomised controlled trials, surveys, qualitative or mixed-method studies) to answer the research question: "Is oral health promotion within dental practice effective and how can its effects be optimized?". The review concluded that the evidence for promoting good oral health in adult patients (or adolescent), in a dental practice setting, is heterogeneous, moreover, the quality of reporting was variable. Similar to the findings of this thesis, the review by Kay and co-workers (2016) showed that oral health promotion (including oral hygiene, plaque control, diet, fluoride use), based on behaviour change theoretical models, was effective in significantly improving oral health. Moreover, verbal advice from a dental professional had a positive

effect on a patient's knowledge, behaviour and for improving oral health, while written advice only promoted oral health knowledge. The review by Kay and co-workers (2016), was published after the systematic search was conducted for this thesis (including reviews published between 1995 and 2015). However, this review did not report interventions specifically for tobacco and alcohol reduction in a dental practice setting (Kay et al., 2016). The interventions reported were for oral health promotion in general, and there was no evidence demonstrating the components of effective interventions to be delivered in a dental practice setting. Therefore, inclusion of this review would not have changed the overall findings of the thesis.

The synthesised finding is that offering an assisted or theory-based intervention, i.e. brief tailored/structured advice (based on motivational interviewing in the majority of included reviews/guidelines) following an assessment of a patient's risk levels and supported by an oral examination component or written materials or pharmacotherapy (where needed), is effective. The text book "Theory of addiction" by West and Brown (2013) describes motivation as being highly dependent on circumstances or contexts and, thus, offering an assistance or support (rather than simple advice) might "increase confidence in success, create a more positive image of the quitting process or trigger a positive response out of a motivation to reciprocate" (Aveyard et al., 2012). This has been further described by Michie and co-workers (2010; 2013), who identified the specific behaviour change techniques for improved outcomes for smoking cessation, and identified four important functions for individual behavioural support: "addressing motivation, maximizing self-regulatory capacity and skills, adjuvant activities, and general aspects of the interaction (for example, communication techniques)". The study further suggests that the healthcare professionals' communication skills affect patient satisfaction and motivation, which could be improved by providing training to practitioners. The work by Michie and co-workers (2010; 2013), forms the basis of research carried out by the "*National Health Service Centre for Smoking Cessation and Training (NCSCT)*". This aims to establish the best practice for the management of smoking cessation and develop learning outcomes for training all practitioners to deliver brief advice for smokers, aimed at motivating them to make a quit

attempt (NCSCT, 2014). Thus, the results of the existing literature, described above, further justifies the findings from this thesis.

There remains a gap around the "active ingredients" for delivering a preventive intervention in a dental practice setting (in particular for alcohol interventions). Overall, the findings recognised that risk factor assessment is an important first step in any prevention intervention (i.e. ask a question to assess the risk levels or dependence and readiness to change), followed by brief advice to quit. Although there remains a knowledge gap for direct evidence in dental practice, it must be acknowledged that there are some important developments in the field of alcohol brief interventions (efficiently using wealth of evidence from other settings), some of which are not yet reflected in current systematic reviews, that could be adopted in a dental practice setting. For example, Michie et al. (2012; 2013), aimed to identify specific behaviour change techniques to reduce excessive alcohol consumption (not to treat alcohol dependence). They identified greater effect sizes from alcohol brief interventions that promoted "self-monitoring", i.e. self-recording of alcohol intake. However, they recommended that further research should be undertaken to identify the effects of other behaviour change techniques and to extend this approach for more intensive interventions.

6.4 Strengths and limitations

This section presents the strengths and limitations of the thesis in its entirety, mainly in relation to the methodologies employed. The strengths and limitations of individual studies have already been detailed and explained in the discussion sections of the relevant chapters (3, 4, and 5).

6.4.1 Strengths

This thesis adopted a comprehensive pragmatic approach, i.e. each method (systematic overview, qualitative interview, and qualitative survey) was chosen to fit particular research questions. This helped to avoid any inherent bias in traditional literature reviews, and in particular belief systems, such as constructivism (qualitative/ inductive) or positivism (quantitative/ deductive) (Teddlie and Tashakkori, 2009; Creswell and Creswell, 2017). The thesis first

conducted an extensive systematic overview, which included a) systematic search of multiple databases and grey literature for relevant systematic reviews and international clinical guidelines; b) quality appraisal using standardised tools; and c) narrative synthesis with novel methods developed for synthesising across systematic reviews and clinical guidelines). Secondly, qualitative in-depth interviews with primary care dental professionals investigated barriers and facilitators to implementing oral cancer behaviour change interventions. Thirdly, patient views and perspectives on receiving these interventions and how these compared and contrasted with the dental professional perspectives were examined in a mixed-methods qualitative survey.

The systematic overview was the first study to develop a novel robust framework to synthesise best practice evidence from both systematic reviews and clinical guidelines. Whilst the appraisal and synthesis methods followed validated protocols and frameworks, the "higher level" synthesis of these two "streams" together (i.e. integrated or combined synthesis of current high-quality reviews and guidelines) was innovative and could be used in other areas of healthcare.

The theoretically-based assessment of barriers and facilitators (using the 'Behaviour Change Wheel') in translating each component of the synthesised evidence-base to practice was thorough. This thesis contributes to the literature in this area, by presenting both dental professional and patient views, and by comparing and contrasting their views in order to capture the most relevant barriers and facilitators to a dental practice setting. Collecting data from one source (dental professionals) and comparing them with another source (patients), in order to validate or confirm the findings and determine the "extent to which different sources provided similar or discrepant data" – has been referred to as data (person) or methodological triangulation of research studies (Adami and Kiger, 2005; Baxter and Jack, 2008). Adopting these different approaches in three research studies helped to achieve a complete picture of the topic being explored, i.e. achieving confirmation and completeness of findings (Adami and Kiger, 2005).

Furthermore, the systematic search was not limited to the dental practice setting, which is a strength. Preventive interventions delivered in all primary

care settings (dental/medical/pharmacy) were included in this overview, in order to not rule out any good guidelines and/or evidence on how to assess risk and deliver prevention for the risk factors (tobacco and alcohol) that may be aimed at another clinical/medical condition (Fiore et al., 2008; NICE, 2010; SDCEP, 2014).

6.4.2 Limitations

The limitations of individual studies have already been detailed in the discussion sections of the relevant chapters (3, 4, and 5). This section particularly considers - what could have been done differently.

As discussed previously in Chapter 3 (Section 3.4.1.2), trial duplication within the systematic reviews was addressed effectively in the overview study, by extracting a list of all included original trials (Appendix 6) within 31 included systematic reviews. This avoided counting findings more than once if repeated in multiple systematic reviews, which would falsely inflate the effect or weight of findings. Nevertheless, there was inevitable overlap in the source trials within the systematic reviews. Conducting a meta-analysis with these original trials was considered during this study; but the work was beyond the scope of this thesis. However, future work could involve a meta-analysis synthesis, given the detailed work done thus far to extract all original trials in this research. In such a meta-analysis, careful consideration would need to be given to pooling trials with different methodology / study designs and contexts - given the high levels of heterogeneity. Furthermore, clinical heterogeneity and the somewhat limited detailed descriptions of interventions would need to be taken into account (Petticrew and Roberts, 2008).

The interview schedule or topic guide for professional and patient interviews was developed based on initial synthesis of the overview findings – this was able to capture the key principles of behaviour change interventions. However, the detailed overview synthesis, which was able to tease out specific effective aspects of the interventions, continued even after the dental professional and patient interviews commenced. This was due to the time constraints of the PhD timescales. This somewhat restricted further in-depth exploration of dental

professional and patient views based on the final findings from the robust overview synthesis. It is unlikely that this more detailed synthesis would have changed the main thrust of the findings from the patient and public perspectives. Furthermore, there would be an opportunity for further feedback from dental professionals and patients if an oral cancer prevention intervention package were to be feasibility or pilot tested.

6.5 Pathways to impact

6.5.1 Recommendations for practice

The findings from this thesis, can contribute to recommendations to inform the development of interventions to support evidence-based oral cancer prevention (tobacco cessation and alcohol reduction interventions) delivered by dental professionals in the primary care dental practice in Scotland and beyond. The Behaviour Change Wheel (as detailed in Chapter 4), was used in this research to identify approaches to the specific barrier types (to be addressed) or facilitator types (to be enhanced and reinforced) in relation to the target behaviours (Michie et al., 2011). The barriers and facilitators (in terms of capability, opportunity and motivation) identified for each component of the best practice evidence synthesis (Chapter 3) were discussed in terms of the recommended intervention possibilities in Chapter 4 and 5 (Sections 4.5.2 and 5.5.2; Table 5.2).

The optimal model of preventive care (from a primary care perspective) could involve providing both opportunistic preventive interventions for all patients through undertaking a planned assessment of smoking and alcohol risk behaviours and the subsequent tailoring of behaviour change interventions.

Strategies that can be applied to address identified barriers at the dental practice level are discussed below.

Providing a detailed specified protocol of requirements in including brief interventions in the routine clinical dental practice

The *National Centre for Smoking Cessation and Training* (NCSCT) has developed "a simple form of advice designed to be used opportunistically in less than 30 seconds in almost any consultation with a tobacco user" (NCSCT, 2014; PHE, 2014a). This is very brief advice, which involves: 1) establishing and recording smoking status (ASK); 2) advising on the personal benefits of quitting (ADVISE); and 3) offering help (ACT). The findings from the systematic overview study in this thesis reported limited trial evidence (compared to longer interventions) for the effectiveness of very brief interventions for smoking cessation, and limited to no evidence for alcohol reduction; yet the guidelines did recommend delivering very brief interventions (as little as 30 seconds to a couple of minutes) in a dental practice setting. However, the definition of "brief intervention" was not consistent in all included reviews and guidelines - mostly it was considered to be an intervention of 5-20 minutes duration. Dental professionals in the interview study considered delivering a very brief intervention (less than 5 minutes) as a more feasible and effective option than brief advice, that could be incorporated in routine patient care. A recent randomised trial further supported this pathway by reporting a dramatic impact for motivating weight loss by primary care physicians in England, suggesting that a behaviour change intervention can be delivered in as little as 30-seconds (Aveyard et al., 2016). Thus, there is potential to use the very brief intervention pathway (30-seconds chat) in order to increase the chance of a successful quit attempt and reduce time of delivery. However, this very brief approach would need to be tested in the dental practice setting, considering a lack of evidence for effectiveness of very brief interventions.

Moreover, there is a need to adapt this pathway for reducing alcohol consumption in a primary care dental practice setting. In order to "Ask/Assess", i.e. screening patients for alcohol consumption in a primary care setting, a range of alcohol screening questionnaires have been developed (for example: AUDIT, AUDIT-C, AUDIT-PC, FAST). These questionnaires have been shown to be a reliable and valid means of detecting alcohol misuse among individuals. However, most of these questionnaires are too long to be incorporated in any healthcare setting, for example, AUDIT being the "gold standard" has ten

questions. However, the brief version of the AUDIT questionnaire i.e. AUDIT-C, takes around 3-minutes to complete, identifies excessive drinking within the last year, and offers honest and personalised feedback to the patients. This AUDIT-C tool was effectively used as a useful training resource for dental teams in the UK, almost two decades ago (Bush et al., 1998). Thus, there is potential for implementing these brief questionnaires in a dental practice setting.

Training and support for dental team in oral cancer prevention

Dental professional interviews showed a need for further education and training interventions to address reflective motivation and psychological capability issues (in particular for giving alcohol advice). As in any area of clinical and preventive practice, appropriate training is essential to enable dental professionals to deliver tobacco cessation and alcohol reduction advice and support. In 2010, the *National Centre for Smoking Cessation and Training* (NCSCT) launched the "first nationally recognized accreditation for delivery of smoking cessation for practitioners" (NCSCT, 2014), by updating the set of competencies published by the *Health Development Agency* (HDA, 2003) which were required to be present in all smoking cessation training courses. The training comprises of a "two-stage knowledge and practice assessment and supporting online training modules" (NCSCT, 2014). As discussed earlier (Section 6.3), the specific behaviour change techniques (BCTs) developed by Michie and co-workers (2010; 2013) form the basis for this training, and suggest that healthcare professionals' communication skills affect patient satisfaction and motivation, which could be improved by providing training to practitioners. In other words, training could help explore best way of providing tailored, motivationally nuanced advice – as implicated from dental professional and patient interviews (Table 5.2).

There is a clear need to support and disseminate this accredited training (NCSCT, 2014) for dental teams in order to ensure they are competent to deliver very brief interventions for tobacco in a primary care dental practice. The training could be delivered in a dental practice setting or could be delivered as part of the dental undergraduate, postgraduate, and/or continuing professional development programmes. The training should be consistent and in accordance with national training standards (NCSCT, 2014; PHE, 2014a). The NCSCT recommends "the minimum standard that every dental practice member should

achieve is: very brief advice, just 30 seconds to ask, advise and act" (NCSCT, 2014; PHE, 2014a). Again, there is a need to adapt these training recommendations for delivering alcohol reduction interventions in a primary care dental practice. Moreover, the provision of training to deliver opportunistic alcohol reduction interventions by dental professionals needs to be considered a high priority, considering it plays a major role in oral cancer development. Lastly, costs for delivering training, including time away from practices needs to be considered within the implementation case.

6.5.2 Recommendations for policy (service organisation level)

The policy categories from the Behaviour Change Wheel (Chapter 4), i.e. the regulatory or authority actions needed to allow the interventions to occur, are addressed in this section. The key policy implications needed to bring about the desired behaviour change are outlined below.

Methods of remuneration

Lack of remuneration or funding issues were reported to be the major barriers in delivering tobacco and alcohol interventions by the majority of dental professionals in this study. This might remain a problem, as the NHS primary care dental contract, i.e. "Statement of Dental Remuneration" (NHS, 2018b), does not support the delivery of smoking cessation or alcohol reduction interventions, and currently there is no structure to reward dental practitioners offering tobacco and alcohol interventions in routine clinical practice (Brocklehurst et al., 2016). In Scotland, where dentists are paid in part by a fee-for-service and capitation remuneration systems (i.e. the volume and type of work undertaken), a fee scale for tobacco and alcohol interventions is worthy of consideration. This might encourage dental professionals to provide these services in day-to-day practice (McAuley et al., 2011; Brocklehurst et al., 2013b; Brocklehurst et al., 2016).

Providing remuneration has been shown to have positive effects on clinician behaviours in a range of healthcare services. For example, a recent Cochrane review (Brocklehurst et al., 2013b) aimed to determine the impact that various remuneration mechanisms (including fee-for-service, fixed salary, capitation and

blended payments) have upon primary care dentists' behaviour to impact a range of activities. The study found a statistically significant increase in clinical activity with the provision of fee-for-service and an educational intervention on the placement of fissure sealants (Brocklehurst et al., 2013b). However, further research was suggested due to the limited number of trials available, and moreover to find impacts on other healthcare services.

Steps are being taken in this area; the recently published "*Scotland's Oral Health Improvement Plan*" (Scottish Government, 2018b) recommends a "new system of enhanced continuing care payments to support the introduction of Oral Health Risk Assessments for adult patients". In addition, it recommends developing the potential for wider prevention in the primary care setting. However, future evaluation would be needed to determine whether provision of payments to deliver tobacco and alcohol interventions in the dental practice setting would have an impact on clinician activity.

Support in implementing guidelines (and quality improvement)

There is a clear need for clinical guidelines to support dental professionals in offering tobacco and in particular alcohol interventions in routine clinical practice. The overview in Chapter 3 draws from preventive best practice that can help to improve not only oral health but also general health. Linking of assessment and advice to wider benefits may enhance acceptability for patients and is in line with moves to a more integrated oral and wider public health agenda (Sheiham and Watt, 2000). The policy context also comes with opportunity regarding enhancing the role of the dental team (Steele, 2014; WHO, 2016b; Scottish Government, 2018b). For example, *"Scotland's Oral Health Improvement Plan"* (Scottish Government, 2018b) focuses on introducing a preventive care pathway and an "Oral Health Risk Assessment" for all adult patients on a regular basis. Oral health risk assessment includes a full dental or oral examination followed by a personalized care plan including a conversation between the dentist and patient about the associated risk factors such as tobacco and alcohol consumption based on the assessment of the risk level to their oral health (Scottish Government, 2018b). Moreover, the *"WHO Global Strategy for Prevention and Control of Noncommunicable Diseases"* is a new

policy relevant for managing the prevention and control of oral diseases, acknowledging the common risk factor approach (Petersen, 2008; WHO, 2016b).

Additionally, the cultural sensitivity / diversity issues (as identified from dental professional and patient interviews; Table 5.2) needs to be incorporated in any generic guidance.

Despite being a priority area, the absorption of guideline recommendations into routine practice requires changes in the attitudes and behaviour of dental professionals and a certain adaptation of the structural environment (Edwards et al., 2006; Fischer et al., 2016). Given the need for more support in guideline implementation, a more active dissemination of guidelines is required to ensure a change in routine practice (Fischer et al., 2016). The existing literature indicates that structured or multi-faceted implementation strategies (for example: educational outreach visits, reminder systems) can improve adherence to guidelines (Edwards et al., 2006; Fischer et al., 2016).

6.6 Future work / research

The overview study highlighted an overall lack of evidence of effectiveness of brief behavioural interventions (for both tobacco and alcohol) directly within a dental practice setting, however, there is more evidence available in the wider primary care settings. It was further identified that, despite this preponderance of evidence in the primary care settings (medical/pharmacy), there was a lack of evidence (no effect sizes) for the effectiveness of individual components of brief interventions (for example, referral to external services, training primary care providers, use of supporting materials), and there was lack of precise reporting of duration and number of sessions of a brief intervention. Thus, further research is needed to test this evidence deficit in implementation, i.e. the acceptability and practicality (feasibility) of an evidence-based preventive intervention in a dental practice setting (the adoption and adaption) - some of which was explored in the dental professional and patient interviews in this research. Moreover, further research is required to explore the optimal level of brief / very brief advice, individual components of brief intervention, and to explore multi-disciplinary cohesion (i.e. dental team, general medical

practitioners, or pharmacist) (Table 5.2). Since the oral adverse effects of alcohol excess are largely linked with tobacco use, one way of overcoming a potential barrier would be to link tobacco advice with that of alcohol (where relevant), i.e. combined interventions (Goldstein et al., 2004). Moreover, as notable in the epidemiologic studies (Coups et al., 2004; Fine et al., 2004), a majority of individuals are at risk from more than one of the four shared or common behavioural risk factors (i.e. tobacco use, unhealthy diet, physical inactivity and harmful use of alcohol), that are associated with major non-communicable diseases (Goldstein et al., 2004; WHO, 2016b).

Intervention development and feasibility trial

It is recommended that an oral cancer prevention intervention package should be developed, drawing from the evidence-base of the systematic overview study (Chapter 3), and adapting suggestions from dental professional and patient interviews (Chapter 4 and 5; Table 5.2) for its effective implementation in a dental practice setting. The future oral cancer prevention intervention/trial could involve testing the implementation and acceptability of the synthesised evidence-base in a dental practice setting (tobacco and alcohol interventions), demonstrating effectiveness and need for brief tobacco and alcohol interventions in routine clinical practice by conducting an initial short feasibility trial. For example, testing the feasibility of very brief (less than 5 minutes) or brief advice (of up to 5 minutes), for tobacco and alcohol respectively, tailored to patient motivational status, in a dental practice setting. In addition, the issues with the individual components, such as follow-up visits, referral to external services, use of supporting materials, training primary care providers, and effectiveness of very brief interventions, would also need to be explored. In line with *Medical Research Council* guidance on the development and evaluation of complex interventions, it would be necessary to undertake a feasibility and pilot study before conducting a definitive trial/intervention to assess its acceptability and practicality to dental professionals and patients (Craig et al., 2008).

The potential role and effectiveness of the use of an oral cancer risk prediction tool in dental practice settings is not known. In the qualitative studies, a risk prediction tool was considered beneficial by most dental professionals and

patients attending primary care dental practices - for capturing risk behaviours and as a means of communicating risk associated with oral cavity and oropharyngeal cancers. However, some concern was raised as to what would be done with that risk information. Such a personalised risk prediction tool is currently being developed and validated by INHANCE (2018) researchers in the United States, specifically targeted at head and neck cancer / oral cancer reduction. This anticipated INHANCE risk prediction tool, however, has yet to be fully validated and did not materialise in time to be demonstrated and discussed in detail with dental professionals and patients in this research, rather risk prediction tools in general were discussed. The INHANCE risk prediction tool "aims to predict risk of future incident disease in asymptomatic individuals" (INHANCE, 2018). This could possibly be used to guide risk factor counselling interventions for behaviour modification (i.e., quitting cigarette smoking or reducing alcohol drinking). The major risk factors included in this risk prediction tool are: age, gender, socioeconomic status, tobacco smoking, alcohol drinking, and family history of head and neck cancer. Thus, based on individuals' characteristics and behaviours, such personalised risk communication could help in improving decision making in relation to oral cancer screening and primary prevention (Edwards et al., 2013). The INHANCE tool needs further development and validation in order to be implemented effectively in a primary care dental practice in the UK setting. Moreover, future research is also needed to assess its effectiveness and cost-effectiveness.

Thus, future oral cancer prevention intervention/trials could involve: a) assessing the feasibility of recruiting for the study; and how best to deliver the intervention; b) designing / testing an appropriate preventive intervention drawing from the evidence-base and adapting suggestions from dental professional and patient interviews; c) testing the INHANCE risk prediction model in Scotland (linked to prevention intervention).

6.7 Future prevention considerations

Besides behavioural preventive interventions, pharmacological interventions (for example, nicotine replacement therapy) through stop smoking services have been shown to be effective in tobacco cessation (Stead and Lancaster, 2012). Moreover, the development of smoking cessation prevention interventions needs to consider one of the evolving technologies, i.e. “Electronic Cigarettes” and how they fit into current brief interventions (McRobbie et al., 2014). A recent Cochrane review examined the effectiveness of electronic cigarettes to help smokers quit over the long-term (McRobbie et al., 2014). This review showed a reduction in cigarette consumption in electronic cigarette users compared with placebo (reported in two trials) and NRT or nicotine patches (reported in one trial). However, the small number of effectiveness trials limits the certainty of these findings. Electronic cigarette has been a topic of interest among smokers, healthcare professionals and policy makers to know if these devices could help in smoking harm reduction. The *Public Health England’s* guidance (NICE, 2013) is fully supportive of electronic cigarettes as a harm reduction approach. The dental community are possibly more reluctant to support this fully, with concerns about unknown impact on oral tissues (Sundar et al., 2016).

Following their invention in China in 2003, electronic cigarettes became more widely available around 2007 (ASH, 2018). Despite unanswered questions about their long-term effectiveness, electronic cigarettes are growing in popularity as a “relatively safe” alternative to tobacco products and are marketed as a healthier alternative to smoking or even to help smokers to quit. As of 2017, there were 2.9 million adults in the UK using electronic cigarettes (ASH, 2018). In the UK, there are now more ex-smokers (52%) using electronic cigarettes than dual users of both cigarettes and electronic cigarettes (45%) (ASH, 2018). The sales for electronic cigarettes are rapidly increasing and some analysts have even predicted they will surpass cigarettes sales within a decade (Bullen et al., 2013). A recent study compared data from 45 countries, relating to prices of combustible cigarettes, disposable e-cigarettes and rechargeable cigarettes (Liber et al., 2017). The study reported that primary care clinicians (general practitioners) recognise electronic cigarettes as a low-cost opportunity to reduce smoking (especially in deprived groups in society, having higher rates of

smoking). The study established that “though start-up costs can be higher, it is likely to be less expensive to use an electronic cigarette over time than it is to smoke” (Liber et al., 2017; ASH, 2018).

Thus, further research is needed to confirm their long-term health implications as they are relatively new to the market (McRobbie et al., 2014; ASH, 2018).

6.8 Thesis conclusions

In conclusion, tobacco and alcohol use are the major risk factors associated with oral cancers (oral cavity and oropharyngeal). The principles of prevention for oral cancer suggests that risk can reduce when behaviours stop. Despite a lack of systematic reviews and clinical guidelines directly within a dental practice setting, best practice was developed from synthesising and drawing from the best evidence and recommendations from other primary care (medical/pharmacy) settings, which could be adapted / adopted to dental practice setting. Overall, the thesis showed evidence for the effectiveness of brief behavioural interventions for sustained tobacco abstinence and reduced alcohol consumption. Dental professionals are in an ideal position to help patients quit smoking and reduce alcohol consumption; their role could be increased substantially, if the identified barriers to implementation in a dental practice setting (from dental professional and patient perspectives) were addressed. Further interventions, including feasibility testing in practice, targeting these issues could have a potential impact on the prevention of oral cancer in the community.

Appendices

Appendix 1: PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources	5a	Indicate sources of financial or other support for the review
Sponsor	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions,

		comparators, and outcomes (PICO)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned

Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

Appendix 2: List of organizations/databases for searching clinical guidelines

	Organizations/Databases	**Website**
1	British Dental Association	http://www.bda.org/
2	British Society for Oral Medicine	http://www.bsom.org.uk/
3	British Association of Head & Neck Oncologists	http://www.bahno.org.uk/
4	National Institute for Health and Care Excellence	http://www.nice.org.uk/
5	General Dental Council	http://www.gdc-uk.org/
6	Scottish Intercollegiate Guidelines Network	http://www.sign.ac.uk/
7	Cancer Research UK	http://www.cancerresearchuk.org/
8	Health Technology Assessment	http://www.hta.ac.uk/
9	European Association of Oral Medicine	http://www.eaom.eu/
10	Mouth cancer foundation	http://www.mouthcancerfoundation.org/
11	Centers for Disease Control and Prevention	http://www.cdc.gov/
12	College of Dietitians of British Columbia	http://www.collegeofdietitiansofbc.org/
13	American cancer society	http://www.cancer.org/
14	US Preventive Services Task Force	http:// www.uspreventiveservicestaskforce.org/
15	World Health Organization	http://www.who.int/
16	EUROPA - European Union website	http://europa.eu/
17	New Zealand Guidelines Group	http://www.health.govt.nz/about-ministry/ministry-health-websites/new-zealand-guidelines-group
18	Agency for Healthcare Research and Quality (AHRQ)	www.ahrq.gov/professionals/clinicians-providers
19	American College of Physicians Clinical Practice Guidelines	www.acponline.org/clinical_information/guidelines/guidelines/
20	ADA Center of Evidence-Based Dentistry	www.ebd.ada.org
21	Australian National Health and Medical Research Council	https://www.clinicalguidelines.gov.au/
22	Institute for Clinical Systems improvement	https://www.icsi.org/guidelines__more/

Appendix 3: MEDLINE search strategy

1. (primary adj3 prevention*).mp.
2. Primary Prevention/ or "primary prevention*".mp.
3. Counseling/ or Patient Education as Topic/ or advice*.mp.
4. "Tobacco Use Cessation"/ or cessation*.mp. or Smoking Cessation/
5. Harm Reduction/ or "harm reduction*".mp.
6. (harm adj3 reduction*).mp.
7. Psychotherapy, Brief/ or "brief intervention*".mp.
8. (brief adj3 intervention*).mp.
9. Early Medical Intervention/ or intervention*.mp.
10. "early intervention*".mp.
11. "minimal intervention*".mp.
12. "general pract* intervention*".mp.
13. "brief counsel?ing".mp.
14. (brief adj3 counsel?ing).mp.
15. "behavio?r* counsel?ing".mp.
16. (behavio?r* adj3 counsel?ing).mp.
17. Sex Counseling/ or "sex* counsel*".mp.
18. Communication/ or Motivational Interviewing/ or "brief communication".mp.
19. "alcohol reduction*".mp.
20. "control* drink*".mp.
21. "health promotion".mp. or Health Promotion/
22. Risk Assessment/ or "risk assess*".mp.
23. "patient recall".mp.
24. referral.mp. or "Referral and Consultation"/
25. signpost*.mp.
26. 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
27. Primary Health Care/ or "primary care*".mp.
28. (primary adj3 care*).mp.
29. General Practice/ or Family Practice/ or "general practice*".mp.
30. (general adj3 practice*).mp.
31. "medical practice*".mp.
32. General Practice, Dental/ or Dental Care/ or "dental practice*".mp.
33. Dental Clinics/ or "dental clinic*".mp.
34. "dental setting*".mp.
35. Dental Offices/ or "dental office*".mp.
36. "community care*".mp. or Community Health Services/
37. Patient Care/ or "patient care*".mp.
38. "shared care*".mp.
39. "clinical care".mp.
40. 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39
41. Alcohol Drinking/ or alcohol*.mp.
42. "Tobacco Use"/ or Tobacco/ or Tobacco, Smokeless/ or tobacco*.mp. or Tobacco Products/
43. Smoking/ or smok*.mp.
44. cigar*.mp.
45. Areca/ or quid*.mp.
46. snuff*.mp.
47. HPV.mp. or Human papillomavirus 16/ or Papillomavirus Infections/
48. "wart* virus*".mp.

49. 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48
50. 26 and 40 and 49

Appendix 4: Search filters to identify systematic reviews and clinical guidelines

1) SIGN search filters to identify systematic reviews or meta-analyses

MEDLINE	EMBASE
1. Meta-Analysis as Topic/	1. exp Meta Analysis/
2. meta analy$.tw.	2. ((meta adj analy$) or metaanalys$).tw.
3. metaanaly$.tw.	3. (systematic adj (review$1 or overview$1)).tw.
4. Meta-Analysis/	4. or/1-3
5. (systematic adj (review$1 or overview$1)).tw.	5. cancerlit.ab.
6. exp Review Literature as Topic/	6. cochrane.ab.
7. or/1-6	7. embase.ab.
8. cochrane.ab.	8. (psychlit or psyclit).ab.
9. embase.ab.	9. (psychinfo or psycinfo).ab.
10. (psychlit or psyclit).ab.	10. (cinahl or cinhal).ab.
11. (psychinfo or psycinfo).ab.	11. science citation index.ab.
12. (cinahl or cinhal).ab.	12. bids.ab.
13. science citation index.ab.	13. or/5-12
14. bids.ab.	14. reference lists.ab.
15. cancerlit.ab.	15. bibliograph$.ab.
16. or/8-15	16. hand-search$.ab.
17. reference list$.ab.	17. manual search$.ab.
18. bibliograph$.ab.	18. relevant journals.ab.
19. hand-search$.ab.	19. or/14-18
20. relevant journals.ab.	20. data extraction.ab.
21. manual search$.ab.	21. selection criteria.ab.
22. or/17-21	22. 20 or 21
23. selection criteria.ab.	23. review.pt.
24. data extraction.ab.	24. 22 and 23
25. 23 or 24	25. letter.pt.
26. Review/	26. editorial.pt.
27. 25 and 26	27. animal/
28. Comment/	28. human/
29. Letter/	29. 27 not (27 and 28)
30. Editorial/	30. or/25-26,29
31. animal/	31. 4 or 13 or 19 or 24
32. human/	32. 31 not 30
33. 31 not (31 and 32)	
34. or/28-30,33	
35. 7 or 16 or 22 or 27	
36. 35 not 34	

2) University of Texas School of Public Health search filters to identify guidelines/recommendations

MEDLINE
practice guideline/ or Health Planning Guidelines/ or guideline*.ti. or (practice adj3 parameter*).ti,ab. or clinical protocols/ or guidance.ti,ab. or care pathway*.ti,ab. or critical pathway/ or (clinical adj3 pathway*).ti,ab. or algorithms/ or consensus development conference.pt. or consensus development conference nih.pt.

Appendix 5: List of excluded studies at the full-text screening stage with reasons for exclusion

Systematic Reviews

Study	Reason for exclusion
Alvarez-Bueno, C.; Rodriguez-Martin, B.; Garcia-Ortiz, L.; Gomez-Marcos, M. A.; Martinez-Vizcaino, V. (2015). Effectiveness of brief interventions in primary health care settings to decrease alcohol consumption by adult non-dependent drinkers: a systematic review of systematic reviews. *Preventive Medicine*.76; S33-8	Review of reviews
Asfar, Taghrid; Ebbert, Jon O.; Klesges, Robert C.; Relyea, George E. (2011). Do smoking reduction interventions promote cessation in smokers not ready to quit? *Addictive Behaviors*. 36(7):764-768	Wrong setting
Aveyard, Paul; Begh, Rachna; Parsons, Amanda; West, Robert (2012). Brief opportunistic smoking cessation interventions: A systematic review and meta-analysis to compare advice to quit and offer of assistance. *Addiction*.107(6):1066-1073	Wrong study design
Bauld, L.; Bell, K.; McCullough, L.; Richardson, L.; Greaves, L. (2010). The effectiveness of NHS smoking cessation services: a systematic review. *Journal of Public Health.* 32(1):71-82	Wrong setting
Boyle, R.; Solberg, L.; Fiore, M. (2014). Use of electronic health records to support smoking cessation. *Cochrane Database of Systematic Reviews*. (12):34	Wrong intervention
Bridle, C.; Riemsma, R. P.; Pattenden, J.; Sowden, A. J.; Mather, L.; Watt, I. S.; Walker, A (2005). Systematic review of the effectiveness of health behavior interventions based on the transtheoretical model. *Psychology & Health*. 20(3):283-301	Wrong setting
Chen, D.; Wu, L. T. (2015). Smoking cessation interventions for adults aged 50 or older: A systematic review and meta-analysis. *Drug and Alcohol Dependence 01*. 154:14-24	Wrong setting
Christakis, D. A.; Garrison, M. M.; Ebel, B. E.; Wiehe, S. E.; Rivara, F. P. (2003). Pediatric smoking prevention interventions delivered by care providers: a systematic review. *American Journal of Preventive Medicine.* 25(4): 358-362.	Wrong population
Coulton, S. (2011). Alcohol misuse. *Clinical Evidence*	Review of reviews
Crouch, R.; Wilson, A.; Newbury, J. (2011). A systematic review of the effectiveness of primary health education or intervention	Wrong intervention

programs in improving rural women's knowledge of heart disease risk factors and changing lifestyle behaviours. *International Journal of Evidence-Based Healthcare*. 9:236-45	
Dennis, S.; Williams, A.; Taggart, J.; Newall, A.; Denney-Wilson, E.; Zwar, N.; Shortus, T.; Harris, M. F. (2012). Which providers can bridge the health literacy gap in lifestyle risk factor modification education: a systematic review and narrative synthesis. BMC Family Practice.13; 44	Wrong outcomes
Ebbert, J.; Montori, V. M.; Erwin, P. J.; Stead, L. F. (2011). Interventions for smokeless tobacco use cessation. *Cochrane Database Syst Rev*. (2):Cd004306	Wrong intervention
Ebbert, J. O.; Rowland, L. C.; Montori, V. M.; Vickers, K. S.; Erwin, P. J.; Dale, L. C. (2003). Treatments for spit tobacco use: a quantitative systematic review. *Addiction*. 98(5):569-583	Wrong setting
Ebrahim, S.; Smith, G. D. (1997). Systematic review of randomised controlled trials of multiple risk factor interventions for preventing coronary heart disease. *BMJ*. 314(7095):1666-74	Wrong setting
Gao, X.; Lo, E. C.; Kot, S. C.; Chan, K. C. (2014). Motivational interviewing in improving oral health: a systematic review of randomized controlled trials. Journal of Periodontology 85(3): 426-437	Wrong population
Goldfarb, M.; Slobod, D.; Dufresne, L.; Brophy, J. M.; Sniderman, A.; Thanassoulis, G. (2015). Screening Strategies and Primary Prevention Interventions in Relatives of People With Coronary Artery Disease: A Systematic Review and Meta-analysis. *Canadian Journal of Cardiology*. 31(5):649-657	Wrong setting
Gordon, A. J. (2006).Screening the drinking: Identifying problem alcohol consumption in primary care settings. *Advanced Studies in Medicine*. 6(3):137-147	Wrong intervention
Green, Amanda C.; Hayman, Laura L.; Cooley, Mary E. (2015). Multiple health behavior change in adults with or at risk for cancer: A systematic review. *American Journal of Health Behavior*. 39(3):380-394 US American Journal of Health Behavior	Wrong intervention
Harris, R.; Gamboa, A.; Dailey, Y.; Ashcroft, A. (2012). One-to-one dietary interventions undertaken in a dental setting to change dietary behavior. *Cochrane Database of Systematic Reviews*. 3():CD006540	Wrong intervention
Ketola, E.; Sipila, R.; Makela, M. (2000). Effectiveness of individual lifestyle interventions in reducing cardiovascular disease and risk factors. *Annals of Medicine*. 32(4):239-251	Wrong setting
Kim, S. S.; Chen, W.; Kolodziej, M.; Wang, X.; Wang, V. J.;	Wrong setting

Ziedonis, D. (2012). A systematic review of smoking cessation intervention studies in China. *Nicotine Tob Res*. 14(8):891-9	
Kottke, T. E.; Battista, R. N.; Defriese, G. H. & Brekke, M. L. (1988). Attributes of successful smoking cessation interventions in medical practice. A meta-analysis of 39 controlled trials. *JAMA,* 259, 2883-9	No separate primary care results (combined results for all hospital settings)
Lancaster, T.; Stead, L. F. (2005). Individual behavioural counselling for smoking cessation. *Cochrane Database of Systematic Reviews*. (2):CD001292	Wrong setting
Law, M.; Tang, J. L. (1995). An analysis of the effectiveness of interventions intended to help people stop smoking *Arch Intern Med*. 155(18):1933-41	Wrong setting
Lundahl, Brad; Moleni, Teena; Burke, Brian L.; Butters, Robert; Tollefson, Derrik; Butler, Christopher; Rollnick, Stephen (2013). Motivational interviewing in medical care settings: A systematic review and meta-analysis of randomized controlled trials. *Patient Education and Counseling*. 93(2):157-168	Wrong setting
McCambridge, J.; Jenkins, R. J. (2008). Do brief interventions which target alcohol consumption also reduce cigarette smoking? Systematic review and meta-analysis. *Drug Alcohol Depend*. (3):263-70	Wrong setting
McCambridge, J.; Kypri, K. (2011). Can simply answering research questions change behaviour? Systematic review and meta analyses of brief alcohol intervention trials. *PLoS One*. 6(10):e23748	Wrong intervention
Okumura, L. M.; Rotta, I.; Correr, C. J. (2014). Assessment of pharmacist-led patient counseling in randomized controlled trials: a systematic review. *International Journal of Clinical Pharmacy*. 36(5):882-891	Wrong intervention
Patnode, C. D.; O'Connor, E.; Whitlock, E. P.; Perdue, L. A.; Soh, C.; Hollis, J. (2013). "Primary care-relevant interventions for tobacco use prevention and cessation in children and adolescents: a systematic evidence review for the U.S. Preventive Services Task Force." Annals of internal medicine 158(4): 253-260	Wrong population
Patton, R.; Deluca, P.; Kaner, E.; Newbury-Birch, D.; Phillips, T.; Drummond, C. (2014). Alcohol screening and brief intervention for adolescents: the how, what and where of reducing alcohol consumption and related harm among young people. *Alcohol Alcohol.* 49(2):207-12	Review of reviews
Ramseier, C. A.; Suvan, J. E. (2015). Behaviour change counselling for tobacco use cessation and promotion of healthy lifestyles: a systematic review. *Journal of Clinical*	Wrong setting

Periodontology. 42 Suppl 16():S47-58	
Ranney, L.; Melvin, C.; Lux, L.; McClain, E.; Lohr, K. N. (2006). Systematic review: Smoking cessation intervention strategies for adults and adults in special populations. *Annals of Internal Medicine*. 145(11):845-856	Wrong setting
Riemsma, R. P.; Pattenden, J.; Bridle, C.; Sowden, A.; Mather, L.; Watt, I. S.; Walker, A. (2003). Systematic review of the effectiveness of stage based interventions to promote smoking cessation. *British Medical Journal.* 326(7400):1175-1177	Wrong setting
Rubak, S.; Sandbaek, A.; Lauritzen, T.; Christensen, B.(2005). Motivational interviewing: A systematic review and meta-analysis. *British Journal of General Practice*. 55(513):305-312	Wrong setting
Satur, J. G.; Gussy, M. G.; Morgan, M. V.; Calache, H.; Wright, C. (2010). Review of the evidence for oral health promotion effectiveness. *Health Education Journal*. 69(3):257-266	Wrong setting
Schroer-Gunther, M. A.; Zhou, M.; Gerber, A.; Passon, A. M. (2011). Primary tobacco prevention in China--a systematic review. *Asian Pac J Cancer Prev*. 12(11):2973-80	Wrong setting
Stead, L. F.; Lancaster, T. (2012). Combined pharmacotherapy and behavioural interventions for smoking cessation. *Cochrane Database Syst Rev*. 10():Cd008286	Wrong intervention
Sullivan, L. E.; Tetrault, J. M.; Braithwaite, R. S.; Turner, B. J.; Fiellin, D. A. (2011). A meta-analysis of the efficacy of nonphysician brief interventions for unhealthy alcohol use: implications for the patient-centered medical home. *American Journal on Addictions*. 20(4):343-56	Wrong setting
Tait, R. J.; Hulse, G. K. (2003). A systematic review of the effectiveness of brief interventions with substance using adolescents by type of drug. *Drug & Alcohol Review*. 22(3):337-46	Wrong setting
Williams, Emily C.; Johnson, M. Laura; Lapham, Gwen T.; Caldeiro, Ryan M.; Chew, Lisa; Fletcher, Grant S.; McCormick, Kinsey A.; Weppner, William G.; Bradley, Katharine A. (2011). Strategies to implement alcohol screening and brief intervention in primary care settings: A structured literature review. *Psychology of Addictive Behaviors*. 25(2):206-214	Wrong intervention

Clinical Guidelines

Guideline	Reason for exclusion
AAOM (2014). Clinical Practice Statement: Risk Assessment.	Wrong study design
AAOM (2013). Clinical Practice Statement: Medical History	Wrong study design
ENTUK (2011). Head and Neck Cancer: Multidisciplinary Management Guidelines, 4th edition. *British Association of Otorhinolaryngology, Head and Neck Surgery, The Royal College of Surgeons of England*	Treatment/Management CG
BASHH (2006). UK National guidelines on undertaking consultations requiring sexual history taking. *British Association for Sexual Health and HIV*	Wrong setting
BTA (2008). Reichert, J., de Araújo, A.J., Gonçalves, C.M.C., Godoy, I., Chatkin, J.M., Sales, M.D.P.U. and de Almeida Santos, S.R.R. Brazilian Thoracic Association (BTA) Guidelines. *J Bras Pneumol*, *34*(10), pp.845-88.	Treatment/Management CG
NHS Health Scotland publication "A Guide to Smoking Cessation in Scotland 2010"	Duplicate - higher quality and large guideline included (NICE 2006, 2008)
NICE (2007). Sexually transmitted infections and under-18 conceptions: prevention. *Public health guideline (PH3)*, *National Institute for Health and Clinical Excellence*	Wrong intervention
NICE (2013). Tobacco: harm-reduction approaches to smoking. *National Institute for Health and Clinical Excellence - Clinical Guidelines 1*	Wrong setting
NGC (2012). Tobacco exposure. In: Expert panel on integrated guidelines for cardiovascular health and risk reduction in children and adolescents. [National Heart, Lung, and Blood Institute (U.S.)] *info@guidelines.gov (NGC) 12*	Wrong intervention
(2008). The New South Wales Health drug and alcohol psychosocial interventions professional practice guidelines. *Clinical Practice Guidelines Portal 1*	Wrong setting
AAFP (2009). Summary of recommendations for clinical preventive services. *American Academy of Family Physicians 7*	Summary document (included full CG)
(2014). South Australian lung cancer pathway. *Clinical Practice Guidelines Portal 2*	Treatment/Management CG
(2014). South Australian head and neck cancer pathway. *Clinical Practice Guidelines Portal 2*	Treatment/Management CG

(2012). Safer Sex. *British HIV Association 1*	Wrong setting
(2010). Prevention of cardiovascular disease. *National Institute for Health and Clinical Excellence - Clinical Guidelines 1*	Wrong setting
(2012). New Zealand primary care handbook 2012. *New Zealand Guidelines Group 3*	Wrong intervention
(2011). Guidelines for the assessment of absolute cardiovascular disease risk. [National Heart Foundation of Australia] *info@guidelines.gov (NGC) 7*	Treatment/Management CG
(2013). Guideline Summary: Risk estimation and the prevention of cardiovascular disease. A national clinical guideline. [Scottish Intercollegiate Guidelines Network] *info@guideline.gov (NGC) 2*	Wrong setting
USPSTF (2013). Guideline Summary: Primary care interventions to prevent tobacco use in children and adolescents: U.S. Preventive Services Task Force recommendation statement. [U.S. Preventive Services Task Force]. *info@guideline.gov (NGC) 12*	Wrong intervention
CDC (2013). Guideline Summary: Human papillomavirus (HPV) infection. In: Sexually transmitted diseases treatment guidelines, 2010. [Centers for Disease Control and Prevention] *info@guideline.gov (NGC) 2*	Treatment/Management CG
USPSTF ((2015). Guideline Summary: Behavioral counseling interventions to prevent sexually transmitted infections: U.S. Preventive Services Task Force recommendation statement. [U.S. Preventive Services Task Force] *info@guideline.gov (NGC) 3*	Wrong setting
MQIC (2013). Guideline Summary: Adolescent health risk behavior assessment. [Michigan Quality Improvement Consortium] *info@guideline.gov (NGC) 4*	Wrong setting
ACCF (2014). Guideline Summary: 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. [American College of Cardiology Foundation]. *info@guideline.gov (NGC) 12*	Wrong intervention
(2012). Facilitating Client Centred Learning. *Registered Nurses' Association of Ontario 1*	Practice/Professional focused
SIGN (2006). Diagnosis and management of head and neck cancer. *SIGN 11*	Treatment/Management CG
NICE (2008). CVD risk assessment and management. *NICE*	Wrong intervention

Clinical Knowledge Summaries 1	
NICE (2011). Cardiovascular disease: identifying and supporting people most at risk of dying early [National Institute for Health and Clinical Excellence (NICE)] *info@guidelines.gov (NGC) 5*	Wrong patient population
(2008). Canadian Consensus Guidelines on Human Papillomavirus. *Society of Obstetricians and Gynaecologists of Canada 4*	Wrong setting
NHMRC (2009). Australian Guidelines to Reduce Health Risks from Drinking Alcohol. *National Health and Medical Research Council 1*	Wrong setting
(2014). ARCHIVED (March 2010)- Contraceptive choices for young people. *Faculty of Sexual & Reproductive Healthcare 8*	Wrong setting
NICE (2010). Alcohol-use disorders: preventing harmful drinking. *National Institute for Health and Clinical Excellence - Clinical Guidelines 1*	Wrong setting

Appendix 6: Trial duplication in the included Systematic Reviews (SRs)

The included trials in systematic reviews were labelled as T1-171; red coloured labels shows duplicate trials.

Systematic Reviews (SRs)	Trials included	
SR1 (Lindson 2015)	T1 T2 T3 T4	
SR2 (Bully 2015)	T5 T6 T7 T8	T9 T10 T11
SR3 (Angus 2014)	T12 T13 T14 T15 T16 T17 T18 T19 T20 T21 T22	T23 T24 T25 T26 T27 T28 T29 T30 T31 T32 T33
SR4 (Morton 2015)	T20 T34 T35 T36 T37	T38 T39 T40 T41 T42
SR5 (Gebara 2013)	T43	
SR6 (Rice 2013)	T11 T44 T45 T46 T47 T48 T49 T50	T51 T52 T53 T54 T55 T56 T57
SR7 (VanBuskirk 2013)	T2 T35 T58	T59 T60 T61

SR8 (Stead 2013)	T1 T6 T7 T44 T47 T62 T63 T64 T65 T66 T67 T68 T69 T70 T71 T72 T73	T74 T75 T76 T77 T78 T79 T80 T81 T82 T83 T84 T85 T86 T87 T88 T89
SR9 (Noordmanz 2012)	T11 T34 T35 T37 T39 T43 T49 T52	T56 T60 T90 T91 T92 T93 T94 T95
SR10 (Willis 2012)	T96 T97 T98	T99 T100
SR11 (Jonas 2012)	T20 T23 T25 T36 T38 T39 T40 T41 T60 T95 T101	T102 T103 T104 T105 T106 T107 T108 T109 T110 T111
SR12 (Carr 2012)	T112 T113 T114 T115 T116 T117 T118	T119 T120 T121 T122 T123 T124 T125
SR13 (Taggart 2012)	T1 T52 T126	T127 T128

SR14 (Brown 2012)	T129 T130 T131 T132	T133 T134 T135
SR15 (Zbikowski 2011)	T47 T54 T72 T136	
SR16 (Cahill 2010)	T6 T7 T137 T138	
SR17 (Kaner 2009)	T20 T23 T25 T34 T38 T40 T41 T101/107 T104 T105 T108 T139	T140 T141 T142 T143 T144 T145 T146 T147 T148 T149 T150
SR18 (Halcomb 2007)	T11 T42 T45 T47	T50 T51 T52 T151
SR19 (Wilhelmsson 2007)	T40 T152	
SR20 (Huibers 2007)	T41 T77 T81 T147	
SR21 (Hyman 2006)	T147 T150	
SR22 (Bertholet 2005)	T20 T25 T34 T38 T40 T41 T105 T139 T141	T143 T144 T145 T146 T147 T149 T153 T154 T155

SR23 (Gorin 2004)	T49 T63 T72 T74 T121 T123 T156 T157	T158 T159 T160 T161 T162 T163 T164
SR24 (VanSluijs 2004)	T1 T6 T52 T137 T138	T157 T165 T166 T167 T168
SR25 (Whitlock 2004)	T20 T25 T38 T40 T41 T101	T102 T104 T105 T107 T108 T169
SR26 (Ballesteros 2004)	T20 T25 T40 T41 T101 T104 T105	T107 T108 T139 T142 T143 T144
SR27 (Sinclair 2004)	T129 T134	
SR28 (Blenkinsopp 2003)	T129 T134	
SR29 (Poikolainen 1999)	T41 T101 T105 T107	T108 T144 T169
SR30 (Ashenden 1997)	T45 T47 T49 T50 T63 T66 T68 T70 T75 T77 T76 T79 T80 T81	T82 T83 T84 T85 T88 T89 T101 T107 T108 T144 T148 T170 T171
SR31 (Kahan 1995)	T101 T107 T108	T144 T148 T169

Appendix 7: Letter from West of Scotland Research Ethics Service (WOSRES)

NHS
Greater Glasgow and Clyde

WoSRES
West of Scotland Research Ethics Service

Ms Sweta Mathur
PhD Student
Glasgow Dental Hospital & School
University of Glasgow

West of Scotland Research Ethics Service
Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT

Date	20th March 2015
Our Ref	WoS ASD 984
Direct line	0141 211 2126
Fax	0141 211 1847
E-mail	Judith.Godden@ggc.scot.nhs.uk

Dear Ms Mathur

Full title of project: Oral Cancer Risk Assessment and Prevention: Best Practice and Implementation of Clinical Guidelines

You have sought advice from the West of Scotland Research Ethics Service Office on the above project. This has been considered by the Scientific Officer and you are advised that based on the submitted documentation (email correspondence 11th February 2015) it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (A Harmonised Edition). This advice is based on the following.

- The participants are neither patients nor relatives or carers of patients (recruited for this reason) and therefore the study does not fall within the scope of the NHS Research Ethics Committee system (GAfREC 2011)

Note that this advice is issued on behalf of the West of Scotland Research Ethics Service and does **not** constitute a favourable opinion from a REC. It is intended to satisfy journal editors and conference organisers and others who may require evidence of consideration of the need for ethical review by an NHS REC prior to publication or presentation of your results.

This project may require NHS Management Approval and you should check with the appropriate Health Board R&D Department before commencing the study.

Kind regards

Dr Judith Godden, WoSRES Scientific Officer/Manager

Appendix 8: MVLS ethical approval for part of the project (dental professional interview study)

1st application

University of Glasgow | College of Medical, Veterinary & Life Sciences

12th June 2015

Dear Dr Ross

MVLS College Ethics Committee

Project Title: Oral cancer risk assessment and prevention: best practice and implementation of clinical guidelines
Project No: 200140156

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. It is happy therefore to approve the project, subject to the following conditions:

- Project end date: 31 March 2018
- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research: (http://www.gla.ac.uk/media/media_227599_en.pdf)
- The research should be carried out only on the sites, and/or with the groups defined in the application.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely

Dr Dorothy McKeegan
College Ethics Officer

Dr Dorothy McKeegan
Senior Lecturer
R303 Level 3
Institute of Biodiversity Animal Health and Comparative Medicine
Jarrett Building
Glasgow G61 1QH Tel: 0141 330 5712
E-mail: Dorothy.McKeegan@glasgow.ac.uk

2nd application

University of Glasgow | College of Medical, Veterinary & Life Sciences

16th June 2016

Dear Dr Ross

MVLS College Ethics Committee

Project Title: Oral cancer risk assessment, examination and prevention: cross national pre-pilot interviews to explore implementation of best practice and clinical guidelines

Project No: 200150168

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. It is happy therefore to approve the project, subject to the following conditions:

- Project end date: 31 October 2016
- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research: (http://www.gla.ac.uk/media/media_227599_en.pdf)
- The research should be carried out only on the sites, and/or with the groups defined in the application.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely

Dr Dorothy McKeegan
College Ethics Officer

Dr Dorothy McKeegan

Senior Lecturer

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Appendix 9: Topic guide or interview schedule for dental professional interviews

University of Glasgow | College of Medical, Veterinary & Life Sciences

Interview Schedule [for oral cancer feasibility interviews in Scotland]

"Oral cancer risk assessment, examination and prevention: dental teams' views and experiences to explore implementation of best practice and clinical guidelines"

1. **INTRODUCTION**

   a) Have you read the information sheet and consent form? Do you have any questions regarding this?
   b) Aim of these interviews: I would like to know your views on current practice and to explore how best practice evidence on oral cancer prevention and early detection (from systematic overviews) can be implemented in general practices.
   c) There are no right answers; I just want to know your views.

2. **GENERAL INFO**

   a) **What is your current role/title? (name for tape)**
   b) **How long have you been practicing? Were you always in GP?**
   c) **What if any is your background relating to oral cancer?**
      i. Any training? CPD? specialty etc.?

3. **RISK FACTORS**

   a) **What risks of oral cancer do you know about?**
      i. Smoking/ alcohol/HPV/sexual behaviours
      ii. Age/gender/socioeconomic status/education/family history

   b) **How do you find out / identify these risks?**
      i. take social history? or as part of medical history?
      ii. Is this as a norm if they have risk factors? or if patients bring it up?
      iii. When do you take social history? Who takes it?
      iv. Do you use any assessment/screening tools? (AUDIT, CAGE, etc.)

   c) **How many patients have you seen with oral cancer / suspicious lesions?**
      i. What happened next?
      ii. What about referral, follow up, recall?

d) **Do you ever discuss oral cancer risks with your patients or <u>bring oral cancer term</u> in discussion (or would it terrify patients)?**
    i. Is it duty of dental professionals to inform patient about their risk for oral cancer?

4. <u>ADVICE/ BRIEF INTERVENTION</u>

a) **Do you ever give people behavioural advice / counselling on smoking?**
    i. How? When?

b) **SR evidence: Brief face-to-face advice for at least 5 min (range 5-10min.)**
Would you be comfortable giving brief advice (up to 5 min.) on Smoking?
    i. If not, why? What would help?
    ii. When would this be possible/ useful, if at all? (would it fit within general oral health assessment or examinations)

c) **Do you ever give people behavioural advice on drinking?**
    i. How? When?

d) **Would you be comfortable giving brief advice (up to 5 min.) on Alcohol?**
    i. If not, why? What would help?
    ii. When would this be possible/ useful, if at all?

e) **Who is the best member of the dental team to give such advice?**
    i. Dentist, nurse, hygienist/therapist; why?
SR evidence: effectiveness of advice by dental team (any member)

f) **What should go alongside brief counselling?**
    i. Self-help materials, follow-up (phone calls or visits), goal setting
SR evidence: effectiveness of these

g) **SR evidence: effectiveness of attending training to learn how to counsel/ advise patients on their behaviours and ½ day is sufficient. Would you attend such training?**
    i. If not, why?
    ii. How much training would you think is appropriate: 1 session (half a day) or 2 sessions (1 day)? Should it be repeated every year or just once?
    iii. What about e-learning/ CPD type activity?

5. <u>REFERRAL</u>

a) **Have you ever referred patients to another service for their smoking/ drinking?**

i. How? What did that involve? cessation /counselling service or signpost or provide smoking quit line telephone number, etc.?
ii. If not- why?

b) SR evidence: effectiveness of referral & follow up by phone calls. Would you be comfortable referring patients to specialist services based on their risks? (if already referring, would they continue in future?)

i. Cessation services, more intensive counselling, NRT/ pharmacological support, self-help or support groups
ii. or even sign-post (no formal referral)

c) Would you/ could you follow patients up to see if referral/signposting worked?

6. RISK PREDICTION/ASSESMENT

a) Are you aware of risk assessment tools for breast cancer, cardiovascular disease, etc.?

b) Would it help to have a tool for oral cancer that profiled/ quantified risk using this type of information? (red, amber or green)

c) How would it work best in practice?

i. Where? When? Who?
ii. 2 ways of using this tool:
    1. self-completion in waiting room- when patient come to you risk already calculated for you (save your time)?
    2. go over with dental professional- as part of oral health assessment (help to break ice and tailor advice)?
iii. Online tool / as an app / paper questionnaire?

d) Would you/ could you use this as a decision tool?

i. To guide Oral exams? Preventive strategies? Recall? Referral?
ii. How would it help? or what would the difficulties be?

e) Would this tool help to introduce patient with term 'oral cancer risk'?

f) What about colleagues/ others that you know about/ work with?

i. What would they think about this type of risk profiling?

7. OTHER

a) Is there anything you think is missing/not working in your practice on oral cancer?

i. What?
ii. What might improve things?

b) **Is there anything about oral cancer early detection/ prevention/ referral we haven't covered?**

c) **Anything else at all you wish to say?**

Thank you very much. I appreciate the time you took for this interview.

Appendix 10: Participant information sheet – for dental professional interviews

University of Glasgow | College of Medical, Veterinary & Life Sciences

INFORMATION ABOUT THE RESEARCH

"Oral cancer risk assessment and prevention: national pre-pilot interviews to explore implementation of best practice and clinical guidelines"

Introduction
You are being invited to take part in a research study. Before you decide whether to take part in the study, it is important that you understand why the research is being done and what it will involve for you. Please take some time to read the following information carefully. Feel free to discuss the study with others before you decide. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
The study is a qualitative study, involving individual interview (one-to-one) to explore the views of dental teams in Scotland on oral cancer examination and prevention guidance. We want to find out the barriers and facilitators to oral cancer risk assessment, oral examination, preventive advice and referral in dental practice.

Why have I been chosen?
You are being asked to take part in the study because you are working in General Dental Practice and can inform us as to the feasibility of translation research evidence and guidelines to everyday working environments.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part, please remember that you are free to withdraw at any time and without giving a reason.

What will happen to me if I take part?
We will invite you to participate in a 30-45 minute face-to-face interview. Questions will focus on the current barriers and facilitators to oral cancer risk assessment, examination, patient recall, advice-giving and referral in dental practice. We would also like to explore which aspect of best practice for oral cancer risk assessment, examination and prevention are transferrable to dental practice to improve outcomes for patients.

We will make sure that you are happy with being tape-recorded beforehand.

What do I have to do?
If you are happy to take part, we will contact you to arrange a mutually convenient time for the interview. If you do not want to take part, we will not contact you again.

What are the possible disadvantages and risks of taking part?
There are no identified risks and it is very unlikely that you will come to any harm as a result of taking part in the study. However, if you feel uncomfortable or do not wish to continue at any time, you can leave the discussion without giving any reason.

What are the possible benefits of taking part?
We hope the information that will be collected during this study will be useful to support implementation and sustained use of oral cancer guidance in risk assessment, prevention and referral for the benefit of the public.

Will my taking part in this study be kept confidential?
Your information will be kept strictly confidential and anonymous. You will only be identified by an ID number, and any information about you will have your name removed so that you cannot be recognized from it. The anonymized interview notes and your records will be held securely for at least 10 years at the University of Glasgow (in accordance with Medical Research Council best research practice guidelines). We will then destroy them.

What will happen to the results of the research study?
The results will be used to write a PhD thesis, and will be made available as scientific papers in journals and presentations at seminars and/or conferences. We can also send you a short summary of the findings if you wish.

Who is organising and funding the research?
The study is being conducted by the Glasgow Dental Hospital and School at the University of Glasgow. The study is funded by NHS Education for Scotland and Glasgow Dental Educational Trust.

Who has reviewed the study?
The project has been reviewed by the College of Medicine, Veterinary and Life Sciences ethics committee, NHS West of Scotland Research Ethics Service (WoSRES) and NHS R&D Management committee. A study proposal has also been submitted to the Glasgow Dental Hospital and School Research Management Committee.

Contact for Further Information:

Please contact Dr Sweta Mathur at s.mathur.1@research.gla.ac.uk or +44 777 839 1940;

If you have any concerns about any aspect of this study, please contact Dr Alastair Ross at alastair.ross@gla.ac.uk or +44 141 211 9811

Thank you for taking the time to read this information.

Appendix 11: Participant consent form – for dental professional interviews

University of Glasgow | College of Medical, Veterinary & Life Sciences

Project Number: 69121

CONSENT FORM

Title of Project:
Oral cancer risk assessment, examination and prevention: national pre-pilot interviews to explore implementation of best practice and clinical guidelines

Name of Researcher(s):
Dr Sweta Mathur; Dr Alastair Ross; Prof David Conway; Prof Lorna Macpherson

Please initial box

I confirm that I have read and understand the information sheet dated May 2016 (version v1.4.1) for the above study and have had the opportunity to ask questions.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.	☐
I give my permission for the interview that I take part in to be tape-recorded.	☐
I agree to take part in the above study.	☐

Name of subject	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

(1 copy for subject; 1 copy for researcher)

Appendix 12: Topic guide or survey instrument for patient interviews

"Oral (mouth) cancer risk assessment, examination and prevention: patients' views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland"

TOPIC GUIDE

INTRODUCTION (introduce self)

- Have you read the information sheet and consent form? Do you have any questions regarding this?
- I would like to know your views and experiences of previous and current dental practice visits in relation to mouth cancer risk factors/ causes and prevention.
- There are no right answers; I just want to know your views.

1) **Thinking of the last 5 years, how often have you visited general dental practice?**

☐ **10+**	☐ **5-4**	☐ **2-4**	☐ **1**
Twice a year or more	About once a year	Less than once a year	Only this time (first visit)

2) **Thinking of the last 5 years, what reasons have you had for visiting general dental practice?** (tick all that apply)

☐ **Check-up** ☐ **Follow-up** ☐ **Pain / Emergency** ☐ **Scaling/ polishing (oral hygiene)** ☐ **Other**

Other, specify: _____

GENERAL AWARENESS AND RISKS

1) **Have you heard of mouth cancer?**

☐ **Yes** ☐ **No**

Prompts: Where have you heard? What have you heard? e.g. from the dental team, any history- you or in family, social media, or other.
If mouth cancer patient- what their case is- how and when detected, referral and treatment?

2) **Do you know what causes mouth cancer?**
   Overall how much do you know about causes for mouth cancer?
   Prompts: Smoking/ alcohol/ other form of tobacco/ age/ gender/ SES/ family history
   Where have you heard? Who told you? e.g. dental team, social media, or other

☐	☐	☐	☐	☐
No knowledge	**Slight/ little knowledge**	**Some knowledge**	**Good knowledge**	**Very good knowledge**

PREVENTION (ADVICE/ REFERRAL)

a) *Smoking or other form of tobacco* *(views and experiences of current/previous visits)*

1) **May I ask, are you a smoker?**
   ☐ **Never** ☐ **Current** ☐ **Ex-smoker**

2) **Do you use any other tobacco products?**
   ☐ **Yes** ☐ **No**
   If yes, which ones? E.g. pipe tobacco, cigars, chewing tobacco, E-cigarettes or other?

3) **Has your dental team ever asked about your smoking status?**
   ☐ **Yes** ☐ **No** ☐ **Not sure**

4) **If smoker (current), have you ever thought about quitting?**
   ☐ **Yes** ☐ **No**
   Prompts: why or why not?

5) **If smoker (current or ex): has your dental team ever offered advice / counselling on smoking (or other form of tobacco)?**
   ☐ **Yes** ☐ **No** ☐ **Not sure**
   Prompts: What did they say? Why you had that conversation? What context- mouth cancer, gum disease, staining, or other?
   What advice do you remember?
   - Harmful effects of smoking or benefits of quitting
   - Any leaflets or educational materials
   - Referral: cessation/counselling services or to pharmacist or provided smoking quit line number or medicines for quitting (NRT- gum, patches, and lozenges), etc.
   - Did it help?
   - Any follow-up (by phone calls or next appointment)

6) **If smoker (current), how do you feel about receiving smoking advice from:**
   - □ **Dental team within the practice (as part of consultation)**
   - □ **Or dentist referring you to cessation services or GP**
   - □ **Both**
   - □ **None**

   Prompts: why or why not?

7) **If current smoker, how would you feel about receiving brief advice up to 5 minutes from your dental team about quitting smoking?**
   Prompts: why or why not? What would help?

☐	☐	☐	☐	☐
Not happy at all 1	**Not happy 2**	**Not sure 3**	**Happy 4**	**Very happy 5**

b) *Alcohol* *(views and experiences of current/previous visits)*

1) **May I ask, how often do you have a drink containing alcohol?**

☐	☐	☐	☐	☐
Never	**Monthly or less**	**2–4 times per month**	**2–3 times per week**	**4+ times per week**

2) **Has your dental team ever asked you about drinking?**
   ☐ **Yes** ☐ **No**

   Prompts: If yes, did they use a tool or questionnaire to ask about alcohol?

3) **Has your dental team ever offered any advice / counselling on alcohol?**
   ☐ **Yes** ☐ **No**

   Prompts: What did they say? Why you had that conversation? What context- mouth cancer, gum disease, trauma, or other?
   What advice do you remember?
   - Harmful effects of alcohol or benefits of moderating/ quitting
   - Talked about safe drinking levels
   - Any leaflets or educational materials
   - Referral: cessation/counselling services or to pharmacist or provided quit line number, etc.
   - Did it help?
   - Any follow-up (by phone calls or next appointment)

4) **How do you feel about receiving alcohol advice from:**
   - □ **Dental team within the practice (as part of consultation)**
   - □ **Or dentist referring you to cessation services or GP**

   Prompts: why or why not?

5) **How would you feel about receiving brief advice up to 5 minutes from your dental team about alcohol?**
   Prompts: why or why not? What would help?

☐	☐	☐	☐	☐
Not happy at all	**Not happy**	**Not sure**	**Happy**	**Very happy**

POTENTIAL INTERVENTION

1) **How would you feel about dentist telling you a risk score as high, medium or low for mouth cancer based on your personal information- e.g. smoking, alcohol, age, years of education, family history?**

   Prompts: Which would then lead onto a mouth cancer check and then appropriate smoking/alcohol behavioural counselling?
   Do you think people will be happy to provide this information correctly to their dental team?

2) **How would you feel or how happy would you be about having a risk score/ categorisation?**
   Prompts: why or why not?

☐	☐	☐	☐	☐
Not happy at all	**Not happy**	**Not sure**	**Happy**	**Very happy**

3) **Would you be happy to enter this information onto a paper form or online form or an app at the practice or would you be happy for someone in the dental team to ask you these directly?**
   Prompts: self-completion in waiting room? Or go over with dental team- as part of consultation?

4) **Which would you prefer to receive risk categorisation as:**
   - □ **Traffic light - Red (for high), Amber (for medium), Green (for low)**
   - □ **High, medium and low**
   - □ **As a number or percentage score or in times**

   e.g. chance of getting cancer in 5 or 10 or 20 years

OTHER

1) **Is there anything else re mouth cancer check, brief advice and referral you wish to say?**

GENERAL BACKGROUND INFORMATION (so we cover a range of patients, we'll not disclose any information)

1) **What year were you born? _____**

2) **Gender:**
   - Male
   - Female

3) **What is your ethnic group?**

White	☐Scottish	☐Northern Irish	☐Gypsy/ traveler
	☐English	☐British	☐Polish
	☐Welsh	☐Irish	☐White Other
Mixed			
Asian, Asian Scottish or Asian British	☐Pakistani, Pakistani Scottish or Pakistani British	☐Bangladeshi, Bangladeshi Scottish or Bangladeshi British	☐Chinese, Chinese Scottish or Chinese British
	☐Indian, Indian Scottish or Indian British		☐Other
African, Caribbean or Black	☐African, African Scottish or African British	☐Caribbean, Caribbean Scottish or Caribbean British	☐Black, Black Scottish or Black British
			☐Other
Any other ethnicity			

4) **Are you currently working?**

☐ **Yes** ☐ **No**

If yes, what is your current occupation/job? _____

5) **What is your postcode? _____**
(It will not be used to look up your address or to identify you in any way. We are asking this so we get people from different parts of Scotland.)

Thank you very much. I appreciate the time you took for this interview.

Appendix 13: Research Ethics Committee (REC) approval letter

NHS
Health Research Authority
South Central - Berkshire B Research Ethics Committee
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

24 January 2017

Prof David Conway
Level 8, Glasgow Dental Hospital and School
378 Sauchiehall Street
Glasgow
G2 3JZ

Dear Prof Conway

Study title:	**Oral (mouth) cancer risk assessment, examination and prevention: patients' views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland and Sultanate of Oman**
REC reference:	**17/SC/0054**
Protocol number:	**N/A**
IRAS project ID:	**218059**

The Proportionate Review Sub-committee of the South Central - Berkshire B Research Ethics Committee reviewed the above application on 24 January 2017.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of

the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of Sponsor insurance]	Version 2.0	12 December 2016
Interview schedules or topic guides for participants [Interview schedule]	Version 2.0	12 December 2016
IRAS Checklist XML [Checklist_13012017]		13 January 2017
Letter from funder [Letter re support for PhD studentship]	Version 2.0	12 December 2016
Other [CV supervisor]	Version 2.0	12 December 2016
Other [PhD award letter]	Version 2.0	12 December 2016
Other [CV supervisor]	Version 2.0	12 December 2016
Other [CV student2]	Version 2.0	12 December 2016
Participant consent form [Participant consent form]	Version 2.0	12 December 2016
Participant information sheet (PIS) [Participant information sheet]	Version 2.0	12 December 2016
REC Application Form [REC_Form_13012017]		13 January 2017
Research protocol or project proposal [Research Protocol]	Version 2.0	12 December 2016
Summary CV for Chief Investigator (CI) [CV Chief Investigator]	Version 2.0	12 December 2016
Summary CV for student [CV student]	Version 2.0	12 December 2016
Summary CV for supervisor (student research) [CV supervisor]	Version 2.0	12 December 2016

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

There were no declarations of interest.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

17/SC/0054	**Please quote this number on all correspondence**

Yours sincerely

pp.

Dr John Sheridan
Chair

Email: nrescommittee.southcentral-berkshireb@nhs.net

Copy to: *Miss Emma-Jane Gault*
Mrs Kayleigh McKenna, Senior Research Administrator - PR Team, NHS Greater Glasgow and Clyde

South Central - Berkshire B Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 24 January 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr John Sheridan	Consultant Toxicologist and Chemist	Yes	
Mrs Mary Sneade	Clinical Trial manager	Yes	
Miss Elena Villarreal	Clinical Trial Manager	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Lucy Roberts	REC Manager

Appendix 14: NHS Research & Development (R&D) approval letter

Senior Research Administrator: Kayleigh McKenna
Telephone Number: 0141 232 1826
E-Mail: Kayleigh.Mckenna@ggc.scot.nhs.uk
website www.nhsggc.org.uk/r&d

Clinical Research & Development
West Glasgow ACH
Dalnair Street
Glasgow G3 8SJ
Scotland, UK

26/01/2017

Professor David Conway
Glasgow Dental Hospital and School
University of Glasgow
378 Suchiehall Street
Glasgow
G2 3JZ

NHS GG&C Board Approval

Dear Professor Conway,

Study Title:	Oral (mouth) cancer risk assessment, examination and prevention: patientsâ€™ views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland and Sultanate of Oman
Principal Investigator:	Professor David Conway
GG&C HB site	NHS Greater Glasgow & Clyde Dental Practices
Sponsor	NHS Greater Glasgow & Clyde
R&D reference:	GN16OD737
REC reference:	17/SC/0054
Protocol no: (including version and date)	V2.0 12/12/16

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

2. **For all studies** the following information is required during their lifespan.
   a. Recruitment Numbers on a quarterly basis
   b. Any change of staff named on the original SSI form

NHS
Greater Glasgow and Clyde

c. Any amendments – Substantial or Non Substantial
d. Notification of Trial/study end including final recruitment figures
e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Kayleigh McKenna
Senior Research Administrator

CC: S.Mathur

Appendix 15: Letter of Access for Research (Research passport)

NHS
Greater Glasgow and Clyde

Senior Research Administrator: Mrs Kayleigh McKenna
Telephone Number: 0141 232 1826
E-Mail: Kayleigh.mckenna@ggc.scot.nhs.uk
Website: www.nhsggc.org.uk/r&d

Research & Development
West Glasgow ACH
Dalnair Street
Glasgow G3 8SW

26 January 2017

Miss Sweta Mathur
University of Glasgow Dental School
378 Suchiehall Street
Glasgow
G2 3JZ

Dear Miss Mathur,

Letter of Access for Research

This letter confirms your right of access to conduct research through **NHS Greater Glasgow and Clyde** for the purpose and on the terms and conditions set out below. This right of access commences on **26.01.17** and ends on **31.08.18** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at **NHS Greater Glasgow and Clyde** has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to **NHS Greater Glasgow and Clyde** premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through **NHS Greater Glasgow and Clyde**, you will remain accountable to your employer **[insert employer]** but you are required to follow the reasonable instructions of **Frances McLinden** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with **NHS Greater Glasgow and Clyde** policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with **NHS Greater Glasgow and Clyde** in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care

for the health and safety of yourself and others while on **NHS Greater Glasgow and Clyde** premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and the **health board's HR department** prior to commencing your research role at the Health board.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

NHS Greater Glasgow and Clyde will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely,

Kayleigh McKenna
Senior Research Administrator

cc: EJ Gault (University of Glasgow)

Appendix 16: MVLS ethical approval for part of the project (patient interview study)

University of Glasgow | College of Medical, Veterinary & Life Sciences

25th January 2017

Dear Dr Ross

MVLS College Ethics Committee

Project Title: Oral cancer risk assessment, examination and prevention: patients¿ views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland and Sultanate of Oman

Project No: 200160052

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. It is happy therefore to approve the project, subject to the following conditions:

- The project and in particular the wording of the Participant Information Sheet is approved by the NHS REC
- The project is approved by the relevant Omani ethics committee
- Project end date: 31st March 2018
- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research: (http://www.gla.ac.uk/media/media_227599_en.pdf)
- The research should be carried out only on the sites, and/or with the groups defined in the application.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely

Dr Dorothy McKeegan
College Ethics Officer

Dr Dorothy McKeegan

Senior Lecturer

R303 Level 3
Institute of Biodiversity Animal Health and Comparative Medicine
Jarrett Building
Glasgow G61 1QH Tel: 0141 330 5712
E-mail: Dorothy.McKeegan@glasgow.ac.uk

Appendix 17: Participant information sheet – for patient interviews

PARTICIPANT INFORMATION SHEET

Title of Project:
Oral (mouth) cancer risk assessment and prevention: patients' views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland

Introduction
You are being invited to take part in a research study. Before you decide whether to take part in the study, it is important that you understand why the research is being done and what it will involve for you. Please take some time to read the following information carefully. Feel free to discuss the study with others before you decide. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
This study will contribute towards a PhD. The study involves short tape-recorded individual interviews (face-to-face) to explore the views and experiences of patients attending general dental practices in Scotland on mouth cancer risk assessment, preventive advice and referral. We want to find out the barriers and facilitators associated with mouth cancer prevention in dental practices, and gather your suggestions to inform the development of a mouth cancer prevention intervention package.

Why have I been chosen?
You are being asked to take part in the study because you are attending general dental practice and can inform us as to the feasibility of implementing research evidence and guidelines to everyday working environments.

Do I have to take part?
No, it is up to you to decide whether or not to take part. If you do decide to take part, please remember that you are free to withdraw at any time and without giving a reason.

What will happen to me if I take part?
We will invite you to participate in a 20-25 minute face-to-face interview. Questions will focus on the current barriers and facilitators to mouth cancer risk assessment, examination, advice-giving and referral among patients attending general dental practices. We would also like to know your views on previous and current practice in relation to mouth check and preventive advice. We will make sure that you are happy with being tape-recorded beforehand.

What do I have to do?
If you are happy to take part, we will invite you to take part in a 20-25 minute interview during this dental practice visit. Interview will be carried out in a separate private space at your dental practice. If you do not want to take part, we will not contact you again. We will ask for your contact details if you agree to be approached with opportunities to take part in further studies.

What are the possible disadvantages and risks of taking part?
There are no identified risks and it is very unlikely that you will come to any harm as a result of taking part in the study. However, if you feel uncomfortable or do not wish to continue at any time, you can leave the discussion without giving any reason.

What are the possible benefits of taking part?
We hope the information that will be collected during this study will be useful to support implementation and sustained use of mouth cancer guidance in risk assessment, prevention and referral for the benefit of the public.

Will my taking part in this study be kept confidential?
Your information will be kept strictly confidential and anonymous. You will only be identified by an ID number, and any information about you (including direct quotations from interviews) will have your name removed so that you cannot be recognized from it. The anonymized interview notes and your records will be held securely in keeping with the Data Protection Act (1998) - records will be retained for 10 years. We will then destroy them.

What will happen to the results of the research study?
The results will be used to write a PhD thesis, and will be made available as scientific papers in journals and presentations at seminars and/or conferences. If you wish to receive a short summary of the findings, we will provide results in a patient accessible format to your dental practice.

Who is organising and funding the research?
The study is being conducted by the Glasgow Dental Hospital and School at the University of Glasgow; and sponsored by NHS Greater Glasgow and Clyde. The study is funded by NHS Education for Scotland and Glasgow Dental Educational Trust.

Who has reviewed the study?
The project has been reviewed by an NHS Research Ethics Committee, NHS R&D department, and Glasgow Dental Hospital and School Research Management Committee.

Contact for Further Information:

Please contact Ms Sweta Mathur at s.mathur.1@research.gla.ac.uk or +44 777 839 1940

If you have concerns about any of the issues raised during the interview – please discuss with your dentist.

If you have any concerns about the research aspects of the study, please contact Dr Alastair Ross at alastair.ross@gla.ac.uk or +44 141 211 9811

The usual NHS complaints procedure will also be available to you
http://www.nhsggc.org.uk/get-in-touch-get-involved/complaints/

Thank you for taking the time to read this information.

Appendix 18: Participant consent form – for patient interviews

Project Number: 169392-01

CONSENT FORM

Title of Project:
Oral (mouth) cancer risk assessment and prevention: patients' views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland

Name of Researcher(s):
Ms Sweta Mathur; Dr Alastair Ross; Prof David Conway; Prof Lorna Macpherson

Please initial box

1. I confirm that I have read the information sheet dated 12 December 2016 (Version 2.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I give my permission for the interview that I take part in to be tape-recorded. ☐
4. I agree to take part in the above study. ☐
5. I agree to be approached with opportunities to take part in further studies (if yes – please complete contact details below) ☐

_____	_____	_____
Name of subject	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Contact details: _____

(When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.)

Appendix 19: Patient interviews - tabulated responses (descriptive statistics)

Figure 1: Patient visits to primary care dental practices in the last five years - by gender

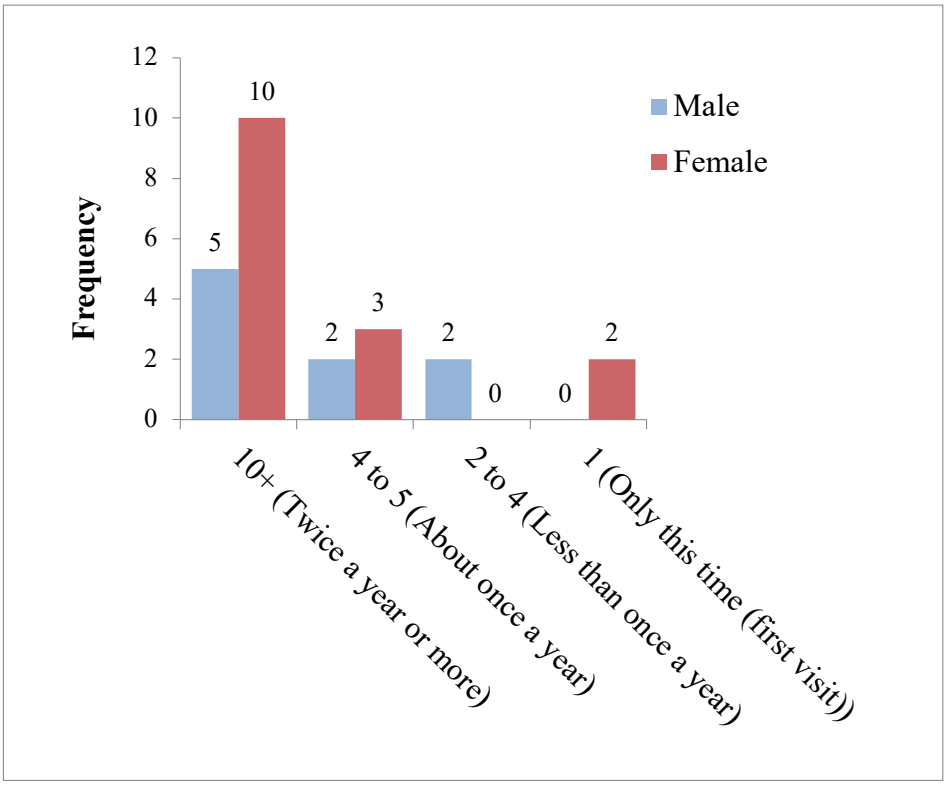


Figure 2: Patient visits to primary care dental practices in the last five years - by age group

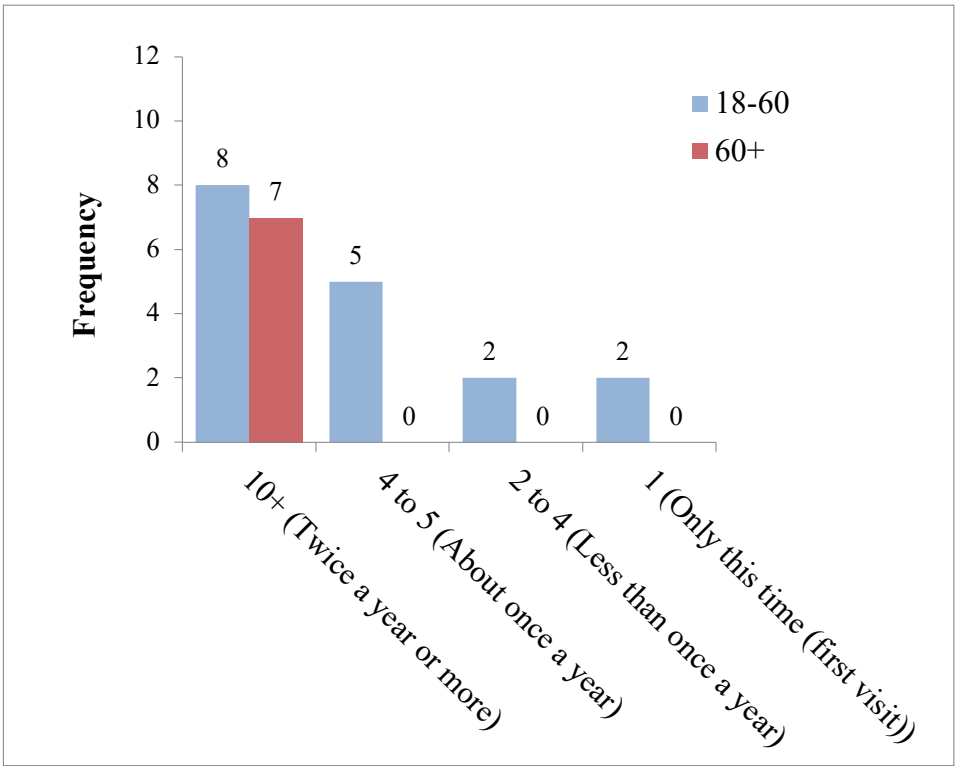


Table 1: Knowledge and awareness of oral cancer – frequency

Sample	Questions	Number	Percent (%)
n=24 (all participants)	Have you heard of mouth (oral) cancer? Yes No Not sure	 22 2 0	 91.7 8.3 0
n=24 (all participants)	Overall how much do you know about causes for mouth (oral) cancer? No knowledge Slight/ little knowledge Some knowledge Good knowledge Very good knowledge	 2 13 7 2 0	 8.3 54.2 29.2 8.3 0

Figure 3: Patient knowledge about causes for oral cancer - by gender

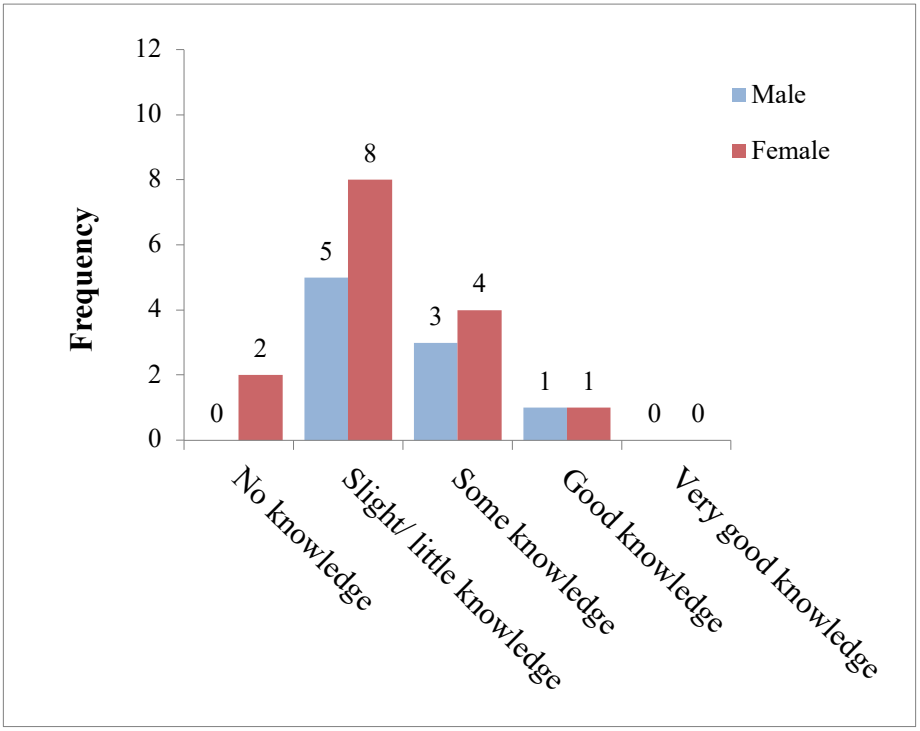


Figure 4: Patient knowledge about causes for oral cancer – by age group

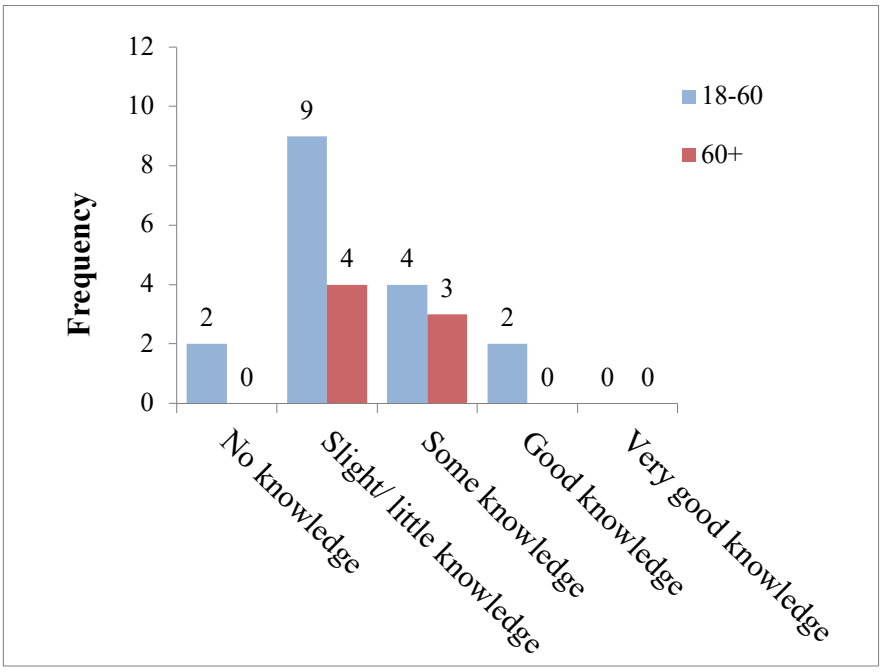


Table 2: Views and experiences for smoking advice/ referral – frequency

Sample	Questions	Number	Percent (%)
n=24 (all participants)	Has your dental team ever asked about your smoking status?		
	Yes	19	79.2
	No	3	12.5
	Not sure	2	8.3
n=13 (current or ex-smoker)	If smoker (current or ex): Has your dental team ever offered advice/counselling on smoking (or other form of tobacco)?		
	Yes	4	30.8
	No	9	69.2
	Not sure	0	0
n=5 (current smoker)	If smoker (current): Have you ever thought about quitting?		
	Yes	5	100
	No	0	0

n=5 (current smoker)	If smoker (current): How do you feel about receiving smoking advice from:		
	Dental team within the practice (as part of consultation)	1	20.0
	Dentist referring you to cessation services or GP	2	40.0
	Both	2	40.0
	None	0	0

Table 3: Views and experiences for alcohol advice/ referral – frequency

Sample	Question	Number	Percent (%)
n=24 (all participants)	How often do you have a drink containing alcohol?		
	Never	10	41.7
	Monthly or less	9	37.5
	2–4 times per month	2	8.3
	2–3 times per week	3	12.5
	4+ times per week	0	0
n=24 (all participants)	Has your dental team ever asked you about drinking?		
	Yes	12	50.0
	No	9	37.5
	Not sure	3	12.5
n=14 (alcohol drinkers)	If alcohol drinker: Has your dental team ever offered any advice / counselling on alcohol?		
	Yes	0	0
	No	13	92.9
	Not sure	1	7.1
n=14 (alcohol drinkers)	If alcohol drinker: How do you feel about receiving alcohol advice from:		
	Dental team within the practice (as part of consultation)	5	35.7
	Dentist referring you to cessation services or GP	8	57.2
	Both	1	7.1
	None	0	0

Figure 5: Views about receiving brief smoking advice up to 5 minutes from the dental team (n=5)

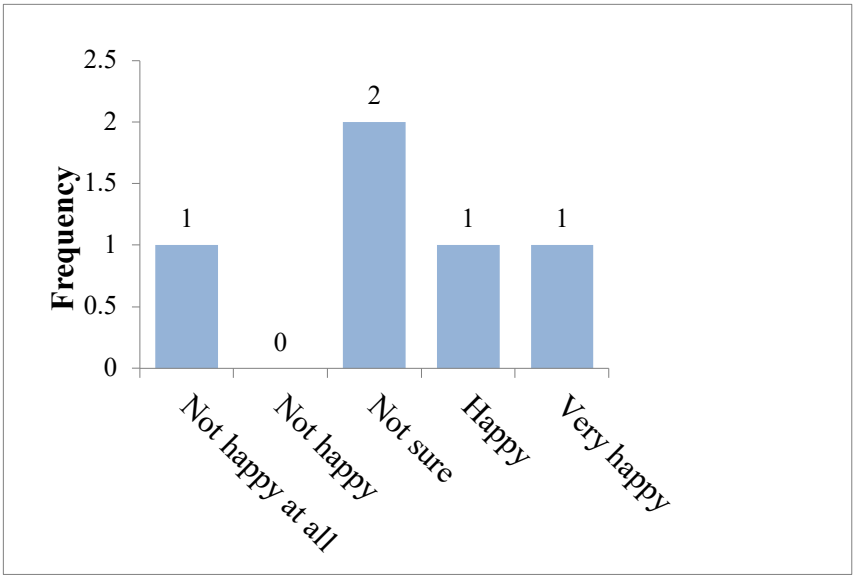


Figure 6: Views about receiving brief alcohol advice up to 5 minutes from the dental team (n=14)

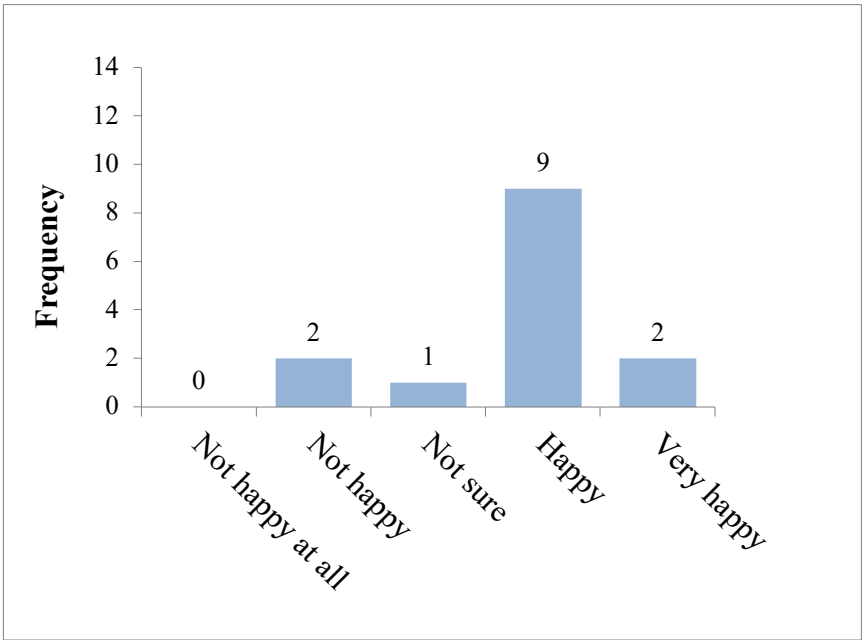
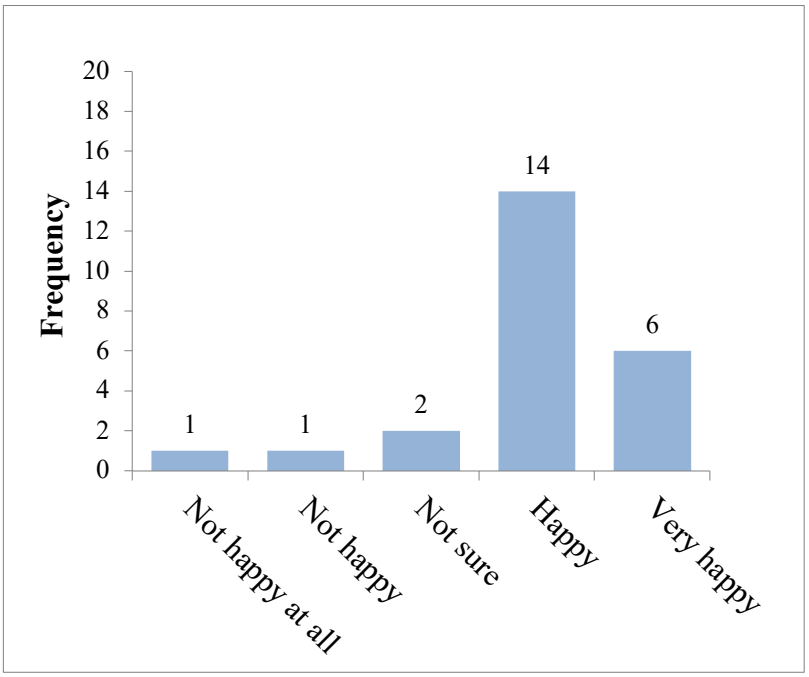


Figure 7: Views on having a risk score/ categorisation (n=24)



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