Smokeless tobacco use among women of reproductive age and during pregnancy in low and middle income countries - distribution and sociocultural characteristics

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Abstract

Aim: Despite widespread use of smokeless tobacco in nearly 140 countries, research in this area is limited., especially that focusing on women and during pregnancy. To reduce smokeless tobacco use among women especially during pregnancy, the aim of my thesis was to understand the distribution (recent prevalence estimates and socio-demographic distribution) and socio-cultural determinants of smokeless tobacco use among women of reproductive age and during pregnancy in low- and middle-income countries (LMICs).

Methods: This was a multi-method thesis that comprised three different studies; a secondary data analysis of the Demographic and Health Surveys (DHS) to estimate the prevalence rates and relative risk ratios (RRR) of tobacco use among pregnant and non-pregnant women in 42 LMICs, a mixed-method systematic review to understand the socio-cultural determinants, beliefs and attitudes related to smokeless tobacco use among women (and in pregnant women) in LMICs, and in-depth qualitative interviews with pregnant women in India to understand the influence of family members on initiation and/or change in practice of smokeless tobacco use during pregnancy.

Implications: The cumulative evidence from all the three studies I conducted suggests that tobacco control among women of reproductive age should be a public health priority in LMICs despite the low prevalence estimates as this may be that LMICs are earlier in epidemiological transition and if ignored may cause an increase in tobacco use later. The norms and general acceptability of smokeless tobacco use among women during pregnancy is changing and a possible approach could be to explore if pregnancy can be an opportunity for targeted and tailored interventions for smokeless tobacco cessation. Furthermore, ASHA workers are an integral part of maternal and child health in India and their inclusion in the tobacco control interventions may be beneficial.

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List of Abbreviations

Abbreviation	Definition
AOR	adjusted odds ratio
ASHA	Accredited Social Health Activist
BMI	Body mass index
CASP	Critical Appraisal Skills Programme
CATCH	Customize Acquire Train Create Harness
CDC	Centers for Disease Control and Prevention
CHD	Coronary Heart Diseases
CHW	Community Health Workers
CI	Confidence Interval
COM-B	Capability-Opportunity-Motivation Behaviour
DALY	Disability-adjusted life years
DHS	Demographic and Health Survey
DRC	Democratic Republic of Congo
EMR	Eastern Mediterranean Region
FCTC	Framework Convention on Tobacco Control
FGD	Focus Group Discussion
GATS	Global Adult Tobacco Survey
GBD	Global Burden Disease
GBP	Great Britain Pound
HIC	High Income countries
HIV	Human Immunodeficiency Viruses
aHR	Adjusted Hazard Ratio
IARC	International Agency for Research on Cancer
IHD	Ischaemic Heart Disease
INR	Indian Rupee
LMIC	Low and Middle-Income Countries
NNK	Nicotine-derived nitrosamine ketone
NNN	N-nitrosonornicotine
NOS	Newcastle-Ottawa Scale
NRT	Nicotine Replacement Therapies
OPMD	Oral Potentially Malignant Disorders
OR	Odds Ratio
mOR	Meta Odds Ratio
OSMF	Oral Submucous Fibrosis
PAH	Polycyclic Aromatic Hydrocarbons
PHC	Primary Health Centre
PPI	Public-Patient Involvement
PRISMA	Preferred Reporting Items for Systematic Review and Meta-analysis
PSU	Primary Sampling Units
RCT	Randomized controlled trials
RR	Relative Risk
RRR	Relative Risk Ratio

SEAR	South-East Asia Region
SGA	Small for Gestational Age
ST	Smokeless tobacco
MeSH	Medical Subject Headings
TCP	Tobacco Control Policy Evaluation
TSNA	Tobacco Specific Nitrosamines
UADT	Upper Aero Digestive Tract
UK	United Kingdom
US	United States
USAID	United States Agency for International Development
WHO	World Health Organization

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Author's Declaration

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

The thesis has partly been disseminated through one journal article and two conference abstracts (mentioned below):

Journal Article:

1. Shukla R, Kanaan M, Siddiqi K, 2021. Tobacco Use Among 1,310,716 Women of Reproductive age (15–49 Years) in 42 Low- and Middle-Income Countries: Secondary Data Analysis From the 2010-2016 Demographic and Health Surveys. Nicotine & Tobacco Research, 2021; ntab131, https://doi.org/10.1093/ntr/ntab131

Conference Abstracts:

2. Poster presentation at the 2020 Society for Research on Nicotine and Tobacco Annual Meeting, 11-14 Mar 2020, New Orleans, USA - Tobacco use among pregnant women: secondary data analysis from the Demographic and Health Surveys (DHS) in 42 low and middle-income countries (LMICs) and sub-group analysis of South East Asia region (SEAR) and Africa.
3. Poster presentation at the 2019 Society for Research on Nicotine and Tobacco – Europe, 12-14 September 2019, Oslo, Norway - Tobacco use among pregnant women in 42 low and middle-income countries: a secondary data analysis from the Demographic and Health Surveys.
4. Symposium presentation at the 2022 Society for Research on Nicotine and Tobacco - 17th March 2022, Baltimore, USA – Smokeless tobacco use during pregnancy in South Asia.

1) CHAPTER I: Background

1.1 Introduction

Tobacco use is one of the most important modifiable risk factors for various health conditions such as cancer, heart diseases, stroke, and adverse pregnancy outcomes (WHO 2021). It accounts for more than 8 million deaths a year, seven million of which are due to direct use of tobacco in various forms. Furthermore, the highest burden of tobacco use is in the low- and middle-income (LMICs) countries, where over 80% of tobacco users live (WHO 2021)

In response to the global tobacco epidemic, the World Health Organization (WHO) in 2007 introduced the Framework Convention on Tobacco Control (FCTC) MPOWER measures.

The 6 MPOWER measures are (source: WHO Factsheets – Tobacco 2021):

Monitor tobacco use and prevention policies.

Protect people from tobacco use.

Offer help to quit tobacco use.

Warn about the dangers of tobacco.

Enforce bans on tobacco advertising, promotion, and sponsorship.

Raise taxes on tobacco.

These measures have improved global tobacco control over time and some progress in the LMICs countries (WHO 2019) however, there is still a gap between cigarettes and smokeless tobacco policies globally (Mehrotra, Grover and Chandra, 2018).

Smokeless tobacco prevention and control is multifaceted due to its predominance in certain regions of the world, socio-cultural integration, diversity of products and related behaviours and lack of data within different populations (Hatsukami et al., 2014). This is a public health challenge that has lacked attention from researchers and policymakers globally and thus it needs to be addressed (Mehrotra, Grover and Chandra, 2018). Furthermore, smokeless tobacco is socially more acceptable and a cheaper alternative than smoking in the South-East Asia Region (SEAR) which leads to a higher prevalence in females (Schensul et al., 2018; Nair et al., 2015; Gilmore and McAuliffe, 2013). It is also at times used to treat common pregnancy related ailments such as morning sickness, and bitter taste in mouth. However, without substantial literature exploring smokeless tobacco use during pregnancy, a more

detailed epidemiological understanding of smokeless tobacco use among women in LMICs and during pregnancy is required.

This thesis is an attempt to address smokeless tobacco use among women during pregnancy in LMICs. In this chapter, I discuss the background related to smokeless tobacco use, its use among women and during pregnancy, and the associated health effects.

1.2 Background

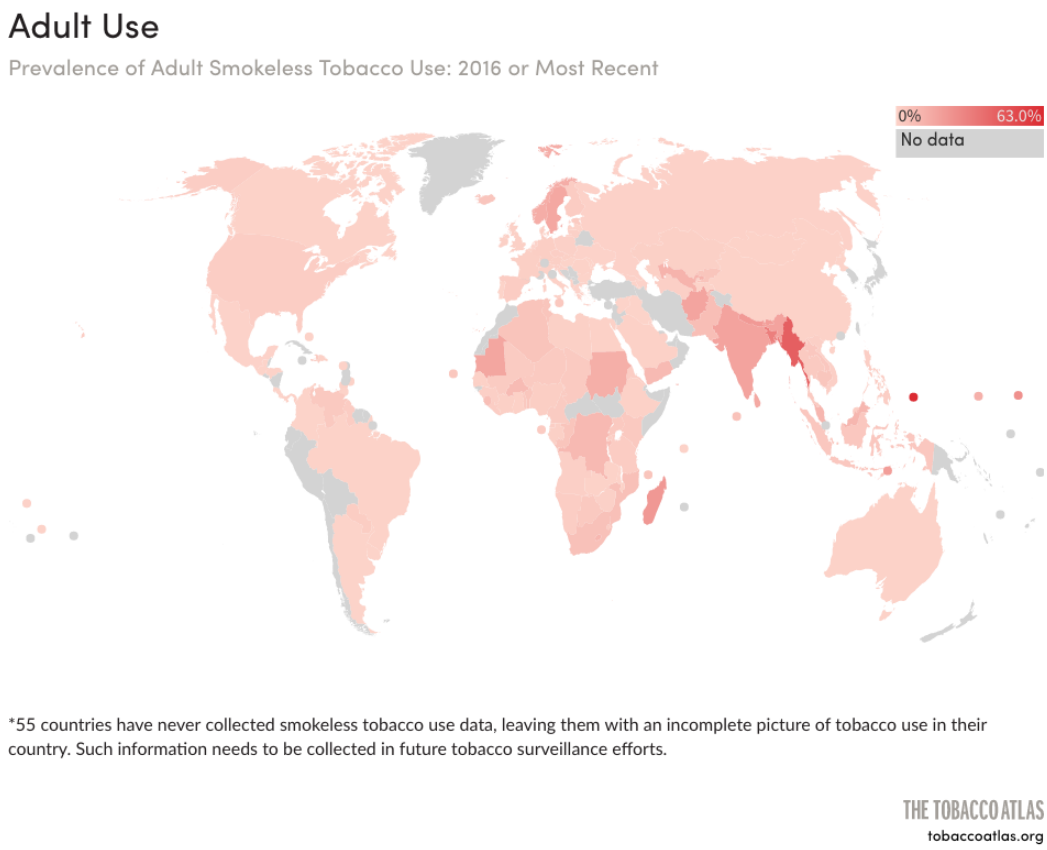
1.2.1 Global use of smokeless tobacco

Smokeless tobacco is not a single product, rather is a wide range of non-combustible tobacco products that are either chewed, snuffed, or applied locally in the oral cavity (Hatsukami et al., 2014). It contains nicotine and various other chemicals that are absorbed through the mucous membranes, some of which are known carcinogens (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, International Agency for Research on Cancer and World Health Organization, 2007). The most harmful constituents in smokeless tobacco are tobacco-specific nitrosamines (TSNAs), the amount of which depends on the smokeless tobacco product and its consumption method. TSNAs are formed by the nitrosation of tobacco during curing, aging and formation of tobacco (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, International Agency for Research on Cancer and World Health Organization, 2007). The two main TSNAs which are highly carcinogenic are 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) and N-nitrosonornicotine (NNN) (Xue, Yang and Seng, 2014). Various smokeless tobacco products and its diversity are further discussed in the next section (section 1.2.1.1).

Sinha et al (2018) estimated that smokeless tobacco is used by 350 million people worldwide based on analysis of 133 countries and about 95% of those smokeless tobacco users were from the developing countries, mainly the SEAR (Sinha et al., 2018). The predominance of smokeless tobacco use in SEAR is further re-iterated from the estimates reported by Siddiqi et al (2020), that estimated the prevalence of smokeless tobacco in 127 countries based on nationally representative cross-sectional surveys (Siddiqi et al., 2020). The highest consumption among males was in Myanmar (62.2%), Nepal (31.3%), India (29.6%), Bhutan (26.5%) and Sri Lanka (26.0%), and among females, the prevalence was 26.8% in Timor Leste, 24.8% in Bangladesh and 24.1% in Myanmar, all of which are South-East Asian countries (Siddiqi et al., 2020).

A vast majority of smokeless tobacco use is in SEAR; however, its use is also highly prevalent in other parts of the world as well, making it a global public health concern. Sreeramareddy et al (2014), reported the prevalence of smokeless tobacco among men in 30 sub-Saharan African countries, where all countries had smokeless tobacco use less than 10% except Madagascar and Mozambique that had a prevalence of 24.7% and 10.9% respectively (Sreeramareddy, Pradhan and Sin, 2014). Among females, prevalence of smokeless tobacco was reported as 19% in Madagascar and 28.3% in Mauritania (Siddiqi et al., 2020; Sreeramareddy, Pradhan and Sin, 2014). Furthermore, Siddiqi et al (2020), reported prevalence of smokeless tobacco use in Sweden as 25.0% and 7.0%, and in Norway as 20.1% and 6.0% among males and females respectively. However, the type of smokeless tobacco products used in these regions vary and details of these regional product differences are discussed in one of the later sections (section 1.2.1.1).

Figure 1.1: Prevalence of Adult Smokeless Tobacco Use



This image (*Figure 1.1*) is from the Tobacco Atlas (based on the 2017 WHO report on global tobacco epidemic) which shows prevalence of adult smokeless tobacco use across the globe. The highest prevalence (63%) is reported in the Republic of Palau, an island country in the western Pacific, followed by 43.2% in Myanmar. Ten countries have zero prevalence of smokeless tobacco use, while 55 countries have never collected data on smokeless tobacco.

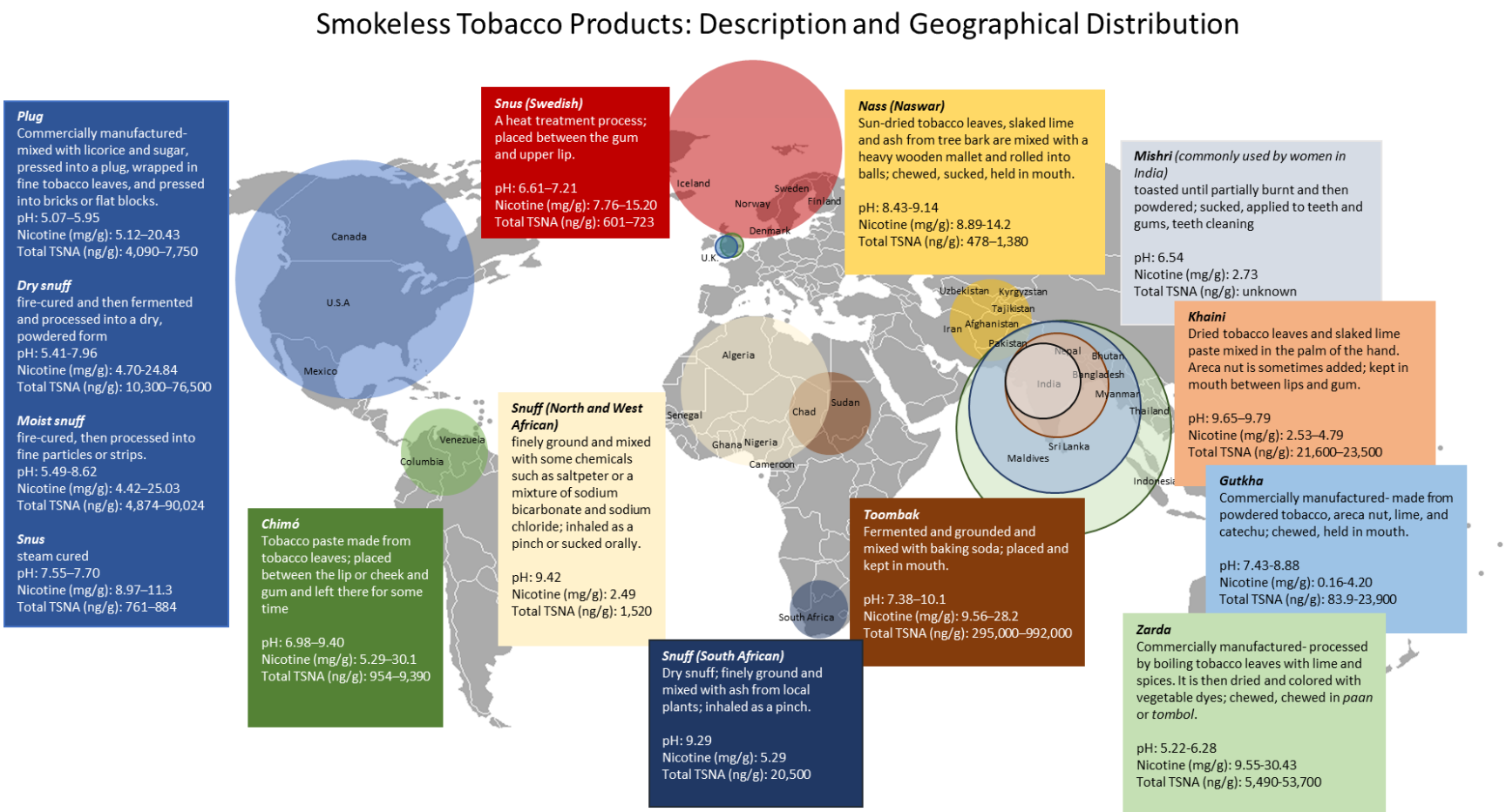
1.2.1.1 Smokeless tobacco products and diversity

Worldwide, smokeless tobacco is used in various forms either based on its constituents of tobacco and non-tobacco contents, or the method by which it is used (chewed, snuffed, locally applied etc) (Hatsukami et al., 2014).

Southeast Asian countries that bear the most burden of smokeless tobacco, have a wide range of smokeless tobacco products in terms of its mode of use and constituents. Some of these are - *guthka* which is placed in the buccal mucosa, *Mishri* that is powdered tobacco locally applied on the gums etc, *khaini* which is dried tobacco leaves placed in the oral cavity and *Zarda* which is mixed with other additives and consumed with betel leaves (Hatsukami et al., 2014). In Scandinavian countries, especially Sweden, snus is commonly used. However, unlike smokeless tobacco commonly used in the SEAR, snus is highly regulated in terms of its manufacturing and contents of TSNAs. Therefore, the adverse health effects often attributed to smokeless tobacco are minimal with snus (Hatsukami et al., 2014; Mehrotra, Grover and Chandra, 2018). In Central Asia, *Naswar* is the commonly used smokeless tobacco which is sun-dried tobacco leaves consumed orally while in Sudan and South Africa, smokeless tobacco that are primarily used are Toombak and snuff (Hatsukami et al., 2014).

The figure below (*Figure 1.2*) visually represents several products used globally, including their description, constituents, and geographical predominance. Each coloured box represents a different smokeless tobacco product and its corresponding circle the geographical area of its use. The image is adapted from Smokeless Tobacco and Public Health: A Global Perspective, Appendix B- Global Smokeless Tobacco Product Factsheets (2014) (Hatsukami et al., 2014). The image highlights the diversity in terms products, their constituents, and varied amounts of nicotine and TSNAs. For example, the TSNAs in Swedish snuff range from 601-723 ng/g compared to smokeless tobacco products used in SEAR where TSNAs are much higher (around 23,000 in *Khaini* and *Gutkha*, and about 53,000 in *Zarda*). Thus, smokeless tobacco control is extremely challenging and warrants public health measures especially for products which potentially have much higher risk of adverse effects (discussed in detail in section 1.2.3) caused by high levels of TSNAs and nicotine.

Figure 1.2: Smokeless tobacco products based on their geographical distribution and description



Source: Adapted from "Smokeless Tobacco and Public Health: A Global Perspective, Appendix B- Global Smokeless Tobacco Product Factsheets (2014)"

1.2.2 Smokeless tobacco use during pregnancy

Smokeless tobacco use among women is highly prevalent in certain parts of the world, mainly LMICs (Warren et al., 2008; England et al., 2003; Reitsma et al., 2017). Social factors such as age, education, income, perceived health benefits, social acceptability and peer habits influence its intake (Kakde, Bhopal and Jones, 2012). Among women in sub-Saharan Africa, smokeless tobacco is the most favoured form of tobacco that is not as socially stigmatized as cigarette smoking and often offered as a gift mainly in rural areas (Diendéré et al., 2020). Due to the ease of availability, these products are extremely popular and are often used as a remedy for common discomforts and families have been seen to reinforce its use (Sinha, Abdulkader and Gupta, 2016; Kakde, Bhopal and Jones, 2012). A Cambodian study shows that 54.9% of pregnant females in the study started a tobacco habit as a relief for morning sickness (Singh et al., 2013).

Caleyachetty et al (2014) conducted secondary data analysis from the DHS data to report tobacco use in pregnant females from 54 LMICs (Caleyachetty et al., 2014). Of those 54 countries, 45 had data on smokeless tobacco use based on which overall maternal smokeless tobacco use prevalence was 1.3% (95% CI of 0.7-2.0). Pooled regional prevalence of SEAR was 2.6% (95% CI of 0.0-7.6), with a significant prevalence in India (7.2%, 95% CI of 6.3-8.1), Nepal (2.8%, 95% CI of 1.6-4.9), and Pakistan (1.9%, 95% CI of 1.0-3.5). There was also a relatively high prevalence in Madagascar (11.8%, 95% CI of 9.6-14.3), in Lesotho (5.1%, 95% CI of 3.2-8.0), in Sierra-Leone (4.6%, 95% CI of 3.0-6.9), in Cambodia (3.5%, 95% CI of 2.4-5.2), in Burkina Faso (2.8%, 95% CI of 2.0-3.8), and in Kenya (2.6%, 95% CI of 0.9-5.6) (Caleyachetty et al., 2014).

A survey conducted in 2004-2005 across nine developing nations, reported smokeless tobacco use of 6% in Democratic Republic of Congo (DRC), 4.9% in Karnataka, India and almost one in every third respondent in Orissa, India (Bloch et al., 2008). Based on two cohort studies, women in South Africa (cohort of 1593 women), reported 7.5% use of snuff during pregnancy (Steyn et al., 2006) and 17.1% use of maternal smokeless tobacco in Mumbai, India (cohort of 1217 women) (Gupta, Subramoney and Sreevidya, 2004), 80% of which was *Mishri* (partially burnt, powdered form of tobacco, applied orally on teeth and gums) (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2007).

1.2.2.1 Socio-cultural context related to smokeless tobacco use in pregnancy: little known so far

Unlike tobacco smoking, the use of smokeless tobacco is acceptable and hence it is commonly used by women in LMICs (Warren et al., 2008; England et al., 2003; Reitsma et al., 2017) and especially in SEAR (Sinha et.al., 2018). This is perhaps due the cultural imbibement as the practice is passed on from elders within the family and is often considered as natural and hence there appears to be lack of knowledge related to its harms. Being an integral part of the culture and customs that are adopted by the elders and lack of stigma associated with smokeless tobacco use, encourage women towards this habit (Kakde, Bhopal and Jones, 2012). Social factors such as age, education, income, perceived health benefits, social acceptability and peer habits influence its intake (Kakde, Bhopal and Jones, 2012). Furthermore, families have reinforced its use as a treatment for common discomforts (Sinha, Abdulkader and Gupta, 2016; Kakde, Bhopal and Jones, 2012).

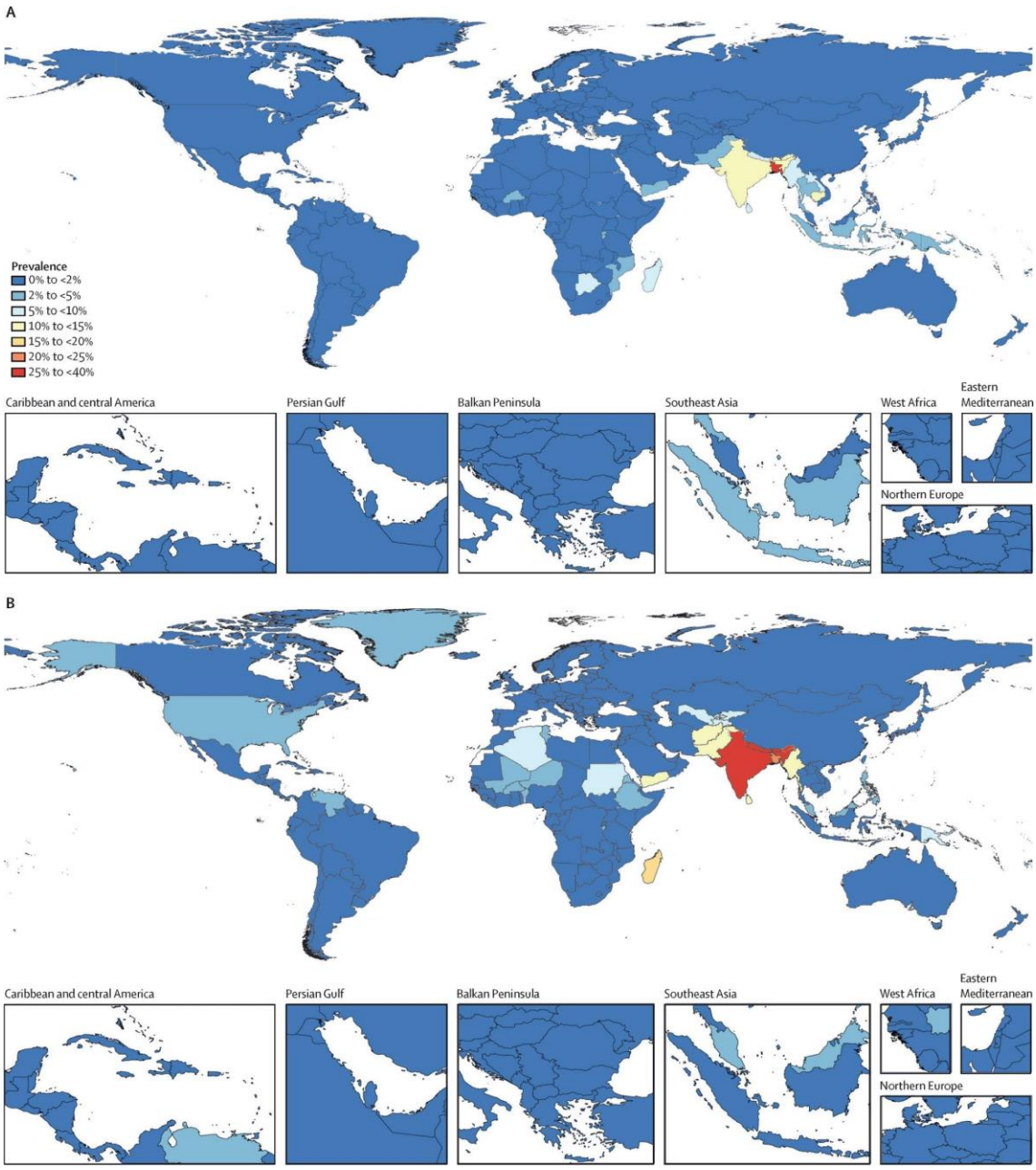
A study (Anwar et al., 2005) reported pregnant women initiating use of smokeless tobacco products to change taste in mouth, however the use continued post pregnancy due to addiction. As per a study from Mumbai, India, 86% of women believed that smokeless tobacco relieves labour pains and 75%, that it strengthens teeth during pregnancy (Schensul et al., 2018). These perceived benefits encourage women to continue using smokeless tobacco during pregnancy. Furthermore, a study from Mumbai, India reports initiation of tobacco products during pregnancy (Nair et al., 2015).

1.2.2.2 Predominance in SEAR and rural populations

Based on analysis from 140 countries, a total of 356 million adult smokeless tobacco users were estimated, 91% of which were from the LMICs, and almost 80% of those were from the countries in SEAR (Sinha et al., 2018). This study also reported that in the SEAR and African region, smokeless tobacco use is high among those living in rural areas and who belong to poor communities. LMICs have the highest (95%) burden of female smokeless tobacco users. This is possibly due to cultural acceptance, affordability, easy accessibility, and false health beliefs of smokeless tobacco use among women (Gupta et al., 2012; Sinha et al., 2018). Another reason for pre-dominance among women from less privileged populations, is use of smokeless tobacco to suppress hunger while performing difficult laborious tasks (Gupta et al., 2012). Predominance of smokeless tobacco use in rural areas was also reported by (Palipudi

et al., 2014) in the analysis from four SEAR countries. The study further reported a declining prevalence of smokeless tobacco use with increasing education and wealth status.

Figure 1.3: Age standardised prevalence of chewing tobacco in women (A) and Men (B) - GBD 2019 Chewing Tobacco Collaborators



The Global Burden Disease (GBD) Chewing Tobacco Collaborators conducted a study to report age-sex specific standardised prevalence of chewing tobacco among adults aged 15 and older, from 204 countries between 1990-2019 (*Figure 1.3*) (Kendrick et al., 2021). Based on their estimates, about 273.9 million people used chewing tobacco in 2019 globally, and most of these (about 228 million. 83%) resided in the South Asia region. Furthermore, the age-

standardised prevalence for females was highest in South Asia (12.13%,) and lowest in Western Europe (0.15%) (Kendrick et al., 2021).

From the evidence available so far it is clear that smokeless tobacco is socially more acceptable than smoking in the SEAR countries which leads to a higher prevalence in females (Gupta et al., 2012; O'Connor, 2012).

1.2.2.3 Summary

Tobacco in any form is harmful, yet the tobacco control policies and research are often focused on smoking. Though the majority of smokeless tobacco is used in SEAR, it is a global public health concern as more than 350 million people worldwide use smokeless tobacco (Sinha et al., 2018). Despite the vast use of smokeless tobacco globally, gathering evidence on it has been a challenge. One of the major reasons is the diversity of smokeless tobacco not only in terms of the variety of products, but also the method they are consumed, the other additives that are often consumed with it and the cultural imbibement related to its use in SEAR.

Though there is some evidence that smokeless tobacco use is common among women in LMICs, especially SEAR, there is a dearth of evidence on smokeless tobacco use during pregnancy. Firstly, in terms of the recent prevalence, Caleyachetty and colleagues reported estimates up to 2012 based on the DHS and more data have become available since. Updated prevalence estimates are required to understand the current tobacco use among pregnant women in LMICs. Secondly, the predominance of smokeless tobacco use among women in SEAR is likely due to socio-cultural factors, but further evidence is required to understand the use of smokeless tobacco during pregnancy. Some studies suggest women initiating the use of smokeless tobacco during pregnancy to combat pregnancy related ailments and later continuing due to habit (Anwar et al., 2005, Schensul et al., 2018, Nair et al., 2015). To prevent the initiation of smokeless tobacco use during pregnancy it is vital to understand the related socio-cultural context and how this can be incorporated in designing tobacco control measures. Additionally, it is not only the prevention of smokeless tobacco use during pregnancy, but also helping women reduce/quit smokeless tobacco during pregnancy because pregnancy is a well-known teachable moment (McBride, Emmons and Lipkus, 2003). I further discuss this in the rationale section towards the end of this chapter.

1.2.3 Health effects of smokeless tobacco

Smokeless tobacco spectrum includes a wide range of products with different constituents, manufacturing methods and cultivation processes, and hence the level of toxicity, nicotine content and carcinogens also vary as discussed in the earlier section (1.2.1.1.) (Hatsukami et al., 2014). Considering the diversity and variation in populations' exposure to smokeless tobacco, Siddiqi et al (2020 and 2015) reported global burden of disease due to smokeless tobacco, using the comparative risk assessment method. In 2015, they reported a total loss of 6,436,920 Disability-Adjusted Life Years (DALYs) and 266,592 deaths due to smokeless tobacco use (Siddiqi et al., 2015). These estimates were updated in 2020 to about 8,691,827 DALYs and 348,798 deaths (Siddiqi et al., 2020). Furthermore, Sinha et al (2018) reported all cause deaths attributed to smokeless tobacco worldwide as 652,494 (95% CI of 234,008–1,081, 437); stroke mortality had the highest burden (103,090, 95% CI of 45,787–162,636), followed by all-cancer mortality (101,004, 95% CI of 57,937–141,353) (Sinha et al., 2018). The apparent difference in these estimates is due to their methodology. Siddiqi et al (2015 and 2020) considered the risk of developing cancers of the oral cavity, pharynx and oesophagus, ischemic heart disease and stroke in their meta-analysis, while Sinha et al (2018) took in account the risk of mortality for all cancers, in addition to cancers of the upper aero-digestive tract (UADT), stomach, and cervical, and ischaemic heart diseases and stroke.

1.2.3.1 Cancers and premalignant lesions:

Smokeless tobacco has several components that potentially lead to cancer formation, i.e., TSNAs, aldehydes, metals, alkaline agents and arecoline. These cause oxidative DNA damage, gene mutations, inflammation, increase cell proliferation and the absorption of carcinogens, all promoting tumour formation (Hatsukami et al., 2014). These components of smokeless tobacco cause local irritation and inflammation, leading to changes in normal oral mucosa over a period (this depends on duration and frequency of smokeless tobacco use). Furthermore, these are absorbed systemically through the oral mucosa and saliva causing other systemic health consequences (National Toxicology Program, 2011).

There is evidence that smokeless tobacco is associated with oral premalignant lesions such a leucoplakia, eyrthoplakia and oral submucous fibrosis (OSMF), which in turn pose a high risk for cancers (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2007; Hatsukami et al., 2014; Datta et al., 2014). A review by based on Indian studies (Datta et al.,

2014), reported a strong association of premalignant lesions and tobacco chewing, where the adjusted odds ratio (OR) for OSMF among ever tobacco chewers was 44.1 (95% CI of 22 – 88.2) (Hashibe et al., 2002), 7.0 (95% CI of 5.9-8.3) for oral leucoplakia which when stratified by sex was 37.7 (95% CI of 24.2 – 58.7) for women (Hashibe et al., 2000). Furthermore, the study also showed dose-response relationship for duration and frequency for tobacco chewing and oral leucoplakia. A recent review and meta-analysis (Khan et al., 2017) reported meta odds ratio (mOR) based on 18 studies for oral potentially malignant disorders (OPMD) with use of any smokeless tobacco as 15.5 (95% CI of 9.9-24.2), and the risk was much higher for women (mOR of 22.2, 95% CI of 2.1 - 34.8).

The association of smokeless tobacco and oral cancers has been researched for a while, especially in SEAR as majority of the burden of smokeless tobacco is in the region (Sinha et al., 2015; Siddiqi et al., 2020), which translates to high incidence of oral cancers in the region as well (Datta et al., 2014; Sinha, Abdulkader and Gupta, 2016; Petti, Masood and Scully, 2013). A recent meta-analysis estimated region-wise odds ratios for four WHO regions and further product wise analysis for different smokeless tobacco products (Asthana et al., 2019). They reported an overall risk of smokeless tobacco and oral cancer as 3.53 (95% CI of 2.75 - 4.51) and this risk was much higher among women (OR = 5.83, 95% CI of 2.93 - 11.58). In their region-wise estimates, SEAR had the highest risk (OR = 4.44, 95% CI of 3.51 - 5.61), followed by OR of 1.28 (95% CI of 1.04 - 1.56) in Eastern Mediterranean Region (EMR), and non-significant estimates in American and European regions.

There is strong and conclusive evidence that smokeless tobacco use, especially the products used in the SEAR, are high in carcinogens and associated with oral cancer. Furthermore, additives along with smokeless tobacco such as areca nut in SEAR increases the risk of pre-malignant lesions and oral cancers (Hatsukami et al., 2014).

In addition to oral cancer, there is some evidence of association with other types of cancers and use of smokeless tobacco. Sinha et al (2018) reported associations of mortality outcomes for a range of cancers with smokeless tobacco use; strongest association for upper aerodigestive tract (UADT) cancer as 2.17 (95% CI of 1.47–3.22), followed by cervical cancer as 2.07 (95%CI of 1.64–2.61), and stomach cancer as 1.33 (95% CI of 1.12–1.59) (Sinha et al., 2018). However, the evidence for cervical and stomach cancer is limited as the estimates for both were derived from a single study based in India. Furthermore, there is some additional evidence related to pre-cancerous cervical lesions among women in Cote d'Ivoire, where the adjusted odds ratio for high grade squamous intraepithelial cervical lesions among tobacco

chewers was 5 times (aOR = 5.6, 95% CI of 2.5 - 12) compared to non-tobacco users (Simen-Kapeu et al., 2009).

Smokeless tobacco use and its association with various forms of cancers is evident, however the strength of evidence for oral and upper aerodigestive tract cancers, compared to others, is stronger, and has a significant association in the SEAR, given the nature of smokeless tobacco products used in this region (Hatsukami et al., 2014).

1.2.3.2 Cardio-vascular diseases:

Tobacco use has various adverse effects on the cardiovascular system such as inflammatory changes, vasoconstriction, atherosclerosis, thrombosis, and direct damage to the cardiac vessels (Barua and Ambrose, 2013; Hatsukami et al., 2014). The mechanism and pathophysiology of tobacco smoking and cardiovascular diseases is well studied (Centers for Disease Control and Prevention, 2011); however, these effects are not just limited to tobacco smoking. Several constituents in smokeless tobacco such as polycyclic aromatic hydrocarbons (PAH), aldehydes, arsenic, barium, nicotine, arecoline and alkaline agents, contribute to atherosclerosis, vasoconstriction, endothelial damage and increase in blood pressure (Hatsukami et al., 2014)

Vidyasagaran et al (2016) estimated the overall risk of fatal and non-fatal Ischaemic Heart Disease (IHD) and stroke, along with estimates for geographical variations (Vidyasagaran, Siddiqi and Kanaan, 2016). The overall relative risk for IHD was not statistically significant (RR 1.14, 95% CI of 0.92 - 1.42), however the studies from Asia showed a 40% increase in risk of IHD among smokeless tobacco users compared to non-users (RR 1.40, 95% CI of 1.01 - 1.95). Furthermore, the overall risk for fatal stroke was 1.39 (95% CI of 1.29 - 1.49) among smokeless tobacco users compared to non- users. However, the overall risk of fatal IHD was reported as 1.15 (95% CI of 1.01 - 1.30); statistically significant increased risk was only noted for studies from Sweden (RR of 1.38, 95% CI of 1.1.3 - 1.67). This is consistent with another review and meta-analysis of global data (Gupta et al., 2019), where the risk of fatal coronary heart diseases (CHD) was significantly increased in the European region (1.30, 95% CI of 1.14 - 1.47) among smokeless tobacco users.

The difference in association based on geographical variation could be due to variation in smokeless tobacco products, its constituents and potential under-reporting. However, the significant association of fatal IHD only in Swedish studies should not take away from the overall risk smokeless tobacco has on cardio-vascular health. About 6 million DALYs lost

and 258,006 deaths due to IHD could be attributed to smokeless tobacco use (Siddiqi et al., 2020). Furthermore, the risk of mortality due to smokeless tobacco was significant for stroke (1.37, 95% CI of 1.24 - 1.51) and IHD (1.10, 95% CI of 1.04 - 1.17) based on meta-analysis conducted by Sinha and colleagues (Sinha et al., 2018).

1.2.3.3 Other conditions:

Smokeless tobacco is also associated with other lesions in the oral cavity such as gum diseases, tooth loss and decay (Piano et al., 2010; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, International Agency for Research on Cancer and World Health Organization, 2007). A recent study on smokeless tobacco use in Sudan, reported that it alters the normal flora in the oral mucosa, which may potentially affect the immunity and systemic health of smokeless tobacco users (Abakar, Omer and Yousif, 2020).

Consumption of tobacco alters the glucose metabolism and leads to increase in blood sugar levels (Surgeon General Report, 2010). Studies suggest that nicotine directly contributes to insulin insensitivity, and causes an increase in cortisol release, which in turn contributes to insulin resistance (Surgeon General Report, 2010; Bajaj, 2012; Bergman et al., 2012). In the context of smokeless tobacco, there is some evidence that the moist snuff use mainly in the Scandinavian countries, increases the risk of metabolic syndrome (Norberg et al., 2006) and type II diabetes (Persson et al., 2000). Furthermore, a study based on five prospective cohorts, reported that the risk to type II diabetes increases with the amount of snus consumed; pooled hazard risk of 1.15 (95% CI of 1.00 – 1.32) among current users compared to never users, which increased to 1.42 (95% CI of 1.07 – 1.87) among those who consumed about five to six boxes per week, and to 1.68 (95% CI of 0.17 – 2.41) among those who consumed more than seven boxes per week (Carlsson et al., 2017).

The evidence thus far on smokeless tobacco use and risk of diabetes is based on snus, which differs in its composition compared to other smokeless tobacco products, but nicotine content irrespective of product is present in all forms of smokeless tobacco. However, further research focused on other types of smokeless tobacco and risk of diabetes and metabolic syndrome are required for conclusive evidence.

1.2.3.4 Reproductive outcomes:

The effect of tobacco smoking on pregnancy and related adverse outcomes is well established, but in the context of smokeless tobacco, the evidence is limited. Some studies report that smokeless tobacco affects pregnancy outcomes such as low birth weight, preterm birth, and stillbirth. Current available literature on the effect of smokeless tobacco use on various perinatal outcomes is discussed in the following section, along with the effect of tobacco and nicotine during pregnancy (1.2.4).

1.2.4 Tobacco use during pregnancy

Adverse effects of tobacco smoking in pregnancy such as preterm births, low birthweight, poor intrauterine growth, and infant death are well established (Marufu et al., 2015; Hackshaw, Rodeck and Boniface, 2011; Dahlin, Gunnerbeck and Wikström, 2016; Pereira et al., 2017; Anderson et al., 2019). In addition to in-utero adverse effects of tobacco, there is also evidence of cognitive and neurological ability of infants and children (Wehby et al., 2011). However, estimating the effect of smokeless tobacco during pregnancy is challenging compared to tobacco smoking for multiple reasons. That is, the diversity of products, mode of use and most importantly, the additives along with smokeless tobacco products which on their own have adverse effects; Kumar S (2013) conducted a literature review on reproductive impairments due to tobacco and areca nut chewing and reported that smokeless tobacco is as harmful as smoking and that combining the use of smokeless tobacco and areca nut may have a compounded effect in causing harm during pregnancy (Kumar, 2013).

In this section, I first discuss the mechanism of tobacco smoking during pregnancy, and then discuss the available literature on smokeless tobacco use during pregnancy.

1.2.4.1 Tobacco smoking during pregnancy

Smoking during pregnancy affects the intrauterine growth of the foetus due to lack of oxygen and nutrition supply, which in turn affects the organ development of the foetus (Rogers, 2009). This is primarily due to various compounds in cigarette smoke such as carbon monoxide, tar, nicotine, and other carcinogens (McDonnell and Regan, 2019).

Carbon monoxide is a gas produced by the tobacco combustion process and the amount of this gas that enters the body depends on the cigarette type and frequency of inhalation (McDonnell and Regan, 2019; Raub et al., 2000). The carbon monoxide absorbed via the process of tobacco combustion, binds with the haemoglobin in the blood to form carboxyhaemoglobin. As a result, oxygen molecules cannot bind to haemoglobin as the iron component of the haemoglobin is already occupied by the carbon monoxide. Thus, impairing the oxygen delivery system in the foetal circulation. In general, the concentration of carboxyhaemoglobin is around 1%, and among smokers it ranges from 3%-8% (Raub et al., 2000).

Tar is also one of the components of cigarette smoke that causes harm to the respiratory tract and enters the body via skin, mucous membranes, and lungs. Tar contains various carcinogens known to cause lung damage as it causes oxidative damage to the respiratory system by interfering with various pathways leading to an inflammatory state (Bhalla et al., 2009). Furthermore, other chemicals (i.e., heavy metals) part of the cigarette smoke are also known to accumulate in the placenta and cause foetal growth restriction (Menai et al., 2012).

Recent (2018) meta-analysis (Quelhas et al., 2018) examined the association between tobacco use during pregnancy and small-for-gestational age (SGA), length/height and head circumference at birth. Smoking during pregnancy was associated with SGA infant (AOR = 1.95, 95% CI of 1.76 - 2.16), length at birth (weighted mean difference = 0.43cm, 95% CI of 0.41 - 0.44) and head circumference at birth (weighted mean difference = 0.27cm, 95% CI of 0.25 - 0.29). Furthermore, dose response relationship across all three growth outcomes was also reported by Quelhas et al (2018). That is compared to never smoking during pregnancy, the odds for SGA infant were 2.17 (95% CI of 1.82 – 2.6) among those who ever smoked during pregnancy while the odds were 2.53 (95% CI of 2.31 – 2.78) among women who smoked more than 10 cigarettes daily.

1.2.4.2 Smokeless tobacco consumption during pregnancy and association with perinatal outcomes

Though smokeless tobacco does not expose women to tobacco smoke and its constituents, the TSNAs and additives in smokeless tobacco pose a risk to women's health and during pregnancy. Several studies have explored the effect of smokeless tobacco on various perinatal outcomes such as preterm delivery, still birth, small for gestational age and some maternal outcomes (pre-eclampsia, anaemia, placental changes). In this section I discuss findings from

various studies related to smokeless tobacco use during pregnancy and further comment on research needs in this context.

England and colleagues (2010) conducted a literature review on non-cigarette tobacco use and adverse pregnancy outcomes and provided a descriptive summary in addition to working group (September 2008) recommendations for further research (England et al., 2010). They concluded that there is a dearth of global data on epidemiology on non-cigarette tobacco use which limits the development of public health response and suggested that it is vital to develop an understanding of type and magnitude of health effects related to alternative tobacco products. High quality research that accounts for potential confounders, error in exposure measurement, under-reporting, and biomarker assessment for key priority perinatal outcomes such as preterm delivery, foetal growth, gestational hypertension, still birth, early pregnancy loss and placental abnormalities are required to establish clear temporal relations.

Following this in 2014, Ratsch and Bogossian reported an integrative review of the literature on smokeless tobacco use in pregnancy (Ratsch and Bogossian, 2014). The review included 21 studies (ten from India, seven from Sweden, two from Alaska, one from South Africa and one from Pakistan), published between 1966 - 2012 which explored association of maternal smokeless tobacco use and placental changes, stillbirth, birth weight, gestational age and after birth outcomes. Due to heterogeneity, the authors conducted a narrative synthesis and concluded that there is some evidence of potential association of smokeless tobacco use with still birth and low birth weight, however, that precise risk could not be estimated as many studies lacked sufficient power.

This was further assessed in a systematic review conducted by Inamdar et al (2015), which reported association of smokeless tobacco use with low birth weight, preterm birth, stillbirth, and SGA based on nine studies (five from India, and one from Bangladesh, Sweden, South Africa, and United States, each) (Inamdar et al., 2015). Of these, seven showed a significant association of maternal smokeless tobacco use with low birth weight, preterm and stillbirth, and like previous reviews, meta-analysis was not conducted due to heterogeneity among studies. However, the review assessed each study for risk of bias based on external and internal validity, and further provided forest plots (*Figure 1.4 and 1.5*) for better representation of risk estimates from individual studies.

Figure 1.4: Forest plot of smokeless tobacco use during pregnancy and low birth weight. The image is taken from Inamdar et al (2015), published in Nicotine and Tobacco Research

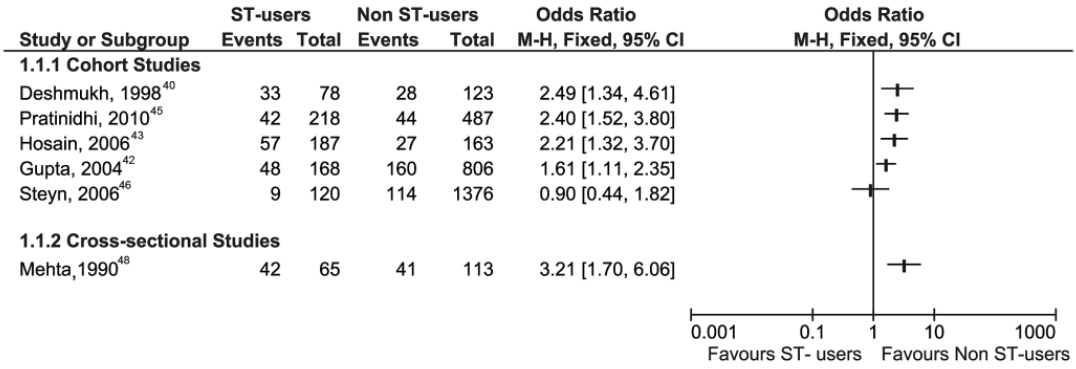
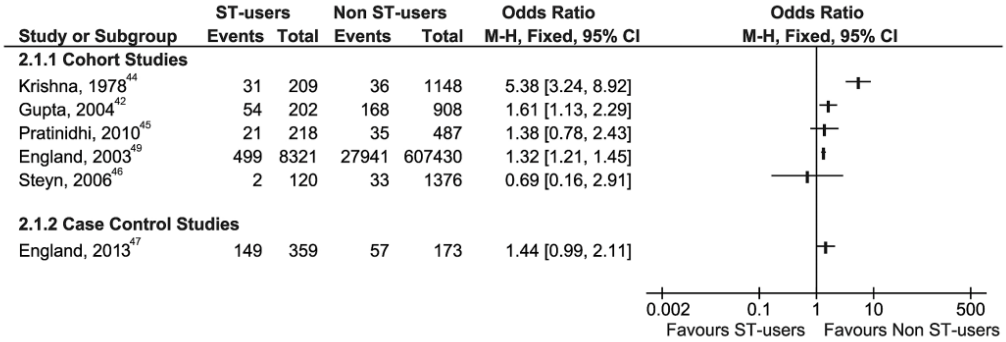


Figure 1.5: Forest plot of smokeless tobacco use during pregnancy and preterm birth. The image is taken from Inamdar et al (2015), published in Nicotine and Tobacco Research



The above forest plots (crude odds ratios from all studies) are taken from the Inamdar et al review (2015), and only used here for better understanding of the available estimates (*Figure 1.4 and 1.5*). Besides one study conducted in South Africa (Steyn et al., 2006), the odds in all other studies showed a possible association of smokeless tobacco with low birth weight and preterm birth. Most estimates were based on crude odds ratios and only few studies reported adjusted odds ratios (aOR); for low birth weight, the reported aOR were 3.14 (95% CI of 2.08 – 4.88) (Deshmukh et al., 1998), and 1.6 (95% CI of 1.1 – 2.4) (Gupta, Subramoney and Sreevidya, 2004) and for preterm births were 1.4 (95% CI of 1.00 – 2.1) (Gupta, Subramoney and Sreevidya, 2004) and 1.29 (95% CI of 1.17 – 1.43) (Baba et al., 2012). In addition to preterm birth and low birthweight, there were four studies (Krishna, 1978; Pratinidhi et al., 2010; Baba et al., 2014; Gupta and Subramoney, 2006) that reported statistically significant crude odds ratios for stillbirth and smokeless tobacco use (ranging from 1.60 – 4.57), and one of those reported an adjusted (age, education, socio-economic status, working status of the mother, parity, antenatal care, and place of delivery) odds ratio of 2.6 (95% CI of 1.4 - 4.8)

(Gupta and Subramoney, 2006). The study also demonstrated dose response relationship with use of *Mishri* (a type of smokeless tobacco) and stillbirth; use of 1- 4 times, adjusted hazard ratio (aHR) = 2.1 (95% CI of 0.9 – 4.7) and use of more than 5 times aHR = 3.8 (95% CI of 1.5 – 10.1). Though these studies, all estimate smokeless tobacco use and perinatal outcomes, it is important to consider the difference in smokeless tobacco products assessed in each study especially bearing the geographical variation. Furthermore, most studies do not account for confounders and hence cautious interpretation is required.

Several studies related to smokeless tobacco use and pregnancy outcomes have been conducted in Sweden. England and colleagues (2003) reported an adjusted mean birth weight loss of 93 grams (95% CI of 38 – 147 grams) in snuff users compared to non-tobacco users (England et al., 2003). Recently, Kreyberg and colleagues (2019) reported an update on prevalence and risk of snus (commonly used in the Scandinavian countries) during pregnancy (Kreyberg et al., 2019). Studies based on data from Swedish Medical Birth Register (population-based cohort) reported increased risk of SGA births (OR = 1.26, 95% CI of 1.09 – 1.46) (Baba et al., 2013), still birth (OR = 1.43, 95% CI of 1.02 – 1.59) (Baba et al., 2014), and neonatal apnoea (OR = 1.96, 95% CI of 1.30 – 2.96) (Gunnerbeck et al., 2011) among snuff users. Furthermore, the risk of preterm increased (OR = 1.29, 95% CI of 1.17 – 1.43) for those who continued snuff use during pregnancy, compared to those who stopped its use before first ante-natal visit (OR = 0.92, 95% CI of 0.84 – 1.01) (Baba et al., 2012). There appears to be some evidence related to snus use on pregnancy outcomes based on large population studies that have accounted for certain confounders such as mother's education, parity, maternal age, and body mass index (BMI). However, further updated estimates (as these estimates are based form Swedish Birth register data till 2010) and detailed understanding is required related to the level of tobacco, nicotine, and other additives in smokeless tobacco products and adverse effects.

In terms of the South Asia context, Suliankatchi and Sinha conducted a systematic review and meta-analysis for tobacco chewing among pregnant women in India (Suliankatchi and Sinha, 2016). The review reported pooled odds ratios for low birth weight (1.88, 95% CI of 1.38 - 2.54), preterm birth (1.39, 95% CI of 1.01 - 1.91) and stillbirth (2.85, 95% CI of 1.62 - 5.01), based on meta-analysis of two cohorts (Pratinidhi et al., 2010; Gupta, Subramoney and Sreevidya, 2004; Gupta and Subramoney, 2006). It also reported that 0.87 million low birth weight babies, 0.19 million preterm births and 0.12 million still births occurring annually in

India could be attributed to maternal smokeless tobacco use. The study followed a systematic PRISMA (Moher et al., 2010) methodology in conducting the review but did not include details of studies identified/excluded to strengthen the rationale for estimating attributable burden for India based on two study results. Furthermore, estimates from both studies were based on a one specific region in the country and hence these findings cannot be generalised for the entire country. Acknowledging this, the authors also concluded that the evidence was neither voluminous nor conclusive.

Adding to the evidence from the South-Asian context, Aziz Ali and colleagues recently (2020) conducted a study based on data from a randomized controlled trial (Women First Study) in Pakistan (Aziz Ali et al., 2020). The study collected preconception nutritional data, and longitudinally followed the participants (n = 2013) till the delivery. The prevalence of smokeless tobacco use among participants was 71.5% (1440 women). The authors assessed for pre-pregnancy use of smokeless tobacco and maternal anaemia (RR = 1.04, 95% CI of 0.92 – 1.16), miscarriage (RR = 1.08, 95% CI of 0.75 – 1.54), pre-term birth (RR = 1.37, 95% CI of 0.64 – 2.93), stillbirth (RR = 1.02, 95% CI of 0.39 – 2.61), and low birth weight (RR = 0.96, 95% CI of 0.72 – 1.28). Based on the univariable and multivariable analysis (adjusting for maternal age, education, parity, working status, BMI, and geographical area), no statistically significant association between smokeless tobacco and maternal/foetal outcomes was found. The findings from this study, contradicted the previously available literature and need cautious interpretation as the use of smokeless tobacco was measured prior to pregnancy, and no further follow-up on its use was noted. Hence women might have stopped, started, or changed their use during pregnancy. Furthermore, the high prevalence (around 71%) of smokeless tobacco use in the study population could have made estimating associations difficult.

In terms of adverse maternal health outcomes, anaemia (haemoglobin less than 10g/dl) was more common among women who used smokeless tobacco during pregnancy (41.1%) compared to non-users (29.1%) (Subramoney and Gupta, 2008) and snuff users showed increased risk of pre-eclampsia (adjusted odds ratio of 1.58, 95% CI of 1.09 – 2.27) (England et al., 2003). Furthermore, placental findings were assessed by three studies (Agrawal, Chansoriya and Kaul, 1983; Sarkar et al., 1991; Ashfaq et al., 2008) in the review conducted by Ratsch and Bogossian (2014), one of which (Agrawal, Chansoriya and Kaul, 1983) reported significant ($p < 0.005$) increase in placental weight of smokeless tobacco consumers.

Ashfaq et al (2008) and Sarkar et al (1991) reported no gross difference in placental weight, however Ashfaq et al (2008) did report significant micro morphological changes in placental structures. These findings are important as reduction in functional components of the placenta may potentially cause hypoxia and in turn affect foetal development. However, very little research on placental changes due to smokeless tobacco is available and more studies in this area are warranted. The review also showed evidence of increased pregnancy complications and operative deliveries in three studies that could be associated with maternal smokeless tobacco use.

1.2.4.3 Summary

Though there is a lack of high-quality studies showing association between maternal smokeless tobacco use and perinatal outcomes, there are few existing reviews that summarize and report associations with various outcomes. Most studies included in these reviews are similar; however, England et.al (2010) and Ratsch et.al (2014) further included studies on maternal outcomes. The evidence so far suggests a possible association of smokeless tobacco use and adverse pregnancy outcomes. However, more conclusive estimates based on different smokeless tobacco products (as they differ in their constituents and use), from representative population data will further help strengthen the evidence. Furthermore, the strength of evidence based on Scandinavian countries is relatively high, given that the data is derived from large population-based cohorts, however, this was not the case in other parts of the world, especially SEAR which bears most of the burden of smokeless tobacco use. Research from SEAR is even further warranted due to easy availability and poor regulation of smokeless tobacco products.

Estimating precise risk of smokeless tobacco use and various perinatal outcomes is challenging due to the diversity of products, geographic variations, method/frequency of its use and most importantly the socio-cultural integration of its use. Further high-quality studies are required to estimate risk of smokeless tobacco use with pregnancy outcomes (prior to conception during pregnancy and breastfeeding phase), based on different products, frequency of use, and accounting for confounders considering the socio-cultural factors as well. Furthermore, studies that can possibly demonstrate change in risk (if any) based on change in frequency (increase, decreased or completely quitting) during different phases of pregnancy may offer added advantage.

In addition to estimating risks associated with smokeless tobacco use and pregnancy outcomes, it is important to understand the epidemiology in terms of the current prevalence of smokeless tobacco use and the socio-cultural context related to its use to better address tobacco use among women of reproductive age. Despite the emerging evidence on smokeless tobacco use and perinatal outcomes, women are still at risk of other adverse effects of smokeless tobacco which demand public health response.

I further discuss the rationale and aims of my thesis, in the following section.

1.3 Rationale and summary of research needs related to smokeless tobacco use during pregnancy in LMICs

Smokeless tobacco is highly prevalent in LMICs and is socially more acceptable than smoking in SEAR, which is highlighted in the literature presented in this chapter. There appears to be a socio-cultural integration of smokeless tobacco practices, however, without substantial literature explaining this phenomenon, it seems reasonable to question whether such social acceptance has reinforced its use even during pregnancy. Furthermore, women are exposed to several adverse health effects of smokeless tobacco in addition to the harms during pregnancy, and thus demand public health attention.

1.3.1. Pregnancy: A teachable moment

> *"The label '**teachable moment**' has been used to describe naturally occurring life transitions or health events thought to motivate individuals to spontaneously adopt risk-reducing health behaviours"* – McBride et al (2003)

A life or health event is a potential teachable moment based on the perceived risk and increase in positive outcomes, increase in emotional responses, and redefinition of self-concept and social roles (McBride, Emmons and Lipkus, 2003). Pregnancy is widely considered a teachable moment as it offers a unique opportunity for health behaviour change and interventions can potentially be integrated during routine ante-natal care (Phelan, 2010). Building on the principles of McBride and colleagues (2003), who reported on smoking cessation as a scenario to explain teachable moments, Phelan (2010) suggested that pregnancy can offer an opportunity for health behaviour change such as weight control. A step further, Olander and colleagues (2016) suggested that there is more to just motivation in pregnancy that affects the concept of teachable moment (Olander et al., 2016). They incorporated the COM-B (Capability-Opportunity-Motivation Behaviour) framework to explain possibilities of capability and opportunity in addition to motivation, that affect intervention efficacy. Lack of capabilities and opportunities, despite strong motivation, may interfere with accurate implementation of intervention (Olander et al., 2016).

Hence, pregnancy offers a unique teachable opportunity, however a female's capabilities and opportunities also need to be considered for effective implementation of interventions during this phase related to health behaviour change. Taking this into consideration, I discuss the rationale and aims for my thesis in the following section.

1.3.2 Aims

In this section, I outline the justification for aims of the thesis. The objectives in each aim along with the approach that was opted to address them is discussed in the next chapter.

Aim I - Estimate recent prevalence of smokeless tobacco use during pregnancy in LMICs

Caleyachetty and colleagues (2014) reported tobacco use in pregnant women from 54 LMICs. Their study included data from the DHS between Jan 1, 2001, and Dec 1, 2012 (DHS phase IV-VI). More DHS waves have concluded, and more data have become available since; updated prevalence estimates are required to understand the current tobacco use among pregnant women in LMICs. Also, for comparative purposes, it is important to understand the tobacco use estimates among women of reproductive age group and whether they differ during pregnancy.

Furthermore, Lange et al (2018) reported global, and regional prevalence of smoking during pregnancy (Lange et al., 2018). The study reported that despite low prevalence of smoking during pregnancy in the African region, the estimated proportion of women who smoked daily and continued to smoke daily during pregnancy was 61.9% (95% CI of 30.6-100.0). Referring to the study by Lange et al (2018), Siddiqi and Mdege (2018) stated that, compared to Europe and the Americas, proportion of women who smoke during pregnancy and women who smoke in general is higher in Africa and Asia, which could indicate fewer quit rates among pregnant women in the latter (Siddiqi and Mdege, 2018).

Aim II – Understand the socio-cultural context related to smokeless tobacco use among women in LMICs

Literature suggests disparity in tobacco preference among women in LMICs. It is important to understand the wider context to better design and implement culturally and socially acceptable prevention/control programmes. Nichter et.al. (2010), in their study related to tobacco use among pregnant women in LMICs, made several recommendations highlighting a need for understanding social and cultural context, and research at individual and household/community level (Nichter et al., 2010). The recommendations outlined a need for both quantitative and qualitative data regarding women's tobacco use, perceptions, knowledge and understanding. Also, a review by Kakde and colleagues (2012) explored the social context of smokeless tobacco use among the South-Asian population (Kakde, Bhopal and Jones,

2012). However, this review restricted its study population, and there remains a need to understand the social and cultural context of smokeless tobacco use in other LMICs.

Aim III – Explore how family influences smokeless tobacco use during pregnancy

There is some evidence in the literature that family influences smokeless tobacco use during pregnancy (Nair et al., 2015). It is reported that women are more likely to use smokeless tobacco if relatives and especially their husband uses smokeless tobacco. This is supported by the review conducted by Kakde and colleagues (2012) which highlights that family and friends tend to act as both facilitators and barriers to smokeless tobacco use. Furthermore, the review reported four studies in the social context where "used by family members" was highly reported (prevalence ranges from 59% - 100%). To further strengthen the evidence of family influence, Begum and colleagues (2015) report several narratives by women which refer to a family member being influential in initiation of their smokeless tobacco habit (Begum et al., 2015).

Therefore, the use of smokeless tobacco in SEAR region is culturally accepted and its use by elders in the family is supportive of the fact that family influences smokeless tobacco use by women (Kakde, Bhopal and Jones, 2012). Hence, exploring the "how" factor is important to understand family influence of smokeless tobacco use during pregnancy, and to further, if possible, modify these influences for tobacco control measures.

2) CHAPTER II: Aims and Objectives

Given the prior understanding of pregnancy as a "teachable moment", preventive/cessation measures related to smokeless tobacco use among women and during pregnancy need socio-cultural adaptation, including influences from family members (Schensul et al., 2018). To do so, an initial understanding of the epidemiology and socio-cultural context related to smokeless tobacco use among women is necessary, to inform and develop tailored interventions and cessation methods.

Thus, as part of this project, I aimed to understand the epidemiology of maternal smokeless tobacco use, including understanding recent prevalence, key determinants and socio-cultural context related with maternal smokeless tobacco use to identify the female predisposition towards use of smokeless tobacco in pregnancy in LMICs and SEAR. This would add to the existing literature on smokeless tobacco use during pregnancy and contribute towards better design/implementation of smokeless tobacco prevention and cessation measures.

In the following sections, I discuss aims/objectives and the studies I conducted to address them. The summary of aims and objectives is reported in Table 2.1

2.1.1 Aim I: Estimate recent prevalence of smokeless tobacco use during pregnancy in LMICs:

There is a need to estiamte recent prevalence rate estimates of smoking and smokeless tobacco use among both pregnant and non-pregnant women, which will allow a better understanding of whether these rates differ between the two groups of women. This form of comparative analysis has not been done previously and will be first of its kind.

Following are the objectives in relation to estimating recent prevalence of smokeless tobacco use during pregnancy in LMICs:

- To estimate recent prevalence of tobacco use (smoking and smokeless) among women of reproductive age (pregnant and non-pregnant) in LMICs.

- To estimate the effect of pregnancy status, education, and wealth index on tobacco use among women of reproductive age in LMICs.

Furthermore, as mentioned in the earlier chapter (1.2.2.2) that more than 80% of smokeless tobacco use is in the SEAR, following are additional objectives:

- To estimate recent prevalence of tobacco use (smoking and smokeless) among women of reproductive age (pregnant and non-pregnant) in SEAR.
- To estimate the effect of pregnancy status, education, and wealth index on tobacco use among women of reproductive age in SEAR.

To address the above-mentioned aim/objectives, I conducted a secondary analysis of the DHS data, details of which are mentioned in Chapter III.

2.2.2 Aim II: Socio-cultural context related to smokeless tobacco use among women in LMICs

Prior to proposing tobacco control measures for smokeless tobacco use, it is important to understand what the social and cultural context is related to its use among women. As evident by existing literature that use of smokeless tobacco is highly prevalent among women in LMICs, especially SEAR, it is warranted to understand the factors that affect its use and the knowledge, beliefs, and perceptions to better design contextual tobacco control measures.

Following are the objectives for understanding socio-cultural context related to smokeless tobacco use among women in LMICs:

- To review existing literature on social and cultural characteristics, perceptions and beliefs/attitudes related to smokeless tobacco use among women in LMICs.
- To review existing literature on social and cultural characteristics, perceptions and beliefs/attitudes related to smokeless tobacco during pregnancy in LMICs.

To address this, I conducted a mixed-method systematic review, details of which are discussed in Chapter IV.

2.1.3 Aim III: Influence of family on smokeless tobacco use during pregnancy - Why explore the "how" instead of "if"?

There is evidence that family influences the use of smokeless tobacco during pregnancy, especially in SEAR where chewing tobacco is a common activity that is performed with family and friends. However, it is yet to explore how the family influences either initiation or change in practice of smokeless tobacco use during pregnancy.

The objective within this aim, is to understand how family members (and additionally peers and/or community members) influence initiation or change in practice, perceptions and attitudes of smokeless tobacco use among pregnant women. To address these, I conducted a qualitative study, details of which are discussed in Chapter V.

Table 2.1: Summary of aims and objectives

Aims	Objectives
To estimate recent prevalence of smokeless tobacco use during pregnancy in LMICs	To estimate recent prevalence of tobacco use (smoking and smokeless) among women of reproductive age (pregnant and non-pregnant) in LMICs. To estimate the effect of pregnancy status, education, and wealth index on tobacco use among women of reproductive age in LMICs. To estimate recent prevalence of tobacco use (smoking and smokeless) among women of reproductive age (pregnant and non-pregnant) in SEAR. To estimate the effect of pregnancy status, education, and wealth index on tobacco use among women of reproductive age in SEAR.
To explore socio-cultural context related to smokeless tobacco use among women in LMICs	To review existing literature on social and cultural characteristics, perceptions and beliefs/attitudes related to smokeless tobacco use among women in LMICs. To review existing literature on social and cultural characteristics, perceptions and beliefs/attitudes related to smokeless tobacco during pregnancy in LMICs.
To understand the influence of family on smokeless tobacco use during pregnancy	To understand how family members (and additionally peers and/or community members) influence initiation or change in practice, perceptions and attitudes of smokeless tobacco use among pregnant women.

3) CHAPTER III: Tobacco use among women of reproductive age in LMICs and a sub-group analysis in the SEAR: prevalence estimates and comparison between pregnant and non-pregnant women

In this chapter, I report findings from the first study to estimate recent prevalence of smokeless tobacco use among pregnant women in LMICs and association of its use with education and socio-economic status. I present the methodology for the analysis conducted and then discuss the results with relevant literature, implications for policy, practice, and further research.

3.1 Research questions

1. What is the prevalence of tobacco use among pregnant and non-pregnant women in LMICs?
2. What is the association between its use and pregnancy status, and the education and socioeconomic status in women in LMICs?
3. What is the prevalence of tobacco use among pregnant and non-pregnant women in SEAR?
4. What is the association between its use and pregnancy status, and the education and socioeconomic status in women in SEAR?

3.2 Methodology:

To estimate prevalence rates and possible association of socio-demographic characteristics with tobacco use behaviour, I sought to use the DHS. These are nationally representative surveys conducted systematically in LMICs.

3.2.1 Data[1]:

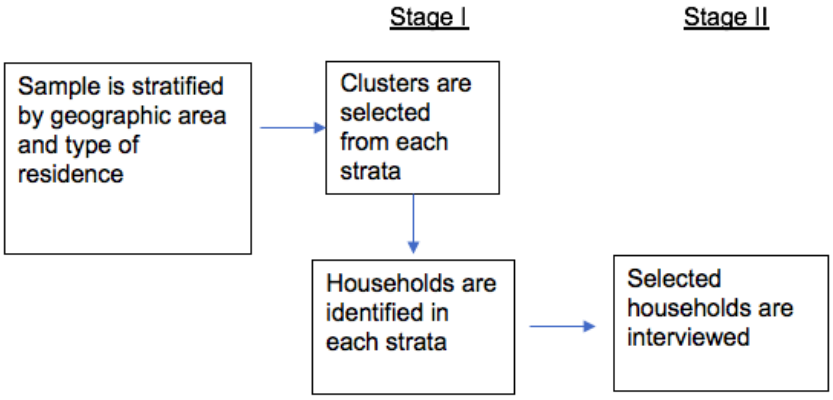
The DHS was established in 1984 by the United States Agency for International Development (USAID). The program collects nationally representative household surveys in the LMICs. Its

[1] This section is summarized from "The guide to DHS statistics" (Rutstein and Rojas, 2006).

first phase ran from 1984-1990 and is currently in its eighth phase. These phases spanned for about 5 years, during which that phase-specific questionnaire was implemented. With each advancing phase, questionnaires were slightly modified, reporting of which was specified in their respective manuals. The sample was generally representative at the national level, at the residence level (urban-rural) and at the regional level (departments, states).

The sample was based on a stratified two-stage cluster design (*Figure 3.1*): In stage one, census files were used to draw enumeration areas, based on which sample of households were drawn in stage two. An initial household questionnaire was collected by interviewing one member, who also provided a list of other household members. All consenting women aged 15 - 49 were further interviewed to answer the women and child questionnaire.

Figure 3.1: DHS Sampling Design



The surveys broadly provided information on socio-demographic characteristics, maternal health, family planning, child health, nutrition, tobacco use, HIV prevalence and attitudes/beliefs, women empowerment etc. These were normally conducted over a period of 18–20 months and were of two types. Standard DHS were conducted about every five years and collected information from a larger sample size (usually between 5,000 and 30,000 households). Interim DHS were mainly conducted for monitoring indicators and were conducted in the duration between standard surveys.

For the purpose of this study, phase VI (2008-2013) and VII (2013-2018) were used. This is because estimates from phase V (which is when tobacco use was introduced in the DHS questionnaires) and some of phase VI have been reported previously (Caleyachetty et al., 2014). Furthermore, countries from these two survey phases which reported tobacco use history (including both smoked and smokeless form) were included for analysis. In total, 42 such countries were included (table 3.3).

3.2.2 Statistical Analysis:

The secondary data analysis was performed in STATA (StataCorp, 2017) version 14, using the *Individual Recode*[2] files from each country. This section includes statistical methods, various steps and STATA commands that were used during analysis for this study.

Due to the complex DHS sample design (two-step stratified cluster design), sampling weights were calculated to account for differential probabilities of selection and participation. In the aim to reduce sampling errors, the DHS uses stratification to divide their sampling frame into subgroups or strata based on geographic region and further urban/rural areas within each region. In each stratum, the Primary Sampling Unit (PSU) forms the survey cluster and a fixed number of households (approximately 25-35) are selected within each cluster. The probability of selection of each household is not a constant and hence the DHS data must be weighted when the analysis is performed to ensure the proper representation of the sample.

The DHS for the women's individual response rate uses the following parameters to account for weights (Croft et al., 2018):

- Women eligible for interview: women aged 15-49 years who stayed in the household the night before the survey.
- Numerator: Number of eligible women who completed the individual interview
- Denominator: Number of eligible women who completed the individual interview + eligible women not interviewed because they were not at home + eligible women with permanently postponed or refused interviews + eligible women with partially completed interviews + eligible women for whom an interview could not be completed due to any reason.

Reported weight variable could not directly be used for analysis, as the DHS calculated weights up to six decimals but reported without decimals in the survey datasets. Thus, a new weight variable was generated.

Weight Variable / 1000000

[2] DHS provides its survey data sets based on the population of interest. Women and child data is provided in the "Individual Recode" files. The data set provides information for every eligible woman identified from the household survey.

For any summary statistics where confidence intervals or standard errors were not required, simple weight command was used. However, when confidence intervals, standard errors or regression analysis was required, sampling units and strata needed to be accounted for. To do so, PSU and strata as reported in survey datasets were incorporated in the weight command.

Svyset [pw=weight variable], psu (psu) strata (strata variable)

In calculating the weights, the Taylor-Linearized variance estimation was used to estimate the standard errors, which is often used for complex surveys to estimate proportions and means (Wolter KM., 2007)

In general, weights were accounted for to restore the representativeness of the sample, such that it represented actual population distribution and to account for non-response.

3.2.2.1 Variables of interest

The survey reported tobacco consumption as a binary variable, as current use of various forms of tobacco. Broadly these included cigarettes, pipes, cigars, chewed, snuffed, and country-specific tobacco. Therefore, to calculate the prevalence, a new variable was generated to classify tobacco use. The outcome variable (*Table 3.1*) for the analysis was tobacco use categorised into exclusive smoking, exclusive smokeless, dual and no tobacco use (reference category). This new variable was generated in two steps mentioned below:

> ***Step 1:*** The extended generation (***egen***) command was used to convert all different smoking variables into one binary variable. The same process was done for all smokeless tobacco used variables. This method addressed the missing values in the set of variables used to combine the variables. The following commands were used for this analysis:
> ***egen smoke = rowtotal (smokescigarettes smokespipe smokescigars), missing***
> ***egen smokeless = rowtotal (chewingtobacco snuff), missing***
>
> ***Step 2:*** These new smoking and smokeless tobacco variables were then combined and recoded into one to generate the new outcome variable "tobacco use" and labelled as exclusive smoking, exclusive smokeless, dual and no tobacco use. Details of how the missing data were addressed during the generation of the new outcome variable are mentioned in section 3.2.2.3.

The covariates (*Table 3.2*) were pregnancy status asked as "are you currently pregnant?" and reported as a binary variable ("Yes" or "No or not sure"), age recorded as a continuous value (years completed), area of residence ("urban" or "rural") and education ("no education", "primary", "secondary" or "higher"), reported as categorical variables. Socioeconomic status is calculated as a combined wealth index for the household based on selected household assets (DHS, 2019) and reported categorically ("poorest", "poorer", "middle", "richer" and "richest").

Table 3.1: Outcome variable (original and modified) "Tobacco Use"

Outcome Variable		
Original variable	**Response**	**Modified variable**
Smokes cigarettes	Yes or No	Exclusive smoking Exclusive smokeless tobacco use Dual tobacco use No tobacco use
Smokes pipe	Yes or No	
Uses chewing tobacco	Yes or No	
Uses snuff	Yes or No	
Smokes cigars	Yes or No	
Use of country specific tobacco	Yes or No	

Table 3.2: Covariates used in the secondary data analysis of the DHS data

Covariates	
Variable	**Response**
Currently pregnant	Yes or No/unsure
Age (current age in years)	Numerical
Area of residence	Rural or urban
Highest education level	No education Primary education Secondary education Higher education
Combined wealth index	Poorest Poorer Middle Richer Richest

3.2.2.2 Calculation of prevalence rates:

Prevalence estimates along with 95% confidence intervals (CIs) for tobacco use among pregnant and non-pregnant women for all 42 LMICs were generated. From each country

survey data set, currently pregnant and non-pregnant women were identified as the sample population and characteristics of these women based on mean age, type of residence, education and wealth index distribution were calculated for each country. The prevalence estimates accounting for weights, were generated for each country for currently pregnant and non-pregnant women using the following command.

svy: tab Pregnancy TobaccoUse, row se ci

To estimate pooled prevalence rates and 95% confidence intervals for all countries combined, ***metaprop*** command was used. This statistical package is developed (Nyaga, Arbyn and Aerts, 2014) specifically, to compute meta-analysis of proportions. It further considers observations with "0" which in case of proportions is still an important observation and thus needs to be accounted for in the meta-analysis.

3.2.2.3 Addressing missing data and constructing outcome variables:

Missing data was accounted for while generating the outcome variable (tobacco use). The definition of missing data (non-response) here, was "women who did not respond to at least one variable in the smoking form of tobacco use and one in the smokeless form of tobacco use. To better understand this, it is important to understand how these variables were generated.

- Uniform labelling of missing data – Use of the ***mvdecode*** command to convert all missing values coded as "9" to "**.**".
- Generating two binary variables; smoking and smokeless. The commands, ***egen*** and ***rowtotal*** were used to generate two new variables using multiple binary variables. This ensured utilisation of all the available data such that the new variable was only considered missing when all its subcategories (multiple binary variables used to compute the new variable) were missing. For example, if the data reported two binary variables of smokeless tobacco use (chewed and snuffed), a new variable "smokeless" was only considered missing when both chewed and snuffed sections were missing.
- Computing a single tobacco use variable (multinomial) – Previously generated smoking and smokeless variables were used to compute this multinomial variable. Here, missing value was considered when either of the binary variables were missing. Therefore, it was necessary for an observation to be present in both the binary variables for that observation to be included.

3.2.2.4 Multinomial logistic regression:

The regression analysis was performed to assess the effect of pregnancy status, type of residence, education, wealth index and age on use of tobacco by women in LMICs. This part of the analysis was initially to be conducted by two methods:

1. Running multinomial logistic regression analysis on individual country data sets and then performing meta-regression. This would have ensured that sampling weights were accounted for.
2. Pooling in data from all countries into one data set and running the logistic regression model, which would not account for weights.

The first method of meta-regression was later excluded due to lack of enough observations in all categories of the tobacco use variable (multinomial). Also, as the desired aim was to assess the effect of independent variables on use of tobacco and not the representativeness of the population, accounting for sampling weights, did not seem necessary. Thus, pooling in data from all countries into one data set appeared logical as that increased the sample size and eventually increased the number of observations in the outcome variable categories.

The outcome variable for the analysis was tobacco use (multinomial variable categorised into exclusive smoking, exclusive smokeless, dual and none). The explanatory variables were pregnancy status, type of residence, education, wealth index and age. The analysis also accounted for clustering based on countries. The following command was used to perform multinomial regression analysis.

mlogit TobaccoUSe Pregnancy Residence Education WealthIndex Age, cluster (country) rrr nolog

3.2.2.5 Sub-group analysis for SEAR

A similar set of analyses were performed for SEAR, which included India, Indonesia, Myanmar, Nepal, and Timor-Leste. Pooled prevalence estimates with 95% confidence intervals were computed and multinomial regression analysis (with a similar outcome and explanatory variables) was performed, accounting for clustering based on countries.

3.3 Results:

The analysis included data of 80,512 pregnant and 1,230,724 non-pregnant women (these include missing data) from 42 countries. The response rate for tobacco use, both smoked and smokeless, among women was more than 99%, which summed up to 80,454 pregnant and 1,230,262 non-pregnant women combined from all 42 countries from 2010 to 2016. Population characteristics of these women from each country are listed in Table 3.3 and 3.4.

Table 3.3: Population characteristics of pregnant women

Characteristics of pregnant women (n = 80512)												
Country	Pregnant women (weighted)	Mean age	Rural dwellers (%)	Highest education level (%)				Wealth Index (%)				
				No education	Primary	Secondary	Higher	Poorest	Poorer	Middle	Richer	Richest
Afghanistan (2015)	6412	27.46	84.6	85.6	6.99	6.15	1.26	22	24.42	21.5	18.98	13.09
Angola (2016)	1364	25.73	38.84	25.36	37.71	33.43	3.5	22.33	22.37	21.98	19.76	13.56
Armenia (2016)	174	26.4	45.25	0	3.56	37.48	58.96	13.34	19.99	22.11	20.09	24.48
Benin (2012)	1556	27.44	63.61	69.71	17.2	11.75	1.34	17.91	22.72	22	20.15	17.22
Burkina Faso (2010)	1730	26.99	82.03	81.93	11.85	5.6	0.46	18.76	22.74	21.78	20.06	16.65
Burundi (2016)	1420	28.42	88.94	43.19	44.35	11.3	1.16	21.74	19.32	20.85	19.35	18.73
Cambodia (2014)	934	25.53	82.8	10.76	47.11	38.07	4.06	17.44	22.57	17.9	20.28	21.8
Cameroon (2011)	1512	26.38	56.29	27.49	37.93	31.58	3	22.54	22.79	17.97	20.37	16.33
Comoros (2012)	351	27.14	75.71	35.32	31.14	29.28	4.13	16.97	25.56	23.02	15.43	19.02
Congo (2012)	1031	26.6	35.45	7.03	27.69	60.73	4.54	20.09	23.45	21.42	20.06	14.98
Cote d'Ivoire (2012)	1032	26.3	58.27	59.28	24.94	13.54	2.24	21.22	23.51	19.6	19.07	16.58
Dominican Republic (2013)	479	24.19	23.34	2.56	34.26	40.4	22.78	23.57	23.96	25.55	16.29	10.63
Ethiopia (2016)	1135	27.23	85.83	53.2	35.03	8.28	3.49	22.67	23.33	18.77	17.45	17.78
Gabon (2012)	814	26.28	12.65	5.42	21.41	63.01	10.16	18.29	22.98	19.06	21.29	18.38
Gambia (2013)	830	26.85	54.38	58.51	18.38	20.31	2.8	20.84	20.95	24.1	16.05	18.07
Ghana (2014)	663	28.81	50.32	23.78	16.62	52.71	6.89	17.97	18.69	20.56	18.14	24.64
Guatemala (2015)	1427	25.04	63.98	13.29	54.99	27.86	3.86	24.83	22.74	20.35	17.07	15.02
Haiti (2012)	837	26.55	62.38	17.49	42.89	35.59	4.03	18.74	20.25	25.36	22.43	13.23
Honduras (2012)	1214	24.62	52.25	4.23	55.51	35.2	5.05	21.43	20.22	21.44	21.04	15.87
India (2016)	31123	24.27	71.5	24.5	12.6	49.3	13.6	23.2	21.6	20.4	18.2	16.6
Indonesia (2012)	1950	27.86	49.97	1	27.89	56.93	14.18	20.81	18.05	21.73	20.7	18.71
Kenya (2014)	1944	26.3	60.54	12.32	50.83	25.85	11.01	23.46	18.27	17.83	19.14	21.3
Kyrgyz Republic (2012)	551	25.81	66.23	0	1.06	55.83	43.11	22.6	18.09	21.09	17.81	20.86
Lesotho (2014)	284	25.18	69.13	1.65	42.54	48.63	7.19	17.26	17.53	22.76	24.21	18.24
Liberia (2013)	765	26.29	48.44	37.19	35.61	24.86	2.35	21.32	22.72	22.52	15.67	17.76
Malawi (2016)	1874	24.92	85.34	9.48	65.02	22.63	2.88	22.98	23.51	18.6	17.51	17.41
Mali (2013)	1202	26.98	84.47	79.58	10.06	9.75	0.62	21.42	19.57	22.65	20.17	16.2
Mozambique (2011)	1516	26.02	74.25	35.46	52.81	11	0.73	25.62	23.65	18.23	19.03	13.48
Myanmar (2016)	466	28.55	77.05	13.59	43.6	33.98	8.84	29.84	20.02	16.34	16.17	17.64
Namibia (2013)	600	26.64	41.85	7.19	19.1	63.21	10.5	16.26	19.69	20	25	19.06
Nepal (2016)	535	23.57	43.46	25.06	19.23	39.72	16	18.65	19.94	24.16	25.06	12.09
Niger (2012)	1591	27.29	86.51	83.25	11.5	4.93	0.28	17.34	19.94	22.7	20.07	19.94
Pakistan (2012)	1461	26.65	73.07	54.69	15.33	20.22	9.76	24.89	22.3	17.48	19.75	15.58
Philippines (2013)	686	26.75	52.97	0.93	18.3	53.24	27.54	26.13	22.25	18.92	18.95	13.74
Rwanda (2015)	984	28.46	82.35	11.15	70.3	15.36	3.19	20.14	20.61	21.07	18.91	19.27
Sierra Leone (2013)	1429	26.93	75.82	63.57	14.95	19.94	1.54	23.55	22.8	20.42	18.97	14.26
Tajikistan (2012)	734	24.59	79.37	2.11	5.57	80.66	11.66	16.51	23.96	20.78	22.75	16
Tanzania (2016)	1135	26.16	70.01	17.59	64.99	16.03	1.38	23.43	20.87	17.82	18.65	19.23
Timor-Leste (2016)	690	26.92	63.53	17.71	15.49	55.04	11.77	15.58	18.71	17.81	24.8	23.1
Togo (2014)	807	28.33	65.54	39.23	34.31	23.99	2.47	20.35	22.69	18.08	20.74	18.13
Uganda (2016)	1843	25.86	76.85	8.26	62.11	23.73	5.9	21.8	21.19	20.04	17.76	19.22
Zambia (2014)	1427	26.88	61.68	11.47	50.11	34.49	3.93	22.22	20.78	18.69	21.02	17.29

The mean age of women varied across countries ranging from 23.6 years (Nepal) to 28.8 years (Ghana) among pregnant women and 27.4 years (Gambia) to 33.2 years (Pakistan) among non-pregnant women. The proportion of pregnant women who resided in rural areas ranged from 12.6% (Gabon) to 88.9% (Burundi), and from 11.2% (Gabon) to 86.9% (Burundi).

The proportion of women with no formal education ranged from 0% (pregnant women) and 0·05% (non-pregnant women) in the Kyrgyz Republic to 85·6% and 82·9% in Afghanistan, respectively. Furthermore, nine countries had more than 50% of pregnant women with no

formal education, while the same was in eight countries for non-pregnant women. The proportion of women in the combined wealth index quintiles, ranged from 13.34% (Armenia) to 29.84% (Myanmar) in the lowest quantile and from 10.63% (Dominican Republic) to 24.64% (Ghana) in the highest quantile.

Table 3.4: Population characteristics of non-pregnant women

Characteristics of non-pregnant women (n = 1230724)												
Country	Non-pregnant women (weighted)	Mean age	Rural dwellers (%)	Highest education level (%)				Wealth Index (%)				
				No education	Primary	Secondary	Higher	Poorest	Poorer	Middle	Richer	Richest
Afghanistan (2015)	23049	32.19	74.48	82.93	8.16	6.84	2.06	19.49	19.24	19.56	20.8	20.9
Angola (2016)	13015	27.83	29.47	21.77	34.5	38.84	4.89	16.28	17.13	19.21	22.74	24.63
Armenia (2016)	5942	31.65	40.06	0.08	6.56	40.04	53.31	17.8	20.31	18.57	21.07	22.25
Benin (2012)	15043	29.05	52.5	58.46	17.54	22.03	1.96	16.73	17.71	18.55	21.57	25.45
Burkina Faso (2010)	15357	29.99	71.91	73.03	13.83	12.08	1.02	17.4	18.2	18.72	19.85	25.83
Burundi (2016)	15849	28.24	86.91	35.62	38.77	24.35	1.25	18.93	19.92	19.94	19.53	21.67
Cambodia (2014)	16644	30.57	81.43	12.92	47.11	35.34	4.64	17.91	18.64	19.31	20.57	23.58
Cameroon (2011)	13914	28.08	45.03	19.19	33.35	41.73	5.73	15.38	17.3	19.06	23.06	25.2
Comoros (2012)	4978	27.61	66.32	30.69	18.82	40.38	9.81	16.24	19.75	20.37	21.46	22.19
Congo (2012)	9788	28.8	30.97	5.63	23.4	65.7	5.27	16.37	19.17	20.58	21.89	21.99
Cote d'Ivoire (2012)	9028	28.61	47.51	52.5	25.41	19.29	2.8	17.17	16.57	18.01	20.96	27.29
Dominican Republic (2013)	8893	30.25	24.21	1.95	30.09	39.82	28.14	15.58	19.53	20.42	22.31	22.17
Ethiopia (2016)	14548	28.24	77.21	47.39	35.01	11.85	5.76	16.33	17.49	19.01	19.94	27.23
Gabon (2012)	7608	28.66	11.22	4.32	21.19	64.7	9.79	14.1	18.85	21.41	22.43	23.21
Gambia (2013)	9403	27.42	43.09	45.42	13.32	35.56	5.7	16.72	18.16	18.37	21.28	25.47
Ghana (2014)	8733	29.95	45.93	18.71	17.88	57.11	6.3	15.94	17.32	20.63	22.87	23.25
Guatemala (2015)	24487	28.91	54.18	14.3	45.59	33.52	6.59	16.91	18.54	19.89	22.18	22.48
Haiti (2012)	13450	28.26	51.89	14.64	35.86	43.8	5.7	15	15.92	19.31	22.84	26.93
Honduras (2012)	21543	29	45.45	3.91	49.83	38.19	8.06	15.57	17.72	20.82	22.94	22.95
India (2016)	668563	30.23	65.1	27.6	12.46	47.22	12.72	17.47	19.47	20.56	21.29	21.21
Indonesia (2012)	43657	31.61	47.73	3.39	33.4	51.13	12.08	16.86	19.31	20.2	21.39	22.23
Kenya (2014)	29135	29.05	59.08	6.65	50.24	31.92	11.19	15.04	17.51	19.51	21.2	26.73
Kyrgyz Republic (2012)	7657	29.95	62.33	0.05	0.38	56.15	43.42	17.46	17.94	18.57	20.49	25.55
Lesotho (2014)	6338	28.53	63.2	1	38.39	51.76	8.85	14.37	15.52	18.61	24.25	27.25
Liberia (2013)	8474	28.77	38.18	32.82	30.71	31.96	4.51	16.73	17.12	18.97	22.74	24.44
Malawi (2016)	22688	28.37	81.39	12.34	61.83	22.8	3.03	19.02	18.74	18.89	19.18	24.17
Mali (2013)	9222	28.83	74.01	75.33	9.15	14.13	1.39	18.38	18.61	18.43	20.49	24.09
Mozambique (2011)	12229	28.91	64.16	30.71	49.92	17.95	1.42	18.06	17.93	18.8	20.4	24.82
Myanmar (2016)	12419	31.79	70.52	12.42	41.09	36.15	10.34	17.19	18.64	20.59	21.15	22.43
Namibia (2013)	8576	29	43.55	4.38	19.63	65.88	10.11	15.52	17.57	19.53	22.93	24.45
Nepal (2016)	12327	29.57	36.97	33.64	16.61	34.91	14.84	16.84	19.62	20	21.35	22.2
Niger (2012)	9569	29.06	80.35	79.46	11.42	8.37	0.63	18.22	18.65	19.23	20.63	23.27
Pakistan (2012)	12097	33.21	65.76	57.35	15.97	17.44	9.24	18.4	19.43	20.21	20.67	21.3
Philippines (2013)	15469	30.17	46.59	1.17	15.95	48.81	34.06	15.78	17.67	19.84	22.25	24.46
Rwanda (2015)	12513	28.79	80.4	12.43	63.83	21.09	2.65	18.88	19.41	19.1	19.57	23.05
Sierra Leone (2013)	15229	28.55	63.31	55.06	13.9	27.9	3.14	18.08	17.86	18.7	20.47	24.89
Tajikistan (2012)	8922	29.23	74.65	2.01	3.71	81.04	13.23	19.7	19.47	19.63	20.22	20.98
Tanzania (2016)	12131	28.93	63.15	14.4	61.61	22.61	1.38	16.32	16.79	17.53	21.52	27.85
Timor-Leste (2016)	11917	28.84	67.02	21.98	15.23	51.87	10.92	16.59	18.11	19.3	21.82	24.18
Togo (2014)	8673	29.44	53.58	31.08	33.4	32.08	3.44	16.31	16.36	18.2	23	26.14
Uganda (2016)	16663	28.16	72.89	9.78	56.92	25.22	8.08	17.07	18.04	18.55	20.14	26.2
Zambia (2014)	14984	28.5	53.03	8.09	46.5	40.24	5.17	16.96	17.12	18.76	21.42	25.74

3.3.1 Prevalence of tobacco use:

Estimates among pregnant women (*Table 3.5*): The response rate for tobacco use among pregnant women in all 42 countries was more than 99%, which summed up to 80454 pregnant women combined. Pooled estimate of exclusive smokeless tobacco use was 0.56% (95% CI 0.33-0.84), with 0% reported in Armenia, Dominican Republic, Gambia, Guatemala, Honduras, Kyrgyz Republic, Mozambique, Myanmar, Tajikistan, and Timor-Leste to as high as 4.71% (95% CI 2.55-8.55) in Lesotho. Prevalence of exclusive smoking among pregnant women ranged from 0% (Armenia, Burkina Faso, Gambia, Lesotho, and Niger) to 4.92% (95% CI 2.85-8.37) in Timor-Leste and pooled estimate of 0.69% (95% CI 0.51-0.90). Dual tobacco use during pregnancy was zero in 25 of the 42 countries, with highest of 0.26% (95%

CI 0.003-1.82) in the Kyrgyz Republic and a pooled estimate of 0.03% (95% CI 0.01-0.06). Armenia and Gambia had an apparent zero use of tobacco during pregnancy.

Table 3.5: Prevalence estimates of tobacco use among pregnant women

Tobacco use during pregnancy					
Country	Response rate %	Response rate n (weighted)	Exclusive smokeless % (95% CI)	Exclusive smoking % (95% CI)	Dual % (95% CI)
Afghanistan (2015)	99.71	6393	1.78 (1.39-2.26)	2.29 (1.77-2.96)	0.25 (0.12-0.52)
Angola (2016)	99.88	1362	0.005 (0.001-0.27)	1.05 (0.62-1.79)	0.12 (0.002-0.55)
Armenia (2016)	100	174	0	0	0
Benin (2012)	100	1556	0.68 (0.33-1.41)	0.21 (0.006-0.66)	0
Burkina Faso (2010)	99.73	1725	2.77 (2.01-3.79)	0	0
Burundi (2016)	100	1420	1.79 (1.11-2.87)	1.76 (1.11-2.78)	0.25 (0.003-1.75)
Cambodia (2014)	99.88	932	1.16 (0.64-2.09)	0.66 (0.25-1.7)	0.39 (0.18-0.88)
Cameroon (2011)	99.69	1507	0.009 (0.002-0.39)	0.12 (0.003-0.52	0
Comoros (2012)	99.22	348	1.34 (0.29-6.06)	1.34 (0.39-4.5)	0
Congo (2012)	99.9	1029	0.75 (0.38-1.48)	0.45 (0.15-1.32)	0.005 (0.001-0.23)
Cote d'Ivoire (2012)	99.86	1031	1.03 (0.52-2.02)	0.42 (0.1-2.21)	0
Dominican Republic (2013	100	479	0	1.69 (0.72-3.92)	0
Ethiopia (2016)	100	1135	0.004 (0.001-0.13)	1.25 (0.38-4.0)	0.001(0.0001-0.009)
Gabon (2012)	99.76	812	0.009 (0.002-0.44)	2.24 (1.0-4.91)	0.008 (0.002-0.33)
Gambia (2013)	100	830	0	0	0
Ghana (2014)	100	663	0.12 (0.001-0.86)	0.008 (0.001-0.6)	0
Guatemala (2015)	100	1427	0	0.11 (0.003-0.36)	0
Haiti (2012)	100	837	2.58 (1.46-4.54)	0.88 (0.45-1.71)	0.15 (0.002-1.06)
Honduras (2012)	99.92	1213	0	0.71 (0.27-1.83)	0
India (2016)	100	31123	3.21 (2.94-3.5)	0.43 (0.35-0.52)	0.005 (0.002-0.11)
Indonesia (2012)	99.96	1949	0.28 (0.12-0.65)	0.73 (0.4-1.35)	0
Kenya (2014)	99.97	1943	0.71 (0.46-1.09)	0.51 (0.18-1.44)	0
Kyrgyz Republic (2012)	99.93	550	0	0.53 (0.13-2.13)	0.26 (0.003-1.82)
Lesotho (2014)	100	284	4.71 (2.55-8.55)	0	0
Liberia (2013)	100	765	0.11 (0.002-0.46)	0.13 (0.004-0.4)	0
Malawi (2016)	100	1874	0.003 (0.0005-0.22)	0.49 (0.21-1.14)	0.009 (0.002-0.33)
Mali (2013)	100	1202	1.16 (0.48-2.78)	0.008 (0.001-0.34)	0
Mozambique (2011)	100	1516	0	0.35 (0.11-1.07)	0.43 (0.17-1.07)
Myanmar (2016)	99.97	465	0	3.36 (1.95-5.73)	0
Namibia (2013)	100	600	0.21 (0.006-0.73)	2.93 (1.73-4.92)	0.3 (0.007-1.19)
Nepal (2016)	100	535	0.46 (0.13-1.63)	1.66 (0.68-3.99)	0
Niger (2012)	99.86	1588	1.1 (0.66-1.82)	0	0
Pakistan (2012)	99.84	1458	1.64 (0.81-3.29)	3.55 (2.38-5.25)	0.21 (0.004-1.11)
Philippines (2013)	100	686	0.36 (0.11-1.16)	2.32 (1.4-3.83)	0
Rwanda (2015)	100	984	1.04 (0.51-2.08)	0.25 (0.007-0.82)	0.15 (0.003-0.66)
Sierra Leone (2013)	99.78	1425	3.45 (2.28-5.17)	2.09 (1.39-3.12)	0.1 (0.001-0.73)
Tajikistan (2012)	99.83	732	0	0.11 (0.001-0.81)	0
Tanzania (2016)	100	1135	0.26 (0.007-0.85)	0.57 (0.24-1.32)	0
Timor-Leste (2016)	100	690	0	4.92 (2.85-8.37)	0
Togo (2014)	100	807	0.26 (0.003-1.85)	0.006 (0.0009-0.48)	0
Uganda (2016)	100	1843	0.76 (0.45-1.27)	0.74 (0.36-1.53)	0.001 (0.0001-0.007)
Zambia (2014)	100	1427	0.82 (0.36-1.88)	0.009 (0.001-0.51)	0
Total		80454	0.56 (0.33-0.84)	0.69 (0.51-0.90)	0.03 (0.01 - 0.06)

Estimates among non-pregnant women (*Table 3.6*): The response rate for tobacco use among non-pregnant women in all 42 countries was also more than 99%, which leads to a total sample of 1230262 women. Pooled estimate of exclusive smokeless tobacco use was 0.78% (95% CI 0.35-1.237), with the lowest of 0% in Armenia to highest of 7.6% (95% CI 6.73-8.57) in Lesotho. Pooled estimate of exclusive smoking was 1.09% (95% CI of 0.81 – 1.42), and that of dual tobacco use was 0.08% (95% CI of 0.05 – 0.11).

Table 3.6: Prevalence estimates to tobacco use among non-pregnant women

Tobacco use among non-pregnant women					
Country	Response rate %	Response rate n (weighted)	Exclusive smokeless % (95% CI)	Exclusive smoking % (95% CI)	Dual % (95% CI)
Afghanistan (2015)	99.65	22968	2.45 (2.08 - 2.87)	3.45 (2.93 - 4.07)	0.26 (0.17 - 0.4)
Angola (2016)	100	13015	0.11(0.006-0.19)	1.8 (1.49 - 2.19)	0.09 (0.05-0.1)
Armenia (2016)	99.98	5941	0	1.07 (0.76 - 1.49)	0.21 (0.09 - 0.51)
Benin (2012)	100	15043	0.61 (0.48 - 0.78)	0.23 (0.16 - 0.33)	0.05 (0.02 - 0.11)
Burkina Faso (2010)	99.9	15342	3.95 (3.44 - 4.55)	0.08 (0.04 - 0.15)	0.02 (0.006 - 0.07)
Burundi (2016)	100	15849	2.66 (2.33 - 3.04)	1.84 (1.56 - 2.16)	0.009 (0.005 - 0.17)
Cambodia (2014)	99.98	16640	3.61 (3.17 - 4.11)	1.89 (1.48 - 2.41)	0.55 (0.41 - 0.74)
Cameroon (2011)	99.81	13887	0.49 (0.33 - 0.71)	0.29 (0.21 - 0.39)	0.04 (0.01 - 0.03)
Comoros (2012)	99.73	4965	2.97 (2.21 - 3.96)	1.59 (1.18 - 2.15)	0.15 (0.06 - 0.32)
Congo (2012)	99.87	9775	1.55 (1.23 - 1.94)	0.47 (0.31 - 0.71)	0.06 (0.04 - 0.11)
Cote d'Ivoire (2012)	99.66	8997	1.23 (0.96 - 1.58)	0.31 (0.17 - 0.58)	0.07 (0.01 - 0.36)
Dominican Republic (201	99.9	8884	0.04 (0.005 - 0.29)	4.66 (4.06 - 5.34)	0.009 (0.001 - 0.06)
Ethiopia (2016)	100	14548	0.05 (0.02 - 0.13)	0.52 (0.33 - 0.84)	0.04 (0.01 - 0.12)
Gabon (2012)	99.69	7585	0.19 (0.008 - 0.4)	3.02 (2.43 - 3.76)	0.17 (0.08 - 0.33)
Gambia (2013)	99.77	9381	0.04 (0.01 - 0.09)	0.19 (0.1 - 0.34)	0.01 (0.001 - 0.08)
Ghana (2014)	99.97	8730	0.32 (0.2 - 0.52)	0.07 (0.02 - 0.23)	0.03 (0.04 - 0.21)
Guatemala (2015)	99.94	24473	0.01 (0.003 - 0.04)	1.59 (1.4 - 1.82)	0.02 (0.006 - 0.03)
Haiti (2012)	99.84	13429	2.82 (2.34 - 3.39)	1.88 (1.59 - 2.22)	0.36 (0.24 - 0.53)
Honduras (2012)	99.94	21530	0.03 (0.01 - 0.07)	1.79 (1.54 - 2.08)	0.006 (0.002 - 0.02)
India (2016)	100	668563	4.61 (4.48 - 4.73)	0.76 (0.72 - 0.81)	0.05 (0.04 - 0.06)
Indonesia (2012)	99.9	43613	0.31 (0.23 - 0.42)	2.37 (2.13 - 2.62)	0.1 (0.06 - 0.17)
Kenya (2014)	99.98	29130	0.4 (0.32 - 0.5)	0.2 (0.13 - 0.31)	0.01 (0.005 - 0.06)
Kyrgyz Republic (2012)	99.94	7652	0.007 (0.001 - 0.05)	2.88 (2.29 - 3.62)	0.02 (0.002 - 0.14)
Lesotho (2014)	100	6338	7.6 (6.73 - 8.57)	0.31 (0.18 - 0.53)	0.02 (0.006 - 0.09)
Liberia (2013)	99.96	8469	0.5 (0.36 - 0.71)	0.35 (0.22 -0.57)	0.007 (0.001 - 0.06)
Malawi (2016)	100	22688	0.11 (0.07 - 0.18)	0.4 (0.31 - 0.52)	0.19 (0.12 - 0.29)
Mali (2013)	100	9222	0.96 (0.69 - 1.33)	0.15 (0.08 - 0.26)	0.05 (0.01 - 0.17)
Mozambique (2011)	100	12229	0.14 (0.06 - .31)	0.8 (0.61 - 1.04)	0.72 (0.54 - 0.98)
Myanmar (2016)	100	12419	0.17 (0.09 -0.29)	3.63 (3.14 - 4.19)	0.03 (0.009 - 0.09
Namibia (2013)	99.91	8567	0.6 (0.46- 0.78)	4.14 (3.6 - 4.76)	0.24 (0.16 - 0.38)
Nepal (2016)	100	12327	2.68 (2.32 - 3.09)	5.29 (4.76 - 5.88)	0.71 (0.51 - 0.99)
Niger (2012)	99.88	9569	2.49 (1.8 - 3.43)	0.02 (0.003 - 0.13)	0.009 (0.001 - 0.06)
Pakistan (2012)	99.84	12087	2.4 (1.91 - 3)	3.94 (3.19 - 4.84)	0.12 (0.06 - 0.24)
Philippines (2013)	99.97	15464	0.38 (0.25 - 0.57)	5.7 (5.26 - 6.18)	0.18 (0.12 - 0.26)
Rwanda (2015)	99.94	12505	1.11 (0.91 - 1.37)	1.05 (0.85 - 1.29)	0.07 (0.03 - 0.14)
Sierra Leone (2013)	99.79	15197	3.63 (3.08 - 4.27)	4.32 (3.78 - 4.93)	0.39 (0.27 - 0.55
Tajikistan (2012)	99.75	8900	0.04 (0.01 - 0.11)	0.2 (0.1 - 0.38)	0
Tanzania (2016)	100	12131	0.45 (0.32 - 0.62)	0.45 (0.27 - 0.74)	0.02 (0.005 - 0.08)
Timor-Leste (2016)	100	11917	0.14 (0.08 - 0.25)	3.97 (3.4 - 4.63)	0.09 (0.04 - 0.17)
Togo (2014)	99.86	8661	0.57 (0.37 - 0.89)	0.16 (0.07 - 0.33)	0
Uganda (2016)	100	16663	0.55 (0.41 - 0.73)	0.78 (0.64 - 0.96)	0.04 (0.02 - 0.08)
Zambia (2014)	99.9	14969	1.1 (0.86 - 1.41)	0.32 (0.23 - 0.44)	0.14 (0.07 - 0.29)
Total		**1230262**	**0.78 (0.35 - 1.37)**	**1.09 (0.81 - 1.42)**	**0.08 (0.05 - 0.11)**

To better visualise and compare the estimates for smoking and smokeless tobacco use among pregnant and non-pregnant women, I further graphed them in a mirror bar chart, based on countries (*Figure 3.2*). The graph offers the advantage to compare the relative difference in use of tobacco based on pregnancy status. For example, the use of smokeless tobacco in Kenya was higher among pregnant women (0.71%) than non-pregnant women (0.4%), while in Nepal the use is much higher among non-pregnant women (2.68%) compared to pregnant women (0.46%).

Figure 3.2: Mirror bar graph for smoking (blue) and smokeless tobacco use (orange/yellow) comparing estimates for pregnant and non-pregnant women in 42 LMICs

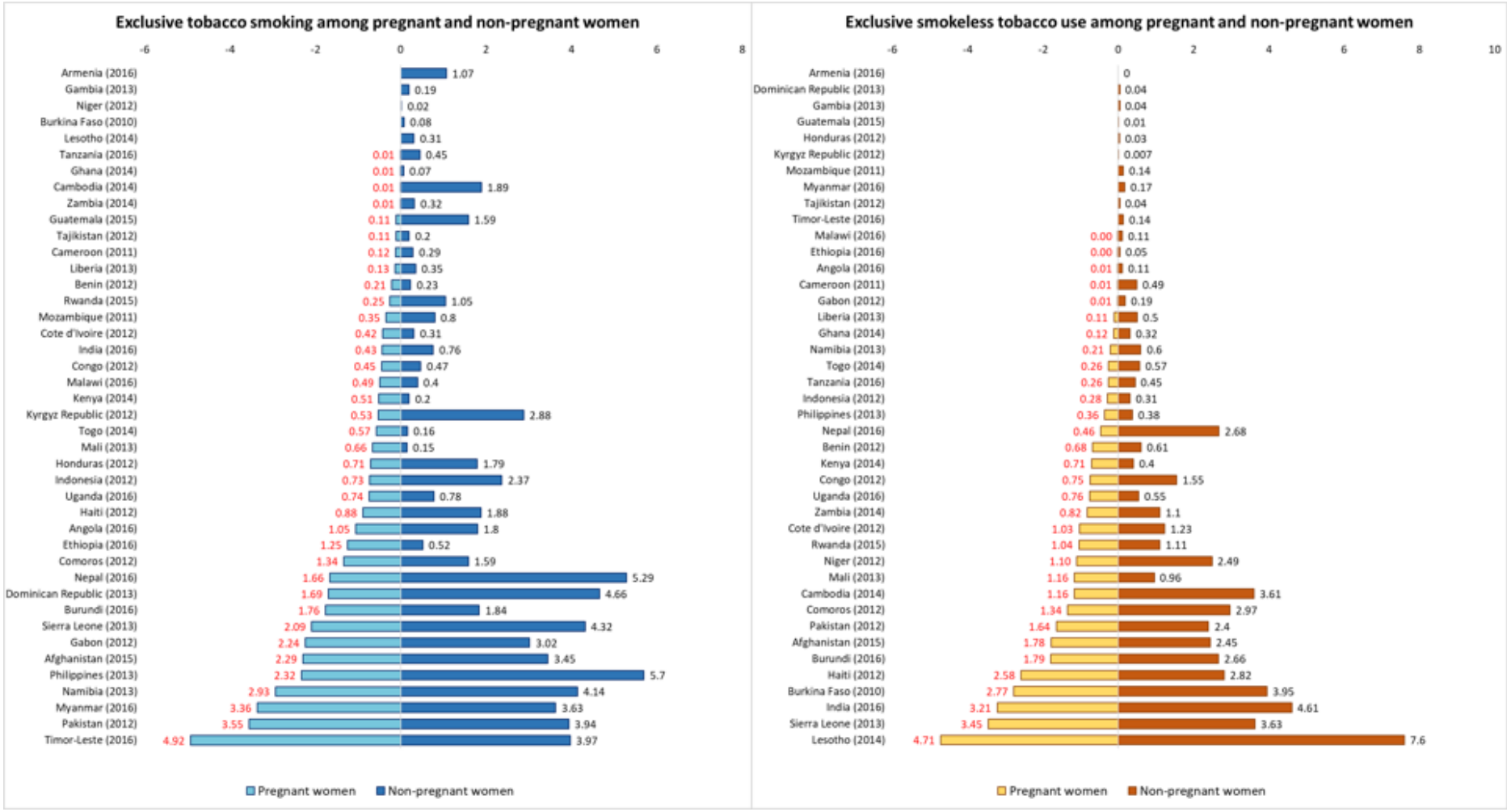
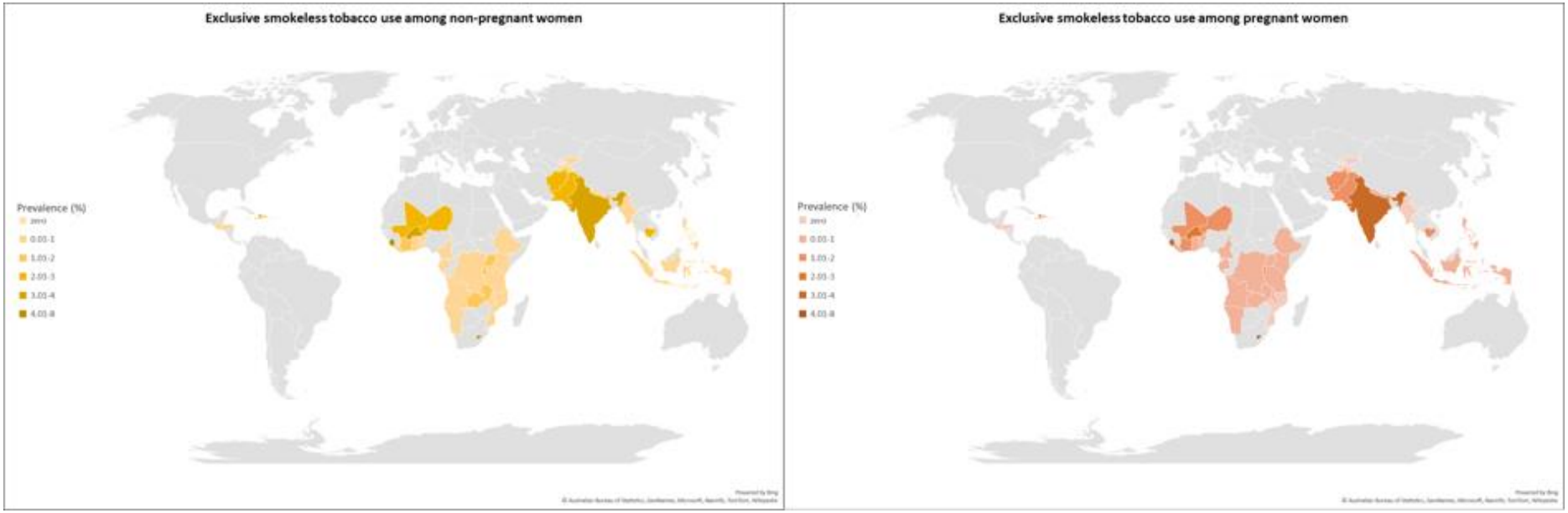


Figure 3.3: World map showing prevalence of exclusive smokeless tobacco use among pregnant (orange) and non-pregnant women (yellow)



Furthermore, I plotted the smokeless tobacco estimates among pregnant and non-pregnant women on the world map (*Figure 3.3*), to gauge the extent of its use based on countries; that is, darker the colour, higher the use of smokeless tobacco.

3.3.2 Logistic regression analysis:

The number of observations in the regression analysis (all eligible women from 42 countries after excluding missing values, which were less than 0.001%) were 1,310,651 (*Table 3.7*). The model accounted for the clustering effect of 42 countries and the overall model was significant with a p-value of less than 0.05 and an R^2 of 0.06.

Table 3.7: Multinomial logistic regression analysis to estimate the RRR for tobacco use

Multinomial logistic regression							
Dependent variable: tobacco use	**RRR**	**P-value**	**95 % CI**				
None		**Base Outcome**					
				Std. Err. Adjusted for 42 clusters			
				Number of observations = 1310651			
				Wald chi2 (30) = 26859.40			
				Prob > chi2 = 0.00			
				Pseudo R2 = 0.0557			
Exclusive smoking							
Pregnant (ref=no)							
Yes	0.85	0.217	0.67-1.09				
Residence (ref=urban)							
Rural	0.56	<0.005	0.44-0.71				
Education (ref=no education)							
Primary	0.87	0.5	0.56-1.32				
Secondary	0.68	0.01	0.51-0.91				
Higher	0.65	0.13	0.37-1.15				
Wealth index (ref=poorest)							
Poorer	0.65	<0.005	0.59-0.71				
Middle	0.47	<0.005	0.39-0.57				
Richer	0.39	<0.005	0.28-0.48				
Richest	0.26	<0.005	0.18-0.39				
Age	1.05	<0.005	1.04-1.06				
Constant	0.009	<0.005	0.006-0.012		**RRR**	**P-value**	**95 % CI**
Exclusive Smokeless				**Dual**			
Pregnant (ref=no)				Pregnant (ref=no)			
Yes	0.81	0.048	0.665-0.998	Yes	1.01	0.94	0.80-1.27
Residence (ref=urban)				Residence (ref=urban)			
Rural	0.89	0.51	0.63-1.25	Rural	0.72	0.02	0.54-0.96
Education (ref=no education)				Education (ref=no education)			
Primary	0.72	0.29	0.39-1.32	Primary	1.11	0.79	0.53-2.29
Secondary	1.07	0.6	0.83-1.39	Secondary	1.14	0.71	0.56-2.32
Higher	0.64	0.03	0.43-0.96	Higher	0.53	0.02	0.31-0.89
Wealth index (ref=poorest)				Wealth index (ref=poorest)			
Poorer	1.01	0.88	0.90-1.13	Poorer	0.73	0.05	0.53-1.0
Middle	0.76	<0.005	0.68-0.85	Middle	0.65	0.07	0.41-1.03
Richer	0.51	<0.005	0.45-0.59	Richer	0.68	0.184	0.38-1.2
Richest	0.24	<0.005	0.19-0.29	Richest	0.39	<0.005	0.24-0.64
Age	1.06	<0.005	1.05-1.07	Age	1.07	<0.005	1.06-1.08
Constant	0.13	<0.005	0.005-0.03	Constant	0.0003	<0.005	0002-0.0005

Pregnant women had a relative risk ratio of 0.85 (95% CI of 0.67 – 1.09) for exclusive smoking, however, the p-value (0.217) and corresponding 95% confidence interval suggest that there was no evidence of a difference in the behaviour of exclusively smoking among those women who were pregnant to those who were not, when compared to no tobacco use. For exclusive smokeless tobacco use, the p-value was 0.048 with a 95% confidence interval

of 0.67 – 1.0. Considering the p-value, it seemed that women who were pregnant were 19% less likely (RRR of 0.81) to use smokeless tobacco compared to women who are not pregnant. However, this requires cautious interpretation, as the upper limit of the 95% confidence interval is just about 1.0 (actual value 0.998).

With respect to the type of residence, women living in rural areas had a lower relative risk of tobacco smoking compared to women living in urban areas (RRR of 0·56, 95% CI of 0·44 - 0·71). However, there was no statistically significant difference in the use of exclusive smokeless tobacco use between women who live in urban and rural areas (RRR of 0·89, 95% CI of 0·63-1·25).

Education, when tested as a variable on its own, was a significant predictor of tobacco use among women when compared to women with no tobacco use. Women with at least secondary education had a statistically significant reduction in exclusive smoking (RRR of 0·68, 95% CI of 0·51 – 0·91) when compared to women with no tobacco use, while women with at least higher education had a statistically significant reduction (RRR of 0·64, 95% CI of 0·43 - 0·96) in smokeless tobacco use and dual tobacco use (RRR of 0.53, 95% CI of 0.31 – 0.89) compared to women with no formal education (p-value 0·03 and 0.02, respectively).

The wealth index was also a significant predictor of tobacco use among women and showed an inverse relationship. The relative risk for smoking reduced from 0·65 (95% CI of 0·59-0·71) in the 2nd quintile (poorer) to 0·26 (95% CI of 0·18-0·39) in the highest quantile (richest) when compared to the reference category of the poorest. Similarly, the relative risk of smokeless tobacco use decreased with every quintile increase in wealth index (RRR of 1.01and 95% CI of 0·9-1·13 in the poorer wealth index to RRR of 0·24 and 95% CI of 0·19-0·29 in the richest wealth index). In terms of dual-use, women in the richest quintile of wealth index had a RRR of 0·39 (95% CI of 0·24-0·64) compared to women in the poorest wealth index quintile.

3.3.3 Sub-group analysis for SEAR

In SEAR countries, during pregnancy the pooled prevalence of smoking was 1·81% (95% CI of 0·61-3·61) and of smokeless tobacco use was 0·45% (95% CI of 0·002-2·29) (Table 3.8), and among non-pregnant women (Table 3.9), the pooled prevalence for smoking was 2.97% (95% CI of 1.3 – 5.29) and for smokeless tobacco use 1.06% (95% CI of 0.01 – 3.86).

Table 3.8: Tobacco use among pregnant women in SEAR

Tobacco use during pregnancy - SEAR					
Country	Response rate %	Response rate n (weighted)	Exclusive smokeless % (95% CI)	Exclusive smoking % (95% CI)	Dual % (95% CI)
India (2016)	100	31123	3.21 (2.94-3.5)	0.43 (0.35-0.52)	0.005 (0.002-0.11)
Indonesia (2012)	99.96	1949	0.28 (0.12-0.65)	0.73 (0.4-1.35)	0
Myanmar (2016)	99.97	465	0	3.36 (1.95-5.73)	0
Nepal (2016)	100	535	0.46 (0.13-1.63)	1.66 (0.68-3.99)	0
Timor-Leste (2016)	100	690	0	4.92 (2.85-8.37)	0
Total		34762	0.45 (0.002 - 2.29)	1.81 (0.61 - 3.61)	0.01 (0.00 - 0.03)

Table 3.9: Tobacco use among non-pregnant women in SEAR

Tobacco use among non-pregnant women -SEAR					
Country	Response rate %	Response rate n (weighted)	Exclusive smokeless % (95% CI)	Exclusive smoking % (95% CI)	Dual % (95% CI)
India (2016)	100	668563	4.61 (4.48 - 4.73)	0.76 (0.72 - 0.81)	0.05 (0.04 - 0.06)
Indonesia (2012)	99.9	43613	0.31 (0.23 - 0.42)	2.37 (2.13 - 2.62)	0.1 (0.06 - 0.17)
Myanmar (2016)	100	12419	0.17 (0.09 -0.29)	3.63 (3.14 - 4.19)	0.03 (0.009 - 0.09
Nepal (2016)	100	12327	2.68 (2.32 - 3.09)	5.29 (4.76 - 5.88)	0.71 (0.51 - 0.99)
Timor-Leste (2016)	100	11917	0.14 (0.08 - 0.25)	3.97 (3.4 - 4.63)	0.09 (0.04 - 0.17)
Total		748839	1.06 (0.01 - 3.86)	2.97 (1.30 - 5.29)	0.14 (0.04 - 0.28)

Table 3.10: Multinomial regression analysis for tobacco use in SEAR

Multinomial logistic regression - SEAR			
Dependent variable: tobacco use	RRR	P-value	95 % CI
None	Base Outcome		
Exclusive smoking			
Pregnant (ref=no)			
Yes	0.88	0.157	0.73-1.05
Residence (ref=urban)			
Rural	0.62	<0.05	0.44-0.87
Education (ref=no education)			
Primary	1.22	0.19	0.9-1.65
Secondary	0.67	<0.005	0.53-0.85
Higher	0.43	<0.005	0.32-0.57
Wealth index (ref=poorest)			
Poorer	0.6	<0.005	0.55-0.65
Middle	0.4	<0.005	0.36-0.45
Richer	0.3	<0.005	0.25-0.37
Richest	0.18	<0.005	0.13-0.25
Age	1.06	<0.005	1.04-1.07
Constant	0.009	<0.005	0.005-0.014
Exclusive Smokeless			
Pregnant (ref=no)			
Yes	1.07	0.01	1.02-1.12
Residence (ref=urban)			
Rural	0.76	0.09	0.55-1.05
Education (ref=no education)			
Primary	1.07	0.82	0.6-1.89
Secondary	0.98	0.92	0.69-1.39
Higher	0.6	0.02	0.39-0.93
Wealth index (ref=poorest)			
Poorer	1.08	0.2	0.96-1.2
Middle	0.81	<0.05	0.67-0.99
Richer	0.55	<0.005	0.41-0.75
Richest	0.28	<0.005	0.18-0.42
Age	1.05	<0.005	1.05-1.06
Constant	0.03	<0.005	0.02-0.04

Regression analysis (*Table 3.10*) which accounted for five countries, had 783,588 observations. Wealth index was a significant predictor for both smoking and smokeless tobacco use; however, higher education was significant smokeless tobacco use. Furthermore, there was no evidence of a statistically significant difference in smoking among pregnant and non-pregnant women (RRR 0·88, 95% CI of 0·73-1·05); in fact, pregnant women were 7% more likely to use smokeless tobacco than non-pregnant women when compared to no tobacco use (RRR 1·07, 95% CI of 1·02-1·12).

3.4 Discussion

In this section, I firstly summarise the study findings, followed by discussion considering relevant literature. I then discuss strengths and limitations of this study and lastly, the implications for policy, practice, and further research.

3.4.1 Summary of findings and discussion with relevant literature

Tobacco smoking: Prevalence of tobacco smoking during pregnancy in LMICs was 0.69% (based on data from 42 LMICs), which is lower than previous estimates by Lange and colleagues (global prevalence based on 147 countries) as 1.7% and by Caleyachetty and colleagues (estimates based on 54 LMICs) as 1.3% (Lange et al., 2018; Caleyachetty et al., 2014). Based on these estimates, it appears that tobacco smoking might have been less prevalent among pregnant women (0.69%) than non-pregnant women (1.09%). However, I found no statistically significant difference in tobacco smoking (RRR = 0.85, 95% CI of 0.67 – 1.09) between pregnant and non-pregnant women even after adjusting for age, type of residence, level of education and wealth index. This is not the case in high-income countries where there is an apparent difference; in the US, the prevalence of smoking dropped from 13.5% (Jamal et al., 2018) in adult women to 7.2% (Drake, Driscoll and Mathews, 2018) during pregnancy in 2016. In Greece, a study reported that 63.4% of pregnant women gave up smoking during pregnancy (Tsakiridis et al., 2018). In LMICs, I found no such difference in the prevalence estimates between pregnant and non-pregnant women. Similarly, it is reported that women who smoke daily and continue to smoke during pregnancy are high in the regions of Africa and Asia, compared to other regions and thus, this could potentially be due to most women not quitting when becoming pregnant in these regions (Siddiqi and Mdege, 2018; Lange et al., 2018). However, given the cross-sectional nature of this study, it cannot be stated

that some women continue to smoke when they are pregnant, as both groups (pregnant and non-pregnant) consisted of different individuals. However, in this study, the difference did become significant in women who were more educated which could be a proxy for heightened awareness of tobacco-related risks to foetus.

Smokeless tobacco: Prevalence of smokeless tobacco during pregnancy in LMICs was 0.56% and that among non-pregnant women was 0.78%. Previously, the reported estimate in LMICs for smokeless tobacco use during pregnancy was 1.3% (95% CI of 0.7 – 2.0) by Caleyachetty and colleagues (2014). However, like tobacco smoking, there was no significant difference (RRR = 0.81, 95% CI of 0.66 – 1.0) in use of smokeless tobacco between pregnant and non-pregnant women. In fact, in SEAR, smokeless tobacco use was more common during pregnancy (RRR = 1.07, 95% CI of 1.02 – 1.12). This may be due to the previous suggestions that some women might start using ST during pregnancy as a relief for morning sickness, to combat bad taste or watery sensation in the mouth (Singh et al., 2013; Begum, Schensul and Nair, 2017; Anwar et al., 2005). However, whether these women started smokeless tobacco use during their course of pregnancy or changed its frequency, cannot be confirmed due to the limitations of DHS questionnaire and further research is warranted to explore this possibility.

Education and combined wealth index were significant predictors of use of tobacco across all three categories of tobacco use when compared to no tobacco use among women. Exclusive smoking was less likely among women with at least secondary education while exclusive smokeless tobacco and dual tobacco use was less likely among women with at least higher education. With respect to the wealth index, an inverse relationship was clearly evident; with every increase in the quintile of wealth index, the RRR of tobacco use decreases for both exclusive smoking and smokeless tobacco use among women. This is consistent with previous literature (Dobe, Sinha and Rahman, 2006; Kakde, Bhopal and Jones, 2012; Gupta et al., 2012; John et al., 2011) which suggests that tobacco use is more prevalent in the low-socioeconomic population and those in women with no formal (Mishra et al., 2015). A reason for pre-dominance among women from less privileged populations besides lack of awareness might be due to the use of smokeless tobacco in suppressing hunger while performing difficult laborious tasks (Gupta et al., 2012); besides smokeless tobacco is generally cheap and its use by women is not stigmatised (Gupta and Ray, 2003; Rahman et al., 2015). Therefore, this study strengthens the evidence as to why tobacco cessation services and awareness need to be targeted to women from low-socioeconomic status.

3.4.2 Strengths and limitations

To the best of my knowledge, this study is the first of its kind providing nationally representative estimates of smoking, smokeless tobacco, and dual use among women in the reproductive age based on a large sample of over 1.3 million from 42 LMICs. This is one of the key strengths of this study. The study provides prevalence estimates for all eligible women in the reproductive age group and for pregnant women. As these estimates are from the same survey data set, they allow comparisons within the country of prevalence rates at that specific time point. In addition to within country comparison, the study offers an added advantage of cross-country comparison due to uniform questionnaires and method of data collection across all countries.

Furthermore, the study is unique as it further quantifies how the use of tobacco varies with pregnancy status, level of education, wealth index, age and residence when compared to women with no tobacco use. In addition to comparing absolute values (prevalence) of tobacco use in various countries, quantifying the estimates for a statistical comparison, offers the advantage of more detailed understanding of the relative use of tobacco accounting for socio-demographic variables, and pregnancy status in particular. This strengthens the evidence and adds to the existing literature on relatively high use of smokeless tobacco during pregnancy in SEAR. This specific analysis not only offers advantage for smokeless tobacco measures but also for tobacco smoking as statistically there appears to be no difference in use among pregnant and non-pregnant women. This is important, as tobacco control in HICs over the years have helped women reduce their tobacco use during pregnancy, however, in LMICs there seems to be a long way to go.

Having said this, the study used data from cross-sectional surveys and as a result only suggests possible sociodemographic predictors and no causation can be elucidated. Furthermore, it cannot be commented upon whether women initiated or stopped their use of tobacco during pregnancy. Another limitation is that all the collected data is self-reported, and no objective measurement of tobacco use was conducted as part of the survey process. Thus, there is a possibility of under-reporting tobacco use estimates. Also, the survey mainly asks women about their extensive reproductive and maternal history, which could potentially cause hesitancy towards accurate tobacco use reporting. This is contradictory to specific tobacco surveys such as the Global Adult Tobacco Survey (GATS) that only aim to collect tobacco use in detail with trained interviewers. For example, the GATS conducted in India in 2016 reported a 2% prevalence of smoking and 12·8% of smokeless tobacco use among women, compared to our estimates of 0·43% and 3·21% respectively (GATS India, 2018). However,

my observations are consistent with results from previously conducted DHS analysis by Caleyachetty and colleagues (Caleyachetty et al., 2014).

An additional limitation not per se of the study but regarding the data was lack of estimates from Bangladesh. This was because, despite regular DHS being conducted in Bangladesh, the section of tobacco history is omitted in the women's questionnaire but is included in the men's questionnaire. The data from Bangladesh would have added value to the study, as the use of smokeless tobacco in the country is relatively high (prevalence of adult smokeless tobacco use is 16.2% among men and 24.8% among women) and about 13.6 million women in the country are current smokeless tobacco users (GATS Bangladesh, 2019). The inclusion of Bangladesh data would have further provided more accurate measures for the sub-group analysis of SEAR. The reason for exclusion of tobacco use in the women's questionnaire is unknown and seems to be a lost opportunity for such valuable data on national level that could help strengthen tobacco control measures in the country.

It is also important to consider the impact of time as the data in this study were collected at different time points. The most recent DHS data from two phases (VI and VII) from each country were included and each DHS phase is conducted over a period of 5 years and the exact time of data collection for each country and within-country varies. That is because of the development of country-specific questionnaires, identification of PSUs and sampling frames, recruitment and training of research staff, depend on individual countries. Hence, the method and questionnaire for each DHS phase are standard but the time of implementation and availability of data of the survey varies. As a result, the data has some variability in terms of the time it was collected in each country (i.e., data from Burkina Faso and India are from phase VII of the DHS but were collected in 2010 and 2012, respectively). This potential difference in the time of data collection could impact the estimates and the pooled prevalence estimate cannot be interpreted as the prevalence at a certain time point. The maximum gap between data is six years and comparing the estimates from this time apart is perhaps not ideal. However, conducting such a large survey in multiple countries with standardized methodology can take time. It would have been ideal if all countries had data from phase VII, but in many countries, the recent data was only available from phase VI. As the aim of this study was to estimate recent prevalence rates of tobacco use among women of reproductive age and compare the estimates based on pregnancy status, it did not seem necessary to exclude any data based on the survey year.

3.4.3 Implications of findings for policy, practice, and future research

3.4.3.1 For policy and practice:

Tobacco use among women in low- and middle-income countries (LMICs) is lower than high income countries (HICs), but this may be because LMICs are earlier in the epidemiological transition of tobacco use. If ignored as a public health issue and the tobacco industry continues to market its products to women, the level of tobacco use may rise as it did in HICs. Also, despite low prevalence rates, almost similar estimates among pregnant and non-pregnant women are concerning as tobacco consumption in any form during pregnancy is associated with poor birth outcomes. This suggests a need for raising awareness about the harms of tobacco use among women in LMICs, especially during pregnancy. There is a need to develop preventive and cessation interventions to decrease tobacco use (smoking and smokeless) among women who are from low socio-economic status and less educated, as they bear the greatest burden of tobacco use. Similar to high-income countries, where many have developed interventions to reduce smoking during pregnancy or offer support to quit during pregnancy (Nichter et al., 2010), may help reduce tobacco use during pregnancy in LMICs. In general, this warrants the need for tailored tobacco cessation advice for pregnant women in LMICs.

3.4.3.2. Further research:

Furthermore, based on the estimates, smokeless tobacco use was more common among pregnant women than non-pregnant women in SEAR. This is an important area where further research needs to focus as the literature suggests women starting smokeless tobacco during pregnancy for multiple reasons and later continuing its use due to addiction (Schensul et al., 2018; Anwar et al., 2005; Nair et al., 2015). Along with a further understanding of smokeless tobacco use in pregnancy, it is also equally important to educate and support women from low socioeconomic status and those with low levels of education. In LMICs, various maternal and child health interventions are delivered through community health workers (CHW) and there is some evidence that the preventive interventions delivered by CHW might be effective (Gilmore and McAuliffe, 2013). Hence, a potential opportunity is to deliver targeted preventive and cessation services through the local CHW as part of routine maternal and child health programmes. This further needs to be investigated in the context of tobacco control interventions aimed during pregnancy and evidence-based interventions need to be developed and assessed for their feasibility prior to implementation.

4) CHAPTER IV: Socio-cultural characteristics, beliefs, and attitudes related to smokeless tobacco use in women in LMICs

This chapter addresses the second aim of the thesis; that is to understand the socio-cultural context and beliefs related to smokeless tobacco use among women from LMICs. I first present a brief rationale, the approach and methodology for this study. I then discuss the study findings with relevant literature, and implications for policy, practice, and future research.

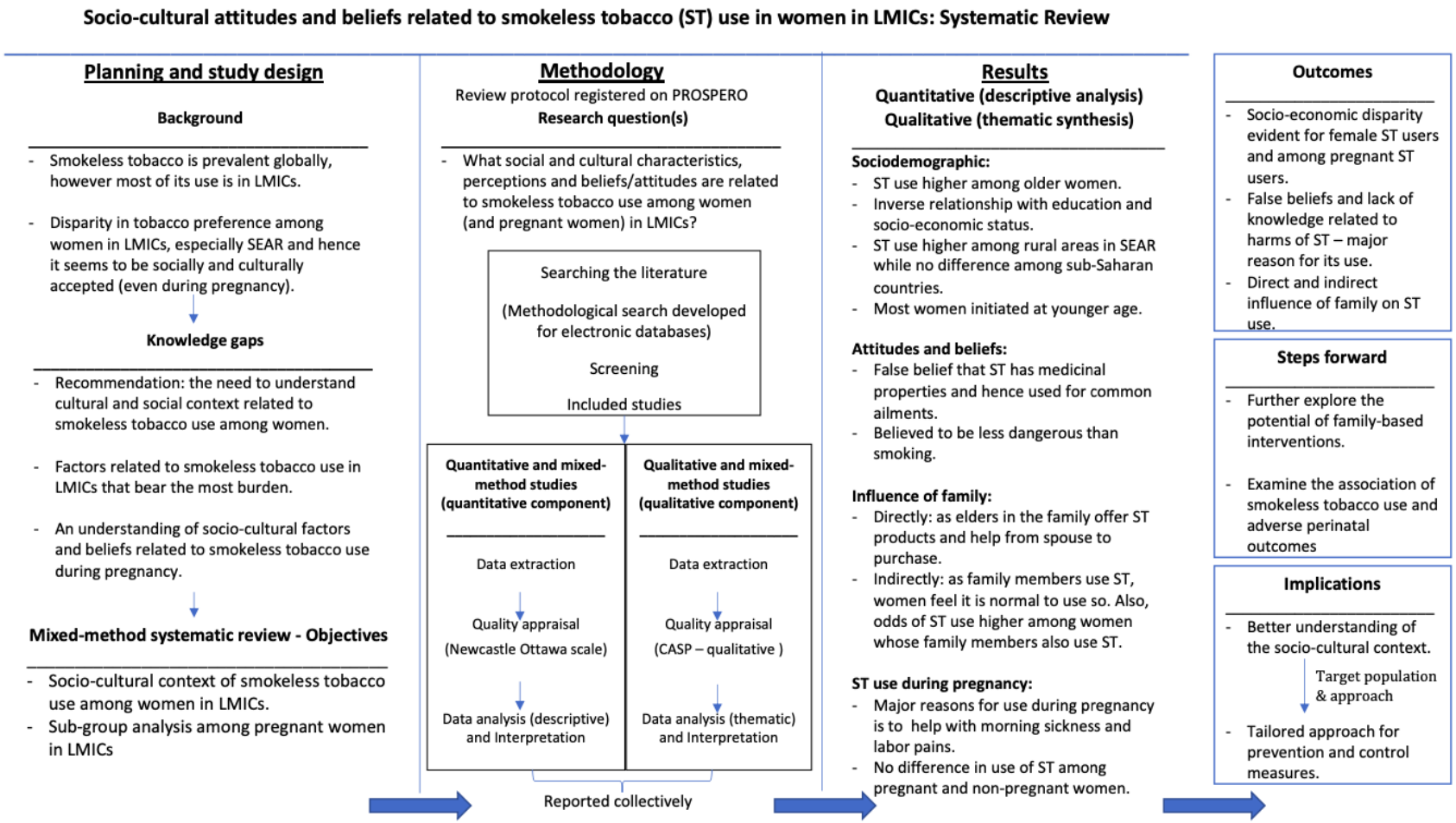
A mixed-method systematic review was conducted, with pre-registered protocol on PROSPERO.[3] A one-page outline/summary of this study is illustrated as a pictograph below (*Figure 4.1*).

The rationale for this study is previously mentioned in Chapter II. Elaborating on that further, here is brief justification for undertaking this review. Kakde and colleagues (2012) explored the social context of smokeless tobacco use among the South-Asian population, however, it restricted its study population to just South-Asians, and there remains a need to understand the social and cultural context of smokeless tobacco use in other LMICs (Kakde, Bhopal and Jones, 2012). Thus, the current study aims to address this knowledge gap and appraise and summarise evidence related to smokeless tobacco use among women and its use during pregnancy; factors of significant concern, especially in developing nations, which bear most of the burden of smokeless tobacco.

The aim of this review was to understand the social and cultural context related to smokeless tobacco use among women. To understand this, I adapted a mixed method review to capture contextual factors both quantitatively and qualitatively. The method offers the advantage of capturing diverse responses related to the same research question and would further provide a more holistic understanding of smokeless tobacco use among women (Tashakkori and Newman 2010). Thus, a mixed method review of observational and qualitative studies was conducted to answer the following questions. Both research questions were explored quantitatively and qualitatively.

[3] International prospective register of systematic reviews

Figure 4.1: Study outline for socio-cultural context related to smokeless tobacco use among in LMICs



1. What social and cultural characteristics are related to smokeless tobacco use among women in LMICs?
2. What perceptions and beliefs/attitudes regarding women's use of smokeless tobacco are prevalent in LMICs? This included perceptions of women themselves (smokeless tobacco users and non-users) and of others (e.g., spouse, family, community members) related to smokeless tobacco use among women.

Furthermore, a subgroup descriptive analysis of both research questions (that is for both quantitative and qualitative studies) in context of the use of smokeless tobacco during pregnancy was also conducted. This allowed a better understanding of characteristics related to its use among women, and whether these were different between women who are pregnant. An additional analysis for pregnant women seemed important due to several reasons mentioned in earlier chapter (1.2.2) such as women initiating smokeless tobacco use to combat various pregnancy related symptoms etc.

4.1 Methodology:

The review was conducted systematically, and the protocol was registered on PROSPERO (PROSPERO 2019 - CRD 4201912506). A methodology overview is outlined in the flow chart (*Figure 4.2*) below, later followed by detailed sections and steps of the review. Also, Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) reporting guidelines, that are specific to systematic reviews were used to write this review (Moher et al., 2010).

4.1.1 Review Questions:

Primary questions:

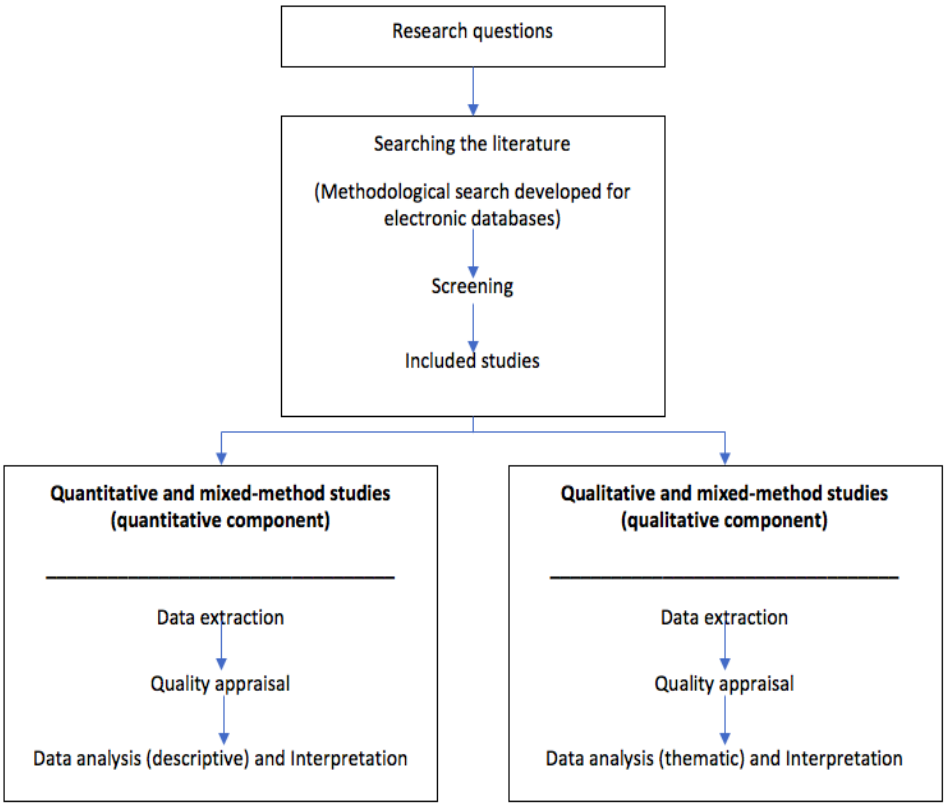
1. What social and cultural characteristics are related to smokeless tobacco use among women in LMICs?
2. What perceptions and beliefs/attitudes are related to smokeless tobacco use among women in LMICs?

Secondary questions:

3. What social and cultural characteristics are related to smokeless tobacco use among pregnant women in LMICs?

4. What perceptions and beliefs/attitudes are related to smokeless tobacco use among pregnant women in LMICs?

Figure 4.2: Methodology overview of the mixed-method systematic review



4.1.2 Search strategy:

The following databases were searched: MEDLINE/PubMed, CINAHL, Cochrane, EMBASE, Web of Science, PsycINFO, Google Scholar and DoPHER (Database of Promoting Health Effectiveness Reviews). Reference and citation searches of the identified studies were performed to find additional relevant studies. In addition to searching the Conference Proceedings Citation Index database, the Society for Research on Nicotine and Tobacco website was also screened for grey literature. The search included studies published up to February 2019 without any language restrictions (the review protocol mentioned about including the non-English language studies in the search and later to exclude them from the review due to the challenges of language translation and limited resources). It would have been ideal to include studies without any language restriction in the review, however, inclusion in the search would have at least identified these studies.

Search terms/pattern: Search terms for smokeless tobacco, social and cultural characteristics were developed from a previous review (Kakde, Bhopal and Jones, 2012), Medical Subject Headings (MeSH) and free text terms. The search was developed on MEDLINE and tested against (to ensure that the search identified) three sample papers (Nair et al., 2015; Tiwari et al., 2015; Shahjahan et al., 2017) prior to using it for other databases. The search tree used for this review is available as *Appendix 4.1*.

4.1.3 Studies included:

All observational studies (cross-sectional, cohort and case-control studies) that reported social and cultural characteristics/factors and all qualitative studies that reported perceptions and attitudes of smokeless tobacco use in women from LMICs were included. The review also included mixed method studies and both the quantitative and qualitative components of those studies were considered. Studies that reported socio-cultural factors related to smokeless tobacco use among both men and women, were included and only the characteristics related to women use were considered in the review (studies where it was not possible to extract data and characteristics related to women were excluded from the review).

Also, studies that performed data analysis on nationally representative survey datasets (e.g., DHS, GATS) were included. However, if multiple studies were identified with analysis from the exact same survey dataset, then only the most appropriate study was included in the review to avoid sample duplication. The selection of this survey-based study was guided by the following:

- Sample size (study with larger and representative sample)
- Confounding factors: the study that accounted for the most relevant confounding variables.
- The study that relatively addressed/described more characteristics or related factors.
- Relatively recent study or an updated version of an old study.

Randomized controlled trials (RCTs) were not included in the review, as the aim of the review was to report characteristics of smokeless tobacco use among women in LMICs and not intervention outcomes.

Quantitative component: As the review was based on observational studies, there was no control/comparator group as such. However, to report characteristics or associated factors, comparison was made with women who do not use smokeless tobacco in LMICs. Furthermore, if studies reported associations with different frequencies of smokeless tobacco use, the comparison was still made with women who do not use smokeless tobacco, in addition to frequency of smokeless tobacco use (i.e., comparison of no smokeless tobacco use vs occasional use vs daily smokeless tobacco use, etc).

Inclusion: Women aged 18 and above from LMICs, who at any point (current users or ex-users) have used any form of smokeless tobacco. Women who are or have been dual tobacco users were included. The reason for the age restriction was because the characteristics or factors in adolescent females may differ compared to adult women. The aim of this review was to understand factors that are possibly related to the adult women population, especially those of reproductive age and therefore, for the purpose of this review, a specific age group was defined. ** Furthermore, the selection criteria may have been too broad if all these were included and wouldn't have been feasible within the scope of this review.

Exclusion: Women who use other forms of tobacco and have never used smokeless forms of tobacco, women from HICs[4], and those below the age of 18.

Qualitative component: narratives by; women who are smokeless tobacco users, family members of women who currently use smokeless tobacco or have used it in the past, community members, women who have not used smokeless tobacco, health care professionals and other relevant individuals who may be able to contribute to perception and beliefs/attitudes regarding smokeless tobacco use among women and during pregnancy in LMICs were considered. To understand the beliefs, and especially the social norms related to smokeless tobacco use among women, it was important to capture the narratives of others in

[4] High income countries as per World Bank list of analytical classification of economies

** A change to age restriction was made at the time of initially screening the search studies, as many studies included women between the ages of 15-49 years (reproductive years). Hence, studies that reported took in account women of reproductive age were included and those studies just focusing on adolescent use were excluded. This change was adapted to avoid losing rich data from survey analysis as most surveys (example: DHS and GATS) include women of reproductive age collectively.

addition to women themselves. This offered the advantage of understanding the holistic socio-cultural environment surrounding and influencing smokeless tobacco use among women.

4.1.4 Exposure(s):

Quantitative component:

Inclusion: The review included studies that measured any social and/or cultural characteristics related to smokeless tobacco use among women in LMICs. This included studies that reported characteristics with other forms of tobacco use among women in addition to smokeless tobacco but only factors related to smokeless tobacco were considered for the review. That is only inclusion of studies where analysis for smokeless tobacco was conducted separately. If characteristics for all forms of tobacco were reported together and associations for smokeless tobacco were not reported separately, then the study was excluded. The following categories were referred to for measurement of these factors:

- Social context refers to the environment an individual is surrounded by and personal traits that identify that individual, such as age, education, workplace, income etc (Green, 2010). For the purpose of this review, the following were considered[5];

    - Socio-demographic factors: Age, marital status, education, income, residential area/environment, socio-economic status, social norms and social acceptability.

    - Cultural factors: Customs, rituals, beliefs, perceptions, cultural norms and acceptability.

Exclusion: Factors related to smokeless tobacco use among women other than social and cultural context, those associated with exclusive use of other forms of tobacco (e.g., tobacco smoking, second-hand smoke and use of e-cigarettes) and/ or those from HICs were excluded.

Qualitative component: For the qualitative component, narratives reflecting perceptions, attitudes and beliefs regarding smokeless tobacco use among women in LMICs were included.

[5] These terms are compiled using the Kakde et.al (2012) review, World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC).

This included narratives by women themselves (whether smokeless tobacco users or not) and those by others as well (families, community members, health care professionals etc.).

4.1.5 Outcome(s):

Quantitative component: The data presented in the papers must in some way help to explain the potential characteristics/factors related to smokeless tobacco use among women. The outcome is use of smokeless tobacco among women in LMICs. Thus, the characteristics or associated factors were assessed in terms of those related to use versus non-use of smokeless tobacco women in LMICs. This included factors/variables measured among user vs non-user and/or against frequency of use. With respect to pregnant women, the outcome was the same and was assessed with use versus non-use of smokeless tobacco.

Qualitative component: The outcome was similar to the quantitative component. The only difference was the method by which socio-cultural context (perception and beliefs, rather than quantitative measurement of characteristics) were explained in relation to outcome (use of smokeless tobacco among women in LMICs).

4.1.6 Data extraction:

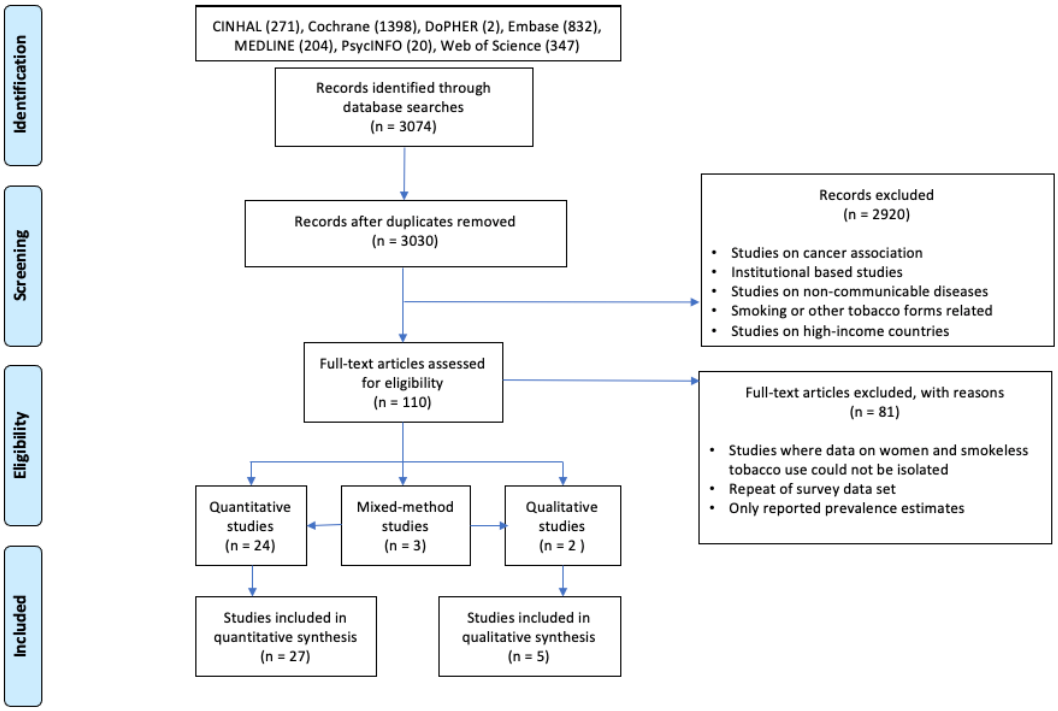
Two reviewers (Zainab Kidwai was the second reviewer) independently screened titles and abstracts from identified searches. Abstracts that met the inclusion criteria were eligible for full paper screening against the inclusion criteria. Guidelines from the PRISMA were followed and a flow diagram (*Figure 4.3*) is constructed below to illustrate the study selection process (Moher et al., 2010).

> Quantitative: The characteristics of the studies were described and reported in tables. Summary statistics and regression analysis results (i.e., comparison of tobacco users vs non-users) were tabulated for each study included. It was pre-decided in the protocol that no statistical analysis will be conducted, and the results will be reported in a descriptive format. As the review objectives were to capture socio-cultural characteristics, attitudes and beliefs, the results would be better reported in form of summaries with appropriate justifications rather than any form of statistical analysis. Furthermore, the inclusion criteria for the review were too broad and hence statistical analysis would not have been feasible given the heterogeneity within studies.

Qualitative: Each qualitative study was independently coded and organized in emerging themes. Data was organized in an excel spreadsheet based on themes and narratives aligned with textual summaries.

The data extraction was done for both quantitative and qualitative studies in one data extraction form (*Appendix 4.2*) and additionally the qualitative studies were separately coded and organised in an excel spreadsheet. These were then arranged collectively (quantitative and qualitative data) based on similar socio-cultural characteristics.

Figure 4.3: PRISMA Flow Chart, search end date = 26-08-2019



4.1.7 Quality assessment:

A key component of a systematic review is quality check for all studies potentially to be included and its critique to provide quality estimates. For this review, quality assessment was performed to understand the strength of the evidence the review would report, however, no studies were excluded based on their quality. This was because, it was pre-decided that the review would be descriptive and including all possible literature seemed important to capture the socio-cultural context in this less researched area.

Quantitative component: Risk of bias for included studies with a quantitative component were assessed using the Newcastle-Ottawa[6] Scale for non-randomized studies (Wells et al., 2014). As the review included observational studies, this tool seemed most appropriate for quality appraisal. The tool is designed to appraise the methodological quality of primary studies to be included in the review. The tool has distinct checklists for cohort and case-control studies, including manuals for both, for guidance. The tool *per se* does not have a specific checklist for cross-sectional studies, however in the literature, the cohort checklist has often been adapted for cross-sectional studies. One such study that has successfully adapted the tool is Herzog et al. (2013) and thus, for this review, a similar approach was followed (Herzog et al., 2013). The adapted NOS tool for cross-sectional studies for this specific review is attached in the supplementary documents (*Appendix 4.3*).

Qualitative component: Quality appraisal of the studies included in the review with a qualitative component or pure qualitative studies, as conducted using the CASP[7] (Critical Appraisal Skills Programme, 2018) tool. The tool is designed to appraise qualitative studies and has previously been used in many reviews. It is a 10-question checklist that addresses three broad domains; Are the results of the study valid? What are the results? Will the results help locally? The tool does not have a scoring system and is rather used to make sense of the qualitative studies. Hence, if the study made sense and the results drawn from it seem valid, then the study was considered appropriate.

4.2 Analysis:

A total of 110 studies were eligible for full paper reads and 29 of these were included in the review for analysis; 24 of these were quantitative, two qualitative and three mixed-method studies. The quantitative component was analysed using descriptive analysis as mentioned in the review protocol. These included frequencies, proportions of individuals with certain beliefs or attitudes and odds ratios of smokeless tobacco use for various socio-cultural factors. The reporting was done in table format which mentions the characteristics of each study and what variables were analysed and the summary statistics and/or the regression analysis results. These later have been summarized individually based on various socio-cultural characteristics in textual format.

[6] Quality appraisal tool, along with its versions included in *Appendix 4.3*.

[7] CASP checklist provided in *Appendix 4.3*.

The qualitative studies have been analysed using thematic synthesis (Green and Thorogood, 2018; Thomas and Harden, 2008). The synthesis has three stages, which is basically coding of findings from primary qualitative studies and constructing themes: The three stages of thematic synthesis are mentioned below:

1. Coding text: All the individual studies were read to familiarise with the content and simultaneously rough notes were made on the side.
2. Developing themes: Emerging themes related to smokeless tobacco use among women from the studies either from the verbatim quotes provided or the interpretation were identified and later coded based on these themes. All the codes and themes were then organized manually on paper and later charted in the Microsoft Excel spreadsheet. This also included summarizing the studies included and their interpretation
3. Generating analytical themes: Data from each study was charted in the matrix and interpreted to understand perceptions, attitudes and beliefs regarding smokeless tobacco use among women in LMICs. Reporting of the data was done as theme summaries and verbatim quotes from individual studies for interpretation.

This is a descriptive review, and thus once the data was extracted and reported in a table format (for individual studies), the results were reported for both the quantitative and qualitative data together to summarise various characteristics of socio-cultural context related to smokeless tobacco use among women in form of narrative synthesis and textual summaries. The themes that emerged from the qualitative evidence synthesis and additional socio-cultural characteristics from the quantitative data were very similar and hence a decision was made to report them collectively (with a clear distinction of which part of the results are derived from the quantitative and which from the qualitative) to make understanding of the context.

4.2.1 Quality of evidence:

All the quantitative studies in the review were cross-sectional while the qualitative studies were a mix of in-depth interviews and focus group discussions. As this review is descriptive and need not require any meta-analysis, the cross-sectional nature of the studies included were acceptable. Further, the qualitative studies explored the cultural context of smokeless tobacco use among women and captured various perceptions related to its use (health care professionals, smokeless tobacco users, non-users, men, and women). Therefore, most studies

in this review were satisfactory to good (based on NOS scale adapted for cross-section studies) and the qualitative studies were appropriate (CASP tool for qualitative studies). Those that were satisfactory (scoring 5-6 based on NOS tool adapted for cross-sectional studies) were mainly due to not accounting for confounders in the analysis. However, these studies reported perceptions, beliefs and knowledge related to smokeless tobacco use, and hence only reported descriptive summary statistics (Murthy et al., 2018; Tiwari et al., 2015; Gupta, 1996; Petersen et al., 2018).

However, a lot of the quantitative studies that were screened for this review, were not included merely because either the data for smokeless tobacco or the data for women was not analysed separately (studies analysed all tobacco products for all adults together and reported the socio-cultural characteristics).

4.3 Results:

There were a total of twenty-nine studies in the review (*Table 4.2*). These were from Cambodia, India, Nepal, Bangladesh, Ethiopia, Madagascar and three studies that analysed surveys from various countries (*Table 4.1*). All the quantitative studies were cross-sectional surveys while the qualitative studies were a combination of in-depth interviews and focus group discussions. Details of the studies included in the review and results that were analysed are reported in a table format that is organized alphabetically by the first author and colour coded (legend provided) to differentiate between quantitative, qualitative, and mixed-method studies are provided in the *Appendix 4.4*.

Table 4.1: Summary of studies based on regions/countries

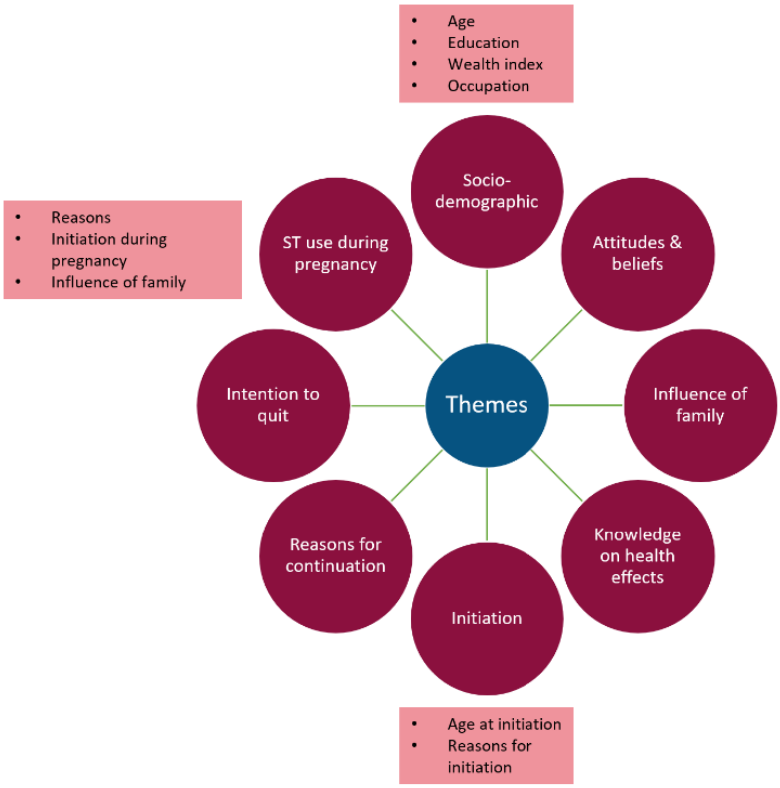
Region	Country	Studies
SEAR	Bangladesh	4
	Cambodia	2
	India	14
	Nepal	3
Africa	Ethiopia	2
	Madagascar	1
Multiple countires		3

4.3.1 Summary of findings

In this section, I first mention the themes that emerged from the analysis in this review and then summarise the findings, which are then described in detail theme-wise in the following sections.

Seven themes emerged from the qualitative evidence synthesis and an additional theme/domain of socio-cultural characteristics from the quantitative data. These are displayed in figure 4.4. This perhaps is not an ideal way of reporting results for a mixed-method review, however, it seemed appropriate to report the quantitative and qualitative findings together for better understanding with a clear distinction of results derived from the quantitative and qualitative analysis.

Figure 4.4: Themes that emerged in the review



Summary of findings from each theme is mentioned below:

- The sociodemographic findings related to smokeless tobacco use among women in LMICs, suggested an increase in smokeless tobacco use with an increase in age and inverse relationship with education and socioeconomic status. Smokeless tobacco use was higher among women living in rural areas and those involved in agricultural or tobacco farming.
- Attitudes and beliefs: In various studies, smokeless tobacco was believed to be natural and used as a remedy for common discomforts such as headaches, toothache, and

stomachache. There was also a belief that the use of smokeless tobacco is normal as many women use it in the community.

- Influence of family: There was a direct and indirect influence of family noted across many studies. That is the common use within the family influenced women to use smokeless tobacco and some studies also reported the direct offering of smokeless tobacco or suggesting its use by family members.
- Knowledge of health effects: The misconception that smokeless tobacco has medicinal properties and that it does not cause any harm was evident in several studies. As mentioned earlier, smokeless tobacco use often used by women to treat common ailments.
- Reasons for use: The common reasons for initiation of smokeless tobacco were experimental, influence of family, for pleasure, to aid with common discomforts and during pregnancy to alleviate morning sickness. Similar reasons were reported for the continuation of smokeless tobacco.
- Smokeless tobacco use during pregnancy: The major reasons for use during pregnancy were to relieve morning sickness, labour pains, body ache, and to strengthen teeth. The influence of family on the use of smokeless tobacco during pregnancy varied; that is some reported families suggesting the use of smokeless tobacco during pregnancy and some suggested against it.

This is just a brief overview of the findings and detailed results, including quotes from the qualitative evidence synthesis are described based on themes in the following sections.

Table 4.2: Characteristics of the studies included in the review

Studies included in the review						
	Authors	**Study type**	**Region/Country**	**Quality**	**Study population**	**Sample size**
1	Azam M et al (2016)	Cross-sectional	Bangladesh	Good (7)	Men and women 15 years and above	230 women
2	Begum S et al (2015)	Mixed-method	India	Satisfactory (6) CASP = appropriate	Married women between the ages of 18 and 40	409 women
3	Bhan N et al (2012)	Cross-sectional	India	Good (7)	Men and women (15-49 years)	255028 women over two survey rounds
4	Bista B et al (2015)	Cross-sectional	Nepal	Good (7)	Women (15-69 years)	2797 women
5	Etu E et al (2018)	Mixed-method	Ethiopia	Good (7) CASP = appropriate	Men and women above 18 years	220 women
6	Gupta B et al (2014)	Cross-sectional survey (GATS)	Multiple countries (11)	Good (7)	Adults aged 15 and above	Individual country samples
7	Gupta PC (1996)	Cross-sectional	India	Satisfactory (5)	Men and women 35 years and above	59527 women
8	Hossain M et al (2014)	Cross-sectional	Bangladesh	Good (7)	Married women aged 18 years and above with at least one pregnancy in their lifetime	8074 women
9	Hossain M et al (2016)	Cross-sectional	Bangladesh	Good (7)	Married women aged 18 years and above with at least one pregnancy in their lifetime.	8074 women
10	Mamudu H et al (2013)	Cross-sectional survey (DHS)	Madagascar	Good (7)	Women aged 15-49 years	17375 women
11	Mathew S at al (2016)	Cross-sectional	India	Satisfactory (6)	Married women (20-50 years)	800 women
12	Mishra G et al (2015)	Cross-sectional	India	Satisfactory (6)	Women tobacco users	
13	Murthy P et al (2018)	Mixed-method	India	Satisfactory (5) CASP = Appropriate	58 key informants (37 smokeless tobacco users and 21 health care providers)	58 key informants
14	Nair S et al (2015)	Qualitative	India	CASP = Appropriate	Married women of reproductive age (18 to 40).	409 women (62 pregnant)
15	Petersen A et al (2018)	Cross-sectional	Ethiopia	Satisfactory (5)	Women 18-55 years	353 women
16	Prabhakar B et al (2012)	Cross-sectional survey (GATS)	India	Good (7)	Men and women aged 15 years and above	35345 women
17	Ray C S et al (2016)	Cross-sectional	India	Good (7)	Men and women aged 15 years and above	4244 women
18	Schensul, J. et al (2018)	Cross-sectional	India	Good (7)	Women aged between 18-40, married and using at least one type of smokeless tobacco.	409 women (62 pregnant)
19	Shahjahan et.al (2017)	Qualitative	Bangladesh	CASP = Appropriate	Respondents were school teachers, community leaders, women representatives and shop owners.	33 informants
20	Shrestha, N et.al (2019)	Cross-sectional survey (DHS)	Nepal	Good (7)	Women aged 15-49 years	12864 women
21	Singh, A et. al (2014)	Cross-sectional survey (GATS)	India	Good (7)	Adults aged 15 and above	35529 women
22	Singh, J et. al (2017)	Cross-sectional survey	Nepal	Good (8)	Pregnant women (13-28 weeks)	426 pregnant women
23	Singh, P et. al (2009)	Cross-sectional survey	Cambodia	Good (7)	Adults aged 18 and over	7858 women
24	Singh, S et. al (2015)	Cross-sectional survey	India	Good (7)	Women aged 18 and above who had given birth between June 2011 - June 2012	400 women
25	Soorensen et.al (2005)	Cross-sectional survey	India	Good (7)	Adults aged 35 and over	59527 women
26	Sreeramreddy et.al (2014)	Cross-sectional survey (DHS)	Multiple countries (8)	Good (7)	Women aged 15-49 years	248840 women
27	Sreeramreddy et.al (2014)	Cross-sectional survey (DHS)	Sub-saharan African countries (30)	Good (7)	Women aged 15-49 years	354927 women
28	Tiwari, R et.al (2015)	Cross-sectional survey	India	Satisfactory (5)	Women between the age of 18-25 years.	2000 women
29	Tonstad, S et.al (2013)	Cross-sectional survey	Cambodia	Good (7)	Adults aged 18 and over	1188 women

4.3.2 Socio-demographic characteristics of smokeless tobacco users:

In this section, I report summaries of the socio-demographic characteristics of smokeless tobacco use, from the quantitative studies.

Age: Seven studies compared age and smokeless tobacco (Table 4.3); all of which reported that use of smokeless tobacco was more prevalent among higher age groups (Singh et al., 2009; Sreeramareddy et al., 2014; Singh, Mini and Thankappan, 2015; Singh et al., 2017; Singh and Ladusingh, 2014; Shrestha et al., 2019). In Bangladesh, the odds of using smokeless tobacco among women aged 45 years and above was nearly 20 times higher (AOR = 19.7 and 95% CI of 14.2-27.2) than those below the age of 24 years (Hossain et al., 2014), in Nepal, the odds of smokeless tobacco use were nearly 12 times (AOR = 11.9 and 95% CI of 5.7-24.9) higher among women between the age of 45-49 years compared to those between the age of 15-19 years (Shrestha et al., 2019), in Cambodia the odds are 50 times higher (OR = 51.1 and 95% CI of 29.8-88.9) among women who are 48 years and above compared to below the age of 25 years (Singh et al., 2009).

Education and Wealth Index: A gradient of inverse relationship across different levels of education and use of smokeless tobacco was seen in several studies (Table 4.4.), i.e., as education level increases, the odds of smokeless tobacco use decreases (Bista et al., 2015; Hossain et al., 2014, 2016; Mishra et al., 2015; Shrestha et al., 2019; Singh et al., 2017; Sreeramareddy, Pradhan and Sin, 2014). In India, compared to postgraduate women, the odds of smokeless tobacco use were about 4 times (AOR = 3.85 and 95% CI of 3.27-4.53 and RRR = 4.41 and 95% CI of 3.38-5.76) higher among women with no education (Bhan et al., 2012; Singh and Ladusingh, 2014), about 8 times (AOR = 8.33, 95% CI of 6.83-10.16) (Prabhakar, Narake and Pednekar, 2012) and as high as 21 times (AOR = 21.02 and 95% CI of 16.6-26.56) (Sorensen, Gupta and Pednekar, 2005).

Several studies also reported comparison of smokeless tobacco use with wealth index (Sreeramareddy et al., 2014; Singh, Mini and Thankappan, 2015; Singh and Ladusingh, 2014; Shrestha et al., 2019; Bhan et al., 2012). All of which reported an inverse relationship; as wealth quintile increased, the odds of smokeless tobacco use decreased (Table 4.5).

Table 4.3: Quantitative findings reporting the OR of ST use and age based on studies included in the review

Age and ST use					
	OR	95% CI		OR	95% CI
Hossain M et al, 2014			**Singh J et al, 2017**		
N= 8074 women			**N= 426 pregnant women**		
reference <24years			reference <20 years		
25-44	3.08	(2.26-4.2)	20-34	4.2	(1.3-14.2)
>45	19.7	(14.2-27.2)	35-45	1.66	(0.6-4.9)
Shrestha N et al, 2019			**Singh P et al, 2009**		
N= 12864 women			**N= 7858 women**		
reference = 15-19 years			reference=18-25 years		
20-24	2.38	(1.19-4.76)	26-36	5.7	(3.4-9.7)
25-29	5.17	(2.55-10.48)	37-48	15.8	(9.1-27.3)
30-34	7.28	(3.58-14.81)	>48	51.5	(29.8-88.9)
			Singh S et al, 2015		
35-39	10.79	(5.54-21.03)	**N= 400 women**		
40-44	11.78	(5.76-24.08)	reference is age <25		
45-49	11.86	(5.66-24.86)	>25 years	8.2	(2.48-27.15)
Singh A et al, 2014			**Sreeramareddy et al, 2014**		
N= 35529 women			**N= 354927 women (30 countries)**		
reference = 15-24 years			reference = 15-19 years		
25-44	1.94	(1.66-2.26)	20-29	1.98	(1.82-2.15)
45-64	3.44	(2.91-4.06)	30-39	4.08	(3.7-4.49)
>65	4.47	(3.67-5.45)	40-49	8.37	(6.7-10.4)

Table 4.4: Quantitative findings reporting the OR of ST use and education based on studies included in the review

Education (Odds of ST use)					
	OR	95% CI		OR	95% CI
Bista B et al, 2015			**Sreeramareddy et al, 2014**		
N= 2797 women			**N = 354927 women (30 countries)**		
Education (reference = no formal education):			Education (reference = higher)		
Primary	0.5	(0.3-0.9)	no education	10.6	(6.6-17.2)
Secondary	0.5	(0.2-1.2)	primary	2.97	(2.56-3.46)
higher	0.1	(0.0-0.3)	Secondary	1.49	(1.36-1.64)
Hossain M et al, 2014			**Prabhakar B et al, 2012**		
N= 8074 women			**N = 35345 women**		
Education (reference = no formal education)			Education (reference post grad completed)		
Primary	0.42	(0.32-0.55)	illiterate	8.33	(6.83 - 10.16)
Secondary	0.39	(0.19-0.78)	primary	7.19	(5.88 - 8.79)
higher	1.16	(0.9-1.3)	secondary	4.36	(3.57 - 5.34)
			higher secondary	2.49	(1.96 - 3.18)
Mishra G et al, 2015			**Soorensen et al, 2005**		
Women tobacco users			**N= 59527 women**		
Education (reference = illiterate)			Education (compared to women with college education)		
literate without formal education	0.6	(0.5-0.8)	Illiterate	21.02	(16.63-26.56)
School	0.53	(0.4-0.58)	Primary education	9.18	(7.27-11.6)
high school/undergraduates	0.2	(0.1-0.25)	middle	5.5	(4.34-6.97)
			secondary	2.7	(2.1-3.48)
Shrestha N et al, 2019			**Bhan N et al, 2012**		
N= 12864 women			**N=255028 women over two survey rounds**		
Education level (reference = no education)			Education (reference = postgraduate)		
Primary	0.94	(0.75-1.19)	no education	3.85	(3.27-4.53)
Secondary	0.39	(0.26-0.6)	primary education	2.87	(2.44-3.4)
higher	0.14	(0.05-0.39)	high-school education	2.19	(1.86-2.57)
			College educated	1.84	(1.55-2.19)
Singh J et al, 2017					
N= 426 pregnant women					
Education (reference is higher education)					
Not educated	9.6	(2.5-32.7)			
Primary	4.5	(1.1-17.1)			
Secondary	2.6	(0.8-7.6)			

Table 4.5: Quantitative findings reporting the OR of ST use and wealth index based on studies included in the review

Wealth and ST use		
	OR	95% CI
Sreeramareddy et al,2014		
N = 354927 women (30 countries)		
Wealth index (reference = richest)		
Richer	1.3	(1.2-1.4)
middle	1.4	(1.3-1.6)
poorer	2.05	(1.7-2.3)
poorest	3.3	(2.7-4.1)
Singh A et al, 2014		
N = 35529 women		
Wealth (reference = rich)		
moderate	1.68	(1.42-1.97)
poor	2.04	(1.71-2.42)
Shrestha N et al, 2019		
N = 12864 women		
Wealth Index (reference = poorest)		
poorer	0.83	(0.58-1.19)
middle	0.54	(0.43-0.85)
richer	0.41	(0.22-0.77)
richest	0.32	(0.18-0.59)
Bhan N et al, 2012		
N = 255028 women over two survey rounds		
Wealth quintiles (reference = richest)		
Richer	1.48	(1.41-1.56)
middle	1.75	(1.66-1.85)
poorer	2.14	(2.02-2.27)
poorest	2.67	(2.5-2.84)

Area of residence: Sreeramareddy et al. (2014) based on secondary analysis of the DHS data, reported that smokeless tobacco use is higher among rural women in India, Pakistan, Nepal, and Cambodia (Sreeramareddy et al., 2014). Tiwari et al. (2015) also reported that 77.4% of smokeless tobacco users were rural dwellers. Bista et al (2015) reported that urban dwellers were 30% less likely to use smokeless tobacco (AOR = 0.7 and 95% CI of 0.2-0.9) compared to rural dwellers in Nepal (Bista et al., 2015). However, in Madagascar, there was no difference in smokeless tobacco use among women living in rural or urban areas (AOR = 1.0 and 95% CI of 0.7-1.3) (Mamudu et al., 2013). Furthermore, a study from Nepal (Shrestha et al., 2019) and from 30 sub-Saharan African countries (Sreeramareddy, Pradhan and Sin, 2014) reported non-statistical significance in reduction of smokeless tobacco use among women living in rural areas.

Occupation: In relation to occupation, (Singh et al., 2009) women involved in tobacco preparation and/or farming had an odds ratio of 2.0 (95% CI of 1.1-3.7) compared to those

with no occupation and similarly, Singh et al (2015) also reported that women involved in agriculture had an odds ratio of 1.30 compared to unemployed women. Furthermore, those who were unemployed (AOR 1.89, 95% CI 1.15-3.12) were more likely to use smokeless tobacco compared to those who were professionals (Sorensen, Gupta and Pednekar, 2005) and similarly, are odds of smokeless tobacco use were higher among non-income earner (AOR 2.08, 95% CI of 1.48-2.91) and those who were unemployed (AOR 7, 95% CI 5.45-8.98) compared to housewife (Hossain et al., 2014).

4.3.3 Attitudes and beliefs:

This section reports findings from both quantitative and qualitative components on attitudes and beliefs related to smokeless tobacco use among women.

Quantitative:

There is a general belief in India that betel leaf with tobacco is natural and does not contain any additives or chemicals (Schensul et al., 2018). The study also reported that it is a common practice to eat smokeless tobacco (betel leaf with chewed tobacco) post meals to help with digestion and hence should be served at weddings or gatherings (Schensul et al., 2018). Hossain et al (2016) reported various beliefs related to smokeless tobacco such as it is good for health (23.8%), helps with digestion (28,7%), other health problems such as headache (17.5%), toothache (18.3%) and stomach-ache (7.3%) (Hossain et al., 2016). The findings from these two studies (Schensul et al., 2018 and Hossain et al., 2016) are reported graphically in figure 4.5. The figure further reports findings from the study by Murthy and colleagues (2018) which reported health care providers' input towards perceived reasons for smokeless tobacco use where about 50% felt it was used because of habit, about 20% feel its use was related to boredom and relief of sadness and in general psychologically helped a person work better. The study also reported a perceived desired effect on women that it helps with uplifting of mood and feel fresh. Smokeless tobacco is also easily available and a belief that smokeless tobacco is less dangerous than smoking hence acceptable (Mathew, Noronha and Kamath, 2016).

Qualitative:

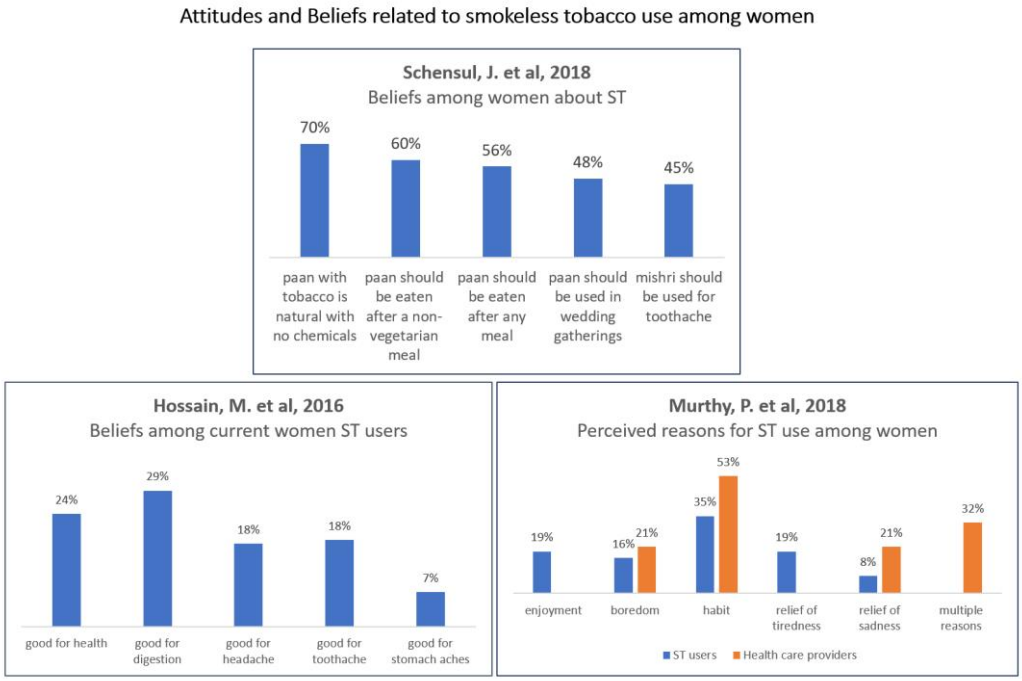
A study by Shahjahan et al. (2017) reported that women consumed *zarda* more than men, although they may not be aware that *zarda* is a raw form of tobacco. An individual also quoted that his grandmother could live without food but cannot live without smokeless tobacco.

A narrative by a 22-year-old female from India, reiterated that use of smokeless tobacco is common to treat toothache and is falsely perceived to be medicinal (Begum et al., 2015). The narrative also highlighted the influence of family members towards exposure, initiation and availability – "*When my husband comes in the evening that time he brings, from one year he is bringing. My husband only suggested me to eat and nobody else suggested. He said that it is good to eat for toothache"; [22 years old female who started using smokeless tobacco a year ago for toothache].*

The use within family and false belief that it aids with various common ailments was seen in a narrative of a 48-year-old smokeless tobacco user in Ethiopia (Etu, Gemeda and Hussen, 2017) - *"My grand-mother showed me how to prepare and chew tobacco every time I stayed with her. She also said that it would help to avoid headache, mouth and teeth diseases."*

It was also evident that the use of smokeless tobacco was very common in the community and hence normalized even for health care professionals. A 43-year-old health care provider in Ethiopia narrates (Etu, Gemeda and Hussen, 2017) - *"Although I don't like chewing tobacco, I feel it's normal. As you see it is very common in our community, it's normal for people to chew tobacco."*

Figure 4.5: Quantitative findings reporting attitudes and beliefs related to ST use among women based on studies included in the review



4.3.4 Influence of family:

This section reports findings from both quantitative and qualitative components on family influence related to smokeless tobacco use among women.

Quantitative:

Survey data showed that the most common means of learning to use smokeless tobacco before marriage was through friends (31.1%) and parents (25%) whereas for those who initiated after marriage but before pregnancy was through neighbours, (22.5%), relatives (22%) and by observing (21.4%) (Begum et al., 2015). Influence of family members was about 20% (Etu, Gemeda and Hussen, 2017) in Ethiopia, 32% in Cambodia (Singh et al., 2009) and about 60% in India (Singh, Mini and Thankappan, 2015). About 2/3 of the women also reported that their husband helped them with the purchase of smokeless tobacco products (Singh, Mini and Thankappan, 2015).

Furthermore, Ray et al (2016) reported that the odds of women using smokeless tobacco was two folds if the father has ever used smokeless tobacco (AOR 2.1, 95% CI 1.8-2.4), four folds if the mother ever used smokeless tobacco (AOR 4.0, 95% CI 3.3 – 4.7), about four folds if the spouse uses smokeless tobacco (AOR 4.3, 95% CI 3.6-5.3) and five folds if a close friend used smokeless tobacco (AOR 5.0, 95% CI 4.3-5.9) (Ray et al., 2016).

Qualitative:

From a study in Bangladesh, it emerged through focus group discussions that elderly women in the family influenced young people towards smokeless tobacco use by offering them the products (Shahjahan et al., 2017). A narrative mentioned in the study by Begum et al (2015) suggested that the initiation of smokeless tobacco was a result of family influence at a very young age - *"So when I was 13 year old I started eating gutka. And my brother's wife was eating Pukar gutka and gutka. So I took one packet and I ate it. I very much liked the taste of gutka that time, but I again started pan with surti tobacco. When I added surti (Tobacco) it would give me the same taste like gutka. So I was eating both the products pan and gutka." [15-year-old female].*

Another example of family influence was a narrative of a 40-year woman residing in Mumbai (Begum et al., 2015), India that suggested that common use of smokeless tobacco in the family exposed women to its use and further its acceptability within the family encouraged the use of smokeless tobacco - "*Madam after my marriage I went to my native place to stay with my in-laws. Maybe I was 13-year-old that time. See at my in-law's place everyone eats pan and*

tobacco …. so, I was observing them and I got tempted to eat pan. So, when no one was at home I had seen my mother in-law keeping a small "Pan Box" and I ate without letting anyone know. ……. In the morning and evening time no one was there, so when no one was around that time I ate, but one day my mother in-law caught me. At that time my mother in-law said, "you can eat how does it matter to us, eat how much ever you want".

4.3.5 Knowledge on health effects:

This section reports findings from both quantitative and qualitative components on knowledge on health effects related to smokeless tobacco use among women.

Quantitative:

Misconception that tobacco has medicinal properties was reported as a major reason and hence the odds of smokeless tobacco use among those with poor awareness were approximately four-folds higher compared to those with good awareness (AOR 4.48, 95% CI 2.0-9.9) (Singh, Mini and Thankappan, 2015). Similarly, Hossain et al (2016) reported that inaccurate knowledge regarding smokeless tobacco was significant among women more than the age of 44 years (AOR 2.71, 95% CI 2.05-3.6), who had no formal education or primary level of education in Bangladesh. The author also reported that women who were unemployed, were 30 times more likely to have inaccurate knowledge about smokeless tobacco compared to those who were employed (Hossain et al., 2016). Tiwari et al (2015) reported that among rural women, knowledge of whether chewing tobacco can cause oral cancer was 77.8% while 100% in all urban women.

On a positive side, a study from Ethiopia (Petersen et al., 2018), reported that about 94% of women thought that use of smokeless tobacco harms her health (Figure 4.6). Also, based on the GATS survey from multiple countries (Figure 4.7), showed that women had a varying knowledge of smokeless tobacco causing serious illness; 92% women in Bangladesh to about 43% in Ukraine believed smokeless tobacco causes serious illness (Gupta and Kumar, 2014).

Figure 4.6: Quantitative findings of the study by Petersen and colleagues (2018)

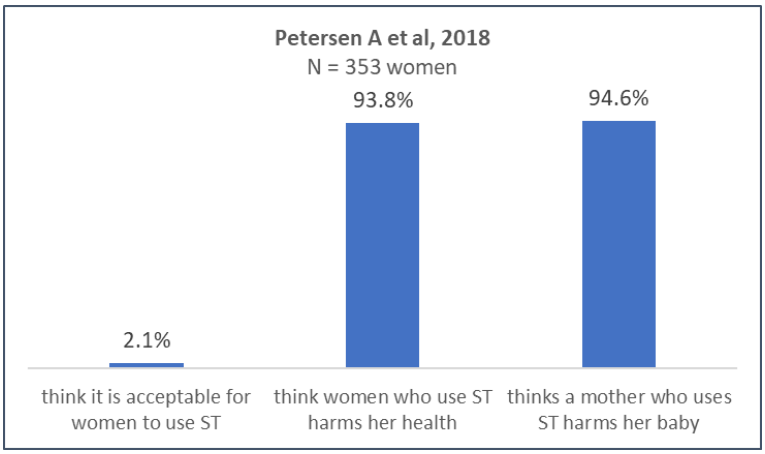
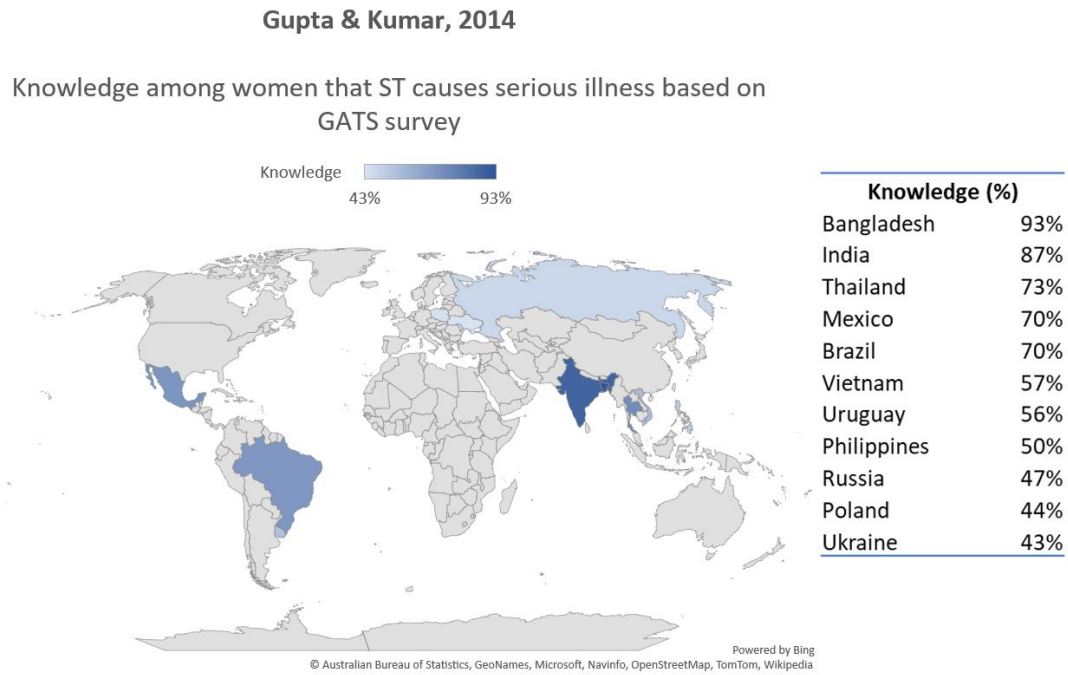


Figure 4.7: Knowledge among women that ST causes serious illness: findings reported by Gupta and Kumar (2014) based on the Global Adult Tobacco Survey (GATS)



Knowledge (%)	
Bangladesh	93%
India	87%
Thailand	73%
Mexico	70%
Brazil	70%
Vietnam	57%
Uruguay	56%
Philippines	50%
Russia	47%
Poland	44%
Ukraine	43%

Qualitative:

It emerged from the focus group discussions that key informants felt smokeless tobacco has no adverse effects (Murthy et al., 2018). In addition to this, a quote mentioned in the Shahjahan et al (2017) study suggested that despite on-going health conditions, women continue to use smokeless tobacco -*"My wife has suffered from a stroke once and is paralyzed and lost her ability to walk properly but she is still using ST. I have tried my level best to stop by informing all health risks involved, but it was in vain."*

Etu and colleagues (2017) also reported that smokeless tobacco users and non-users have insufficient knowledge about its effect on health. A narrative of a 65-year-old smokeless tobacco user highlighted that smokeless tobacco is rather believed to have medicinal properties - *"...personally, I do not know any health problem caused by using smokeless tobacco. It may cause discoloration of teeth; of course, this is not a big problem. Rather it serves as painkiller for teeth and head ache"*

A 41-year female smokeless tobacco user also narrated on the same lines (Etu, Gemeda and Hussen, 2017) - *"I think chewing helps us care for our teeth, I've tried to chew tobacco but I always got dizzy, then I stopped. I sometimes put a small amount of tobacco to crush with my teeth when I have toothache."*

4.3.6 Initiation of smokeless tobacco use:

This section reports findings from both quantitative and qualitative components on initiation of smokeless tobacco use among women.

Quantitative:

In Bangladesh, 8% of the women initiated smokeless tobacco use below the age of 15 years and mean age at initiation is 25.83 ± 9.75 (Azam et al., 2016). About 25% of the women initiated their smokeless tobacco use under the age of 25 years in Ethiopia (Etu, Gemeda and Hussen, 2017). While in rural India, mean age of initiation among pregnant women was reported as 17.1+-3.4 years (Singh, Mini and Thankappan, 2015)and 26.23 years in urban Indian women (Mishra et al., 2015).

Tonstad et al (2013) reported that the most common reason to initiate smokeless tobacco use in Cambodia was experimental (68%) (Tonstad et al., 2013). Another study from Cambodia (Singh et al., 2009) reported that the most common reasons to initiate among women were influence of older relatives (31.9%), alleviating morning sickness (17%) and experimental (13.95%). In India, initiation was due to parental influence (6.7%), peer influence (13,3%), just for fun (24.4.%), personal problems (26.7%) and toothache (28.9%) (Mathew, Noronha and Kamath, 2016). Teeth and gum problems were also a major reason reported by Begum et al (2015).

Furthermore, Begum et al (2015) reported that the primary reason for initiating smokeless tobacco before marriage was pleasure (feel fresh, feel happy, like the smell and taste, and for passing time) and post marriage but prior to first pregnancy was tooth and gum problems.

Qualitative:

Murthy et al (2018) reported several reasons for initiation among women based on focus group discussions with key informants. These were to feel warm or reduce discomfort after a meal, a female role model in the family of society as an influence, and most importantly the general feeling that the community accepts use of smokeless tobacco by women.

4.3.7 Reasons for continuation:

This section reports findings from both quantitative and qualitative components on reasons for continuation related to smokeless tobacco use among women.

Quantitative:

Mathew et al (2016) reported that in India, 36.7% of the women continued their use to relieve tension, about 63% continued as a result of habit and Tonstad et al (2013) reported that about 23% continued the use to get rid of fatigue and about 30% due to influence of older relatives in Cambodia.

Qualitative:

It emerged from focus group discussions of key informants that women continued their use of smokeless tobacco due to their liking, craving of smokeless tobacco and eventually are habituated (Murthy et al., 2018).

4.3.8 Intention to quit:

This section reports findings from both quantitative and qualitative components on intention to quit related to smokeless tobacco use among women.

Quantitative:

Tonstad et al (2013) reported that in Cambodia, 45% of the current smokeless tobacco users intend to quit in the future. Intent to quit was higher among younger adults (OR 4.67 for those aged 18-25 years), among Muslims (OR 3.32 compared to Buddhist) and those whose

initiation age was more than 25 years (OR 2.26, compared to those who started smokeless tobacco use at the age of 18 or less).

Schensul et al (2018) reported that, most women (67%) in the study thought the best way to quit was on their own. However, half of the women (54%) also said that someone from their family would support them to quit. Most of the women also expressed their interest in speaking to a local health care worker about reducing their smokeless tobacco use. Proportion of women who planned to quit or have attempted to quit vary significantly; 5.6% (Etu, Gemeda and Hussen, 2017), 12.2% (Mathew, Noronha and Kamath, 2016) and 45% (Tonstad et al., 2013). Furthermore, the Ethiopian study also reported that 12.9% of the women were advised by health care professionals to stop their smokeless tobacco use in the past 12 months (Etu, Gemeda and Hussen, 2017).

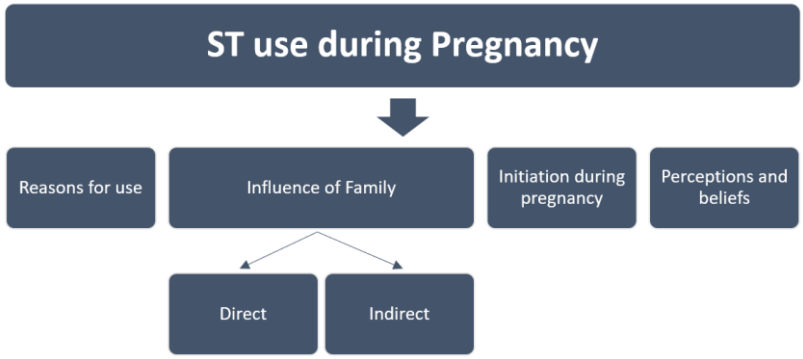
Qualitative:

Most of the women smokeless tobacco users in the FGDs had not heard of or been exposed to any prevention programs. They felt that there was active promotion of the products in the shops and hence did not feel the need to quit (Murthy et al., 2018).

4.3.9 Smokeless tobacco use during pregnancy:

This section reports findings from both quantitative and qualitative components of smokeless tobacco use during pregnancy. The results for smokeless tobacco use during pregnancy are reported based on four sub-themes displayed in figure 4.8.

Figure 4.8: Themes that emerged for ST use during pregnancy



Quantitative:

About eight studies reported smokeless tobacco use during pregnancy and two of these were specifically aimed at understanding smokeless tobacco use among pregnant women in India.

Major reasons for using smokeless tobacco during pregnancy were morning sickness (Begum et al., 2015; Singh et al., 2009; Singh, Mini and Thankappan, 2015), to relieve labour pains (Singh, Mini and Thankappan, 2015; Schensul et al., 2018), to relieve body ache and strengthen teeth during pregnancy (Schensul et al., 2018).

Singh et al (2009) reported that 17% of women in Cambodia initiated smokeless tobacco use to alleviate morning sickness. Similarly, Begum et al (2015) reported that in India, main reasons for initiating during the first pregnancy were to avoid symptoms of pregnancy (vomiting, nausea, morning sickness and gastric problems). During the first pregnancy women mentioned learning to use smokeless tobacco on their own by observation (32.4%) followed by influence from neighbours (20.3%). About 12% of women learned to use smokeless tobacco from their husbands who also consume smokeless tobacco at different points post marriage (before and after first pregnancy) (Begum et al., 2015). However, Singh et al (2015) reported that no women in the study conducted in India, initiated smokeless tobacco use during pregnancy; 78% did not change their habit, while 18.6% decreased their use of smokeless tobacco use during pregnancy.

Singh et a. (2017) reported that pregnant women who were stressed and those who were not attending regular mothers' group meeting in Nepal had higher odds of using smokeless tobacco AOR of 5.0 (95% CI of 1.8-14) and 4.6 (95% CI of 1.4-15.2), respectively). Furthermore, the same study also reported that pregnant women who had no education had AOR of 9.6 (95% CI of 2.5-32.7), primary education had AOR of 4.5 (95% CI of 1.1-17.1) compared to those who had higher education and pregnant women who were between the age of 20-34 years had AOR of 4.2 (95% CI of 1.3-14.2) compared to those women who were below the age of 20.

On the contrary, a study from Ethiopia (Petersen et al., 2018), reported that the majority thought smokeless tobacco was harmful for women (93.8%) and for the child (94.6%) whose mother uses smokeless tobacco.

Qualitative:

Based on the focus group discussions among Bangladeshi adults, it was reported that some elderly women advised pregnant women to chew betel leaf with *zarda* to avoid nausea and who later continue their use due to addiction (Shahjahan et al., 2017)**.**

A narrative reported by Nair et al (2015), suggested that during pregnancy, cravings of smokeless tobacco increased, however later with the support and advice from family, she was

able to reduce her smokeless tobacco use - *"Initially I used to have 2–3 times in a day, at times 3–4 times in a day and then one packet in a day, then 2 packets in a day. I eat only gutkha, because I like the taste. It contains supari (betel nut), chemicals, zarda and tobacco. When I came to know that I am pregnant that time I felt more craving and started eating 15–20 packets in a day. But my sister, mother-in- law and husband made me understand that it is not good for me because I am pregnant. Then I reduced eating and started eating only 4 times in a day". [19-year-old pregnant female]*

To reiterate the fact that women felt using smokeless tobacco to help with labour pains, was also reported in a narrative (Nair et al., 2015) by a 32-year-old smokeless tobacco user - *"At the time of my first delivery, when the ward boy shifted me to the bed and left, I opened the packet and made tobacco and put it in my gum. Then I felt relief because during delivery when I was having labour pain that time, I was very tired so I felt like eating tobacco. . ."*

Another narrative reported by Begum et al (2015) suggested the initiation of smokeless tobacco during pregnancy and this was due to a suggestion from family - *"I never used it before, but in this pregnancy, I started getting some kind of watery sensation in my mouth. I was talking to my aunty about it and she told me to apply. I applied it and washed my mouth, because when I had for the first time, I felt giddy".*

4.4 Discussion:

The findings of this study highlight the socio-cultural characteristics are related to smokeless tobacco use among women in LMICs. In this discussion section, I report summary of findings from this review and discuss them with relevant literature. I then discuss the strengths and limitations, and the implications for policy, practice, and further research.

4.4.1 Summary of findings

In this section, I summarise the results from this review and discuss them based on social factors, attitudes and beliefs, and the influence of family related to smokeless tobacco use among women. I further discuss the socio-cultural context specific to smokeless tobacco use during pregnancy.

4.4.1.1 Social factors related to use of smokeless tobacco:

Almost all studies that report on education and socio-economic status and use of smokeless tobacco, show a statistically significant higher use among those who are less educated and those from low socioeconomic status. This strengthens the current literature that social disparity is evident with use of smokeless tobacco across countries of low and middle income. This potentially relates to lack of knowledge regarding harms of smokeless tobacco and belief in false myths and practices as reported by Hossain et al (2016) that women with no formal education have higher odds (AOR = 2.18, 95% CI of 1.6-2.8) of inaccurate knowledge related to smokeless tobacco use compared to women with secondary/tertiary education.

Even with smoking, this relationship with social disadvantage is noted. That is, an increase in smoking among those who experience social disadvantage, and further its use, deprives existing resources and indirectly leads to social inequalities (Hiscock et al., 2012; Siahpush, Borland and Scollo, 2003). Furthermore, individuals exposed to communities and their families, who commonly smoke, tend to get accustomed to smoking as a normal behaviour, and are likely to adapt the habit themselves (Stead et al., 2001).

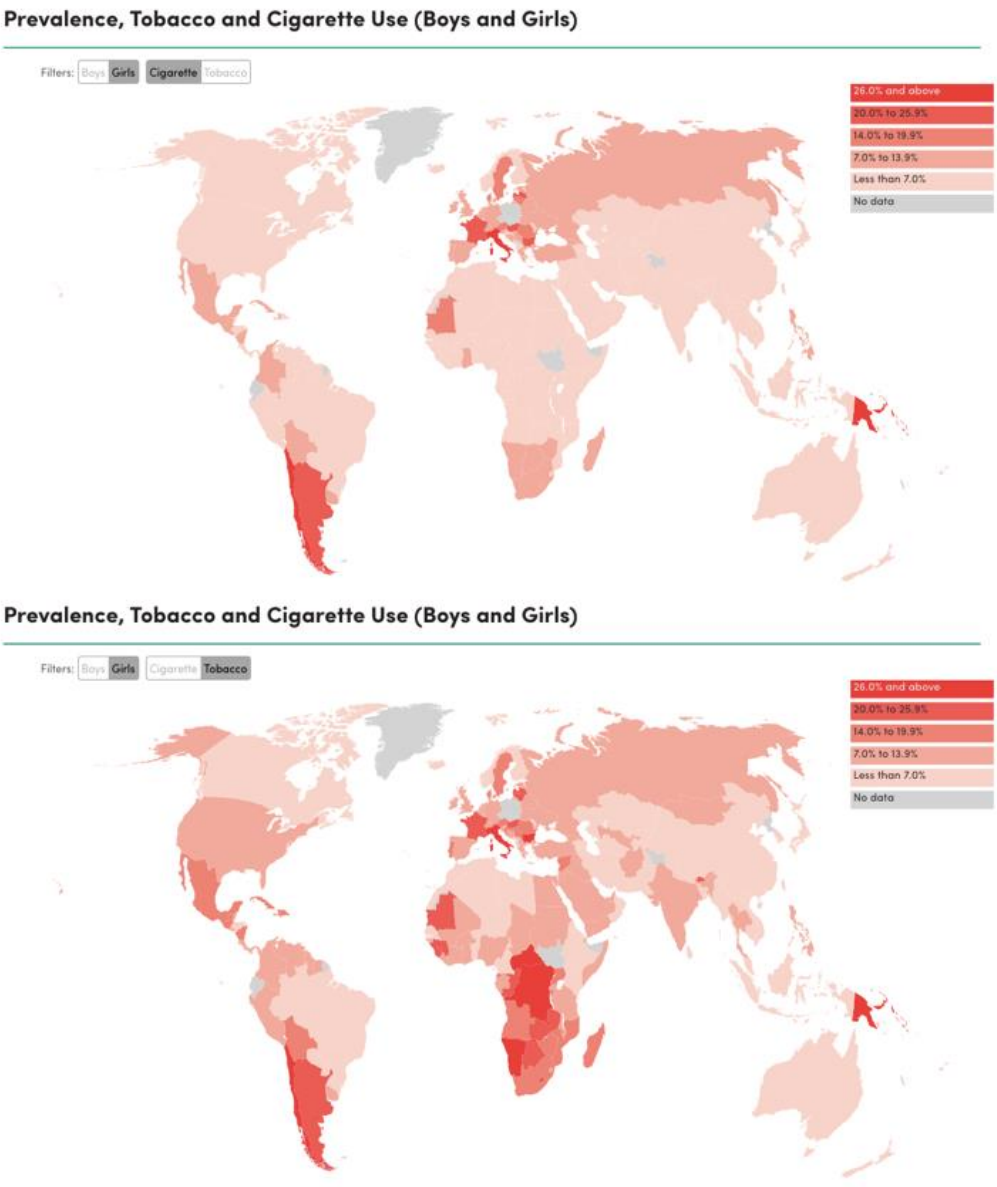
An important factor that comes across through this review is age at initiation for smokeless tobacco use. That is women often initiate the use of smokeless tobacco in their younger age. A study from Bangladesh, reported mean age of initiation as 25 years and about 8% of women initiated below the age of 15 years (Azam et al., 2016), while a study from India reported mean age of initiation as 20 years (Begum et al., 2015) and Etu et al (2017) reported that 25% of the women initiated before the age of 25 years. The initiation of smokeless tobacco consumption was due to various reasons; a general belief that it is acceptable and relieves indigestion (Murthy et al., 2018), experimental (Tonstad et al., 2013), toothache, peer influence (Mathew, Noronha and Kamath, 2016; Hossain et al., 2016; Begum et al., 2015) and during pregnancy due to influence of older relatives to combat various pregnancy related symptoms (Singh et al., 2009).

This early initiation of tobacco use is comparable with smoking, where average age at initiation based on five European countries (Sweden, Ireland, France, Italy, and Czech Republic) was 18.2 years and about 80% of women smokers had initiated smoking before the age of 20 (Oh et al., 2010). Among adolescents, smokeless tobacco use is prevalent in 106 countries, and it is estimated that about 3.6% of female students (13-15 years) use smokeless tobacco (Sinha et al., 2017). The study suggests that the prevalence is more prominent in LMICs possibly due to easy accessibility and affordability to adolescents, which makes

tobacco control challenging in these countries. To visually represent this, the figures from tobacco atlas (*Figure 4.4*) compare the use of cigarettes and tobacco as a whole in girls (13-15 years). The images clearly show that tobacco use (which includes cigarettes and other forms, such as smokeless tobacco) is relatively higher in certain parts of the world.

This highlights the importance of increasing awareness and preventive interventions amongst the youth in LMICs; that is either strengthen the preventive measures to reduce initiation by youth or offer effective cessation interventions early in age as they may not be that habituated to smokeless tobacco yet and hence quitting may be easier. This comes across in the Cambodian study, as women between the age of 18-25 years have a higher intent to quit (AOR = 7.13, 95% CI of 1.8-27.11) compared to women above the age of 48 years (Tonstad et al., 2013). Hence targeted intervention to help these women in addition to community-based increase in awareness might help and something that needs to be explored further.

Figure 4.9: Prevalence estimates of tobacco use among girls for cigarettes (top) and all tobacco (bottom), taken from the Tobacco Atlas



4.4.1.2 Knowledge, attitudes and beliefs related to use of smokeless tobacco:

The false perception and belief related to smokeless tobacco is evident among women. It is thought to be natural, free of any additives/chemicals, and medicinal to treat headache, mouth, and dental diseases. Further, the use within the community and family, has almost normalised its use among women and is considered natural and free of any additives/chemicals. This belief further extends during pregnancy and smokeless tobacco is commonly used for oral problems, to avoid nausea, oral and gastric problems and to relieve labour pains (Begum et

al., 2015; Hossain et al., 2016; Mathew, Noronha and Kamath, 2016). There is also a belief that smokeless tobacco brings freshness and lifts up mood (Murthy et al., 2018; Schensul et al., 2018). Similarly, the review by Kakde and colleagues (2012) also reported that there is casual attitude and lack of awareness towards adverse health effects of smokeless tobacco and that its use is very much normalised within social units, which act as a barrier to cessation.

This normality is however not the case in smoking among women. In many developed countries (i.e., USA, UK, and Canada), there is an evident decrease in smoking among women due to awareness of health lifestyle and their attitudes towards smoking (Shafey et al., 2009). Even in developing countries, the awareness related to smoking is evident among women. In a cross-sectional study conducted in Pakistan, most of the women were aware of active smoking as a cause of lung disease (Bhanji et al., 2011).

The social acceptance of smokeless tobacco use among women appears to be related to the lack of awareness and perceived benefits for common ailments. However, as discussed in the earlier chapter (section 1.2.3), smokeless tobacco is associated with several adverse effects. A systematic review and meta-analysis reported association of smokeless tobacco with oral cancer among women in India, with a pooled odds ratio of 12.03 (95% confidence interval of 9.49-15.25), along with its association with other forms of cancer both in men and women, such as pharyngeal, laryngeal, esophageal and stomach cancers (Sinha, Abdulkader and Gupta, 2016). Another review of observational studies reported increased risk of fatal ischaemic heart disease and stroke among ever users of smokeless tobacco (Vidyasagaran, Siddiqi and Kanaan, 2016). Furthermore, a recent *in silico* study suggested association of chemical compounds in different smokeless tobacco products with neurodegenerative, immune, and cardiac diseases (Bhartiya et al., 2018).

Hence, it is evident across several studies that there is lack of knowledge and false beliefs related to smokeless tobacco use among women. To reduce the prevalence of smokeless tobacco use and prevent its initiation by women in LMICs, it is important to target on increasing awareness related to smokeless tobacco. Furthermore, the general beliefs related to smokeless tobacco are common across communities and cultural imbibement and acceptance of its use stand out. This strengthens already existing literature to address the cultural context related to false beliefs and lack of knowledge related to smokeless tobacco.

4.4.1.3 The importance of family and their influence towards use of smokeless tobacco among women:

The influence of family towards use of smokeless tobacco among women in LMICs is both direct and indirect. That is, women who have family members that use smokeless tobacco are more likely to use smokeless tobacco; the odds of women using smokeless tobacco are nearly four times if mother or spouse use smokeless tobacco and further five times if a close friend uses smokeless tobacco (Ray et al., 2016) and the direct influence of family members either offering smokeless tobacco or normalizing its use. Female role models in the family or society influences the initiation of smokeless tobacco among women (Murthy et al., 2018). It was noted across several studies that family members have an influence on initiation of smokeless tobacco among women. This is either in premarital stage as an influence of parents or post-marital due to influence of husband or in-laws; as seen in a study from India, where 25% of women learnt the use of smokeless tobacco through parents before marriage and about 12 % learned from their smokeless tobacco consuming husbands post marriage (Begum et al., 2015).

Studies also report that family members have an impact on the use of smokeless tobacco among women and further the narratives of women also show that elderly family members offer young people smokeless tobacco (Shahjahan et al., 2017). However, at the same time, there is also evidence that family members have discouraged the use of smokeless tobacco when pregnant and that has had an influence on the woman on reducing the use of smokeless tobacco (Nair et al., 2015). Hence, it can be said that the family has an influence on smokeless tobacco use among women in either direction; that is cultivating or influencing the use of smokeless tobacco and also in discouraging its use. This paves an important pathway for tobacco control programs, especially in LMICs.

In general, there is limited context related to smokeless tobacco interventions, especially in LMICs which bear high burden of smokeless tobacco use and perhaps behavioural interventions for these low resource countries might be beneficial (Nethan et al., 2018). In designing these behavioural interventions focused on smokeless tobacco use among women, it will need to bear in mind the significance of family influence on smokeless tobacco use as highlighted by this review.

4.4.1.4 Smokeless tobacco use during pregnancy:

Tobacco use during pregnancy is a complex phenomenon affected by several inter-related factors such as social, environmental, and psychological (Sieminska and Jassem, 2014). Some common beliefs that are highlighted by this review are use of smokeless tobacco for relief of morning sickness, to help with labour pains and indigestion during pregnancy. Also, a study in this review highlights the social disparity related to smokeless tobacco use during pregnancy. That is pregnant women who were less educated had higher odds of using smokeless tobacco (AOR = 9.6, 95% CI of 2.5-32.7 and AOR = 4.5, 95% CI of 1.1-17.1 for no education and primary education, respectively) compared to women with higher education (Singh et al., 2017). Therefore, social disparities related to smokeless tobacco use is evident even among pregnant women. This is comparable with smoking during pregnancy, as prenatal smoking is influenced by low socio-economic status, among those who are less educated, and presence of other members in the family who smoke (Al-Sahab et al., 2010; Thrift, Nancarrow and Bauman, 2011; Chaaya et al., 2003).

Further, Nair et al (2015) reported that there is no significant difference between currently pregnant and non-pregnant women in use of smokeless tobacco. This is of concern as tobacco use among women of reproductive age, especially while pregnant can cause several adverse effects, such as increased risk of foetal growth restriction, preterm birth, stillbirth, perinatal deaths, sudden infant death syndrome and placental abnormalities (Hossain et al., 2017; England et al., 2003; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2007)

Despite lack of quality evidence on risk of perinatal outcomes related to smokeless tobacco use and pregnancy, there is strong evidence of harmful effects of smokeless tobacco, as mentioned in an earlier section (1.2.3) Hence, the lack of quality evidence of smokeless tobacco use during pregnancy should not take away from the key message that smokeless tobacco is harmful. Its use during pregnancy, either like pre-pregnant state or an increase in frequency to counter pregnancy related symptoms, is still causing harm to the woman. Rather, if women tend to increase their use in pregnancy (as seen in some studies part of this review), their exposure to tobacco and other harmful chemicals in smokeless tobacco also increases.

In HICs, adults and pregnant women are aware of adverse effects of smoking and the potential ill effects it may have during pregnancy (Kim et al., 2009; Arnold et al., 2001). A range of information, support and interventions are also available for pregnant women to help them reduce/quit tobacco (Kim et al., 2009; Bauld, 2009; Coleman-Cowger et al., 2014). But, even

in HICs where smokeless tobacco use during pregnancy is prevalent (i.e., Alaska), these false beliefs are evident among women (Patten et al., 2008; Renner et al., 2004). The smokeless tobacco used in Western part of Alaska, "*Iqmik",* is considered natural and healthier than smoking, which influences its use during pregnancy due to the cultural acceptance. However, unlike LMICs, several studies have explored interventions to reduce tobacco use among these women and during pregnancy (Patten, 2012; Patten et al., 2010; Koller et al., 2017).

This review strengthens the existing literature that beliefs and perceived benefits related to smokeless tobacco use among women in LMICs, extends into pregnancy which is influenced by community, family, and the normality towards smokeless tobacco in general. This highlights the need to increase awareness related harms of smokeless tobacco among women and pregnancy can offer opportunities to deliver these tobacco control measures. Hence, like HICs, tailor made interventions need to be explored to reduce tobacco use among women and during pregnancy.

4.4.2 Strengths and limitations

There are several strengths of this review. Firstly, the systematic approach to synthesise the available literature related to the socio-cultural context of smokeless tobacco use among women. Even though no meta-analysis was performed in this review, a systematic approach was adopted to appropriately synthesise the findings, including quality assessment of the studies. Given the descriptive nature of the review, no studies were excluded based on quality to capture all relevant literature. Secondly, the inclusion of both quantitative and qualitative studies, and the amalgamation of the findings that further complement each other. The reporting of findings in this review, are organised based on themes that emerged from the qualitative components of the review. The findings from both (quantitative and qualitative) components echo each other and provide a more holistic understanding of various socio-cultural factors. Lastly, most studies are from the SEAR, which strengthens the evidence on socio-cultural factors in this region and allows for a comparison specific to this population.

The review also has a few limitations which are important to consider when interpreting the results. Firstly, there is a possibility of reviewer bias. That is because full paper reads, data extraction and quality assessment of studies were all done by one reviewer (PhD candidate). I acknowledge that ideally two reviewers should independently screen all the studies, perform full paper reads, extract data and check for quality of studies. These are then compared, and a third reviewer is involved if there are any discrepancies. However, due to resource limitations

within the constraints of a PhD, only the initial title and abstract screening were independently performed by two reviewers.

Secondly, the broad inclusion criteria and diversity of studies, made the evidence synthesis a challenge. Perhaps, a more focused review (either geographically or exploration of only certain related factors) might have eased the synthesis and overall reporting of the review. However, given the sparse literature on smokeless tobacco use among women, especially those pregnant, I wanted to capture all possible available literature related to socio-cultural context.

Lastly, the majority of the studies are from the SEAR, which of course is because the region bears the most burden due to smokeless tobacco. However, smokeless tobacco is prevalent in many other LMICs, which have sparse literature exploring smokeless tobacco use among women. Hence the results cannot be generalised as there may be variations in other countries and population specific socio-cultural context needs to be explored.

4.4.3 Implications for practice, policy, and further research

4.4.3.1 For policy and practice

The understanding of socio-cultural context through this review, highlights two key aspects for tobacco control interventions for women in LMICs.

Community based interventions: The common misconceptions and false beliefs related to smokeless tobacco have been reported in several studies. Their repetitiveness across studies strengthens cultural imbibement and the general acceptability of its use in the community encourages women to use smokeless tobacco. Therefore, community level awareness related to the harms of smokeless tobacco is likely to help decrease the prevalence of smokeless tobacco. Either preventive measures or cessation aids that educate the women collectively will help as peer influence and offering by elders in the family are common reasons to initiate and/or continue the use of smokeless tobacco. Furthermore, a lot of these studies have focused on specific communities that are likely to have higher prevalence of smokeless tobacco use, which re-iterate that need for community-based interventions. Additionally, the community-based programs will aid in increasing awareness among all, however an additional focus on limiting the initiation is also important, especially among young women who are less educated

and belong to low socio-economic status. Also, the role of family-based interventions or incorporating the support of families is something that needs to be explored further.

Targeted interventions for pregnant women: Some studies report that women increase their use of smokeless tobacco during pregnancy, while some report no change in their use. However, pregnancy is a "teachable moment" and despite the frequency of smokeless tobacco use, cessation interventions may help. Along with community-based interventions that target on increasing awareness and knowledge related to harms of smokeless tobacco, women when pregnant might benefit from additional targeted interventions. Firstly, this will help with tobacco related harms to the foetus and secondly, the woman herself will benefit from quitting. However, as of now, no study has explored any form of intervention to help women quit smokeless tobacco during pregnancy and further research is warranted in this context.

4.4.3.2 Future research

Based on this descriptive review, one aspect that stood out strongly is that use of smokeless tobacco has a lot to do with false beliefs, misconceptions and lack of knowledge related to its harms. Despite strong evidence related to several adverse effects of smokeless tobacco on health, there is lack of awareness towards these. Effective tobacco control measures specific to the women population in LMICs are required and this perhaps is an area that needs further research. Furthermore, there is a need for more studies that explore context specific to smokeless tobacco use during pregnancy. To understand the barriers and facilitators of smokeless tobacco cessation during pregnancy and perhaps whether this opportunity of pregnancy can potentially be used for tobacco control measures.

It is evident that family has an influence on the use of smokeless tobacco among women and during pregnancy. This influence is seen across many studies, and this highlights that there is a need to incorporate family support or develop family-based interventions. However, how to, is the question. Firstly, an in-depth exploration of views of women and families towards cessation interventions. Secondly, in general, smokeless tobacco cessation research is minimal and especially those specifically for women are even lower. Hence, helping these women quit smokeless tobacco, increase their awareness, and prevent initiation is highly warranted.

5) CHAPTER V: Familial influence on initiation/change in practice in smokeless tobacco use during pregnancy in India

This chapter addresses the third aim of the thesis; to understand how family members influence initiation or change in practice of smokeless tobacco use during pregnancy and in addition, explore peer and community member's influence on use of smokeless tobacco. A qualitative study using a framework analysis approach was conducted in selected Indian populations. This study explored how family members influence pregnant women's behaviour, attitudes, and perceptions, such that interventions and cessation/prevention methods can be tailored and targeted accordingly. A one-page outline/summary of this study is illustrated as a pictograph (*Figure 5.1*).

5.1 Rationale

This section briefly summarises the rationale for this study, followed by the primary and secondary research questions.

5.1.1 Why explore the "how" instead of "if"?

In the qualitative part of Nair's (2015) study, familial influence stands out strongly on its use during pregnancy; one narrative report mother-in law's influence to consume a certain type and amount of smokeless tobacco throughout pregnancy, while other narrative points towards family encouraging women to quit smokeless tobacco once pregnant. The study also reports that women are more likely to use smokeless tobacco if relatives and especially their husband is a smokeless tobacco user. This is supported by the review conducted by Kakde and colleagues (2012) which highlights that family and friends tend to act as both facilitators and barriers to smokeless tobacco use. Furthermore, the review reported four studies in the social context where "used by family members" was highly reported (prevalence ranges from 59%-100%).

To further strengthen the evidence of family influence, Begum and colleagues (2015) reported several narratives by women which refer to a family member being influential towards

initiation of their smokeless tobacco habit. These narratives are from women across different reproductive age groups. One such narrative of a woman during pregnancy stated use of smokeless tobacco for the first time while she was pregnant because it was recommended by her aunt to combat the watery sensation in mouth (Begum et al., 2015).

5.1.2 Need for this qualitative study

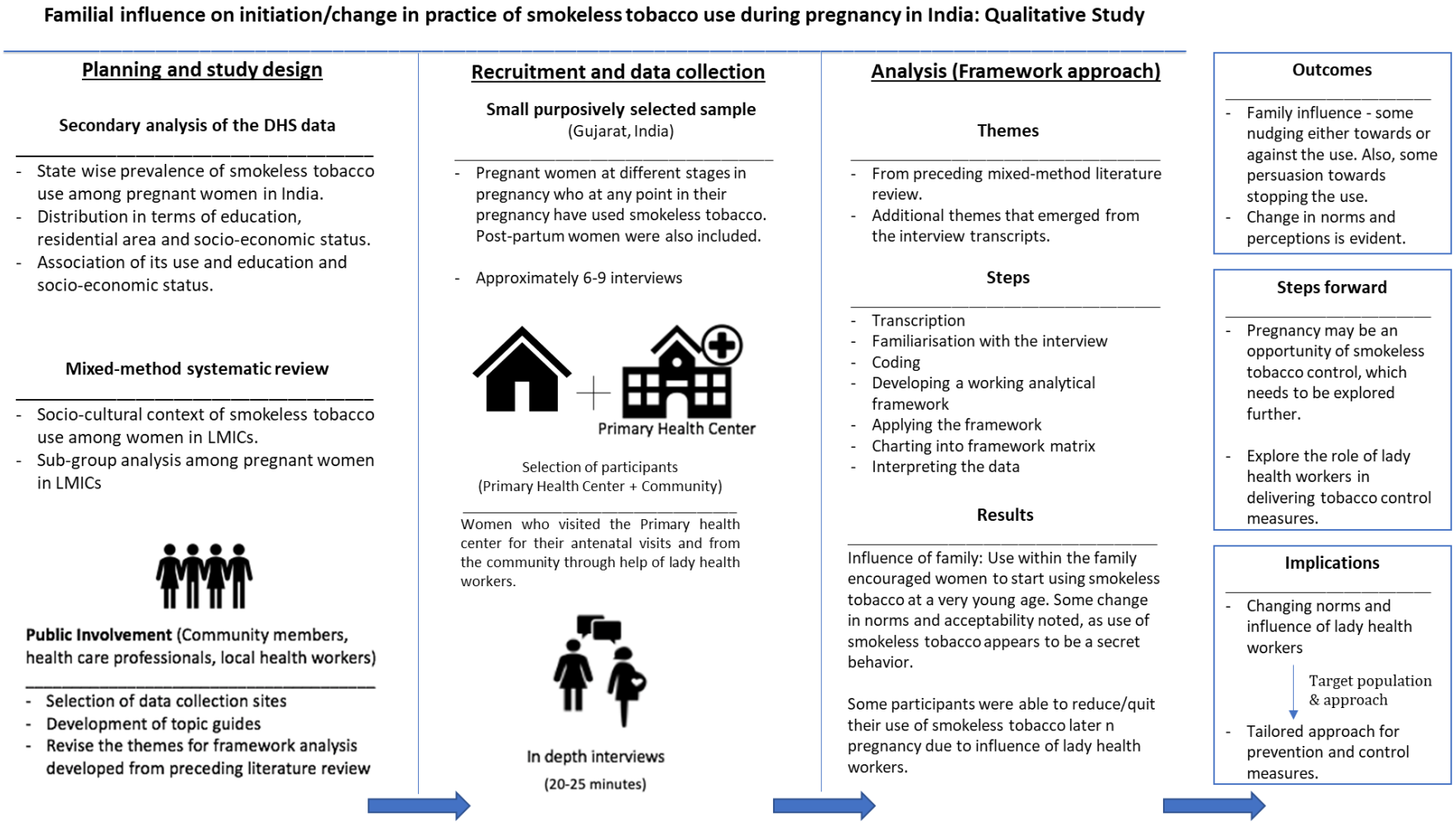
Current literature that has explored familial influence towards initiation of smokeless tobacco use during pregnancy, include systematic review by Kakde and colleagues (2012), Nair's mixed-method study (2015), another mixed-method study by Begum and colleagues (2015), and a pure qualitative study by Shahjahan and colleagues (2017).

The review by Kakde et al (2012), focuses on South-Asian population in general, and the only reference to smokeless tobacco use during pregnancy is addressed in their qualitative part, which reports that pregnant women initiate smokeless tobacco to change the taste in their mouth and later continue due to addiction. Nair's (2015) and Begum's (2015) mixed-method study both report family as an influence towards initiation of smokeless tobacco in pregnancy. However, the focus of both studies is women from reproductive age groups and thus, views of pregnant women only account for a small fraction of the literature presented.

The qualitative study by Shahjahan and colleagues (2017) looked specifically at factors influencing initiation of smokeless tobacco in low socio-economic groups in Bangladesh. The study reported (based on four focus group discussions) initiation of smokeless tobacco during pregnancy to relieve morning sickness in the first trimester under the influence of elders in the family. This is one of the most recent studies which tried to understand initiation factors of smokeless tobacco use in adults via a qualitative method. However, the focus group discussions reinstated and strengthened the fact already known, that is initiation of smokeless tobacco during pregnancy to overcome morning sickness in low-socioeconomic population.

Therefore, preventive/cessation measures related to smokeless tobacco use during pregnancy need socio-cultural adaptation, including influences from family members (Schensul et al., 2018). This study will allow an understanding of how family members influence pregnant women's behaviour and to further understand how these influences can be modified (that is reducing the influence of those promoting the use and increasing the influence of those preventing the use).

Figure 5.1: Study outline of the qualitative research conducted in India – Familial influence on initiation/change in practice of smokeless tobacco use during pregnancy



5.2 Research questions

1. Primary question: How do family members influence initiation or change in practice, perceptions and attitudes of smokeless tobacco use among pregnant women?
2. Secondary question: How do peers and/or other community members influence initiation or change in practice, perceptions and attitudes of smokeless tobacco use among pregnant women?

5.3 Methodology

5.3.1 Study design and setting

This study is the third part of this sequential/longitudinal thesis exploring distribution and socio-cultural context of smokeless tobacco use in pregnant women in LMICs. The preceding two studies allowed an understanding of the distribution in terms of prevalence rates, socio-demographics (mainly association with education and socio-economic status) and socio-cultural correlates of smokeless tobacco use among pregnant women in LMICs. Therefore, the design of this qualitative study depended on the themes and literature review that emerged from the preceding studies. Also, as a method of analysis, it followed a framework approach based on themes emerging from the preceding systematic review. This allowed comparison of how perceptions and influence compare with women who use smokeless tobacco in LMICs, to when they are pregnant as the review was not limited to pregnant women.

The area in the province of Gujarat, India that was selected for the study was Bhadran. The selected area is a rural area with a primary health centre that delivers antenatal and basic health services via the Accredited Social Health Activist (ASHA[8]) and has relatively high smokeless tobacco use which helped with the recruitment (this information was obtained via discussions with the co-investigator from India and the medical officer at the Primary Health Centre). I acknowledge that the population at target here is surely different, as it is focused on one specific province. However, the population is comparable nationally; prevalence of smokeless tobacco use among adults in India is 21.4% and that in the province of Gujarat is 19.2% (GATS India, 2018). Also, the culture and customs are relatable to other south-Asian countries

[8] ASHA (Accredited social health activist) – These are trained female community health workers, who the community and public health. Each ASHA worker is assigned a specific area and is aware about the households and its members in their respective areas (National Health Mission, 2013).

and therefore, it is likely that the findings from this population/research zone could be generalized to the country and SEAR *per se* to some extent.

5.3.2 Recruitment and sampling

This section addresses the recruitment and sampling for this study, later followed by a pictorial representation of the same.

5.3.2.1 Initial recruitment plan

At the time of study design, I purposely aimed to recruit pregnant women in their third trimester who at any point in their pregnancy used smokeless tobacco to better capture influences throughout its course retrospectively. The recruitment was planned via two methods; those accessing primary health centres (PHC) for routine ante-natal check-up, identified by health care professionals and those in the community who routinely do not visit a health facility, recruited with the help of community health facilitators (ASHA workers). It seemed important to recruit by the above two methods, as 20% of deliveries in India are non-institutional (NFHS, 2016) and this is possibly influenced by education, economic status and community access in rural India (Kesterton et al., 2010). It was therefore assumed that women who do not prefer institutional delivery, would routinely not access health facilities for antenatal workup and thus, views of those women would also be equally important to understand the complete context. Therefore, I estimated approximately 12-18 interviews combined from the recruitment at Primary Health Centre and by the ASHA workers. Thus, approximately about 6-9 interviews with each strategy.

5.3.2.2 Improvised recruitment and sampling

At the actual time of recruitment and initial visits to the PHC, it was noticed that almost all of the antenatal care is through ASHA workers. The medical officer at the PHC, was barely involved in the ante-natal care and everything was managed by the ASHA workers. In case a female needed a higher level of care, the ASHA worker would guide her to the secondary health centre and so forth. Furthermore, contrary to the assumption made at the initial planning stage of this study about certain women not accessing health care facilities for their ante-natal needs, it did not apply in this selected data collection site, as every pregnant woman in the area was offered care through ASHA workers. Hence, a decision was made to revise the sampling frame to just recruitment via the ASHA workers (*Figure 5.2*).

Another change in the sampling and recruitment was the participant eligibility. Initially while designing the study, I thought to include pregnant women in their third trimester, who at any point in their pregnancy had consumed smokeless tobacco, such that their change in use of smokeless tobacco throughout the pregnancy could be reflected upon. However, recruiting participants was extremely challenging (discussed in the reflections section, later in the chapter). Many women refused to participate and some initially agreed and were very keen on participating, however later refused at the time of the interview. Hence, a decision to expand the participant eligible criteria to pregnant women or up to 6 weeks postpartum women, who at any point in their pregnancy have consumed smokeless tobacco was made. The final recruitment and sampling are illustrated in Figure 5.2. The information sheet and consent form (English and translated versions) are provided in the *Appendix 5.1*.

Identification of eligible women:

- Pregnant women or postpartum women (up to 6 weeks), who at any point in their pregnancy have consumed smokeless tobacco, were identified by the ASHA workers in the community of the selected area.

Approaching eligible women for participation:

- The ASHA workers only identified eligible women and did not approach them to participate in the study.
- These identified eligible women were approached by the researcher for participation in the study. At that point, women were verbally briefed about the study by the researcher.
- In addition to the information sheet (written in local language), these women were also briefed about the study and were given at least a week's time to consider voluntary participation.

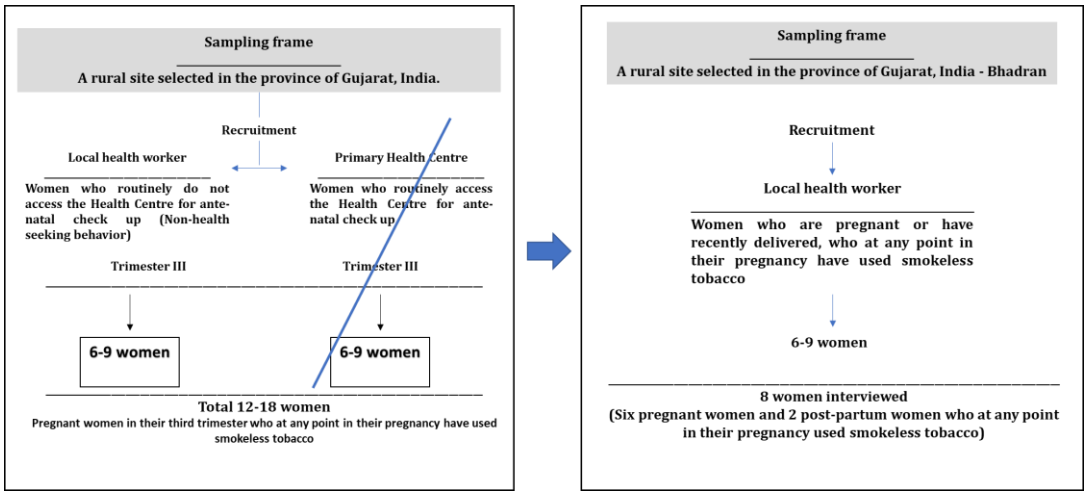
Recruitment:

- Voluntarily consenting women were recruited for the study.
- Women were offered the choice of place, where they were most comfortable for the interview. This was either at their home (in a separate room or at a time when family members were not around, to avoid any influence), selected PHC or elsewhere if they preferred.
- Despite where they chose to be interviewed, privacy and confidentiality of the participant was always ensured.

- A convenient time for the interview (roughly lasting for 30-45 minutes) was identified for the participant.

Sampling frame overview is outlined in the flow chart (*Figure 5.2*) below.

Figure 5.2: Initial and modified sampling frame



5.3.3 Incentives and reimbursement:

Participants were given a small incentive to appreciate their time for the interview in the form of a prepaid calling card for local talk time. The amount for this was 100 INR (Indian rupee) which is approximately 1.1 GBP. The incentive was only a token of appreciation and was unlikely to exert any undue influence on an individual's decision to participate in the study.
For those participants who preferred being interviewed at the PHC, were additionally reimbursed for their travel expenses to and from the facility. This included travel expenses for the participant themselves and anyone who accompanied them.

5.3.4 Data collection

A topic guide (*Table 5.1*) for the interviews was developed to ensure consistency of approach across the interviews. The development of the topic guide was largely informed from the preceding systematic review titled “Social and cultural characteristics and perceptions related to smokeless tobacco use among women in LMICs: a mixed method approach”, and the input from the collaborating researcher and health care providers at the selected PHC in India. Before it was used in the study, the topic guide was piloted with three participants as part of

the public-patient involvement and modified accordingly (changes discussed in the PPI section 5.4).

Table 5.1: Topic guide

Topic	Questions
Current smokeless tobacco use	What is your current smokeless tobacco use like? Can you please tell me the frequency and type of products you use?
Smokeless tobacco and pregnancy	Before pregnancy, what were your smokeless tobacco habits like? Has pregnancy changed any smokeless tobacco use of yours? In what sense? Can you possibly tell me more about the change? During the course of pregnancy, have there been any changes in your smokeless tobacco use?
Smokeless tobacco initiation	When did you first use smokeless tobacco? How did the habit start? What factors influenced your use of smokeless tobacco?
Familial influence	What are smokeless tobacco habits in the family like? How do those influence your smokeless tobacco behaviour? How has the influence changed throughout the course of pregnancy? How does you perceive these influences as? Who amongst the family influences your behaviour the most?
Knowledge and accessibility	What according to you is smokeless tobacco? How accessible are these products for you? Note: To be extra careful of not mentioning the words harm or danger to avoid the feeling of guilt and anxiety.

Questions for the interview were broadly based on the following topics: current smokeless tobacco use, smokeless tobacco initiation, knowledge about smokeless tobacco use in pregnancy, influence of in-laws, husbands, maiden family, community members and peers. The translated version of the topic guide is provided in *Appendix 5.1*.

Interviews were conducted in the local language by the researcher who acquired prior training to conduct qualitative interviews. To ensure better quality, the researcher practiced some mock

interviews using the topic guide. The interviews were audio recorded and imported to the virtual desktop services provided by the university IT services as soon as possible.

5.3.5 Data analysis

This study was analysed using framework analysis method (Gale et al., 2013). As an initial step, the interviews were translated and back translated to ensure that the context in local language was retained.

5.3.5.1 Why framework analysis over other qualitative approaches?

What is framework analysis: Framework analysis is an approach to analyse qualitative research, that was initially developed in the 1980s by Jane Ritchie and Liz Spencer for policy research (Ritchie J and Lewis J., 2003). It is now an integral part of qualitative health research that broadly falls under the umbrella of qualitative content analysis (Gale et al., 2013). The advantage of this method is that it provides a structure for data organisation such that the researcher can systematically summarise, analyse, and interpret the data.

Framework development: A preceding study as part of this PhD project, was a mixed-method systematic review exploring the socio-cultural context of smokeless tobacco use among women (chapter II). The review essentially aimed to understand various social and cultural contexts related to smokeless tobacco use among women in LMICs and additionally a sub-group analysis for pregnant women. As a result of the thematic synthesis, various themes, codes, and a basic framework were identified. As this qualitative study was a further extension of the review to understand a specific research object of familial influence on smokeless tobacco use during pregnancy, it seemed most appropriate to utilise the evidence from preceding review to build the framework for this study. Hence the framework used for this study was developed from the preceding systematic review. Additionally, the “open coding” method (mentioned in the steps below, 5.3.5.2), allowed modification of the framework for this study and addition of any new themes that emerged from the in-depth interviews.

5.3.5.2 Framework analysis (steps)

Stages of the framework analysis were followed as listed below. NVivo data management software (Castleberry, 2014) for qualitative research was used for coding, development of framework matrix and data management. Microsoft excel was also used to create the framework matrix based on the preceding systematic review.

I. Transcription: The translated interviews were transcribed *verbatim* by the researcher (myself) to allow better understanding of the interview content. Transcription was done in a manner that coding and making notes was feasible in the same document.

II. Familiarisation with the interview: All the interview transcripts were read to familiarise with the content and additional notes (if required) were made on one side of the margin. This was also an opportunity to incorporate interview reflective notes in the transcripts, if any.

III. Coding: First few transcripts were labelled line by line using an "open coding[9]" method initially to get an idea of the emerging codes and framework categories they relate with. Later, remaining transcripts were labelled using these identified codes.

IV. Developing a working analytical framework: a thematic framework matrix was developed based on themes that emerged from the preceding systematic review and the current study topic guide. These developed themes were then applied against the initial transcripts which were coded by "open coding" method and refined, if necessary, to incorporate new emerging themes. The framework matrix was developed in Microsoft excel software.

V. Applying the analytical framework: The working analytical framework was applied to the subsequent transcripts based on codes and categories developed.

VI. Charting data into the framework matrix: Data was charted and arranged in the NVivo tool, which allowed various ways of organising and visualising the data for interpretation.

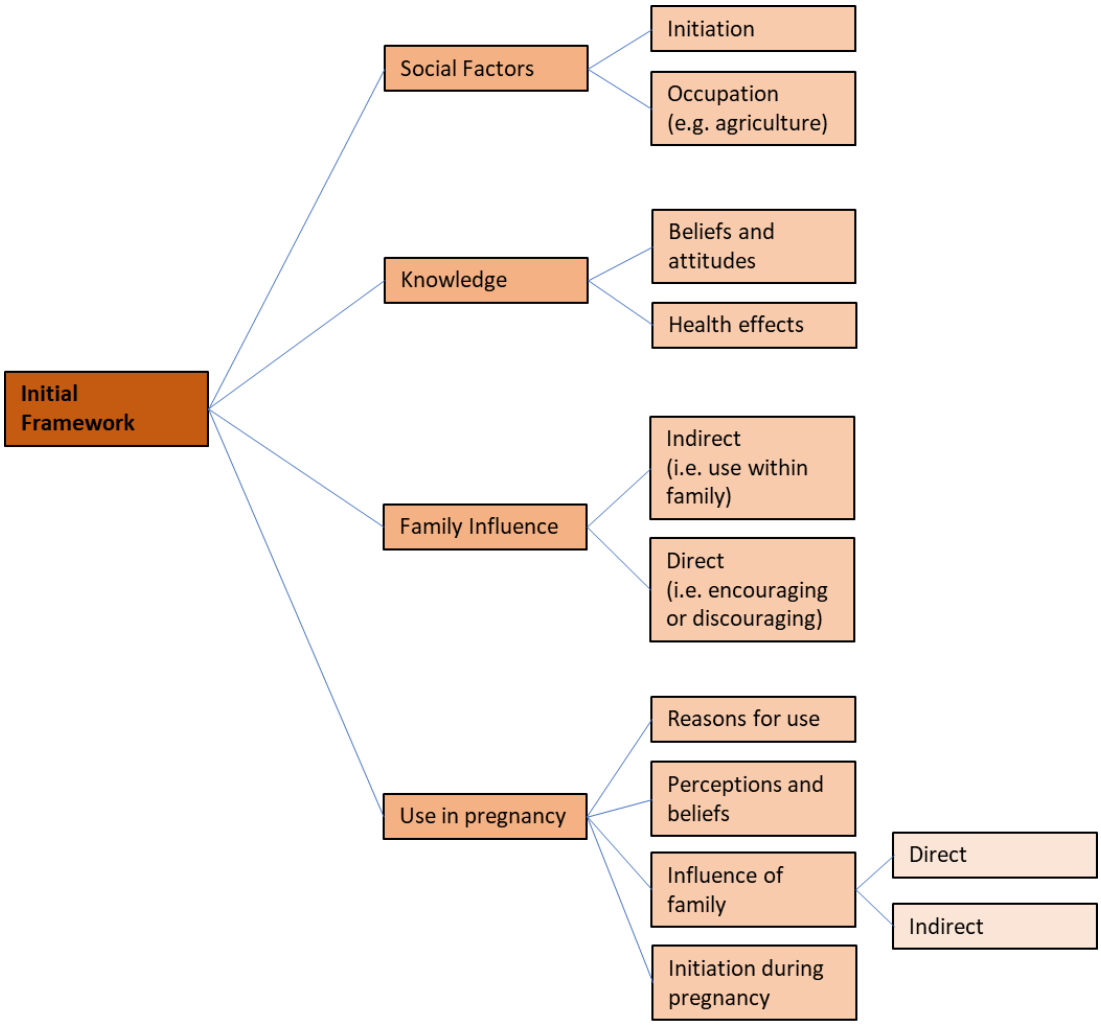
VII. Interpreting the data: The charted data in the matrix and the interviewer reflective nodes were interpreted. Data was interpreted to understand the family influences including a comparison of these influences at different stages of pregnancy. Reporting of the data included summaries of responses and verbatim quotes when necessary for mapping and interpretation.

[9] Coding anything relevant from different perspectives if possible. Therefore, not following pre-set codes (Gale et.al., 2013).

5.3.5.3 Framework developed from the preceding mixed-method review

This (*Figure 5.3*) framework was developed based on the results of the preceding mixed-method review, which was used to design this qualitative study and develop a topic guide for the in-depth interviews. Four themes were identified, each of which had multiple sub-themes. One of the key focuses for this qualitative study was the influence of family (direct and indirect) on the use of smokeless tobacco and also during pregnancy.

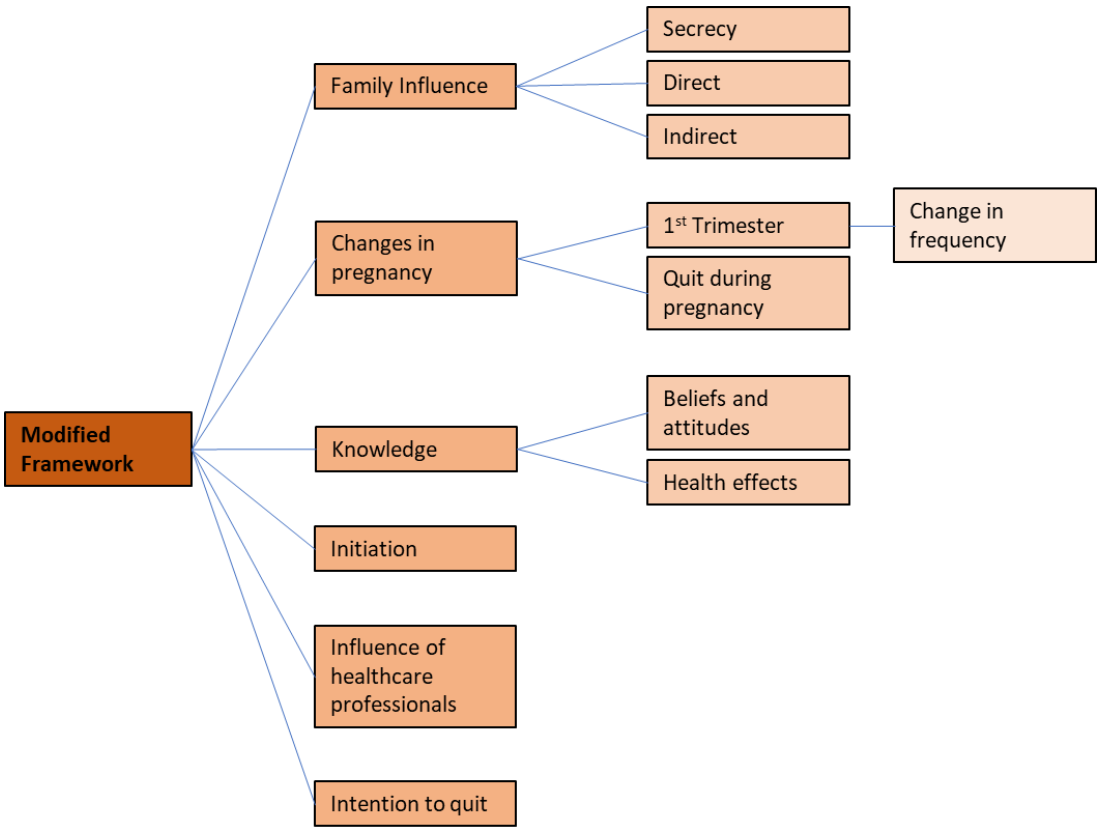
Figure 5.3: Framework developed from the preceding mixed-method review (themes and sub-themes)



5.3.5.4 Adaptation of the framework for this study

This (*Figure 5.4*) is the modified framework used for the analysis for this qualitative data based on the interview transcripts. Changes from the preceding framework were addition of two new themes (influence of healthcare professionals and intention to quit, and a new sub-theme of secrecy under the theme of familial influence).

Figure 5.4: Modified framework adapted for this qualitative study based on the interview transcripts



5.4 Public-Patient Involvement (PPI)

The PPI was arranged at the local PHC with help of the ASHA workers and co-investigator (Associate) Prof. Jaishree Ganjiwale. The PPI was not one single event and rather multiple interactions with the community members and women who used smokeless tobacco. Initially they were contacted to understand the context of smokeless tobacco use during pregnancy and inform the development of the framework and topic guide, and later during the piloting phase of the topic guide, to obtain their feedback and practice interviews.

Based on the PPI engagement, few terminologies in the topic guide (translated versions) were modified such that the terms were better understood in the local context. One such change was to refer to smokeless tobacco as the actual brand name of smokeless tobacco used locally. However, at the time of recruitment, smokeless tobacco as a general term was used first and if the potential participant did not understand, only then the local brand name was substituted. Additionally, in every interview it was confirmed whether the participant actually consumed tobacco, as the same brand also has non-tobacco products. Another recommendation from the PPI was to reduce the interview time to maximum 20-25 minutes as women may not be able to commit for a longer time.

In addition to this, and prior to the recruitment of participants, I had met with the medical officer at the selected primary health centre, a couple of ASHA workers in the PHC catchment area to understand the context related to smokeless tobacco among women, the ante-natal care services, and best method to approach women in the area. As a result of this, the sampling frame was revised, as mentioned earlier (*Figure 5.2*).

5.5 Research Governance:

The detailed protocol submitted for research governance and the respective approvals are provided in the *Appendix 5.2*.

5.6 Results:

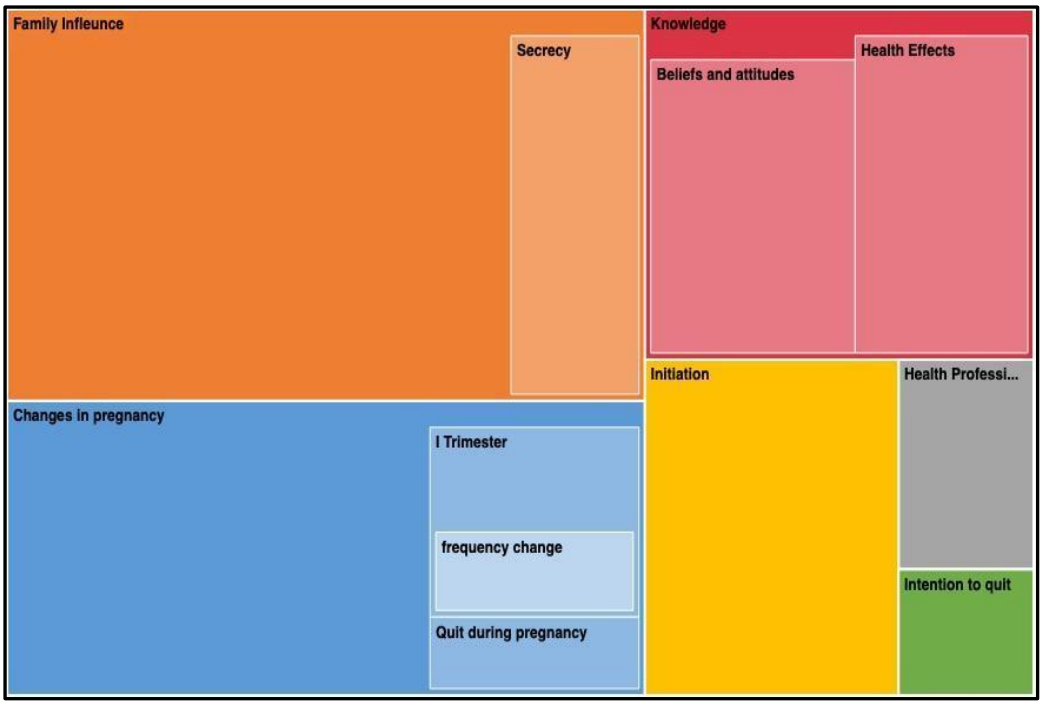
A total of nine in-depth interviews were conducted, however one of the participants at the time of the interview was discovered being ineligible and hence eight interviews were analysed using framework analysis. Participant characteristics are listed in the table 5.2.

Findings from the analysis are summarized below (*Figure 5.5*) in a framework hierarchy chart (based on the area a theme occupies in the chart, that reflects which themes/codes emerged most from all the interviews combined). These are individually described in detail, in the following sections.

Table 5.2: Information of participants interviewed in this study

Participant Information			
1	Age: 23 years Second pregnancy 7 months pregnant Education: not educated	5	Age: 25 years Second pregnancy 8 months pregnant Education: completed grade 7th
2	Age: 22 years First pregnancy 4 weeks post-partum Education: not educated	6	Age: 24 years Second pregnancy 8 months pregnant Education: not educated
3	Age: 26 years Third pregnancy 6 weeks post-partum Education: not educated	7	Age: 33 years First pregnancy 5 months pregnant Education: not educated
4	Age: 25 years First pregnancy 5 months pregnant Education: completed grade 12th	8	Age: 26 years Third pregnancy 8 months pregnant Education: not educated

Figure 5.5: Hierarchy chart of the codes/themes from the framework analysis



5.6.1 Influence of family on use of smokeless tobacco

The influence of family on initiation or change in practice of smokeless tobacco use was one of the main aims of the study and as a result majority of the transcripts contributed to this specific theme (as seen in the hierarchy chart in *Figure 5.5*). It was noted that the influence of family members was oppositional, in either influencing the woman's use of smokeless tobacco or on the other hand discouraging the use of smokeless tobacco by women.

The use within the household and among close family members, has influenced the use of smokeless tobacco among women from a very young age. It was noted that parents who were using smokeless tobacco, offered it to their children (as young as 3 years of age).

A participant elaborated on how her father's habit of using smokeless tobacco got her initiated towards the same whilst within the same family her mother was opposing the use of it. She further added that her husband also discourages her use of smokeless tobacco now, however due to the addictive nature of the habit she is unable to stop.

> *"So, my father use to eat right, so I also ate a little and then I learnt using it. My mother use to yell at me for it, but my father would sneakily give it to me……. My husband knows, and he tells me a lot to forget about it but I am not able to stop using it" (26 years, 6 weeks post-partum)*

Similarly, other participants also mentioned about their spouse and other family members, suggesting stopping their use of smokeless tobacco.

> *(talking about her husband suggesting stopping smokeless tobacco use) "It gives me a little bit of tension. So, then it feels like to stop using it." (25 years, 5 months pregnant)*
>
> *"My mother-in-law says, and my husband also says to stop, but I am not able to quit. If I want to stop, I really feel like stopping. Many times, I have thought that I won't eat, but then still I feel like it and get tempted to eat it because until I don't eat it, I feel very uneasy. Don't feel like doing any work, nothing feels nice, and then the moment I put a little portion in the mouth, quickly I get all my work done." (25 years, 8 months pregnant)*

However, the participant further adds that despite her husband suggesting stopping the use of smokeless tobacco, his opinion doesn't matter, as the spouse himself consumes smokeless tobacco.

"He doesn't affect me. He eats it himself when he goes to the town … in the house he never asks or tells me if I want to consume it." (25 years, 8 months pregnant)

On the other hand, there was evidence that a strong family influence helped a woman quit smokeless tobacco during her first pregnancy but eventually during her second pregnancy, she continued using smokeless tobacco without her family noticing.

Before, then I use to not consume it. My father had made me swear by God (a personal belief) ……. So, the first one, my elder son time, I use to not use it. This time I am, but not a lot." (24 years, 8 months pregnant)

The influence of family members through this study appears to be mostly nudging, either in terms of using smokeless tobacco or suggesting stopping its use. A strong persuasive influence also comes across, especially with quitting the use of smokeless tobacco during pregnancy.

5.6.1.1 Secrecy behaviour related to smokeless tobacco use

One of the themes that strongly stood out during the interview process and the analysis was the secret behaviour related to smokeless tobacco use. The participants mentioned that no one in the family is aware of their smokeless tobacco habit and that it is something they consume secretly while doing their routine housework. Some exceptions were where a few participants mentioned that only their spouses were aware of the smokeless tobacco use within the family. Few narratives that highlight this secret behaviour are mentioned below.

"No, no one in the house knows. No even my father. No one" (23 years, 7 months pregnant)

"If my father finds out, he will yell at me. This I eat sneakily while doing work." (25 years, 5 months pregnant)

"Not even my father-in-law ... my mother-in-law consumes that also my father-in-law does not know." (26 years, 8 months pregnant)

However, this secret behaviour seems to be within the family only, as other women/peers who often work together in the community were aware of each other's smokeless tobacco use.

5.6.1.2 Accessibility of smokeless tobacco

The influence of family in relation to accessibility of smokeless products was also noted. Women mentioned that they were supplied the smokeless tobacco packets by family members. This contrasts with the previous section of secret behaviour of smokeless tobacco use. One of

the participants mentioned that she only gets the smokeless tobacco packets from her husband and if he doesn't get it for, she won't individually go to get them and at that point will eat food instead.

> *"If my husband provides only then … what to do, I am habituated now so. Can't do without it." (25 years, 5 months pregnant)*

Similarly, another participant mentioned that she craves smokeless tobacco to such an extent, that even an hour without it leads to a fight and as a result her father-in-law will get her the smokeless tobacco packet.

> *"If I don't eat it for even half hour, then I feel like fighting with someone. I am just not able to stop it. I end up fighting with my father-in-law, then he brings it for me … an hour I go without using it, I become all flighty." (26 years, 6 weeks post-partum)*

5.6.2 Changes in smokeless tobacco use during pregnancy

The women who were interviewed were at different time points during their pregnancy, including those who had just delivered. Hence, the responses captured their overall change in frequency of smokeless tobacco use, changes during the first trimester (participants were asked if there were any changes in their smokeless tobacco use in all three trimesters and the only changes, they reported were in first trimester) and attempt to quit during pregnancy.

5.6.2.1 Change in frequency

This section highlights the overall change in frequency of smokeless tobacco use during pregnancy. When participants were asked about their smokeless tobacco use and specifically if there had been any change in their use in general, three distinct scenarios were reported. Either women decreased or increased their use of smokeless tobacco at some point during their pregnancy or it was very much like their use of smokeless tobacco compared to pre-pregnant state. A participant reported that her use of smokeless tobacco increased compared to initial months of the pregnancy due to the watery sensation in the mouth (saliva build up in the mouth, which is often a symptom experienced by pregnant women).

> *"During the initial 2-3 months of the pregnancy, I use to eat it less … and then later as months progressed right. So, then I started consuming a little more … that watery feeling in the mouth happens right. So, I feel like to eat something. So, then I eat little portions of the this and so it has increased …. this watery feeling in the mouth, so that tempts to eat. What I can eat so that it feels good." (25 years, 8 months pregnant)*

"During the first pregnancy, I use to eat a lot of it. My daughter the first born right, that one year I use to eat a lot. One pouch I get, that will last for 2 days or 3 days. It's not like I won't eat it and it's also not like I keep eating it … little portion I put and then again it feels like that in the mouth, so then I gargle it off. Then again pop in little portions in the mouth." (26 years, 8 months pregnant)

The decrease in use of smokeless tobacco was primarily due to the influence of local health care workers and this is further discussed in the later sections.

"Before, I use to eat about 2-3-4 times a day. Now I have reduced a lot as madam said to not eat (referring to the local ASHA worker) … once in a while when I feel like it, I eat it." (24 years, 8 months pregnant)

Participants also mentioned that there was absolutely no change during pregnancy in their use of smokeless tobacco. This was noted not just with their current pregnancies, but also women reflecting back on their previous pregnancies.

"During all three pregnancies I use to eat. Not a lot, no increase, no decrease." (26 years – 6 weeks post-partum)

5.6.2.2 Changes during Trimester I

Participants were retrospectively asked to reflect on whether their smokeless tobacco use changed during their pregnancy. As such, they did not report or specific changes during trimester two and three but had reasons for change in increase and decrease in use of smokeless tobacco during their first trimester. Participants often reported that their use of smokeless tobacco during initial months of the pregnancy was similar to, and a continuation of, their use from the pre-pregnancy phase. This was reported in multiple ways; either of them clearly stating that their use was similar or reporting similar quantities when specifically asked about the quantity consumed before and during the pregnancy. Additionally, it was also noted that the use of smokeless tobacco either increased or decreased in the first trimester in response to pregnancy related symptoms.

"During the initial 2-3 months of the pregnancy, I use to eat it less … and then later as months progressed right. So, then I started consuming a little more" (25 years, 8 months pregnant)

Furthermore, not exactly a change in smokeless tobacco use during the first trimester, but very much related to the above narrative was the use of smokeless tobacco to combat the weird taste in the mouth.

> *"With these pills (medicines taken as part of ante-natal care), my mouth feels bitter right. So, then I pop a little in my mouth." (24 years, 8 months pregnant)*

On the flip side, the same participant reported that her use of smokeless tobacco was relatively less due to the nausea during the first trimester and that smokeless tobacco actually triggered nausea.

> *"No, there was no change as such. Initially during the pregnancy, that time "Vimal" doesn't taste that good the tobacco one. Feels like vomiting. So, can't eat a lot. As soon as I try to eat it, it would feel like vomiting so didn't eat then … then some day when I feel like tit, I ate it." (24 years, 8 months pregnant)*

Participants also often mentioned about having decreased their use of smokeless tobacco mostly later in their pregnancy. These were related potential harms smokeless tobacco could have on their pregnancy outcome and/or health in general and specifically related to trimester changes. Hence, these are reported in the following section.

5.6.2.3 Quit during pregnancy

Across various interviews, it came across that women attempted to consciously either reduce their use of smokeless tobacco or actually quit it during the pregnancy phase. This was mainly due to the influence and constant motivation from the local health workers (this is also described later in one of the sections and as part of the interviewer reflections). It seems that they tried to cut down on their use of smokeless tobacco due the potential harms or complications it can cause during pregnancy.

Some of the narratives that highlight key reasons for which the participants attempted to quit during their pregnancy are mentioned below.

> *"Thoughtfully I have decreased my use. Because blood is less right in my body. So, I don't eat it now. Then, at the time of delivery, they say of transfusion. So that's why, I have myself decreased the use. And don't eat it." (23 years, 7 months pregnant)*

"Everyone use to say these ladies and all that if I don't stop, they will have to transfuse blood and all. Maybe I have to have C-section. So, then I stopped." (22 years, 4 weeks post-partum)

Additionally, a participant also reported that perhaps quitting now for the benefit of the child and eventually completely quitting for her own good. Hence, realising that smokeless tobacco not only would affect her child but also is harmful for her own health.

"For the child … and now if I can stop it then it's good, right …. I always feel like it but won't eat it." (25 years, 5 months pregnant)

5.6.3 Knowledge about smokeless tobacco

This section was intentionally the last part of the topic guide to not provoke any guilt or anxiety related to smokeless tobacco use of the participants. As an observation, throughout the interviews, many participants were hesitant when questioned about their knowledge or awareness about what was being consumed. However, many beliefs and attitudes were picked up through the interviews which were related to the knowledge and awareness about smokeless tobacco.

5.6.3.1 Beliefs and attitudes

The general belief that consuming smokeless tobacco is so normal and that it will absolutely cause no harm was mentioned by many participants. This was often mentioned in the context of peers influencing the use of smokeless tobacco and persuading that it is completely fine to do so.

"So, all our friends that are there right. They all say, nothing will happen, just eat it…. So, I would put it in my mouth and it would feel nice. So then again, I would get it myself and eat it, like that." (25 years – 5 months pregnant)

The use of smokeless tobacco as an activity to kill boredom was also mentioned by one of the participants. Furthermore, the extent of smokeless tobacco use within the community highlights how normal and acceptable it is.

"This when I am not able to pass time so then I eat it. So, let me tell you. If anyone wants to eat they can eat. Who doesn't eat right now, everyone has it in their mouth." (26 years – 8 months pregnant)

It was strongly seen in many interviews that the use of smokeless tobacco was initiated as a result of peer and/or community influence. That is, it seemed so normal and common to women when they started the use of smokeless tobacco and that was related to the belief that there is no harm associated with it. It was perceived to be such a normal thing to do and hence there was no awareness about the product being consumed.

> *"This everyone before use to eat right, so little portions I also put in my mouth. From that got addicted." (25 years – 8 months pregnant).*

> *"To me, it is like, everyone is eating it then I also put small portions in my mouth ... that's what I feel." (23 years – 7 months pregnant)*

However, this appears to be the general belief at the time of initiating the use of smokeless tobacco, likely at a very young age. The following section highlights the change in beliefs and attitudes as a result of more awareness related to smokeless tobacco.

5.6.3.2 Knowledge related to the effect of smokeless tobacco on health

Participants generally were aware that the smokeless tobacco pouches (referred to as *Vimal*, which is a brand name, and that is how it is locally identified) contain tobacco and other additives. However, most were not aware that tobacco is a harmful substance in general. This lack of awareness was mainly when they had started the use of smokeless tobacco at an early age.

> *"If I had known, why would I have eaten it." (26 years, 8 months pregnant)*
> *"Everyone say that this is "Vimal" like that ... even if you ask a little child, they know about this. Inside, it has areca nut, and tobacco and then mix it all. That much I know." (24 years, 8 months pregnant)*

Over a period of time and there was an increase in awareness and realisation that what is consumed in form of these smokeless tobacco pouches is actually harmful. This increase in awareness was either via family influence (in one of the narratives reported below, a participant mentions about her husband telling her that it is harmful) or through the ASHA workers educating about potential complications or outcomes related to smokeless tobacco use during pregnancy.

> *"He says forget about it ... "Vimal" is not nice, it causes harm." (26 years, 6 weeks post-partum)*

"Thoughtfully I have decreased my use. Because blood is less right in my body. So, I don't eat it now. Then, at the time of delivery, they say of transfusion. So that's why, I have myself decreased the use. And don't eat it." (23 years, 7 months pregnant)

This section is relatively small as participants when questioned about their awareness mostly replied as one-word answers of "No" or "I don't know". There was also hesitancy and reluctance towards answering this question. This is an important finding suggesting the lack of awareness about product consumed and the harms associated with it initially to later increase in awareness. This new dimension of changing perceptions, or at least the knowledge that the use of smokeless tobacco is associated with some form of ill effect on health, is discussed later in this chapter (5.7.2.3).

5.6.4 Initiation of smokeless tobacco use

Conversations related to initiation of smokeless tobacco use among these women were around various aspects. Earlier, the influence of family towards initiation of smokeless tobacco was mentioned in section (8.1 Influence of family on use of smokeless tobacco). In terms of age at initiation and approximately when and how the use of smokeless tobacco started, it was noted that the habit formulated in early childhood for most women. They couldn't recall an exact age, however they mentioned that they have been using smokeless tobacco for a very long time, ever since they were a child.

"Ever since I was like this (referring to her first born, who is around 4 years), since then." (26 years, 6 weeks post-partum)

"Must be small ... 5-6 years." (33 years, 5 months pregnant)

While most of the participants mentioned about initiated the use of smokeless tobacco much earlier, one of the participants started using smokeless tobacco during the adolescent phase.

"Long time, ever since I finished 12th grade ... since then." (25 years, 5 months pregnant)

Additionally, peer and community influence towards initiation of smokeless tobacco use among women at an early age was evident in the interviews. Women often mentioned about initiating the use early in childhood/teen years as an influence of peers while performing routine chores.

"For no particular reason ... like this that I go to the farm right, so everyone eats. So that way started eating it and then go addicted to it." (25 years, 5 months post-partum).

The habit perhaps also started by experimenting or trying as it was consumed by everyone in the community surroundings of these women.

"Everyone was eating. So, 2-2 dana[10] (small pinch like portions) I ate. So, from that got habituated." (23 years, 7 months pregnant)

5.6.5 Influence of health care workers on use of smokeless tobacco

A new theme that strongly stood out in many interviews was the influence of health care workers on the use of tobacco among pregnant women. Participants often shared that they were trying to reduce the use of smokeless tobacco during their pregnancy based on the advice of the local lady health workers known as ASHA (Accredited Social Health Activist).

"Till 6 months of pregnancy, I was eating this. Then, I stopped. The sister (referring to the ASHA worker) use to tell me a lot so that's why." (22 years, 4 weeks post-partum)

"Before, I use to eat about 2-3-4 time a day, now I have reduced a lot as this madam said to not eat (referring to the local ASHA worker) .... once in a while when I feel like it, I eat it." (24 years, 8 months pregnant)

It was also noted that ASHA workers often shared extreme worst-case scenarios (some of which, potentially not evidence based) with pregnant women to encourage them to quit the use of smokeless tobacco during pregnancy. One of the post-partum participants shared the reason for which she quit the use of smokeless tobacco during her pregnancy.

"Everyone use to say these ladies and all that if I don't stop, they will have to transfuse blood and all. Maybe I have to have C-section. So, then I stopped." (22 years, 4 weeks post-partum

[10] *Dana* – is a local term which refers to small pinch like portions. To not take away from the actual meaning, the word is used as it is.

5.6.6 Intention to quit smokeless tobacco

In addition to an earlier theme about "quitting during pregnancy", women also mentioned about intention to quit in general. The willingness to reduce the use of smokeless tobacco gradually and slowly was mentioned by one of the participants.

> *"Yes, that if I can slowly reduce the use … so that way can stop it … so won't cause problem … and can stop it right." (25 years, 5 months pregnancy)*

Furthermore, one of the participants had tried to quit the use of smokeless tobacco before marriage and started again afterwards.

> *"I had tried before ... But then I came here (post marriage) and started again." (33 years, 5 months pregnancy)*

5.6.7 Postpartum phase

This section is about the two postpartum participants who had delivered just about a month before the interview. Interestingly, one of the participants reported no change in her smokeless tobacco use throughout any of her pregnancies, while the other person had consciously reduced her use of smokeless tobacco towards the end of her pregnancy. This highlights a very important aspect of pregnancy being the motivating factor. This change in reduction of smokeless tobacco use was due to the efforts of ASHA workers in spreading awareness related to harms of smokeless tobacco during pregnancy.

5.7 Discussion:

The findings of this study are important to understand how family, community and peers influence the use of smokeless tobacco among pregnant women. In this discussion section, I report some reflections from the in-depth interview process, summarise the key findings and interpret them with context of other relevant research findings. I then discuss strengths and limitations of the study and implications for policy, practice, and further research.

5.7.1 Interviewer reflections

This subsection highlights some of the observations from the in-depth interview process, which are an integral part in interpreting this qualitative study results.

Firstly, communicating with the participants was challenging despite spending a fair amount of time building rapport and interviewing them in a comfortable environment as per their preference. It was difficult to engage the participants in an effective conversation and their responses were often yes/no. This was potentially because the ASHA workers in the selected area were very active in educating women towards tobacco harms. Hence, the interviewees were conscious while responding towards their smokeless tobacco use. However, the participants did respond to most questions even if the replies were short.

Secondly, most women were unaware of what smokeless tobacco is and the effect it may have on the body when they initially started using smokeless tobacco. However, they were now aware that it is harmful and hence often they were hesitant or ignored when questioned about their knowledge of smokeless tobacco. Respecting their choice to not respond or comment on this, the interviewees were not further questioned on this. Later, I separately met with the medical officer and a few ASHA workers in the area and learnt that they were routinely engaging in tobacco prevention and control workshops or events to spread awareness and educate women towards harms of smokeless tobacco.

Lastly, the recruitment of participants was extremely challenging. As mentioned earlier in the methodology section (4.2), I had to expand the participant selection criteria from pregnant women in the third trimester who used smokeless tobacco to pregnant and/or post-partum who at any point in their pregnancy used smokeless tobacco. At the time of recruitment, many women agreed to participate in the interview and even shared their details to schedule the interview. However, later they denied that they ever used smokeless tobacco. Furthermore, one participant during the initial interaction was very positive about participating, and also engaged in an informal conversation with the researcher and later at the time of interview denied using smokeless tobacco ever (despite having talked about her smokeless tobacco use with the researcher earlier). This highlights that tobacco use estimates that are reported in national population surveys could potentially be under reported. Smokeless tobacco use is perceived to be acceptable within the community and does not have a taboo associated with it unlike tobacco smoking (Kakde, Bhopal and Jones, 2012; Shahjahan et al., 2017), however with increasing knowledge related to smokeless tobacco, this could potentially be changing. In India, the prevalence of smokeless tobacco use among women has declined from 18.4% (Singh et al., 2015) to 12.8% (Ruhil, 2019).

5.7.2 Key observations:

In this section, I discuss three key observations that emerge from this study analysis and discuss them with relevant literature.

5.7.2.1 Familial influence on use of smokes tobacco:

Firstly, with respect to the initiation of smokeless tobacco use. The use within the household and among close family members, has influenced the use of smokeless tobacco among women from a very young age. This is consistent with the GATS report, that about 17% of the women in India, start the use of smokeless tobacco before the age of 15 years (GATS India, 2018) and that the smokeless tobacco initiation is often linked to purchase activities for family members in early childhood (Narain et al., 2011).

Secondly, the current study also suggested that parents who were using smokeless tobacco, offered it to their children and that even during pregnancy women were supplied the smokeless tobacco packets by family members. A large Tobacco Control Policy Evaluation (TCP) India wave I survey conducted in 2018, indirectly quantifies this and reports that the odds of exclusive smokeless tobacco use among women were 2.1 (95% CI of 1.8-2.4) if the father ever used smokeless tobacco, 4.0 (95% CI of 3.3-4.7) if the mother ever used smokeless tobacco, 5.0 (95% CI of 4.3-5.9) if a close friend ever used smokeless tobacco and 4.3 (95% CI of 3.6-5.3) if the spouse ever used smokeless tobacco (Ray et al., 2016).

Lastly, it was noted that participants mentioned their spouse and other family members, suggesting stopping their use of smokeless tobacco during pregnancy. This opens a new dimension to tobacco control among women in LMICs, where family members are discouraging the use of smokeless tobacco during pregnancy and hence a possible opportunity to develop interventions in this context. This is discussed in detail in later sections (5.7.2.3). However, the study also highlights that even though the partner suggests stopping smokeless tobacco use during pregnancy, it potentially is not a strong influence if the partner uses smokeless tobacco as well. Quoting a participant's response that despite the husband suggesting stopping the use of smokeless tobacco, his opinion does not matter, as he himself consumes smokeless tobacco.

> *"He doesn't affect me. He eats it himself when he goes to the town … in the house he never asks or tells me if I want to consume it." (25 years, 8 months pregnant)*

This is an important finding as it mirrors the views of women who continue to smoke during pregnancy, when the partners ask a woman to stop smoking whilst continuing the habit themselves (Flemming et al., 2013). Furthermore, with respect to tobacco smoking, it is reported that quitting while living with a partner who smokes as well makes it more difficult and perhaps act as a barrier (Flemming et al., 2013). This potentially translates to smokeless tobacco use as well, given that women feel when others use it, why cannot they. This highlights the need to address smokeless tobacco control measures on a community level and inclusion of family in intervention development.

5.7.2.2 Attitudes related to smokeless tobacco use during pregnancy:

It is suggested that women initiate tobacco use often during pregnancy for various perceived benefits to combat pregnancy related symptoms such as nausea, constipation, vomiting (Kakde, Bhopal and Jones, 2012; Shahjahan et al., 2017). None of the participants from the current study started smokeless tobacco use during their pregnancy. However, the increase in their use of smokeless tobacco to combat common pregnancy related symptoms was evident. One such scenario was to use smokeless tobacco to avoid the watery feeling in the mouth. This is called ptyalism gravidarum, which refers to excessive saliva secretion during pregnancy (Van Dinter, 1991). This is often experienced by women during pregnancy along with nausea and vomiting. On the contrary to existing literature suggesting women using smokeless tobacco during pregnancy to avoid nausea (Shahjahan et al., 2017), one of the participants mentioned the nausea and vomiting during pregnancy was the reason to decrease smokeless tobacco use during pregnancy.

5.7.2.3 The perception and beliefs are changing:

Contrary to an earlier perception about smokeless tobacco use being acceptable in pregnancy, it would appear from the views expressed by the women in the study that this appears to be changing. Through these study results, it came across twice, slowly but surely, that views and beliefs are changing. Firstly, through a few participants mentioning about their family members unaware of their use of smokeless tobacco, and in a few instances the family members discouraging the use of smokeless tobacco during pregnancy. If the social acceptance and use of smokeless tobacco behaviour was considered normal, women would not feel the need to hide it. Hence, this suggests that the socio-cultural integration of smokeless tobacco use among women is slowly changing. However, it is important to bear in mind that the socio-cultural integration still exists, but the small change is evident.

Secondly, this study highlights a very important potential aspect of tobacco control, that is integration of ASHA workers in intervention delivery. Participants mentioned having reduced or completely quit their smokeless tobacco use during pregnancy as they had low haemoglobin and/or to avoid blood transfusions. The participants were told so by the ASHA workers, that if they continue to use smokeless tobacco, this could potentially be one of the complications. There is some evidence in the literature that suggests that use of smokeless tobacco during pregnancy may lead to anaemia and affect the health of the foetus and the mother (Subramoney and Gupta, 2008) and the toxins in smokeless tobacco may lead to poor nutrition outcomes in mother and foetus (Pednekar et al., 2006). However, the method by which these messages are delivered to women needs to be done in a systematic way by offering the ASHA workers appropriate training and spreading awareness based on evidence. A possible approach that can be researched further is to adapt, assess the feasibility and acceptability is the use of the 5A screening tool (WHO 2017). This tool is a five-step screening tool designed for health care providers to firstly identify women who smoke and then help women communicate if they desire to quit. This approach may help integrate ASHA workers in offering cessation interventions for pregnant women who wish to quit or reduce their smokeless tobacco use during pregnancy. This is further important as, women in general (based on GATS survey 2016-2017), who attempted to quit, only 2.7% opted for pharmacotherapy and about 8% who opted for counselling. The majority of women attempted to quit smokeless tobacco without any assistance. This could potentially be due to low support for cessation and hesitancy of women smokeless tobacco users to access cessation centres and/or quit lines (Murthy and Saddichha, 2010). Hence, if pregnancy can potentially be a motivating factor and if these women are offered the appropriate support, the quit attempts and quit success can potentially be improved.

In general, the normality towards a common and acceptable behaviour of smokeless tobacco use among family members is perhaps changing for women. The secret behaviour of smokeless tobacco of women within the family is contradictory to the perceived norms that it is acceptable and socially well taken. Perhaps, it could be explored if familial support and encouragement combined with the cessation help during pregnancy through ASHA workers (however this needs to be properly evidenced based and systematic) might help reducing smokeless tobacco use during pregnancy.

5.7.3 Strengths and limitations:

5.7.3.1. Strengths:

In this sub-section I discuss some strengths of the study.

Firstly, the diversity of the participants (even though initially the idea was to recruit participants in the third trimester of the pregnancy) really added to the richness of the data. Especially inclusion of postpartum women, allowed to capture how smokeless tobacco use was throughout the pregnancy and whether the changes during pregnancy persisted or changed (if at all). This enriched the study by understanding that pregnancy was a motivation to reduce/quit smokeless tobacco use and once the pregnancy ended, so did the motivation and hence the participant started smokeless tobacco use as a pre-pregnant state. This could potentially be explored further to understand whether providing appropriate and adequate support to women who were motivated to reduce/quit during pregnancy, would help maintain the quit attempt longer.

Secondly, the broader context related to socio-cultural context. The objective of this study was to capture how family members, community and peers influence smokeless tobacco use initiation or change in practice during pregnancy. In addition to the study objectives, the interviews were also able to capture other socio-cultural aspects related to smokeless tobacco use among women in India, such as how women started the use of smokeless tobacco, their attitudes/beliefs, and their knowledge of smokeless tobacco.

Lastly, the framework approach for analysis of this qualitative research. The preceding systematic (literature) review related to smokeless tobacco use among women from LMICs built the base of the framework used for analysis in this study. Firstly, this provided a basic guidance for the topic guide and made the analysis more systematic. Secondly, the inductive and deductive approach of data analysis, added onto the already pre-existing themes around the topic. This was a great opportunity to compare what was already known and contrast at the same time with newer data from this study. Also, the study findings further added a new pregnancy related dimension to the context of smokeless tobacco use among women in LMICs.

5.7.3.2. Limitations:

In this subsection, I discuss a few limitations of this study, along with some reflections on how the study could have been conducted better.

Small number of women recruited in the study: Given that only eight women were interviewed, it is difficult to generalise from this study, but there is an indication of various aspects related to familial influence on use of smokeless tobacco among women, especially during pregnancy. Furthermore, the use of smokeless tobacco, beliefs surrounding its use and to an extent of familial influence towards smokeless tobacco use among women, especially during pregnancy are somewhat picked up in the preceding review as well. This validates the findings from this study, along with adding new dimensions and more in-depth understanding of familial influence on smokeless tobacco use during pregnancy.

Recruitment process: As the ASHA workers in the area identified participants who were then approached for the interviews (just the identification part), there was a general hesitancy. This of course was evident as the recruitment was challenging, but also the participants who were part of the study appeared to be slightly conscious during the interview. This was particularly the case when asked about their knowledge related to smokeless tobacco. As mentioned earlier in the interviewer reflection section (5.7.1 Interviewer reflections), the ASHA workers routinely engaged in tobacco control education workshops and events, and hence participants were consciously addressing this. Potentially, if the recruitment was independent of ASHA workers, the interviewees may have engaged in effective communication with the researcher.

Reluctance of the participants to discuss things in detail during the interview: In general, talking about tobacco use during pregnancy is a sensitive topic and hence it was not a surprise when women were somewhat hesitant or reluctant to discuss things in detail during the interview. This was especially the case when questioned about their knowledge related to the product and smokeless tobacco per se. Throughout the interview and whole data collection process, it was ensured that participants' comfort and willingness to answer was maintained and hence when slightest discomfort was noted, no further questions into that context were continued. However, the interviews still offered some very valuable information which would strengthen the existing literature on smokeless tobacco use in pregnancy.

Environmental considerations with respect to the secret behaviour of women related to smokeless tobacco use: A point that stood out here is that how able participants were to discuss things they likely keep secret from their family. Given that their use of smokeless tobacco was

very much a personal thing, hidden from the family (especially parents), makes it challenging to understand the influence family potentially has on the behaviour. However, the secret behaviour from the family, on its own, is an indirect family influence challenging the previous literature that suggest a normality and acceptance of smokeless tobacco use among women.

First time interviewer: In addition to achieving the objectives of the study, the whole process of planning and conducting this study was also a learning experience for me as a PhD student. Prior to this, I did not have the experience of conducting the interviews and hence the whole process was challenging. To overcome this, I did use the resources provided by the university and engaged in multiple online tutorial videos to understand the art of being an interviewer. Furthermore, the PPI engagement also provided the opportunity to practice the interview skills. However, the initial couple of interviews could have been better and I was much more comfortable after a few interviews and was better able to present the questions. But, as this was a learning opportunity and due to lack of resources as a PhD study, this was the best possible option. In future, perhaps a more experienced interviewer and one from the community or someone with better understanding of the culture might be able to conduct the interviews more effectively.

Resource limitation: The initial interview material (consent forms, patient information sheets and topic guides) was translated and back translated by two individuals (fluent in both Gujarati and English), but this protocol was not followed for the interview transcripts due to resource limitation and feasibility. I do acknowledge that ideally, the interview transcripts need to be translated and back translated by two independent individuals who are bilingual to ensure the correct interpretation of the interviews. However, as part of a PhD study and resource constraints, all the transcripts were first transcribed verbatim and later translated to English only by me. I did back translation just to check any alterations in interpretation however, a researcher bias is likely.

5.7.4 Implications for policy, practice, and further research

Key recommendations or considerations to further tobacco control efforts in India that are highlighted through this study is discussed in this subsection.

5.7.4.1 For policy and practice:

Community based interventions: if the overall perceptions and norms related to smokeless tobacco are starting to change, which of course is seen more now than before, it is likely to prevent women from initiating the experimental or peer influenced use of smokeless tobacco, eventually preventing the cultivation of habit. A positive change that comes out from this study is the secret behaviour related to smokeless tobacco use with the family members. This suggests that women generally do not talk about their smokeless tobacco use within the family but are very comfortable among her peers who often work together or share a similar environment with her. Hence, if the general awareness related to smokeless tobacco harms, especially targeting the overall belief of normality is addressed, it is likely to help decrease smokeless tobacco use among women.

5.7.4.2. Further Research:

Inclusion of ASHA workers in tobacco control: To consider inclusion of ASHA workers to deliver tobacco control prevention and control interventions. However, to offer the appropriate training and knowledge to educate women with evidence-based facts. This could potentially be combined with community-based interventions or with inclusion of family support. As mentioned earlier one of the approaches to address this could be to adapt, assess feasibility and acceptability of the 5A screening tool (WHO 2017).

Furthermore, the study could have benefitted or further strengthened if women's partners were also interviewed. This would have contributed to the perceptions and beliefs within the family and especially of the partners who may be key facilitators/barriers. Additionally, the partners may not be as hesitant as the women themselves and might have contributed to more detailed responses. Hence, this perhaps could be researched further to better inform tobacco control measures during pregnancy.

6) CHAPTER VI: Overall discussions and conclusions

In this chapter, I firstly summarise and combine the evidence from all three studies. Secondly, I discuss the overall implications for policy and practice and the way forward with respect to recommendations and need for further research. I then discuss the strengths, limitations, and reflections of my research. Lastly, I conclude with some key contributions of the thesis.

6.1 Summary of evidence

Tobacco use among women in LMICs is lower than HICs, however tobacco consumption between pregnant and non-pregnant women in 42 LMICs did not differ, which is concerning. On the other hand, a significantly higher use of smokeless tobacco among pregnant women compared to non-pregnant women in SEAR warrants further investigation and public health measures to address this. Furthermore, the secondary data analysis of the DHS also suggests social disparities with the use of smokeless tobacco across LMICs. That is smokeless tobacco use is significantly higher among those who are less educated and those from low socioeconomic status. This trend further extends to smokeless tobacco use during pregnancy and strengthens the current literature that social disparity is evident with use of smokeless tobacco across LMICs.

An important factor in the socio-cultural context related to smokeless tobacco use among women is age and reasons for its initiation. Women often initiate the use of smokeless tobacco in their younger age due to various reasons; a general belief that it is socially acceptable and relieves indigestion and toothache (Murthy et al., 2018). Other reasons include experimenting (Tonstad et al., 2013), peer influence (Mathew, Noronha and Kamath, 2016; Hossain et al., 2016; Begum et al., 2015), and to combat various pregnancy related symptoms (Singh et al., 2009). The qualitative study I conducted, further strengthens this evidence. That is, the habit of smokeless tobacco formulated in early childhood for many women. Peer and community influence towards initiation of smokeless tobacco use among women at an early age was also evident in the interviews. Women often mentioned about initiating the use early in childhood/teen years as an influence of peers while performing routine chores.

It is evident from various studies included in the systematic review I conducted, that family members have an impact on the use of smokeless tobacco among women. Further the narratives of women also show that elderly family members offer young people smokeless tobacco (Shahjahan et al., 2017), and that pregnant women initiated due to influence of older relatives to combat various pregnancy related symptoms (Singh et al., 2009). However, at the same time, there is also evidence that family members have discouraged the use of smokeless tobacco when pregnant and that has had an influence on the woman on reducing the use of smokeless tobacco (Nair et al., 2015). Similarly, Singh et al (2015) reported that no women in the study conducted in India, initiated smokeless tobacco use during pregnancy; 78% did not change their habit, while 18.6% decreased their use of smokeless tobacco use during pregnancy. This is further strengthened through the qualitative study I conducted in India, where participants have mentioned about their spouse and other family members, suggesting stopping their use of smokeless tobacco during pregnancy, while some participants kept their use of smokeless tobacco a secret from their family members. Hence, it appears that the normality towards a common and acceptable behaviour of smokeless tobacco use among family members is perhaps changing for women when pregnant.

The qualitative study also reported the influence of ASHA workers on the use of smokeless tobacco among pregnant women. Participants often shared that they were trying to reduce the use of smokeless tobacco during their pregnancy based on the advice of ASHA. However, these messages need to be delivered to women in a systematic way by offering the ASHA workers appropriate training and spreading awareness based on evidence. A possible approach that can be researched further is to adapt, assess the feasibility and acceptability is the use of the 5A screening tool (WHO 2017). Perhaps, it could be explored if familial support and encouragement combined with the cessation help during pregnancy through ASHA workers might help reducing smokeless tobacco use during pregnancy.

6.2. Implications for public health policy and practice:

The need to address tobacco use among women of reproductive age in LMICs: The prevalence estimates of tobacco use in LMICs among women may seem low but is still a concern globally and strong implementation of the WHO Framework Convention on Tobacco Control measures are required to prevent the rise in its use among women (Mehrotra et al., 2019). Behavioural interventions for smokeless tobacco cessation seem suitable for LMICs (Nethan et al., 2018) and integration of socio-cultural context specific to women is warranted to potentially increase the acceptability of tobacco control interventions. Hoe and colleagues

suggest a framework to help implement tobacco control policies in LMICs and a component of it mentions integration of norms, practices, and beliefs for policy compliance (Hoe et al., 2019). Therefore, there is a need to develop preventive and cessation interventions to decrease tobacco use (smoking and smokeless) among women who are from low socio-economic status and less educated, as they bear the greatest burden of tobacco use. If ignored as a public health issue and the tobacco industry continues to market its products to women, the level of tobacco use may rise as it did in HICs.

Integration of socio-cultural context to address smokeless tobacco control in SEAR: The common misconceptions and false beliefs related to smokeless tobacco have been reported in several studies. Their repetitiveness across studies strengthens cultural imbibement and the general acceptability of its use in the community encourages women to use smokeless tobacco. These beliefs are not related to smoking tobacco but very evident for smokeless tobacco (Graham, 2012). Therefore, the integration of socio-cultural context in addressing smokeless tobacco use among women in SEAR is required. Perhaps, community level awareness related to harms of smokeless tobacco, is likely to help decrease the prevalence of smokeless tobacco. Either preventive measures or cessation aids that educate the women collectively will help as peer influence and offering by elders in the family are common reasons to initiate and/or continue the use of smokeless tobacco. Furthermore, a lot of these studies have focused on specific communities that are likely to have higher prevalence of smokeless tobacco use, which re-iterate that need for community-based interventions.

The CATCH approach for smokeless tobacco cessation in SEAR, recommends developing gender-friendly and culturally appropriate cessation aids (WHO 2018). Perhaps, the evidence from this study might help design appropriate interventions for women. This is especially important as despite India setting a good example with availability of quit lines, about 90% of the women who attempted to quit smokeless tobacco, did so without any assistance (GATS India, 2018). Additionally, as mentioned in the earlier recommendation that integration of socio-cultural context is important for acceptability of tobacco control measures (Hoe et al., 2019).

Pregnancy, a potential opportunity for smokeless tobacco cessation: Some studies report that women increase their use of smokeless tobacco during pregnancy, while some report no change in their use. However, there is some evidence now that women are likely to quit smokeless tobacco use during pregnancy. Pregnancy is a motivating factor for smoking cessation (Van T. Tong et al., 2013) and women often spontaneously quit when pregnant. Therefore, if pregnancy is a “teachable moment” (Olander et al., 2016), then despite the

frequency of smokeless tobacco use, tobacco control interventions may help if appropriately designed (Phelan, 2010). Olander and colleagues (2016) further build on this context and suggest that pregnancy not only is a motivating factor but also changes a woman's capabilities and opportunities for behaviour change.

However, it is essential to consider the approach for behaviour change among pregnant women. That is to develop supportive approaches such that pregnant women seek cessation interventions rather than feel guilty and move away from the need to seek help (Wigginton and Lee, 2013). Even though the didactic advice by ASHA workers seems to have helped women quit smokeless tobacco during pregnancy, the approach adopted is not appropriate. A study related to smoking among pregnant women suggests that the didactic tone from health professionals irritates women and further makes them feel secluded (Grant et al., 2020). Therefore, it is vital to not stigmatise pregnant women using smokeless tobacco and adapt more sensitive approaches to support these women.

As mentioned in the previous chapter, a possible approach that can be researched further is to adapt, assess the feasibility and acceptability is the use of the 5A screening tool (WHO 2017). This approach may help integrate ASHA workers in offering cessation interventions for pregnant women who wish to quit or reduce their smokeless tobacco use during pregnancy.

6.3. Recommendations for further research

Community based interventions in SEAR to address the norms and cultural acceptance of smokeless tobacco: To address smokeless tobacco control during pregnancy, it is important to develop community-based interventions. This could potentially help change the overall perceptions, norms and acceptability related to smokeless tobacco which is likely to prevent women from initiating the experimental or peer influenced use of smokeless tobacco, eventually preventing the cultivation of habit. Firstly, there is a need to develop interventions that incorporate the cultural context related to address the beliefs and attitudes related to smokeless tobacco use. Secondly, the evidence suggests the importance of increasing awareness and preventive interventions amongst the youth; that either strengthen the preventive measures to reduce initiation by youth or offer effective cessation interventions early in age as they may not be that habituated to smokeless tobacco yet and hence quitting might be easier.

Inclusion of ASHA workers in tobacco control: To consider inclusion of ASHA workers to deliver tobacco control prevention and control interventions. However, to offer the appropriate training and knowledge to educate women with evidence-based facts. This could potentially be combined with community-based interventions or with inclusion of family support. As mentioned earlier one of the approaches to address this could be to adapt, assess feasibility and acceptability of the 5A screening tool (WHO 2017).

This could perhaps also be explored in other South-Asian countries as they share similar socio-cultural context. The inclusion of primary health care setups and lady health workers to deliver tobacco control interventions might help reduce the use of smokeless tobacco among women. The CATCH approach for smokeless tobacco cessation in India, suggest that the existing health capacities are inadequate and recommend inclusion of smokeless tobacco cessation in routine public health programs (WHO 2018). An addition to this recommendation could possibly be the inclusion of ASHA workers, of course with appropriate training and resources.

Targeted and tailored interventions for pregnant women: Women are likely to reduce or quit smokeless tobacco during pregnancy, as evident from the qualitative study conducted in India. This was influenced by family members of pregnant women and advice from the ASHA workers. Perhaps, it can be further explored how to increase these influences to help more women quit during pregnancy. Additionally, it is also important to provide adequate support and access to cessation aids to quit during pregnancy which may also help sustain quit rates longer. However, smokeless tobacco cessation interventions among pregnant women need to be investigated further, especially avoiding any stigmatization. A potential step ahead is intervention development that is socio-culturally appropriate, that can be delivered in a systematic way, and test its feasibility and acceptability.

6.4. Strengths of the research

Tobacco control research has generally been focused on smoking, however, research on other forms of tobacco is also gaining some attention. But there is still a dearth of evidence related to smokeless tobacco use and even more sparse literature on its use among women, and during pregnancy. Hence, one of the major strengths of my thesis is its focus on smokeless tobacco use among women and during pregnancy, especially in the LMICs which bears most of its burden. In this section, I further discuss some of the strengths of the thesis and the contribution of my thesis to the existing literature.

6.4.1 Strengths

A key strength of this thesis is its robustness and systematic methodology for all the studies, to address the research objectives of my doctoral work.

- **Study A (secondary data analysis of the DHS data):** The study offered the advantage of a large, nationally representative sample of women of reproductive age, that was collected using standardised methodology across all countries. Furthermore, regression analysis on large sample of about 1.3 million women to estimate the relative risk ratios of tobacco use, accounting for clustering based on countries, strengthens the reported estimates. To ensure proper statistical analysis and to account for missing data, such that all available data was included in the analysis, a statistical plan was followed.

- **Study B (mixed-method systematic review):** Though the review, had a very broad inclusion criteria which made the analysis a challenge, but the fact that it was able to capture several socio-cultural factors both quantitative and qualitatively, related to smokeless tobacco use among women in LMICs is a key strength of the review. A predefined protocol of the review was registered on PROSPERO, which ensured that appropriate steps were followed in conducting the review and that the reporting of findings was guided by the PRISMA guidelines (Moher et al., 2010). Furthermore, the review provides robust findings on socio-cultural context, as the quantitative and qualitative findings echo each other.

- **Study C (In-depth qualitative interviews in India):** The design of this qualitative study, was guided by the preceding mixed-method systematic review, which on its own ensured appropriate literature-based development and planning of the study. The thematic synthesis from the review was used to develop a topic guide and framework for the qualitative data analysis. In addition to that, PPI engagement and informal meetings with the ASHA workers, medical officer, and some community members, offered the advantage to better design the study based on the local population centric input. Moreover, the participant information sheet and consent forms were translated and back translated to ensure that the correct and complete information was being given to the participants. The study also received dual ethics approval, which further ensured that the sensitivity related to the topic and the participants were considered and maintained throughout. Furthermore, the in-depth interviews were able to capture information from women during different stages of pregnancy and hence allowed for

an understanding of how their smokeless tobacco use and influences changed throughout pregnancy.

Another key strength is the multi-method approach used to address the research objectives of my doctoral work. The diversity of the studies, and their ability to complement, and feed into each other have allowed for a better understanding of the context related to smokeless tobacco use among women of reproductive age and during pregnancy in LMICs; a quantitative study first estimating the recent most prevalence rates of tobacco use among pregnant and non-pregnant women, followed by a mixed-method systematic review understanding the socio-cultural context related to smokeless tobacco use among in LMICs and lastly a qualitative study to further explore the familial influence on its use during pregnancy. Furthermore, the inclusion of quantitative and qualitative studies in the review allowed to capture all possible literature available in this regard from LMICs. The in-depth interviews were especially key in terms of understanding the "how" factor related to familial influence on smokeless tobacco use during pregnancy. The diversity is not just limited to the studies, but also the analysis method for the qualitative parts of this thesis. That is the use of thematic synthesis for the qualitative component of the systematic review and using that for the framework development for the analysis of in-depth interviews conducted as part of the qualitative work in India.

6.4.2 Importance of the research and contributions

Despite widespread use of smokeless tobacco in nearly 140 countries, research in this area is limited. Let alone the scarcity of research on smokeless tobacco, the focus on women, especially during pregnancy, is even more scarce. To reduce smokeless tobacco use among women and during pregnancy, it is first important to understand the extent of its use, the population it is mainly prevalent among and the socio-cultural context. Hence, the findings from my doctoral work contribute to the existing literature on smokeless tobacco use among women of reproductive age and further extends to its use during pregnancy in LMICs. In this section, I discuss the contributions and importance of findings from each study.

Study A (secondary data analysis of the DHS data): Through this study. I have updated the previously reported estimates by Caleyachetty and colleagues (2014) and provided more robust findings. Firstly, the estimates were generated for exclusive smoking, exclusive smokeless tobacco use and dual tobacco use which is more specific than the previously reported estimates (i.e. smoking, smokeless tobacco use and any tobacco use). Secondly, a comparison of estimates among pregnant and non-pregnant women further provides a more

detailed understanding of its use among women of reproductive age. Lastly, the multinomial regression analysis to estimate the relative risk ratios, is a unique contribution to the existing literature by quantifying tobacco use based on pregnancy status, accounting for various socio-demographic factors. Furthermore, pregnant women being 7% more likely to use smokeless tobacco compared to non-pregnant women in SEAR is alarming, and an important finding for future tobacco control measures in the region.

Another important contribution from this specific study is findings related to smoking during pregnancy in LMICs that emerged from the secondary data analysis. Though the thesis was focused on smokeless tobacco use among women of reproductive age and during pregnancy, the secondary data analysis (Chapter III) additionally reported prevalence estimates for smoking among women. This perhaps is very important evidence for public health measures in LMICs, novel in terms of estimating the relative risk ratios of smoking based on pregnancy status on such a large sample. The lack of statistically significant difference in smoking among pregnant and non-pregnant women, is alarming and warrants the need for more awareness and cessation support for pregnant women in LMICs.

Study B (mixed-method systematic review): The amalgamation of quantitative and qualitative findings related to socio-cultural context of smokeless tobacco use among women in LMICs strengthens the current evidence in this regard. The findings from the review have added to the previously conducted review by Kakde and colleagues (2012), which included the socio-cultural context to South Asian Populations. My findings extend beyond the South-Asian population and further are focused on women's use of smokeless tobacco in LMICs (which includes Africa and South Asia). This is significant as the extensive use of smokeless tobacco in LMICs, and especially the inclination of its use among women during pregnancy for various reasons (4.4.1.4), require an understanding of the socio-cultural factors, beliefs, attitudes and perceptions related to smokeless tobacco. The findings from this review provide integral information (such as social disparity, reasons and age of initiation, influence of family and peers etc) to develop tobacco control measures and public health awareness to decrease the use of smokeless tobacco among women.

Study C (In-depth qualitative interviews in India): The qualitative study conducted in India is unique on its own as the whole study was focused on smokeless tobacco use during pregnancy, especially on how the family and community/peers influence its use. To the best of understanding, no study thus far has explored this context of smokeless tobacco use during pregnancy, especially qualitatively by interviewing pregnant women themselves. The findings contribute towards better understanding of smokeless tobacco use during pregnancy, and

further highlight an important context related to influence of family and community/peers on its use. Additionally, a new perspective, about potentially a small but evident change in the norms and acceptance related to smokeless tobacco is a very novel finding. This perhaps is an opportunity for tobacco control measures in India, that can be explored further to curb the smokeless tobacco use among women. Furthermore, the influence of ASHA workers and the potential of them delivering tobacco control interventions is an extremely important finding and warrants further research.

6.5. Limitations of the research

The quantitative findings of my doctoral work are all derived from cross-sectional data (i.e., secondary analysis of the DHS data and quantitative studies included in the systematic review) which is mostly self-reported and hence is one of the limitations of this research. Women often fear judgement and guilt when questioned about tobacco use in conjunction with maternal and child health history. Hence, the fact that the DHS is mainly a maternal and child health survey, under-reporting is expected. This is evident as the estimates reported through DHS are much lower than those reported by GATS; the GATS conducted in India in 2016 reported a 2% prevalence of smoking and 12.8% of smokeless tobacco use among women (GATS India, 2018), compared to estimates of 0.43% and 3.21% respectively from this thesis based on the DHS data. Having said this, the DHS data allows to compare tobacco use and pregnancy status/outcomes, which other data sets do not offer, and hence was the appropriate data for the research objectives.

Another limitation is the generalisation of findings from the qualitative study. Given that the study was focused in one selected population with only eight in-depth interviews, generalising the findings would be inappropriate. But the use of smokeless tobacco in the study population is not much different than the rest of the country; prevalence of smokeless tobacco use among adults in India is 21.4% and that in the province of Gujarat is 19.2% (GATS India, 2018). Also, the culture and customs are relatable within the country and perhaps to other south-Asian countries and therefore the findings from this population/research zone could be generalized to the country and SEAR *per se* to some extent. However, findings from my study serve as an initial step to explore this further and strengthen the evidence related to influence of family on use of smokeless tobacco during pregnancy and potential of inclusion of community health workers in tobacco control measures targeted at women of reproductive age.

6.6. Reflections

On a personal front, the whole journey of my doctoral studies has truly been rewarding in terms of learning new skills, to understanding the field of research and global public health, and most importantly developing a passion to continue working in this area. Prior to commencing my PhD journey, my knowledge and skills related to quantitative analysis was very minimal and hence learning statistics and its implication in epidemiology is one of the key skills I have developed. The secondary data analysis of the DHS data is not only an important study that has contributed to smokeless tobacco research, but also given me the opportunity to learn and polish my quantitative analysis skills. Working on such a large data set from several countries was a challenge, especially when I have re-done the analysis countless times, but that has only worked in my favour. Later in the PhD journey, the literature and systematic review pointed towards a familial influence on smokeless tobacco use during pregnancy and I adopted to conduct a qualitative study in India. This further added to my data analysis skills, especially in public health to amalgamate quantitative and qualitative findings. Furthermore, learning and adapting two different qualitative analysis methods gave me the opportunity to better understand qualitative health research and broaden my skills to be able to perform multi-method analysis/studies. I am truly grateful for the opportunity to learn these diverse skills and apply them to my doctoral work.

However, this has been a learning journey and retrospectively looking back, if I was to do anything differently, I would have rather opted for a mixed-method approach rather than multi-method approach to address my doctoral research. Perhaps, if the mixed-method approach was prespecified prior to commencing the studies, I would have been able to amalgamate both quantitative and qualitative findings in a more systematic way. Also, in relation to the systematic review, maybe a scoping review would have been better suited as the studies were cross-sectional and it was challenging to report the descriptive analysis in a review format. Having said that, the systematic review approach assured a more quality controlled reporting of findings.

In addition to study objectives, I was also very much interested in understanding the association of smokeless tobacco with various perinatal outcomes. This is an area which I would like to explore further, especially with very diverse smokeless tobacco products, the associations need to account for various constituents and composition of products. A prospective cohort study accounting for these variations is required to further strengthen the current literature regarding association of smokeless tobacco use during pregnancy and perinatal outcomes.

6.7 Conclusion

Smokeless tobacco use during pregnancy in LMICs is an important public health concern which is understudied. I have attempted to address this knowledge gap and strengthen the already existing evidence related to tobacco control among women in LMICs. The cumulative evidence from all the three studies I conducted suggest the following:

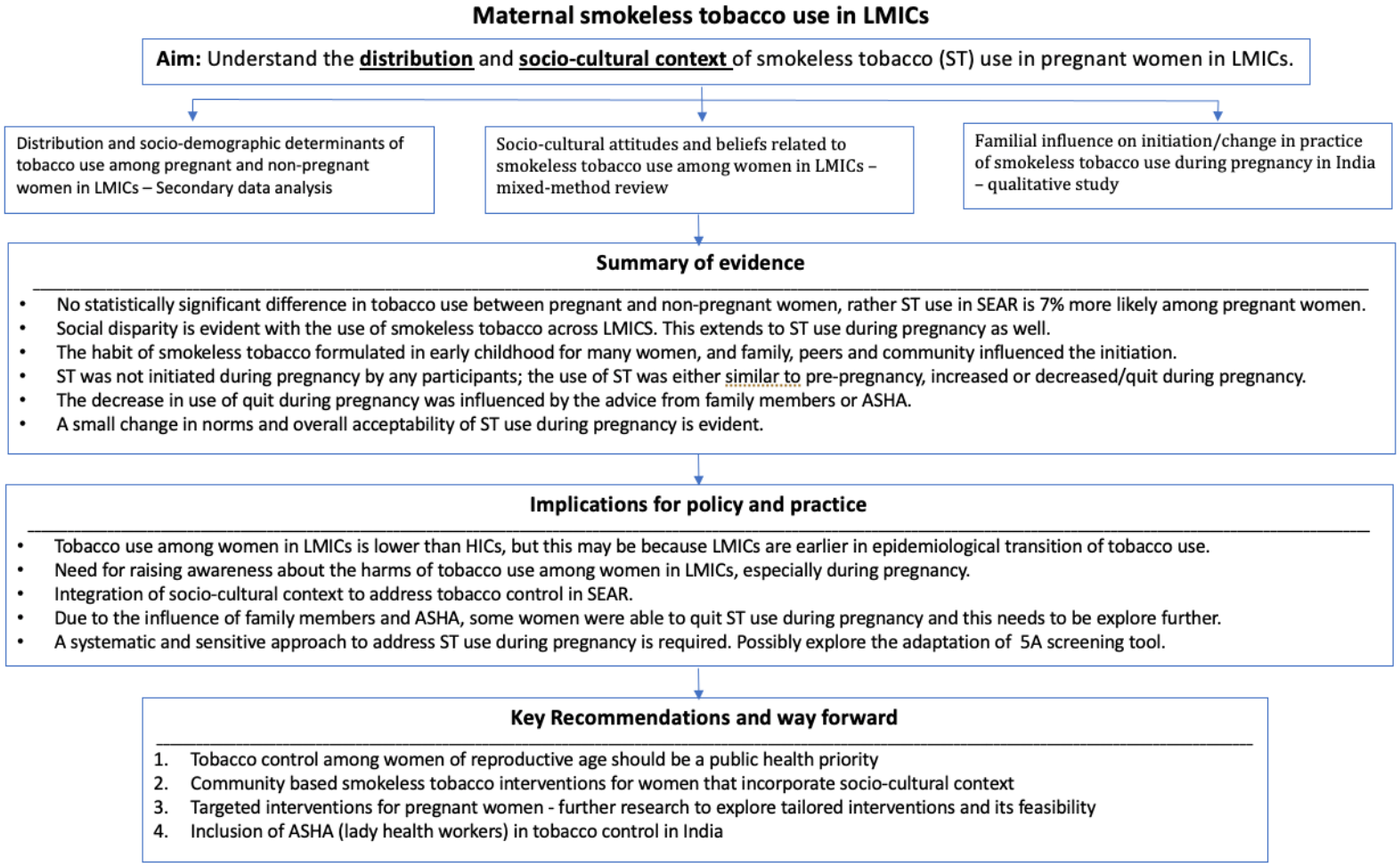
1. Tobacco control among women of reproductive age should be a public health priority in LMICs despite the low prevalence estimates as this may be that LMICs are earlier in epidemiological transition and if ignored may cause an increase in tobacco use later.

2. To address the use of smokeless tobacco during pregnancy, integration of socio-cultural context is very important, either through tobacco control policies or implementation of tobacco control interventions. A possible approach is to develop and implement community interventions to prevent the initiation of smokeless tobacco use, especially among the youth.

3. Targeted and tailored interventions for smokeless tobacco cessation during pregnancy – the norms and general acceptability of smokeless tobacco use among women during pregnancy is changing. The change is small but definitely evident. Perhaps, pregnancy is possibly an opportunity for smokeless tobacco control interventions in India and maybe in other countries of the SEAR. Hence, this needs to be explored further, especially offering the women a choice whether she wants cessation support. Also, potentially inclusion of family support along with behavioural interventions might help reduce smokeless tobacco use during pregnancy and need to be studied further.

4. Inclusion of ASHA workers in tobacco control in India – ASHA are an integral part of maternal and child health in India and their inclusion in the tobacco control interventions may be beneficial. However, this needs to be researched further and a systematic approach accounting for appropriate evidence-based knowledge dissemination, sensitivity towards the context and most importantly, offering women the choice to seek support is required. One of the approaches to address this could be to adapt, assess feasibility and acceptability of the 5A screening tool for smokeless tobacco cessation.

Figure 6.1: Info-graphic summary of the thesis and the way forward.



7) Appendices

Appendix 3.1. Statistical analysis for the secondary analysis of the DHS data (42 LMICs)

Population characteristics and summary statistics: Following commands were used in STATA to generate descriptive summary statistics.

List of variables for distribution and population characteristics

Variable	**Label**	**Response**
V213	Currently pregnant	Yes or No/unsure
V012	Age (current age in years)	Numerical
V025	Area of residence	Rural or urban
V106	Highest education level	No education Primary education Secondary education Higher education
V190	Combined wealth index This is calculated based on assets the family has and thus the combined wealth index is common among all household members.	Poorest Poorer Middle Richer Richest

Weight Variable / 1000000
Svyset [pw=weight variable], psu (primary sampling unit variable) strata (strata variable)

tab v213
tab v213[iweight=wgt]
by v213: summarize v012[iweight=wgt]
by v213, sort: tab v025[iweight=wgt]
by v213, sort: tab v106[iweight=wgt]
by v213, sort: tab v190[iweight=wgt]

Generating outcome variable: The following commands were used to generate the variable "tobacco use" categorised as exclusive smoking, exclusive smokeless tobacco use, dual tobacco use and no tobacco use.

List of tobacco use variables

Variable	Label	Response
V463a	Smokes cigarettes	Yes or No
V463b	Smokes pipe	Yes or No
V463c	Uses chewing tobacco	Yes or No
V463d	Uses snuff	Yes or No
V463e	Smokes cigars	Yes or No
V463f onwards	Use of country specific tobacco	Yes or No

STEP I:

```
egen smoke = rowtotal (v463a v463b v463x), missing
codebook smoke
recode smoke 2=1 3=1
codebook smoke
egen smokeless = rowtotal (v463c v463d), missing
codebook smokeless
recode smokeless 2=1 3=1
codebook smokeless
```

STEP II:

```
gen tobacco = .
replace tobacco = 1 if (smoke == 1 & smokeless == 0)
replace tobacco = 2 if (smoke == 0 & smokeless == 1)
replace tobacco = 3 if (smoke == 1 & smokeless == 1)
replace tobacco = 0 if (smoke == 0 & smokeless == 0)
codebook tobacco

label define TobaccoUse 0 "None" 1 "Exclusive Smoking" 2 "Exclusive
smokeless" 3 "Dual"
label values tobacco TobaccoUse
```

Generating prevalence estimates: The following commands were used to generate prevalence estimates of tobacco use for pregnant and non-pregnant women in 42 countries.

```
by v213, sort: tab smoke[iweight=wgt], missing
by v213, sort: tab smokeless[iweight=wgt], missing
by v213, sort: tab anytobacco[iweight=wgt], missing
by v213, sort: tab tobacco[iweight=wgt], missing

svy: tab v213 smoke, row se ci
svy: tab v213 smokeless, row se ci
```

svy: tab v213 anytobacco, row se ci
svy: tab v213 tobacco, row se ci

For meta-analysis of tobacco use, following commands were used for pregnant and non-pregnant women.

metaprop ExSmoke_Preg Tobacco_response_rate_n, random by(Country) ftt cimethod(score) dp (4)
metapropExSmokeless_PregTobacco_response_rate_n,randomby(Country) ftt cimethod(score) dp (4)
metaprop Dual_Preg Tobacco_response_rate_n, random by(Country) ftt cimethod(score) dp (4)
metaprop None_Preg Tobacco_response_rate_n, random by(Country) ftt cimethod(score) dp (4)

Multinomial regression analysis: As an initial step, data from all countries were appended to a single data file in STATA. A new variable was generated in file labelled as "country" before appending to account for the clustering in the regression analysis. Following logistic regression commands were then run on the compiled data for the regression analysis.

mlogit tobacco i.v213 i.v025 i.v106 i.v190 v012, cluster (country) rrr nolog
mlogitgof
mlogtest, wald
bootstrap, bca reps (500) seed (1345) : mlogit tobacco i.v213 i.v025 i.v106 i.v190 v012, cluster (country) rrr nolog

Appendix 4.1. Systematic review search tree

#1	attitude
#2	approach
#3	belief
#4	character
#5	disposition
#6	mindset
#7	opinion
#8	perspective
#9	behaviour
#10	philosophy
#11	point of view
#12	standpoint
#13	view
#14	prejudice
#15	sentiment
#16	manner
#17	conduct
#18	etiquette
#19	ethics
#20	morals
#21	habit
#22	performance
#23	practice
#24	ritual
#25	demeanour
#26	tradition
#27	inner nature
#28	mentality
#29	awareness
#30	knowledge
#31	cognisance
#32	reasoning
#33	understanding
#34	traditional customs
#35	culture
#36	influence
#37	customs
#38	values
#39	rural
#40	urban
#41	education
#42	literacy
#43	wealth
#44	socioeconomic
#45	poverty
#46	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 40 or 41 or 42 or 43 or 44 or 45
#47	smokeless tobacco

#48 spit tobacco
#49 chewing tobacco
#50 snuff
#51 oral tobacco
#52 quid
#53 chew
#54 plug
#55 paan
#56 betel nut
#57 reca nut
#58 gutka
#59 ipping
#60 naswar
#61 zarda
#62 mishri
#63 khaini
#64 mawa
#65 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64
#66 woman
#67 women
#68 female
#69 gender disparity
#70 girls
#71 maternal
#72 mother
#73 pregnant
#74 prenatal
#75 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74
#76 Afghanistan
#77 Benin
#78 Burkina faso
#79 Chad
#80 Comoros
#81 Democratic Republic of Congo
#82 Ethiopia
#83 Gambia
#84 Guinea
#85 Haiti
#86 Korea
#87 Liberia
#88 Madagascar
#89 Malawi
#90 Mali
#91 Mozambique
#92 Nepal
#93 Niger
#94 Rwanda
#95 Senegal
#96 Sierra Leone
#97 Somalia
#98 Tanzania

#99 Togo
#100 Uganda
#101 Zimbabwe
#102 Armenia
#103 Bangladesh
#104 Bhutan
#105 Bolivia
#106 Cambodia
#107 Cameroon
#108 Cote d'Ivoire
#109 Egypt
#110 Ghana
#111 Guatemala
#112 Honduras
#113 India
#114 Indonesia
#115 Kenya
#116 Kyrgyz Republic
#117 Leostho
#118 Mauritania
#119 Mongolia
#120 Morocco
#121 Myanmar
#122 Nigeria
#123 Pakistan
#124 Papua New Guinea
#125 Philippines
#126 Sri Lanka
#127 Sudan
#128 Swaziland
#129 Tajikistan
#130 Timor-Leste
#131 Ukraine
#132 Vietnam
#133 Yemen
#134 Zambia
#135 Low-Middle Income countries
#136 Developing countries
#137 LMICs
#138 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123 or 124 or 125 or 126 or 127 or 128 or 129 or 130 or 131 or 132 or 133 or 134 or 135 or 136 or 137
#139 46 and 65 and 75 and 138

Appendix 4.2. Data extraction form (quantitative and qualitative)

This data extraction form is adapted from the Cochrane Public Health Group Data Extraction and Assessment template and further modified for this review.

1.

Study ID:	**Report ID:**	**Date form completed:**
First author:	Year of study:	Data extractor:
Citation:		

2. Study Eligibility

Study Characteristics			**Page/ Para/ Figure #**
Type of study (Review authors to add/remove designs based on criteria specified in protocol)	☐ Cross-Sectional ☐ Case-Control ☐ Cohort	☐ Qualitative	
	☐ Mixed-Method	☐ Other design (specify):	
	Does the study design meet the criteria for inclusion? Yes ☐ No ☐ →Exclude Unclear ☐		
	Description in text:		
Participants (Review authors insert inclusion criteria as defined in Protocol)	Describe the participants included:		
	Are participants defined as a group having specific social or cultural characteristics?	Yes ☐ No ☐ Unclear ☐ Details:	
	How is the geographic boundary defined?	Details: Specific location (e.g. state / country):	
	Do the participants meet the criteria for inclusion?	Yes ☐ No ☐ →**Exclude** Unclear ☐	

Include in review ☐ **Exclude from review** ☐	
Independently assessed, and then compared? Yes ☐ No ☐	Differences resolved Yes ☐ No ☐
Request further details? Yes ☐ No ☐	Contact details of authors:

Notes:

3. Study details

Study intention	**Descriptions as stated in the report/paper**	**Page/ Para/ Figure #**
Aim of study		
Inclusion		
Exclusion		
Equity pointer: Social context of the study	*e.g. was study conducted in a particular setting that might target/exclude specific population s? See also Inclusion/exclusion criteria under Methods, below.*	

4. Participant Characteristics

	Descriptions as stated in the report/paper	**Page/ Para/ Figure #**
Total number of participants	Male = Female =	
Country of study		
Context of the study		
Age group		
Education		
Income		
Socio-economic status		
Pregnancy status		
Notes	Focused group Personal interviews	

5.1 Outcome: Social correlates

Social correlates	**Context/quantitative assessment**	**Page/ Para/ Figure #**
Age	Method: Sample size: Response rate: Analysis: Results:	
Education	Method: Sample size: Response rate: Analysis: Results:	
Socio-economic status	Method: Sample size: Response rate: Analysis: Results:	
Attitudes and beliefs	Method: Sample size: Response rate: Analysis: Results:	
Social acceptability	Method: Sample size: Response rate: Analysis: Results:	
Cultural norms and acceptability	Method: Sample size: Response rate: Analysis: Results:	
Family influence	Method: Sample size: Response rate: Analysis: Results:	

Knowledge about harms and health effects	Method: Sample size: Response rate: Analysis: Results:	

5.2 Outcome: Cultural Correlate

Cultural correlates	**Context/quantitative assessment**	**Page/ Para/ Figure #**
Initiation reasons		
Continuation reasons		
Pregnancy		
Other		

6. Comments

Appendix 4.3. Quality assessment tools

Adapted New-Castle Ottawa Scale for Cross-Sectional Studies

Domain		**Grading**
Selection	Representativeness of the sample	Truly representative of the average in the target population (i.e., All subjects or random sampling). - **1 point** Somewhat representative (non-random sampling). - **1 point** Convenience sample or no description. - **0 points**
	Sample size	Satisfactory (includes sample size calculations) or representative. - **1 point** Not justified or no information. - **0 points**
	Non-respondents	Satisfactory recruitment (proportion of target sample size achieved) or description of non-respondents reported. - **1 point** Recruitment unsatisfactory or no information provided. - **0 points**
	Ascertainment of the exposure (risk factor)	Recall/self-reported and records verified - **1 point** Recall and self-reported only - **0 points**
Comparability	Comparability of subjects in different outcome groups Confounding factors are controlled	Data adjusted for relevant confounders (i.e., age, sex, education etc) - **2 points** Data not adjusted for relevant confounders or information not provided. - **0 points**
Outcome	Assessment of outcome	Use of tobacco validated by objective methods (i.e., cotinine levels) - **2 points** Self-reported use of tobacco measurement. - **1 point** No description or no information - **0 points**
	Statistical testing	Appropriate statistical test used for data analysis and measures of association presented clearly (i.e., confidence intervals, p-values etc) - **1 point** Statistical test no appropriate, not described or no information provided. - **0 points**
Total		

Very Good Studies: 9-10 points

Good Studies: 7-8 points

Satisfactory Studies: 5-6 points

Unsatisfactory Studies: 0 to 4 points

NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE

CASE CONTROL STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Selection

1) Is the case definition adequate?
    a. yes, with independent validation ∗
    b. yes, eg record linkage or based on self-reports
    c. no description
2) Representativeness of the cases
    a. consecutive or obviously representative series of cases ∗
    b. potential for selection biases or not stated
3) Selection of Controls
    a. community controls ∗
    b. hospital controls
    c. no description
4) Definition of Controls
    a. no history of disease (endpoint) ∗
    b. no description of source

Comparability

1) Comparability of cases and controls on the basis of the design or analysis
    a. study controls for _____ (Select the most important factor.) ∗
    b. study controls for any additional factor □ (This criteria could be modified to indicate specific control for a second important factor.)

Exposure

1) Ascertainment of exposure
    a. secure record (eg surgical records) ∗
    b. structured interview where blind to case/control status ∗
    c. interview not blinded to case/control status
    d. written self report or medical record only
    e. no description
2) Same method of ascertainment for cases and controls
    a. yes ∗
    b. no
3) Non-Response rate
    a. same rate for both groups ∗
    b. non respondents described
    c. rate different and no designation

NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE

COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

Selection

1) Representativeness of the exposed cohort
    a. truly representative of the average _____ (describe) in the community ∗
    b. somewhat representative of the average _____ in the community ∗
    c. selected group of users eg nurses, volunteers
    d. no description of the derivation of the cohort
2) Selection of the non exposed cohort
    a. drawn from the same community as the exposed cohort ∗
    b. drawn from a different source
    c. no description of the derivation of the non exposed cohort
3) Ascertainment of exposure
    a. secure record (eg surgical records) ∗
    b. structured interview ∗
    c. written self report
    d. no description
4) Demonstration that outcome of interest was not present at start of study
    a. yes ∗
    b. no

Comparability

1) Comparability of cohorts on the basis of the design or analysis
    a. study controls for _____ (select the most important factor) ∗
    b. study controls for any additional factor ∗ (This criteria could be modified to indicate specific control for a second important factor.)

Outcome

1) Assessment of outcome
    a. independent blind assessment ∗
    b. record linkage ∗
    c. self report
    d. no description
2) Was follow-up long enough for outcomes to occur
    a. yes (select an adequate follow up period for outcome of interest) ∗
    b. no
3) Adequacy of follow up of cohorts
    a. complete follow up - all subjects accounted for ∗
    b. subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost) ∗
    c. follow up rate < ____% (select an adequate %) and no description of those lost
    d. no statement

CASP Checklist: 10 question checklist for qualitative research

Are the results of the study valid? (Section A)
What are the results? (Section B)
Will the results help locally? (Section C)

Section A:

1. Was there a clear statement of the aims of the research?
2. Is a qualitative methodology appropriate?
3. Was the research design appropriate to address the aims of the research?
4. Was the recruitment strategy appropriate to the aims of the research?
5. Was the data collected in a way that addressed the research issue?
6. Has the relationship between researcher and participants been adequately considered?

Section B:

7. Have ethical issues been Yes taken into consideration?
8. Was the data analysis sufficiently rigorous?
9. Is there a clear statement of findings?

Section C:

10. How valuable is the research?

Appendix 4.4. Characteristics and results of included studies in the mixed-method review (provided as a separate MS Excel document)

Quantitative studies | Mixed method studies | Qualitative studies

	Author Year	Study objective	Study population Sample size	Prevalence estimates	Method (analysis)	Results (related to ST use only)	Additional information
1	**Azam M et al 2016**	To investigate the prevalence of smokeless tobacco, its initiation influence and risk factors associated with the practice among the low socio-economic populations of Bangladesh.	Adults aged 15 years and above (460 consecutive eligible SLT users) 230 women	Mean age (females) = 43.97±11.24 All ST users as part of inclusion.	Descriptive and logistic regression (not applicable as relates to other diseases).	**Family history of ST use** = 63 (27.4%). **Initiation of ST:** 8% initiated SLT habits below the age of 15 years. Mean age at initiation = 25.83±9.75. **Duration of use of ST (years):** mean = 18.13+/-11.91	
2	**Begum S et al 2015**	To examine initiation of ST use among women across different reproductive stages.	ST using married women between the ages of 18 and 40 409 women 42 in depth interviews (half of them pregnant)	Mean age 30.1 (±6.2) years and mean age at marriage was 16.2 (±2.9) years.	Descriptive and logistic regression. Dependent variable: Initiation of ST use before and after marriage. Independent variables: age, education, childhood exposure, age at marriage, reason for initiation. Thematic analysis	Mean age at initiation = 20.1 (±7.5) years. Initiation post marriage = 68% - Out of the total 44.5% initiated after marriage but before first pregnancy, 18.1% during their first pregnancy, and another 5.1% between pregnancies. Main reason for initiating SLT use was alleviation of teeth and gum problems. About 12% of women learned to use SLT from their SLT - consuming husbands at different points in their post marital reproductive stages. **AOR(95% CI) for initiation of ST use (reference = pre-marriage)** **Age (reference >30years):** those <30 = 0.53(0.32-0.87). **Education (reference = literate):** Illiterate = 0.9(0.53-1.52). **Childhood exposure (reference = no):** Yes = 0.34(0.15-0.77). **Age at marriage (reference >18years):** <18 years = 2.43(1.4-3.9) **Reason for initiation (reference = other):** oral problems = 1.85(1.13-3.02).	**Initiating before marriage** = pleasure (feel fresh, feel happy, like the smell and taste, and for passing time) and means of learning to use SLT before marriage was through friends (31.1%) and parents (25%). **Initiation post marriage but prior to first pregnancy** = tooth and gum problems and means of learning was through neighbours, (22.5%), relatives (22%) and by observing (21.4%). **Initiating during first pregnancy** = to avoid symptoms of pregnancy (vomiting, nausea, morning sickness and gastric problems). During first pregnancy women mentioned learning to use SLT on their own by observation (32.4%) followed by neighbour (20.3%). Several narratives in the text
3	**Bhan N et al 2012**	To provide prevalence estimates and OR patterns of tobacco consumption in India based on two rounds of a national survey.	Adults (15-49 years) 255028 women over two survey rounds	2 rounds of NFHS survey (1998-1999 and 2005-2006) 255028 women over two survey rounds.	Logistic regression analysis Dependent variable: Chewing tobacco Independent variables: Wealth index, education, area of residence, caste, survey year.	**ORs (95% CI) for chewing tobacco (reference = non users)** **Education (reference = postgraduate):** College educated = 1.84(1.55-2.19), high-school education = 2.19(1.86-2.57), primary education = 2.87(2.44-3.4) and no education = 3.85(3.27-4.53). **Wealth quintiles (reference = richest):** Richer = 1.48 (1.41-1.56), middle = 1.75 (1.66-1.85), poorer = 2.14 (2.02-2.27) and poorest = 2.67 (2.5-2.84). **Area of residence (reference = large city):** Small city = 1.23(1.13-1.32), town = 1.36(1.27-1.45) and village = 1.07(1.01-1.14).	
4	**Bista B et al 2015**	To assess women tobacco habits with reference to socio-demographic data.	Women (15-69 years) 2797 women	Current use of any form of chewing tobacco = 4.8% (3.8-6.0)	Frequency and multivariable logistic regression Dependent variable: Current daily ST use Independent variables: age, ecological region, residence, education and marital status.	**AOR for current daily ST users compared to non users:** **Age (reference = 15-29 years)**: 30-44 years = 3.0(1.3-7.2) and 45-69 years = 4.1(1.5-10.9). **Residence (reference = rural):** urban = 0.7(0.2-0.4). **Education (reference = no formal education)**: primary = 0.5(0.3-0.9), secondary = 0.5(0.2-1.2) and higher = 0.1(0.0-0.3). **Marital status (reference = never married)**: currently married = 1.1(0.3-3.7) and divorced/widowed = 0.6(0.1-2.9).	
5	**Etu E et al 2018**	To estimate the prevalence and health effects of ST use in a region of Ethiopia.	Adults aged above 18 years 220 women	79 (12.4%) prevalence of daily ST use among females. 31 (4.9%) prevalence of occasional ST use among females.	Descriptive and multi-variable logistic (not applicable as analysis performed for all participants together and hence female users cannot be isolated). Thematic analysis	**Intention to quit:** 16 (5.6%) = tried to stop in the past 12 months. 37 (12.9%) = advised by health professionals to stop using ST in past 12 months. **Family Influence:** 56 (19.5%) = family members using ST 83 (28.9%) = close friend smokes or chews ST. **Socio-cultural characteristics:** 53 (25.2)% initiated ST use under the age of 25. 23 (8%) = dual users (smoking and smokeless)	Several narratives in the text

	Author Year	Study objective	Study population Sample size	Prevalence estimates	Method (analysis)	Results (related to ST use only)	Additional information
6	**Gupta B et al 2014**	To determine the nature, extent and demographic correlates of knowledge, attitudes and percentages of tobacco use among adults.	Adults aged 15 and above Individual country samples	Bangladesh, Brazil, India, Mexico, Philippines, Poland, Russia, Thailand, Ukraine, Uruguay, Vietnam	Summary statistics	**Percentage (95% CI) of females who believe that using ST causes serious illness:** Bangladesh 92.9(91.4-94.1), Brazil 69.5(68.5-70.5), India 87.3(86.3-88.2), Mexico, 70.3(68.5-72), Philippines 50.2(47.9-52.5), Poland 44(41.4-46.7), Russia 47.3(44.2-50.4), Thailand 72.9(71.3-74.5), Ukraine 42.9(40.4-45.4), Uruguay 55.6(52.4-58.7) and Vietnam 57.1(55-59.1).	
7	**Gupta PC et al 1996**	Socio-demographic characteristics related to tobacco use for a prospective cohort study to assess cause-specific mortality attributable to use of tobacco.	Adults aged 35 years and above 59527 women	Current ST use: 34019 (57.1%). Dual use: 94 (0.2%). Ex-ST users: 1284 (2.2%)	Frequency and descriptive	**ST use and education (description)** 72.2% of illiterate = ST users 52% of primary educated women = ST users 39.5% of middle school educated, 23.9% of secondary level educated and 10% of college educated = ST users. **Religion and ST use:** 57.7% Hindus are ST users, 83.5% Buddhist, 48.7 Muslims, 17.4% Christians, 13.1% others.	
8	**Hossain M et al 2014**	To estimate prevalence and correlates of ST use among women living in rural areas of Bangladesh.	married women aged 18 years and above with at least one pregnancy in their lifetime 8074 women	Mean age = 38.5 +- 15.3 Average age at first use = 31.5 +- 11.7 years.	Descriptive and multivariate regression analysis Dependent variable = Current ST users Independent variables = age, education, religion, income, occupation and marital status.	**AOR: Current ST users compared to never users** **Age (reference <24years):** 25-44yr = 3.08 (2.26-4.20) and >45yr = 19.7 (14.2-27.2). **Education (reference = no formal education)**: primary education = 0.42(0.32-0.55), secondary = 0.39(0.19-0.78) and tertiary = 1.16(0.9-1.3). **Religion** compared to Muslims, Hindus/other = 0.46(0.31-0.69). Compared to **income earner**, non income earner = 2.08 (1.48-2.91). **Occupation** (reference = housewife): unemployed = 7(5.45-8.98) and employed = 2.1(1.02-4.3). **Marital status** (reference = currently married): Divorced/widowed = 1.8(1.4-2.2).	**Never consumption** = 2488, 30.8% 29.8-31.8 **Ever but not current** = 3559, 44.1% 42.9-45.2 **Current consumption** = 2027, 25.1% 24.2-26.1
9	**Hossain M et al 2016**	Investigate women's knowledge regarding the health effects of ST use and their quit attempts and intention.	married women aged 18 years and above with at least one pregnancy in their lifetime 8074 women	*Same as the study Hossain M et.al (2014). Mean age = 38.5 +- 15.3 Average age at first use = 31.5 +- 11.7 years.	Frequency, summary statistics, proportions. Logistic regression for associations between inaccurate knowledge. Dependent variable: Inaccurate knowledge Independent variables: age, education, occupation, religion and marital status.	**AOR (95% CI) of inaccurate knowledge related to ST use compare to those with accurate knowledge (reference)** **Age (reference <25 years):** 25-44 years = 0.95(0.73,1.24) and >44yrs = 2.71(2.05-3.58). **Level of education (reference=secondary/tertiary):** primary = 1.81(1.38-2.38) and no formal education = 2.18(1.66-2.85). **Religion (reference=Hindu/others)**: Muslims = 17(12-23.9). Occupation (reference=housewife): Unemployed = 29.7(25.2-35.1) and employed = 1/07(0.48-2.40). **Marital status (reference= currently married)**: divorced/widowed = 0.80(0.65-0.98).	Current consumers (2027): 23.8% think ST is good for health, 28.7% think it is good for digestion, 17.5% think its good for headache, 18.3% for toothache and 7.3% for stomach ace.
10	**Mamudu H et al 2013**	Estimate tobacco use prevalence in 17 sub-Saharan African countries and further identify key determinants of tobacco consumption choices in Madagascar.	Women aged 15-49 years 17375 women	ST prevalence = 9.6%	Prevalence estimates Multinomial regression analysis dependent variable: tobacco use Independent variables: age, residence, occupation and wealth index	Compared to no tobacco use: **RRR Occupation (reference = unemployed):** agriculture = 2.36 (1.76-3.16), manual labourer = 2.44 (1.77-3.37). **Age** (linear, with every unit increase in age): RRR 1.05 (1.04=1.05. **Wealth index** (linear, with every unit increase in wealth index): RRR = 0.59 (0.52-0.66). **Residence** (reference = rural): Urban = 1.0 (0.76-1.31). **For females, comparison not made for education due to insufficient sample.**	
11	**Mathew S at al 2016**	To identify the practices of ST use among married women (20-50 years).	Married women (20-50 years) 800 women	90/800 = 11.25% (ST prevalence)	Descriptive	Easily available = 100% Family members provide ST = 51.1% Awareness on ST = 16.7% ST is less dangerous than smoking = 95.6% 6.7% = parental influence led to initiation Use by other family members = 95.6%	Thought about quitting = 12.2% **Initiation reasons:** Parental influence = 6.7%, peer influence = 13.3%, just for fun = 24.4%, personal problems = 26.7%, toothache = 28.9% **Continuation reasons:** Relieves tension = 36.7%, habituated = 63.3%

	Author Year	Study objective	Study population Sample size	Prevalence estimates	Method (analysis)	Results (related to ST use only)	Additional information
12	**Mishra G et al 2015**	Understand the patterns and predictors of ST use among urban low socio-economic women in India	Women tobacco users	Women tobacco users (22.3% of the total female population in the survey area).	Descriptive for type of tobacco use (various types of ST) and frequencies. Multivariate regression for tobacco use as dependent variable and age, education, income, occupation and marital status as independent variables	**Multivariate regression analysis: OR** **Age (reference = 30-40 years):** 35-39 = 1.25(1.1-1.4), 40-44 = 1.5(1.3-1.7), 45-49 = 1.7(1.5-1.9), 50-54 = 2.2(1.9-2.6), 55-59 = 2.4(2.03-2.9) and 60-64 = 2.04(1.6-2.5). **Education (reference = illiterate):** literate without formal education = 0.6(0.5-0.8), school = 0.53(0.4-0.58), high school/undergraduates = 0.2(0.1-0.25) and graduates/above = 0.1(0.06-0.2). **Income (reference = <2000 INR):** 2001-5000 = 1.09(0.8-1.4), 5001-10,000 = 0.9(0.7-1.3), 10,000-15,000 = 0.6(0.4-0.9) and >15,000 = 0.6(0.4-1). **Occupation (reference = housewife):** Manual labour = 1.2(1.1-1.4), service = 0.7(0.5-0.9) and self-employed = 0.7(0.6-0.9). **Marital status (reference = single):** married = 1.6(1.1-2.2), divorced/separated = 2.4(1.8-3.8) and widowed = 1.8(1.2-2.5).	The mean age at initiation of tobacco use was 26.23 years
13	**Murthy P et al 2018**	To understand the perception of why ST is used and examine if user and health provider perceptions can provide insights for tobacco control.	58 key informant interviews; 37 ST users and 21 health care providers	Among the 37 SLT user KI's, a majority were males (62%). A third (32.3%) was illiterate, 6 (16.2%) educated to the primary level and the remaining educated up to high school or higher. KI's included house- wives (16.2%), skilled/semi-skilled workers (27%), blue collar workers (27.2%), daily wage earners (8%), executives (5.4%) and unemployed persons (16.2%).	Descriptive and themes in FGDs.	**Perceived reasons for use of ST among women:** **Health care providers:** 21% = boredom, 53%=habit, 21%=relief of sadness and 32%=multiple reason. **ST users:** 19%=enjoyment, 16%=boredom, 35%=habit, 19%=relief of tiredness and 8%=relief of sadness. **Continuation:** Because of liking, habit and cravings. **Beliefs:** Perceived desired effect on women: most commonly lifts up mood, freshens up. Health workers think it also helps with psychological relief and helps person work better.	**Knowledge:** feels causes no adverse effects. **Intention to quit:** Most the women SLT users in the FGDs had not heard of or been exposed to any prevention programs. They felt that there was active promotion of the products in the shops. They complained that the price had gone up (the concept of demand and supply). Hence did not feel the need to quit. **Initiation:** Female role model in family or society, feel warm or reduce discomfort after a meal. The general feeling among the women SLTusers was that the community accepts it.
14	**Nair S et al 2015**	Patterns of daily tobacco use and correlates of poly-ST use among married women aged 18-40 years. A mixed-method study, however, the quantitative part is for frequency and patterns of ST use. Hence only the qualitative part of the study is part of this review.	Married women of reproductive age (18 to 40). 409 women (62 pregnant) 42 in-depth interviews	Participants were married daily ST users living in a slum community in India.	Thematic analysis	There were no significant differences between currently pregnant and non-pregnant women by type of users (single vs poly SLT user), or daily frequency or amount of use. Further, though the survey data revealed no consistent trajectories of change in SLT use across pregnancies, the following qualitative examples show that there are increases and decreases in SLT use as well as consistency of use prior to and during pregnancy. "Initially I used to have 2–3 times in a day, at times 3–4 times in a day and then one packet in a day, then 2 packets in a day. I eat only gutkha, because I like the taste. It contains supari (betel nut), chemicals, zarda and tobacco. When I came to know that I am pregnant that time I felt more craving and started eating 15–20 packets in a day. But my sister, mother-in- law and husband made me understand that it is not good for me because I am pregnant. Then I reduced eating and started eating only 4 times in a day". {PD15: 19 year old, 1st pregnancy- , single user (gutkha)}	*At the time of my first delivery, when the ward boy shifted me to the bed and left, I opened the packet and made tobacco and put it in my gum. Then I felt relief because during delivery when I was having labour pain that time I was very tired so I felt like eating tobacco. . . " {PD 24: She is a 32 year old, poly SLT user (chewed tobacco, mishri) with two children}.* *Pan and guthka are different; it does not have the same taste; pan is spicy and it gives "jum jum" feeling in the teeth. But in gutkha there is less spice and the smell is good. It gives freshness in the mouth—". {PD 10: 22 year old pregnant woman, poly SLT user (pan with tobacco, gut- kha and gul), one child}* Several other narratives in the text
15	**Petersen A et al 2018**	To explore Ethiopian women's knowledge, attitudes and beliefs related to tobacco use, second-hand smoke exposure and khat use	Women 18-55 years 353 women		Frequencies	7 (2.1%) think it is acceptable for women to use SLT 331 (93.8%) - think women who use SLT harms her health. 333 (94.6%) - thinks a mother who uses SLT harms her baby. How much influence your religion have on your attitude towards tobacco use (all tobacco) - 73.2% say "a lot", 34% say somewhat, a little or none.	
16	**Prabhakar B et al 2012**	To assess disparities in use of tobacco based on education and occupation.	Adults aged 15 years and above 35345 women	16.9% = SLT users 9.6% in 15-19 years age group 13.4% in 21-25 years age group	Prevalence estimates and multivariate analysis Dependent variable = Current tobacco use Independent variable = age, education and occupation	**AOR: current ST use only (reference = never tobacco users)** **Education (reference post grad completed):** higher secondary = 2.49 (1.96 - 3.18), secondary = 4.36 (3.57 - 5.34), primary = 7.19 (5.88 - 8.79) and illiterate = 8.33 (6.83 - 10.16). **Occupation (Reference self-employed)**: student = 0.48 (0.39-0.48), homemaker = 0.5 (0.46-0.55), retired = 0.61 (0.38-0.79).	
17	**Ray C S et al 2016**	To quantify the associations of tobacco use with its use by close social contacts, according to sex.	Adults aged 15 years and above 4244 women	2552 women ST users (42.6%).	Binary logistic regression analysis: Dependent variable = exclusive ST use in women Independent variables = father, mother, close friend and spouse use of ST products. Adjusted for age, residence, income	**AOR: for exclusive ST use among women compared to no use.** 2.1 (1.8 - 2.4) = father ever used SLT 4.0 (3.3 - 4.7) = mother ever used SLT 5.0 (4.3 - 5.9) = close friend uses SLT 4.3 (3.6 - 5.3) = Spouse uses SLT	

	Author Year	Study objective	Study population Sample size	Prevalence estimates	Method (analysis)	Results (related to ST use only)	Additional information
18	**Schensul, J. et al 2018**	To identify women ST users' challenges to quitting and multilevel correlates of readiness to quit.	Women aged between 18-40, married and using at least one type of SLT. 409 women (62 pregnant)	SLT prevalence rate among women in the study area = 31.4%	Percentages, Chi Square and Multinomial logistic regression Dependent variable = Readiness to quit Independent variables = age, literacy, type of user, amount of ST use, health warnings, advice on quitting	"paan with tobacco is natural with no chemicals" (70%). Most frequently mentioned were "paan should be eaten after a non-vegetarian meal (60%) or after any meal" (56%), "paan should be used in wedding gatherings" (48.4%) and "mishri should be used for toothache"45%). Most (67%) thought that the best way to quit was on their own and only 12% mentioned help from a health care provider. However, 54% reported that someone in their family would support them to quit and 65% expressed interest in speaking to an anganwadi worker about reducing their use. Sixty-nine percent of respondents reported that a person close to them had advised them to quit.	The most frequently mentioned beliefs "which" were "smokeless tobacco relieves "labour pain" (86%) and body pain" (81%), "mishri strengthens the teeth during pregnancy" (75%). The study's 39% 12 month quit attempt rate among single users is comparable to the overall 42% reported by Srinivasan et al., 2013) but in that study males had a much higher probability of quit attempts than women and the study did not distinguish between smoked and smokeless tobacco.
19	**Shahjahan et.al 2017**	To explore the factors influencing initiation of ST use among low socio-economic community.	Respondents were school teachers, community leaders, women representatives and shop owners. 4 FGDs with total of 33 informants	Respondents were school teachers, community leaders, women representatives and shop owners. Mean age of respondents = 30, SD 6.8	Thematic analysis	Women consumed zarda more than men, although they may not be aware zarda is raw form of tobacco. Some elderly advised pregnant women to chew betel leaf with zarda to avoid nausea. Many women initiated it during first trimester due to elderly influence. So many women started using ST products during pregnancy and became addicted eventually. Women with no formal education use more ST during pregnancy. Elderly women in the family influenced young people to use ST by offering.	*"My wife has suffered from a stroke once and is paralyzed and lost her ability to walk properly but she is still using ST. I have tried my level best to stop by informing all health risks involved, but it was in vain".* *"My grandmother can live w/o food but can't live w/o ST".* Narratives in the text.
20	**Shrestha, N et.al 2019**	To explore demographic, socio-economic and geographic correlates of current tobacco use in Nepal. To examine trends in prevalence in Nepal from 2006-2016.	Women aged 15-49 years 12864 women	Current ST use among women = 420 (3.8%)	Prevalence estimates and multiple logistic regression Dependent variable = ST use Independent variables = age, education level, place of residence, wealth index, ecological zones, frequency of various media exposure.	**AOR: ST use only compared to no tobacco use** **Age (reference = 15-19 years):** 20-24 =2.38 (1.19-4.76), 25-29 = 5.17(2.55-10.48), 30-34 = 7.28(3.58-14.81), 35-39 = 10.79(5.54-21.03), 40-44 = 11.78(5.76-24.08) and 45-49 = 11.86(5.66-24.86). **Education level (reference = no education):** primary = 0.94(0.75-1.19), secondary = 0.39(0.26-0.6) and higher = 0.14(0.05-0.39). **Place of residence (reference = urban):** rural = 1.06(0.8-1.4). **Wealth Index (reference = poorest):** poorer = 0.83(0.58-1.19), middle = 0.54(0.43-0.85), richer = 0.41(0.22-0.77) and richest = 0.32(0.18-0.59).	
21	**Singh, A et. al 2014**	To examine the regional variations and correlates of tobacco use in India.	Adults aged 15 and above 35529 women	Prevalence estimates for regions separately and pooled country estimates not reported.	Prevalence estimates (regional) Multinomial regression analysis dependent variable: tobacco use Independent variables: age, sex, residence, education, occupation, ST causes serious illness	**RRR: ST use only, compared to no tobacco use.** **Age (reference = 15-24 years):** 25-44 years = 1.94(1.66-2.26), 45-64 years = 3.44 (2.91-4.06) and >65 years = 4.47 (3.67-5.45. Residence: compared to urban dwellers, rural dweller have RRR of 1.13(0.97-1.32). **Education (reference = more than secondary):** up to secondary = 1.71(1.29-2.27), up to primary = 3.38(2.57-4.44) and no education = 4.41(3.38-5.76). **Wealth (reference = rich):** moderate = 1.68(1.42-1.97) and poor = 2.04(1.71-2.42). ST causes serious illness (compared to yes), No = 0.95(0.79-1.14)	
22	**Singh, J et. al 2017**	Explore factors related to ST use among pregnant women in rural southern area of Nepal	Pregnant women (13-28 weeks) 426 pregnant women	ST use = 13.4% (n=57) Frequency: <1/day = 24.5% (n=14) 1-3 times a day = 52.6% (n=30) >3times a day = 22.8% (n=13)	Prevalence estimates and multiple logistic regression Dependent variable = ST use among pregnant women Independent variables = age, caste, education, mass media exposure, mother's group meetings, spousal violence/stress, diet, alcohol consumption.	**AOR: ST use among pregnant women** **Age (reference <20 years):** women between ages 20-34 AOR 4.2 (1.3-14.2) and those between 35-45 years AOR 1.66 (0.6-4.9) **Education (reference is higher education)**: not educated AOR 9.6 (2.5-32.7), primary educated AOR 4.5 (1.1-17.1) and secondary educated 2.6 (0.8-7.6). **Caste (reference is upper caste):** adivashi AOR 3.1(1.2-19.6) and Dalit AOR 3.9(1.1-13.8).	AOR: **Alcohol consumption (reference = no):** AOR for yes = 3.86(1.23-12.08). **Stress (reference = no):** AOR for yes = 5.04 (1.8-14). **Mass media exposure (reference = yes):** AOR for no = 5 (1.9-13.3). **Mother's group meeting attended (reference = yes)**: AOR for no = 4.6 (1.4-15.2).

	Author Year	Study objective	Study population Sample size	Prevalence estimates	Method (analysis)	Results (related to ST use only)	Additional information
23	**Singh, P et. al 2009**	To identify demographic characteristics of current tobacco use and explore the reasons for current tobacco use.	Adults aged 18 and over 7858 women	ST use = 17% (15.2 - 19)	Multivariable regression analysis Dependent variable = tobacco use Independent variables = demographic characteristics	**OR age (reference=18-25 years):** 26-36 = 5.7(3.4-9.7), 37-48 = 15.8(9.1-27.3), >48= 51.5(29.8-88.9). **Years of education (reference=0-6 years):** 7-12 = 0.2(0.1-0.4) **Income per day in USD (reference <1):** 1-2 = 0.9(0.6-1.4), >2-3 = 0.6 (0.3-1), >3 = 0.4(0.2-0.7). **Marital status (reference = never married):** currently married = 1.4(1-2.1), divorced = 1.8(1.1-2.9), widowed = 3.10(1.8-4.7) **Occupation, ethnicity and religion non-significant.**	**Common reason for initiation** = influence of older adults (31.9%), to alleviate morning sickness during pregnancy (17%) (this belief was 17.8% among rural and 7.5% among urban women), wish to experiment (13.9%).
24	**Singh, S et. al 2015**	To examine the prevalence and correlates of tobacco use during pregnancy in a rural area of India.	Women aged 18 and above who had given birth (live, still or infant death) during survey year. 400 women	59 women of the 400 used tobacco. 58 (98.3%) of those used ST. Mean age of tobacco initiation = 17.1+-3.4.	Prevalence estimates and frequencies Multivariate logistic regression: dependent variable = use of tobacco during pregnancy and independent variables = age, awareness of adverse health effects and living with a smoker	**AOR: tobacco use during pregnancy** **Age (reference is age <25),** those >25 years of age AOR=8.2(2.48-27.15). **Awareness of adverse health effects (reference = good)**, AOR for those with poor awareness = 4.48 (2.03-9.9).	35 of the 59 initiated on their mother's advice, 9 due to influence of friends, 9 due to relatives and 3 due to husband's influence. 2/3 of the 59 purchased with help of the husband. Misconception that tobacco has medicinal properties was reported as the major reason.
25	**Soorensen et.al 2005**	Assess social disparities in the prevalence of overall tobacco use, smoking and smokeless tobacco use in Mumbai based on education, occupation and gender specific patterns.	Adults aged 35 and over 59527 women	Current ST use among women = 56.9%	Prevalence estimates Multivariate analysis for adjusted Odds Ratios: Dependent variable = current ST Use Independent variables = education and occupation	**Education (compared to women with college education):** AOR for illiterate women = 21.02 (16.63-26.56), Primary education = 9.18(7.27-11.6), middle 5.50(4.34-6.97) and secondary = 2.70(2.1-3.48). **Unemployed women (compared to professionals)** = AOR 1.89 (1.15-3.12). Other professions (unskilled, trader, service, skilled) non-significant.	
26	**Sreeramreddy et.al 2014**	To provide national estimates of prevalence and social determinants of smoking and smokeless tobacco use among men and women.	Women aged 15-49 years 248840 women (8 countries)	Prevalence estimates (95%CI): India 9.0(8.8-9.21) Pakistan 2.44(1.94-2.96) Nepal 4.75(3.8-5.68) Philippines 0.32(0.23-0.41) Maldives 4.23(3.46-5) Indonesia 0.41(0.29-0.52) Cambodia 5.13(4.52-5.75) Timor Leste 1.93(1.65-2.2)	Prevalence Binary logistic regression Dependent variable = ST use Independent variables = residence, age, marital status, education, wealth index and religion Estimates reported individually for all countries.	Logistic regression summary: ST use higher among rural women in India, Pakistan, Nepal and Cambodia. Inverse relationship with education and wealth index. Older women more likely in all countries. Married women more likely in Nepal	

	Author Year	Study objective	Study population Sample size	Prevalence estimates	Method (analysis)	Results (related to ST use only)	Additional information
27	**Sreeramreddy et.al 2014**		Women aged 15-49 years 354927 women (30 countries)		Prevalence Multiple logistic regression (pooled estimates for all 30 countries combined) Dependent variable = ST use Independent variables = age, education, wealth index, religion, marital status, residence and occupation.	**AOR (95% CI) for ST use** **Age (reference = 15-19 years):** 20-29 years = 1.98(1.82-2.15), 30-39 years = 4.08(3.7-4.49) and 40-49 years = 8.37(6.7-10.4). **Education (reference = higher)**: Secondary = 1.49(1.36-1.64), primary = 2.97(2.56-3.46) and no education = 10.6(6.6-17.2). **Wealth index (reference = richest):** Richer = 1.3(1.2-1.4), middle = 1.4(1.3-1.6), poorer = 2.05(1.7-2.3) and poorest = 3.3(2.7-4.1). **Marital status (reference = non in union):** Married = 1.01(0.88-1.1), living together = 1.2(1.1-1.3) and single = 1.7(1.4-2.1). **Residence (reference = urban):** Rural = 0.92(0.7-1.07). **Occupation (reference = unemployed):** professional = 0.8(0.7-1.02), agricultural= 1.3(1.1-1.5) and unskilled = 1.1(0.9-1.3).	Prevalence estimates mentioned for all 30 countries
28	**Tiwari, R et.al 2015**	To assess the tobacco use among urban and rural women. The discrepancy in knowledge, belief and behaviour towards tobacco consumption among urban and rural women.	Women aged 18-25 years 2000 women interviewed	23% = ST users 4.3% = dual	Frequency distribution, Chi square and Logistic regression Dependent variable: use of various tobacco forms (we report on ST use) Independent variable = place of residence Questionnaire for knowledge and beliefs.	77.4% ST users = rural (pvalue<0.001) **Odd Ratio and 95% CI for ST use:** **Residence (reference = rural):** urban = 1.15 (0.62-2.1)	**knowledge whether chewing tobacco can cause oral cancer** - 77.8% rural women said no while all of the urban women replied yes. - Other questions general for tobacco and hence only above mentioned result is relevant to use of ST.
29	**Tonstad, S et.al 2013**	To identify determinants of intent to quit tobacco among adults in Cambodia.	Adults aged 18 and over 1188 women	538 = intent to quit 650 = do not intent to quit	Descriptive and logistic regression analysis Dependent variable = intent to quit (yes/no) Independent variables = age, age at initiation, ethnicity, education, income and occupation.	**AOR(95% CI) for intent to quit (reference = no intent)** **Age (reference >48years):** 18-25 years = 7.13(1.88-27.11), 26-36 years = 0.94(0.57-1.55), 37-48 years = 0.92(0.68-1.26). **Age at initiation (reference <18 years):** 18-25 years = 1.9(1.01-3.6) and >25 years = 2.26 (1.23-4.13). **Education (reference = 0-6 years):** >7 years = 2.11(0.81-5.38). **Income per day (reference <1 USD)**: >1 USD = 1.05(0.6-1.77). **Occupation (reference = none):** professional = 0.92(0.11-7.42). Education, income and occupation non-significant.	**Continuation reasons:** 23% = to get rid of fatigue 30% = influence of older relatives 45% ST users plan to quit in future. **Initiation reason (most common)** = 68%, experimental

Appendix 5.1. Information sheet and consent forms (English and translated versions)

UNIVERSITY of York
The Department of Health Sciences

[Familial influence on initiation/change in practice of smokeless tobacco use during pregnancy in India]

Participant Information Sheet

Title of Study: Familial influence on initiation/change in practice of smokeless tobacco use during pregnancy in India

We would like to invite you to take part in the above-named study but before you decide, kindly read the following information

What is the purpose of this study?

The purpose of this study is to understand how family members influence initiation of smokeless tobacco use during pregnancy and/or its change in use during the course of pregnancy. The importance of this study is to understand social and cultural background related to smokeless tobacco use during pregnancy, due to its wide use in the area and country.

Who is doing the study?

The study is being conducted as part of a PhD project. Details of the researcher and supervisors are mentioned below

Radha Shukla
(Chief investigator)
PhD Student
Department of Health Sciences
University of York

Prof Kamran Siddiqi
(Supervisor)
Professor in Global Health
Department of Health Sciences
University of York

Dr Mona Kanaan
(Supervisor)
Senior Lecturer
Department of Health Sciences
University of York

Why have I been asked to participate?

For this study, we need pregnant women who are in their third trimester (28 weeks and above), and who have used smokeless tobacco at any point during their current pregnancy. As you meet these criteria, you have been asked to participate in the study.

Do I have to take part?

Your participation in the study is entirely voluntary and will not have any consequences to your routine care if refused. Also, you are free to withdraw your participation from the study at any time, till 4 weeks after the completion of the interview. No questions will be asked for your refusal.

You do not need to consent immediately and are free to think about your participation in the study and inform about your decision later. In addition to verbally informing you about the study, this information sheet will be of your help.

What will be involved if I take part in this study?

If you wish to participate in the study (after your thorough consideration and voluntary consent) we will identify a convenient time for the interview which will last for about 30-45 minutes. Where the interview is held, is up to you. If you prefer, we can have the interview at your home in a separate area, or in a park or outdoor setting. We also have the provision of conducting the interview at the Primary Health Centre in a private setting. If you choose to be interviewed at the Primary Health Centre, your travel expense will be reimbursed, and you can have one person accompany you. Irrespective of the place you choose to be interviewed, we will ensure privacy and confidentiality at all times.

In the interview, you will be asked about your smokeless tobacco use and how the family influences its use during pregnancy. These interviews will be tape recorded. No personal identifiable data will be asked in the interview nor will it be recorded.

You will be given a small incentive to appreciate your time for the interview in form of a pre-paid calling card for local talk time. The amount for this will be 100 INR (India rupee) which is approximately 1.1 GBP.

What are the advantages/benefits and disadvantages/risks of taking part?

The advantage of your participation in the study, is that you will contribute to the overall knowledge about smokeless tobacco use during pregnancy. It may not directly benefit you but will help women make informed choices in the future with better knowledge about smokeless tobacco use.

The risk of taking part in the study is that at the time of interview, we will ask you about your smokeless tobacco use. This may make you uncomfortable, sensitive or anxious. The way the interview will be conducted, we will try our best to not let this happen. However, if we notice slightest discomfort in you or if you feel and report discomfort, we will stop the interview at the point and your comfort will be the priority.

Can I withdraw from the study at any time?

You can withdraw from the study at any time till 4 weeks after the interview completion, without justifying any reason. This means at any point during the interview, or after the interview till the data has been analysed.

Therefore, if you intend to withdraw after the data analysis procedure has started (4 weeks after the interview is completed), the information will still be analysed and interpreted.

Your withdrawal will bear no consequences and no questions will be asked.

How will the information and personal data I give be handled?

All interview data will be collected by the researcher using two tape recorders, which upon completion will be transferred on a personal computer which will be secure (password protected). Once the recordings are transferred onto the computer, the recording on both the tape recorders will be destroyed.

The recording on the computer will then be analysed and interpreted. The data will be stored for 10 years post completion of the study.

What will happen to the results of the study?

The results of the study will be used to make public health programs regarding smokeless tobacco use during pregnancy. This will be by means of presenting the results at conference proceedings and publishing in scientific journal.

Who has reviewed and approved this study?

Ethical approval for this study has been obtained from the University of York's Health Sciences Research Governance Committee and from the Foundation for Diffusion of Innovations, an organization based in the province of Gujarat.

Who do I contact for more information about the study?

Please contact the chief investigator (Radha Shukla) for any information regarding the study

Radha Shukla
PhD student, Department of Health Sciences, University of York
RCSS, 6 Innovation Close, Heslington, York - YO10 5ZF
Email: rs1658@york.ac.uk
Phone: 07548282714, +91 9974226615

Who do I contact in the event of a complaint?

For general complaints, contact either of the supervisors (details mentioned below).

Prof Kamran Siddiqi
Professor in Global Health
Department of Health Sciences
University of York
kamran.siddiqi@york.ac.uk
+44 01904321335

Dr Mona Kanaan
Senior Lecturer
Department of Health Sciences
University of York
mona.kanaan@york.ac.uk
+44 0190432137

In case of any complaints regarding personal data management, please feel free to contact the University's Data Protection Officer at dataprotection@york.ac.uk
If still not satisfied, concerns can be reported to the Information Commissioner's Office at www.ico.org.uk/concerns.

Thank you for taking the time to read this information sheet.

Participant Consent Form

Title of Study: Familial influence on initiation/change in practice of smokeless tobacco use during pregnancy in India

	Please confirm agreement to each statements by putting your initials in the boxes below
I have read and understood the participant information sheet [date ..., version ...]	
I have had the opportunity to ask questions and discuss this study	
I have received satisfactory answers to all of my questions	
I have received enough information about the study	
I understand my participation in the study is voluntary and that I am free to withdraw from the study:- At any time during the interview till about four weeks post-interview Without having to give a reason for withdrawing *If the participant withdraws within 4 weeks of interview completion, the data will be destroyed and not included in the analysis.*	
I understand that my interview will be audio-recorded.	
I understand that the interview data collected during the study may be looked at by study team. I give permission for these individuals to have access to my records.	
I understand that any information I provide, including personal data, will be kept confidential, stored securely and only accessed by those carrying out the study.	
I understand that any information I give may be included in published documents, but all information will be anonymised.	
I agree to take part in this study	
Participant Signature/thumb print …… Date	
Name of Participant	
Researcher Signature …….. Date	
Name of Researcher	

UNIVERSITY of York
The Department of Health Sciences

Interview Topic Guide

Preparatory phase: (approximately 5 – 10 minutes)

The initial few minutes will be taken to introduce the interviewer and to orient the interviewee to the project. A recap of the participant information sheet to make sure the interviewee is well aware of all aspects of the study. This will also be the time for the interviewee to clarify any concerns regarding the interview and/or study.

Interview phase: (approximately 20-25 minutes)

Topic	Questions
Current smokeless tobacco use	What is your current smokeless tobacco use like? Can you please tell me the frequency and type of products you use?
Smokeless tobacco and pregnancy	Before pregnancy, what were your smokeless tobacco habits like? Has pregnancy changed any smokeless tobacco use of yours? In what sense? Can you possibly tell me more about the change? During the course of pregnancy, have there been any changes in your smokeless tobacco use?
Smokeless tobacco initiation	When did you first use smokeless tobacco? How did the habit start? What factors influenced your use of smokeless tobacco?
Familial influence	What are smokeless tobacco habits in the family like? How do those influence your smokeless tobacco behaviour? How has the influence changed throughout the course of pregnancy? How does you perceive these influences as? Who amongst the family influences your behaviour the most?
Knowledge and accessibility	What according to you is smokeless tobacco? How accessible are these products for you? Note: To be extra careful of not mentioning the words harm or danger to avoid the feeling of guilt and anxiety.

ગર્ભાવસ્થા દરમ્યાન પારીવારીક દૃષ્ટિથી / ધુમ્રપાન વગરના તમાકુનો પ્રભાવ / ફેરફાર કઈ રીતે થાય છે.

પૂરક દસ્તાવેજો

યોર્ક વિશ્વવિદ્યાલય – આરોગ્ય વિજ્ઞાન ખાતુ

અભ્યાસનું શિર્ષક :

ગર્ભાવસ્થા દરમ્યાન પારિવારીક દૃષ્ટિથી ધુમ્રપાન વગરના તમાકુનો પ્રભાવ કે ઉપયોગ ભારતમાં થાય છે.

નકકી કરતા પહેલા ઉપર્યુકત નામના અભ્યાસમાં ભાગ લેવા માટે અમે તમને આમંત્રિત કરીએ છીએ. મહેરબાની કરીને નીચે દર્શાવેલી માહીતી વાંચો.

અભ્યાસ કરવનો હેતુ શું છે ?

અભ્યાસ કરવાનો હેતુ એ છે કે કુટુંબના સભ્યો પર ધુમ્રપાન વગરનું તમાકુ, ગર્ભાવસ્થા દરમ્યાન / અથવા તેનો ઉપયોગ કઈ રીતે થાય છે. અભ્યાસ કરવાની અગત્યતા એ છે કે સામાજીક / સાંસ્કૃતિક ભૂમિકા ધુમ્રપાન વગરના તમાકુનો ઉપયોગ ગર્ભાવસ્થા દરમ્યાન થાય છે. કારણકે તેનો ઉપયોગ / દેશના વિસ્તારમાં છે.

અભ્યાસ કોણ કરે છે ?

અભ્યાસ PHD ના આયોજન માટે સંચાલિત કરવામાં આવ્યો છે. સંશોધકો અને નિરિક્ષકો (તપાસ કરનાર)ની ઉડાણ પૂર્વકની માહીતી નીચે મુજબ છે.

રાધા શુકલ (મુખ્ય તપાસક) PHD Student આરોગ્ય વિજ્ઞાન ખાતુ યોર્ક વિશ્વવિદ્યાલય	**પ્રો. કામરીન સીડીકી** (તપાસ કરનાર) વૈશ્વિક આરોગ્ય અધ્યાપક આરોગ્ય વિજ્ઞાન ખાતુ યોર્ક વિશ્વ વિદ્યાલય	**ડો. મોના કાનન** વરિષ્ઠ ભાષણક આરોગ્ય વિજ્ઞાન યોર્ક વિશ્વ વિદ્યાલય

મને ભાગ લેવાનું શા માટે કહયું છે ?

અભ્યાસ અર્થે અમારે ગર્ભવતી સ્ત્રીની જરૂર છે. જેણે ત્રણ મહિના (૨૮ અઠવાડિયા અને ઉપર) અને જેણે ધુમ્રપાન વગરનું તમાકુનું સેવન ગર્ભાવસ્થા દરમ્યાન કર્યું હોય. જો તમે આ માપદંડ સુધી પહોચ્યા હોવ તો આ અભ્યાસમાં ભાગ લઈ શકો.

મારે પણ ભાગ લેવાનો ?

આ અભ્યાસમાં ભાગ લેવાનું સંપૂર્ણ સ્વૈચ્છિક છે. તમારી રોજ બરોજની સંભાળ પર એના પરિણામની અસર નહીં થાય. જો તમે નકારશો / અસ્વીકાર કરશો તો. તમારે તરત જ સંમતી આપવાની જરૂર નથી.

તમે અભ્યાસમાં ભાગ લેવા વિશે વિચારી શકો છો અને તમારો નિર્ણય પછી પણ જણાવી શકો છો. ઉપરાંત અભ્યાસ બાબતે મૌખિક તમને માહિતી આપવા છતાં આ માહીતી તમને મદદરૂપ થશે.

જો હું આ અભ્યાસમાં ભાગ લઉં તો શેનો સમાવેશ થશે ?

તમારી વિચારણા અને મૌખિક સંમતિ પછી જો તમે અભ્યાસમાં ભાગ લેવાની ઈચ્છા ધરાવતા હોવ તો તમારો છેલ્લી ૩૦ – ૪૫ મિનિટનો ઈન્ટરવ્યુ તમારી સમયની અનુકૂળતા પ્રમાણે નકકી કરશે. એ તમારા ઉપર છે.

જો તમે પસંદ કરશો તો તમારા ઘરના અલગ વિસ્તામાં ઈન્ટરવ્યું ગોઠવી શકાશે. મારે અ

મારે અભ્યાસની વધુ માહીતી જોઈતી હોય તો કોનો સંપર્ક કરૂ ?

મહેરબાની કરીને મુખ્ય તપાસક (રાધા શુકલ) નો સંપર્ક કરવો.

રાધા શુકલ

PHD વિદ્યાર્થીની
આરોગ્ય વિજ્ઞાનખાતુ,
યોર્ક વિશ્વ વિદ્યાલય.
ઈનોવેશન કલોસ, હેસલીગ્ટન, યોર્ક
ઈ–મેઈ : vs.1658@york.ac.uk
ફોન : 07548282714 (૦૭૫૪૮૨૮૨૭૧૪)
સ્થાનિક નંબર સંશોધક થકી અભ્યાસના હેતુથી પ્રાપ્ત થશે.
(ભારતમાં મુસાફરી કરશે તે દરમ્યાન)

ફરીયાદ દરમ્યાન હું કોને સંપર્ક કરી શકું ?

સામાન્ય ફરીયાદ માટે અવેક્ષક (Supervisor) ને સંપર્ક કરવો.

ભારતમાં ગર્ભાવસ્થા દરમ્યાન થતું ધુમ્રપાન મુકત તમાકુની કુટુંબના સભ્યો પર થતી અસર

પૂરક દસ્તાવેજો

યોર્ક વિશ્વવિદ્યાલય

આરોગ્ય વિજ્ઞાન ખાતુ

	મહેરબાની કરીને નીચે દર્શાવેલ નિવેદનોમાં બોક્ષમાં સહી કરવી.
મેં માહીતીપત્રને વાંચ્યુ છે અને હું સમજી છું (તારીખ .... આવૃતિ) ભાષાંતર	
મને આ અભ્યાસની ચર્ચા કરવાની તક મળી છે. પ્રશ્ન પણ પૂછી શકું છું.	
મને તમામ સવાલના જવાબનો સંતોષકારક મળ્યા છે.	
મને અભ્યાસ માટે પૂરતી માહીતી મળી છે.	
હું સમજી છું કે અભ્યાસમાં ભાગ લેવો તે સ્વૈચ્છિક છે અને હું ગમે ત્યારે પાછું અભ્યાસમાંથી પાછું ખેંચવા મુકત છું. ઈન્ટરવ્યું દરમ્યાન ચાર અઠવાડિયા પોસ્ટ ઈન્ટરવ્યું પાછું ખેંચવાનું કારણ આપ્યા સિવાય ચાર અઠવાડિયા સુધીમાં ભાગ લેનાર જો પાછું ખેચેં તો માહિતીનો નાશ થશે. એને વિશ્લેષણમાં ગણવામાં નહીં આવે.	
સમજી શકુ છું કે મારી રૂબરૂ મુલાકાત ઓડીયો રેકોર્ડેડ રહેશે.	
અભ્યાસ દરમ્યાન જે માહિતી એકત્ર કરવામાં આવી હોય મારી ટીમ જોઈ શકશે. હું સમજીને મારા રેકોર્ડ જોવાની પરવાનગી આપું છું.	
સમજી શકુ છું કે જે માહિતી આપી છે, વ્યકિતગત માહિતી પણ પ્રાપ્ત રહેશે તેને સલામતીથી સંઘરી રાખવામાં આવશે (જે લોકોએ અભ્યાસ કર્યો છે.)	
સમજું છું કે જે કોઈ માહિતી મેં આપી છે. તેમા જાહેર દસ્તાવેજ નો પણ સમાવેશ થાય છે. પરંતુ એ બધી માહિતી કોઈના નામ વગર રહેશે .	
હું અભયાસમાં ભાગ લેવા સંમત છું.	
ભાગ લેનારની સહીં / અંગુઠાનું નિશાન	
ભાગ લેનારનું નામ : તારીખ	
સંશોધકની સહીં :	
સંશોધકનું નામ : તારીખ	

ગર્ભાવસ્થા દરમ્યાન પારિવારીક દૃષ્ટિથી ધુમ્રપાન વગરનાર તમાકુનો પ્રભાવ કે ઉપયોગ ભારતમાં થાય છે.

પૂરક દસ્તાવેજો

યોર્ક વિશ્વવિદ્યાલય
આરોગ્ય વિજ્ઞાન ખાતુ

રૂબરૂ મુલાકાત વિષય માર્ગદર્શન

પ્રારંભિક તબક્કો (અંદાજે ૫–૧૦ મિનિટ)

- શરૂઆતની થોડી મિનિટ જે ઈન્ટરવ્યુ લેનાર છે તેની ઓળખાણ જેનો ઈન્ટરવ્યું લેવાનો છે તેની સાથે થાય છે.
- ભાગ લેનારની તમામ માહિતીનું સંક્ષીપ્ત કરીને તે અભ્યાસના પાસા વિષે ચર્ચા થાય છે. અને સાવધાની વતાવાય છે. આ એ પણ સમય છે કે જેનો ઈન્ટરવ્યું લેવાનો છે. તેની સાથે સ્પષ્ટતા અભ્યાસ સંબંધે કરવામાં આવે છે.
- ઈન્ટરવ્યુ તબક્કો (અંદાજે ૪૦ – ૫૦ મિનિટ)

ઈન્ટરવ્યું તબક્કો	પ્રશ્ન	નોંધ
વર્તમાન એસ. એલ. ટી. તમાકુ સેવન	વર્તમાનમાં ધુમ્રપાન વગરનું કયું તમાકુ વાપરો છો ? મહેરબાની કરીને તમે કહી શકો કે કેટલી વાર અને કયું ઉત્પાદન વાપરો છો ? ગર્ભાવસ્થા પહેલા SLT આદત કેવા પ્રકારની હતી ? કયા અર્થમાં અને તે ફેરફાર વિષે વધુ કહી શકો ?	
SLT અને ગર્ભાવસ્થા	ગર્ભાવસ્થા દરમયાન SLT ના ઉપયોગમાં કોઈ ફેરફાર થયો હતો ? ગર્ભાવસ્થા દરમ્યાન (શરૂઆતમા) અને હમણા ઉપયોગ કર્યો હોય તો કોઈ ટીકા ટિપ્પણ છે?	
SLT શરૂઆત	આ આદત કઈ રીતે શરૂ થઈ ? SLT ઉપયોગમાં કયા પરિબળોએ ભાગ ભજવ્યો કુટુંબમાં ધુમ્રપાન વગરનું તમાકુની આદત કેવી લાગે છે ? ધુમ્રપાન વગરનું તમાકુથી કેવું વર્તન થાય છે ?	
પારિવારિક પ્રભાવ	ગર્ભાવસ્થાના અભ્યાસક્રમ દરમ્યાન એનો પ્રભાવ કેવી રીતે બદલાયો ? તમે એના પ્રભાવને કઈ રીતે સમજયા ? તમારા કુટુંબમાં આના પ્રભાવથી કોના વર્તનમાં અસર થઈ ?	
જ્ઞાન અને પ્રવેશ માર્ગ	તમારા પ્રમાણે ધુમ્રપાન વગરનું તમાકુ એટલે શું ? આ ઉત્પાદન મળવાનું તમને કેટલું ઉપલબ્ધ છે ?	

(શબ્દથી હાની ન પહોંચે કે તનાવ ન આવે અને દોષ ન લાગે તેની વિશેષ કાળજી લેવી.

Appendix 5.2. Research governance application

UNIVERSITY of York
The Department of Health Sciences

RESEARCH GOVERNANCE COMMITTEE

SUBMISSION FORM

GENERAL INFORMATION

1. Please give the full title of your study and provide a short title for reference.

Full title	Familial influence on initiation/change in practice of smokeless tobacco use during pregnancy in India
Short title	Familial influence on smokeless tobacco use during pregnancy in India

2. If you are an academic member of staff, please provide the following details about yourself.

Name and title	
Post	
Institution (including address if other than Health Sciences)	
Email and telephone number	

3. If you are a research student, please provide the following details.

Your name and title	Dr Radha Shukla
Name and level of course/degree	PhD Health Sciences (Year II)
Institution (including address if other than Health Sciences)	
Email and telephone number	rs1658@york.ac.uk 07548282714
Name and email address of supervisor(s)	Prof Kamran Siddiqi (kamran.siddiqi@york.ac.uk) Dr Mona Kanaan (mona.kanaan@york.ac.uk)

4. Please briefly describe the specific expertise, including experience and training, you and your research team will bring to the study.

The chief investigator (Radha Shukla) for this study has previously taken the Qualitative Health Research Module as part of the PhD training, which will provide some of the necessary training for pursuing the current research project. Additional online workshops will be referred to gain interview skills prior to commencing the study. The co-investigator (Jaishree Ganjiwale) from India, has been trained in qualitative health research and is well versed with the area the study will be conducted in. Dr. Kate Flemming (expertise on qualitative health research) is on the Thesis Advisory Panel for this PhD project.

5. If the research is funded, please provide the following details.

Name of funding body	n/a
Duration of the grant	n/a
Describe any influence the funding body has on the conduct or dissemination of the research	n/a

6. If the research is to be reviewed by an ethics committee other than HSRGC, please provide details.

Approval from the Foundation for Diffusion of Innovations (FDI) will be obtained prior to commencing the study. The application will be made by the co-investigator (details mentioned below) from India to the FDI. Results of the review will be submitted to HSRGC. Co-Investigator (India), is a statistician by background, but is also trained in qualitative health research. Jaishree Ganjiwale Assistant Professor (Bio-statistics), Department of Community Medicine Pramukhswami Medical College, Gujarat, India

THE PROJECT

7. Explain the aims, objectives and scientific justification of the research, in a maximum of 200 words, and in language comprehensible to a layperson.

Research Question: How do family members influence initiation or change in practice of smokeless tobacco use among pregnant women in India?

Most of the smokeless tobacco users are from developing nations especially in South-East Asia Region (Sinha et.al., 2018). Being an integral part of the culture and customs that are adopted by the elders and little stigma associated with smokeless tobacco use, encourage women towards this habit (Kakde et.al, 2012). Perceived benefits and ignorance towards harm of smokeless tobacco, further encourage women to continue using smokeless tobacco during pregnancy.

There are few studies that slightly explore familial influence towards initiation of smokeless tobacco use during pregnancy.

- The review by Kakde et.al. (2012) reports that pregnant women initiate smokeless tobacco to change the taste in their mouth and later continue due to addiction.
- Nair's (2015) and Begum's (2015) mixed-method studies both report family as an influence towards initiation of smokeless tobacco in pregnancy. However, the focus of both studies is women from reproductive age groups and thus, views of pregnant women only account for a small fraction.
- The qualitative study by Shahjahan and colleagues (2017) study reported initiation of smokeless tobacco during pregnancy to relieve morning sickness in the first trimester under the influence of elders in the family. However, the focus group discussions only re-instated the fact already known; which is initiation of smokeless tobacco during pregnancy to overcome morning sickness in low-socio economic population. The study reported this qualitative finding via focused group discussions and therefore, understanding the views of pregnant women who use smokeless tobacco is equally important and need to be explored.

8. Please provide a brief summary of the research design/method, in a maximum of 200 words, and in language comprehensible to a layperson.

This qualitative study is the third part of the sequential/longitudinal project exploring distribution and socio-cultural context of smokeless tobacco use in pregnant women in

LMICs (low and middle income countries). The preceding two studies will allow an understanding of the distribution in terms of prevalence rates, socio-demographics (mainly association with education and socio-economic status) and socio-cultural correlates of smokeless tobacco use among pregnant women in LMICs.

- The study will be conducted in the province of Gujarat, India. An area in the province will be selected based on input from the co-investigator in India, and the aim will be to recruit participants from areas where smokeless tobacco use is relatively high.
- Eligible women: Pregnant women in their third trimester who at any point in their pregnancy have used smokeless tobacco.
- Data collection: In-depth interviews (audio recorded) lasting roughly about 45 minutes – 1 hour will be conducted till data saturation is attained. Questions for the interview will broadly be based on the following topics; current smokeless tobacco use, smokeless tobacco initiation, knowledge about smokeless tobacco use in pregnancy, influence of in-laws, husbands, maiden family, community members and peers. However, these are subject to variation upon formal patient and public involvement.
- Data will be analysed using thematic content analysis method

9. Please outline any patient and public involvement (PPI) in the study.

As of now there has been no patient and public involvement. However, we plan to conduct one, just prior to data collection.

The PPI will be setup with the help of co-investigator and ASHA (Accredited Social Health Activists) workers in the area prior to data collection. This will tentatively include community members and pregnant women who use smokeless tobacco in the Primary Health Centre (PHC) catchment area. The purpose of PPI will be to test topic guides and at the same time an opportunity for the researcher to practice mock interviews. No personal data from the PPI will be taken, neither will the interviews be recorded.

This will also be an opportunity to ensure that the translation of the topic guides, information sheet and consent forms is appropriate and acceptable to the participants.

10. If the study requires statistical analysis, please explain your statistical methods.

The study requires no statistical analysis

11. For qualitative studies, please outline your method of analysis.

Data: In-depth interviews lasting roughly about 45 minutes – 1 hour will be conducted till data saturation is attained of pregnant women who at any point during their pregnancy have used smokeless tobacco. This would include women who have continued using smokeless tobacco products, who might have started or stopped using smokeless tobacco products in the due course of pregnancy. Questions for the interview will broadly be based on the following topics; current smokeless tobacco use, smokeless tobacco initiation, knowledge about smokeless tobacco use in pregnancy, influence of in-laws, husbands, maiden family, community members and peers. However, these are subject to variation upon formal PPI.

Method of analysis: Thematic content analysis method will be applied to analyse the data generated from this study. As an initial step, the transcripts will be translated and back translated (translation will be done by the co-investigator in India, who will also identify a person fluent in both languages for back translation) to ensure that the context in local language is retained. The transcripts will then be coded separately by two researchers using the NVivo software package (Version 12, 2018).

Interpreting the data: This will be conducted using the interview data coded in NVivo and the interviewer reflective notes made at the time of the interview. Data will be interpreted to understand how the family influences including a comparison of these influences at different stages of pregnancy (the interview will capture smokeless tobacco and familial influences in the first two trimesters, retrospectively) and between the two groups of women (those who routinely access the PHC for health care and those who access basic health care by the ASHA workers). Reporting of the data will include summaries of responses and verbatim quotes when necessary for mapping and interpretation.

RECRUITING PARTICIPANTS

12. Please explain how research participants will be (a) identified (b) approached and (c) recruited.

We purposively aim to recruit pregnant women who are in their third trimester, who at any point in their pregnancy have used smokeless tobacco to better capture influences throughout the pregnancy. Recruitment will be conducted via two methods; pregnant women who access the PHC for routine ante-natal check-up, identified by health care

professional at the facility and women with non-health care seeking behaviour, recruited with help from the local health facilitators (ASHA workers). Therefore, we estimate approximately 12-18 interviews combined from the recruitment at Primary Health Centre and by the ASHA workers.

Identification of eligible women:

- Pregnant women who are in their third trimester, who at any point in their pregnancy have consumed smokeless tobacco, will be identified by the health care professional at the identified PHC and by AHSA workers in the community.
- This identification of third trimester (28 weeks and above) will estimated by ultrasonographic age (if available), or fundal height or based on last menstrual period (LMP).

Approaching eligible women for participation:

- The health care professional at the PHC and ASHA worker will only identify eligible women and will not approach them to participate in the study. This is because, if women are directly approached by the health care personnel, they routinely seek medical advice from, they might feel the obligation to participate. They may also fear, that refusal to participate may affect their routine medical care.
- The identified eligible women will be approached by the researcher for participation in the study. At this point, women will be verbally briefed about the study by the researcher. As the researcher is not part of routine health care team these women approach, there won't be an obligation to enrol in the study and thus participation will strictly be voluntary.
- In addition to information sheet (written in local language), these women will also be briefed about the study and will be given time to consider voluntary participation.

Recruitment:

- After thorough consideration, voluntarily consenting women will be recruited for the study.
- Women will be given the option, as to where they are most comfortable for the interview. This could either at their home (in a separate room or at a time when family members are not around, to avoid any influence), selected PHC or elsewhere if they prefer.

- Privacy and confidentiality of the participant will be ensured at all times.
- A convenient time for the interview (roughly lasting for 45 minutes - hour) will be identified in consultation with the participant.
- For those women who choose to be interviewed at the selected primary health care facility, they will be reimbursed for the travel expense, for themselves and an additional accompanying person (if any). The accompanying person will only offer support during travel and will not hinder the confidentiality or privacy of the participant at the time of interview. During the time of the interview, the accompanying person will be made comfortable in a designated waiting area at the PHC.

13. If participants are to receive incentives to take part in the study, or reimbursement of expenses, please give details and rationale.

Participants will be given a small incentive to appreciate their time for the interview in form of a pre-paid calling card for local talk time. The amount for this will be 100 INR (India rupee) which is approximately 1.1 GBP. The incentive is only as a token of appreciation and is unlikely to exert any undue influence on individual's decision to participate in the study.
For those participants who prefer being interviewed at the PHC, will be reimbursed for their travel expense to and from the facility. This will include travel expense for the participant themselves and the accompanying person if any.

14. If your study includes participants from vulnerable groups, please provide details and rationale.

The study does not include any participants from vulnerable groups.

15. Please explain any arrangements for participants who do not understand English well.

The consent forms and information sheet will be systematically translated to the local language (Gujarati). Translation will be done by the co-investigator in India, who will also identify a person fluent in both languages for back translation.
All the interviews will be conducted by the chief investigator, who is fluent in the local language and English.

ETHICAL ISSUES

16. Please clarify and justify potential harms to participants.

Ethical considerations that can potentially arise at different stages of the study are listed below, along with measures that will be taken to address them. All attempts will made to ensure comfort and wellbeing of participants at all times.

Coercion: It is possible that at the time of identification of eligible women and recruitment, women feel influenced to enrol in the study.

- To avoid this, firstly health care professional at the PHC and ASHA workers will only be asked to identify eligible women and not talk to them about the study at all. This is because, if women are directly approached by the health care personnel, they routinely seek medical advice from, they might feel the obligation to participate. They may also fear, that refusal to participate may affect their routine medical care. Therefore, identified women will then be approached by the researcher separately to talk about the study and participation. As the researcher is not part of routine health care team these women approach, there won't be an obligation to enrol in the study and thus participation will strictly be voluntary.
- Secondly, the health care professional staff at the PHC and ASHA workers, will be trained prior to data collection to ensure they are aware of the principle of coercion and thus not directly or indirectly influence an individual's decision to participate.

Voluntary consent:

- Eligible women may feel obliged to participate in the research or may fear that their refusal to participate my lead to some adverse consequences. Thus, to address this, study participation will be entirely voluntary and will not have any consequences if refused. Also, participants will be free to withdraw from the study at any time till 4 weeks after interview completion (as this will be approximately when the data analysis will start), without having to justify their reason for leaving.
- Eligible women who are approached by the researcher, may feel pressured to consent immediately at the time of initial contact. To avoid such circumstance, individuals will be verbally informed about the study in addition to the information sheet and will be assured that they can take time to thoroughly consider their participation and need not consent right then.

Privacy and Confidentiality:

- At the time of recruitment: Health care professionals who will identify women will be trained prior to ensure they are aware of privacy and confidentiality.
- At the time of interview: To avoid any influence of accompanying person or family member on the participants, interviews when held at the allocated PHC will be conducted in a designated setting. If the interviews are conducted at home, then a separate room or area in the house which will ensure privacy will be selected.

Anxiety/guilt/sensitivity of the participant:

- Interviews will involve talking about tobacco use by the participant, and at times the participant might feel some form of embarrassment or get concerned about their tobacco use. To overcome this, firstly, participants will be assured that the information is strictly confidential and secondly, the topic guide for interviews will be designed such that use of tobacco is not addressed as a problem. Also, the researcher at the time of interview will ensure not to impose any views on the use of tobacco by the participant directly or indirectly (body language or expressions etc). However, at any point during the interview, if slightest discomfort is noted, the interview will be stopped right then to ensure participant comfort.

17. If your study is likely to elicit information requiring disclosure – such as incidental medical findings, evidence of professional misconduct or neglect, or criminal behaviour – please explain how you will proceed.

- Given the nature of the study, it is unlikely to come across any incidental medical findings. However, if any, the participant will be advised to consult the medical officer at the PHC or their designated ASHA worker.
- At the time of interview, it may be possible to come across some incidental findings which may require disclosure. This may include any domestic abuse, self-harm, mental state of the participant etc. These will not be addressed directly with the participant, but rather have them talk it out with the ASHA worker to offer support and provide them with a leaflet with useful information (details mentioned below).

Irrespective of any disclosure, the health care professional staff at the PHC and AHSA workers will be approached in advance to offer support to any participants if required. This would be in form smokeless tobacco related information or any health concern the participants might have. The setting of the study is such that women are most comfortable

with ASHA workers as they are from the same area, they provide services to. Thus, they tend to be the first point of contact for any advice or guidance. The ASHA workers are also well aware of different channels to approach for further information and help. Additionally, prior to data collection a meeting will be held with ASHA workers to obtain information of resources or helplines woman can contact. This will be put together in form of a leaflet, which if required will be given to the participant for information.

18. Please explain and justify any deception of participants required by the study.

None

19. Please describe any potential benefits to participants.

The results from this study may not be of direct benefit to study participants. However, they will contribute to knowledge about smokeless tobacco use during pregnancy and indirectly benefit from potential future cessation/ preventive interventions.

20. Please clarify and justify potential harms to researchers.

We do not expect any potential harms to the researcher. However, as the researcher is required to go in the community and participants' home, we will ensure the following and comply with University's lone worker policy.

- Carry out risk assessment of the field before visits.
- Using a mobile phone to be in contact with the co-investigator, who lives in Gujarat and will be the point of contact.
- The co-investigator will also be informed about the research activities on daily basis and will be aware of the location of the researcher at all times.
- An official university identification card will be carried at all times.

21. Please provide details of any conflicts of interest created by the research and explain how they will be resolved.

n/a

22. Please provide details of any personal material benefits researchers will receive for undertaking this study, including personal payment over and above their normal salary.

n/a

23. Please describe any other ethical problems you think the proposed study raises, explaining what steps you will take to address them.

During data entry and transfer:
All interview data will be collected by the chief investigator using audio recordings, which upon completion will be transferred onto a password protected personal laptop. The recordings will then be electronically transferred to secure data storage folders at the University of York, which will be password protected. The audio recordings will be handled by the chief investigator, who will also be responsible for securely transferring them to University of York network.

DATA MANAGEMENT

24. Please explain what, where, and for how long data will be stored.

Data for this study will be in form of in-depth face to face interviews. The interviews will be audio recorded on two separate devices (in case one device fails to record due to any unexpected technical error) dedicated for the study only, which will be transferred to a personal laptop at the first instance possible, before transferring them to secure data storage folders at the University of York.
Approximately, 4 weeks after interview completion, transcription and analysis will begin. Thus, the participants can withdraw from the study any point till the start of analysis (i.e. 4 weeks).
The interviews will then be transcribed, translated, back translated and stored on to secure data storage folders at the University of York. Translation will be done by the co-investigator in India, who will also identify a person fluent in both languages for back translation.
The data will be stored for 10 years post completion of the study. Data management will be compliant with GDPR and Data Protection Act (2018).

25. Please explain the process by which data will be transferred.

All interview data will be collected by the chief investigator using audio recordings, which upon completion will be transferred onto a password protected personal laptop on the same day of the interview. The audio recordings on the physical devices will be destroyed once transferred to a secure laptop.

The recordings will then be electronically transferred from the personal laptop to secure data storage folders at the University of York, which will be password protected. This will be done at the first instance possible to avoid any loss of data.
The audio recordings will be handled by the chief investigator, who will also be responsible for securely transferring them to University of York network.

26. Please set out how anonymity of data will be ensured; if data are not anonymised, explain why not and describe how data confidentiality will be maintained.

Participant name and personal details will only be on the consent form. No additional personally identifiable data such as date of birth, or address will be collected from study participants during the interview
Each study participant will be allocated a unique participant ID, which will be recorded on the consent form. Therefore, no participant will be identifiable based on transcripts.

27. Please state who will have access to data generated by the study.

The data will be accessed by the chief investigator (Radha Shukla) and the co-investigator (Jaishree Ganjiwale) in India for the purpose of coding.

28. Please state who will act as custodian of data generated by the study.

The chief investigator (Radha Shukla) will act as the custodian of the data generated.

29. Please state whether the study requires a Privacy Impact Assessment.

We are aware of the GDPR requirements for a privacy impact assessment, none of which apply to this study and therefore, the assessment is not required.

DISSEMINATION

30. Please explain how you plan to disseminate your results.

The purpose of this study at large, is to understand the socio-cultural context of smokeless tobacco use by pregnant women and how family members influence initiation and/or change in its practice. The results from this study will help with background information on smokeless tobacco use among pregnant women and aid with future public health programs. Therefore, dissemination of results will include scientific presentation at conferences and seminars and publication in a scientific journal.

31. If results will be made available to participants and the communities from which they are drawn, please explain how.

The results from this study may not be of direct benefit to study participants and will not be disseminated to them directly. However, they will be summarised and made available to the collaborators in India who cater health services in the elected area. It will help them plan public health programs to address smokeless tobacco.

INDEMNITY

32. Please confirm the indemnity arrangements for your study.

Standard University of York indemnity arrangement	University of York indemnity will apply
Other indemnity arrangement	

Your signature:

Supervisor(s)' Signature

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