



Ministry of Health and Family Welfare
Government of India



SMOKELESS TOBACCO AND PUBLIC HEALTH IN INDIA

EXECUTIVE SUMMARY

SMOKELESS TOBACCO AND PUBLIC HEALTH IN INDIA

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



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स्वास्थ्य एवं परिवार कल्याण मंत्री
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Government of India

Message



India has always reaffirmed its position as the global leader in the area of tobacco control. I commend my Ministry for taking concrete steps in advancing tobacco control initiatives at National, State and Sub-National levels through National Tobacco Control Programme.

2. Tobacco use is the foremost preventable cause of death and disease globally as well as in India. As per the Global Adult Tobacco Survey (GATS) – India, 2010, smokeless tobacco/chewing forms are the most prevalent forms with 206 million Indians using it. As such, the consequent burden of mortality and morbidity due to consumption of smokeless tobacco (SLT) is very high in India. Available evidence suggest that India shares the maximum burden of oral cancer in the world. The use of SLT is associated with high prevalence of oral cancer in India and almost 90% of these oral cancers are linked to tobacco use.
3. The challenges before the nation are formidable, both in their number and in their complexity, especially, in view of the growing Non-Communicable Diseases (NCDs), and that too amongst disadvantaged people who live in rural areas. Therefore, it becomes imperative to take all social determinants of NCD into account, and to curb the use of tobacco at large.
4. I believe that the monograph on Smokeless Tobacco and Public Health in India will bridge a very important gap in the area of public health, as it provides a comprehensive review on impact of smokeless tobacco consumption. The compilation of scientific studies on smokeless tobacco provides abundant information on consumption patterns and associated usage risks. Since the problem of SLT usage is unique to South Asia, the monograph would be extremely useful for public health managers both in India and neighbouring countries especially South-East Asian countries, to promote effective initiatives for curbing SLT usage.
5. I applaud the efforts made by the Healis Sekhsaria Institute for Public Health; Public Health Foundation of India; World Health Organization (WHO); the Centers for Disease Control and Prevention, U.S.A; National Cancer Institute, U.S.A., and other eminent organisations/experts in bringing out a comprehensive report with empirical evidences on smokeless tobacco, which would be able to generate interest amongst stakeholders to address the problem adequately.

(Jagat Prakash Nadda)

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Message from the Regional Director WHO South-East Asia Region



Smokeless tobacco products use is increasingly becoming a serious public health issue in WHO South-East Asia Region. Nearly 80% of global smokeless tobacco users live in the Region, which has myriad varieties of smokeless tobacco products.

Traditionally betel quid was the most commonly used product. However, in recent years, there has been a shift towards manufactured smokeless tobacco products, such as khaini. In many countries, while the prevalence of smoking is decreasing, the use of smokeless tobacco is on the rise. In India, in 2010, an estimated 368 127 deaths (217 076 women and 151 051 men) were attributable to smokeless tobacco use.

Smokeless tobacco causes oral and gastrointestinal cancers, and a number of other cardiovascular diseases. The incidence of mouth cancer is increasing in SEAR countries especially among the younger generation. The situation is grim and calls for urgent and focused action to stop this epidemic.

WHO welcomes this joint initiative of the Ministry of Health and Family Welfare, Government of India, and global experts for detailing issues relating to smokeless tobacco use in this document.

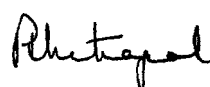
WHO is pleased to note that individual states in India invoked food safety laws in 2011 to ban gutka and pan masala containing tobacco, and banned the production and sale of flavored and packaged smokeless tobacco products. India and other countries in the Region have rolled out intensive mass media campaigns to inform people about the harmful health impact of smokeless tobacco use. India has also introduced presumptive taxes, resulting in a fourfold increase in revenue collection from taxation on smokeless tobacco in the last five years.

Health education and counseling, changing cultural norms associated with smokeless tobacco, strict implementation of anti-tobacco laws in the community and work places, and providing cessation support are important measures for preventing initiation and continuation of tobacco use.

We need to make more efforts for strengthening smokeless tobacco control policies and their implementation, increasing awareness on the harmful effects of smokeless tobacco use and effective cessation programmes.

This document is a welcome move by the Ministry of Health and Family Welfare, Government of India, and international partners for identifying gaps and providing comprehensive strategies and recommendations for smokeless tobacco control.

WHO hopes that all countries in the Region and beyond are able to make the best use of the evidence, guidance and recommendations in this document to curb smokeless tobacco use.



Dr Poonam Khetrpal Singh
Regional Director
WHO South-East Asia Region

Message from WHO Representative to India



This monograph is a timely and a welcome initiative as it puts the spotlight on the serious public health challenge posed by the consumption of smokeless tobacco. Unlike cigarettes, smokeless tobacco often doesn't get enough attention despite being a serious health hazard; this monograph addresses the gap not only by providing evidence on how smokeless tobacco impacts health and the economy but also recommending a comprehensive strategy to deal with the unique challenge it poses.

The widespread use of Smokeless Tobacco (SLT) is unique to India and South-East Asia, with a range of SLT products being produced and consumed. Each state in India has its own variants of SLT products, which may be produced industrially or assembled locally using tobacco and other condiments. SLT use is associated with cancer of the oral cavity, oesophagus, pancreas heart disease and stroke, as well as adverse reproductive outcomes and developmental effects including still-birth, preterm birth and low birth weight. One in four adults and one in ten school students (13-15 years) in India use SLT and are at grave risk due to their addiction. India bears the highest burden of oral cancer globally, due to high prevalence of smokeless tobacco use.

SLT products in India are attractively packaged in colorful sachets that are widely retailed at very low cost making them easily affordable, even for children. Although advertising of tobacco products is prohibited in India, SLT manufacturers are using surrogate means by advertising non-tobacco variants of these products through deceptive brand sharing strategies. The worrisome issue is that these brands are being endorsed by film stars and celebrities, thereby increasing the appeal of these deadly products to the masses and especially to vulnerable youth and poor.

Government of India has been progressively regulating SLT products through various strategies by using the environmental, food safety and other regulations. States have prohibited manufacture, sale, transportation and storage of packaged SLT products under the Food Safety Act. A number of hard hitting national level public awareness messages with specific focus on SLT usage have been released using real stories of victims who lost their lives to this deadly addiction in the prime of their youth.

The Global Knowledge Hub on Smokeless Tobacco has been set up in India in collaboration with the WHO FCTC Secretariat. Tobacco testing laboratories are in the process of being established to test the constituents and emissions of all tobacco products. Tobacco cessation services have also been strengthened through the launch of the National Tobacco Cessation Quitline and mCessation initiatives.

WHO India has been working closely with the Ministry of Health & Family Welfare (MoHFW) in this crucial public health endeavor. In partnership with MoHFW, a number of consultations have been organized to bring greater attention to the issue and build partnerships to strengthen policy interventions for curbing consumption of smokeless tobacco. In addition, a number of research studies have been undertaken to build the evidence-base.

With strong political commitment at the highest level, India is well positioned to take on the challenge of SLT usage, which is putting a huge burden on the health care system as well as on the economy. There are multiple litigations opposing the prohibition on SLT products and, against this background, the release of this report is

strategic. The prohibitions imposed on the packaged SLT products need to be strictly enforced, and the use of SLT to be de-normalized in the society by raising awareness about the negative health impacts and drain on economy. There is an urgent need to uncover the indirect advertising strategies of the SLT manufacturers and advocate for policies to reduce youth exposure and initiation.

I urge all stakeholders to come together to use the evidence and recommendations contained in this report to address this epidemic in a comprehensive manner and save precious lives.



Henk Bekedam
WHO Representative to India

PREFACE

Tobacco use is now universally considered the most important preventable cause of adult death and disease in the world. In most countries, cigarette smoking is the predominant form of tobacco use, and most research and prevention efforts are directed toward it. In some countries, however, other forms of tobacco are more prevalent. In India, smokeless tobacco is the dominant form of tobacco used, although little comprehensive documentation is available on this subject. Regardless of the type of product used, it is a well-established scientific fact that tobacco use in any form affects health adversely.

The idea for this monograph emanated during the National Consultation on Smokeless Tobacco organised by Ministry of Health & Family Welfare, Government of India (MOHFW) in collaboration with World Health Organization Country Office (WCO) India and Public Health Foundation of India (PHFI) during 4-5 April, 2011. The idea got further crystalized during a stakeholders' meeting in New Delhi (17 October 2011) organized by the Healis-Sekhsaria Institute for Public Health. Joining Healis-Sekhsaria Institute in moving this project forward were PHFI, the World Health Organization (WHO), and the U.S. Centers for Disease Control and Prevention (CDC), under the auspices of India's Ministry of Health and Family Welfare (MoHFW). This group undertook the task of developing an evidence-based, peer-reviewed report in the form of a scientific monograph to be issued by the MoHFW. The U.S. National Cancer Institute (NCI) provided the technical support to develop this report.

A concept proposal was developed, along with a list of chapters to be included in the monograph. Possible editors, reviewers, and authors were then identified. Scholars with specific expertise in smokeless tobacco control were invited to contribute to defined chapters. In several authors' meetings, drafted chapters were thoroughly reviewed and modified based on the editors' suggestions. These modified drafts were then reviewed by independent experts. A meeting of authors and reviewers that included Indian and international subject experts extensively reviewed each chapter, cross-checking and suggesting modifications. After a lengthy process consisting of multiple rounds of reviews and editing as well as consultation between Healis, PHFI, WHO and NCI, the report underwent technical editing at BLH Technologies, Inc.

This monograph provides a comprehensive overview of the public health burden of smokeless tobacco use in India for anyone interested in this topic: public health practitioners, researchers, policy-makers, policy advocates, activists, and many others. This report attempts to offer specific directions on addressing the public health impact of smokeless tobacco use in India, and it identifies a number of relevant research, capacity building, and policy needs. Special care has been taken to keep the language of this report free from technical jargon for wider understanding. The chapters incorporate data available until 2014 and later data are included in an Appendix.

The editors are thankful to all who contributed to this report for their enthusiasm and support for this project. We deeply appreciate the efforts of all the authors and co-authors for their hard work. We are grateful to the MoHFW for assigning us a task of such great importance for advancing public health in India. We hope the information in this report increases awareness of smokeless tobacco use and the death and disease it causes, and leads to widespread recognition of smokeless tobacco use as a high-priority public health issue. We hope that this increased awareness will lead to timely action, which is critical to saving lives now endangered by the epidemic of smokeless tobacco use.

Prakash C. Gupta Monika Arora Dhirendra N. Sinha Samira Asma Mark Parascandola

INTRODUCTION

Smokeless tobacco (SLT) is available in many forms in India and is widely used by all social groups. It is more prevalent among the disadvantaged and people who live in rural areas, and is common among women of all ages, including reproductive age. There is a wide spectrum of morbidity and mortality related to SLT use, but SLT has not yet received the attention it deserves as a public health problem. Tobacco control policies have not been sufficient to curb its use. SLT use is high not only in India, but also in South East Asia and many other countries globally. The Ministry of Health and Family Welfare, Government of India, proposed the development of a comprehensive peer-reviewed report and invited the collaboration of Healis-Sekhsaria Institute of Public Health, PHFI, WHO, CDC, and NCI, U.S.A. This monograph is a response to a recommendation from the National Consultation on Smokeless Tobacco, held on 4th–5th April 2011 in New Delhi.

This monograph is a comprehensive document intended to raise the profile of the challenge posed by SLT so that tobacco control efforts can effectively respond to this epidemic. The monograph describes the background, economics, and science of SLT use; the characteristics of SLT products; and policy efforts to combat this public health threat. This report also documents sources of information, discusses gaps in knowledge, describes research and policy needs, and provides recommendations. One goal of this report is to help the various stakeholders understand how they can work together to fight the menace of SLT.

HISTORICAL AND SOCIOCULTURAL OVERVIEW OF SMOKELESS TOBACCO IN INDIA

Originating in the Americas, tobacco came to India through Portuguese traders in the early 1600s. Tobacco was introduced first among the nobility and soon became popular among the common people. For millennia, betel quid (pan) chewing was a socially accepted practice and a part of culture and religious customs. Soon after tobacco arrived in India, it was added as an ingredient in betel quid, and this combination is still widely used. The use of SLT has been justified for its purported medicinal properties, although no system of medicine in India has ever encouraged its medicinal use. Tobacco has been an important cash crop since the early 1600s and an important item of trade both domestically and internationally.

New SLT products containing areca nut were introduced in the early 1970s (pan masala with tobacco, gutka, mawa, etc.); some of these products are vendor made and others industrially made. With vigorous marketing these products soon became very popular.

ECONOMICS OF SMOKELESS TOBACCO IN INDIA

The SLT market in India is the world's largest. Over the last two decades, the SLT industry in India has grown exponentially, mostly in the unorganised sector. About 14% of land under tobacco cultivation is used for growing SLT varieties, and one-fifth of total tobacco production is used for SLT.

The cumulative tax rate, 76%, is similar across all SLT products. Excise revenue from chewing tobacco has increased 15-fold in 10 years, from Rs 722 million in 1990-1991 to Rs 10,532 million in 2010-2011. However, the share of chewing tobacco in overall gross tax revenue has been less than 1%. Although the tax rate has gone up over time, it has never been high enough to reduce consumption, due to very low unit prices.

From 1991 to 2010 the value of SLT exports from India increased ninefold, from Rs 181 million to Rs 1,648 million. Over 70% of SLT exports from India go to the Eastern Mediterranean Region, followed by the Western Pacific and American Regions.

SMOKELESS TOBACCO USE AMONG YOUTH

SLT use usually begins in youth and continues through adulthood. SLT is easy to hide from elders who might disapprove. Youth typically start using SLT as a dentifrice (mishri, gul, lal dant manjan, tobacco toothpastes) or gutka and other flavoured SLT products as mouth freshener. The Global Youth Tobacco Survey (GYTS) in India in 2003 revealed that prevalence varied widely among the states, ranging from 1% in Himachal Pradesh to 56% in Bihar. Between 2006 and 2009 there was no change in prevalence of SLT use by school-going youth. In 2009, GYTS found that nearly one in ten students in India ages 13–15 years used some form of SLT (9.4% overall; 10.7% boys; 7.5% girls). The most important factors affecting SLT use by youth in India are advertisements, promotions, and price, all of which can be influenced by policy. Surveys conducted in India in 2006 and 2009 showed that seven in ten students ages 13–15 years were exposed to SLT advertisements. Psychosocial variables affecting SLT use include sociodemographics, school characteristics, social norms, SLT use by parents and peers and knowledge of health effects.

SMOKELESS TOBACCO USE AMONG ADULTS IN INDIA

The Global Adult Tobacco Survey (GATS) conducted in India in 2009–2010 among those ages 15 years or over revealed that smokeless tobacco was the most common form of tobacco used. Prevalence of current SLT use was 26% (33% men; 18% women) and of daily use, 21%. The average age of initiation to SLT was 17.9 years, similar to that for smoking.

Product preferences varied by gender and by region. Men generally preferred khaini, followed by gutka and betel quid (the last two contain areca nut). The pattern of product preferences for women is more complicated. In the South and North-East, women preferred betel quid; in the Western, Central, and Eastern regions, women used SLT products mainly for dental application; and they preferred khaini in the Eastern, North-Eastern, and Central regions and gutka in the Central and North-Eastern regions. In the North, very few women used SLT.

The low rate at which SLT users quit use is indicated by the fact that former daily use of SLT was 1.2%.

DUAL TOBACCO USE IN INDIA

A dual tobacco user uses both smoking and smokeless forms of tobacco. According to GATS India 2009–2010, the prevalence of dual tobacco use was 5.3% (men 9.3%; women 1.1%), amounting to 42.3 million adults. The North-East region had the highest prevalence (9.8%). The interval between starting the use of the two forms of tobacco was two years or less for over half of all dual users. Somewhat more than half of dual users used both forms daily. Over one-third of daily dual users were interested in quitting all tobacco, but only 5% were former users. In an intervention study, dual tobacco users were only half as successful in quitting tobacco compared to exclusive smokers and one-third as successful as exclusive SLT users.

Dual users show higher risk of diseases than single users; for example, among dual users the risk of oral cancer is 2–12 times higher, and risk of heart attack is twice as high compared to single users.

DETERMINANTS OF SMOKELESS TOBACCO USE IN INDIA

Determinants of SLT use are gender (men), wealth index (inverse association), and belonging to a scheduled tribe. Parental use, peer use, exposure to advertising and promotions of SLT, and lack of knowledge of health risks conferred higher risk of SLT use. Awareness of SLT harms was somewhat higher in men, younger adults, students, individuals with higher levels of education, and urban residents. This knowledge of SLT harms was higher in the North and lowest in the West, and declined with increasing age. A widespread misconception is that SLT is good for dental health.

ADVERTISING AND MARKETING OF SMOKELESS PRODUCTS

Tobacco marketing in India can be divided into three time periods: pre-1985, 1985 through 2003, and 2004 through 2013.

Phase I: SLT marketing in India evolved with the introduction of new products and the diffusion of mass media. Most mass media advertising for SLT products containing areca nut began with pan masala in 1973. Celebrity endorsement was an important marketing strategy.

Phase II: In the 1980s, with the introduction of the low-priced, single-portion pouch, sales of gutka and of pan masala with tobacco increased greatly, and many more manufacturers entered this market. Television ads promoted these products. In 2000, the Cable Television Networks Ordinance Rules (1994) were amended to prohibit advertisements of tobacco and alcohol on television, but there was no restriction on advertising pan masala that did not contain tobacco, even under the same brand names as tobacco products.

Phase III: In 2004, although the Cigarettes and Other Tobacco Products Act (COTPA) 2003 prohibited tobacco advertising in all media, advertising for identical brands of pan masala without tobacco continued in all media. Corporate social responsibility campaigns, cultural events, and sponsorship activities also made use of brand stretching. GATS India 2009-2010 showed that 55% of adults had noticed promotion of SLT products within the previous month. In 2012, when states started banning gutka under Food Safety and Standards Act (FSSA) Rule 2.3.4, manufacturers intensified their marketing by special offers to small-scale distributors and retailers. Several television news channels began featuring news breaks sponsored by a pan masala manufacturer. Packets of chewing tobacco were given away free along with areca nut mixtures without tobacco. Brand names and imagery on areca nut products were often aimed at children and women.

WOMEN AND SMOKELESS TOBACCO: SPECIAL CONSIDERATIONS

Smoking by women in India is still socially unacceptable but SLT use is common. Currently, 70 million women age 15 and older use SLT. Easy availability and low cost of SLT are key factors promoting SLT use by women. One factor influencing SLT use among disadvantaged women is the desire to suppress hunger while performing difficult and labourious tasks.

In addition to a number of other disease risks, SLT use raises women's risk of adverse reproductive outcomes. The prevalence of SLT use while pregnant or breastfeeding is similar to prevalence of use among all women of reproductive age in India. Using SLT during pregnancy results in:

70% higher risk of anaemia in pregnant women

2–3 times higher rate of low birthweight

2–3 times higher rate of stillbirth.

Areca nut use also has adverse reproductive effects of its own.

The relative risk of oral cancer among women SLT users is 8 times higher than that for men, and the relative risk of cardiovascular disease among women SLT users is 2–4 times higher than in men. Relative risk of all-cause mortality due to SLT use is higher among women than among men.

SMOKELESS TOBACCO AND ALL-CAUSE MORTALITY

Three large cohort studies from India have shown a higher age-adjusted relative risk of death among SLT users. Corroborating this, four large studies in Western countries (two from Sweden and two from the United States) have also shown significantly higher mortality in SLT users. Except for one study in India, where after adjustment, there was a slight reversal of risk for SLT users (men and women), relative risks of death among SLT users in all other studies were significantly elevated, from 10% to 96%. In other studies where women participated, the relative risk of death in women SLT users was higher than that for men. All-cause mortality was higher in dual tobacco users in one study. Additional risk factors contributing to higher mortality from SLT use were alcohol use, hypertension, and being grossly underweight or grossly overweight. Causes of death associated with SLT use were circulatory system diseases, malignant neoplasms, and pulmonary diseases.

SMOKELESS TOBACCO USE AND CANCER

Cancers of the oral cavity and pharynx are an important public health problem in India, with nearly 85,000 new cases among men and 34,000 among women in India each year. At least 90% of these cancers are caused by tobacco use in some form, and more than half are caused by SLT use. The association between SLT and cancers of the oral cavity and pharynx in India has been studied and documented for several decades. All cohort and case control studies from India confirm a strong association between SLT use (which includes betel quid with tobacco) and cancers of the oral cavity (Odds Ratios of 3 to 22) and pharynx (Odds Ratios of 2 to 4). At least two studies in India have shown an association between use of SLT containing areca nut and oesophageal cancer (Odds Ratios of 2 to 7), and one of these showed an association of plain tobacco use with oesophageal cancer (Odds Ratio=4.9).

CARDIOVASCULAR DISEASES AND OTHER HEALTH CONSEQUENCES OF SMOKELESS TOBACCO USE

SLT use causes more prolonged and sustained levels of nicotine in the body than cigarette smoking. Acute cardiovascular (CVD) effects of SLT use seem to be similar to those caused by cigarette smoking, including increased heart rate and blood pressure.

Epidemiologic studies suggest an association between SLT use and CVD morbidity and mortality, including myocardial infarction (heart attack), stroke, and coronary artery disease. Risks of myocardial infarction among SLT users increased from 30% to 220%, as reported in the INTERHEART case control study, which included India; the Cancer Prevention Study cohorts (CPS-I and CPS-II) in the United States; and a case control study in Bangladesh. SLT is a risk factor for stroke (40%–70% higher risk), and in association with hypertension, SLT use markedly increases the risk of stroke. In a few studies from India, chewing tobacco, like smoking, was also found to be associated with higher risks of high blood pressure and dyslipidemia.

A few studies provide evidence for an association with other diseases including diabetes, tuberculosis, asthma, cataract, and infertility.

ORAL HEALTH CONSEQUENCES OF SMOKELESS TOBACCO USE

Like studies from other parts of the world, studies from India, although limited, show association between SLT use and gingival inflammation, loss of attachment, and tooth wear.

SLT use is strongly associated with various oral lesions, including precancerous lesions. Some 70% of oral cancers in India are estimated to be preceded by oral precancer.

Oral submucous fibrosis (OSF) is a high-risk precancerous condition caused by using areca nut in such products as pan, gutka, and mawa, or by itself. Incidence of OSF has increased over the last three decades in India. The increase in OSF among youth is of great concern as it puts young people at risk of early cancers.

Leukoplakia is a major precancerous lesion that develops in users of all kinds of SLT. Behavioural interventions directed toward tobacco use have been shown to reduce tobacco use and consequently lower the incidence of leukoplakia, which could lower the risk of cancer.

CHEMISTRY AND TOXICOLOGY OF SMOKELESS TOBACCO

Even the simplest SLT products are chemically complex, containing nearly 4,000 different chemicals, many of them toxic, mutagenic, and carcinogenic. The alkaloid nicotine, the primary addictive substance in tobacco, causes elevated heart rate and blood pressure. Use of slaked lime with SLT increases the bioavailability of nicotine.

Of the 36 known carcinogens in SLT, the most abundant strong carcinogens in Indian products are tobacco-specific nitrosamines (TSNAs), which arise from nitrosation in the process of drying tobacco leaves.

Areca nut, which is combined with tobacco in several SLT products, is also a confirmed carcinogen. Areca nut contains alkaloids, the most abundant among them being arecoline, from which areca nut-specific nitrosamines, known carcinogens, are formed. Adverse health effects of consuming SLT products that contain areca nut, as assessed through some human data and many animal experiments, include liver and intestinal abnormalities, diabetes, damage to testes and sperm, and low birthweight offspring.

Polycyclic aromatic hydrocarbons including the carcinogen benzo[a]pyrene occur mainly in products such as *gul* and *mishri* that are made from pyrolysed tobacco. Toxic and carcinogenic elements such as arsenic, cadmium and polonium-210 have also been found in Indian SLT products.

Detection of TSNA in saliva samples from SLT users as well as the presence of nicotine and cotinine in saliva, urine, or gastric fluid samples indicates that internal tissues are exposed to tobacco toxicants. Biological fluids as well as extracts of SLT products have all elicited a mutagenic response in various in vitro assays and have caused chromosomal (DNA) damage to oral cells or lymphocytes both in vivo and in vitro. SLT exposure contributes to cancer initiation, promotion, and progression as well as adverse reproductive outcomes in animal experiments. Despite popular misconceptions about SLT having health benefits, chemical analysis and toxicology experiments clearly show that SLT is very harmful to health.

SMOKELESS TOBACCO: ADDICTION, WITHDRAWAL, AND CESSATION

A major reason for the high prevalence of SLT use is the addictive property of nicotine, the main active chemical in tobacco. Nicotine absorption is slower among smokeless tobacco users than among smokers, but peak venous levels are similar. Blood nicotine falls rapidly after smoking, but levels off much more slowly among SLT users.

Criteria for nicotine dependence include continuing use despite knowledge of potential physical or psychological harm. Questionnaires for assessing nicotine dependence have not yet been validated for SLT use in India.

Pharmacological and behavioural processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine. Nicotine acts by binding to receptors on neurons in a reward pathway. Nicotine produces the same kind of psychoactive effects whether tobacco is smoked or used in smokeless forms. Because of its addictive nature, cessation of tobacco use may temporarily lead to specific withdrawal symptoms.

To help people quit using tobacco, several Tobacco Cessation Clinics (TCCs) were set up in 2002, and these clinics became part of the National Tobacco Control Programme (NTCP) in 2007-2008. Between 2002 and 2007, SLT users represented 65.5% of enrolled cases at the TCCs. Behavioural counselling is the primary strategy for cessation intervention at these clinics, although pharmacotherapy was also given in about 30% of cases. The quit rate among all men attending cessation clinics was 31.1%.

Other tobacco cessation efforts in India include mass media campaigns, targeted campaigns at work places, and community-based programmes.

ADVOCACY AND POLICY MEASURES

Policy developments to reduce the SLT use include COTPA 2003, other laws, and specific court orders. Committed government leadership in policy development, sustained and effective advocacy by NGOs were instrumental in facilitating the passage of COTPA, a comprehensive tobacco control law which dealt with SLT as well as smoked products. Continued commitment of government to strengthen tobacco control, led to stringent laws that banned gutka. Right-to-information initiatives have revealed tobacco

industry interference in implementation of pictorial warnings, which have been used by NGOs to advocate for stronger pictorial warnings. Media advocacy by NGOs has highlighted SLT in general as a menace and gutka in particular as a especially harmful product. Public interest litigation (PIL) by NGOs helped in implementing labelling and pictorial warnings laws. Coupled with government's efforts of presenting courts with evidence on adverse health effects of SLT, a PIL has led to prohibition of plastic packaging and development of laws regulating or banning dentifrices and food items containing tobacco.

MoHFW has sent advisories to all states to raise taxes on tobacco products. State governments have been consulting multi-stakeholder groups to strengthen enforcement of tobacco control laws and other tobacco control measures. GATS India 2009-2010 revealed that SLT use was very high, leading MoHFW and WHO to organise the first National Consultation on Smokeless Tobacco in India.

Although gutka has been banned in almost all states of India, effective implementation leaves a lot to be desired. Related challenges in implementation include procedures for disposing of seized products, preventing interstate smuggling, preventing sale of gutka in separate packets of tobacco and pan masala, restricting surrogate advertising, preventing tax evasion, not exempting export-oriented units, and increasing cessation services.

LITIGATION AND JUDICIAL MEASURES

The tobacco industry challenges almost every tobacco control measure in the court of law. The government, aided by civil society interventions, has responded successfully to many of these challenges.

Court decisions have helped in prohibiting the use of tobacco as an ingredient in toothpastes and tooth powders (1992); banning storage, packing, or selling of gutka, as well as tobacco and pan masala in plastic sachets (2011); and stopping advertisements and sponsorships by the tobacco industry (2012-13).

In 2011, Rule 2.3.4 under the Food Safety and Standards Act, 2006 (FSSA, 2006) prohibited the use of tobacco and nicotine as ingredients in any food product. Earlier, in connection with a court case, the Supreme Court had ruled that gutka was a food product. This led to a ban in 2012 on the manufacture, storage, and sale of gutka and pan masala containing tobacco in the vast majority of states and Union Territories of India.

The Indian judiciary has not only delivered strong judgements in favour of SLT control but has also followed through with monitoring of enforcement. In April 2013, the Hon'ble Supreme Court sought reports from the states that had not banned gutka and compliance reports from states governments that have banned gutka.

HEALTH COMMUNICATION FOR SMOKELESS TOBACCO CONTROL IN INDIA

MoHFW, Government of India has invested substantial budget in raising public awareness on health impact of SLT use and has aired several mass media campaigns. Intervention through personal and community channels of communication have been evaluated as effective in promoting cessation and reducing the use or uptake of SLT. These interventions have targeted the general population, school-children, teachers, and blue collar workers. Several interventions were designed as part of cancer prevention programs.

Since 2002, health communications efforts such as the school-based health education programmes of HRIDAY-CATCH (Health Related Information Dissemination Among Youth – Child & Adolescent Trial for Cardiovascular Health) and MYTRI (Mobilising Youth for Tobacco Related Initiatives in India) have used a theory based multicomponent intervention model to provide behaviour change for preventing tobacco use among adolescents.

Pack warnings offer governments an easily enforceable means of reaching large segments of the population; the messages they deliver are brief and pictorial warnings are especially effective.

Using the yardstick of reach and cost-effectiveness, community media such as audio-visuals have greater potential than interpersonal communication. Mass media campaigns that employ health-focused messages have impacted diverse groups.

Anti-SLT mass media campaigns have also influenced social norms and beliefs, and have been helpful in advocating for effective public policy. A holistic approach using various means to reach the public will involve different media supplementing and reinforcing common messages.

STRATEGIC PARTNERSHIPS AND INTEGRATION

Reaching out to other stakeholders as partners is an essential component of the holistic approach to comprehensive tobacco control.

Tobacco goes through a ‘life cycle’ of four stages. Each stage represents an opportunity for specific interventions in partnership with various stakeholders:

1. *Tobacco cultivation* – Tobacco is a cash crop which is promoted by government, the tobacco industry, financial institutions, and middle men. Reduction in cultivation of tobacco would require the engagement of the political establishment, bureaucracy, and farmers by encouraging alternative crops and withdrawing incentives to produce tobacco.
2. *Tobacco manufacture* – A large number of unregistered manufacturers escape the reach of regulatory bodies. Local law enforcers, workers unions, and vigilant society groups can be engaged to monitor these manufacturers.
3. *Tobacco marketing* – Aggressive promotion and novel supply chains are used to increase the sales of SLT products. Intervention is necessary through a comprehensive ban on advertising and implementing larger pictorial health warnings. Education of youth and the community about the deceptive nature of tobacco marketing is also needed.
4. *Tobacco use* – Informing potential consumers of the risks posed by SLT products and offering help to quit tobacco addiction are essential interventions in this phase.

Control measures at different stages of the life cycle of tobacco can be seen as falling into three major categories, each of which requires strategic partnerships:

Law and policy interventions: Initiating judicial interventions, advocacy by civil society organisations, and active partnerships between health and developmental groups have helped states adopt and enforce appropriate laws.

Educational interventions: The success of educational interventions in schools has been primarily due to partnerships among non-governmental organisations in health and development, funding organisations, government, and the community. Evidence on effectiveness of such interventions led MoHFW to issue guidelines on Tobacco Free Schools, which were released by Central Board of Secondary Education to all schools in India.

Health system interventions: Tobacco Cessation Clinics set up by the Government of India and WHO have been training health professionals in cessation support. The Ministry of Health and Family Welfare is integrating tobacco control into health programmes and providing health education to motivate and assist users to quit.

RECOMMENDATIONS

High prevalence of smokeless tobacco (SLT) use in India and its significant adverse health consequences make SLT control an important area of focus for policy, programmes, and research. To meet the multiple challenges of the epidemic, five dimensions of SLT problems—health, economic, social, environmental, and demographic—must be addressed. The following recommendations for policy, programme, and research aim to contain the SLT epidemic in India and are derived from the evidence and conclusions presented in each chapter of this report. These recommendations are in alignment with the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) Articles and MPOWER measures.

POLICY RECOMMENDATIONS

The policy recommendations on SLT products in this report are based taking into account the specific situation in India. The key recommendation is to enforce a countrywide ban on production, supply and distribution of all packaged SLT products.

Tobacco Manufacture, Storage & Sale Bans

India has made significant policy strides in prohibiting gutka under FSSA, 2006 Regulation 2.3.4 and in initiating supply-side tobacco control measures. Bans on manufacturing, storage and sales of gutka products are currently being implemented in India; similar bans on SLT products are being phased in. Many states in India have banned all SLT products. For the SLT products that are currently not banned, the subsequent recommendations apply.

- The scope of all supply-side tobacco control measures should be expanded to include all types of packaged smokeless tobacco products, so that all products are regulated in a uniform manner, and to prevent users from replacing banned SLT products with unbanned products.
- The sale of pan masala and areca nut, which are strongly associated with smokeless tobacco use, should be banned because of their carcinogenicity and the increasing prevalence of oral pre-cancerous and cancerous conditions attributable to these substances, especially among youth.
- Pan Masala and flavoured chewing tobacco are currently being sold separately to circumvent law and this should be strictly prohibited. Strict orders from FSSAI and court should restrict sale in this form.
- Policies should be implemented to prevent the sale of tobacco products in places that also sell basic food items or medicines.

Tobacco Marketing Bans

Measures to reduce pro-tobacco advertising, promotion, and sponsorship include the following:

- Tobacco control laws prohibiting direct and indirect advertising, product displays, promotion and sponsorship should be strengthened. This can be achieved through partnerships between the Food Safety and Standards Authority of India (FSSAI), the Ministry of Health and Family Welfare, and the Ministry of Information and Broadcasting.

- Mechanisms should be developed for monitoring and reporting tobacco marketing infractions (e.g., registering brand names of tobacco products under non-tobacco categories under the Trademark Act) at state and national levels.

Implementation and Enforcement

- The effectiveness of existing measures—such as prohibiting the sale of tobacco to and by minors, prohibiting sale within 100 yards of educational institutions, and requiring health warnings at the point of sale—should be evaluated, and possible means of improving these measures should be examined.
- The ban on indirect and surrogate advertising of SLT products should be strictly enforced.
- Partnerships should be established with civil society groups to actively monitor, report, and penalise activities that violate tobacco control laws.
- Criminal and civil suits should be allowed for claims involving injuries to person, community, consumer, or the environment caused by tobacco manufacture and use, as is done in other parts of the world (e.g., the United States, Canada, and Australia).
- Mechanisms for monitoring and prohibiting tobacco advertising on the internet, including promotional emails, websites, blogs, and social media sites, should be imposed.

Taxation

Raising taxes on tobacco products is one of the most effective ways to discourage young people and other segments of the population from initiating tobacco use and to encourage tobacco users to quit. Considerations for effectively using the tobacco tax strategy include:

- Taxes on SLT should be increased to uniformly high level in each state in India. Taxes should also be increased regularly to keep up with inflation and income level.
- Reduce the price differential between smoked and smokeless tobacco products, and address the minimum price for SLT products in price policies (with the goal of making SLT less affordable for more consumers).

Packaging

Prescribe a minimum pack size, by weight, for all SLT products so that they are not sold in small packs and are not easily accessible and affordable for youth.

PROGRAMME RECOMMENDATIONS

Targeted Interventions

- Targeting interventions toward SLT use among women, youth, and rural populations could reach SLT users more effectively.
- Counselling against SLT use should be incorporated in women's routine prenatal and antenatal health care.

Public Awareness Campaigns

- Campaigns should work to raise public awareness of the economic, social, and environmental impacts of SLT use, in addition to its health consequences.

- Campaigns should educate the public about specific tobacco control policies—such as those that ban gutka and other SLT products, prohibit sale of tobacco to and by minors, and ban sale of tobacco within 100 yards of an educational institution—in order to increase compliance.

Cessation Programmes

- High priority should be given to including SLT cessation programmes in health care systems and implementing national SLT cessation guidelines.
- SLT cessation training packages should be tailored for professionals in the health system, frontline health workers, other community outreach programmes, counsellors, teachers, and other stakeholders.
- Tobacco treatment programmes should be targeted for high-risk and vulnerable groups such as youth, women, rural populations, and the economically underprivileged, and should include an SLT focus. More intensive programmes could be beneficial with dual users.

Tobacco Testing Laboratories

- Laboratories should be established that are mandated to test harmful ingredients in all SLT products registered under the Trademarks Act as tobacco products.

Multisectoral Integration

Successful control of SLT use will depend on the involvement and cooperation of stakeholders in multiple sectors:

- In the health sector, interventions should be integrated into programmes associated with tobacco control—for example, the Revised National TB Control Programme (RNTCP); the Reproductive and Child Health Project (RCH); the National Programme for Prevention and Control of Cancer, Diabetes and Cardiovascular Disease and Stroke (NPCDCS), National Oral Health Care Programme and National Mental Health Programme. Oral health professionals are particularly strong potential partners in combatting SLT use.
- Programmes not directly focused on health, such as poverty alleviation, rural development, woman and child welfare, and tribal welfare, have extensive reach and should engage vulnerable populations around preventing and quitting SLT use.
- To incorporate tobacco control training into the legal profession, tobacco control policies should be introduced into the current curriculum of legal education as elective courses.

RESEARCH RECOMMENDATIONS

This report has revealed the following research gaps:

Economics

- Data on revenue generated by different SLT products should be disaggregated in order to understand the patterns of tobacco revenue and to inform tobacco control policies.
- Profitability and diversification plans of the SLT industry should be studied in greater depth to better understand illicit trade of smokeless tobacco between states.

- Analysis should be undertaken to understand the spending pattern of SLT industry on indirect advertising.

SLT Use by Youth

- The determinants influencing SLT use among youth, such as individual, psychosocial, and environmental factors, are subjects for further investigation.
- To produce state-specific results, the Global Youth Tobacco Survey should be conducted on a representative sample in each state in India.
- An industry monitoring study should be conducted to provide information on SLT industry marketing tactics that target youth and adolescents in India and the South-East Asia Region.

Adult Use

- Trends in attitudes, behaviours, knowledge of policies, awareness of SLT's adverse impacts, and social norms related to SLT use by adults should be tracked over time.
- Standardised tobacco use questions should be included in all relevant national surveys with a tobacco use component in order to produce comparable data across surveys.

Dual Use

- Determinants of initiation of dual use, dependence and withdrawal symptoms, variations in exposure levels from using different products, and lack of success in cessation efforts are all subjects in need of further study.

SLT Use by Women

Given that the rate of SLT use among women is high, it is important to better understand women's usage and cessation patterns. Suggested initial steps include the following:

- All studies and national data should report data disaggregated by gender.
- Factors that may influence SLT use among women before, during, and after pregnancy should be examined in order to design evidence-based intervention models and guidelines for cessation across the life course.
- Research on tobacco industry tactics targeting women could help to better inform programme and policy interventions to protect girls and women from initiating use and help those who already use SLT to quit.
- Further investigation is needed of the health effects of SLT use on women throughout the life course, including pregnancy complications, placental function, menstrual function, infertility, and menopause.

Health Effects

- Further research is needed in order to better quantify:
 - The effects of smokeless tobacco on all-cause and cause-specific mortality
 - Risk of cardiovascular diseases, cancers of cervix and pancreas, and other diseases that may be caused by SLT use
 - Excess risks associated with specific products of regional preference.

Addiction, Withdrawal, and Cessation

- A behavioural scale that tests levels of addiction to SLT should be developed for India.
- The effectiveness of nicotine replacement therapy (NRT) and pharmacotherapy for SLT cessation is in need of further study in India.
- Biochemical methods for validating use and non-use of SLT, such as urine cotinine testing, should be studied at the clinic and population levels.

Advocacy and Policy

- The impact of current tobacco policies, especially the SLT ban, should be researched to strengthen the evidence base used by states when broadening the ban to all SLT products.
- Successes and challenges related to enforcement of the SLT ban should be documented and analysed in terms of implementation and impact.

Legal

- Legal systems that are implementing effective public health laws and providing the judicial basis for the right to health should be researched to assist litigation and strengthen the legal basis for tobacco control policies.

Strategic Partnerships

- The feasibility and cost-effectiveness of integrating brief interventions for tobacco control and tobacco cessation into different health and development programmes should be studied in order to propose models for scaling up integrated programmes at the national and state levels.



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**Ministry of Health and Family Welfare
Government of India**