सत्यमेव जयते

Ministry of Health and Family Welfare
Government of India

Smokeless Tobacco and Public Health in India

Smokeless Tobacco and Public Health in India

Scientific Editors

Prakash C. Gupta

Monika Arora

Dhirendra Sinha

Samira Asma

Mark Parascondola

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Editorial Assistants

Cecily S. Ray

Manu Raj Mathur

Lauren Bartell

राष्ट्रीय स्वास्थ्य मिशन

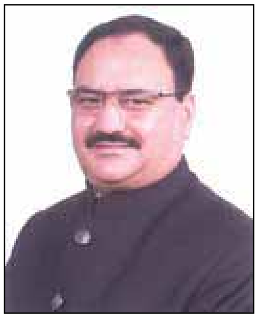
जगत प्रकाश नड्डा
Jagat Prakash Nadda

सत्यमेव जयते

स्वच्छ भारत
एक कदम स्वच्छता की ओर

स्वास्थ्य एवं परिवार कल्याण मंत्री
भारत सरकार
Minister of Health & Family Welfare
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)

348, ए-स्कंध, निर्माण भवन, नई दिल्ली-110011
348, A-Wing, Nirman Bhawan, New Delhi - 110011
Tele.: (O) +91-11-23061661, 23063513 Telefax : 23062358
E-mail : hfwminister@gov.in

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 Khetrapal 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

Contributors

Authors

Manu Raj Mathur
Ph.D. Fellow
Public Health Foundation of India (PHFI)
PHD House, Second Floor, 4/2, Sirifort
Institutional Area, August Kranti Marg
New Delhi – 110 016, India
manu.mathur@phfi.org

Gaurav Kumar
Research Associate
Public Health Foundation of India (PHFI)
New Delhi, India
Gaurav.kumar@phfi.org

Richa Wahi
Research Associate
Public Health Foundation of India (PHFI)
New Delhi, India
richawahi@yahoo.com

Sakhtivel Selvaraj
Senior Public Health Specialist (Economics & Financing)
Public Health Foundation of India (PHFI)
PHD House, Second Floor, 4/2, Sirifort
Institutional Area, August Kranti Marg
New Delhi – 110 016, India
shakti@phfi.org

Sarit Kumar Rout
Senior Research Associate
Public Health Foundation of India (PHFI)
New Delhi, India
Sarit.kumar@phfi.org

B. Ravi Kumar
Research Associate
Public Health Foundation of India (PHFI)
New Delhi, India
ravi.kumar@phfi.org

Swati Srivastava
Research Associate
Public Health Foundation of India (PHF) New Delhi, India
swati.srivastava@phfi.org

Dhirendra N. Sinha
Regional Advisor, Surveillance (Tobacco Control), Tobacco Free Initiative World Health House, Indraprastha Estate Mahatma Gandhi Marg
New Delhi – 110 002, India
sinhad@searo.who.int

Neha Mathur
Course Coordinator
Distance Learning, PROJECT STEPS
Public Health Foundation of India (PHFI)
New Delhi, India
neha.m@phfi.org

Gaurang P. Nazar
Research Fellow
HRIDAY-SHAN, C1/52, 3rd Floor
Safdarjung Development Area
New Delhi – 110016, India
gaurang@hriday-shan.org

V. Gajalakshmi Vendhan
Director
Epidemiological Research Center
New No. 27, Canal Road
Kilpauk Garden Colony, Chennai 600 010
Tamil Nadu, India
gajaerc@gmail.com

Krishna M. Palipudi
Senior Service Fellow
Centers for Disease Control and Prevention
Building: CHAM
Room: NCCDPHP Station
Chamblee, GA 30341-3717, USA
krishna.palipudi@cdc.hhs.gov

Samira Asma
Chief, Global Noncommunicable Diseases Branch
Division of Global Health Protection
Centers for Disease Control and Prevention
1825 Century Center Boulevard, MS E-98
Atlanta, GA 30345, USA
sasma@cdc.gov

Monika Arora
Head, Health Promotion & Tobacco Control & Adjunct Assistant Professor
Public Health Foundation of India (PHFI)
PHD House, Second Floor, 4/2, Sirifort Institutional Area August Kranti Marg
New Delhi – 110 016, India
monika.arora@phfi.org

Mark Parascandola
Epidemiologist
Tobacco Control Research Branch
Behavioral Research Program
Division of Cancer Control and Population Sciences
National Cancer Institute
Bethesda, MD, USA
mark.parascandola@nih.hhs.gov

Jagdish Kaur, MD
Chief Medical Officer
Ministry of Health & Family Welfare
Directorate General of Health Services
Room No. 352 A, A Wing
Nirman Bhawan
Maulana Azad Road
New Delhi – 110108, India
drjagdishkaur@gmail.com

Prakash C. Gupta
Director
Healis-Sekhsaria Institute for Public Health
601/B Great Eastern Chambers
Plot No. 28, Sector 11 CBD Belapur
Navi Mumbai – 400 614, India
guptapc@healis.org

Prabhat Jha
Professor
Dalla Lana School of Public Health
University of Toronto, 6th Floor
155 College Street
Toronto, ON, M5T 3M7, Canada
prabhat.jha@utoronto.ca

Cecily S. Ray
Senior Scientific Officer
Healis-Sekhsaria Institute for Public Health
601/B Great Eastern Chambers
Plot No. 28, Sector 11 CBD Belapur
Navi Mumbai – 400 614, India
rayc@healis.org

Ankur Singh
Research Associate
Public Health Foundation of India (PHFI)
Plot Number 47, Sector 44
Institutional Area
Gurgaon – 122002, India
a.singh@adelaide.edu.au

Bhavna B. Mukhopadhyay
Executive Director
Voluntary Health Association of India
B-40 Qutab Institutional Area
New Delhi – 110 016, India
bhavna.alok@yahoo.co.in /
healthpromotion@vhai.org

Chandra Ramakrishnan
Manager, Development Communications
Voluntary Health Association of India
B-40 Qutab Institutional Area
New Delhi – 110 016, India
chandrar@vhai.org

Sreevidya Subramoney
Former Senior Research Scientist
Healis-Sekhsaria Institute for Public Health
B 202, Orange County Phase I
Pashan Baner Link Road
Pune – 411021, India
subramoneys@gmail.com

Mira B. Aghi
Behavioral Scientist
Communication Expert
P-14, Green Park Extension
New Delhi – 110 016, India
mirabaghi@gmail.com

Mangesh S. Pednekar
Director (Development & Research)
Healis-Sekhsaria Institute for Public Health
601/B, Great Eastern Chambers
Plot No. 28, Sector 11, CBD Belapur
Navi Mumbai – 400 614, India
pednekarm@healis.org

P. Gangadharan
Amrita Institute of Medical Sciences &
Research Center, Amrita Lane
AIMS Ponekkara P.O.; Kochi-682041
Kerala, India
gangadharanp@aims.amrita.edu

Surendra Shastri
Head, Department of Preventive Oncology
Head, WHO Collaborating Centre for Cancer
Prevention, Screening and
Early Detection
Tata Memorial Centre
Parel, Mumbai – 400012, India
surendrashastri@gmail.com

Pankaj Chaturvedi
Associate Professor
Head and Neck Service
Tata Memorial Hospital
Parel, Mumbai – 400012, India
chaturvedi.pankaj@gmail.com

Sourav Datta
Head and Neck Surgeon
Tata Memorial Centre
Parel, Mumbai – 400012, India
souravnrs1@gmail.com

Aditi Shastri
Assistant Professor, Oncology and
Hematology
Albert Einstein College of Medicine and
Montefiore Medical Center
1300 Morris Park Avenue
Bronx, NY 10461, USA
shastriaditi84@gmail.com

Salman Salahuddin
Cardiologist
Malabar Institute of Medical Sciences
Mini By-pass Road, Govindapuram
Calicut – 673016, Kerala, India
drsalmans@gmail.com

Sailesh Mohan
Senior Public Health Specialist
Public Health Foundation of India (PHFI)
Plot Number 47, Sector 44
Institutional Area
Gurgaon – 122002, India
Sailesh.mohan@phfi.org

Ambuj Roy
Associate Professor
Department of Cardiology
All India Institute of Medical Sciences
Ansari Nagar
New Delhi – 11029, India
drambujroy@gmail.com

K. Srinath Reddy
President
Public Health Foundation of India (PHFI)
PHD House, Second Floor, 4/2, Sirifort
Institutional Area August Kranti Marg
New Delhi – 110 016, India
ksrinath.reddy@phfi.org

Vijay Mathur
Department of Dental Surgery
All India Institute of Medical Sciences (AIIMS)
Ansari Nagar
New Delhi – 110 029, India
vijaymathur7@gmail.com

Tanupriya Gupta
Assistant Professor
Dept. of Public Health Dentistry
New Delhi, India
dr.tanupriyagupta@gmail.com

Paluri Rama Murti
Former Director, School of Dentistry
School of Dentistry
University of the West Indies
G4 Ratna Riveria, AU Down Road
59 Kirlampudi Lay-out
Waltair, Vishakhapatnam – 530017, India
prmurti@gmail.com

Rajani A. Bhisey
Former Sr. Scientist, Cancer Research Institute, Tata Memorial Center
7-Yug, Prabhat Co-op. Hsg. Soc.
Sitaladevi Temple Road
Mahim, Mumbai – 400 016, India
rajani.bhisey@gmail.com

Stephen B. Stanfill
Research Chemist
Centers for Disease Control and Prevention
Building: CHAM, Room: NCEH Station
Chamblee, GA 30341-3717, USA
stephen.stanfill@cdc.hhs.gov

Raj Kumar
Professor & Head, Respiratory Allergy & Applied Immunology and
Head, University Dept. of Pulmonary Medicine, VP Chest Institute
University of Delhi
Delhi – 110 007, India
rajkumarvpci@gmail.com

Nitin Goel
VP Chest Institute
University of Delhi
Delhi – 110 007, India
drnitingoel@gmail.com

Deepti Singh
Legal Officer
Public Health Foundation of India (PHFI)
New Delhi, India
deepti@hriday-shan.org

Raghavendra Madhu
Research Associate
Public Health Foundation of India (PHFI)
New Delhi, India
raghavendra.madhu@phfi.org

Shekhar Salkar, MS FICS (Onco)
Manipal Goa Hospital
Dona Paula, Panaji, Goa & General Secretary
National Organization for Tobacco Eradication (NOTE)
Panaji, Goa, India
salkar.shekhar@gmail.com

Amit Yadav
Manager (Legal)
HRIDAY, C-1/52, 3rd Floor
Safdarganj Development Area
New Delhi – 110 016, India
amit@hriday_shan.org

Ranjit Singh
Legal Consultant
National Tobacco Control Programme
Ministry of Health & Family Welfare
New Delhi, India
singhranjit617@gmail.com

Arpita Singh
Legal Officer
Healis-Sekhsaria Institute for Public Health
601/B Great Eastern Chambers
Plot No. 28, Sector 11 CBD Belapur
Navi Mumbai – 400 614, India
singha@healis.org

Nandita Murukutla
Director, Research and Evaluation
World Lung Foundation
A-11 Green Park Extension
New Delhi – 110016, India
NMurukutla@worldlungfoundation.org

Tahir Turk
Senior Technical Advisor – Mass Media
World Lung Foundation
61 Broadway, 6th Floor
New York, NY 10006, USA
tturk@bigpond.com

Sandra Mullin
Senior Vice President
Policy and Communications
61 Broadway, Suite 2800
New York, NY 10006, USA
SMullin@worldlungfoundation.org

Vineet Gill Munish
National Professional Officer
Tobacco Free Initiative
WHO Country Office for India
537, A Wing, Nirman Bhawan
New Delhi – 110 011, India
munishvg@who.int

Praveen K. Sinha
Ministry of Health & Family Welfare
Nirman Bhawan
New Delhi – 110 108, India
pravsinha@gmail.com

Rajmohan Panda
Public Health Specialist
Reproductive and Child Health
Public Health Foundation of India (PHFI)
PHD House, Second Floor, 4/2
Sirifort Institutional
Area August Kranti Marg
New Delhi – 110 016, India
raj.panda@phfi.org

Divya Persai
Research Consultant
Public Health Foundation of India (PHFI)
Plot Number 47, Sector 44
Institutional Area
Gurgaon – 122002, India
dpersai@gmail.com

Reviewers

Rijo M. John
Mullanmadackal House
Ayiroor P.O., Kurumasseri
Ernakulam Dt. Kerala, PIN 683579, India

rmjohn@gmail.com

Deliana Kostova
Economist, Global Noncommunicable
Diseases Branch
Division of Global Health Protection
Centers for Disease Control and Prevention
1825 Century Center Boulevard, MS E-98
Atlanta, GA 30345, USA
kiv0@cdc.gov

Pranay Lal
Technical Advisor (Tobacco Control),
The Union South-East Asia Office
International Union Against Tuberculosis and
Lung Disease (The Union)
C-6, Qutub Institutional Area
New Delhi – 110016, India
PLal@theunion.org

Mangesh S. Pednekar
Director (Development & Research)
Healis-Sekhsaria Institute for Public Health
601/B, Great Eastern Chambers
Plot No. 28, Sector 11, CBD Belapur
Navi Mumbai – 400 614, India
pednekarm@healis.org

Yvonne Hunt
Program Director
Tobacco Control Research Branch
Behavioral Research Program
Division of Cancer Control and
Population Sciences
National Cancer Institute
Bethesda, MD, USA
huntym@mail.nih.gov

P. Gangadharan
Consultant Bio-statistician
Cancer Registry
Amrita Institute of Medical Sciences
AIMS Ponekkara
Kochi – 682041, India
gangadharanp@aims.amrita.edu

Saritha Nair
Scientist C
National Institute for Research in
Reproductive Health
Jehangir Merwanji Street,
Parel, Mumbai – 400 012, India
nairs@nirrh.res.in; saritha_nair@yahoo.co.uk

Michele Bloch
Chief, Tobacco Control Research Branch
Behavioral Research Program
Division of Cancer Control and
Population Sciences
National Cancer Institute
Bethesda, MD USA
blochm@mail.nih.gov

Lucinda England
Medical Officer
Centers for Disease Control and Prevention
4770 Buford Highway, N.E.
Atlanta, GA 30341, USA
lbe9@cdc.gov

Ramesh B. Bhonsle
The Manipal-Goa Cancer and
General Hospital
Dental Department
Dr. E. Borges Road
Dona Paula
Goa – 403004, India
rameshbhonsle9@gmail.com

Gregory N. Connolly
Professor of the Practice of Public Health
Director, Center for Global Tobacco Control
Department of Society, Human Development, and Health
Harvard School of Public Health
401 Park Drive
Landmark Center – 3rd Floor (East)
Boston, MA 02215, USA
gconnoll@hsph.harvard.edu

Zubair Kabir
Visiting Scientist
Harvard School of Public Health
Center for Global Tobacco Control
Department of Society, Human Development, and Health
Harvard School of Public Health
401 Park Drive
Landmark Center – 3rd Floor (East)
Boston, MA 02215, USA
zkabir@tri.ie

Gary A. Giovino
Department of Community Health and Health Behavior
School of Public Health and Health Professions
University at Buffalo, The State University of New York
310 Kimball Tower
Buffalo, NY 14214-8028, USA
ggiovino@buffalo.edu

Rajeev Gupta
Department of Medicine
Monilek Hospital and Research Centre
Jaipur – 302017, India
rajeevg@satyam.net.in

Paluri Rama Murti
Former Director, School of Dentistry
School of Dentistry
University of the West Indies
G4 Ratna Riveria, AU Down Road
59 Kirlampudi Lay-out
Waltair, Vishakhapatnam – 530017, India
prmurti@gmail.com

Vinay Hazarey
Dean, Government Dental College
Nagpur, India
vinay.hazarey@gmail.com

Girish B. Maru
Principal Investigator
KS 217, Cancer Research Institute
Advanced Centre for Treatment, Research and Education in Cancer (ACTREC),
Tata Memorial Centre
Kharghar, Navi Mumbai – 410 208, India
gmaru@actrec.gov.in

Irina Stepanov
Assistant Professor
Division of Environmental Sciences
University of Minnesota
Minneapolis, MN 55455, USA
stepa011@UMN.EDU

Pratima Murthy
Professor, Dept. of Psychiatry, & Chief, De-addiction Services
National Institute of Mental Health and Neuro Sciences
Bangalore – 5600029, India
pratimamurthy@gmail.com

Dorothy K. Hatsukami
Forster Family Professor in Cancer Prevention
Professor of Psychiatry
University of Minnesota
717 Delaware Street, S.E.
Minneapolis, MN 55414, USA
hatsu001@umn.edu

Rakesh Gupta
President, Rajasthan Cancer Foundation, Jaipur
Head, Cancer and Tobacco Control
Sr. Consultant
Cancer Surgery, Soni Group of Hospitals and SEAROC Cancer Center, Jaipur
B-113, 10 B Scheme, Gopalpura Bypass
Jaipur – 302018, India
rakesh.gupta.acs@gmail.com

Nyo Nyo Kyaing
Regional Advisor
Tobacco Free Initiative
Regional Office for South-East Asia
World Health House
Indraprastha Estate
Mahatama Gandhi Marg
New Delhi – 110 002, India
kyaingn@searo.who.int

Farida Poonawala Tata
Solicitor
102-104 Bhagyoday, 1st Floor
79, Nagindas Master Road
Fort, Mumbai – 400023, India
faridapt@gmail.com

Amal Pusp
Director
Ministry of Health and Family Welfare
Nirman Bhawan, Maulana Azad Road,
New Delhi - 110108, India
amal.pusp@gmail.com

Vandana Shah
Director of South East Asia Programs
Campaign for Tobacco-Free Kids
1400 Eye Street, N.W., Suite 1200
Washington, DC 20005, USA
VShah@TobaccoFreeKids.org

Rana J. Singh
Technical Advisor
The Union South-East Asia
International Union Against Tuberculosis and Lung Disease (The Union)
C-6, Qutub Institutional Area
New Delhi – 110016, India
RJSingh@theunion.org

April Roeseler
California Department of Public Health
California Tobacco Control Program
P.O. Box 997377, MS 7206
Sacramento, CA 95899-7377, USA
April.Roeseler@cdph.ca.gov

Lauren Billick
Public Health Advisor, Avram Coorporation
Global Noncommunicable Diseases Branch
Division of Global Health Protection
Centers for Disease Control and Prevention
1825 Century Center Boulevard, MS E-98
Atlanta, GA 30345, USA

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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

Executive Summary

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.

Chapter 1

Historical and Sociocultural Overview of Smokeless Tobacco in India

Manu Raj Mathur[1], Gaurav Kumar[1],
Richa Wahi[1]

[1]Public Health Foundation of India, New Delhi

INTRODUCTION

Although tobacco has been established as the cause of the largest number of preventable deaths and diseases in the world[1], its use has increased with time and modernisation[2]. Despite repeatedly countering the tobacco industry's varied strategies to preserve and enlarge its markets, public health institutions face high mortality and morbidity rates due to cancers, cardiovascular diseases, oral diseases, infertility, and other consequences of tobacco use[1]. Cigarette smoking accounts for most of the tobacco consumption in the economically developed countries of the world[1]. However, in South-East Asia, particularly India, smokeless tobacco (SLT) is the dominant form of tobacco use and a major causal factor for many tobacco-attributable diseases[3]. Although smokeless tobacco products have been consumed in India for several hundred years, their use has surged in recent decades because of an increase in the availability of new commercial SLT products and the advent of mass-produced, cheap, easily accessible, and attractive packaging[2].

DEFINITIONS OF SMOKELESS TOBACCO

Various agencies and experts have defined smokeless tobacco in different ways, mainly according to its mode of consumption. The World Health Organization's Framework Convention on Tobacco Control (WHO FCTC), the first treaty intended to combat the globalisation of the tobacco epidemic, defines smokeless tobacco as 'tobacco that is consumed in un-burnt form, either orally or nasally'[4]. According to the International Agency for Research on Cancer (IARC):

> The agent termed 'smokeless tobacco' includes a large variety of commercially or non-commercially available products and mixtures that contain tobacco as the principal constituent and are used either orally or nasally without combustion (p. 33)[5].

In an attempt to coin a valid and complete definition of smokeless tobacco for the Indian subcontinent, we suggest that it can be defined as:

> *All commercial/noncommercial products that contain tobacco, but which are not ignited at the time of their consumption; are either consumed nasally or orally; and may or may not be mixed with other condiments such as sweetening agents, aromatic spices, areca nut (supari), and lime.*

SMOKELESS TOBACCO PRODUCTS COMMONLY USED IN INDIA

Myriad varieties of smokeless tobacco products are used in India. Table 1.1 gives a brief overview of these different tobacco products, classifying them based on their mode of consumption. (For detailed descriptions of individual smokeless products, see the factsheets in Appendix 1.)

Table 1.1: Varieties of smokeless tobacco products used in India

Smokeless tobacco product	Product description
	For chewing and sucking
Products with areca nut	
Betel quid (pan) with tobacco	Tobacco + areca nut + slaked lime + catechu + condiments, wrapped in betel leaf
Gutka	Tobacco + areca nut + slaked lime + catechu + condiments
Kharra	Tobacco + areca nut + slaked lime + catechu + condiments (locally made)
Mainpuri	Tobacco + finely cut areca nut + slaked lime + powdered cloves, cardamom, Kewara essence, sandalwood powder, camphor, peppermint
Dohra	Wet mixture of tobacco + areca nut + slaked lime + catechu (kattha), peppermint and cardamom (elaiachi), May be sold in two separate pouches, one containing tobacco and the other containing non-tobacco ingredients.
Mawa	Tobacco + areca nut shavings + slaked lime
Products without areca nut	
Khaini	Tobacco + slaked lime
Zarda	Tobacco blended with perfumes and flavours
Khiwam	Thick paste of tobacco leaf extract with flavourings and spices
Chewing tobacco	Tobacco (raw, finely cut)
Loose tobacco leaf	Strip or piece of air-cured tobacco leaf
	For application
Mishri	Roasted and powdered tobacco
Gul	Pyrolysed tobacco powder
Gudakhu	Paste of tobacco and molasses
Tapkeer/Bajjar/snuff	Dry powdered tobacco for oral or nasal use
Tobacco-containing toothpowder	Herbal tooth powder containing a small amount of tobacco. Used primarily for dental hygiene.
Creamy snuff/toothpaste	Tobacco-based toothpaste with clove oil, glycerine, menthol, camphor as other ingredients
	For gargling
Tuibur	Tobacco-smoke-infused water

HISTORICAL OVERVIEW OF SMOKELESS TOBACCO

The Origins of Tobacco Use

The tobacco plant originated in the Americas. Native Americans began to cultivate it in about 6000 BCE[6]. On Christopher Columbus's travels through the West Indies and the Caribbean in 1492, Europeans first encountered tobacco, reporting that they found natives who 'drank smoke'[7]. A Franciscan monk named Friar Roman Paine, who accompanied Columbus on his second voyage to the New World in 1493, recorded the first reference to smokeless tobacco use in the world when he noted that the Native Americans sniffed finely powdered tobacco leaves[7]. Paine took a supply of this form of tobacco back to Portugal, from which the practice of sniffing tobacco spread throughout the region, and tobacco became a major trading commodity between the Old World and the New.

Another record of tobacco use comes from Amerigo Vespucci, who in 1499 described Native Americans chewing green leaves mixed with a white powder[8]. They would carry two gourds around their necks, precursors of the contemporary South East Asian tobacco pouch. One gourd was filled with leaves, the other with powder. After putting leaves in their mouths they dampened a small stick with saliva and dipped it in the powder, mixing the two into a kind of chewing tobacco product[8]. Native Americans also devised an alternative method of consumption, inhaling the fine tobacco powder through the nose from a Y-shaped hollow piece of pipe. Placing a forked end of the pipe into each nostril and the other end close to the powdered tobacco, they snorted it up, causing a 'sneeze' reflex. Such snuffing pipes were called 'tobago' or 'tobaca', like the name of the island of Tobago in the West Indies, which some believe to be the origin of the word *tobacco*[9].

Smokeless tobacco came to Asia through Portuguese trade routes to Japan, and from there to China, where it became popular at the courts of the Ching Dynasty[7]. The Chinese kept their tobacco in bottles made from precious materials such as porcelain, ivory, brass, jade, coral, cinnabar, quartz, turquoise, amethyst, amber, as well as bone, horn, and bamboo. They would remove a small portion of snuff with a spoon, place it on the left thumbnail, and inhale it forcefully into the nostrils. The Chinese believed tobacco was beneficial for treatment of cold, throat ailments, asthma, constipation and toothache[7]. Smokeless tobacco gained wide popularity and rapidly spread to many countries of Central and South East Asia[8].

> The Spanish upon their journey met with great multitudes of people, men and women with firebrands in their hands and herbs to smoke after their custom.
>
> —Christopher Columbus[8]

> Placed in the mouth, it [tobacco] produces dizziness and stupefies.
>
> —Sahehum, a priest who
> lived among the Mexicans,
> 1529–1590[9]

> Chewing tobacco is tobacco's body, smoke is its ghost and snuff is tobacco's soul.
>
> —Bob Stevens, 1976[10]

Traditional Use of Betel Quid (Pan) and the Evolution of Smokeless Tobacco Products

To understand the spread of smokeless tobacco in India, it is important to understand the tradition of chewing pan, which dates back at least 2,000 years in India, long before the arrival of tobacco in South Asia, and still continues today[6]. The traditional ingredients in pan are areca nut (*Areca catechu*), cinnamon, cardamom, sweeteners, slaked lime, mint, and other exotic spices, which are packed in the leaf of the betel vine. Pan chewing has been deeply rooted in the social customs, heritage, and diversity of India. It is embedded in Hindu culture and is referred to as one of the eight bhogas (enjoyments) of life.

Between the 8th and 18th centuries, it was fashionable for betel chewers to carry a case to hold the components of pan from which they would serve their guests. The betel cases of the wealthy were usually of silver or gold, while the poor used brass boxes or mat bags. The betel quid was presented as a token of hospitality and courtesy. It was considered rude to decline it, or for a person of lower hierarchy to address a superior without chewing pan before speaking. Chewers usually swallowed the juice. Pan was used by both sexes from early childhood until old age, when toothlessness meant that the ingredients would have to be reduced to a paste so they would dissolve in the mouth[15].

During the Mughal period, Portuguese traders introduced tobacco in South Asia, specifically the South Indian kingdom of Adil Shah, in Bijapur city. At first, the mode of use was primarily smoking, then snuff and chewing tobacco became common[11]. When Europeans first arrived in India, pan was presented to them as a symbol of courtesy and respect because they were considered honored guests. The Europeans soon adopted India's customary use of pan and experimented by adding tobacco to it, which led to the regular practice of using smokeless tobacco with betel quid[3,18].

Tobacco use spread to northern India when Asad Beg, one of the courtiers of Adil Shah, took tobacco with him to present it to King Akbar. Tobacco was widely appreciated and became quickly popular among Mughal courtiers[12]. Its popularity was attributed to its unusual euphoric properties and the many forms in which it was available. There were many attempts to define tobacco by those addicted to it. Artists depicted it in their art, poets and writers in their literary works, and singers through their music—all further spreading the habit of tobacco use[13].

Noor-e-Jahan, mother of Emperor Shah-e-Jahan, who built the Taj Mahal, popularised the tradition of chewing betel leaf with tobacco in the Mughal courts by offering it to guests to welcome them, and also at their departure[11]. Although pan chewing and associated tobacco use began among the nobility, it soon spread to the common folk, and its importance as an obligatory social custom was established at all levels of society. By 1617, SLT use had become so popular among all classes that Jahangir, who came to the throne after Akbar, issued a decree identifying tobacco's potential harms and forbidding its use[14].

Thomas Bowery, an English traveler to India, gave an account of betel, areca nut, and tobacco chewing during the years 1669–1679. He noted that tobacco was included among gift items to fakirs (holy men) in northern India. In the Coromandel region, it was mixed with betel leaf and areca nut (pan and supari), forming a quintessential betel quid with tobacco, which was served at Hindu weddings and many such important social occasions[13]. The earliest account of tobacco being chewed with areca nut or lime is from 1708[10]. Such a mixture is commonly called pan.

Pan stains chewers' saliva, lips, and teeth red, and pan use became so prevalent that red-stained lips and teeth soon not only became acceptable but were considered a mark of beauty for women and a mark of wealth among men[15]. John McCulloch underscored the social importance of pan use, writing in 1832: 'No one of inferior rank addresses a dignified individual without the previous precaution of chewing betel; two people seldom meet without exchanging it; and it is always offered on the ceremonious interviews of public missionaries'[11].

Betel leaf itself is not harmful, but as a wrapper for areca nut and SLT, both of which are carcinogenic, it lends its name to a harmful quid.

> According to the Hindu Dharma Sastra (code of behaviour), areca nut pleases God Brahma (the creator), the betel leaves pay homage to Vishnu (the protector), and slaked lime bows to Siva (the destroyer).
>
> —P.K. Gode, 1961[16]

> The chewing of betel provokes much spitting of reddish-coloured saliva; and the Indians have an idea that by this means the teeth are fastened, the gums cleaned, and the mouth cooled.
>
> —Dr. Ainslie, 1836, p. 26[17]

The preparation of a typical pan with tobacco was tedious and time consuming. The market for pan in India changed in the mid-20th century, when consumers demanded an easier and faster method of use, and ingredients and packaging also evolved. To simplify the effort required to prepare pan, manufacturers created a powdered mixture of its contents that could be readily consumed from a tin, or later from a pouch or packet. This form of pan became known as pan masala, a popular product amongst youth and elders. Some varieties, which contained tobacco, were marketed as mouth fresheners. Many brands of pan plus tobacco were packaged in colourful, eye-catching wrappers that could attract young adults and make them addicts for life.

Early Tobacco Cultivation and Growth of the Tobacco Industry

The earliest significant cultivation of tobacco in India was recorded in 1604-1605 in Gujarat (Surat-Bharuch area)[13,18] near western coastal areas that were important to trade between Portugal and India, such as Cochin and Goa. (In the east, Machilipatnam in Andhra Pradesh was also important to Portuguese–Indian trade[13].)

Tobacco growing quickly spread to other areas of the country. During Jahangir's reign (1605–1627), tobacco became a major cash crop[19]. Regions of Bengal, Bihar, and Orissa, as well as northern and central India cultivated tobacco extensively in the 17th century[13]. With improved means of transportation and increased mobility of population, the demand for tobacco rose steadily and spread even to remote villages. As it grew, this demand stimulated other industries, such as metalworking and pottery and jewelry production, to make the decorative boxes in which aristocrats kept tobacco plugs (formed from loose tobacco and a binding sweetener) and other ingredients of pan at the optimum moisture level. With the rise of tobacco as a consumer product, a new class of traders emerged who linked the peasant with government and with the non-farming consumer[13].

The area under tobacco cultivation in India tripled between the years 1891 and 1921[21]. Since independence, the area under cultivation has varied widely, particularly between 1950 and 2002. During this period, tobacco production varied as well[26], but the quantity of tobacco produced has increased overall since the 1950s[22].

Barter and Early Trade of Tobacco in India

After the British East India Company established trading posts in India, they began importing American tobacco into India. When the beginning of the American Revolution interrupted this trade in 1776, the East India Company undertook tobacco cultivation in India[20].

According to William Methwold, an English merchant and administrator during British rule in India, tobacco produced in India was traded with other countries, and was exported to Mocha, Arakan, the Red Sea, and coastal Burma before 1622[22]. South Indian tobacco was exported mainly to Javin and Achin, and occasionally to Persia. Surat tobacco was traded within India from Sindh in the north to Goa in the south[23], eventually in such large quantities that by 1647 tobacco became scarce in Surat, indicating that demand had outrun supply. A private illegal trade of tobacco came to light in 1628 when it caused complaint, and by 1630 the East India Company prohibited private consignments of tobacco on its ships[24].

Tribal communities in India also regularly traded agricultural produce for tobacco. The Shompens and Nicobarese tribes, residing in the jungles and outer areas of the Nicobar Islands, respectively, regularly bartered locally produced honey, lemons, and resin for tobacco, cloth, and machetes, ranking tobacco as an essential commodity rather than a luxury item[25].

HISTORICAL SNAPSHOT OF MEDICINAL USES OF SMOKELESS TOBACCO

Tobacco has been used for its medicinal properties for as long as its use has been recorded. Native Americans once consumed tobacco through enemas as a spiritual–medical ritual[12]. Monardes, a Spanish doctor in the 16th century, wrote that tobacco could cure 36 conditions, including headache, toothache, 'falling fingernails', lockjaw, halitosis, worms, and cancer[8].

Indian traditional medicine, Ayurveda, was based on the concepts of hot, cold, and balance, but unlike Chinese and European medicine, it never encouraged the use of tobacco for medicinal purposes[27]. The medical compendium *Yogratnakara*, written sometime between 1625 and 1750 C.E., attributes both positive and negative health effects to tobacco use[28].

While smoking tobacco was recognised to have some adverse effects on health, smokeless tobacco was widely perceived in medieval India to have health benefits. Smokeless tobacco use was believed to have antiseptic properties and to result in improved oral health, relief from tooth pain, better digestion, and improved memory[28]. These myths have supported and increased the use of smokeless tobacco in India for generations, and some of these misconceptions, such as the belief that tobacco is helpful for cleaning teeth, are still prevalent in rural areas and some urban populations in India today[29].

SMOKELESS TOBACCO, RELIGION, AND RITUALS

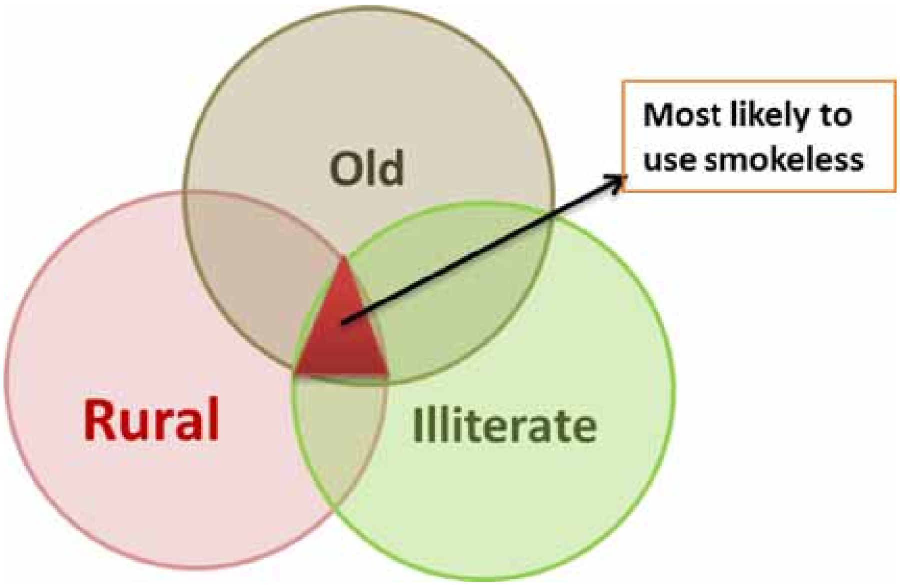
Although Indian religious texts make no specific references to smokeless tobacco, the use of tobacco has been condemned directly or indirectly in all the major religious texts of India[6,30]. Tobacco leaves are an important element in Muria Gond tradition[31]. The Muria Gonds, a tribe from Bastar District in Chhatisgarh, consider tobacco a valuable commodity and consume it during social occasions as an indicator of brotherhood and unity[31].

SOCIODEMOGRAPHIC PROFILING OF SMOKELESS TOBACCO IN INDIA

In India and other South-East Asian countries, the prevalence and patterns of use of the numerous smokeless tobacco products available vary from one region and population to another. Historically, smoking by women has been condemned in Indian culture. Using smokeless tobacco, however, has been widely accepted, which has led women and youth to actively follow this practice. Characteristics of smokeless tobacco—such as its low price, lower detectability than smoking, and added flavours (e.g., elaiachi and clove)—appeal to youth and women. Manufacturers have taken advantage of the misconceptions surrounding smokeless tobacco and have launched many varieties of SLT products, making them easily affordable and accessible even by poor and vulnerable sections of society.

Daily and occasional users of smokeless tobacco, among males and females, are proportionately more prevalent in rural areas than urban areas. Current use of smokeless tobacco increases with increasing age (16% among ages 15–24 years, and 34% among people 65 years and older). Daily use of smokeless tobacco among males and females has been found to decrease as educational levels increase. Figure 1.1 illustrates the interplay of these demographic factors.

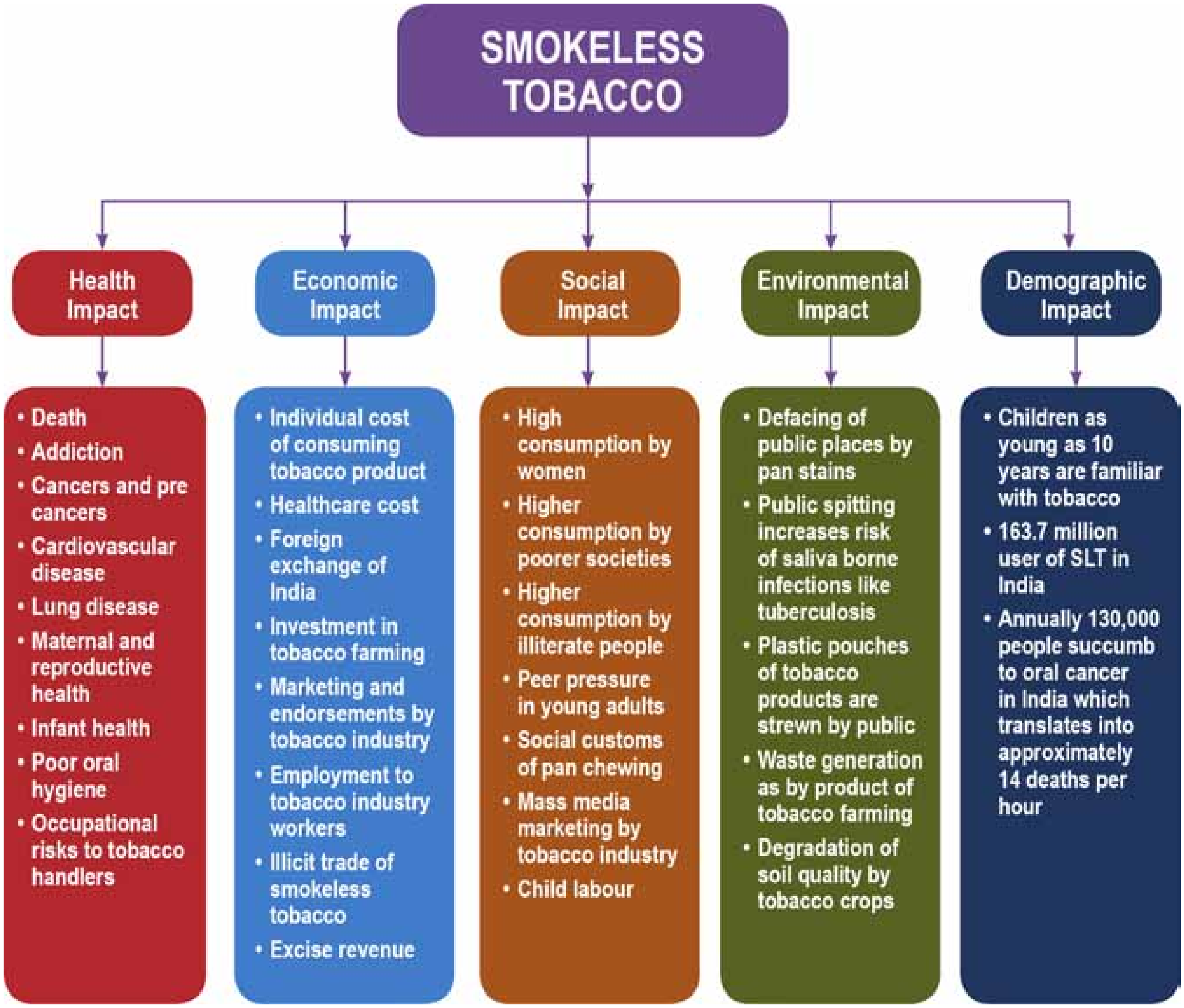
Figure 1.1: Triad of predisposing factors of smokeless tobacco use



CONCLUSION

Since tobacco was first introduced in India, smokeless tobacco has become the dominant form of tobacco used in the country. Studies show the wide range of adverse impacts that smokeless tobacco has for individuals and the nation as a whole. Figure 1.2 depicts these impacts across various dimensions of health and development. Detailed discussion of the adverse effects of smokeless tobacco will follow in subsequent chapters of this report.

Figure 1.2: Impact of smokeless tobacco



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Chapter 2

Economics of Smokeless Tobacco in India

Sakhtivel Selvaraj[1], Sarit Kumar Rout[2],
B. Ravi Kumar[3], Swati Srivastava[1]

[1]Public Health Foundation of India, New Delhi
[2]Indian Institute of Public Health, Bhubaneswar
[3]Indian Institute of Public Health, New Delhi

INTRODUCTION

In contrast to the rest of the world, the consumption of smokeless tobacco (SLT) in India is substantially higher than that of smoked tobacco. Because of the increasing demand, producers are manufacturing diverse categories of smokeless products. SLT product preference varies across population groups; for instance, youths tend to prefer gutka, while gul/gudakhu is primarily used by women for cleaning teeth. The size, nature, and structure of the SLT industry in India—its growth trends and its contributions to employment, trade, revenue, and foreign exchange earnings—should be examined carefully in order to design suitable strategies to curb its growth.

ECONOMIC BURDEN

The economic burden of tobacco-attributable disease is substantial. One study in 1999 estimated that the total direct and indirect cost attributable to three major tobacco-related diseases in India was US$ 6.5 billion[1]. This amount increased by 11% in 2001-2002[2]. Another study[3] observed that the direct medical costs of treating tobacco-related diseases in India in 2009 amounted to US$ 907 million for smoked tobacco and US$ 285 million for SLT. Indirect costs of use were US$ 398 and US$ 104 for smoking and SLT, respectively. According to that study, the cost of tobacco use was about 16% higher than the total tax revenue from tobacco and considerably exceeded expenditures on tobacco control by the Government of India.

The tobacco-attributable cost of tuberculosis was three times higher than the expenditure on tuberculosis control in India[3]. It has also been estimated that accounting for direct expenditure on tobacco would increase the rural and urban poverty rates by 1.5% (affecting 11.8 million people) and 0.72% (affecting 2.3 million people), respectively[4]. Since the poor use tobacco at higher rates than other groups, rates of tobacco-related illness and the resulting economic burden would be greater among the poor[5]. Those who use tobacco also have a higher risk of borrowing and selling assets during hospitalisation than others[6]. The evidence therefore indicates that the poor are particularly vulnerable to the economic cost of tobacco use.

TOBACCO CULTIVATION IN INDIA

India produces several types of tobacco, which belong to two botanical species, *Nicotiana tabacum* and *Nicotiana rustica.* Though the country grows both species, the largest area under cultivation is planted in *N. tabacum*. More than nine *N. tabacum* varieties are grown in different regions of the country, including cigarette tobacco (Virginia flue cured), bidi, chewing, hookah, cigar, cheroot, snuff, natu, and burley tobacco. Tobacco has been grown in India since the Portuguese introduced it the early 1600s. It was first grown in the state of Gujarat and later spread to other areas of the country[7].

The main tobacco-growing states are Andhra Pradesh, Karnataka, Tamil Nadu, Gujarat, Punjab, Uttar Pradesh, Assam, Bihar, Orissa, and West Bengal. Three states, Andhra Pradesh, Karnataka, and Gujarat, contain 84% of the total land area for growing tobacco[8]. Andhra Pradesh accounts for 44% of the total land under tobacco cultivation, followed by Karnataka with 28% and Gujarat with 13%[8].

In addition to the overall reduction in land area cultivated in tobacco, the amount of tobacco produced fluctuated between 1990 and 2008. In 1990-1991, 410,800 hectares of land was used for growing tobacco, with a total production of 556,000 tonnes (Table 2.1). The area declined to

348,000 hectares in 2007-2008, but production did not decline proportionally; while the cultivated area declined by 15%, production declined by only 11%, indicating increased productivity during the period. Both area and production declined sharply in 2000-2001 due to a crop holiday in Andhra Pradesh. Area under cultivation increased again after 2000-2001 but remained smaller than the area used for growing tobacco during the 1990s. On average, 426,000 hectares of land was used for tobacco cultivation during 1990–2000, and this declined to 357,000 hectares during the years 2001–2008. However, the average yield per hectare increased from 1,387 kgs during 1990–2000 to 1,481 kgs during 2001–2008.

Table 2.1: Area and production of tobacco in India

Year	Area (000 hectares)	Production (000 tons)	Yield (kg/hectare)
1990-91	410.8	555.9	1,353
1991-92	427.0	584.4	1,369
1992-93	418.5	596.5	1,425
1993-94	384.8	562.9	1,463
1994-95	381.4	566.7	1,486
1995-96	394.6	535.2	1,356
1996-97	432.4	599.1	1,386
1997-98	465.0	637.9	1,372
1998-99	508.1	736.2	1,449
1999-00	432.6	524.0	1,211
Average (1990 to 2000)	425.52	589.88	1,387
2000-01	261.5	344.7	1,318
2001-02	348.4	545.5	1,566
2002-03	326.6	491.7	1,506
2003-04	369.7	549.9	1,487
2004-05	366.5	549.1	1,498
2005-06	372.3	551.9	1,482
2006-07	368.2	519.3	1,410
2007-08	347.9	493.03	1,417
Average (2000 to 2008)	357.09	528.63	1,481

Source: Government of India, Ministry of Agriculture, Directorate of Tobacco Development[9].

Area Grown and Crop Production in India

Unlike other major tobacco-growing countries in the world, in India tobacco for different types of products (bidi, cigar, hookah, chewing, and snuff) as well as types of tobacco (Virginia, natu) is grown in specific areas of the country. Tobacco to be used in SLT products is mainly grown in Tamil Nadu, Gujarat, Bihar, West Bengal, and Uttar Pradesh, according to the Directorate of Tobacco Development, Government of India[9]. Of the total land area on which tobacco is grown, the greatest proportion is used for Virginia tobacco (mainly grown in Andhra Pradesh and Karnataka), followed by bidi tobacco (mainly grown in Gujarat and Andhra Pradesh).

As shown in Table 2.2, total land area under tobacco cultivation has declined from 410,800 hectares in 1990-1991 to 347,900 hectares in 2007-2008. The area planted in tobacco to be used in smokeless products has declined more sharply than the area planted in tobacco for smoked products. Tobacco for SLT was grown on 40% less land area in 2007-2008 than in 1990-1991. This reduction was particularly steep in 2000-2001 and the previous year because of a crop holiday declared by farmers growing Virginia tobacco in Andhra Pradesh. On average, between 1990 and 2008, 13.5% of the land area in tobacco cultivation was used for growing tobacco for smokeless products, compared to 86% for smoked tobacco.

Table 2.2: Land area of various tobacco crops in India (000 hectares) (percent)

Year	Chewing varieties	Snuff varieties	Smokeless varieties (chewing + snuff)	Smoked varieties	Total
1990-91	58.5 (14.2)	8.5 (2.1)	67.0 (16.3)	343.8 (83.7)	410.8 (100)
1991-92	54.7 (12.8)	8.1 (1.9)	62.8 (14.7)	364.2 (85.3)	427.0 (100)
1992-93	52.2 (12.5)	6.0 (1.4)	58.2 (13.9)	360.3 (86.1)	418.5 (100)
1993-94	48.5 (12.6)	5.1 (1.3)	53.6 (13.9)	331.2 (86.1)	384.8 (100)
1994-95	62.2 (16.3)	7.6 (2.0)	69.8 (18.3)	311.6 (81.7)	381.4 (100)
1995-96	65.4 (16.6)	6.0 (1.5)	71.4 (18.1)	323.2 (81.9)	394.6 (100)
1996-97	65.7 (15.2)	7.0 (1.6)	72.7 (16.8)	359.7 (83.2)	432.4 (100)
1997-98	51.0 (11.0)	8.2 (1.8)	59.2 (12.7)	405.8 (87.3)	465.0 (100)
1998-99	52.4 (10.3)	9.6 (1.9)	62.0 (12.2)	446.1 (87.8)	508.1 (100)
1999-00	43.3 (10.0)	5.8 (1.3)	49.1 (11.3)	383.5 (88.7)	432.6 (100)
2000-01	36.5 (14.0)	5.0 (1.9)	41.5 (15.9)	220.0 (84.1)	261.5 (100)
2001-02	35.6 (10.2)	4.7 (1.3)	40.3 (11.6)	308.1 (88.4)	348.4 (100)
2002-03	30.0 (9.2)	4.1 (1.3)	34.1 (10.4)	292.5 (89.6)	326.6 (100)
2003-04	33.0 (8.9)	6.0 (1.6)	39.0 (10.5)	330.7 (89.4)	369.7 (100)
2004-05	33.1 (9.03)	9.0 (2.45)	42.1 (11.4)	324.4 (88.5)	366.5 (100)

Year	Chewing varieties	Snuff varieties	Smokeless varieties (chewing + snuff)	Smoked varieties	Total
2005-06	33.6 (9.0)	9.1 (2.5)	42.7 (11.5)	329.6 (88.5)	372.3 (100)
2006-07	33.2 (9.0)	9.0 (2.4)	42.2 (11.5)	326.0 (88.5)	368.2 (100)
2007-08	31.37 (9.0)	8.5 (2.4)	39.87 (11.5)	308.01 (88.5)	347.9 (100)
Average (1990 to 2008)	45.57 (11.7)	7.07 (1.8)	52.64 (13.5)	337.15 (86.5)	389.83 (100)

Source: Government of India, Ministry of Agriculture, Directorate of Tobacco Development[9].

As shown in Table 2.3, approximately 83,000 tonnes of chewing tobacco were produced in 2007-2008, constituting 17% of total tobacco production. With the addition of snuff, the total production of tobacco for smokeless products was 92,000 tonnes, or about 19% of total tobacco production in that year. Therefore, one-fifth of the total tobacco produced was the SLT variety. Production of tobacco for smokeless products declined in absolute terms during this period, and as a share in the total tobacco production. However, the production of chewing tobacco remained stable at around 17% of total production during the 2000s, compared with its fluctuating trend in the 1990s. Although both land area and production of SLT declined between 1990 and 2008, production declined less in comparison to land size, indicating productivity gains in SLT in more recent years. The productivity rate increased from 1,352 kgs per hectare in 1990-1991 to 2,318 kgs per hectare in 2007-2008, whereas productivity of smoked varieties remained more or less the same during these years[9].

Table 2.3: Production of various types of tobacco crops (000 tonnes) (percent) and yield per hectare (kg/hectare)

Year	Chewing varieties	Snuff varieties	Smokeless tobacco varieties		Smoked tobacco		Total tobacco production (smoked + smokeless)
			Production (000 tonnes)	Yield (kg/hectare)	Production (000 tonnes)	Yield (kg/hectare)	
1990-91	78.8 (14.7)	11.8 (2.1)	90.6 (16.2)	1,352	465.3 (83.7)	1,353	555.9 (100)
1991-92	79.0 (13.5)	14.4 (2.4)	93.4 (16.0)	1,487	491 (84.01)	1,348	584.4 (100)
1992-93	71.2 (11.9)	13.3 (2.2)	84.5 (14.1)	1,452	512 (85.8)	1,421	596.5 (100)
1993-94	65.7 (11.7)	11.8 (2.1)	77.5 (13.7)	1,446	485.4 (86.2)	1,466	562.9 (100)
1994-95	138.3 (24.4)	11.7 (2.1)	150.0 (26.4)	2,149	416.7 (73.4)	1,337	566.7 (100)
1995-96	118.8 (22.2)	11.0 (2.1)	129.8 (24.3)	1,818	405.4 (75.5)	1,254	535.2 (100)
1996-97	159.6 (26.6)	9.8 (1.6)	169.4 (28.3)	2,330	448.5 (74.86)	1,247	599.1 (100)

Year	Chewing varieties	Snuff varieties	Smokeless tobacco varieties		Smoked tobacco		Total tobacco production (smoked + smokeless)
			Production (000 tonnes)	Yield (kg/hectare)	Production (000 tonnes)	Yield (kg/hectare)	
1997-98	139.2 (21.82)	9.3 (1.4)	148.5 (23.3)	2,508	486.4 (76.2)	1,199	637.9 (100)
1998-99	150.4 (20.4)	20.2 (2.7)	170.6 (23.1)	2,752	565.6 (76.3)	1,268	736.2 (100)
1999-00	88.0 (16.79)	6.6 (1.25)	94.6 (18.1)	1,927	429.4 (81.4)	1,120	524 (100)
2000-01	75.0 (21.7)	8.0 (2.3)	83.0 (24.1)	2,000	261.7 (75.3)	1,190	344.7 (100)
2001-02	96.7 (17.7)	7.3 (1.33)	104 (19.1)	2,581	441.5 (81)	1,433	545.5 (100)
2002-03	84.9 (17.26)	6.4 (1.3)	91.3 (18.5)	2,677	400.4 (81.4)	1,369	491.7 (100)
2003-04	94.9 (17.25)	11.3 (2.1)	106.2 (19.3)	2,723	443.7 (81)	1,342	549.9 (100)
2004-05	92.8 (16.9)	10.2 (1.8)	103.0 (18.7)	2,447	446.1 (81.2)	1,375	549.1 (100)
2005-06	93.3 (16.9)	10.2 (1.8)	103.5 (18.7)	2,424	448.2 (81.2)	1,360	551.9 (100)
2006-07	87.7 (16.8)	9.6 (1.8)	97.3 (18.7)	2,306	421.8 (81.2)	1,294	519.3 (100)
2007-08	83.3 (16.8)	9.11 (1.8)	92.41 (18.7)	2,318	400.61 (81.2)	1,301	493.03 (100)

Source: Government of India, Ministry of Agriculture, Directorate of Tobacco Development[9].

SLT MANUFACTURE

Categories of SLT Manufacturers

Tobacco manufacturing in India, like most Indian manufacturing, falls into two categories: registered or organised, and unregistered or unorganised. Under the Bidi and Cigar Workers Act of 1966, tobacco product factories with 20 or more workers, or at least 10 workers plus electricity, are required to be registered. The Annual Survey of Industry (ASI) is the main source of data for all registered manufacturing. The unregistered manufacturing sector is tracked by the National Sample Survey Organisation (NSSO) through the countrywide Economic Censuses undertaken by the Central Statistical Organisation (CSO). NSS data are collected periodically, which can result in gaps in data on the unregistered sector.

Both the NSSO and CSO surveys define the SLT industry using the National Industrial Classification (NIC). Table 2.4 describes the five-digit classification of tobacco manufacturing according to NIC 2004, which further categorises the tobacco industry into three major categories: tobacco leaf processing, smoked tobacco manufacturing, and smokeless tobacco manufacturing. Within these three categories are nine subgroups. Data are analysed for the years 2000-2001, 2005-2006, and 2010-2011 using both ASI annual data and NSS data.

Table 2.4: Structure of the tobacco manufacturing industry as defined by the National Industrial Classification (NIC), 2004

Broad classification	NIC 2004 codes	Process or product
Tobacco leaf processing	16001	Tobacco stemming, re-drying, etc., of tobacco leaf
Smoking tobacco products	16002	Bidis
	16003	Cigarettes and cigarette tobacco
	16004	Cigars and cheroots
SLT products	16005	Snuff
	16006	Zarda
	16007	Catechu (katha) and chewing lime
	16008	Pan masala and related products
	16009	Chewing tobacco and other tobacco products

Source: National Industrial Classification, 2009[10].

Estimating the Size of India's SLT Industry

The size of India's smokeless tobacco industry can be estimated using the gross value added (GVA), a parameter that is defined as total outputs minus total inputs of an industry. In general, total outputs are the sum of the values of products and byproducts produced by an industry, and income from services, value of electricity generated and sold, and sale value of goods sold in the same condition as purchased. Total inputs are the sum of the values of work done by others on materials supplied, all repair and maintenance, operating and non-operating expenses, and insurance charges.

Table 2.5 shows the GVA for *registered and unregistered manufacturing* of various SLT products at three points between 2000 and 2011. The GVA for SLT products, registered and unregistered, showed a declining trend over 10 years. Between 2001-2002 and 2005-2006, the GVA declined almost 32%, from Rs 12,516 million in 2000-2001 in absolute terms, to just under Rs 8,455 million in 2005-2006. By 2010-2011 the GVA increased 14%, to Rs 9,614 million, but still fell short of its 2000-2001 level.

The contribution of *unorganised/unregistered manufacturing* to GVA increased more than 6 times from 2000-2001 to 2005-2006, growing from 3% in 2000-2001 to 25% in 2005-2006. Although the share of unregistered manufacturing declined to 11% by 2010-2011(a 50% decline), the unorganised sector continues to contribute a large share of the smokeless industry. This trend mirrors conditions in the Indian economy as a whole, where the unorganised sector has a dominant share in the total employment.

In terms of the contribution of *specific SLT products*, between 2000 and 2001 the GVA of zarda shows a rise in absolute value as well as in value relative to other smokeless products categories. Overall, however, the GVA of smokeless products declined over these 10 years, which could be associated with implementation of tobacco control laws, especially the bans on advertisement and promotions as well as the ban on sale and production of gutka and pan masala.

Table 2.5: Gross value added of the SLT industry (in Rs millions) (percent) for both unregistered and registered manufacturing

	2000-01			2005-06			2010-11		
	Unreg-istered	Registered	Total	Unreg-istered	Registered	Total	Unreg-istered	Registered	Total
Type of product									
Snuff	16.40	1,060.00	1,076.40 (8.60)	136.00	86.10	222.10 (2.63)	97.00	274.00	371.00 (3.86)
Zarda	7.40	1,200.00	1,207.40 (9.65)	88.80	1,870.00	1,958.80 (23.17)	89.80	3,780.00	3,869.80 (40.25)
Catechu (katha) and chewing lime	38.20	126.00	164.20 (1.31)	160.00	295.00	455.00 (5.38)	92.70	494.00	586.70 (6.10)
Pan masala and related products	115.00	632.00	747.00 (5.97)	1,330.00	3,540.00	4,870.00 (57.6)	280.00	1,720.00	2,000.00 (20.80)
Chewing tobacco and other tobacco products	181.00	9,140.00	9,321.00 (74.47)	404.00	545.00	949.00 (11.22)	497.00	2,290.00	2,787.00 (28.99)
Total SLT	358.00	12,158.00	12,516.00 (100)	2,118.80	6,336.10	8,454.90 (100)	1,056.50	8,558.00	9,614.50 (100)
Share of registered & unregistered (%)	2.86	97.14	100	25.06	74.94	100	10.99	89.01	100
Share in total tobacco (%)			19			10			7

Sources: Estimated from the unit-level records of the Annual Survey of Industry (ASI) (registered units) and National Sample Survey (NSS) data (unregistered units).

EMPLOYMENT PATTERNS IN THE SLT INDUSTRY

Tobacco manufacturing is an important source of jobs in India, providing employment to a large number of workers, the majority of whom are employed informally. The tobacco workforce constitutes workers employed in agriculture, manufacturing, and trade-related activities. In India in 2011-2012, 6,872,000 people were employed in various tobacco-related activities, including cultivation, manufacturing, and trade, constituting around 1.26% of total employment[12].

Approximately 75% of the tobacco workforce is employed in the manufacturing sector, followed by almost equal shares in trade and cultivation (see Table 2.6). In the manufacturing sector, the bidi industry employs a major chunk of the total workforce. Total tobacco employment declined marginally (about 1%) between 2004-2005[11] and 2011-2012[19]. Across the three sectors, the greatest decline was seen in the trade sector, where employment fell 50% from 2004-2005 to 2011-2012.

During the early 2000s, tobacco trade was a major economic activity, accounting for a 27% share of the total tobacco workforce, compared to a 5% share in 1983, showing that increasing numbers of people were employed in wholesale and retail tobacco trade during this period. The significant decline in employment in tobacco trade by 2011-2012, like the decline in the GVA of the tobacco industry, could be attributed to India’s implementation of tobacco control laws.

Table 2.6: Structure of employment in the tobacco industry in India

Numbers of workers (thousands)							
	2004-2005[a]			2011-2012[b]			% change, 2004-2005 to 2011-2012
Activity	**Rural**	**Urban**	**Total**	**Rural**	**Urban**	**Total**	
Cultivation	663	11	674	752	52	828	22.84
Manufacturing	3,212	1,198	4,410	3,849	1,234	5,127	16.27
Trade	1,034	826	1,861	430	513	917	-50.74
All tobacco activities	4,910	2,035	6,945	5,031	1,799	6,872	-1.05
% share of workers, by activity							
Activity	**Rural**	**Urban**	**Total**	**Rural**	**Urban**	**Total**	
Cultivation	13.51	0.53	9.71	14.95	2.88	12.05	
Manufacturing	65.43	58.87	63.5	76.50	68.62	74.61	
Trade	21.06	40.60	26.79	8.54	28.51	13.34	
All tobacco activities	100	100	100	100	100	100	
% of all employment			1.52			1.26	

Sources: (a) John et al., 2010[11]. (b) Estimated from the unit-level records of the National Sample Survey (NSS), 2011-2012[12].

These measures could have led to a decline in trading activities without reducing employment in manufacturing and cultivation, which showed positive growth between 2004-2005 and 2011-2012. Employment in tobacco cultivation rose 23%, and tobacco manufacturing employment increased 16% during this period. In 2011-2012, SLT manufacturing employed 70,151 workers, or 1.37% of the total tobacco manufacturing workforce in that year (Table 2.7). Of the total employed, more than two-thirds were involved in manufacturing pan masala and related products, and about 22% in manufacturing chewing tobacco. Ten percent of total tobacco manufacturing employment, or 7,229 workers, were employed in manufacturing zarda.

Table 2.7: Employment in SLT manufacturing

	2011–2012	% of total
By type of product		
Snuff	307	0.44
Zarda	7,229	10.31
Catechu (katha) and chewing lime	1,795	2.56
Pan masala and related products.	45,623	65.04
Chewing tobacco and other tobacco products	15,196	21.66
Total employment in SLT manufacturing	70,151	100
Total tobacco manufacturing employment	5,127,471	100

Source: Estimated from the unit-level records of the National Sample Survey (NSS), 2011–2012[12].

Because most activities involved in SLT manufacturing, including packaging, are done by machines, SLT manufacturing is not labour intensive. This is one of the reasons for the low employment intensity of the industry as compared to tobacco manufacturing as whole, which employs more than 5 million people. Bidi manufacturing, in particular, requires a large workforce, employing more than 95% of the total employed in tobacco manufacturing.

TAX STRUCTURE AND TAX REVENUE OF SLT PRODUCTS

Current evidence indicates that increasing taxation on tobacco products is a cost-effective means of reducing consumption. In India, how responsive consumers are to rising taxes varies depending on the product. One study estimated that a 10% increase in the price of bidis could reduce demand 9.2% in rural areas and 8.5% in urban areas. For cigarettes, demand is relatively inelastic to the increase in price[13]. Another study[14] also found a higher price elasticity of demand for bidis, but estimated a higher own-price elasticity for cigarettes than has been previously observed.

In terms of the effect of higher taxes and prices on tobacco use, people of low socioeconomic status are more responsive to price changes than those of high socioeconomic status. Designing a tax structure for tobacco products that will influence consumption is complex, however, because of variations in tax rates across products. The tax rate on bidis is especially low, and market prices for smokeless products are too low to influence consumption decisions. This section examines the tax structure, tax rate, and tax revenue for smokeless products, raising issues of policy level actions that need to be addressed.

In a federal structure like India, the constitution defines and delineates financial power between the central and state governments. The central government imposes the central excise on tobacco products, and the state units levy sales tax or value added tax (VAT). Under the tax rental agreement of 1956-1957, states transferred their rights to impose sales tax on tobacco, textiles, and sugar to the central government. The central government later imposed additional excise duty on these products, and the proceeds were distributed among the states according to the formula suggested by the Finance Commission. However, the Additional Duties of Excise (Goods of Special Importance) Act of 1957 was revoked, and as of March 2006, the states were assigned the power to impose sales tax or VAT on tobacco products[15].

The central excise tax can be specific or ad valorem. Specific excise duty can be imposed on the basis of weight, length, volume, or thickness of a product. For instance, different taxes apply based on cigarette length or presence of a cigarette filter. Similarly, bidis are taxed differently depending on whether they are manmade or machine-made. Ad valorem tax, on the other hand, is imposed as a percentage of the retail price of the product. In India, all tobacco products except cigarettes and bidis are taxed on an ad valorem basis, which means that SLT bears ad valorem taxes.

Taxes on SLT Products

For smokeless products, particularly gutka, a compounded levy scheme is applicable, in which duty is imposed on the basis of the capacity of the machine installed by the manufacturer. Three types of duties—Basic Excise Duty (BED), Additional Duty of Excise (ADE), and National Calamity Contingency Duty (NCCD)—are imposed on SLT. The BED on chewing tobacco, pan masala containing tobacco, and snuff is 60% of the value of the product. This has not changed from 2010-2011 to 2012-2013 (see Table 2.8). However, the 60% rate represents an increase over past years; the tax rate was 16% in 2002-2003, increased to 50% in 2007-2008, and then to 60% in 2010-2011[16].

Table 2.8: Tax rate on smokeless products (percent)

Product categories	2010-2011 to 2011-2012				2012-2013			
	BED	ADE on pan masala	NCCD	Total	BED	ADE on pan masala	NCCD	Total
Chewing tobacco/ preparations containing chewing tobacco	60	6	10	76	60	6	10	76
Pan masala containing tobacco	60	6	10	76	60	6	10	76
Snuff of tobacco and preparation containing snuff of tobacco	60	6	10	76	60	6	10	76
Tobacco extracts and essence	60	6	10	76	60	6		76
Zarda-*s*cented tobacco	60	6	10	76	60	6	10	76

Notes: BED = Basic Excise Duty. ADE = Additional Duty of Excise, or health cess, applied to pan masala and other tobacco products for National Rural Health Mission. NCCD = National Calamity Contingency Duty

In addition to the above, an education cess at 2% and a secondary and higher education cess at 1% on aggregate duties of excise are charged.

Source: Jain (various years)[16].

The NCCD was introduced by the Finance Act of 2001 to provide financial resources for natural disasters. The Government of India imposed NCCD at the rate of 10% on chewing tobacco, pan masala, and snuff tobacco, and this did not change between 2001 and 2013. Moreover, to provide financial resources for the National Rural Health Mission, in 2005 the Government of India imposed a new duty called ADE, known as health cess, on pan masala and other tobacco products.

Because the tax rate is similar for all smokeless products, the tax burden is similar across products, which might prevent product substitution due to similar increases in the product prices after a rise in the tax. However, in the smokeless market, the unit price of products is low, so that an increase in the tax rate does not cause enough increase in prices to deter consumption.

The main advantage of the ad valorem tax system on SLT products in India is that it is simple and easy to administer. One of the major disadvantages of the ad valorem tax is that manufacturers are able to influence the tax by keeping the base price as low as possible. Thus, prices do not rise in spite of a high rate of tax. For this reason, designing the tax structure so that it will have maximum impact on prices is an important policy issue.

Excise Revenue from Tobacco Products

During the first decade of the 2000s, the Indian government reported significant growth in revenue collection from tobacco products (Table 2.9). Data on revenue collected from various tobacco products show that cigarettes contribute substantially to the total tobacco excise revenue. On average, 82% of tobacco tax revenue was collected from taxes on cigarettes during the period 1990-1991 to 2010-2011. From 2002 onward, the share of revenue from cigarettes declined slightly, from an average of 86% of the total tobacco tax revenue during the 1990s, to an average of 79% in the 2000s. In contrast, excise revenue from chewing tobacco rose during these years.

As a share of total tobacco excise revenue, chewing tobacco was 5% on average during the 1990s and increased to 7% in the subsequent decade. In monetary terms, tax revenue from chewing tobacco rose from Rs 722 million in 1990-1991 to Rs 3,512 million in 1999-2000, a fivefold increase, and it continued to rise, amounting to Rs 10,532 million in 2010-2011. Revenue from other tobacco products (unmanufactured tobacco wholly or partly stemmed, preparations containing chewing tobacco, zarda-scented tobacco, snuff, etc.) shows an increasing trend over the same years, growing from 3% on average during the 1990s to 9% during the 2000s. In spite of changes in the pattern of revenue collection from various tobacco products, with increasing share of revenue from chewing tobacco and other products, tax revenue from cigarettes makes up the largest share of the total. Revenue from smokeless tobacco grew at a higher rate after 2007-2008 when government increased the basic excise duty.

Table 2.9: Excise revenue from different tobacco products (in Rs millions) (percent)

Year	Cigarettes and cigarillos of tobacco or tobacco substitutes	Bidis	Chewing tobacco	Others *	Excise revenue from all tobacco products
1990-1991	20,843.9 (88.98)	1,656.5 |(7.07)	722.7 (3.09)	202.9 (0.87)	23,426 (100)
1991-1992	23,870.7 (88.71)	2,002.2 (7.44)	779.8 (2.9)	255.4 (0.95)	26,908.1 (100)
1992-1993	27,676.6 (89.14)	2,317.8 (7.47)	792.6 (2.55)	260.5 (0.84)	31,047.5 (100)
1993-1994	27,395.7 (87.62)	2,195.3 (7.02)	1,137.5 (3.64)	538.3 (1.72)	31,266.8 (100)
1994-1995	27,429 (78.38)	2,199.7 (6.29)	1,507.6 (4.31)	3,856.4 (11.02)	34,992.7 (100)
1995-1996	34,268.7 (84.91)	2,232.6 (5.53)	2,165.3 (5.36)	1,693.3 (4.2)	40,359.9 (100)
1996-1997	39,826.6 (86.55)	2,414.5 (5.25)	2,121.1 (4.61)	1,651.2 (3.59)	46,013.4 (100)
1997-1998	44,924.4 (86.16)	3,237.7 (6.21)	2,660.6 (5.1)	1,320.5 (2.53)	52,143.2 (100)
1998-1999	45,919.6 (82.15)	3,232.8 (5.78)	5,555.3 (9.94)	1,187.7 (2.12)	55,895.3 (100)
1999-2000	48,625.5 (86.18)	3,216.7 (5.7)	3,511.8 (6.22)	1,066.6 (1.89)	56,420.6 (100)
Average share (1990-2000)	85.88	6.38	4.77	2.97	
2000-2001	51,804.5 (84.75)	3,538.3 (5.79)	4,257.5 (6.96)	1,528.4 (2.5)	61,128.7 (100)
2001-2002	50,595.1 (78.52)	3,571.5 (5.54)	6,307 (9.79)	3,963.5 (6.15)	64,437.1 (100)
2002-2003	51,399.7 (80)	3,603.5 (5.61)	6,319.9 (9.84)	2,923.2 (4.55)	64,246.3 (100)
2003-2004	54,953.4 (82.82)	3,364 (5.07)	6,135.1 (9.25)	1,903.8 (2.87)	66,356.3 (100)
2004-2005	59,948.5 (83.6)	3,481.5 (4.86)	5,772.8 (8.05)	2,505.6 (3.49)	71,708.4 (100)

Year	Cigarettes and cigarillos of tobacco or tobacco substitutes	Bidis	Chewing tobacco	Others *	Excise revenue from all tobacco products
2005-2006	69,889.9 (83.38)	3,706.9 (4.42)	3,678.2 (4.39)	6,545.7 (7.81)	83,820.7 (100)
2006-2007	77,013.5 (83.73)	4,275.7 (4.65)	4,211.8 (4.58)	6,473.1 (7.04)	91,974.1 (100)
2007-2008	81,488.2 (79.36)	4,839.7 (4.71)	6,915.9 (6.74)	9,436.7 (9.19)	102,680.5 (100)
2008-2009	93,102.4 (70)	4,885.1 (3.67)	9,166.2 (6.89)	25,849.5 (19.44)	133,003.2 (100)
2009-2010	95,556.7 (68.98)	4,896.8 (3.53)	10,620.4 (7.67)	27,459.6 (19.82)	138,533.5 (100)
2010-2011	11,1704.6 (72.06)	4,716.2 (3.04)	10,532.2 (6.79)	28,070.8 (18.11)	155,023.8 (100)
Average share (2001-2010)	78.84	4.63	7.36	9.18	

*Includes unmanufactured tobacco, wholly or partly stemmed; preparations containing chewing tobacco; zarda-scented tobacco; snuff; preparations containing snuff; tobacco extracts and essence; cut tobacco.

Source: Government of India, Ministry of Finance, Directorate of Data Management[17].

The five-year nominal average growth rates of excise revenue indicate that cigarettes had the most consistent performance between 1990 and 2011 (Table 2.10). In the first 5 years and the last 5 years of this period, revenue from cigarettes grew at 10% and had a similar growth rate. Tax revenue from bidis grew the least, reflecting the low tax rate on bidis. Revenue from chewing tobacco fluctuated—declining between 2001-2002 and 2005-2006, and then growing, on average, at 28% between 2006-2007 and 2010-2011. However, revenue from tobacco products as a whole increased to 14% during 2006-2007 to 2010-2011, while the overall central excise revenue declined to almost half of what was achieved in the previous 5 years, as a result of the effects of the global economic slowdown on the Indian economy.

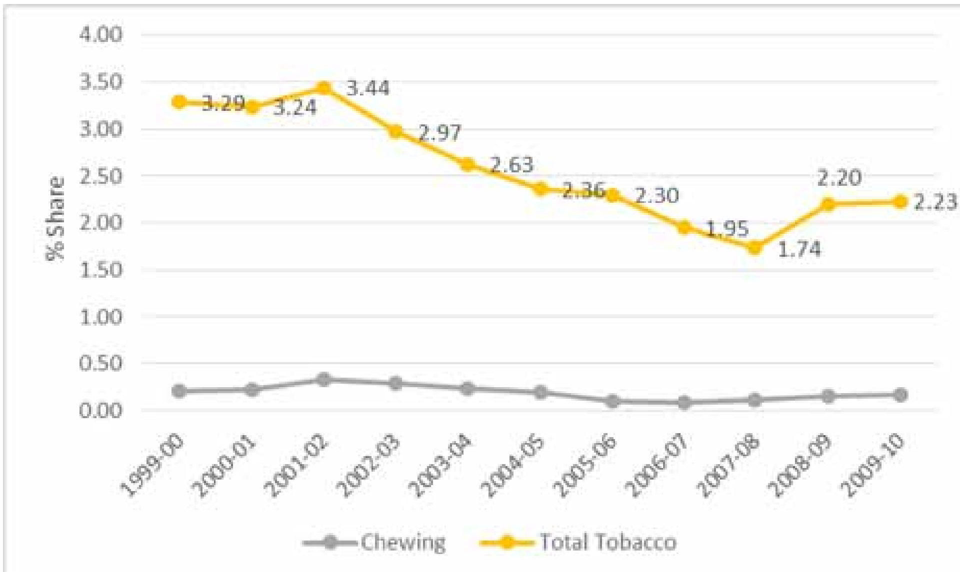
Table 2.10: Annual average growth rate in revenue from tobacco products versus total central excise revenue (percent)

Year	Cigarettes and cigarillos of tobacco or tobacco substitutes	Bidis	Chewing tobacco	All tobacco products	Total central excise revenue
1991-92 to 1995-96	10.00	3.04	30.33	10.84	10.29
1996-97 to 2000-01	6.86	10.86	29.67	7.45	11.40
2001-02 to 2005-06	8.54	1.05	–11.23	6.99	11.24
2006-07 to 2010-11	9.90	2.67	27.94	14.31	5.32

Source: Government of India, Ministry of Finance, Directorate of Data Management[17].

The share of the tobacco excise revenue in the overall tax revenue of the central government has declined over the years. Tobacco tax revenue made up 3.29% of gross tax revenue in 1999-2000 and had declined to 2.23% by 2009-2010 (Figure 2.1). The decline began in 2002-2003 and reached its lowest point in 2007-2008. The share of chewing tobacco in gross tax revenue was less than 1% during this 20-year period, and declined after 2005-2006. On average, tobacco taxes accounted for 2.58% of gross tax revenue, and chewing tobacco accounted for just 0.19% of gross tax revenue between 2000 and 2011. Although revenue from tobacco products showed an absolute increase during the decade before 2011, its share in total central government tax revenue declined. This declining share could be attributed to the great increase in tax revenue that resulted from growth in the Indian economy as a whole during the last one decade.

Figure 2.1 Share of tobacco in gross tax revenue of Government of India (%)



Sources: Tobacco tax data: Government of India, Ministry of Finance, Directorate of Data Management, Customs and Central Excise[17]. Gross tax revenue data: Government of India, Ministry of Finance, Controller General of Accounts[18].

INTERNATIONAL TRADE IN SLT PRODUCTS IN INDIA

Export Earnings from Tobacco (Both Unmanufactured and Manufactured)

India is one of the largest exporters of unmanufactured tobacco, particularly flue-cured Virginia tobacco. In the manufactured product category, India mainly exports cigarettes, bidis, and smokeless tobacco, the major varieties of which are chewing tobacco, zarda, and snuff. The total value of exports of tobacco products as of March 2010 was Rs 43,444 million, and only 3.79% of this total is accounted for by SLT products (Table 2.11). SLT exports showed a 13% growth rate between 1996 and 2000, after an annual average growth rate of 5% between 1991 and 1996. Like total tobacco exports, SLT exports reached their highest annual average growth rate in 2006-2010: 29%.

Exports of tobacco (both unmanufactured and manufactured) increased between 2005 and 2010. These years saw growth in SLT exports as well, from Rs 436 million in March 2005 to Rs 1,648 million in 2010. However, the average share of SLT in total export earnings from tobacco products during each 5-year period from 1996 to 2010 has remained fairly constant.

Table 2.11: Export earnings of tobacco in India (includes both unmanufactured and manufactured)

Year	Value of tobacco exports (Rs million)	Value of SLT exports (Rs million)	Share of SLT in total tobacco exports (%)
Mar-91	1,536.09	181.33	11.80
Mar-92	3,162.52	190.00	6.01
Mar-93	3,432.35	304.13	8.86
Mar-94	4,612.02	246.11	5.34
Mar-95	2,547.53	177.92	6.98
Average Annual Growth Rate (AAGR) (%)	26	4.52	7.8*
Mar-96	4,468.21	250.19	5.60
Mar-97	7,567.72	331.98	4.39
Mar-98	10,702.41	314.16	2.94
Mar-99	7,617.83	459.54	6.03
Mar-00	10,089.20	355.15	3.52
AAGR (%)	28.60	12.72	4.49*
Mar-01	8,709.82	584.32	6.71
Mar-02	8,077.02	506.31	6.27
Mar-03	10,282.21	444.74	4.33
Mar-04	10,964.70	436.67	3.98
Mar-05	12,546.13	436.01	3.48
AAGR (%)	10.27	–6.87	4.95*
Mar-06	13,306.56	645.24	4.85
Mar-07	16,851.64	905.69	5.37
Mar-08	19,318.89	1101.80	5.70
Mar-09	34,610.47	1816.29	5.25
Mar-10	43,444.04	1647.82	3.79
AAGR (%)	36.49	29.40	4.99*

*Average share in 5 years.

Source: Government of India, Ministry of Commerce, Directorate General of Commercial Intelligence and Statistics (various years)[19].

Export Earnings from SLT (Both Unmanufactured and Manufactured)

SLT is exported in unmanufactured as well as manufactured form. There are only two forms of unmanufactured chewing tobacco: stemmed (wholly or partly) and not stemmed. Chewing tobacco, snuff, and zarda are exported in manufactured form. The time trend of SLT exports shows that in the early 1990s unmanufactured SLT constituted a significant portion of total smokeless exports, but export earnings from unmanufactured SLT (not stemmed and stripped) fell from 82% of total SLT export earnings in 1991 to 47% of the total in 1997 (Table 2.12). After 1997, the share of unmanufactured tobacco for making chewing products (not stemmed and stripped) declined, and the share of export earnings from manufactured chewing tobacco products increased. In 1998, total export earnings from chewing tobacco products (Rs 125 million) constituted 40% of total export earnings from various types of SLT. This increased to 61% of total SLT export earnings (Rs 1,003.7 million) by the end of March 2010. Thus, export earnings from chewing tobacco increased eightfold during a span of 12 years, and the average annual contribution of chewing tobacco was 57% of total SLT exports during the 12 years. Indian manufacturers began to export two varieties of SLT products—snuff and preparations containing chewing tobacco—in 2004-2005.

Table 2.12: Export of varieties of SLT in India (in Rs millions) (percent)

Year	Tobacco for manufacturing of chewing tobacco		Chewing tobacco products	Products contain-ing chewing tobacco	Zarda-scented tobacco	Snuff	Products contain- ing snuff	Total SLT export earnings
	Tobacco not stemmed or stripped	Tobacco partly or wholly stemmed or stripped						
March 1991	148.1 (81.65)	0 (0.02)	12.6 (6.94)	NA	18.7 (10.29)	2.0 (1.1)	NA	181.3 (100)
March 1992	106.5 (56.03)	20.5 (10.79)	26.3 (13.86)	NA	33.9 (17.82)	2.9 (1.5)	NA	190.0 (100)
March 1993	55.7 (18.31)	10.2 (3.37)	112.4 (36.95)	NA	54.2 (17.81)	71.6 (23.55)	NA	304.1 (100)
March 1994	73.4 (29.81)	82.5 (33.52)	42.4 (17.25)	NA	43.3 (17.58)	4.5 (1.84)	NA	246.1 (100)
March 1995	29.3 (16.44)	45.2 (25.39)	41.3 (23.22)	NA	56.0 (31.49)	6.1 (3.45)	NA	177.9 (100)
March 1996	136.5 (54.56)	2.1 (0.82)	45.2 (18.08)	NA	60.7 (24.25)	5.7 (2.28)	NA	250.2 (100)
March 1997	155.7 (46.91)	7.9 (2.39)	87.1 (26.24)	NA	72.9 (21.95)	8.3 (2.51)	NA	332.0 (100)
March 1998	38.1 (12.14)	17.8 (5.66)	125.4 (39.9)	NA	126.0 (40.1)	6.9 (2.2)	NA	314.2 (100)
March 1999	105.8 (23.03)	32.7 (7.12)	167.8 (36.51)	NA	142.5 (31)	10.8 (2.34)	NA	459.5 (100)
March 2000	41.5 (11.69)	39.0 (10.99)	181.4 (51.09)	NA	81.7 (23)	11.5 (3.23)	NA	355.2 (100)
March 2001	133.9 (22.92)	14.5 (2.49)	334.2 (57.2)	NA	92.6 (15.85)	9.1 (1.55)	NA	584.3 (100)
March 2002	49.7 (9.82)	46.4 (9.16)	345.0 (68.13)	NA	53.0 (10.47)	12.3 (2.43)	NA	506.3 (100)
March 2003	43.9 (9.86)	2.6 (0.59)	298.6 (67.15)	NA	92.1 (20.72)	7.5 (1.69)	NA	444.7 (100)
March 2004	24.2 (5.54)	2.7 (0.62)	220.2 (50.43)	30.7 (7.02)	121.2 (27.75)	37.2 (8.52)	0.5 (0.11)	436.7 (100)
March 2005	16.4 (3.76)	6.1 (1.4)	283.6 (65.05)	57.1 (13.1)	43.9 (10.06)	28.9 (6.63)	0 (0.01)	436.0 (100)
March 2006	56.5 (8.76)	12.0 (1.85)	455.7 (70.62)	36.0 (5.58)	63.8 (9.89)	21.2 (3.29)	0 (0)	645.2 (100)
March 2007	16.9 (1.87)	15.5 (1.71)	688.2 (75.99)	98.4 (10.86)	71 (7.84)	15.5 (1.71)	0.1 (0.01)	905.7 (100)
March 2008	34.8 (3.16)	30.6 (2.78)	578.2 (52.48)	401.3 (36.43)	46.2 (4.19)	9.8 (0.89)	0.9 (0.08)	11,01.8 (100)
March	41.6	28.3	898.6	658.9	86	102.0	0.9	1,816.3

Year	Tobacco for manufacturing of chewing tobacco		Chewing tobacco products	Products contain-ing chewing tobacco	Zarda-scented tobacco	Snuff	Products contain- ing snuff	Total SLT export earnings
	Tobacco not stemmed or stripped	Tobacco partly or wholly stemmed or stripped						
2009	(2.29)	(1.56)	(49.48)	(36.28)	(4.73)	(5.61)	(0.05)	(100)
March 2010	13.7 (0.83)	53.5 (3.25)	1,003.7 (60.91)	470.2 (28.54)	83.6 (5.07)	20.8 (1.26)	2.3 (0.14)	1,647.8 (100)

Source: Government of India, Ministry of Commerce, Directorate General of Commercial Intelligence and Statistics[19].

Exports of SLT to Different Regions of the World

Data on exports of SLT to different regions of the world, as defined by the World Health Organization, indicate that most SLT exports (more than 70%) go to the Eastern Mediterranean Region, followed by the Western Pacific and American Regions (Table 2.13). Smokeless products are exported to both low- and high-income countries of the world.

Table 2.13: Export of manufactured and unmanufactured SLT, by World Health Organization Regions of world (in Rs millions) (percent)

WHO Region	March 2004	March 2005	March 2006	March 2007	March 2008	March 2009	March 2010	Annual Average
Africa	16.8 (3.84)	19.0 (4.35)	37.9 (5.87)	52.0 (5.74)	16.9 (1.53)	57.8 (3.18)	81.5 (4.95)	40.3 (4.21)
America	20.4 (4.67)	26.0 (5.97)	15.3 (2.37)	47.7 (5.26)	116.9 (10.61)	112.8 (6.21)	153.7 (9.33)	70.4 (6.34)
South-East Asia	43.6 (9.98)	4.3 (0.98)	13.4 (2.07)	22.6 (2.49)	110.9 (10.07)	95.6 (5.26)	69.7 (4.23)	51.4 (5.01)
Europe	12.8 (2.92)	19.6 (4.49)	19.9 (3.08)	25.9 (2.86)	57.3 (5.2)	63.4 (3.49)	36.5 (2.21)	33.6 (3.46)
Eastern Mediterranean	317.8 (72.77)	338.7 (77.69)	521.1 (80.76)	690.9 (76.28)	734 (66.62)	1353 (74.49)	1135.7 (68.92)	727.3 (73.93)
Western Pacific	24.4 (5.59)	28.5 (6.53)	37.7 (5.84)	66.6 (7.35)	65.8 (5.97)	132.7 (7.31)	166.3 (10.09)	74.6 (6.96)
Unspecified	1.0 (0.22)	0 (0)	0.1 (0.01)	0 (0)	0 (0)	1.0 (0.05)	4.4 (0.26)	0.9 (0.08)
Total	436.7 (100)	436.0 (100)	645.2 (100)	905.7 (100)	1,101.8 (100)	1,816.3 (100)	1,647.8 (100)	998.5 (100)

Source: Government of India, Ministry of Commerce, Directorate General of Commercial Intelligence and Statistics[19].

The United Arab Emirates (UAE), Afghanistan, and Iran are the largest markets for India's chewing tobacco exports. The highest share of exports, 47%, went to UAE, up from 33% in 2004 (Table 2.14). In 2004, the second highest share of chewing tobacco exports went to Afghanistan, followed by Iran, Canada, and Saudi Arabia. Of the top 10 countries importing India's chewing tobacco products, Australia received the smallest amount: less than 2% of total chewing tobacco exports. In 2010, there were minor changes in the export to top 10 countries. Afghanistan, which had the second highest share in 2004, became the third, with a 17% share in the total exports, and new export destinations were added, including Malaysia, Singapore, and Nepal.

Table 2.14: Top 10 export destinations for chewing tobacco (in Rs millions) (percent)

	Country	March 2004	Country	March 2007	Country	March 2010
1	United Arab Emirates	69.76 (33.32)	United Arab Emirates	258.01 (39.62)	United Arab Emirates	452.07 (46.75)
2	Afghanistan	59.41 (28.38)	Yemen	116.05 (17.82)	Saudi Arabia	180.04 (18.62)
3	Iran	20.65 (9.87)	Afghanistan	94.29 (14.48)	Afghanistan	166.89 (17.26)
4	Canada	14.44 (6.9)	Saudi Arabia	66.03 (10.14)	Malaysia	38.07 (3.94)
5	Saudi Arabia	11.34 (5.42)	Iran	48.09 (7.38)	Singapore	33.68 (3.48)
6	Japan	10.53 (5.03)	Vietnam	21.8 (3.35)	Nepal	26.63 (2.75)
7	Tanzania	8.35 (3.99)	Tanzania	15.71 (2.41)	South Africa	23.26 (2.41)
8	Yemen	7.76 (3.71)	Malaysia	15.65 (2.4)	Yemen	21.31 (2.2)
9	United States	3.95 (1.89)	United States	9.76 (1.5)	Kenya	12.74 (1.32)
10	Australia	3.16 (1.51)	Nepal	5.77 (0.89)	Netherland	12.39 (1.28)
	Totals	209.34 (100)		651.14 (100)		967.09 (100)
	% of total chewing export	95.07		94.62		96.35

Source: Government of India, Ministry of Commerce, Directorate General of Commercial Intelligence and Statistics[19].

CONCLUSIONS

Because the market for smokeless tobacco products continues to grow, the economic potential of SLT, though not as large as that of the cigarette industry, cannot be ignored. The area under cultivation in tobacco for SLT has diminished over the years, but productivity is growing. Tax revenue collection increased, particularly after 2007-2008, when the basic excise duty on SLT was increased.

Ad valorem taxation does not lead to higher prices for smokeless tobacco prices. To make SLT products unaffordable and thereby deter SLT consumption, tax structure reform is needed. Possible loss of tax revenue and jobs are not important arguments against undertaking this reform. SLT taxes generate less than 1% of the government's total tax revenue, and total employment in SLT production represents 1% of total employment in tobacco manufacturing. A factor that militates against tax reform, however, is the high value of SLT production. In 2010-2011, Rs 9,614 million worth of smokeless products was produced, constituting more than 7 percentage of the value of total tobacco products. This growth raises concerns about the growth of the unorganised sector, which makes monitoring production and price structure difficult.

Large-scale product and price distortion take place because of lack of information. Government authorities need to design strict guidelines to check fraudulent practices adopted by the industry.

One indication that tobacco control policies are working is that the gross value added of smokeless products has declined. This decline, in turn, strengthens the case for the implementation of tobacco control laws in the country.

International demand for smokeless products has grown, and exports of chewing tobacco are quickly surpassing exports of unmanufactured tobacco which dominated the export market during 1990s. Strict measures are needed to curtail export demand so that it does not boost production in circumvention of domestic laws.

Demand in India itself is a critically important concern. More than one-fourth of all adults consume some form of SLT, and consumers begin to use SLT at early ages because of the availability of low-priced products in the market. Government measures to combat domestic demand are critical.

Curbing the supply of SLT is essential for effective tobacco control policy in India. Meeting the growing cost of tobacco-related diseases has become increasingly challenging for the publicly funded health care system, which is already grappling with low resource allocation, even at the primary health care level. In this context, resources need to be carefully allocated among the health sector's various competing priorities. To reduce tobacco-related health care costs, the prevalence of tobacco use must be reduced substantially. Among several supply side measures mentioned in the WHO's Framework Convention on Tobacco Control (FCTC), controlling production and reducing areas under tobacco cultivation are vital. The tax structure need to be simplified; where possible, the differential tax rate should be minimised, and the tax structure should be adjusted to price and income changes periodically, as recommended by the FCTC.

Research Priorities

Though the government has enacted legislation including increasing the tax rate especially at the state level to curb the growth of smokeless tobacco use, it is essential to examine the impact of tax increases on consumption at the provincial level. Further, industry profitability, tactics, and price strategy should be studied and evidence collected on how SLT manufacturers manipulate prices in order to maintain demand for their products. The growing external demand for SLT products is a matter of concern, and export prices, volume of trade, and the possibility that external demand could be a source of revenue for the manufacturers ought to be examined. Researchers should also consider whether domestic measures will be ineffective if external demand is sufficient to drive the growth of industry. The livelihood concerns of the smokeless growers and workers engaged in trade are important in Indian context. However, insufficient evidence is available on alternative options that could be equally remunerative and provide better livelihood opportunities. Taking into consideration the slow progress on Article 17 of the Framework Convention of Tobacco Control (FCTC), evidence should be generated in this area.

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Chapter 3

Smokeless Tobacco Use Among Youth

Dhirendra N. Sinha[1], Neha Mathur[2], Gaurang P. Nazar[3],
V. Gajalakshmi Vendhan[4], Krishna M. Palipudi[5], Samira Asma[5],
Monika Arora[2,3], Mark Parascandola[6], Jagdish Kaur[7]

[1]World Health Organization, Regional Office for South-East Asia, New Delhi
[2]Public Health Foundation of India, New Delhi
[3]Health Related Information Dissemination Amongst Youth (HRIDAY), New Delhi
[4]Epidemiological Research Centre, Chennai
[5]Centers for Disease Control and Prevention, Atlanta, GA, USA
[6]National Cancer Institute, Rockville, MD, USA
[7]Ministry of Health and Family Welfare, Government of India, New Delhi

INTRODUCTION

The prevalence of current smokeless tobacco (SLT) use among youth is an important predictor of the future burden of tobacco-related diseases. The increased prevalence of certain forms of SLT products among Indian youth has directly contributed to an alarming increase in the incidence of oral cancers among younger age groups[1]. Preventing young people from beginning to use SLT requires intervention in early adolescence, before they experiment with it. Thus, the youth population is a critical target for tobacco control efforts. This chapter consolidates the evidence on prevalence of SLT use and use of specific SLT products, compares prevalence of smoking and SLT use, and tracks trends in SLT use and factors associated with its acquisition among youth in India.

SOURCE OF DATA: THE GLOBAL YOUTH TOBACCO SURVEY, INDIA (2003, 2006, 2009)

This chapter presents data on prevalence of SLT use among youth ages 13–15 years which was collected using the Global Youth Tobacco Survey (GYTS) in India for the years 2003, 2006, and 2009[2]. GYTS is a nationally representative school-based survey of students in grades associated with the ages of 13–15 years that is designed to produce cross-sectional estimates for each country. GYTS uses standardised sample design, core questionnaire, and data collection procedures. The survey assists countries in fulfilling their obligations under the World Health Organization (WHO) Framework Convention on Tobacco Control (WHO FCTC) to generate comparable data within and among countries.

GYTS uses a two-stage sample design with schools selected based on enrollment size. Classrooms within selected schools are chosen randomly, and all students in selected classes are invited to participate in the survey. The survey uses a globally standardised core questionnaire with a set of optional questions about tobacco use and key tobacco control indicators, which permits adaptation to meet the needs of the country. The questionnaire covers the following topics: tobacco use (smoking and smokeless), cessation, exposure to secondhand smoke (SHS), pro- and anti-tobacco media and advertising, access and ability to obtain tobacco products, and knowledge and attitudes about tobacco. The questionnaire is self-administered, uses scannable answer sheets, and is anonymous to ensure confidentiality. A more detailed description of the GYTS methodology can be found elsewhere[2-5].

During the years 2000 through 2005, the GYTS in India was administered separately in the 28 states and 2 Union Territories in which 93.9% of India’s total population live. In total, 68,077 students participated in the 28 surveys. The majority of states finished data collection in 2003.

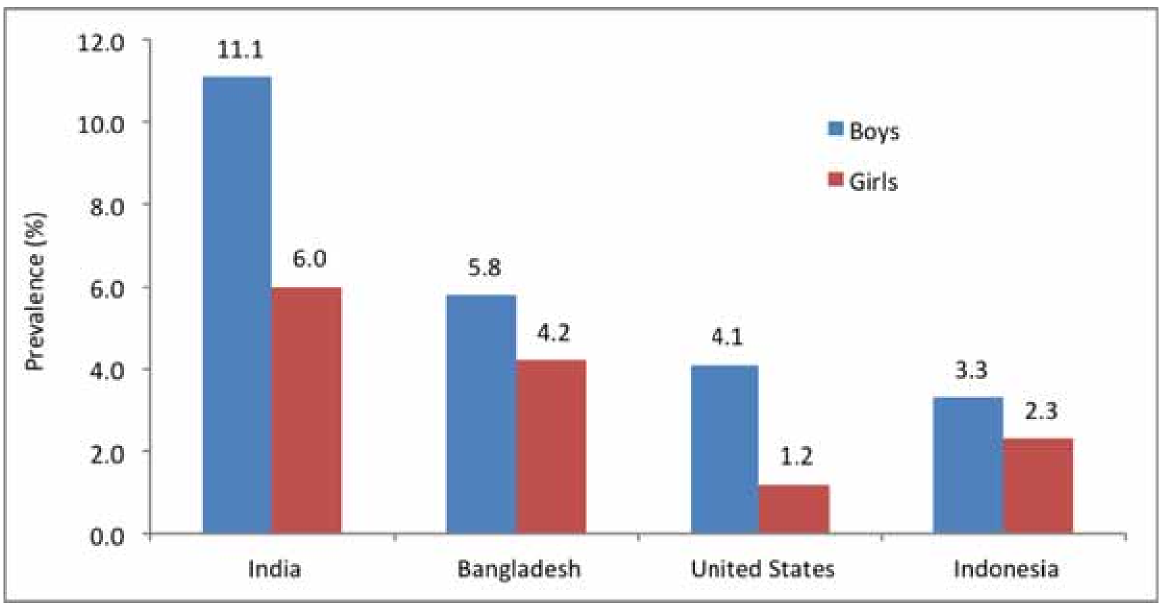
The 2006 GYTS in India employed the same sampling procedure that was used in 2003, except that the samples were designed for six independent geographic regions instead of for states. These six regions were: North (Chandigarh, Delhi, Haryana, Himachal Pradesh, Jammu and Kashmir, Punjab, Rajasthan, Uttaranchal, and Uttar Pradesh), South (Andhra Pradesh, Karnataka, and Tamil Nadu), East (Bihar, Jharkhand, Orissa, and West Bengal), West (Goa, Gujarat, and Maharashtra), Central (Chhattisgarh and Madhya Pradesh), and North-East (Arunachal Pradesh, Assam, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim, and Tripura). These regions represent 99.7% of the total population of India. In total, 12,086 students participated in the six regional surveys. Fieldwork was completed during the first half of 2006.

The 2009 GYTS India also employed the same sampling procedure that was used as in the two earlier surveys. Minor modifications were made in the distribution of states by region to mirror the regional composition of states in the Global Adult Tobacco Survey (GATS), which was also conducted in India in 2009-2010. Uttar Pradesh and Rajasthan were included in the Central Region instead of the North region in 2009 GYTS in India. The six regions in the 2009 GYTS represent 99.7% of India's total school-going student population. In total, 11,768 students participated in the six regional surveys.

PREVALANCE OF SLT USE

To put India's prevalence data in a global context, it is notable that India ranks highest in prevalence of SLT use among both boys and girls in the four most populous countries for which comparable estimates are available (Figure 3.1). Prevalence of SLT use, from GYTS 2007–2009, are as follows: in India, among boys, 11.1%, and among girls, 6%; in Bangladesh: boys, 5.8%, and girls, 4.2%; in the United States: boys, 4.1%, girls 1.2%; in Indonesia: boys, 3.3%, and girls, 2.3%[7].

Figure 3.1: SLT use in four of the world's most populous countries



Source: National Cancer Institute and Centers for Disease Control and Prevention, 2014[7].

Some countries with smaller populations reported higher prevalence of SLT use among boys than India. Prevalences in countries such as Congo (18.3%), Namibia (15.6%), Djibouti (15.2%), Lesotho (14.7%), and Bhutan (14.1%) were higher than India's rate of 11.1%. Similarly, among girls, prevalence was higher in some countries with smaller populations, such as Namibia (15.8%), Congo (14.1%), Lesotho (13.6%), Botswana (11.4%), Uganda (9.6%), Djibouti (9.0%), Jamaica (8.5%), Yemen (8.4%), and Barbados (8.2%), as compared to India's 6% prevalence[7].

Within India, SLT use has varied over time and by state. The national-level prevalence of current SLT use by school-going youth in 2003 was 14.6% (18.5% for boys, and 8.4% for girls). SLT use varied among all states, from 2% in Himachal Pradesh to 55.6% in Bihar[6]. Each North-Eastern state showed a prevalence of more than 35% except Assam (25.3%)[5]. According to

GYTS 2006, the prevalence of current SLT use in the country was 9.4% (10% for boys, and 75% for girls)[4] whereas, in GYTS 2009, the prevalence of SLT use in the country was 9% (boys, 11.1%; girls, 6%)[4].

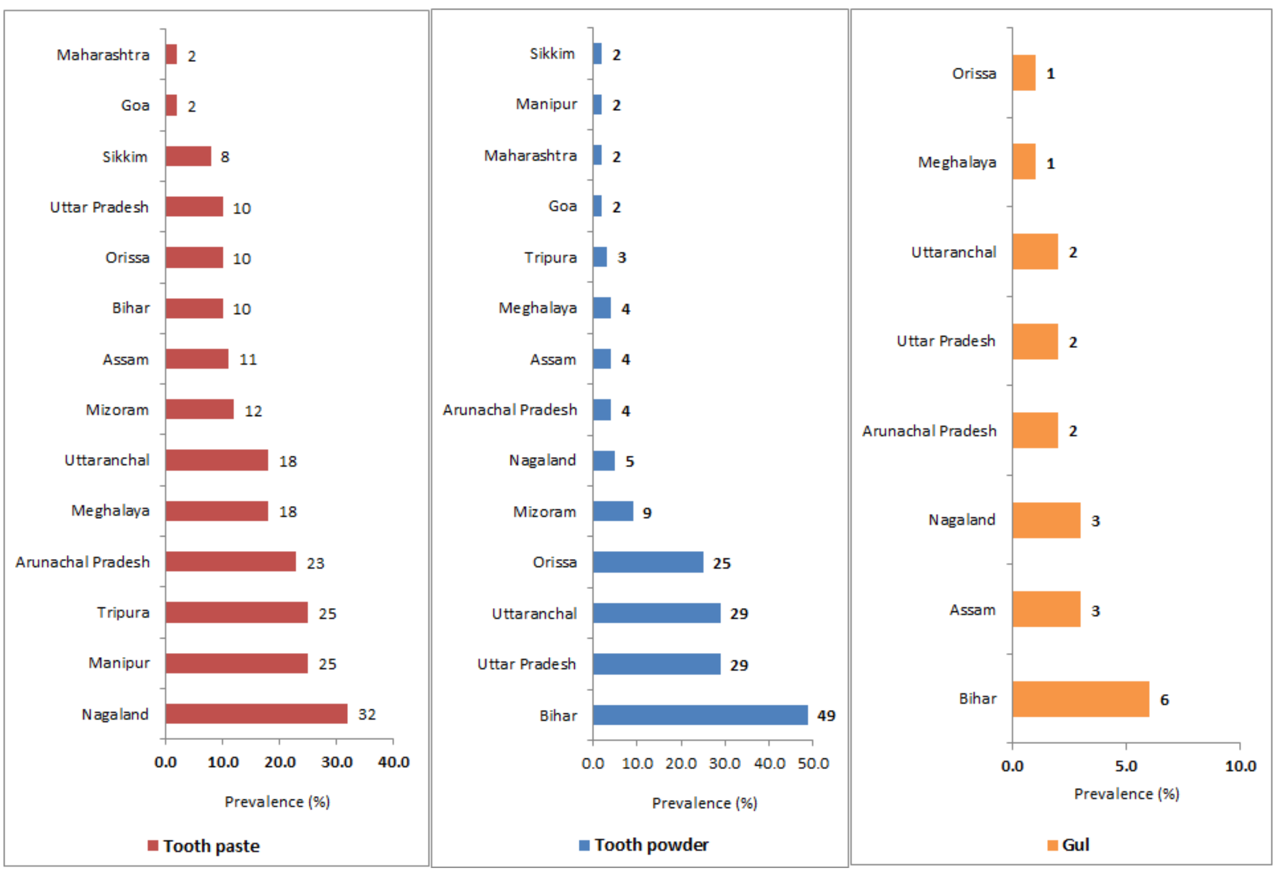
PREVALENCE OF SLT USE, BY SPECIFIC PRODUCT

As described in chapter 1 and the accompanying factsheets, myriad varieties of SLT products are available and used in various ways in India. The following subsections present data on specific SLT product use by youth.

SLT Products Used as Dentifrices

Several varieties of SLT products are consumed in India as a dentifrice or for the treatment of oral and dental problems. Figure 3.2 is a graphic depiction of GYTS data on the use of three SLT products as a dentifrice by youth—tobacco toothpastes (e.g., Ipco, Dentobac), other paste-like material (e.g., gudakhu), and tooth powder (e.g., lal dant manjan, gul, mishri)—in 14 Indian states (Maharashtra, Goa, Sikkim, Uttar Pradesh, Orissa, Bihar, Assam, Mizoram, Uttaranchal, Meghalaya, Arunachal Pradesh, Tripura, Manipur, and Nagaland)[8].

Figure 3.2: Prevalence of using various SLT products as a dentifrice among 13- to 15-year-old students in selected Indian states (GYTS 2000–2002)



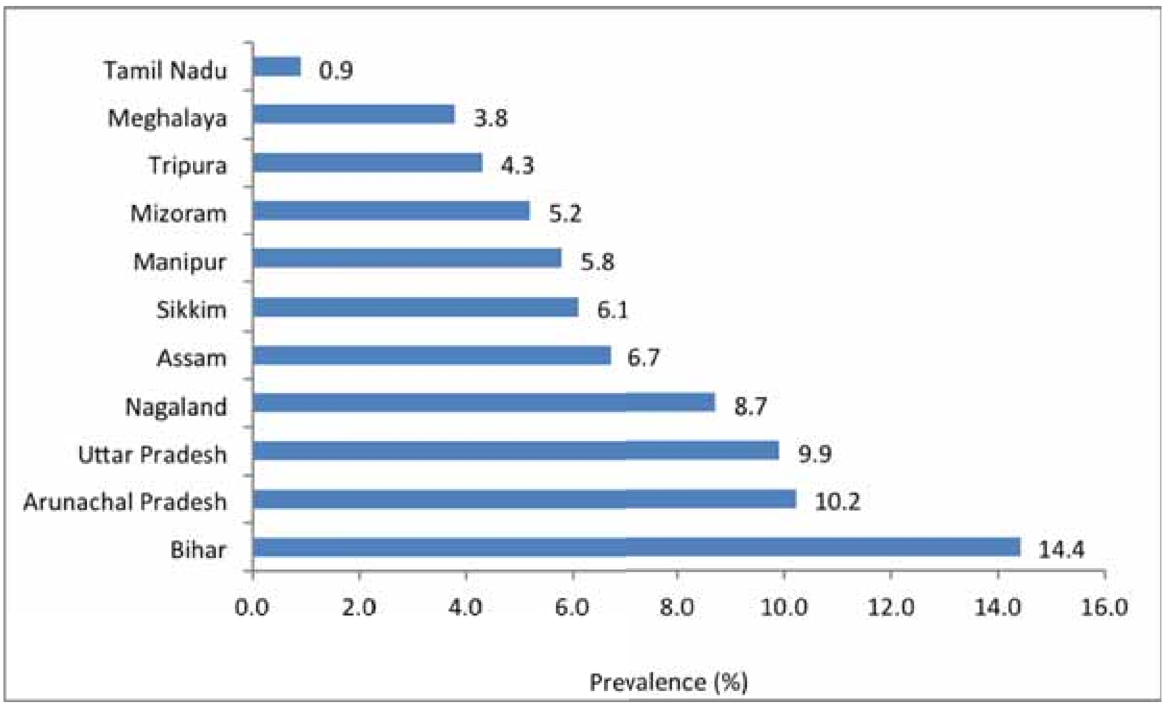
Source: Sinha et al., 2004[8].

The prevalence of use of toothpaste containing tobacco ranged from a low of 2% in Maharashtra and Goa to a high of 32% in Nagaland. The prevalence of tooth powder containing tobacco ranged from 2% in Sikkim, Manipur, Maharashtra, and Goa to 49% in Bihar and was higher than 24% in four other states. Use of gul was lowest in Odisha and Meghalaya (1%) and highest in Bihar (6%) of the eight states studied[8].

Prevalence of Gutka Use

Gutka is a cheap, mass-produced, widely available SLT product. It can be easily purchased by children from shops and kiosks. GYTS 2000–2002 revealed that the prevalence of current gutka use ranged from a low of 0.9% in Tamil Nadu to a high of 14.4% in Bihar, and was higher than 5% in most of the states studied (Figure 3.3)[9-11].

Figure 3.3: Prevalence of gutka use among students aged 13–15 years in selected states of India (GYTS 2000–2002)

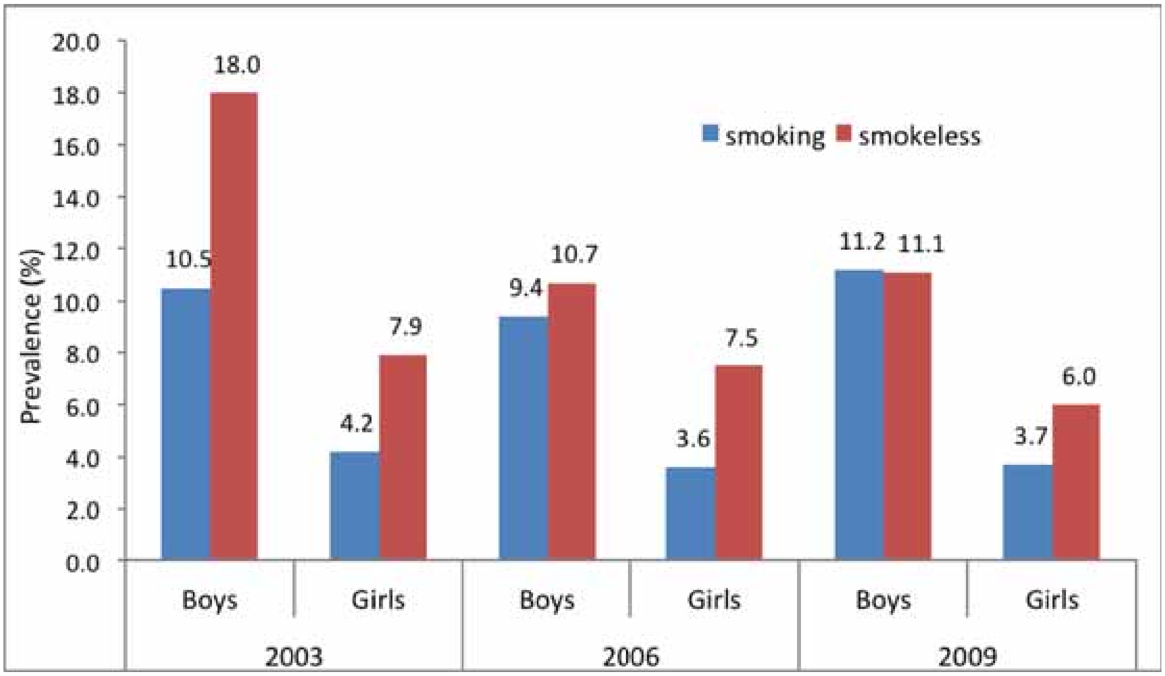


Sources: Gajalakshmi et al., 2004[9]; Sinha et al., 2005[10], Sinha et al., 2003[5].

Tobacco Smoking Versus SLT

The prevalence of current use of SLT products was higher than current tobacco smoking among boys and girls in the 2003 and 2006 surveys, but prevalences of SLT and smoking among boys were almost identical in 2009 (Figure 3.4)[2-4].

Figure 3.4: Prevalence of using smoked and smokeless forms of tobacco products among 13- to 15-year-old boys and girls (GYTS 2003, 2006, and 2009)

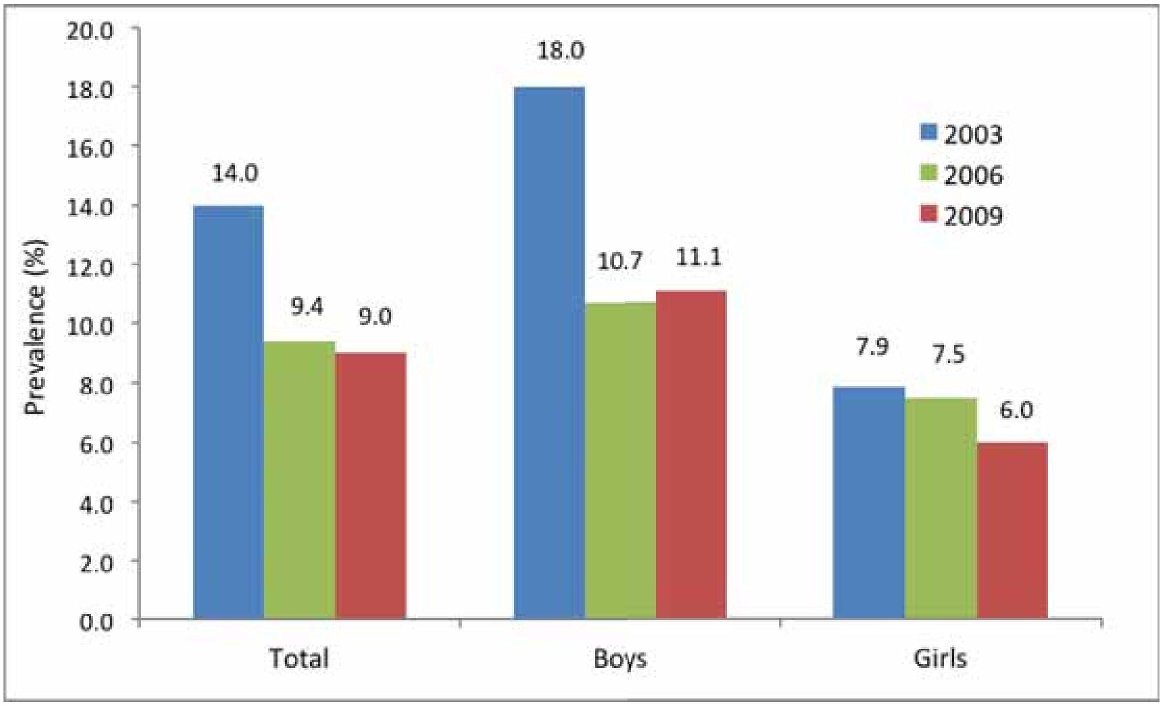


Sources: Sinha et al., 2008[2]; Global Youth Tobacco Survey (GYTS) 2003-2009[3]; Gajalakshmi et al., 2010[4].

NATIONAL TRENDS IN SLT USE AMONG YOUTH

Current use of SLT in India significantly decreased between 2003 (14.0%) and 2006 (9.4%) but then remained unchanged until 2009 (9.0%) (Figure 3.5). A decrease in SLT use occurred for boys (18.0% in 2003 to 10.7% in 2006 and 11.1% in 2009) but not for girls. In 2009, boys (11.1%) had significantly higher use of SLT than girls (6.0%)[2-4]. Trend data on the use of specific SLT products like gutka are not known at the national level.

Figure 3.5: Prevalence of using SLT products, by gender (GYTS 2003, 2006 and 2009)



Sources: Sinha et al., 2008[2]; Global Youth Tobacco Survey (GYTS), 2003-2009[3].

FACTORS ASSOCIATED WITH YOUTH ACQUISITION OF SLT USE

People usually begin using SLT products during adolescence. In addition to the influence of family members and peers[12-14], important factors associated with acquisition of SLT use among youth include the school environment[15], exposure to tobacco advertisements[16-23], and exposure to depictions of tobacco use in movies[18]. Low price[24], easy availability of tobacco products, and lack of knowledge and positive attitudes about tobacco use also contribute to adoption of tobacco use by youth.

School Environment

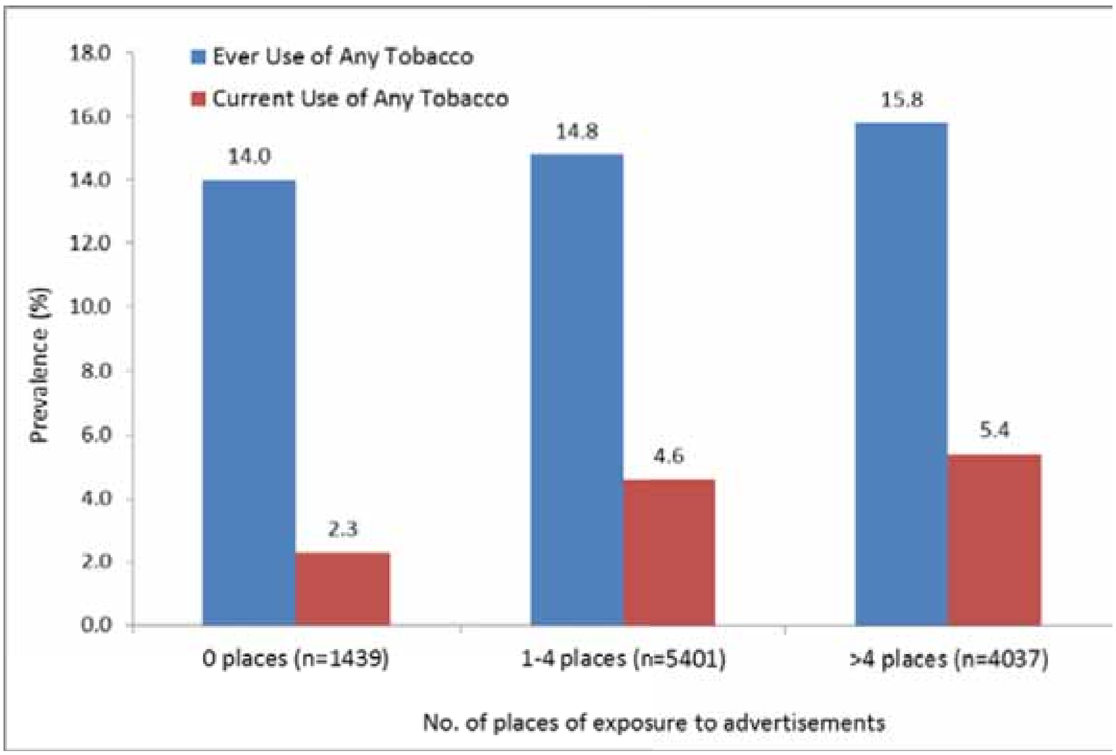
Use of SLT products was more prevalent among students in schools managed by the state government than among students in schools managed by the central government. Central government schools had a policy of banning use of tobacco products by students, school personnel, and others on school premises[15].

Exposure to Advertisements

As with cigarettes, a strong association has been found between exposure to SLT advertisements, both direct and indirect (e.g., on television, in magazines, on buses and billboards, and at point of sale) and gutka use among youth[10,16-20]. Point-of-sale advertisements increased nationwide after the implementation of the Tobacco Control rules of 2004[20]. GYTS results show that about 7 out of 10 students saw advertisements for SLT products on billboards in 2006 and 2009[2-4].

Results of a cross-sectional study of 11,462 school-going adolescents (6th and 8th graders) in 32 schools in Delhi and Chennai suggested that students with higher exposure to tobacco advertising (that is, they saw advertisements in more than 4 locations) were at higher risk (5.4%) of being ever tobacco users (15.8%) or current tobacco users (5.4%), compared to those with lower exposure [those who saw advertisements in no places (2.3%) or 1–4 places (4.6%)] (Figure 3.6). For 6th graders, a dose–response relationship existed[16]. A longitudinal follow-up of 2,782 students over 2 years suggested that boys who were receptive to tobacco advertising were at 2.36 times greater risk of becoming tobacco users[17].These results underscore the finding that exposure to tobacco advertising is associated with higher tobacco use.

Figure 3.6: Differences in tobacco use by exposure to advertising among students

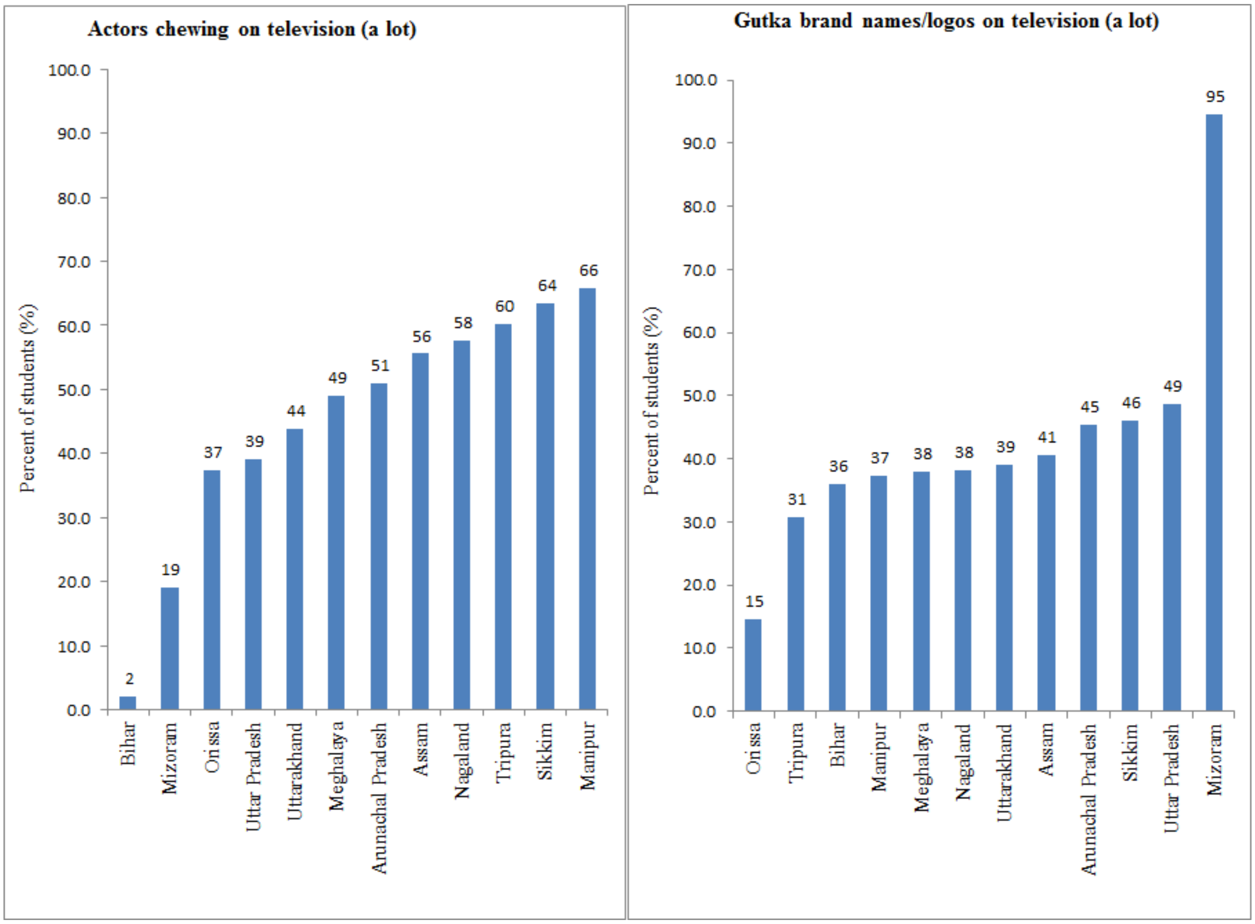


Source: Arora et al., 2008[16].

An analysis of a subset of GYTS India in 12 states found the following data on exposure to tobacco advertising (Figure 3.7):

- On average, over 50% of the students reported having seen actors chewing SLT on television 'a lot' in 6 out of the 12 states studied (ranging from 65.9% in Manipur to 2% in Bihar).
- On average, over 35% of the students in 10 out of 12 states studied reported having seen 'a lot' of gutka advertisements (ranging from 94.6% in Mizoram to 14.6% in Orissa).

Figure 3.7: Students' exposure to smokeless tobacco advertisements on television (GYTS, 2000–2002)

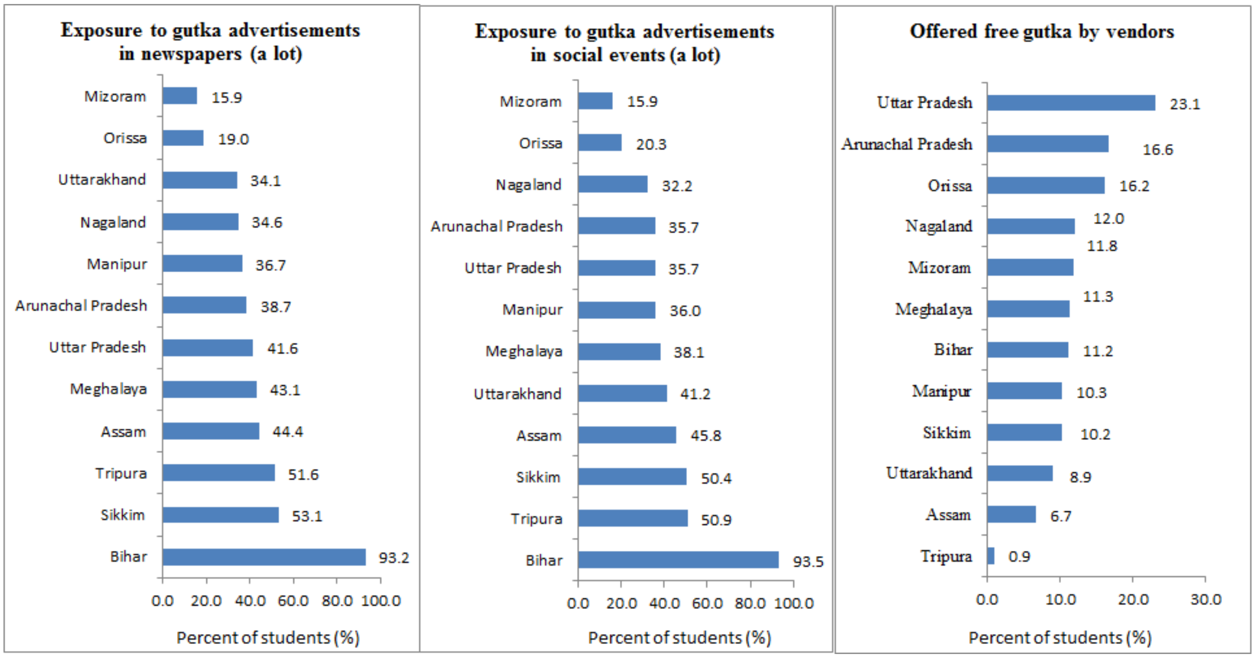


Source: Adapted from Sinha, 2003[21].

GYTS 2000–2002 provides evidence about the role of tobacco advertisements in newspapers and magazines and distribution of free tobacco samples at sports and social events in leading to initiation and use of tobacco products by students[21] (Figure 3.8). GYTS findings showed that:

- More than 30% of the students in most of the states under study had seen 'a lot' of gutka advertisements in newspapers/magazines in the past month (ranging from 93.2% in Bihar to 15.9% in Mizoram).
- More than 30% of the students in most of the states saw 'a lot' of gutka advertisements at sports and other social events (from 15.9% in Mizoram to 93.5% in Bihar).
- More than 10% of the students had been offered free gutka in 9 of the 12 states (from 23.1% in Mizoram to 0.9% in Bihar)[21].

Figure 3.8: Students' exposure to tobacco advertisements and distribution of free tobacco samples at events



Source: Sinha, 2003[21].

Tobacco Use in Movies

Studies among school-going adolescents in Delhi showed that depiction of tobacco use in Bollywood movies was associated with more than twice the risk of tobacco use in the highly exposed group as compared to those least exposed. In addition, adolescents who were receptive to tobacco promotions were two times more likely to have tried tobacco[18]. Findings from the GYTS (2000–2002) suggest that SLT products such as gutka are highly promoted through electronic media. In response to GYTS 2000–2002 survey questions, students reported that they were exposed to gutka advertisements 'a lot', 'sometimes', or 'never'[21] (Figure 3.8).

Price

The low cost of SLT products is a major contributor to the problem of youth tobacco use. GYTS 2000–2004 findings showed a strong positive association between availability of pocket money and SLT use in different states of India. This association was highest in Uttaranchal [odds ratio (OR) =15.19, 95% confidence interval (CI) 11.08-20.84], indicating that youth with more disposable income are at higher risk for SLT use[24].

Access and Availability

Another important risk factor for tobacco use is easy availability of tobacco products, which are widely available for sale, and especially around educational institutions. To control access to tobacco products by youth, the sale of tobacco products inside the premises and within the radius of 100 yards from school/educational institutions was prohibited by law; however, effective enforcement of these provisions is a big challenge. COTPA 2003 banned the sale of tobacco products to and by minors[25], but full, effective implementation of this provision requires overcoming many obstacles. GYTS 2009 data show that nearly half of students who currently smoke bought tobacco products in stores, and of these, 56.2% were not refused because of their age[3].

Knowledge and Attitudes Toward Smokeless Tobacco Use

Studies conducted in India with school-going adolescents have shown that psychosocial factors such as intentions to use tobacco and susceptibility to its use, positive reasons to use tobacco, and normative expectations are all associated with greater tobacco use (including SLT use), with the younger students having a higher psychosocial risk profile for tobacco use compared with older students[26]. The tobacco industry has traditionally attempted to target this group by influencing these risk factor—for example, by increasing tobacco advertising in media, movies, and other marketing campaigns; and by creating a physical and psychosocial environment that promotes tobacco use among children and adolescents. Knowledge about harmful consequences of tobacco use, positive reasons to use tobacco, and normative beliefs are important mediators of both tobacco use intentions and behaviour[27]. School-based multicomponent interventions such as Project MYTRI have successfully targeted these mediating factors among adolescents in India, thereby bringing about a change in tobacco use intentions as well as behaviour[28]. (See Appendix 2 for a description of Project MYTRI and another well-known intervention among youth, Project ACTIVITY.)

The GYTS conducted from 2000 to 2002 in eight North-Eastern states (Arunachal Pradesh, Assam, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim, and Tripura) reported on knowledge and attitudes about tobacco use among SLT users[5]. Table 3.1 shows that students who used SLT were 1.5 to 6 times more likely than never-users to think that boys who smoke or chew tobacco are more attractive. This difference was highest in the state of Meghalaya and lowest in Mizoram. In seven of the eight states studied, over 60% of SLT users thought that boys who smoke or chew tobacco are more attractive than nonusers. The percentage of SLT users who thought that girls who smoke or chew tobacco have more friends was 1 to 2.5 times higher than the percentage of students who had never used tobacco. This difference was largest in Sikkim and lowest in Nagaland. In six out of eight states studied, more than 20% of the SLT users believed that girls who smoke or chew tobacco have more friends than nonusers[5].

Misconceptions related to tobacco use were highly prevalent among students. Table 3.1 shows that the percentage of student SLT users who believed that tobacco helps to relieve toothache or facilitate morning bowel movement was about 1.5 to 6.5 times higher than the percentage of never tobacco users who held these beliefs. This difference was highest in Sikkim and lowest in Mizoram. In six out of eight states studied, over 64% of SLT users consistently believed that tobacco helps with toothache or bowel movement. The percentage of SLT users who stated that tobacco use makes them feel comfortable at parties was 5.5 times higher than the percentage of never-users who subscribed to this belief in the state of Tripura, and about 0.5 times higher in the state of Mizoram. In six out of eight states studied, over 80% of the SLT users believed that tobacco use makes them feel comfortable at parties[5].

Lack of knowledge about the harms associated with use of SLT was also prevalent. Table 3.1 shows that the percentage of never tobacco users who believed that SLT use is harmful was 1.2 to 7.5 times higher than the percentage of SLT users who believed SLT use is harmful. The difference was highest in the state of Tripura and lowest in the state of Mizoram. In seven out of the eight states studied, less than 17% of SLT users believed that SLT use is harmful[5].

GYTS data from the majority of the North-Eastern states studied consistently demonstrates that SLT users have more positive attitudes toward use of tobacco, including chewing tobacco, and less knowledge as well as more misconceptions about the harms associated with tobacco chewing or smoking. Considering the role that knowledge about tobacco use plays in mediating tobacco use behaviours, mentioned earlier in this section, it can be concluded that having positive attitudes toward tobacco, misconceptions about it, and poor knowledge of tobacco-related harms leads to SLT use among children and adolescents, a relationship that is reflected in the GYTS results[5].

Table 3.1: Knowledge and attitudes of adolescents (ages 13–15) toward tobacco use (GYTS 2000–2002 conducted in 8 North-East Indian states) (percent)

	Assam		Arunachal Pradesh		Manipur		Meghalaya		Mizoram		Nagaland		Sikkim		Tripura	
	Never-user	SLT user	Never-user	SLT user	Never-user	SLT user	Never-user	SLT user	Never-user	SLT user	Never-user	SLT user	Never-user	SLT user	Never-user	SLT user
Boys who smoke or chew look more attractive	22 (±4.0)	78.9 (±5.4)	15.9 (±4.1)	79 (±10.9)	17.1 (±7.1)	83.3 (±11.1)	12.4 (±3.1)	76.3 (±11.4)	11.1 (±3.2)	18.1 (±3.5)	11.7 (±4.6)	62.4 (±13.2)	20.8 (±6.6)	89.3 (±4.7)	20.5 (±7.2)	89.5 (±6.2)
Boys who smoke or chew have more friends	35.6 (±5.4)	40 (±8.0)	27 (±4.0)	29 (±7.4)	26.3 (±9.0)	35.7 (±5.4)	31.4 (±6.9)	24.2 (±5.3)	33 (±5.7)	50 (±4.3)	40.1 (±6.8)	32 (±8.6)	47.2 (±5.8)	68.9 (±8.4)	28.8 (±4.5)	21 (±13)
Girls who smoke or chew look more attractive	16.6 (±3.6)	43.7 (±7.1)	11.4 (±3.7)	30.9 (±6.6)	13.6 (±6.5)	35.8 (±7.0)	6.1 (±2.7)	33.9 (±8.7)	11.5 (±4.2)	15.1 (±3.3)	8.7 (±3.0)	17.2 (±4.2)	10.4 (±3.9)	63.8 (±9.7)	14.3 (±5.3)	39.2 (±16.2)
Girls who smoke or chew have more friends	20.1 (±4.4)	35.7 (±7.9)	16.1 (±4.0)	22.9 (±6.3)	18.1 (±7.2)	32.9 (±6.8)	17.6 (±3.6)	19.4 (±4.7)	25.9 (±6.5)	35.1 (±4.0)	21.2 (±5.7)	22.5 (±5.8)	26.1 (±5.4)	64.9 (±9.2)	14.8 (±3.7)	19.9 (±11.8)
Tobacco helps in relieving toothache/morning motion	25.6 (±4.6)	66.4 (±10.6)	16.4 (±5.1)	72.1 (±5.9)	17.8 (±7.1)	86.8 (±7.1)	15.1 (±5.6)	59.6 (±13.2)	16.1 (±4.6)	23.6 (±4.0)	13.5 (±3.7)	64.8 (±9.7)	13.5 (±4.1)	89.3 (±4.5)	17.1 (±7.2)	66.4 (±10.5)
Tobacco helps to feel more comfortable at parties	35.8 (±4.9)	82.5 (±5.9)	17.1 (±4.4)	81.8 (±8.6)	24 (±8.2)	83.2 (±10.2)	20.3 (±5.4)	80.5 (±9.3)	43.1 (±14.9)	33.2 (±7.4)	21.1 (±4.5)	69.4 (±9.5)	25.2 (±5.2)	89.5 (±5.0)	16 (±8.0)	87.1 (±9.0)
Smokeless tobacco is harmful	71.8 (±5.2)	17 (±5.9)	76.2 (±4.9)	16.4 (±9.0)	61 (±14.1)	5.8 (±4.9)	70.8 (±5.7)	15 (±8.5)	64 (±7.1)	50.3 (±4.4)	55.6 (±9.2)	15 (±6.0)	69.1 (±5.1)	9.5 (±5.3)	73.4 (±6.8)	9.9 (±9.4)

Note: Figure in parenthesis denotes 95% CI.
Source: Sinha et al., 2003[5].

The baseline data from the non-school-based project ACTIVITY (Table 3.2) comparing the intervention and control communities showed no significant difference in intentions to use any type of tobacco among ever-users (p=0.21). Susceptibility of ever-users was also not significantly different between the two communities: 3.80% of youth in intervention communities and 3.66% of youth in control communities were susceptible to using tobacco (p=0.96)[29].

Table 3.2: Intention and susceptibility at 2009 baseline survey, Project ACTIVITY, by trial condition (mixed-effects regression models) (n=6,023)

Product use	Intervention community		Control community		P value
	Prevalence	95% CI	Prevalence	95% CI	
Intention					
Any tobacco	10.75	2.88–18.61	3.75	-3.95–11.46	0.2113
Smoking tobacco	6.94	1.99–11.90	2.63	-2.19–7.46	0.2196
Chewing tobacco	2.39	-1.62–6.41	2.47	-1.48–6.41	0.9802
Other tobacco	2.53	-0.97–6.03	0.00	-3.46–3.46	0.3109
Susceptibility					
Any tobacco	3.80	-0.44–8.04	3.66	-0.50–7.82	0.9632
Smoking tobacco	1.22	-1.71–4.15	2.41	-0.50–5.32	0.5701
Chewing tobacco	1.23	-1.82–4.28	2.43	-0.58–5.44	0.5800
Other tobacco	1.21	-0.52–2.95	0.00	0.00–1.73	0.3297

Source: Arora et al., 2010[29].

DATA LIMITATIONS AND RESEARCH NEEDS

Youth who are out of school, less educated, employed, and living in rural areas are more likely to use tobacco and to start using it during their pre-teen years[30]. This finding is derived from a variety of studies from different parts of India, which used different study protocols. A standard protocol is needed for monitoring tobacco prevalence among this segment of the youth population.

Due to lack of state-specific information on SLT use among youth, it would be beneficial to collect information at the state level periodically to assess the health issues among youth and address them accordingly.

CONCLUSIONS

In India, according to GYTS data, almost one in ten students aged 13–15 years uses some form of SLT product. Prevalence of SLT use among student youth varies widely across states, ranging from 1% in Himachal Pradesh to 56% in Bihar. According to GYTS data, the prevalence of SLT use among students aged 13–15 years did not change between 2006 and 2009. Among girls, prevalence of SLT use is higher than prevalence of smoking. The prevalence of SLT use among students aged 13–15 years did not change between 2006 and 2009.

Prevalence of SLT use among student youth varies widely across states, ranging from 1% in Himachal Pradesh to 56% in Bihar. SLT use among India's youth is influenced by a number of environmental and individual-level factors, including price, availability, and social norms. Tobacco industry advertisements and promotions and are also important factors influencing SLT use among youth. The evidence from school-based interventions, such as Project MYRTRI, suggests that multicomponent interventions are effective in preventing adolescents from starting tobacco use in school settings and in changing community norms around tobacco use and denormalising SLT use among all community members.

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Chapter 4

Smokeless Tobacco Use Among Adults in India

Krishna M. Palipudi[1], Prakash C. Gupta[2], Samira Asma[1],
Dhirendra N. Sinha[3], Prabhat Jha[4]

[1]Centers for Disease Control and Prevention, Atlanta, GA, USA
[2]Healis-Sekhsaria Institute for Public Health, Navi Mumbai
[3]World Health Organization, Regional Office for South-East Asia, New Delhi
[4]Centre for Global Health Research, New Delhi

INTRODUCTION

India is home to over 70% of the world's adult smokeless tobacco users[1]. In order to understand the public health consequences of smokeless tobacco (SLT) use, a detailed study of prevalence of SLT use among adults is critical. The present chapter attempts to understand the pattern of SLT use among adults in India by drawing on national as well as subnational data (regional and state-specific).

SOURCES OF DATA

Global Adult Tobacco Surveys (GATS) conducted in India during 2009-2010[2] were the primary source of data for understanding prevalence and patterns among adults. GATS data were reported for various sociodemographic subgroups, including age, gender, education, place of residence, region, and state of India. Other datasets used were those from the National Family Health Surveys (NFHS) conducted between 1998 and 2005[3-5] and the Integrated Disease Surveillance Project (IDSP) during 2007-2008[6].

Global Adult Tobacco Survey (GATS) (2009-2010)

GATS India 2009-2010[2] used global standards for systematically monitoring tobacco use (smoking and smokeless forms) and tracking key indicators of tobacco control. This nationally representative survey elicits information on the respondent's background characteristics, tobacco use (smoking and smokeless), cessation, exposure to secondhand smoke (SHS), economic status, awareness of media, knowledge about tobacco, and attitudes and perceptions about tobacco use. The GATS survey was conducted in India during 2009-2010 as a household survey of people aged 15 years or older (considered adults for this report). A multistage, stratified cluster sample design was used to provide estimates at the national level and by residence (urban and rural) and gender. Survey information was collected using handheld devices. More details on GATS methodology can be found elsewhere[7].

National Family Health Survey (NFHS) (1998-1999, 2005-2006)

The National Family Health Survey[3-5] was a nationally representative household survey that employed a multistage, stratified sampling design. The two waves of NFHS that were conducted in India during 1998-1999 and 2005-2006 included questions on SLT use (gutka, other chewing tobacco, and snuff).

Integrated Disease Surveillance Project (IDSP) 2007-2008

The Integrated Disease Surveillance Project (IDSP)[6] was a state-based survey which was first conducted in India in 2007-2008 with the assistance of the World Bank, with periodic surveillance of noncommunicable disease risk factors planned for subsequent years. This survey, covering the population between the ages of 15 and 64, provides data on risk factors related to NCDs including tobacco use. The 2007-2008 survey also aimed to establish the baseline database of NCD risk factors needed to monitor trends in population health behaviour and risk factors for chronic diseases over time in seven states—Andhra Pradesh, Kerala, Madhya Pradesh, Maharashtra, Mizoram, Tamil Nadu, and Uttarakhand.

PREVALENCE OF SLT USE

By way of global context, SLT use prevalence among males ages 15–48 was highest in India (36.9%) in comparison with the 31 countries that participated in the Demographic and Health Surveys (DHS)[8]. However, the STEPS surveys show that, among males, India ranks second (32.9%) in prevalence of SLT use after Myanmar (51.4%); among females, India has the third highest prevalence of SLT use (17.3%), after Bangladesh (27.9%) and Madagascar (19.5%)[9].

Prevalence of SLT Use, by Demographic Characteristics

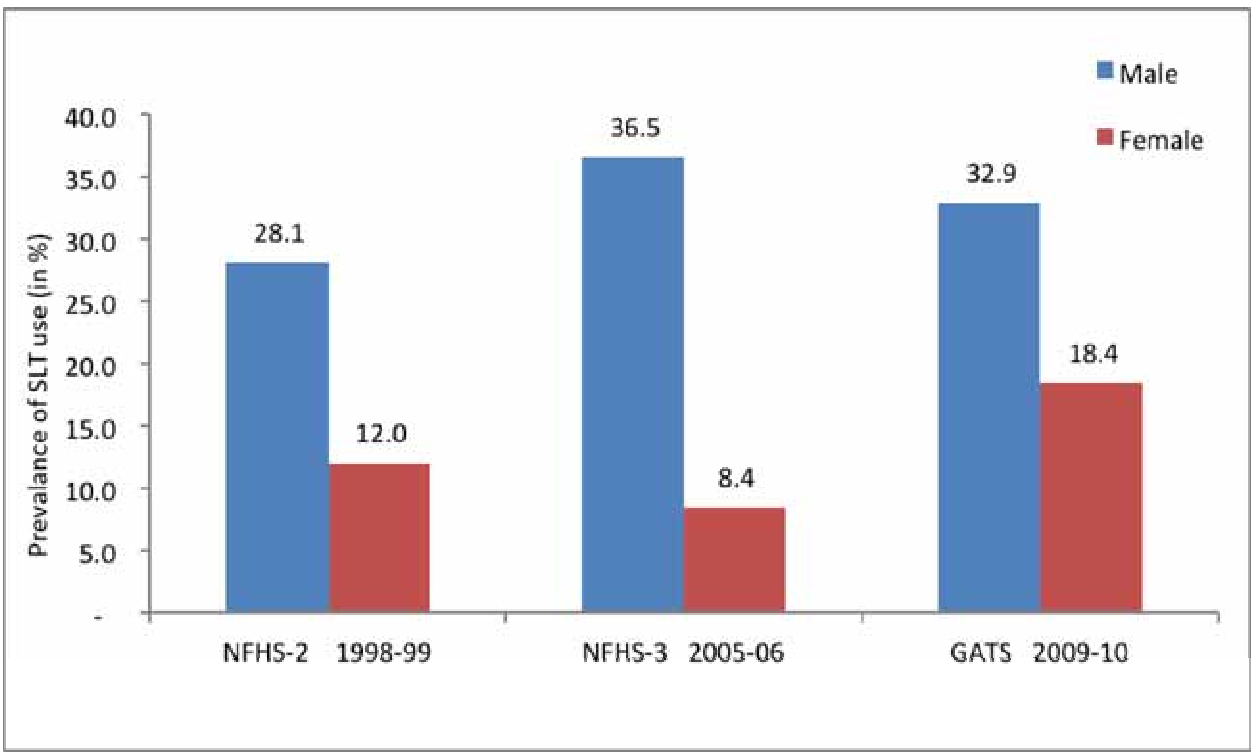
Information on prevalence of SLT use at the national level is available from national surveys[2-4], although their methodologies and tools vary, and is represented in Figure 4.1.

According to the GATS India 2009-2010[2], a quarter (26%) of all adults aged 15 years and older in India use SLT. They chew it, or apply it to the teeth and gums, or sniff it through the nose.

The following associations between SLT use and demographic characteristics were found:

- *Gender:* Prevalence of SLT use was higher among males than females[2-4] (Figure 4.1). Higher prevalence of SLT use among males has been reported in most of the states in India except Mizoram, Meghalaya, Tripura, Tamil Nadu, and Pondicherry, where prevalence of SLT use among females was higher than among males[2,6]. According to GATS, nearly one-third (32.9%) of men and one in five (18.4%) women use SLT in India.

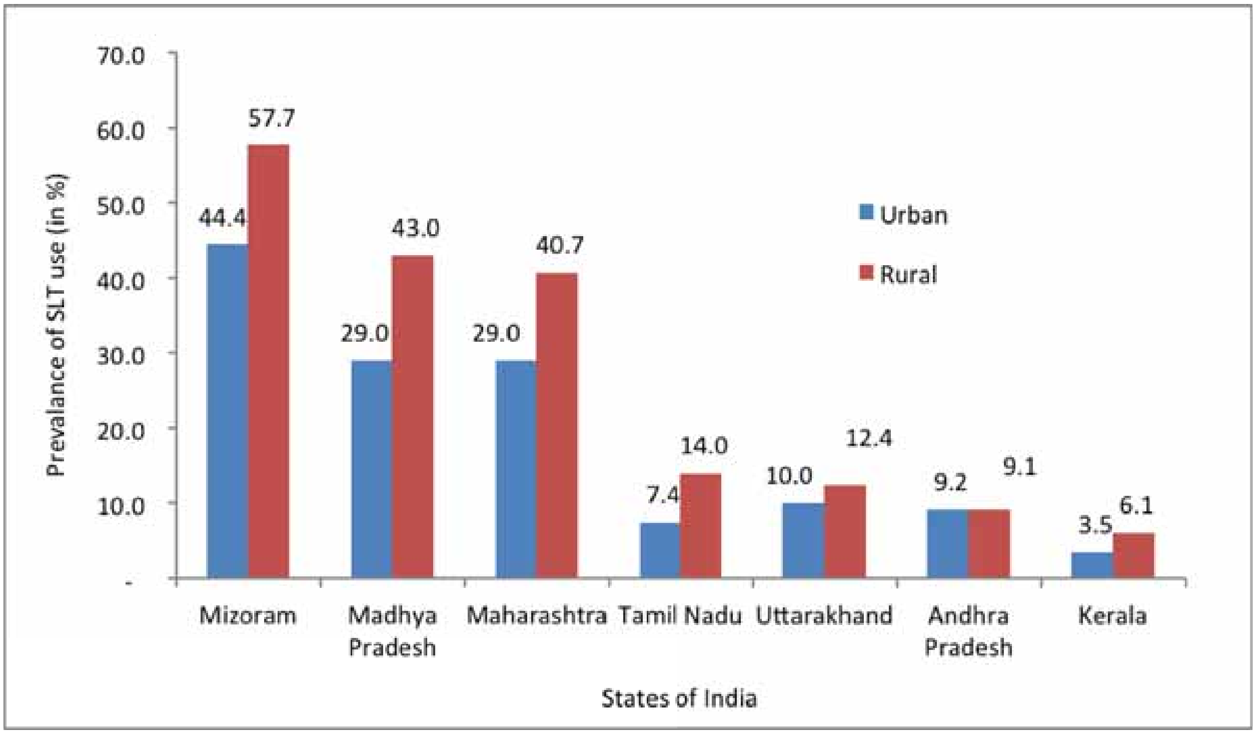
Figure 4.1: Prevalence of SLT use among adults (ages 15 years and older) in India



Sources: National Family Health Survey, 1998-99 (NFHS-2)[3]; National Family Health Survey, 2005-06 (NFHS-3)[4]; Global Adult Tobacco Survey (GATS), 2009-10 [2].

- *Residence:* SLT use is higher among the rural population (29.3%) than among the urban population (17.7%)[2]. Similar findings were observed in other national and subnational surveys[4,6]. The IDSP 2007-2008 survey findings show the prevalence of SLT use in seven states of India, with the highest prevalence in Mizoram (urban=44.4%; rural=57.7%) and the lowest in Kerala (urban=3.5%; rural=6.1%)[6] (Figure 4.2).

Figure 4.2: Prevalence of SLT use among adults (age 15 years and above), by residence in 7 states

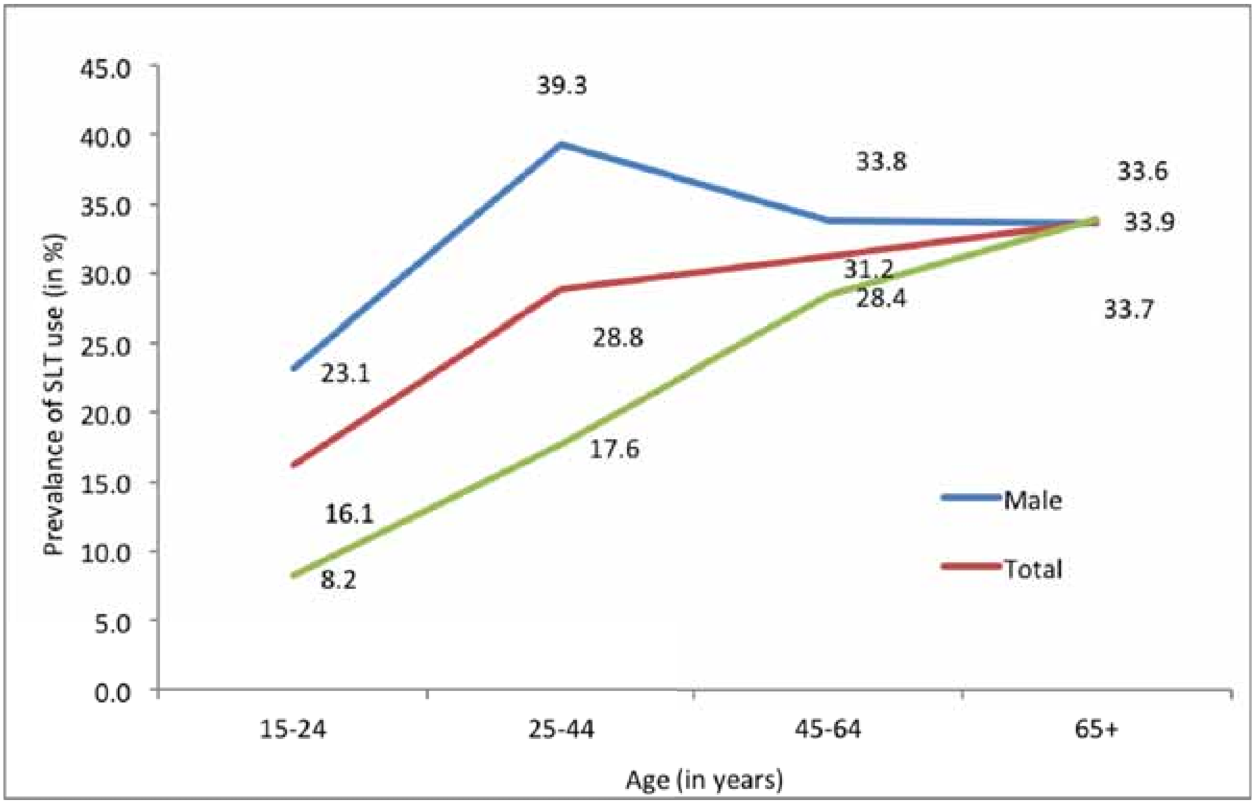


Source: Integrated Disease Surveillance Project (IDSP), 2007-2008[6].

- *Age:* In NFHS-2 (1998-1999), the prevalence of chewing tobacco increased with age until age 50 and then remained constant or declined[5]. In GATS India 2009-2010 also, SLT use increased with age; among men there was a sharp rise between ages 15 and 24 and between 25 and 44 years, and then a decline. However, among females, SLT use increased with age until old age, when the difference in use between males and females disappeared (Figure 4.3). IDSP, which examined use in seven states (Andhra Pradesh, Kerala, Madhya Pradesh, Maharashtra, Mizoram, Tamilnadu, and Uttarakhand), also found that SLT use increased with age[6].
- *Education:* Higher prevalence of SLT use has been reported in poorer and less educated populations compared to wealthier and more educated populations[2-5]. The socioeconomic gradients (by wealth as well as by education) were steeper for women than for men for chewing and smoking tobacco. Men in the poorest quintile had 3.7 times higher odds of being SLT users than men in the richest quintile, and women in the poorest quintile were 4.8 times more likely to be SLT users than those in the richest[5]. Men with no schooling were 3.1 times more likely to use SLT than men with more than 11 years of schooling; similarly, women without schooling were 13 times more likely to chew than women who had 11 or more years of education[5]. GATS data show that the prevalence of SLT use

among people with no formal schooling was 34%, while among people with a secondary education or higher, prevalence of use was 15%[2].

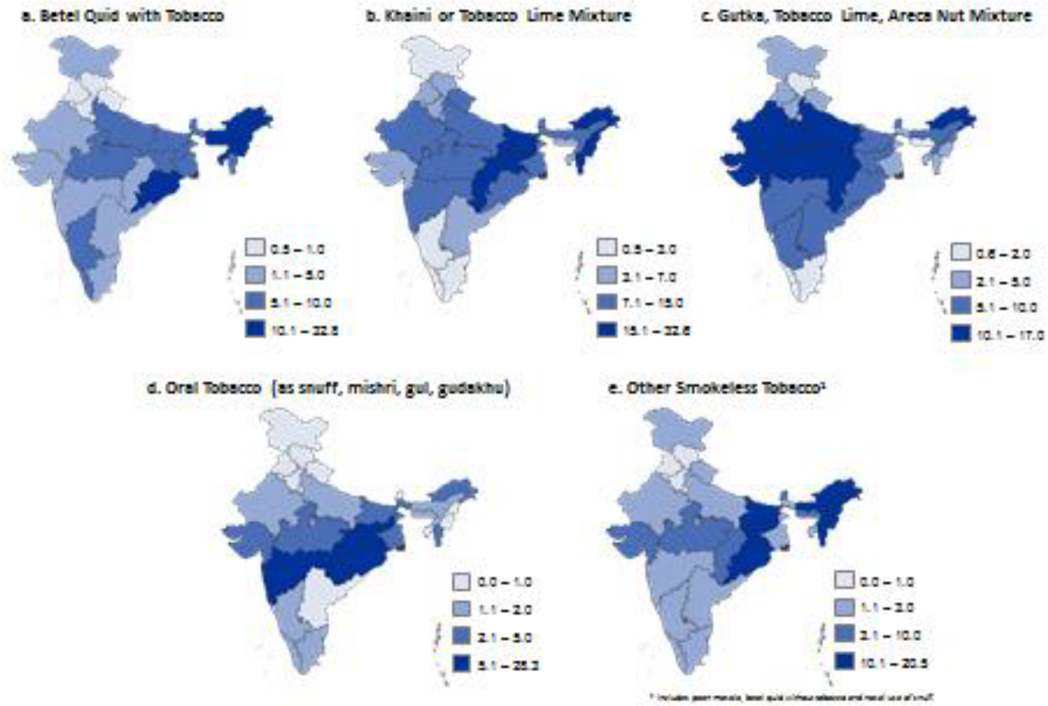
Figure 4.3: Prevalence of SLT use among adults (aged 15 years and older), by age



Source: GATS India, 2009-2010[2].

- *Castes and Religion:* Prevalence of SLT use was highest among the scheduled tribe (ST) population compared to general category. Among the Sikh community, the prevalence of chewing tobacco is almost negligible[5].
- *Geographical region and state/Union Territory (UT):* The GATS data show wide variation in the prevalence of SLT use among adults aged 15 years and older, by regions[2] and states (see Figure 4.4). Other national surveys report much greater variation in prevalence of use by females [3,5,6].

Figure 4.4: Prevalence of using smokeless tobacco in general and using specific SLT products, by region/states, Union Territories, and gender in India



Source: GATS India, 2009-2010[2].

Total SLT Users by Demographic Group

According to GATS India 2009-2010 data, the number of adult current users of SLT in India was 206.0 million, much higher than the number of current tobacco smokers (111.2 million). The number of male SLT users (135.2 million) was almost twice that of female SLT users (70.7 million). The number of SLT users in rural areas (164.9 million) was almost four times that in urban area (41.0 million). There were 170.1 million adults (112.8 million males and 57.3 million females) who used SLT every day, and an additional 35.8 million people (22.4 million males and 13.4 million females) used SLT occasionally[2].

Among the 206 million SLT users, numbers of users by product are as follows:

- 92.3 million (74.1 million males and 18.2 million females) chewed khaini
- 65.1 million (53.9 million males and 11.1 million females) consumed gutka
- 49.7 million (30.7 million males and 18.9 million females) chewed betel quid with tobacco
- 37.5 million (13.4 million males and 24.1 million females) used tobacco for oral application
- 35.1 million (14.4 million males and 20.7 million females) used other SLT products.

Males' prevalences were higher than females' for each kind of SLT product except products for oral application (such as snuff, mishri, gul, gudakhu) and other products (pan masala, betel quid without tobacco and nasal use of snuff), which females used at higher rates. The number of rural users of all SLT products combined (164.9 million) was higher than the number of urban users (41.0 million)[2].

PREVALENCE OF SLT USE, BY SPECIFIC PRODUCT

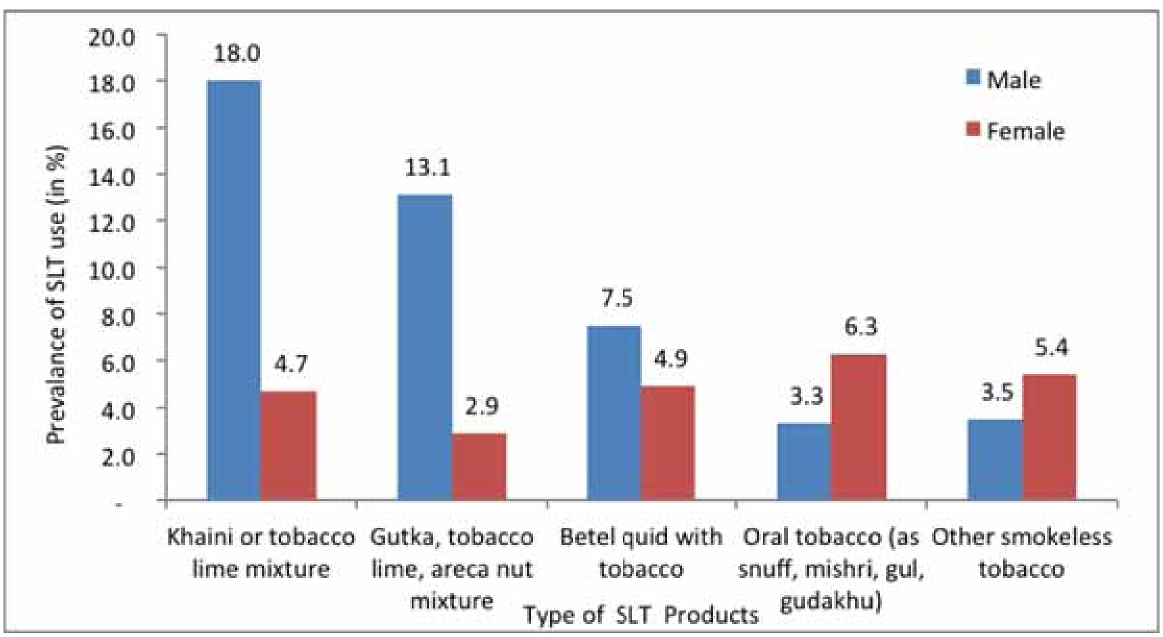
According to GATS 2009-2010 data[2], khaini (11.6%) was the most commonly used SLT product, followed by gutka (8.2%) and betel quid with tobacco (6.2%). Products in the 'oral tobacco' category (such as snuff, mishri, gul, and gudakhu) were less prevalent (4.7%). In the 'other smokeless tobacco' category, products such as nasal snuff had a prevalence of 4.4%[2].

Prevalence of khaini, gutka, and betel quid with tobacco was found to be higher among males compared to females, while prevalence of other tobacco and of oral tobacco used as dentifrice was higher among females than among males (Figure 4.5).

Among males, khaini was the most commonly used SLT product; however, among certain groups of males such as adolescents (ages 15–24), urban males, males with secondary or higher education, and male students, gutka is the most commonly used SLT product. Among females in general, SLT is used mainly by oral application (6.3%), followed by other smokeless tobacco (5.4%), betel quid with tobacco (4.9%), khaini (4.7%), and gutka (2.9%).

Among men, prevalence of using khaini and using betel quid with tobacco increases with age. Khaini use increases from 5% among men in the 15– 24 age group to 9% among those ages 25–44; use of betel quid with tobacco increases from 10% in the 15–24 age group to 22% among men ages 25–44. Men's use of both products remains almost unchanged in subsequent age groups. Prevalence of gutka use increases from 14% among males ages 15–24 to 17% among those age 25–44, but then decreases to 5% among men ages 65 and older. Men's use of khaini and oral tobacco products decreases with rising education[2].

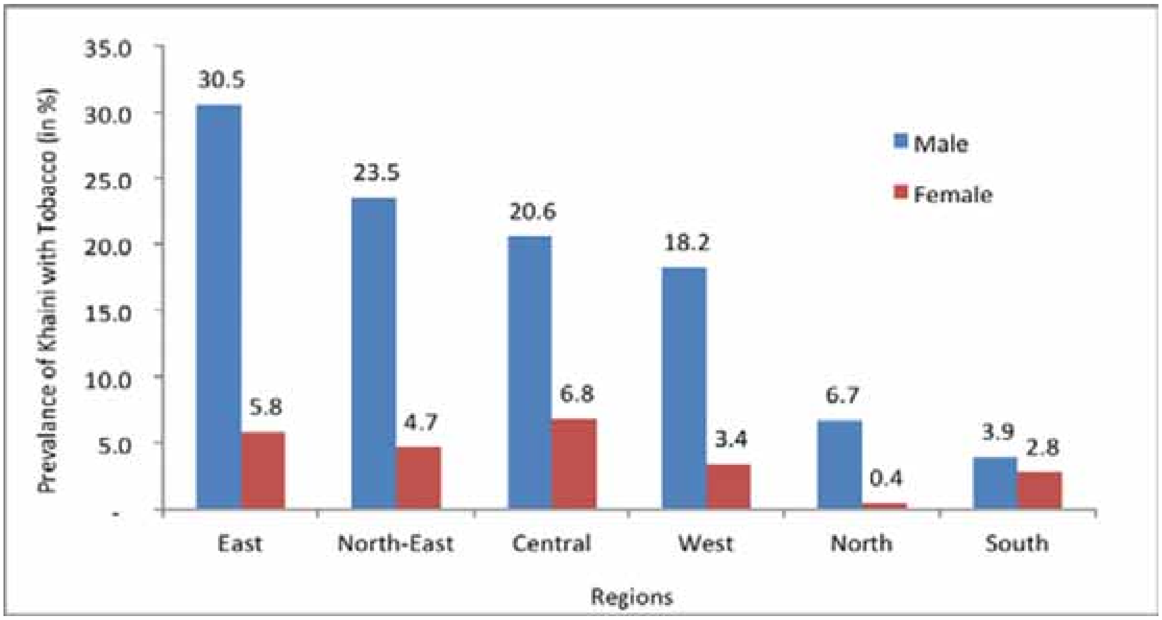
Figure 4.5: Prevalence of specific SLT product use among adults (15 years and older), by gender



Source: GATS India, 2009-2010[2].

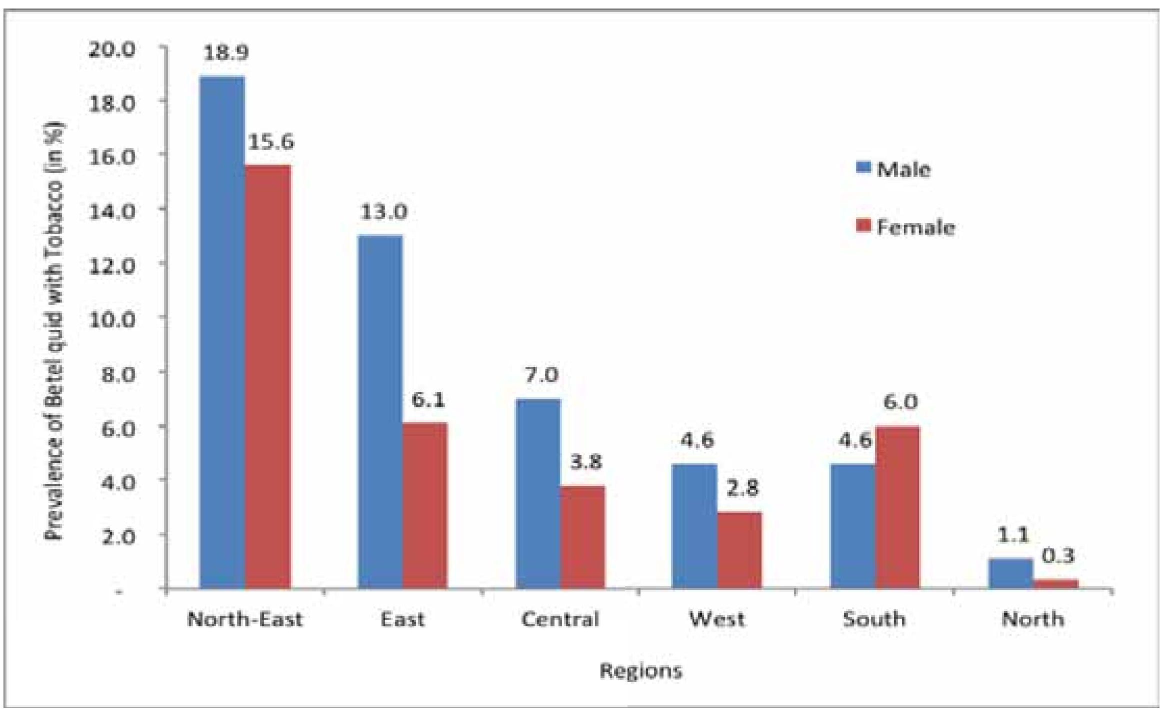
Males use khaini more than females in all regions (Figure 4.6). Use of betel quid is more prevalent among males than females in all regions except the South, where betel quid prevalence is higher among females (Figure 4.7).

Figure 4.6: Prevalence of khaini use, by gender and region



Source: GATS India, 2009-2010[2].

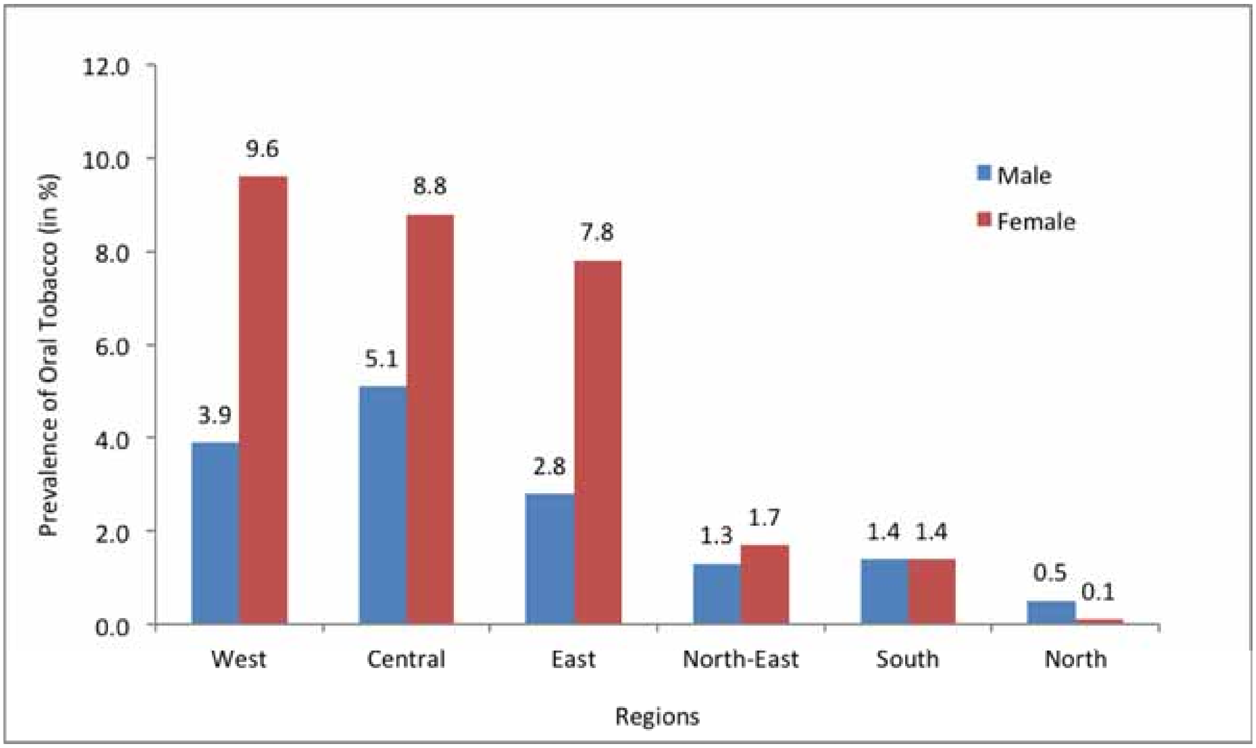
Figure 4.7: Prevalence of use of betel quid with tobacco, by gender and region



Source: GATS India, 2009-2010[2].

Prevalence of oral tobacco (e.g., snuff, mishri, gul and gudahku) use is higher among females than males in the West, Central, East, and North-East regions. In the South, prevalences of use among both genders are more similar, while prevalence of oral tobacco use is higher among males than females in the North region (Figure 4.8).

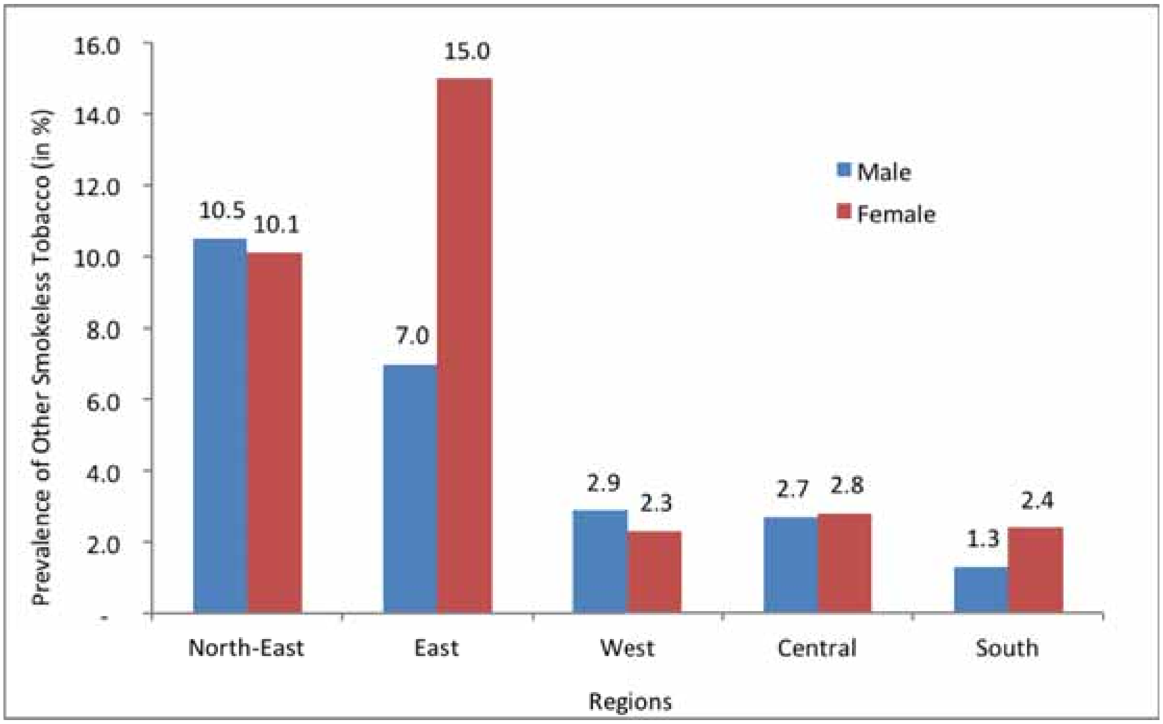
Figure 4.8: Prevalence of oral tobacco use, by gender and region



Source: GATS India, 2009-2010[2].

Highest prevalences of using other smokeless tobacco (e.g., nasal snuff) are found in the North-East and East regions (Figure 4.9)[2]. Prevalence of other tobacco use is reported more among females in the East and South regions; in all other regions, prevalence was similar among both genders.

Figure 4.9: Prevalence of other smokeless tobacco use, by gender and region



Source: GATS India, 2009-2010[2].

DAILY, OCCASIONAL, AND PAST USE OF SMOKELESS TOBACCO

According to GATS 2009-2010 data, of the 26% of adults in India who use SLT, 21% use it daily, and the remaining 5% use it only occasionally. Among the 33% of males who use SLT, 27% use it every day, and the remaining 5% use it occasionally. Similarly, 15% of females use a smokeless product every day, and only 4% use occasionally. Proportionally more adults in rural areas use SLT both daily and occasionally than adults in urban areas. The proportion of daily users of SLT among males increases with age, from 17% in the 15–24 age group to 33% in the 25–44 age group, but then decreases to about 30% among males age 45–64 and 65 and older. The prevalence of daily SLT users among females increases from 6% in the 15–24 age group to 30% among females age 65 and above. Among adolescents ages 15–17, 8% of males and 6% of females use SLT every day, and 4% of males and 2% of females use it occasionally[2].

GATS India 2009-2010 shows that former daily use of smokeless tobacco was 1.2% (1.4% among males; 0.9% in females) and former occasional use, 1.1% (1.2 in males; 0.9% in females). Thus, past use did not differ much by gender, but there was greater variation in former occasional use across states, with a range of 0.1% to 3.3%. Overall, it is clear that prevalence of past use was quite small—less than 5% everywhere except in Jharkhand, where former occasional use was 6.1% (Table 4.1)[2].

Table 4.1: Prevalence of past use of smokeless tobacco among adults (GATS India 2009-2010)

	Overall (%)	Male (%)	Female (%)
Frequency of SLT use			
Former daily user	1.2	1.4	0.9
Former occasional user	1.1	1.2	0.9
Range in different states			
Former daily user	0.1[a] – 2.7[b]	0.1[e] – 3.0[f]	0.0[i] – 3.9[j]
Former occasional user	0.1[c] – 3.3[d]	0.2[g] – 3.4[h]	0.0[k] – 6.1[l]

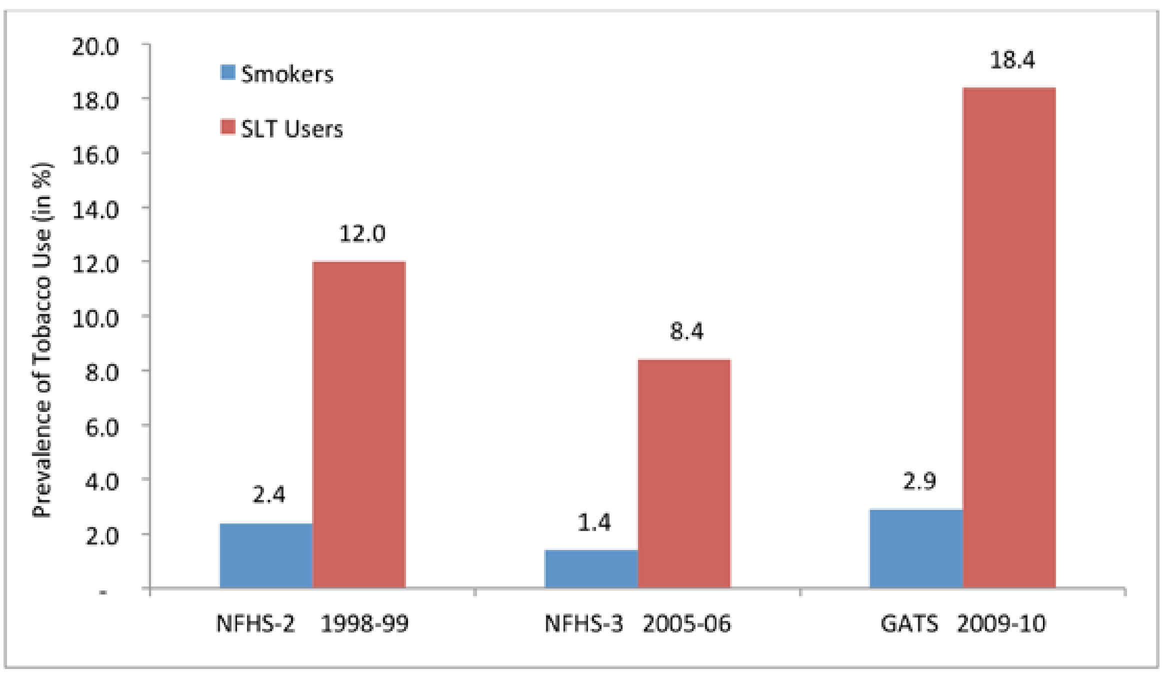
Notes: a Chandigarh, b Nagaland, c Punjab, d Jharkhand, e Delhi, f Gujarat, g Delhi, Goa, Tamil Nadu, h Madhya Pradesh, i Mizoram, j Bihar, k Punjab, Haryana, Mizoram, l Jharkhand.

Source: GATS India, 2009-2010[2].

NATIONAL TRENDS IN SLT USE AMONG ADULTS

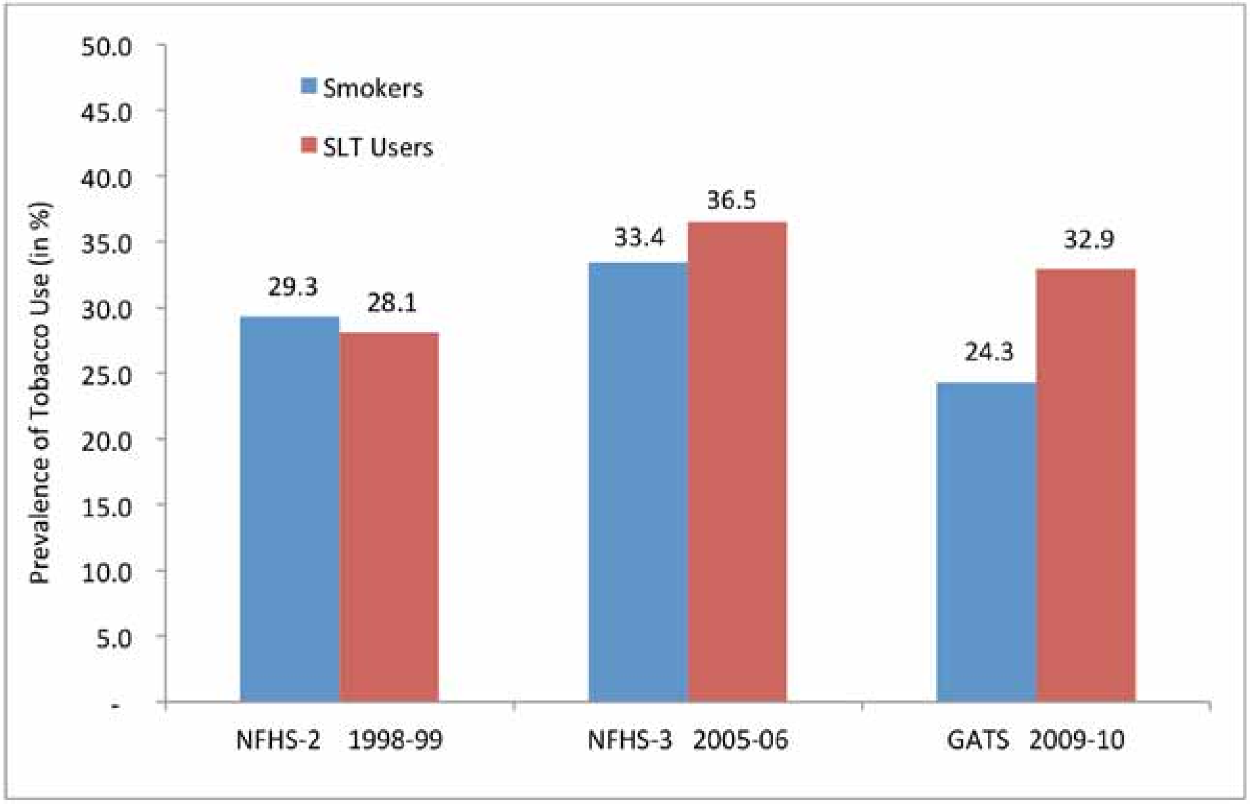
Although repeated national surveys using the same methodology have not been conducted in India, comparing the available national survey data over the last decade shows an increase in the prevalence of SLT use (Figure 4.1)[2-4]. Among females, the difference between prevalence of smoking and SLT use was greater in GATS compared to NFHS, with SLT use increasing (Figure 4.10). Males' rates of smoking and SLT use were similar in the earlier two surveys but diverged in GATS India 2009-2010, which showed an increase in SLT use and a decrease in smoking (Figure 4.11). In India as a whole the prevalence of SLT is greater than that of smoking both among men and women[2].

Figure 4.10: Prevalence of smoking and smokeless tobacco use among females



Sources: National Family Health Survey, 1998-99 (NFHS-2)[3]; National Family Health Survey, 2005-06 (NFHS-3)[4]; GATS India, 2009-2010[2].

Figure 4.11: Prevalence of smoking and smokeless tobacco use among males



Sources: NFHS-2[3]; NFHS-3[4]; GATS India, 2009-2010[2].

DATA LIMITATIONS AND GAPS

The different methodologies, age ranges, definitions, survey questions, and sample representativeness of the surveys cited in this chapter (GATS, NFHS, IDSP, etc.) limit the comparability of their data. A common feature of all these data sources was the cross-sectional nature of data, which limits the scope for causal inference. Another characteristic of these surveys is that their data were collected from the self-reports of a randomly selected respondent from each selected household without any objective validation. The study design of these surveys allowed for the investigation of only a limited number of sociodemographic variables.

These surveys also focused on different subjects: GATS India 2009-2010 had questions on tobacco cessation, whereas NFHS and IDSP did not. Tobacco use was a small component of both NFHS-2 and NFHS-3, rather than the central focus, and only few questions were used to determine the prevalence of tobacco use. NFHS is primarily a reproductive health survey which sampled women ages 15–49. Men were sampled in the households of the female sample. This sampling introduces the potential for downward bias. Since the sample of men is conditional on the households from which women were sampled, and since women are much less likely to be tobacco users than men, the pool of men sampled may not be representative of male users. These surveys do not provide detailed data on the type or volume of tobacco use or for the frequency of use of SLT products.

The NFHS-2 survey was administered through proxy respondents, in which one household member answered questions for other members. This is a serious limitation because the information provided by one member for others may not be accurate. Also, NFHS-2 lacked in-depth classification of tobacco products; for example, SLT use was represented only by chewing, and chewing of other products, such as betel quid with tobacco, gutka, khaini, gul, and mishri, was not considered.

The IDSP survey included other focus areas such as alcohol, diet, and physical activity, and is not primarily concerned with tobacco. It included limited indicators related to tobacco control and provided data on a limited number of states in India.

CONCLUSIONS

Data from various sources show that India is home to over 70% of global smokeless tobacco users. Prevalence of SLT use in India is one of the highest among the most populous countries of the world. SLT use is more prevalent among males than females in most of the country; in a few areas, prevalence is higher among females than males. Prevalence of SLT use is also higher among the poor and uneducated. Prevalence of using different SLT products varies widely among India’s regions and states. Currently, no surveys provide comparable data that can be used to monitor trends in SLT use among adults in India.

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Chapter 5

Dual Tobacco Use in India

Prakash C. Gupta[1], Krishna M. Palipudi[2], Dhirendra N. Sinha[3], Cecily S. Ray[1]

[1]Healis-Sekhsaria Institute for Public Health, Navi Mumbai, India
[2]Centers for Disease Control and Prevention, Atlanta, GA, USA
[3]World Health Organization, Regional Office for South-East Asia, New Delhi

INTRODUCTION

In this chapter, a dual tobacco user is defined as a person who concurrently uses both smoked and smokeless forms of tobacco. In contrast, single tobacco users are exclusive users of only smoked or smokeless forms. In India, smoked forms of tobacco include bidis, cigarettes, cigars, cheroots, chuttas, rolled tobacco, dhumti, and pipes (e.g., chilum, hookli, and hookah). Smokeless forms of tobacco used in India include chewing products (e.g., khaini, pattiwala, zarda, qiwam, and gundi) and products containing areca nut (e.g., gutka, pan masala with tobacco, mawa, and Mainpuri tobacco); products used for oral application (mishri, gul, bajjar, gudakhu, and creamy snuff) and for nasal inhalation (snuff). Chewing tobacco products are often incorporated into betel quid[1]. (See the factsheets in Appendix 1 for a description of Indian SLT products.) Thus, a wide choice of tobacco products, both smoked as well as smokeless, are available to consumers, and it is not surprising that some people will choose to use both forms.

This chapter reviews the findings on dual tobacco use from early large population surveys and provides recent national prevalence data. To characterise this group, the chapter provides a sociodemographic profile of dual users in India based on the GATS India report and a more recently published analysis of GATS data. This chapter also aims to synthesise available epidemiological information on risks of cancer and heart disease among dual tobacco users, in comparison with single tobacco users and non-users.

PREVALENCE OF DUAL TOBACCO USE

Dual tobacco use has been documented throughout the country among youth and adults from various surveys. **Among youth**, dual tobacco use among students aged 13–15 years was 5.4%[2], as reported by the first Global Youth Tobacco Survey in India (GYTS 2003), which was conducted during 2000–2005. **Among adults**, prevalence of dual use among adults (aged 15 years and above) has varied by regions of the country. In the late 1960s, surveys of seven large rural areas in six different states found that dual tobacco use in men varied from 2.4% to 26.2% and in women, from nil to 3.8% [3-5]. In five out of seven areas, dual use was over 12% among men (Table 5.1). In a later survey in rural areas of Bhavnagar District (1993-1994), dual use prevalence among men was 4.8%[6].

Table 5.1: Prevalence of dual tobacco use and all tobacco use, and the proportion of dual use among all tobacco users, among men and women, from house-to-house surveys in rural areas of India in the 1960s

State. rural district, and reference	Number surveyed	Men			Women		
		Dual users (%)	All tobacco users (%)	% of tobacco users who are dual users	Dual users (%)	All tobacco users (%)	% of tobacco users who are dual users
Andhra Pradesh: Srikakulam (Mehta et al., 1969)[3]	10,169	12.6	80.6	15.6	2.7	67.2	4.0
Bihar: Singhbhum (Mehta et al., 1969)[3]	10,048	14.0	81.0	17.3	1.7	32.6	5.2
Bihar: Darbhanga (Mehta et al., 1969)[3]	10,340	26.2	78.0	33.6	3.8	51.4	7.4

State. rural district, and reference	Number surveyed	Men			Women		
		Dual users (%)	All tobacco users (%)	% of tobacco users who are dual users	Dual users (%)	All tobacco users (%)	% of tobacco users who are dual users
Gujarat: Bhavnagar (Mehta et al., 1969)[3]	10,071	6.2	70.9	8.7	--	15.0	–
Kerala: Ernakulam (Mehta et al., 1969)[3]	10,287	22.0	67.6	32.5	0.6	11.9	5.0
Maharashtra: Pune (Mehta et al., 1972)[4]	101,761	2.4	81.2	3.0	--	38.9	–
Uttar Pradesh: Mainpuri (Wahi et al., 1968)[5]	34,997	19.7	61.6	32.0	1.2	48.9	2.5

Note: The age group was ≥15 years for all surveys except the survey in Uttar Pradesh[5], where the age group was ≥35 years.

In a survey conducted in 1992–1994 among adults aged 35 years and above in Mumbai, prevalence of dual use was 9.9% among men, 0.2% among women, and 4.1% among the total population[7].

In the National Family Health Survey, second round (NFHS-2), conducted in 1998-1999, the prevalence of dual tobacco use was 6.5% among adults (aged 15 years and older)[8].

The Global Adult Tobacco Survey (GATS) conducted in 2009-2010 among adults (aged 15 years and older) revealed that, compared to some other low- and middle-income countries, India has a much higher prevalence of dual tobacco use: 5.3% of all adults[9,10]. Dual users in India, as in Bangladesh and Myanmar, constitute a larger proportion of all tobacco users than in other countries of the South-East Asia Region of the World Health Organization (WHO)[11].

PROFILE OF ADULT DUAL USERS

Basic information on dual tobacco users in India is available from GATS India 2009-2010, which was administered to a country-wide representative sample of 69,296 individuals aged 15 years and over[10].

Numbers and Proportions

The number of adult dual users (≥ 15 years) in India was estimated at 42.3 million. This was 15.4%, or about one-sixth, of the total of 275 million tobacco users in India. More than one-third (38.0%) of tobacco smokers and one-fifth (20.5%) of SLT users were dual users.

Sociodemographic Profile

Dual users were predominantly men, with a prevalence of 9.3%. Women had a dual use prevalence of 1.1%. The male:female ratio was 8.5:1. The 25–44 age group had the highest prevalence overall (6.4%). Analysing for educational level, the highest prevalence of dual tobacco use was among adults with some primary education (8.3%). Among all occupational groups, the prevalence was lowest among students (0.9%) and was highest among working people, with 8.3% each among government/non-government employees and the self-employed. The prevalence was substantially higher in rural areas (6.0%) than urban areas (3.6%) (Table 5.2).

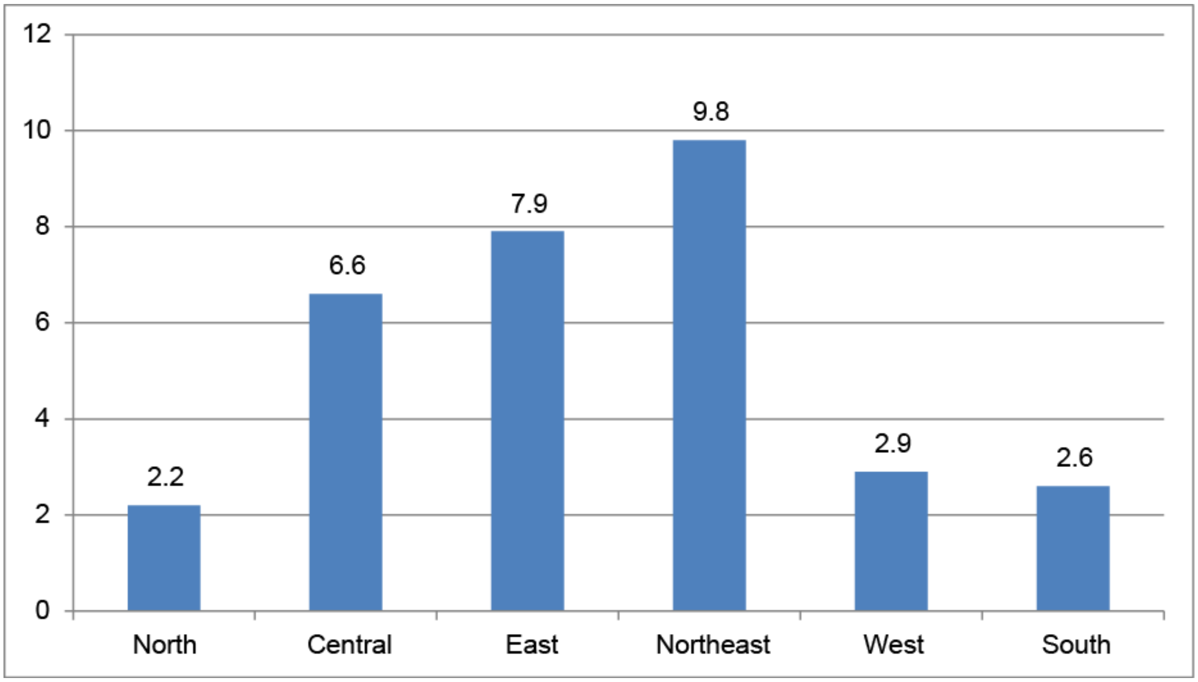
By region, the highest prevalence was found in the North-East (9.8%) and the lowest in the North (2.2%). The Central and the East Regions had higher-than-average prevalence. The Central Region is the most highly populated region of the country, hence it has a large number of dual users (Figure 5.1)[10].

Table 5.2: Prevalence and sociodemographic profile of dual tobacco users and all tobacco users, and proportion of dual users among all tobacco users, among adults, by age

Background Characteristics	Men			Women			Overall		
	Dual users (%)*	All tobacco users (%)*	% of tobacco users who are dual users	Dual users (%)	All tobacco users (%)*	% of tobacco users who are dual users	Dual users (%)*	All tobacco users (%)	% of tobacco users who are dual users
All India	9.3	47.9	19.4	1.1	20.3	5.3	5.3	34.6	15.4
By Age									
15–24	5.4	27.4	19.8	0.3	8.3	3.1	3.0	18.4	16.2
25–44	11.7	54.6	21.4	0.8	19.0	4.1	6.4	37.3	17.1
45–64	10.1	61.1	16.5	1.9	32.1	6.0	6.1	47.1	13.0
65+	8.9	55.7	16.0	3.7	40.2	9.1	6.2	47.8	13.0
Residence									
Urban	6.4	37.5	17.2	0.4	11.8	3.5	3.6	25.3	14.1
Rural	10.5	52.3	20.0	1.3	23.7	5.7	6.0	38.4	15.7
Education									
No formal	13.9	68.0	20.5	2.1	32.7	6.3	6.0	44.4	13.5
<Primary	13.9	61.6	22.6	0.6	23.1	2.7	8.3	45.2	18.3
Primary but < secondary	9.1	48.1	18.9	0.4	11.5	3.3	5.4	32.7	16.6
Secondary and above	4.8	30.5	15.7	0.1	3.6	2.5	3.1	20.7	14.8
Occupation									
Government & non-government employee.	10.5	51.7	20.2	2.5	27.7	8.9	8.3	45.1	18.3
Self-employed	10.5	55.7	18.8	0.6	25.0	2.6	8.3	48.9	17.0
Students	1.4	9.5	14.5	0.0	4.3	1.1	0.9	7.5	11.5
Homemakers	13.3	55.7	23.8	1.0	19.0	5.0	1.4	20.5	7.0
Retired & unemployed	9.8	51.9	18.9	2.1	34.9	5.9	7.5	46.8	16.0

Sources: Data obtained or calculated from the GATS India, 2009-2010 dataset including from country reports[10] and Gupta et al., 2012[12].

Figure 5.1: Prevalence of dual use among adults age 15 years and older in India, by region



Source: GATS India, 2009-2010[10].

The state-wise prevalence of dual tobacco use ranged from 0.7% in Goa (in the Western Region) to 20.0% in Nagaland (in the North-East Region) (Table 5.3). The dual use prevalence in all the states of the Central, East, and North-East regions exceeded the national average of 5.3%.

Table 5.3: Prevalence of dual tobacco use and all tobacco use, and proportion of dual users among all tobacco users, among adults age 15 years and older, by region and state

Region and state	Men			Women			Overall		
	Dual users (%)*	All tobacco users (%)	% of tobacco users who are dual users †	Dual users (%)*	All tobacco users (%)	% of tobacco users who are dual users †	Dual users (%)*	All tobacco users (%)	% of tobacco users who are dual users †
All India	9.3	47.9	19.4	1.1	20.3	5.4	5.3	34.6	15.4
North	3.7	31.7	11.7	0.3	3.7	8.1	2.2	18.9	11.5
Jammu & Kashmir	4.2	41.6	10.1	1.6	10.3	15.5	3.0	26.6	11.1
Himachal Pradesh	3.3	38.5	8.6	0.0	3.7	0.0	1.6	21.2	7.7
Punjab	3.2	21.6	14.8	0.0	0.5	0.0	1.7	11.7	14.7
Chandigarh	3.6	23.7	15.2	0.0	1.7	0.0	2.1	14.3	14.5
Uttarkhand	4.5	43.9	10.3	0.1	5.8	1.7	3.0	30.7	9.6
Haryana	4.1	39.6	10.4	0.2	5.6	3.6	2.3	23.7	9.6
Delhi	6.3	40.9	15.4	0.2	3.7	5.4	3.6	24.3	14.7
Central	11.0	53.4	20.6	1.7	21.1	8.1	6.6	38.1	17.4
Rajasthan	9.7	50.5	19.2	0.8	12.9	6.2	5.4	32.3	16.7
Uttar Pradesh	10.5	48.8	21.5	1.3	16.9	7.7	6.2	33.9	18.3
Chhattis-garh	9.5	63.9	14.9	3.7	41.6	8.9	6.7	53.2	12.6
Madhya Pradesh	15.3	58.5	26.2	1.7	18.9	9.0	8.8	39.5	22.3
East	14.5	59.0	24.6	1.0	31.2	3.2	7.9	45.4	17.4
West Bengal	12.9	52.3	24.7	0.4	19.3	2.1	6.9	36.3	18.9
Jharkand	14.2	63.6	22.3	0.4	35.9	1.1	7.5	50.1	14.9
Odisha	14.5	56.1	25.8	0.0	36.2	0.0	7.3	46.2	15.7
Bihar	16.2	62.2	26.0	2.4	40.1	6.0	9.5	53.5	17.7
North-East	16.0	56.9	28.1	3.2	30.8	10.4	9.8	44.1	22.1
Sikkim	14.2	48.7	29.2	6.0	33.2	18.1	10.4	41.6	25.0
Arunachal Pradesh	28.8	64.0	45.0	7.2	31.7	22.7	17.9	47.7	37.5
Nagaland	32.6	69.2	47.1	6.0	43.0	14.0	20.0	56.8	35.2
Manipur	25.7	66.6	38.6	6.6	41.8	15.8	16.1	54.1	29.7
Mizoram	19.5	72.5	26.9	6.5	61.6	10.6	13.2	67.2	19.6
Tripura	19.6	63.4	30.9	5.7	48.1	11.9	12.8	55.9	22.9
Meghalaya	14.4	73.2	19.7	2.8	36.7	7.6	8.7	55.2	15.8
Assam	13.2	52.6	25.1	2.1	25.3	8.3	7.8	39.3	19.9
West	5.2	43.4	12.0	0.4	16.1	2.5	2.9	30.5	9.6
Gujarat	5.0	46.2	10.8	1.2	11.3	10.6	3.2	29.4	10.7
Maha-rashtra	5.3	42.5	12.5	0.0	18.9	0.0	2.8	31.4	9.0

Region and state	Men			Women			Overall		
	Dual users (%)*	All tobacco users (%)	% of tobacco users who are dual users †	Dual users (%)*	All tobacco users (%)	% of tobacco users who are dual users †	Dual users (%)*	All tobacco users (%)	% of tobacco users who are dual users †
Goa	1.3	13.1	9.9	0.0	4.1	0.0	0.7	8.8	7.6
South	4.8	34.6	13.9	0.5	13.7	3.6	2.6	24.1	10.9
Andhra Pradesh	5.3	39.7	13.4	1.4	18.8	7.4	3.3	29.2	11.3
Karnataka	6.0	39.8	15.1	0.1	16.3	0.6	3.1	28.2	11.0
Kerala	5.5	35.5	15.5	0.0	8.5	0.0	2.6	21.4	12.3
Tamil Nadu	2.8	24.0	11.7	0.1	8.4	1.2	1.5	16.2	9.0
Puducherry	2.5	23.5	10.6	0.0	6.3	0.0	1.3	15.1	8.4

Sources: Data obtained or calculated from the GATS India, 2009-2010 dataset including from country reports[10] and Gupta et al., 2012[12].

FURTHER ANALYSIS OF GATS DATA

A special analysis of the GATS-India data[12] reveals additional characteristics of dual users, as discussed in this section.

Association Between Smoking and Smokeless Forms of Tobacco Use

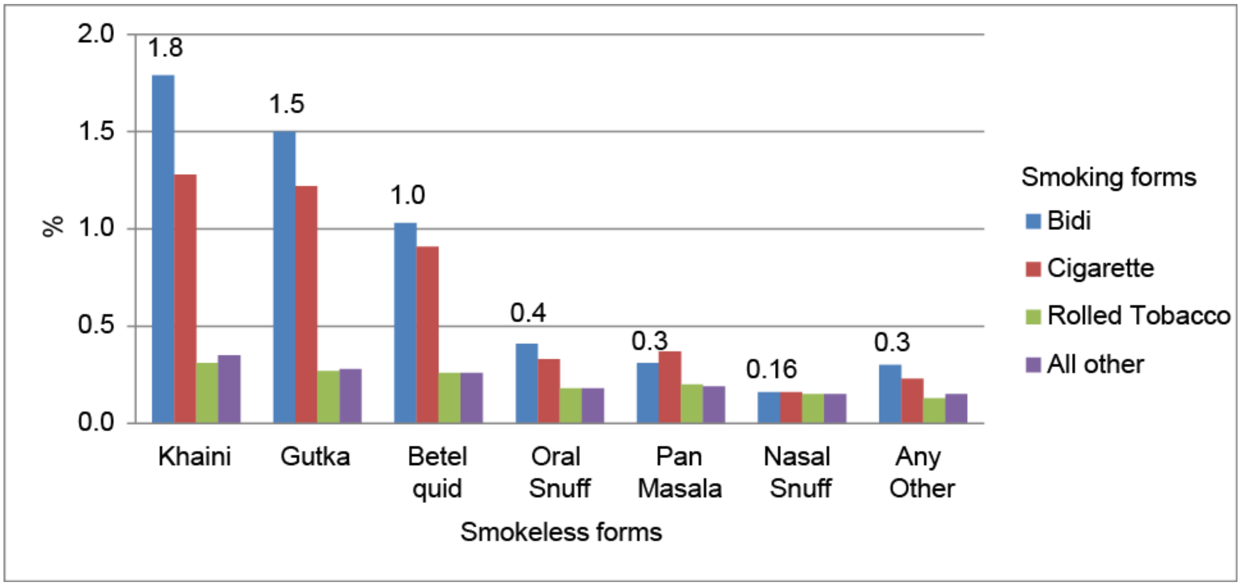
Odds ratios (OR) for current SLT users also being smokers compared to non-SLT users being smokers, as calculated by logistic regression, were significantly elevated, especially in urban areas, even after adjusting for state, gender, age, residence, education, and occupation[12]. At younger ages (15–44 years) there was a positive association between SLT use and smoking, but at older ages (45 years and above) the association was negative. The association was highest among 15- to 24-year-olds (OR=4.0, 95% CI 2.9–5.5). For individuals with secondary education and above, the association between SLT use and smoking was positive, but among those having no education it was negative. Among occupational groups, students who used SLT had the highest odds of concurrent smoking (OR=12.8, 95% CI 6.9-23.7), even though they had the lowest prevalence of dual tobacco use.

In 12 states and 1 union territory (UT; Chandigarh) out of 31 states and UTs, there was a significantly high odds ratio for SLT users being smokers compared to non-users. The association was significant in six of eight states in the North-East, where prevalence was high.

Product Combinations

The most prevalent product combination, used by about one-third of dual users, was bidi and khaini (1.79%) (Figure 5.2). The next most prevalent combinations were bidis and gutka (1.5%), cigarettes and khaini (1.28%), and cigarettes and gutka (1.22%). The popularity of a particular combination reflected the popularity of the products used singly: As the data from GATS India 2009-2010 showed, bidis and cigarettes were the most popular smoking products; khaini, gutka, and betel quid were the most popular smokeless products. Products containing areca nut predominated (gutka, betel quid, and pan masala) over other tobacco smokeless products (Figure 5.2). Many dual users reported using two or more products within the smoking or smokeless category—in other words, they reported use of more than one combination.

Figure 5.2: Product combination profile (%) of dual users in India



Source: Gupta et al., 2012[12].

Daily Dual Use

Over half (54.6%) of dual users used both types of products daily. Among all dual users, nearly four-fifths used SLT daily, while two-thirds smoked daily. Among those dual users who used only one type of product on a daily basis, SLT was the favoured type. Only 8.4% of dual users used both types of product on a non-daily basis.

Frequency of Daily Dual Use

Daily dual users smoked slightly fewer bidis per day than single users (dual users: 9.7; single users: 12.3). Dual users also smoked fewer cigarettes per day than single users (4.3 versus 5.4, respectively), and dual users chewed gutka slightly less frequently than single users did (3.7 versus 4.2, respectively). However, dual users chewed more khaini than single users did (dual users: 6.2; single users: 5.9), and dual users consumed more betel quid than single users (4.9 versus 4.2, respectively).

Among daily dual users, for most product combinations, there was a significant positive correlation between the daily frequency of SLT use and the daily frequency of smoking. This correlation was strongest for the combination of nasal snuff with rolled tobacco, cigars or cheroots and hookah. It was weakest for cigarettes and khaini, but still highly significant. Thus, somewhat paradoxically, those who smoked more also used SLT more often, although to get the same amount of nicotine that a single user normally ingests each day, a dual user who smokes more might be expected to use less SLT, and vice versa.

Initiation Pattern

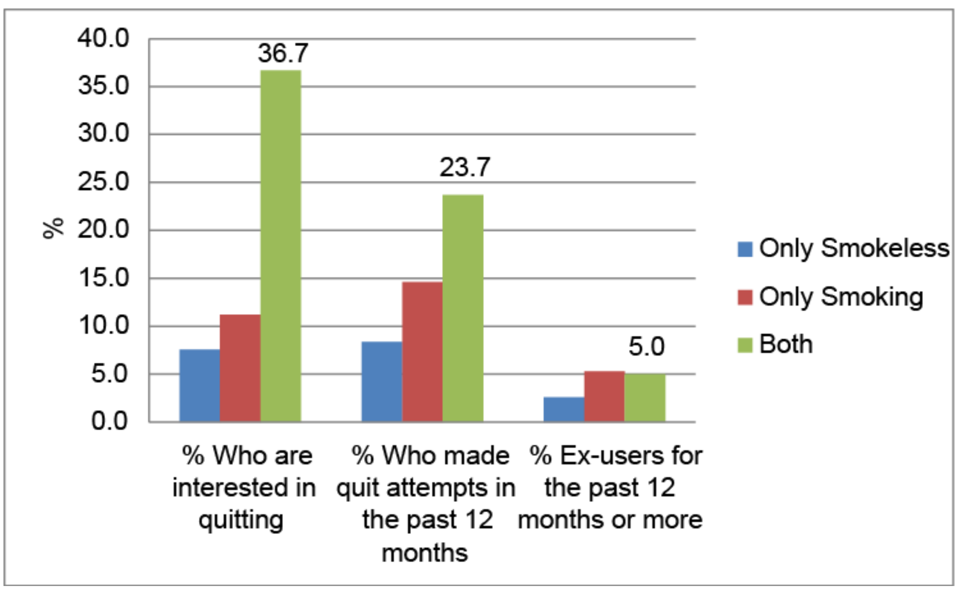
Among ever daily tobacco users, the mean age of initiation to daily use was 17.8 years[10]. The age of initiation to smoking did not differ from that for initiation to SLT.

An analysis of the difference in age of initiation to the two types of products revealed that, although starting use of a second product could occur any time after the start of the first (up to 59 years), more than half of dual users (52.6%) started using the second product within only 2 years of the starting use of the first one, and almost one-third (31.6%) started using both products in the same year. This seems to indicate that most daily dual users started using both products at a young age. Some 43.0% of dual users started smoking at least 1 year before starting SLT use, and 25.4% started using SLT at least 1 year before starting smoking. For those who started using both in the same year, it was not possible to find out which product was used first.

Cessation Profile

Over one-third of dual tobacco users (36.7%) were interested in quitting both forms of tobacco use some time in the future (which included in the next month, the next 2 months, and some day). The percentage of dual users who were interested in quitting both forms of use far exceeded the proportion of dual users interested in quitting only smoking (11.2%) or only SLT use (7.6%) (Figure 5.3). Nearly one-fourth of daily dual users had attempted to quit both forms of tobacco use in the 12 months before the survey, much more than the percentage who had tried quitting single use. However, of people who had ever been dual users, only 5.0% had actually managed to quit both forms of tobacco in the past year.

Figure 5.3: Cessation profile of dual users in India

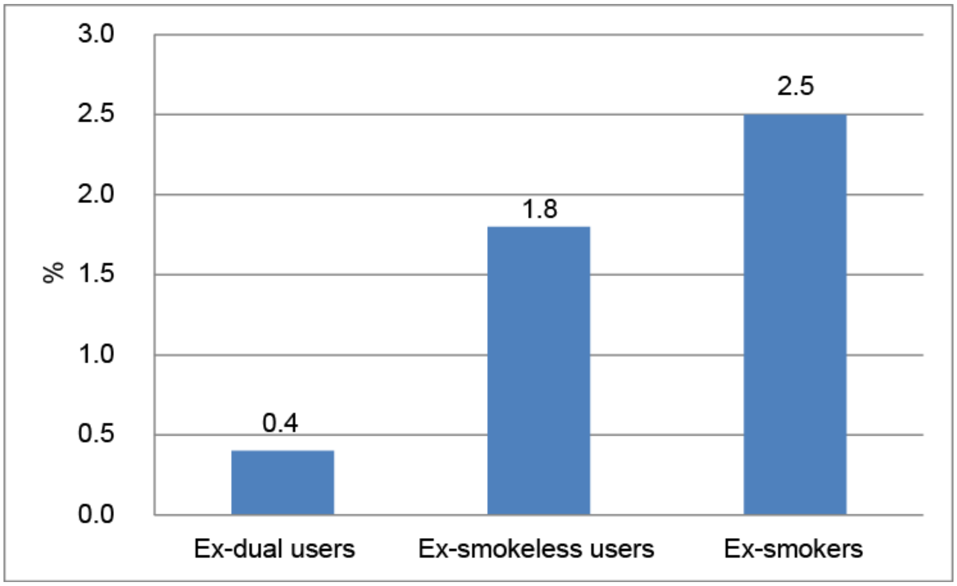


Source: Gupta et al., 2012[12].

In the entire GATS sample, the prevalence of former dual tobacco users (those who have abstained for the past 12 months or more) was four to six times smaller than the prevalence of former single users (Figure 5.4).

In long-term intervention studies, quit rates of dual users in India have been substantially lower than those of single users. For example, among men, after an intervention of 5 years in the rural district of Ernakulam, dual users were about one-third as successful in quitting (3.3%) as exclusive SLT users (10.2%) and half as successful as exclusive smokers (6.2%)[13]. Clearly, although many dual tobacco users have a strong desire to quit using both, quitting dual tobacco use is more difficult than quitting use of a single product.

Figure 5.4: Prevalence of former tobacco users (abstained for the past 12 months), by form of tobacco used



Source: Gupta et al., 2012[12].

HEALTH RISKS OF DUAL TOBACCO USE

A review of published information on the health risks of dual use indicates that as a group, dual users have higher health risks than single users. In India, increased risks of oral leukoplakia and certain cancers (oral, pharyngeal, and oesophageal) have been documented in cross-sectional studies (as higher prevalence) and case control studies (as odds ratios)[3,5, 14-17]. In addition, higher odds ratios for heart disease have been documented in dual users compared to single users in India and other countries[18,19].

Higher Prevalence of Oral Leukoplakia

The prevalence of oral leukoplakia among adult (≥15 years) dual users from five rural areas of India was 2.5%, according to a 1960s house-to-house surveys of 50,915 adults, which included 30,265 tobacco users. Prevalence of leukoplakia among 8,534 exclusive bidi smokers was 2.0%, and among 6,106 exclusive SLT users was 1.0% (Table 5.4)[3].

Excess Risk of Oral Cancer

In the same study of 50,915 adult residents from rural areas of five districts in four states, dual users had almost twice the prevalence of oral cancer (0.20%), compared to exclusive SLT users (0.10%), and about ten times higher prevalence of oral cancer than exclusive bidi smokers (0.02%) (Table 5.4)[3].

Table 5.4: Prevalence of oral leukoplakia and cancer among dual tobacco users and single tobacco users in large rural populations surveyed in India

Disease	Study years	Population surveyed	Prevalence in dual tobacco users (%)	Exclusive SLT users (%)	Prevalence in exclusive tobacco smokers (%)	Reference
Leukoplakia	1966–69	50,915 (men & women)§	2.5	1.0 (chewers)	2.0 (bidis)	Mehta et al., 1969[3]
Oral cancer	1966–69	50,915 (men & women)§	0.20	0.10 (chewers)	0.02 (bidis)	Mehta et al., 1969[3]
Oral cancer	1964–66	20,709 (men)	7.9	4.0 (Mainpuri tobacco)	0.6	Wahi et al., 1968*[5]
Oral cancer	1964–66	14,262 (women)	13.0	6.4 (Mainpuri tobacco)	0.25	Wahi et al., 1968*[5]
Oral cancer	1964–66	20,709 (men)	1.7	0.8 (other tobacco)	0.6	Wahi et al., 1968*[5]
Oral cancer	1964–66	14,262 (women)	3.4	0.8 (other tobacco)	0.25	Wahi et al., 1968*[5]

*Period prevalence. § Of which, 30,265 used tobacco in any form.

In a study in Uttar Pradesh conducted during 1964 to 1966 among 20,709 men and 14,262 women, the period prevalence of oral and oropharyngeal cancers among male dual tobacco users who both smoked and used Mainpuri tobacco (7.9%) was 12 times greater than that of exclusive smokers (0.6%) and nearly double that of exclusive users of SLT (4.0%). Men who were dual users who both smoked and used ‘other tobacco’ (mainly plain tobacco with lime) had a prevalence of oral cancer (1.7%), which was nearly three times higher than that of exclusive smokers (0.6%), and double the prevalence found among exclusive SLT users (0.8%). Women dual users had higher prevalence of oral and oropharyngeal cancer compared to single users; they also had twice the oral cancer prevalence compared to men dual tobacco users (Table 5.4)[5].

Four case control studies in India further illustrate the higher risks of oral, pharyngeal, and oesophageal cancer in dual tobacco users compared to single users and never-users, where odds ratios of disease for dual users are significantly elevated compared to never-users and even higher than for single tobacco users (Table 5.5).

Table 5.5: Dual tobacco users and single users compared to never tobacco users: case control studies with odds ratios (OR) of diseases and 95% confidence intervals (CI)

Disease	Study years	Study samples	Dual tobacco users	Exclusive SLT users	Exclusive tobacco smokers	Reference (Country)
			OR (95% CI)	OR (95% CI)	OR (95% CI)	
Buccal and labial cancer	1983–1984	Ever-users vs. never-users; men only 414 cases, 895 controls	21.5 (11.9–38.5)	14.3 (8.2-24.8) (pan with tobacco)	4.2 (2.1–8.5)	Sankaranarayanan et al., 1990[14] (India)
Gingival cancer	1983–1984	Ever-users vs. never-users; men only; stratified (excludes alcohol drinking) 187 cases, 895 controls	16.3 (6.5–40.9)	8.8 (3.6–21.5) (pan with tobacco)	3.8 (1.2–11.7)	Sankaranarayanan et al., 1989[15] (India)
Oral cancer	1993–1999	Ever-users vs. never-users; men only; stratified (excludes alcohol drinking) 588 cases, 1,313 controls	8.5 (6.1–11.9	9.3 (6.8–12.7) (pan with tobacco)	2.5 (1.9–3.1)	Znaor et al., 2003[16] (India)
Pharyngeal cancer	1993–1999	Ever-users vs. never-users; men only; stratified (excludes alcohol drinking) 232 cases, 1,313 controls	4.6 (2.7–7.6)	3.7 (2.2–6.3) (pan with tobacco)	3.5 (2.5–4.9)	Znaor et al., 2003[16] (India)
Oesophageal cancer	1993–1999	Ever-users vs. never-users; men only; stratified (excludes alcohol drinking) 238 cases, 1,313 controls	7.2(4.5–11.6)	5.7 (3.5–9.4) (pan with tobacco)	3.6 (2.5–5.1)	Znaor et al., 2003[16] (India)
Oesophageal cancer	1997–1998	Ever-users vs. never-users; men only; stratified (excludes alcohol drinking) 358 cases, 716 controls	8.4 (2.6–14.3)	3.4 (1.2–9.5) (pan with tobacco)	1.9 (0.3–5.6)	Phukan et al., 2001[17] (India)

Disease	Study years	Study samples	Dual tobacco users	Exclusive SLT users	Exclusive tobacco smokers	Reference (Country)
			OR (95% CI)	OR (95% CI)	OR (95% CI)	
Non-fatal myocardial infarction	1999–2003	Current users vs. never-users 12,461 cases, 14,637 controls	4.1 (3.0–5.6)	2.2 (1.4–3.5) (chewing any form of tobacco)	3.0 (2.7–3.1) (cigarettes) 2.9 (2.1–4.0) (bidis)	Teo et al., 2006[18] (52 countries, including India)
Incident coronary heart disease	2006–2007	Ever-users vs. never-users; adjusted for gender, age, hypertension 69 cases, 138 controls	17.4 (5.2–58.1)	2.8 (1.1–7.3)	2.8 (1.0–8.3)	Rahman and Zaman, 2008[19] (Bangladesh)

Notes: P values not available except for Phukan et al., 2001[17].
Particular smokeless and smoking products used are indicated where relevant.

In a study in Trivandrum of 414 cases of buccal (cheek) and labial (lip) cancer and 895 controls, dual users had an odds ratio of 21.5 for having these cancers compared to never tobacco users. This was 50% higher than the odds ratio for exclusive SLT users (OR=14.3) and five times higher than that for exclusive bidi smokers (OR=4.2)[14].

In another study in Trivandrum of 187 cases of cancer of the gingiva (gums) and 895 controls, dual tobacco users had an odds ratio of 16.3, which was 40% higher than that for exclusive pan-tobacco chewers (OR=8.8) and four times higher than that for exclusive bidi smokers (OR=3.8)[15].

In a case control study in Chennai and Trivandrum, there were 1,058 cases of oral, pharyngeal and oesophageal cancers among people who did not consume alcohol, as well as 1,313 non-drinking controls. Among dual tobacco users, the odds ratio was 8.5 for oral cancer (at all subsites) compared to non-tobacco users. This was a little lower than the odds ratio for exclusive chewers (OR=9.3) but nearly three times higher than that for exclusive smokers (OR= 2.5). Additionally, dual users had an odds ratio of 4.6 for pharyngeal cancer, which was more than 30% higher than that faced by exclusive smokers (OR=3.5) and more than 20% higher compared to that for exclusive pan-tobacco chewers (OR=3.7)[16].

In the same study, dual users had an odds ratio of 7.2 for oesophageal cancer compared to non-tobacco users. This was 26% higher than that for exclusive pan-tobacco chewers (OR=5.7) and twice that for exclusive smokers (OR=3.6)[16].

In a study in Assam of 358 cases of oesophageal cancer and 716 controls, after excluding alcohol drinkers, dual users had an odds ratio of 8.4 compared to never tobacco users, which was more than double the odds ratio of those who only chewed (OR=3.4) and four times the odds ratio of exclusive smokers (OR=1.9)[17].

Higher Risks of Heart Disease

Two case control studies have shown greater risk of heart attack and heart disease in dual tobacco users compared to single users (Table 5.5).

INTERHEART was a case control study of 12,461 cases of first acute myocardial infarction and 14,637 controls in 52 countries including India. This study found that dual tobacco users had an odds ratio of 4.1 with respect to never-users, which was almost 30% higher than the odds ratio for exclusive smokers (OR=2.9 for bidis) and almost double the odds ratio for exclusive SLT users (OR=2.2)[18].

In a case control study of incident coronary heart disease in Bangladesh with 69 cases and 138 controls, dual tobacco users had an odds ratio of 17.4 compared to never-users, which was more than six times greater than the odds ratio for exclusive smokers (OR=2.8) or SLT users (OR=2.8)[19].

A study of the association of body mass index (BMI) with tobacco use found that dual users as a group had the lowest BMI values. Men who used both forms of tobacco had an odds ratio of 1.83 (95% CI 1.67–2.00) and women had an odds ratio of 2.19 (95% CI 1.40–3.41) for low BMI, with respect to non-users of tobacco[20].

DISCUSSION

The higher risks to health posed by dual use, as just described, appear related to dual users' high level of tobacco usage: over half of dual users use both products daily, and daily users tend to use each of the two products almost the same number of times as single users. This frequency exposes daily dual users to nearly twice as much nicotine and harmful chemicals as users of only one form of tobacco. In addition, the range of harmful chemicals to which a dual user is exposed compared to a single user is broader because it includes both the unburnt leaf in direct contact with the oral and digestive mucosa as well as tobacco smoke in the mouth and respiratory tract. SLT contains at least 28 carcinogens[21], and tobacco smoke contains at least 69 potentially cancer-promoting constituents[22]. The high level of tobacco exposure among dual users would affect blood nicotine levels, blood pressure, and mucosal cell health more intensely than a single form of tobacco use. Dual use thus has clear implications for addiction and cessation as well as promotion of disease, especially heart disease and cancer.

Dual users' total nicotine absorption may be a combination of the differing absorption patterns of smoking and SLT use. Within 30 minutes of placing a single dose of SLT in the mouth, the blood nicotine level peaks, then slowly tapers off over the next few hours if not replenished by another dose. Smoking a single cigarette causes blood nicotine to spike to its maximum level within just a few minutes, after which it falls off rapidly within half an hour to about half that level and, if not replenished by another smoke, gradually tapers off thereafter. Tobacco users typically smoke or use SLT at intervals frequent enough to maintain a constant level of nicotine[23]. As suggested by the findings from GATS, a typical daily dual tobacco user in India uses SLT about as often as an exclusive user of SLT; a dual user also smokes about as many times as he/she uses SLT in a day. Thus, daily dual users[12] may be maintaining a consistently very high level of nicotine throughout the day, which is a hypothesis that deserves to be validated.

A study in Sweden found that symptoms of dependence and withdrawal were stronger in dual users than in single users[24]. Stronger dependence symptoms may also be experienced by dual users in India, as indicated by the data presented in this chapter as well as the following points.

All the major smokeless products used by dual users in India (khaini, betel quid, gutka and pan masala) contain lime (calcium hydroxide), and thus they provide ample free nicotine[25], which is easily absorbed by the body. Khaini (tobacco flakes used with lime) provides the highest amount of free nicotine and related nitrosamines per dose. Thus, the most favoured combination used by dual users, bidis and khaini, is not only the cheapest but also provides the most nicotine to the user. Smokers who use gutka or pan masala, betel quid with tobacco—products that contain areca nut—also experience great difficulties in quitting and high risks to health.

The doses of SLT used by dual users and single users have not been well documented and thus cannot be compared, but some packages of tobacco (such as khaini) suggest that 10g is a typical dose. Gutka, which contains mostly areca nut and only a small amount of tobacco, comes in 5g or 1g packets.

The daily 24-hour nicotine level profile of dual tobacco users has not yet been documented. A study of dual users' 24-hour nicotine levels, along with self-reported withdrawal symptoms experienced by dual users of different product combinations during 24-hour periods, would be useful in order to understand dual users' tolerance to nicotine and their withdrawal experience. Such an understanding is needed in order to design strategies to help them quit tobacco use.

CONCLUSIONS

This chapter has reviewed the prevalence and profile of dual tobacco users in India and the health risks they face. Although prevalence of dual use is higher in older age groups, young adults (15–24 years) who initiate any kind of tobacco use are at the highest risk of being dual users. The combination of bidis and khaini is the single most prevalently used. However, products containing areca nut (gutka, betel quid, and pan masala) predominate over all other smokeless tobacco products used by dual users. Bidis and cigarettes are the most prevalent smoking products among dual users.

Dual use is more prevalent among women ages 65 and older than among younger women. Overall, dual use is low because of the low prevalence of smoking among women in India.

This review has shown that dual tobacco users in India constitute an important and specific risk group because of their high prevalence, high levels of tobacco consumption among daily users, higher risks of cancers of the oral cavity, pharynx, and oesophagus as well as heart disease and heart attack. Preliminary evidence suggests that women dual users may have twice the risk of oral cancer compared to male dual users. This chapter also explores a plausible explanation for greater difficulties quitting and higher health risks based on the apparently larger amounts of tobacco consumed by dual users compared to single users.

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Chapter 6

Determinants of Smokeless Tobacco Use in India

Ankur Singh[1], Manu Raj Mathur[1],
Krishna M. Palipudi[2], Monika Arora[1]

[1]Public Health Foundation of India, New Delhi
[2]Centers for Disease Control and Prevention, Atlanta, GA, USA

INTRODUCTION

One of the key objectives of the World Health Organization's draft *Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020* is reducing modifiable risk factors and addressing the underlying social determinants by creating health-promoting environments[1]. With the increasing global burden of tobacco-related noncommunicable disease and the ongoing epidemiological transition in many low- and middle-income countries including India, action to reduce the related risk factors seems a more logical approach than inaction.

Health-related behaviours play important roles in the causation and prevention of chronic diseases. Tobacco use, among other risk factors, has been established as a detrimental behaviour causing morbidity and mortality[2–4]. Tobacco use is closely associated with the markers of social and economic disadvantage[5]. Studies from the West have extensively assessed the association between tobacco use and its social as well as psychosocial determinants. Many studies from India have also explored similar associations for tobacco use overall[6–13].

In comparison with Western countries, India faces a complex challenge in tobacco control because of the greater prevalence of smokeless tobacco (SLT) use in India compared to use of smoked tobacco products[14]. The public health burden caused by the high prevalence of SLT use is well explicated in the literature[15–18]. While some studies have discussed the determinants of SLT use, they have mainly been either regional or in Western settings[19]. Until now, very few Indian studies have explored determinants of SLT use among the Indian population.

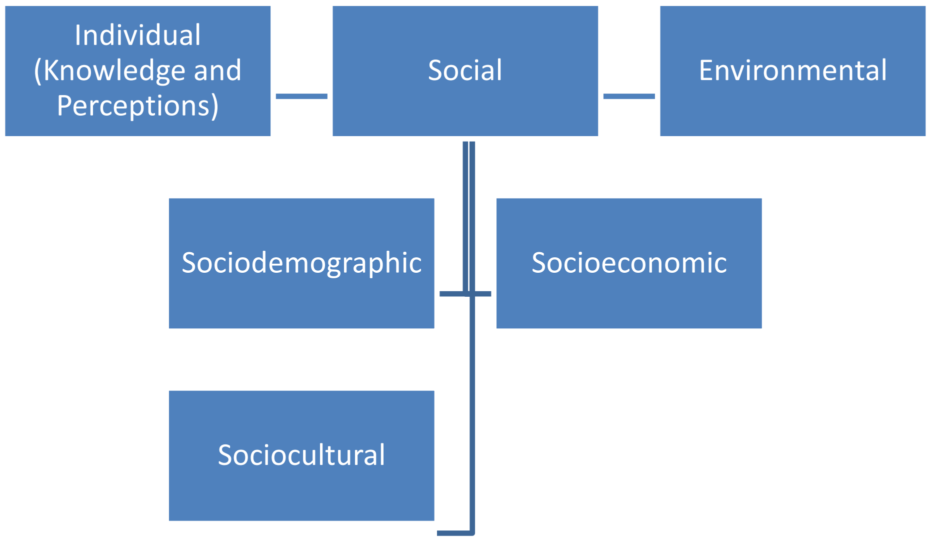
An understanding of the various factors that determine SLT use will help in developing appropriate programme and policy responses to these factors. Further, it is of utmost importance to identify and address the determinants of tobacco-related behaviours in order to reduce the prevalence of health-compromising behaviours. This chapter aims to identify and highlight the determinants of SLT use in India by collating the existing evidence. The association of knowledge and perceptions with SLT use, the social determinants and the role of media is discussed in details.

DETERMINANTS OF SLT USE

As mentioned in earlier chapters, SLT use has increased at a rapid rate among the Indian population. Some studies have attributed this increase to the availability of myriad varieties of smokeless tobacco, the varying consumption patterns, the integration of SLT use into cultural practices, and wide acceptance of SLT in Indian societies[37]. Because of the observed differences in SLT use in India and the West, studying multilevel determinants is important to understanding the multitude of factors that contribute to increased SLT use in the Indian context.

Global evidence has established associations between the following psychosocial factors and SLT use: knowledge among adults[20], and self-image, risk-taking, and peer influence as well as socio-economic determinants among adolescents[21]. Studies in India have looked at the possible association of SLT use with various determinants such as gender, ethnicity, socioeconomic status, and education, among others[10–12,19,22,23]. The collective evidence on determinants of SLT use will be discussed under the broad categories represented in the Figure 6.1.

Figure 6.1: Multiple factors determining SLT use



KNOWLEDGE AND PERCEPTION OF THE HARMS OF SLT USE

Knowledge in some form is a logical prerequisite for intentions to perform health-related behaviours[24]. Interventions designed to increase awareness related to tobacco avoidance and control have been associated with reductions in tobacco use among adults[25,26]. The Knowledge, Attitude, and Behaviour model (KAB) implies that an increase in knowledge will lead to change in the attitude of an individual, which will further lead to behaviour change. Scientific evidence on associations between knowledge/perceptions and SLT use derived from studies conducted worldwide and in India is summarised in Table 6.1, and described in more detail in the sections that follow.

Table 6.1: Scientific evidence on associations between knowledge/perceptions and SLT use

Study (reference No.)	Country	Study population	Objectives	Method/study design	Key results
GLOBAL STUDIES					
Lee et al., 1994[20]	USA	2,257 teenagers	To explore the psychosocial correlates of smokeless tobacco (SLT) use in a sample	Cross-sectional	80% of the overall respondents reported SLT harms the gums; 34.1% believed that SLT can cause hypertension.
Horn et al., 2000[30]	USA	9th grade participants (n-883), Virginia	To identify and compare the determinants of different types of tobacco use among rural youths	Cross-sectional	Unlike smokers only or SLT users only, lack of knowledge about tobacco was a significant determinant among conjoint users (OR=1.39).
Goebel et al., 2000[27]	USA	1,834 total 5th, 8th, and 11th grade students in West Virginia public schools	To identify knowledge and attitude variables that correlate with smokeless tobacco use among youth	Cross-sectional	Important differences exist in knowledge and attitudes regarding SLT between users and non-users.

Study (reference No.)	Country	Study population	Objectives	Method/study design	Key results
Khawaja et al., 2006[29]	Pakistan	(n=425) Karachi, Pakistan	To establish the pattern of use of pan, chaalia, gutka, niswar, tumbaku, and naas among the population of a Karachi squatter settlement, and to determine the perceptions and knowledge of these products' role in the etiology of head and neck cancers	Cross-sectional	79% of the participants were classified as having poor knowledge about the carcinogenicity of SLT products. Knowledge increased with age and level of education.
Monson & Beaulieu, 2011[28]	USA	University students (n=417)	To explore the use, demographics, knowledge, and impact of a statewide smoking ban on smokeless tobacco use among students	Cross-sectional	Participants reported mean knowledge score of 7.8 on 9 survey items. Non-users scored higher than users, and females scored higher than males ($p<0.001$).
Palipudi et al., 2012[23]	Multi-country study	13 low- and middle-income countries (LMICs) including India	To examine the role of social determinants on current tobacco use	Secondary analysis of GATS data	Smokeless tobacco use was higher among individuals with a lower level of knowledge [little knowledge (30%), some knowledge (34.3%), and good knowledge (26.5%)].
Kakde et al., 2012[8]	Multi-country study	South Asian population	To help inform interventions for prevention and cessation of SLT use by reviewing the social context around that use	(Systematic review)	The South Asian population lacked awareness regarding the ill effects of SLT use.
INDIAN STUDIES					
Gupta et al., 1986[25]	India	36,471 tobacco chewers and smokers from the rural population in three areas of India	To determine the effectiveness of mass media and personal advice in helping users quit SLT	Interventional study	The 5-year age-adjusted incidence rate of leukoplakia in Ermakulam district was 11.4 in the intervention group versus 47.8 among men in control group, and 5.8 versus 33.0 among women in control group. For palatal lesions in Srikakulam district, the corresponding figures were 59.8 versus 260.8 among men and 289.5 versus 489.5 among women.
Seth et al., 2004[33]	India	596 senior secondary school-children in Delhi	To estimate the magnitude of tobacco consumption among adolescent school- children in Delhi; the association of tobacco use with awareness; and risk-taking attitude and alcohol usage; and to understand the role of gender, age, and social-economic status	Cross-sectional	The prevalence of correct knowledge about tobacco was only 37.75% (Cl 33.84–41.78). Students with less knowledge, higher risk-taking attitude, and those who drank alcohol used tobacco and betel nut more than others.
Sinha et al., 2004[32]	India	School students ages 13–15 in Bihar	To determine prevalence and attitudes toward tobacco use	Cross-sectional, secondary analysis (GYTS)	72.0% (± 4.8) of non-users, 50.8 (± 13.4) of current smokers, and 62.7 (± 5.7) of current SLT users believed SLT is harmful.
Saddichha et al., 2010[13]	India	Dental surgeons in Bangalore	To assess the knowledge, attitudes, and practices of dental surgeons concerning their patients' use of tobacco	Cross-sectional	73% of clinicians believed that the majority of tobacco users in India were smokers; 17% assumed more people used chewable forms of tobacco.

Study (reference No.)	Country	Study population	Objectives	Method/study design	Key results
Raute et al., 2011[9]	India	SLT users in Maharashtra and Bihar	To examine beliefs about the harms of SLT use, knowledge of health effects, and intentions to quit among current SLT users	Cross-sectional, secondary analysis [International Tobacco Control (ITC) Policy Evaluation Project]	About 77% believed that SLT use causes mouth cancer; 66% believed SLT causes gum disease, and 56% believed it caused difficulty in opening the mouth. Significant differences were found in health knowledge between urban and rural SLT users in both states.
Murukutla et al., 2012[45]	India	2,898 participants, nationally representative	To evaluate a mass media campaign intervention to increase knowledge to SLT users	Intervention study (mass media campaign)	Those who notice campaigns were 2.4 times more likely to report than SLT causes mouth cancer ($p<0.001$).

Global Evidence on Knowledge of Harms Caused by SLT Use

A study of 2,257 teenage military dependents assessed the association between knowledge of the harmful effects of SLT and its use among people who have tried it, people who have not tried it, users, and non-users. The findings suggested that overall knowledge of adverse health outcomes of SLT use had a moderate effect. This study also suggested that knowledge of the harms of SLT had an impact on actual behaviour only among female users and males who tried SLT[20]. Another study of 1,834 U.S. schoolchildren revealed important differences in knowledge and attitudes regarding SLT between users and non-users in the 5th, 8th, and 11th grades, a finding that points towards differences in awareness levels with increasing age and education[27].

Monson and Beaulieu, in a study of the effect of knowledge of SLT on use among U.S. university students, reported a higher level of knowledge among students regarding the harm of SLT use, but it had no influence on the prevalence of its use. Based on the findings they concluded that knowledge is not the only predictor of SLT use[28].

Palipudi and colleagues, in a multicountry study which also included India, reported that prevalence of SLT use was higher in Bangladesh among individuals having lower knowledge levels. However, maximum prevalence was observed in individuals having some knowledge (34.3%) compared to little knowledge (30%) and good knowledge (26.5%)[23]. Similarly, a few more studies were conducted globally to assess the association of knowledge of SLT's harms with SLT use[29,30].

It is observed from the global evidence that innovative educational efforts through media or the health system to increase knowledge about the harms of SLT use are a key component of large-scale interventions for SLT control[31]. Overall, the global evidence indicates that higher knowledge levels are associated with low SLT use; however, knowledge is not the only determinant of SLT use.

Knowledge, Attitudes, and Behaviour: Evidence from India

Many Indian studies have assessed the association between knowledge, attitude, and behaviour or practice related to smokeless tobacco use (Table 6.1). Data from the Global Youth Tobacco Survey (GYTS 2002) in the Indian state of Bihar showed that awareness of SLT harms was greater among students using SLT than among non-users. Also, current users were more likely to think that boys and girls who smoke or chew have more friends [current users: boys, 34.7%

(±6.0) and girls, 26.2% (±6.1), compared to non-users: boys, 20.0% (±5.1) and girls, 12.2% (±3.9)][32]. A study conducted by Seth and colleagues reported a significant association between SLT use and lack of knowledge, risk-taking attitude, and alcohol use in children in secondary schools in Delhi[33].

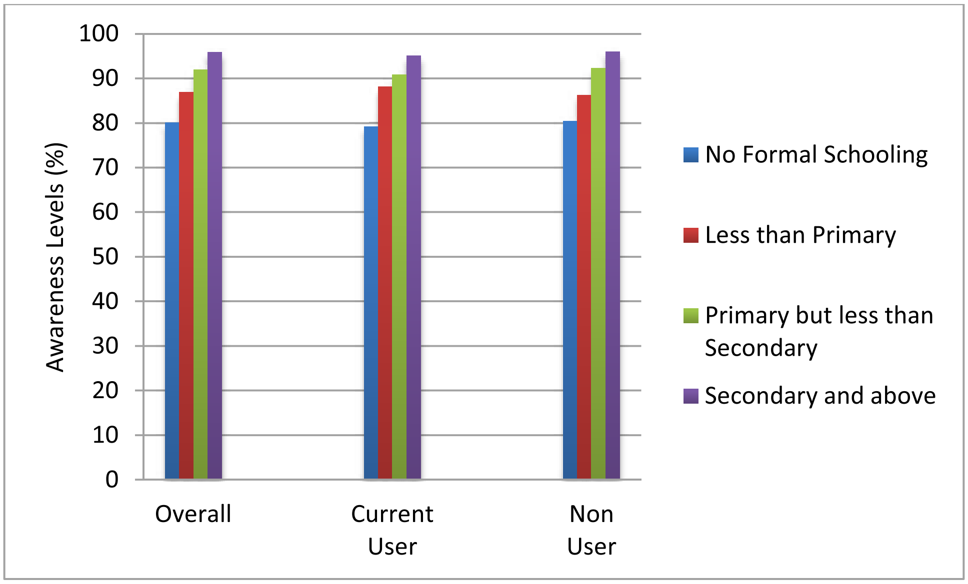
A study of adults in the Indian states of Bihar and Maharashtra reported significant rural and urban differences in opinions towards SLT use. The majority of urban SLT users were more likely than rural users to report SLT use as 'not good' for health (p=0.01). Significant urban and rural differences were reported in Maharashtra, with 42% of rural SLT users believing that SLT can cause oral cancer compared to 88% of urban SLT users (p<0.001). In both states, 94% of SLT users with intentions to quit believed that SLT use could cause oral cancer, but 75% of SLT users who had no intention to quit believed that SLT use could cause oral cancer (p<0.001)[9].

Low levels of knowledge among dental professionals regarding tobacco use were reported in another study from India[13]. A systematic review exploring social context of smokeless tobacco use among the South Asian population highlighted the lack of awareness of the ill effects of SLT use; Indians believed that while tobacco is a carcinogen, areca nut has no potential to harm. Also, it was found that users were uncertain about the harmful effects of SLT because they perceive that SLT users generally experience varying negative health effects[8].

The Global Adult Tobacco Survey (GATS) is the first ever nationally representative survey conducted to assess tobacco use and key tobacco control indicators in India. It comprehensively assessed knowledge about the ill effects of SLT use at a national level and provided state-specific information. GATS India 2009-2010 found that a majority (88.8%) of respondents believed that smokeless tobacco use could cause serious illness[14]. A 2011 survey conducted by World Lung Foundation found that only 39% of SLT users believed that SLT use causes low birthweight in babies[46]. Knowledge of SLT's harmful effects ranged from 79.1% in Meghalaya to 97.3% in Chandigarh. Knowledge levels were high among both current users (86.5%) and non-users (89.6%), indicating that knowledge is not the only predictor of SLT use in India and highlighting the need to focus on socioenvironmental and policy determinants as well[14].

In India, awareness of the harmful effects of smokeless tobacco use also varies according to socioeconomic characteristics. Further, with increasing age, the belief that SLT use causes serious illness decreases amongst all the participants, whether they are current users or non-users, males or females. Females (87.3%) had lower knowledge levels compared to males (90.1%). Similarly, participants from urban areas (93%) reported higher knowledge levels than those from rural areas (87%). An educational gradient was also observed: With increasing educational attainment, the level of knowledge of harmful effects of SLT use increased. This was observed amongst both current users and non-users of SLT (Figure 6.2). In terms of occupational groups, students (94.9%) had greater knowledge of the role of SLT use in causing serious illness, followed by government/non-government employee (90.1%), the self-employed (87.7%), homemakers (87.3%), and the retired/unemployed (83.9%)[14]. Hence, in India, levels of awareness of the harms caused by SLT use vary according to age, gender, area of residence, and occupation, suggesting a need for tailored interventions to address these inequalities.

Figure 6.2: Knowledge of the harms of SLT use, by education



Source: GATS India, 2009-2010[14].

Myths Associated with Smokeless Tobacco Use in India

Studies have reported on tobacco-containing products used as dentifrices[34, 35]. The misconception that tobacco is good for teeth is widespread in India[35]. GYTS data revealed that 6% to 68% of schoolchildren currently used products containing tobacco for oral care, considering these products good for oral health[34]. A study conducted in Ernakulum reported that 3,013 of 3,261 (or 92%) of female tobacco users and 2,159 of 7,575 (28%) male users reported that they initiated SLT use to treat tooth-related problems[34].

Studies have also reported that the belief that SLT use is less harmful than smoking is widespread within South East Asia, including India. This belief has caused a shift of women from smoking to SLT use during pregnancy[36].

Overall, the current evidence indicates social inequalities in awareness levels with respect to the harms of SLT use. The existing literature has consistently highlighted gender inequalities in knowledge levels, whereby women's lack of awareness of SLT's harms makes them more vulnerable to SLT use. Similarly, rural populations have been reported to have lower awareness levels than urban populations. These findings suggest that future interventions to increase awareness of SLT's should be tailored to address these social inequalities.

SOCIAL DETERMINANTS OF SLT USE

As discussed earlier, there is plentiful evidence suggesting that health-related behaviours are causes of morbidity and mortality. However, a global consensus with strong supporting evidence is that behaviours are not randomly distributed in the population, and that there are factors that determine their occurrence within the population, which are known as the 'Causes of the Causes' or the 'Social Determinants of Health'. These determinants have direct impact on health and predict the status variance. They also interact with each other and structure the health-related behaviours within a society. These determinants of SLT use are further discussed under the following headings: Sociodemographic Determinants, Socioeconomic Determinants, and Sociocultural Determinants.

Sociodemographic Determinants (Age, Gender, and Area of Residence)

Sociodemographic Determinants of Prevalence of SLT Use

Studies have described the variations in prevalence of SLT use according to sociodemographic determinants such as age, gender, and area of residence[11,19,37]. Rani and colleagues (2003) analysed the data from National Family Health Survey (NFHS-2) to identify predictors of tobacco use in India; they found higher odds of SLT use with increasing age among both genders. Male respondents 60 years of age and older were 3.71 times more likely to be SLT users than those within the age group of 15–24, after adjusting for potential confounders ($p<0.001$), while females ages 60 and older were 8.47 times more likely to use SLT than females ages 15–24 ($p<0.001$). A significant gradient according to age, after adjusting for all potential confounders, was also observed ($p<0.001$)[19].

Males from rural areas were 1.73 times more likely to be SLT users compared to those from the urban areas ($p<0.001$). A similar association was reported among females (OR=1.63, $p<0.001$); however, after adjusting for potential confounders, the results changed (OR=0.87, $p<0.05$)[19].

According to the 2009-2010 GATS India report, the prevalence of any SLT use was higher among males (32.9%) than among females (18.4%). In terms of area of residence, the prevalence of SLT use in rural areas was higher (29.3%) than in urban areas (17.7%)[14].

Sociodemographic Determinants of Initiation of SLT Use

Chewing tobacco products have been reported as 'starter tobacco products' for adolescents because they are cheap and easily accessible, which at a later age initiates dual use of tobacco products[37]. Thus, initiation of SLT is a gateway for prolonged use of tobacco[38]. Studies have explored the determinants of initiation of SLT use in youth. A study by Riley and colleagues (1991) reported that age of SLT initiation is significantly and negatively correlated with nicotine intake among adolescents—that is, the earlier the age of SLT initiation, the higher the level of use. In another study of adults, SLT use reported during preadolescence, before the age of 12 years, was associated with greater adult use[39]. Ravishankar and Nagarajappa (2009) reported parental use of tobacco as a strong predictor of initiation of SLT use by adolescents in the Indian state of Uttar Pradesh[40].

GATS India 2009-2010 assessed the determinants of initiation of SLT use among adults ages 15 years and above. This survey found that females had a lower mean age of initiation (17.1 years) than males (18.2 years), and respondents from rural areas had a lower mean age of initiation (17.8 years) than residents from urban areas (18.3 years). Overall, 41.9% of the ever-daily users of SLT reported initiation between the ages of 20 and 34 years; 24.6% initiated between 15 and 17 years; 17.9% initiated at 18 or 19 years of age; and 15.6% initiated SLT use even before the age of 15 years[14].

Sociodemographic Determinants of SLT Quitting Behaviour

Effect of sociodemographic factors, nicotine dependence levels, and self-efficacy have been identified as strong predictors of quitting tobacco use in the West[41]. Tonstad and colleagues in their study on Cambodian adults reported that SLT users were 10 times (OR=0.10) less likely to quit compared to smokers[42]. The GATS India 2009-2010 report found that overall, 42.7% of current users of SLT were not interested in quitting. Among these 42.7%, more females (48.2%) were not interested in quitting than males (39.8%), and it was also reported that interest in quitting SLT use decreased as age increased[14].

Socioeconomic Determinants

This section discusses socioeconomic determinants of SLT use that have been explored in the literature, such as income (wealth), educational attainment, employment, and occupation.

Socioeconomic Determinants of Prevalence of SLT Use

Income (Wealth)

There is strong evidence that income or wealth is associated with the health of an individual, and it has been observed that health-compromising behaviours tend to occur and cluster more among the poor rather than the wealthy. Rani and colleagues' 2001 study of the association between SLT use and income in India showed a clear social gradient according to household wealth for both genders, indicating that susceptibility to use SLT rises with decreasing household income; the gradient was significant even after adjusting for potential confounders ($p<0.001$)[19]. Similar gradients were reported in another study that analysed both NFHS-2 and NFHS-3 and reported pooled estimates for SLT use: The poorest individuals were twice as likely (OR=2.3, 95% CI 1.99–2.2) to use SLT as the richest ones[11].

When prevalence of SLT use was cross-tabulated with income quintiles using GATS India 2009-2010 data, the highest use of SLT was found among those in the lowest quintile of income. An inverse gradient was observed in the association of income and use of gutka (the most prevalent SLT product). Higher use was correlated with lower income among male users of all SLT products. Similarly, positive gradients were observed in males for all products except nasal snuff while the same was observed for all products except betel quid with tobacco and pan masala and betel quid without tobacco among females (Table 6.2).

Table 6.2: Prevalence of smokeless tobacco use according to wealth quintiles

	Betel quid with tobacco		Khaini or tobacco–lime mixture		Gutka or tobacco/lime/ areca nut mixture		Oral tobacco (snuff, mishri, gul, gudakhu)		Pan masala and betel quid without tobacco		Nasal snuff		Any others	
	% (95% CI)		% (95% CI)		% (95% CI)		% (95% CI)		% (95% CI)		% (95% CI)		% (95% CI)	
Wealth Quin-tiles	M	F	M	F	M	F	M	F	M	F	M	F	M	F
1st	9.7 (8.3, 11.3)	6.2 (5.2, 7.4)	31.8 (29.4, 34.3)	9.4 (8.2, 10.9)	15.2 (13.6, 17.0)	4.2 (3.4, 5.2)	4.8 (3.9, 5.8)	10.0 (8.6, 11.6)	2.0 (1.5, 2.6)	2.2 (1.7, 2.8)	0.3 (0.2, 0.6)	1.8 (1.3, 2.5)	2.6 (1.9, 3.4)	6.4 (5.3, 7.8)
2nd	9.0 (7.8, 10.3)	6.3 (5.5, 7.4)	18.9 (17.1, 20.8)	5.5 (4.6, 6.5)	14.9 (13.2, 16.6)	4.2 (3.4, 5.1)	4.4 (3.6, 5.5)	8.4 (7.2, 9.8)	2.3 (1.8, 3.0)	2.3 (1.8, 2.9)	0.4 (0.3, 0.7)	1.5 (1.1, 2.0)	1.8 (1.4, 2.5)	6.0 (4.7, 7.5)
3rd	7.8 (6.8, 8.9)	5.1 (4.4, 5.9)	14.1 (12.8, 15.6)	3.9 (3.3, 4.7)	14.2 (12.9, 15.7)	2.9 (2.3, 3.5)	3.5 (2.8, 4.4)	5.3 (4.4, 6.3)	2.3 (1.9, 2.9)	1.7 (1.3, 2.3)	0.8 (0.6, 1.3)	1.2 (0.8, 1.7)	1.6 (1.2, 2.2)	3.0 (2.3, 3.9)
4th	6.8 (5.8, 7.9)	3.5 (2.9, 4.2)	10.1 (8.8, 11.5)	2.0 (1.5, 2.6)	10.9 (9.6, 12.4)	2.1 (1.6, 2.8)	1.4 (1.0, 1.9)	3.4 (2.7, 4.2)	2.0 (1.5, 2.6)	1.2 (0.9, 1.6)	0.4 (0.3, 0.7)	0.8 (0.5, 1.2)	1.2 (0.8, 2.0)	1.3 (1.0, 1.8)

	Betel quid with tobacco		Khaini or tobacco–lime mixture		Gutka or tobacco/lime/ areca nut mixture		Oral tobacco (snuff, mishri, gul, gudakhu)		Pan masala and betel quid without tobacco		Nasal snuff		Any others	
	% (95% CI)		% (95% CI)		% (95% CI)		% (95% CI)		% (95% CI)		% (95% CI)		% (95% CI)	
Wealth Quin-tiles	M	F	M	F	M	F	M	F	M	F	M	F	M	F
5th	3.7 (2.9, 4.6)	2.6 (1.9, 3.5)	5.5 (4.4, 6.7)	0.8 (0.5, 1.3)	7.4 (6.0, 9.1)	0.9 (0.6, 1.3)	0.9 (0.6, 1.4)	2.6 (1.9, 3.5)	1.5 (1.1, 2.1)	1.0 (0.7, 1.5)	0.3 (0.1, 0.6)	0.2 (0.1, 0.4)	0.3 (0.2, 0.5)	0.3 (0.1, 0.7)

Source: GATS India, 2009-2010[14].

Educational Attainment

Educational attainment has been widely used as a proxy for socioeconomic status, and evidence suggests that education is a strong predictor of health and health-related behaviours. Studies that have assessed the socioeconomic correlates of SLT use have reported variation in prevalence of SLT use according to educational attainment. This section will discuss variations in prevalence of SLT use according to educational attainment and its association with initiation and cessation of SLT use.

Associations between education and prevalence of SLT use were similar to those found between SLT use and income. Rani and colleagues reported clear and significant educational gradients among males ($p<0.001$) but not as clearly among females. Greater susceptibility to SLT use was found among less-educated females (OR=2.82, $p<0.05$ for 1 to 6 years schooling; OR=6.25, $p<0.001$ for no education; compared to women with 11+ years of schooling)[19]. Another study reported clear and significant educational gradients, with non-educated individuals being three times more likely (OR=3.18, 95% CI 2.96–3.43) to be SLT users compared to postgraduates[11].

An assessment of social disparities in tobacco use in Mumbai reported that illiterate women were about 20 times more likely (OR=21.02, 95% CI 16.63–26.56) to be SLT users than were women college students. This study also found clear and significant educational gradients in the overall population[12].

According to GATS India 2009-2010 data, similar inverse educational gradients were observed for prevalence of current use of SLT products except gutka. Strangely, those with primary or less than primary education were more likely to use gutka (10.1%) than those with no formal schooling (7.1%). However, those with higher educational attainment reported lesser gutka use (6.5%). A similar relationship was found between education and daily use of SLT among occasional users of SLT: the lower the education, the higher the prevalence of daily SLT use[14].

Employment or Occupation

A 2005 study by Sorenson and colleagues reported higher susceptibility to SLT use among both unemployed males (OR=1.79, 95% CI 1.36–2.36) and unemployed females (OR=1.89, 95% CI 1.15–3.12) in Mumbai compared to professional workers in that city. Stronger associations between occupation and SLT use were observed among males than among females[12].

Socioeconomic Determinants of Initiation of SLT Use

Educational attainment was also observed as a key predictor of initiation of smokeless tobacco use. There were clear differences in mean age of initiation of SLT use according to level of educational attainment. The mean age for beginning SLT use for those who attended secondary school was 19.1 years, while the mean age of initiation for those with no formal schooling was 17.0, which is below the legal age to buy tobacco products in India. An educational gradient was also observed among those who reported beginning SLT use before the age of 15 years, a finding that highlights the importance of education in protecting individuals from initiation of SLT use. According to the GATS 2009-2010 report, mean age of initiation of SLT was lower for students (16.8 years), retired and unemployed people (17.3 years), and homemakers (17.6 years) when compared to government and non-government employees (17.9 years) and the self-employed (18.2 years).

Socioeconomic Determinants of SLT Quitting Behaviour

According to 2009-2010 GATS data, individuals with higher educational attainment were more interested in quitting SLT than those with less education[14]. Among all occupations, the highest rate of willingness to quit SLT use within the next month was found among students (31.4%), followed by the retired or unemployed (15.2%), self-employed people (14.3%), government and non-government employees (14.2%), and homemakers (13.3%)[14].

Sociocultural Determinants

The social and cultural patterns within the human community that affect health, including such factors as shared belief systems, family structures, and social contracts, are known as the sociocultural determinants of health. Evidence suggests that betel quid use has been embedded in the cultural system of India for a very long time (Figure 6.3). After tobacco was introduced in this region, it became an ingredient in betel quid, which became one of the most commonly used SLT products[43].

Figure 6.3: Smokeless tobacco (tambul) in a traditional utensil for serving guests in Assam

Source: Field visit during NTCP Evaluation (Ankur Singh)

Sociocultural factors are crucial determinants of SLT use in India. Smoking in front of family elders in India is still considered taboo, and SLT products, which have fewer odours and are less noticeable, represent an acceptable alternative. Tobacco use is considered acceptable or desirable male behaviour in Indian culture, which has led to SLT use initiation among women and youth who wish to attain the same social status as the dominant males. Research has shown an association between tobacco use initiation and power dynamics in India's sociocultural system[43].

Summary of Social Determinants

The evidence on social determinants of SLT use highlights consistent social gradients with educational level, suggesting the importance of educational attainment in preventing initiation and continuation of SLT use. The current evidence in India corresponds with global evidence on health behaviours that emphasise the importance of social determinants in structuring health behaviours and the need to address social determinants in order to reduce the prevalence of SLT-related morbidity and mortality. The integration of SLT use into the sociocultural milieu is unique to India and requires interventions that can address sociocultural norms and expectations.

MEDIA AS A DETERMINANT OF SLT USE IN INDIA

A review of 2,000 published research studies reported a causal relationship between tobacco promotion and increased tobacco use, but at the same time also reported that social marketing campaigns through mass media are effective methods of tobacco control[44]. Article 13 of the World Health Organization's Framework Convention on Tobacco Control (FCTC) identified media as a key factor in tobacco use and has translated the evidence on the role of media in tobacco use to a prescription for action by requiring ratifying countries to adopt a total ban on tobacco advertising, promotion, and sponsorship (TAPS), barring any constitutional limitations in those countries.

Evidence shows that mass media campaigns through television and radio were more effective in reaching more marginalised populations, such as rural residents and those of lower socioeconomic status, and facilitating behaviour change[45]. Among SLT users, a significant relationship between campaign awareness and *campaign-relevant* knowledge and attitudes toward SLT has been observed, which suggests that media can be useful in promoting SLT control messages among populations at high risk. Also, the choice of medium in promoting these messages is of key importance[45].

According to the GATS report, inequalities in reception of health-related information can be observed across the population. Overall, 54.7% of the respondents noticed any advertisement or promotion of SLT products. More current users of SLT (61.6%) than non-users (52.7%) noticed any advertisement or promotion. More people noticed SLT advertisements on television than on other media, and both females and rural residents showed greater likelihood of noticing advertisements on the most popular medium (television) and of identifying SLT advertisements anywhere. Table 6.3 shows the higher vulnerability of rural residents and females to smokeless tobacco use as measured by the rate at which they notice SLT advertising through television[14].

Table 6.3: Percentage of adults (age 15 years and older) who noticed smokeless tobacco advertising, by gender and residence

	In Stores	TV	Radio	Bill-boards	Posters	News-papers or maga-zines	Cine-mas	Internet	Public transport	Public walls	Some-where else	Any-where
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
National	9.4 (8.7, 10.0)	29.5 (28.3, 30.8)	5.4 (4.9, 5.8)	17.9 (17.1, 18.8)	2.4 (2.1, 2.7)	4.7 (4.3, .2)	3.2 (2.9, 3.6)	1.3 (1.1, 1.6)	7.4 (6.7, 8.0)	5.9 (5.4, 6.5)	0.4 (0.3, 0.5)	72.4 (70.9, 74.0)
Male	1.7 (1.1, 2.8)	36.5 (31.9, 41.4)	25.7 (20.5, 31.8)	10.3 (7.5, 13.9)	1.5 (0.9, 2.6)	2.2 (1.4, 3.5)	2.4 (1.1, 5.1)	0.4 (0.2, 1.0)	0.5 (0.2, 1.3)	1.5 (0.8, 2.8)	0.2 (0.1, 0.7)	55.4 (50.3, 60.3)
Female	1.2 (0.3, 3.9)	37.3 (25.7, 50.6)	24.1 (12.2, 42.0)	15.3 (6.0, 33.9)	3.2 (1.1, 8.8)	1.4 (0.2, 8.8)	3.3 (0.7, 14.1)	0.0	1.2 (0.2, 5.4)	0.7 (0.1, 4.8)	0.0	61.8 (47.6, 74.2)
Urban	1.6 (0.5, 5.3)	36.9 (26.5, 48.7)	29.8 (20.0, 41.7)	4.3 (2.2, 8.3)	0.9 (0.2, 3.5)	2.7 (1.0, 7.4)	1.1 (0.2, 7.2)	0.6 (0.1, 3.8)	0.8 (0.2, 3.3)	2.0 (0.8, 4.9)	1.3 (0.4, 4.5)	44.6 (33.6, 56.2)
Rural	2.6 (1.3, 5.0)	40.4 (33.1, 48.1)	23.0 (16.2, 31.5)	13.2 (9.0, 18.9)	1.2 (0.4, 2.9)	3.9 (2.1, 7.0)	4.6 (1.8, 11.6)	0.8 (0.3, 2.5)	0.5 (0.1, 1.8)	2.7 (1.0, 6.7)	0.2 (0.0, 1.1)	61.0 (53.3, 68.1)

Source: GATS India, 2009-2010[14].

GATS India 2009-2010 also evaluated messages against SLT use, and reported that males noticed anti-SLT messages in newspapers and magazines and on billboards almost twice as often as females. Anti-SLT messages on television were noticed by 31.3% of males (95% CI 29.8–32.7) and 27.7% of females (95% CI 26.3–29.2). The difference in proportions of men and women noticing anti-SLT information on television was less for television than for other media. In urban and rural areas, television was reported as the most popular medium for receiving anti-SLT information (Table 6.4). Anti-SLT information is not reaching to majority of women and rural residents, and counter strategies and mass media campaigns need to be tailored to provide health messaging for these population groups[14].

Table 6.4: Percentage of adults (age 15 years and older) who noticed anti-smokeless tobacco information in various media, by gender and residence

	Newspapers or magazines	TV	Radio	Billboards	Somewhere else	Anywhere
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
National	21.2 (20.4, 22.0)	29.5 (28.3, 30.8)	13.4 (12.6, 14.1)	17.9 (17.1, 18.8)	2.4 (2.1, 2.7)	44.0 (42.8, 45.3)
Male	28.7 (27.6, 30.0)	31.3 (29.8, 32.7)	15.7 (14.7, 16.7)	22.8 (21.6, 24.1)	2.5 (2.2, 3.0)	50.3 (48.8, 51.8)
Female	13.2 (12.3, 14.0)	27.7 (26.3, 29.2)	10.9 (10.0, 11.8)	12.6 (11.8, 13.6)	2.2 (1.9, 2.5)	37.3 (35.8, 38.9)
Urban	32.3 (30.7, 33.8)	43.2 (41.3, 45.0)	13.4 (12.4, 14.4)	26.7 (25.3, 28.2)	3.3 (2.8, 3.8)	56.8 (54.9, 58.6)
Rural	16.6 (15.8, 17.6)	23.9 (22.5, 25.4)	13.3 (12.4, 14.3)	14.2 (13.3, 15.3)	2.0 (1.7, 2.3)	38.7 (37.2, 40.3)

Source: GATS India, 2009-2010[14].

The collective evidence on media as a determinant of SLT use strongly suggests that there are social inequalities in reception of both SLT advertisements and anti-SLT messages. While fewer women and rural residents notice anti-SLT messages, both females and rural residents have noticed more SLT advertisements in the most popular communication media than males and urban residents[14]. This finding highlights the vulnerability of women and rural residents to initiating and continuing SLT use as a result of advertisements and promotions used by the industry.

GAPS IN RESEARCH

Most studies of knowledge, attitudes, behaviour, and practices have focused on overall tobacco use, but only a few studies specifically address SLT use. While evidence is available on knowledge levels regarding the harmful effects of smoking—which include diseases such as cancer, hypertension, diabetes—local and national surveys have not assessed knowledge levels specifically regarding the harms of SLT use. Most studies of professional groups have focused on awareness levels of health professionals regarding SLT use; it is suggested that future studies should also assess the awareness levels of other professionals such as teachers and lawyers.

Studies have mostly assessed the association of determinants and SLT use in various parts of the country. The available evidence was characterised by geographical variation and was not geographically representative of India until GATS was conducted in India. The association between various determinants and SLT use should be further studied by applying multivariate and multilevel analytical techniques to the GATS data. Further, although studies have assessed the role of determinants for initiation of overall tobacco use, few have focused specifically on the determinants of smokeless tobacco initiation, which is a gap that needs to be addressed[40]. Similarly, future studies should also assess the determinants of cessation of SLT use.

Little research has explored upstream social determinants and their association with SLT use in India. Studies in the West have explored the association of smoking with key social determinants like social capital, social support, social exclusion, trade, governance, and policy[5], but the association between these determinants and the most prevalent form of tobacco use in India, SLT use, has not been explored. The recent SLT ban in India is a whole-population approach for addressing the burden of SLT; studies should further assess how this SLT ban addresses the existing social inequalities in SLT use.

Research is also needed to explore the myths associated with SLT use in India, along with other sociocultural determinants, and their impact on prevalence of SLT use, a subject which represents another significant gap in the literature.

CONCLUSIONS

The current evidence on determinants of SLT use has consistently reported social inequalities in awareness levels and in regard to other social determinants. These inequalities reflect not only a concern for social injustice and the complexity of health determinants in the present world; they also highlight the importance of building evidence on social determinants of SLT use in order to form policies and tailor interventions to address the root causes of SLT use in India.

Results of the studies of determinants have also revealed the vulnerability of women, youth, and rural residents to initiation of SLT use[11,19]. There is an urgent need for innovative health promotion strategies using media and health communication strategies to raise awareness of the harms of SLT use among these vulnerable populations.

Lack of data on the epidemic necessitates continuous monitoring of SLT use and its determinants in order to generate evidence and information on trends over time, which in turn will expand our understand of the changing nature of the epidemic as well as its determinants.

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Chapter 7

Advertising and Marketing of Smokeless Products

Bhavna B. Mukhopadhyay[1], Chandra Ramakrishnan[1]

[1]Voluntary Health Association of India, New Delhi

INTRODUCTION

The term *marketing* has been defined as 'the process by which an organisation relates creatively, productively, and profitably to the marketplace'; it is 'the art of creating and satisfying customers at a profit' and 'getting the right goods and services to the right people at the right places at the right time at the right price with the right communications and promotion' (p. 31)[1]. Effective marketing, therefore, includes creating value for customers and building strong customer relationships. It involves several strategies that underlie sales techniques, and business communication and advertising is one of its primary components. Marketing theory emphasises that while designing a marketing strategy, it is essential to adopt the '4 Ps' formula—that is, product, price, place, and promotion—which originated in 1960[2]. The 4 Ps were later modified to become the '7 Ps', a product-oriented approach, with the addition of packaging, positioning, and people. More recently, two more customer-oriented approaches have been introduced: the 4 Cs: customer benefit, cost to customer, convenience, and communication[2]; and 'SAVE': solutions, access, value, and education[3].

The tobacco industry uses diverse marketing strategies to advertise and promote tobacco products tailored to specific market environments. These strategies include direct and indirect promotional tactics, targeting vulnerable populations such as women and children, introducing new tobacco products designed to avoid marketing restrictions and taxes, maintaining the social acceptability of tobacco use, and countering tobacco control efforts. Over the years, SLT marketing in India has evolved from simple to more sophisticated strategies. As tobacco control legislation has changed, SLT manufacturers have responded by changing their strategies, using various loopholes to circumvent these laws, and continuing to promote their harmful products to current and potential consumers who are mostly unaware of the harms. The SLT industry's marketing strategies are similar to those of other tobacco industries in that they ignore the evidence on the harmfulness of their products. This chapter aims to describe the marketing strategies of the smokeless tobacco industry in India and illustrate how they have changed as new tobacco control policies have been adopted over the years.

POLICY ENVIRONMENT AND SLT MARKETING TIMELINE

Over time, SLT marketing in India has been shaped by tobacco control policies such as the World Health Organization's Framework Convention on Tobacco Control adopted by the World Health Assembly in 2003; the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply, and Distribution) Act (COTPA), 2003; an amendment in 1986 to the Prevention of Food Adulteration Act (1955); and the Food and Safety Standards Act (2006), Amendment, 2011; among other policies. Chapter 15, 'Advocacy and Policy Measures', provides details of these policies and describes how they have affected SLT marketing.

Table 7.1 displays the timeline of the major events that have shaped SLT marketing in India in the last five decades, which are divided into three periods: through 1984, between 1985 and 2003, and from 2004 until the present (2013). These divisions reflect two specific events: the launch of single-portion pouches of pan masala (with and without tobacco) in 1985, and the entry into force of the major comprehensive tobacco control law in 2004.

Table 7.1: Timeline of smokeless tobacco control and marketing

Year	Milestones in Smokeless Tobacco Control and Marketing in India
Through 1984	
1966	The Indian government set up the Directorate of Areca Nut and Spices Development, under the Ministry of Agriculture, to promote the production and marketing of areca nut[4].
1973 (July)	Areca nut farmers form a multistate cooperative, the Central Arecanut and Cocoa Marketing and Processing Co-operative, Ltd. (CAMPCO) at Mangalore[5].
1973 (August)	Pan Parag pan masala in large tins is launched, and advertisements for it appear on television[6].
1985–2003	
1985	Launch of Pan Parag pan masala in single-portion pouches[6].
1985	International Agency for Research on Cancer (IARC) releases its report *Tobacco Habits Other Than Smoking; Betel-Quid and Areca-Nut Chewing; and Some Related Nitrosamines* (volume 37 in its series Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans), which finds sufficient evidence that chewing betel quid containing tobacco is carcinogenic to humans, and that oral use of tobacco mixed with lime (khaini) is carcinogenic to humans[7].
1986	Release of U.S. Surgeon General's Report, *The Health Consequences of Using Smokeless Tobacco,* which concludes that SLT can cause cancer, addiction, and dependence[8].
1986	New rule added to the Prevention of Food Adulteration Rules, 1986 (under PFA, 1955): 'Every package of chewing tobacco shall bear the following label, namely: "Chewing of tobacco is injurious to health"'[9] (in effect from 13 December 1986).
1990	New rule added to the Prevention of Food Adulteration Rules 1990 (under PFA, 1955): 'Every package of pan masala and advertisement relating thereto shall carry the following warning, namely: "Chewing of Pan Masala may be injurious to health"'[9] (in effect from 9 August 1990).
1992	In 1992, an amendment to the Drugs and Cosmetics Act, 1940, barred manufacturers from using tobacco as one of the ingredients in toothpaste and toothpowder[10].
1990s	During the 1990s, many new companies enter the pan masala/gutka business. Several of these companies become very large.
1999	The Trade Marks Act, 1999, allows a single brand to be registered for more than one product, allowing the SLT industry to advertise for nontobacco products with the same brand name as tobacco products[11].
1994, 2009	The Cable Television Networks Rules, 1994[12], was amended on 25 February 2008, prohibiting direct and indirect advertisement of tobacco products in cable and television networks, but this amendment was diluted in another notification on 27 February 2009.
2002	Gutka is banned in several states, until this ban was reversed by the Supreme Court.
2003	Framework Convention on Tobacco Control is ratified by India[13].
2003	The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act (COTPA), 2003, Advertising Rules (2004) prohibit direct and indirect advertising of all tobacco products including smokeless tobacco[14] (in effect from 1 May 2004).
2004–2013	
2004	Surrogate ad for Chaini Khaini is broadcast from a cricket match in Australia and is viewed in India[15]. The Supreme Court had ruled in 2004, during the hearing of a case, that pan masala, gutka, and supari are all food within the meaning of Section 2(v) of the PFA Act (1954), and later under the Food Safety and Standards Act[16]. Only 2 boards of 60 cm x 90 cm were permitted at point of sale[14].

Year	Milestones in Smokeless Tobacco Control and Marketing in India
2005	Amendment Rules to Section 5 of COTPA go into force, prohibiting all advertising except point of sale (with effect from 1 August 2005)[17]. Size of boards was amended to 60 cm x 45 cm[14].
2009	Ministry of Health and Family Welfare, World Lung Foundation, and Voice of Tobacco Victims launch anti-tobacco campaigns[18].
2010	The Supreme Court directs the Ministry to issue an order banning packaging of smokeless tobacco in plastic pouches[19].
2011	Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011[20], Rule 2.3.4: 'Product not to contain any substance which may be injurious to health: Tobacco and nicotine shall not be used as ingredients in any food products' (in effect from 5 August 2011).
2012–2013	States begin to announce bans on sale of gutka and pan masala, flavoured smokeless tobacco, under FSSA Regulations[20], 2011, Rule 2.3.4.

MARKETING STRATEGIES IN RESPONSE TO POLICY

Period I: Through 1984

Products

Because SLT use has been traditional in India for over four centuries, a vast range of SLT products such as gutka, khaini, zarda, mawa, and others, have been produced for the Indian market for a long time. There is little documentation on marketing strategies prior to 1985. Some of the large SLT manufacturers of today have shown on their websites that they were making chewing tobacco products from the mid-20th century (or 1940s, e.g., TRDP Group, Dharampal Satyapal (DS) Group, Dilbagh Group). Products were marketed for use by themselves and/or with betel quid. Regional preferences prevailed, and product marketing remained fairly localised.

For at least 20 centuries, pan or betel quid—a product made with areca nut, betel leaf, and lime—has been widely used as an after-meal supplement, mouth freshener, and digestive aid. Many users also added tobacco to this combination and became daily users (see chapter 1).

In 1966, the Indian government set up the Directorate of Arecanut and Spices Development, under the Ministry of Agriculture, to promote the production and marketing of areca nut[4]. In the early 1970s there was a glut in the areca nut market due to increased production outside the traditional growing areas, and prices fell drastically. In response, in July of 1973 the areca nut farmers, mostly located in Karnataka, formed a multistate cooperative, the Central Arecanut and Cocoa Marketing and Processing Co-operative (CAMPCO), with a major objective of stabilizing areca nut prices, on recommendation of Karnataka State[21]. Although the exact connection between these events and subsequent new SLT product developments is not known, it is likely that a high level of areca nut production was instrumental in the product innovations during this period.

In the early 1970s, pan vendors in some parts of India began making mixtures of crushed areca nut, slaked lime, catechu, flavourings, and tobacco wrapped in cellophane, which were known as mawa, kharra (see chapter 1). Consumers would either buy SLT products or preparations from the pan vendor, or buy the ingredients from shops to make their preferred preparations at home[22].

In August 1973, Kothari Products launched Pan Parag, a brand of pan masala that was packed in tins of 100g or more[23]. This was the first commercial pan masala to enter the Indian market. It was available in two types, one with tobacco and the other without. Premixed products packed in large tins were the first branded products in this category.

Place

The introduction of conveniently packaged pan masala changed where and how people could buy SLT and led to the rise of the new readymade pan masala industry, with new players entering the market, mainly by the early 1980s. Users no longer had to assemble SLT for their own use or make frequent trips to vendors to buy the highly perishable traditional product; they could now buy and store the readymade preparations.

Price

SLT belonged to a low-priced tobacco segment. The new areca nut–based tobacco products initially belonged to a higher priced segment (although they were priced lower than cigarettes) partly because they were sold in large tins.

Positioning

The new areca nut–based tobacco products were positioned as luxury products based on claims of high quality ingredients as well as high prices.

Promotion

Because a very low percentage of the population had access to radio and television, and only one nationalised radio station and television channel were available, advertising of SLT products was initially limited to outdoor media, print media, or other traditional media. A large proportion of the market was made up of pan vendors, from whom the public would in turn purchase. Promotion beyond the presence of pan vendors was not required to sell betel quid or other tobacco, smokeless or otherwise.

When the readymade pan masala was developed, the manufacturer began advertising pan masala through the mass media, including on television, this product sold well among the class of people in cities who had exposure to television at that time and could afford expensive luxuries. While marketing strategies had remained low key for a long time, with pan masala containing tobacco, there began an explosion of SLT promotion began. This also roughly coincided with the advent of national transmission of television in 1982.

Period II: 1985 Through 2003

Products

The year 1985 marked the launch of small, convenient, low-priced pouches or sachets of the Pan Parag brand of pan masala with tobacco, which were manufactured in modern, automated plants. This brand of pan masala was the main SLT product widely promoted in mass media[23], while other traditional SLT products continued to be widely used without much promotion.

Pan Parag soon became a household name, as its availability in portion-sized packages in 1985 brought the product within the financial reach of most potential consumers[23], and a major shift took place in the SLT market. The revolutionary success of Pan Parag products soon spurred imitators to make similar new products such as pan masala (usually without tobacco), gutka (with tobacco), zarda, and other tobacco products, which they began to market in single-portion sachets.

In this period, manufacturers used frequent launches of new products or even just new flavours as a marketing strategy. For example, the DS Group launched five chewing tobacco and related products between 1964 and 1990—Baba, Tansen pan masala, Tulsi zarda, Rajnigandha pan masala, and Tulsi mix. It also launched saffron-flavoured chewing tobacco. On its website this company claims to be the only chewing tobacco company in India to get ISO 9001:2000 certification, positioning its products as pure and of superior quality[24].

Price and Packaging

Widespread tax evasion and a supportive tax structure fueled the production of low-priced sachets. Unlike other tobacco products, zarda and gutka are subject to a compounded levy scheme, wherein the rates of duty are based on the speed of the packing machines installed in the factory premises[25]. This taxation scheme acted as an incentive to produce pouches at lower cost.

In 1986, a new rule added to the Prevention of Food Adulteration Rules (under Prevention of Food Adulteration Act, 1955) required that chewing tobacco packages bear statutory text warnings in English and at least one Indian language, stating, 'Chewing of tobacco is injurious to health'. In 1990, an amendment required a text warning on pan masala: 'Chewing of Pan Masala may be injurious to health'. In practice, such warnings were easy to miss, as they were printed in very small text on the back of the package, and not always in an Indian language.

Promotion

Firms selling pan masala and gutka increased their customer base and sales by advertising and promotion through print and electronic media, as well as outdoor media such as billboards and signs on public conveyances. Examples of these advertisements are shown in Figure 7.1[26].

Figure 7.1: Pre-COTPA SLT ads for gutka and zarda

One brand of Zarda

One brand of Gutka

One brand of Gutka

One brand of Gutka

Source: Miller, 2007[26].

During three decades from the mid-1970s, the pan masala and gutka industry registered phenomenal growth, 25%–30% per year, with gutka being responsible for the extraordinary rise in sales and consumption[27]. The most widely visible SLT marketing has been for this segment.

In 1991, broadcasting was opened to private and foreign television channels. In 2000, the Cable Television Networks Rules, 1994 were amended to prohibit advertisements of tobacco and alcohol on television. In response, the manufacturers of gutka began to advertise pan masala not containing tobacco. Twin products with and without tobacco were marketed under the same brand names and packaged similarly by various companies. The fact that the rules explicitly prohibit indirect ads as well did not seem to matter.

States Begin Banning Gutka

In 2002, there was alarming evidence that oral cancer was increasing in young men, women were showing a preference for SLT and a vulnerability to starting gutka use, children were increasingly becoming addicted, and magnesium carbonate was being added to pan masala and gutka in excess of amounts permitted in food. This evidence was presented to state governments, and as a result, several states began banning the manufacture, sale, and storage of gutka within their borders[27].

Period III: 2004 Through 2011

During this period, the smokeless tobacco industry experienced intense growth. Between 1999 and 2009, retail volume sales of SLT increased by 82%[28]. In 2009, the top six smokeless tobacco manufacturers in India accounted for 31.2% of sales[29]. The rest of the sales were controlled by regional and local players[29]. By 2011, there were 375–400 manufacturers of chewing tobacco products in India[30]. Much of this industry growth was fueled by the marketing strategies adopted.

A New Regulatory Environment

In 2003, a comprehensive tobacco control law was enacted in India, the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, or COTPA[14]. Under the first Rules to the Act, notified on 2004 February 25, tobacco advertising in mass media and outdoor media was prohibited except at warehouses and points of sale on boards no larger than 90 cm x 60 cm, where the warning, ‘Tobacco Causes Cancer’ or ‘Tobacco Kills’ was required.

In 2005, advertising rules under COTPA were amended, severely restricting point-of-sale (POS) advertising so that no brand names, pack shots, or logos were to be visible on POS advertising boards. This new restriction, however, was not observed, and this law was stayed in a Court around 2006 in response to a writ petition from the tobacco industry. Thus, the previous advertising practices prevailed until the stay was lifted in January 2013.

Price

The gutka industry in general is highly fragmented with regard to pricing. The market is led by the RMD, Baba, Shikhar, Tulsi, and Kamla Pasand brands, which are all marketed as pan masala. The national market has only a few big names, such as RMD and Pan Parag, which are strong in the Rs 7–10 per sachet segment. Dozens of regional players dominate the Rs 1–2 per sachet segment[31]. Gutka was priced only slightly higher than pan masala without tobacco.

Product and ‘Customer Benefit’

Misleading descriptions of gutka, like ‘*taazgi dene wala’* (something that gives freshness) and *‘kesaryukt’* (saffron blended), have been used to create illusionary impressions in the mind of the consumers about potential benefits or harmlessness of the products. Brands like Vimal claim that each grain of their gutka contains the aroma of saffron (‘*dane dane mein haike sarkadum’*) which is the most expensive spice in the world, traditionally used to enhance flavour and colour in food preparations. Rajnigandha pan masala (named after the tuberose flower, also the name of a film) is advertised as having ‘*bemisal* flavour, *lajawab swaad’* (unparalleled flavour, unequalled taste). This type of message distracts the consumer from focusing on the hazardous carcinogens in SLT and instead gives the illusion that it is a high-quality product that gives pleasure and which may be ‘good for the body’.

The effect of this type of advertising was illustrated in an intervention study among 986 rural schoolchildren (10–15 years) in Madhya Pradesh, where most children considered gutka a mouth freshener and a status symbol. None of the children were aware that gutka was harmful or contained tobacco, although the vast majority were aware that khaini and zarda were harmful tobacco products[32].

Promotion

Indirect Advertising

Indirect advertising is used by SLT manufacturers to circumvent increasingly restrictive tobacco control laws. It includes ads for other products (typically pan masala without tobacco) that have the same brand name and colours as the tobacco product package. A study of the effectiveness of indirect advertising, which was conducted by a Mumbai-based NGO, exposed the strong hold of tobacco advertising on the minds of Mumbai teenagers. A survey of 3,260 children ages 12 to 17 years from 15 municipal and private schools found that 77% of the children recalled a gutka/pan masala advertisement, 17% remembered a raw tobacco advertisement, and only 4% recalled a cigarette advertisement. Over 70% of the children actually recalled the slogan of an advertisement for Manikchand Pan Masala/Gutka[33].

The practice of brand stretching and trademark extension is supported by the Trade Marks Act of 1999, which allows a trademark to be registered under different categories. Many tobacco brands and trademarks registered under Class 34 of the Act are also registered under non-tobacco categories such as food and clothing. Most SLT companies produce a single brand but use different flavour variants and packet sizes to popularise the brand in a market flooded with scores of local players. The Trade Marks Act also allows the company to circumvent the law and advertise the same brand name when it is used for a non-tobacco product, pan masala. Many smokeless product brands like Kamla Pasand, Goa, Soni, and Chaini have the same brand name for tobacco as well as non-tobacco products. In addition, brand stretching is closely linked with packaging as package design and colour can be identical for both tobacco and non-tobacco products. Several brands, like Shikhar, Chaini, Soni, Raj Durbar, RMD, Tulsi, and Kamla Pasand, also have identical gutka and pan masala packet designs (Figure 7.2).

Figure 7.2: Two examples of brand stretching: Soni Gutka and Soni Pan Masala; Chaini Khaini and Chaini Chaini

Photographs courtesy of VHAI Photobank.

Corporate social responsibility campaigns, cultural events, and sponsorship activities also play a part in brand stretching—for example, the Kamla Pasand MAX Stardust Award 2013 and the Manikchand Filmfare Awards until 2007. The Stardust Awards in 2010 and 2013 were sponsored by Kamla Pasand, which is the brand name for both gutka and pan masala products. Health advocates and activists in India in 2010 were also shocked to see pan masala advertisement boards for Chaini Chaini, which were seen as surrogate ads for the Chaini Khaini brand of smokeless tobacco, immediately behind the pitch at a televised cricket match being played at Sydney, Australia. The offending ads were removed following protests from Action on Smoking on Health (ASH) and others to the Australian Department of Health and to Cricket Australia.

A study by Salaam Bombay Foundation in 2011 found that both children and adults made a mental association between advertised pan masala brands and gutka. A total of 1,500 children ages 12–18 and an equal number of adults ages 19–50 from various areas in Mumbai were shown flashcards of three advertised pan masala brands and asked to identify what they were. The respondents' association of the two products was demonstrated by the fact that an overwhelming majority of both groups, 82% of the children and 84% of the adults, said the products were gutka[34].

As direct advertising is increasingly banned, the industry has responded by attempting to reach its target audiences via indirect or surrogate advertising (ostensibly advertising pan masala*)* on billboards, buses, TV, radio, banners at community festivals, and regional electronic media. In a study conducted by the Indian Cancer Society[35], the annual cost of advertising for one of the most popular brands of plain pan masala, Pan Parag*,* far exceeded its annual sale value, indicating that the pan masala advertisements are surrogates for ads for the tobacco-containing product of the same brand. During major festivals like *Ganesh Chaturthi* in Mumbai, the city is flooded with surrogate advertisements at bus stops and on buses and pandals (large temporary structures erected for religious observances). The Salaam Bombay Foundation conducted a pilot study on the issue during *Ganesh Chaturthi* in 2010 and found that SLT brands use names similar to names of tobacco products when they advertise on pandals and at bus stops, which indicates that tobacco companies are promoting gutka through strategic surrogate advertisements[36].

The results of a 2010 study conducted by the Voluntary Health Association of India (VHAI)[37] and its state partners revealed that, for brands such as Shikhar, Kamla Pasand, RMD, and Goa, only gutka was available at outlets surveyed. The retailers themselves admitted during face-to-face interviews that only gutka is available under the brand name. The companies perhaps manufacture negligible quantities of mouth fresheners/pan masala in order to continue indirect marketing.

Violation of Advertising Rules at Points of Sale

The latest COTPA Rules on Section 5 limit point-of-sale advertising to just a listing of the products for sale by their generic names, along with health warnings, on two prescribed boards per shop. However, the industry manipulates the allowances or overtly flouts restrictions. Many tobacco company brands sponsor the boards at these small shops. In Delhi, a number of kiosks outside prominent cinema halls and shopping malls have brightly lit coloured boards advertising the SLT product bearing similar colours and designs as on the packaging of SLT products, with a small underplayed warning at the bottom saying 'Sale of tobacco products to minors is a punishable offence' or 'Tobacco is injurious to health'. Figure 7.3 shows a marketplace in Jaipur where a series of pan and bidi shops displayed company-sponsored boards that violate all POS regulations: The boards were bigger than the mandated 60 cm x 45 cm size, they displayed no warnings, and nearly 80% of the board space was taken up by the brand name and package design. There are other similar examples of SLT sponsorship of shop boards.

Figure 7.3: POS board in Jaipur, Rajasthan

Photograph courtesy VHAI Photobank.

In addition to signboards, the strips of product pouches themselves serve to advertise the products at point of sale. Figure 7.4 shows the array of colourful single-portion pouches hanging at a shop in Delhi to attract customers.

Figure 7.4: Display of SLT products outside a shop in South Delhi

Photograph courtesy of VHAI Photobank.

Further, all kinds of danglers, display racks/boxes, and stickers are often visible at points of purchase, which is not allowed under the law (COTPA, 2003, Advertising Rules, 2005). These displays attract children and youth who come to the shops to buy candies, snack items, and soft drinks.

Use of Outdoor Media

Advertising in outdoor media is another form of promotion used by the SLT industry. When ad bans are not comprehensive, as in India, the tobacco industry switches its marketing efforts to unrestricted outlets. For example, railway properties like overbridges are governed by the Railway Act, which allows outdoor media advertising on billboards and hoardings and does not mention any ad bans. Similarly, some properties under the Delhi Metro are governed by the Delhi Metro Rail Corporation Act of 2002. The SLT industry cleverly circumvents the law to advertise on the Delhi Metro and on hoardings on railway overbridges. Pan Bahar and Kuber are examples of brands that are advertised on these properties (Figure 7.5). Figure 7.6 shows an example of advertising in parking lots.

SLT ads are often seen on public transport like buses and autorickshaws. In 2009 in Mumbai, pan masala advertisements were seen on 700 buses—a clear case of surrogate advertising. However, continued advocacy and anti-tobacco campaigns by civil society organisations resulted in the removal of these ads[38].

Figure 7.5: Hoarding at a railway property overbridge, near Pragati Maidan, New Delhi

Photograph courtesy of VHAI Photobank.

Figure 7.6: Billboard at a shopping mall parking lot in Rajouri Garden, New Delhi

Photograph courtesy of VHAI Photobank.

Marketing in Rural Areas

In rural areas, industry distributes incentives and spin-off accessory items like pocket calendars, playing cards, mobile phone covers, matchboxes, and even kites with packet images and logos of their products. Gutka can be found for sale on trains, along with toys and eatables.

Illustrating another form of marketing, Godfrey Philips markets their product, Pan Vilas pan masala, through road shows in local towns and villages. These shows consist of mobile vehicles fitted with loudspeakers that stop periodically and offer free samples and promotional talk about the product to groups of people.

The YouTube links below show footage from a road show in Balasore, Orissa, and sale of gutka on trains:

1. http://www.youtube.com/watch?v=ck7ZVji0g7k – link on Pan Vilas Roadshow in Balasore
2. http://www.youtube.com/watch?v=hYGB0jmEoEU&feature=related – featuring sale of gutka on trains.

People: Marketing to Children and Youth

Much SLT marketing is directed at youth. '*Muh main Rajnigandha, kadmo main duniya'* (Rajnigandha in the mouth, the world at your feet) is a tagline used by DS Group to market their pan masala to 'quality conscious young consumers in India and overseas', creating a false impression that eating Rajnigandha would give them confidence, status, and all they aspire to. Similarly, Pan Parag uses the tagline 'Choice of young India' on their sachets and tins (Figure 7.7).

Figure 7.7: Targeting youth with pan masala ads: an ad hoarding on the main road in Laxmi Nagar, New Delhi; and the tagline on a sachet, 'Choice of Young India'

Photographs courtesy of VHAI Photobank.

SLT companies also continually target children. SLT products are displayed for sale beside candies, cold drinks, chips, and other products targeted particularly at kids, exposing them to pro-tobacco statements and imagery. In India, free distribution of gutka during marriage celebrations and social functions encourages a perception that it is a 'family product'.

Marketing on social networking sites is intended to lure youth. Today, social media websites like Facebook, YouTube, and Orkut offer unlimited potential for tobacco marketing. Research on these sites shows that several SLT brands, such as Pan Vilas, Chaini Khaini, and Goa Gutka, have Facebook accounts that are open for members and allow participation and discussion platforms for promotion. Since these sites have negligible regulation, they can freely show direct advertisements that are banned on TV, radio, and in print media, thus circumventing the law completely. For two examples of this social marketing, see:

1. http://www.youtube.com/watch?v=SUMXKrztcU4&feature=relmfu – Rajshree pan masala ad targeted at youth
2. http://www.youtube.com/watch?v=2gK6XVlfdK0 – Goa Gutka ad featuring Sanjay Dutt and Ravi Kishen.

Public Awareness of Promotions

According to GATS India 2009–2010, nearly two-thirds of all adults in India noticed the promotion of any tobacco product (69% males and 59% females). Some 55% of adults overall (59% of males and 49% of females) had noticed any advertisement or promotion of SLT products within 30 days prior to the GATS India 2009-2010 survey. More adults noticed promotions of SLT products than other tobacco products—47% noticed bidi advertisements, and 28% noticed cigarette ads—and more SLT users than non-users noticed ads for SLT products (62% compared to 53%, respectively)[39].

Public awareness of promotions varied in terms of the location of these promotions or the means by which they were delivered. Data from GATS India 2009-2010 reveal that advertisements delivered by electronic media, such as television or the Internet, were noticed by the highest percentage of survey respondents (22.2%), but this proportion was only slightly higher than the percentage of people who noticed SLT advertisements outdoors (on billboards, hoardings, posters, public transportation, stations, or public walls) (21.6%). Some 7% had noticed SLT advertisements in the print media, while 10% had noticed ads at point of sale. More people (8.8%) noticed promotions of SLT products via free samples, discounts, and gifts than noticed similar promotions of smoked products (cigarette promotions: 7.4%; bidi promotions: 6.8%). More youth and young adults than older adults noticed any SLT advertisements or promotions, according to GATS India 2009-2010 (youth/young adults: 59%; adults over 25: 53%)[39].

To summarise, Indian adults were most likely to notice promotions or advertisements for SLT products that were delivered via electronic media, outdoor advertising, and at point of sale. Men were more likely than women to notice SLT promotions, and young people ages 15–24 were more likely to notice SLT promotions than older adults. These groups differed only slightly in the rates at which they noticing SLT promotions delivered via electronic media[39].

Packaging

Manufacturers consider it vital for SLT products to retain their flavour and fragrance as these add taste to the key ingredients. Packaging, therefore, becomes an important factor. Sachets are preferred for freshness, because tinned products lose flavour and aroma after some time as they are reopened again and again. Some manufacturers, such as Ganesh Zarda claim[40] that they use an exclusive packaging technique known as the 'snus packaging' which helps preserve colour, flavour, and fragrance.

SLT is also sold in the form of single-use packets so that the consumer returns again and again to buy more. Single-use packets are also easy to dispose of after use, and one does not have to carry or store them. These packets are brightly coloured and attractive, and many have either pictures of gods, goddesses, or women. Because of the ad ban, companies try to advertise on the packaging itself, using words like 'fresh', '*sabki pasand'* (everybody likes it), and other expressions. Further, most SLT product packets do not list ingredients or details of nutritional value, which violates packaging laws for food products and restricts the consumer's right to information.

Since COTPA permits in-pack and on-pack advertising with restrictions, tobacco companies have focused on creating premium-looking packaging to communicate the brands' message to consumers. The major SLT companies have developed different pack and tin designs as a means of brand building.

The mandatory pictorial health warnings, which were first implemented in May 2009, are barely legible in the midst of the packages' bright, shiny design and colour.

On December 2010, the Supreme Court directed the Ministry of Environment to restrain manufacturers from using plastic material in the sachets of gutka, tobacco, and pan masala under the Environmental Protection Act, 1986, as the used plastic sachets caused a problem of non-biodegradable litter. This direction came into force on 1 March 2011[41]. After that date, VHAI conducted a study in eight states—Assam, Andhra Pradesh, Bihar, Madhya Pradesh, Orissa, Rajasthan, Tamil Nadu, and Uttar Pradesh—to collect evidence on implementation of the new rules on plastic under the Plastic Waste and Management Act of 2011. State-wise results revealed widespread violations of the new rules. Manufacturers were using multilayered packaging, with one layer of plastic in combination with other materials such as paper, aluminium foil, or metallic board. This new packing material reduced the shelf life of the product, according to news items and reports from a random survey of SLT sellers in Delhi also conducted by VHAI[42]. By and large, manufacturers did not adhere to the new law but continued to use plastic[43].

Positioning

The industry targets traditional sentiments to give credibility to its brands. Industry does not hesitate to position its products within the sociocultural milieu and often plays with religious and cultural sentiments to sell and promote its product. During festivals, special packs with attractive designs are produced, and products and brand names are aggressively marketed through print ads. A case in point is the issue of *Dainik Bhaskar* dated 26 October 2011 in which quarter-page ads for Jafri brand pan masala wished readers a Happy Diwali and prominently displayed pictures of the package. In *Rajasthan Patrika* dated 25 October 2011, an ad for the brand Dilbagh wished readers *Shubh Deepawali (*Happy Diwali). In a *Dainik Bhaskar* issue dated the same day, an ad for Vimal pan masala wished its readers '*Damdaar Shubh Kamnayen*' (Heartiest Best Wishes).

Industry uses celebrity endorsements in an attempt to give SLT products a more upscale image. Traditionally, SLT has been considered a poor man's tobacco, a product for the masses not the classes, which preferred cigarettes. In the 1980s the tobacco companies began a marketing blitzkrieg using celebrity endorsements. Senior character actors like Jalal Agha, Ashok Kumar, and Shammi Kapoor memorably endorsed Pan Parag pan masala on TV with the slogan '*baraatiyon ka swagat, Pan Parag se kijiye'* (welcome the groom's procession with Pan Parag). Thereafter, popular personalities endorsed gutka and pan masala brands. Currently (2014) film stars Manoj Bajpai, Sanjay Dutt, Malaika Arora, and Fardeen Khan endorse Pan Vilas, Goa, Chaini Chaini, and Baba brands. Their advertisements are often accompanied by catchy slogans like '*shauq badi cheez hai'* (passion matters) and *'chain se maza lo'* (relax and enjoy), creating an impression that using these products is stylish, glamorous, and associated with an up-market lifestyle. Examples of these advertisements can be found at the following locations:

1. http://www.youtube.com/watch?v=9ru-SJuLuZ0 – link of Chaini Chaini ad, featuring Malaika Arora Khan
2. http://www.youtube.com/watch?v=E4_fUsqw_LA&feature=related – pan parag ad featuring Shammi Kapoor.

In 2010, Indian cigarette manufacturer Godfrey Phillips, a joint venture of the multinational Philip Morris, entered the pan masala segment by launching Pan Vilas. The company describes this product as targeted at the discerning premium pan masala consumer and claims that it was India's first pan masala to fully comply with Prevention of Food Adulteration (PFA) Rules.

Place

Easy accessibility and wide availability is another key strategy in marketing that the consumer enjoys with regard to SLT. These products are available everywhere: at street corners, grocery shops, pan shops, petty shops, juice corners, canteens, community markets, shopping centres, small kiosks outside government offices, and snack kiosks that are often found near schools, colleges, and bus stops. It is easy to buy tobacco anywhere. Even mobile kiosks selling ice cream and cold drinks sell tobacco discreetly. Unlike alcohol, which can only be sold at selected outlets or government-owned shops, no license is required to sell tobacco.

According to GATS India 2009-2010, 55% of users of SLT purchased it from a store, 32% from kiosks, and 10% from a street vendor. Stores are the most popular place to purchase SLT products for adults in 20 states/UTs, with the highest rate of store purchase in Mizoram (98%). Kiosks are the most preferred source in eight states, led by Delhi. Arunachal Pradesh (85%) has the highest proportion of users buying SLT from street vendors[39].

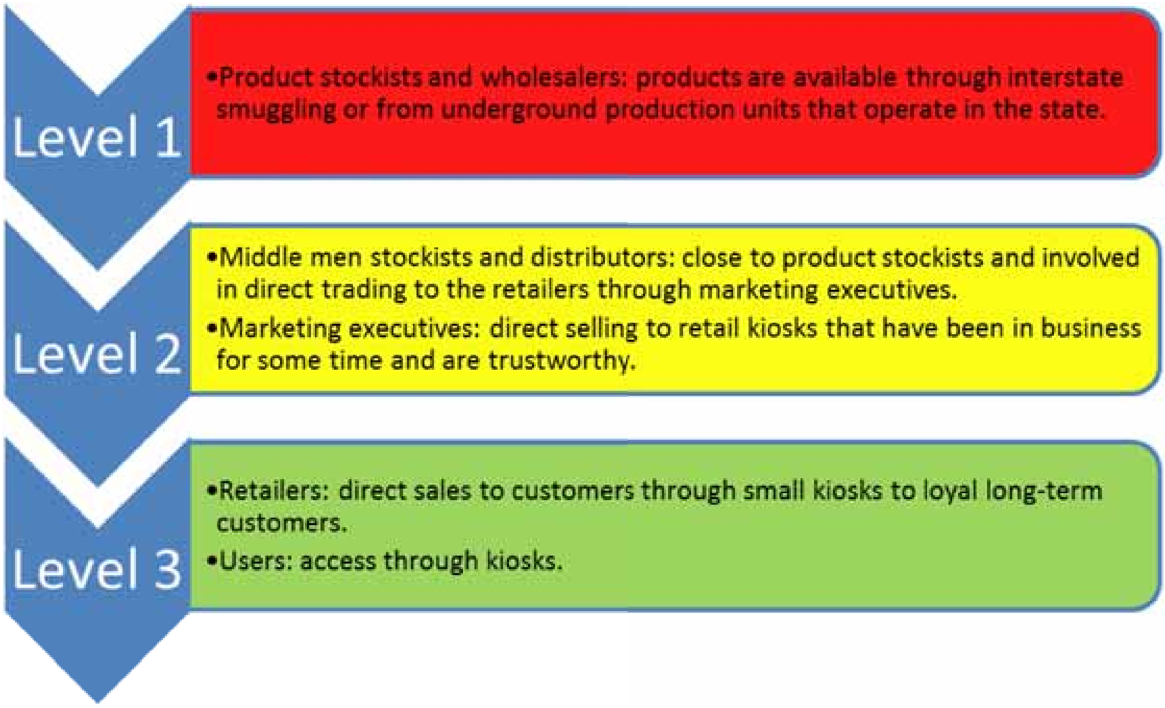
Period IV: 2012 Through 2014

This section describes the marketing strategies observed after gutka was banned under the Food Safety and Standards Act (2006) and Regulations thereunder, which came into force in August 2011.

Product and Packaging

After the gutka ban in Madhya Pradesh[44] and Maharashtra, registered units in the states were raided and forced to shut down, and many manufacturers shifted their production base to nearby states where the ban was not yet enforced. Other manufacturers shifted to increasingly small-scale operations to escape the law. A rapid impact assessment (RIA) conducted by VHAI revealed that the supply mechanism of the products was significantly affected during the first few months of the ban, and there was a shortage of supply to retailers[45]. After the ban, methods of distribution and marketing changed (Figure 7.8). Retailers received stock from marketing executives who made weekly discreet visits to their shops on their two-wheelers/cycles and delivered the wrapped products when few other people were around. The retailers surveyed said that the products were coming from states like UP and Gujarat to which the factories had relocated after the ban. The RIA observed that gutka stocks are usually kept close to the kiosk desk so the shopkeeper can easily hide them in case the authorities inspect or raid the shop. Shopkeepers were also keen to ensure that they sold their products only to regular customers. Some kiosk owners complained that the government is taxing retailers for whom SLT sales are the major source of income, rather than targeting wholesalers[45].

Figure 7.8: Post-ban SLT distribution and marketing channels in Madhya Pradesh: a rapid impact assessment



Users have been switching from gutka to traditional pan (betel quid), saying that the traditional betel leaf–wrapped product has no ‘chemicals’ or ‘hazardous material’ and is, most importantly, ‘legal’. A switchover to pan masala also exists, but is minimal. Some brands have now started labeling the product as ‘not a tobacco product under COTPA’.

Instead of the earlier ‘ready to consume mixes’, some companies have introduced products packed in separate sachets, where chewing tobacco and pan masala are sold loose or in separate sachets, and advertisements reflect this. For example, on 93.5 Red FM (as of 2 June 2013), an advertisement for Shudh pan masala mentions *‘Shudh pan masala, ab chhotu kesaath’* (‘Pure pan masala, now with a small companion packet’). *‘Chhottu’* refers to a smaller pouch of loose tobacco sold separately with the pan masala (Figure 7.9).

Figure 7.9: Shudh and Rounaq pan masala twin packs

Photograph courtesy of VHAI Photobank.

According to *Outlook Business India*, 'Local vendors point out that the DS Group sells Rajnigandha pan masala paired with sachets of Tulsi tobacco—pop both into the mouth and, *voila,* there's "legal" gutka'. Of course, DS Group is not the only company offering this completely legal way of circumventing the ban—many other former gutka brands are now available as two separate pouches of pan masala and chewing tobacco'[31]. This gimmick would fall under the customer access and value marketing approaches.

Many gutka manufacturers are following the same strategy, and some charge a higher price for the paired sachets than for the previous form of the product. The new packaging does not affect the company's business much, except to increase packaging costs. Manufacturers also have to shell out more money to support the distributors and pay retailer commissions and bribes. It is logical to believe that a portion of this is being transferred to users, as prices have shot up 200% to 300% since the FSSA ban went into effect.

In Andhra Pradesh, door-to-door delivery and telemarketing are the techniques adopted by manufacturers following the ban. They relocated the stock from warehouses to the outskirts of urban areas and developed these alternative marketing channels which enable personalised service[46].

The ban on gutka sales has revived the demand for the traditional 'pan'. Customers used to gutka are buying pouches at Rs 3 per sachet or switching over to 'pan' at the same price[47].

Gateway Products to SLT

Since the gutka ban, packets of areca nut mixtures without tobacco have become commonly available because gutka cannot be openly sold. Areca nut, or supari, can be a 'gateway' to future tobacco use, especially when conveniently and attractively packaged in low-priced single portions. There is a perception among health professionals that the prevalence of, and dependence on areca nut product use in India is increasing rapidly, especially among youth, and that this often leads to tobacco use, especially the use of gutka[48]. Areca nut in the form of sweet supari and pan masala is now easily available in rural and urban areas, usually at the same places where tobacco is sold, and there are no age limits to purchase and use this substance.

A recent study using a retrospective collection of data to evaluate the prevalence of areca nut chewing among children showed that 27% of schoolchildren had the habit of areca nut chewing, and 81% of them used sweetened areca nut products marketed in various flavours[49].

Salaam Bombay Foundation conducted an analysis of the packaging of areca nut brands used commonly by children in Mumbai. The parameters included brand name, visual imagery, and product information. Areca nut packaging was also compared to packaging of gutka and pan masala, which are banned in many Indian states. Two out of three types of areca nut packaging had bright, eye-catching, and attractive background colours (yellow, red, and blue). One of these two brands was known as Mogali, a popular Indian cartoon character. Another brand was named Ritik, after a popular Indian movie actor, Hrithik Roshan. One sachet of the Ritik brand of areca nut showed a picture of young boy in clothes similar to what the actor wore in his first movie, which catapulted him to fame. Packaging for the Milan brand of supari was not colourful and openly stated its areca nut contents to be a 'proprietary food product'. All these areca nut sachets were marketed as having pleasant flavours (Mogali: kesar- [saffron-]scented; Ritik: mint supari and kesar-scented supari; and Milan: classic sugandhi supari, which means classic scented, flavoured areca nut)[50].

Price

The increased black market price of gutka products and reduced consumption by young casual users who previously constituted the main group of consumers are given as the major reasons for the 50% decline in daily turnover of gutka estimated by retailers after the ban, as found in the rapid impact assessment of retailers by VHAI. On average, before the ban, a retailer used to sell pouches of gutka worth an average of Rs 2,000–2,500 a day, but after the ban, retailers' net daily sales were reduced to Rs 1,000–1,500 a day[45].

Promotion

A study of the website of the MR Group, manufacturer of Soni, Pan King, Mast, Mughal Gutka, and Mughal Pan Masala, shows that their marketing strategies have included adopting a customer-centric approach, assessing the 'needs' of the market, maintaining a loyal client base, and word-of-mouth publicity[51]. Being in the tobacco business, they face legal and regulatory pressures that prohibit them from using traditional modes of advertising, so word-of-mouth publicity has become a crucial means of communicating about their product[52]. The MR Group's focus on the customer is well illustrated by the company's constant efforts to expand its market base by 'catering to new and unexplored demographic profiles, as regulations in India do not allow them to cater to children below 18 years'. Their website claims that 'in spite of handicaps, the company has managed to achieve their sales target due to their loyal customer base cultivated over many years'[52].

Manufacturers claim on their websites that their feedback systems are very effective. They consist of a Management Information System (MIS) and online connectivity with the all the carrying and forwarding agents, wholesale distributors, and stockists through video conferencing, emails, and faxes. Thus, the manufacturers are able to receive minutely detailed information about their product performance, consumer feedback, new product launches, pricing, and different market strategies of their competitors.

The rapid impact assessment of VHAI studied the impact of the gutka ban established by FSSA Rule 2.3.4 in two states of India, Madhya Pradesh and Maharashtra, in 2012[45]. Overall, the ban succeeded in curtailing both the supply and visual display of gutka. It considerably reduced access for casual users, children, and women. Black market trading from other states was supplying a limited amount of gutka packages[53].

Customer-Centric Approach

Some manufacturers, like DS Group, maker of Rajnigandha, published newspaper advertisements claiming that their SLT products do not contain tobacco or nicotine (Figure 7.10).

Figure 7.10: An advertisement for pan masala claims that the product does not contain tobacco or nicotine

Photograph courtesy of VHAI Photobank.

Recognizing the gaps in implementation of the FSSA Rules, in April 2013 the Supreme Court directed 23 states and 5 Union Territories to report on their compliance with the ban on gutka and pan masala containing tobacco, stating that 'manufacturers were misleading people and creating confusion, and selling gutka and pan masala in separate sachets'[54].

SAVE: Solutions, Access, Value, and Education

A study of 347 shops in Mumbai revealed that gutka continued to be sold in side streets to regular customers, with prices having more than doubled, from Rs 2 per sachet to Rs 5. The newer product replacements identified by the Mumbai study were scented supari mixes with flavours and scents similar to gutka, sold either alone or along with a smaller, separate pouch of tobacco at Rs 2–3 per pair. However, manufacturers have had to undertake considerable retailer education, as shopkeepers were reluctant to store the new twin versions and mixes, fearing penalties. Industry agents convinced the shop owners that only gutka is banned, but the new products are not, hence they are safe to keep and sell. These agents also reassured the vendors that the new products did not contain magnesium carbonate, a regulated food additive. In addition to these new supari mixtures and paired tobacco pouches, these shops sold other products, such as potato chips, shampoos, and soaps[55].

Following the ban, the Smokeless Tobacco Association (STA) released a series of advertisements in several newspaper editions across India questioning the SLT ban. The advertisements, released jointly by the Central Arecanut and Cocoa Marketing and Processing

Co-operation Ltd., the STA, and the All India Kattha Factories Association, presented incorrect information in order to create confusion among the public and enforcement agencies in the states that had not yet implemented the ban. This deceptive strategy was a ploy by the gutka industry to scuttle the FSSAI notification and its new rules (Figure 7.11).

Figure 7.11: Advertisements published by the Smokeless Tobacco Association, October 2012

Photographs courtesy of VHAI Photobank.

After releasing these advertisements, the industry initiated a number of promotional steps to retain its customer base. The companies using a value approach continued to promote the products widely with attractive offers to retailers and small-scale distributors. In the national capital, soon after the ban, several bus stops at prominent places took advertisement contracts and now carry big hoardings and colourful displays of SLT brands and companies. To boost sales of the new substitute for gutka, companies are offering incentives to salespersons, including cars, bikes, and other items[56]. Currently, several news channels such as NDTV, Aaj Tak, and India TV feature '*Rajshree Pan Masala news break'* between news programmes (NDTV, Aaj Tak, India television new programmes, 20–30 June 2013).

The VHAI assessment shows that the retailer respondents are aware of the implementation and know the exact date when the notification came into force. The sale of gutka and pan masala has not stopped completely in the shops, because they can get supplies of the products delivered right to their shops. Selling gutka gives them a good margin, and the demand from regular users is not yet reduced. During the interviews, the retailers supported the ban, but they also asserted that sales would continue as long as the supply exists[45].

CHALLENGES AND SUCCESSES

SLT is a multifaceted challenge and a key example of how the profit interests of a few dominate over the indirect costs borne by the nation in the form of diseases and health care costs. Policy actions by government over the years have continually been diluted or defeated by the SLT industry's purported contribution to the economy, employment, government income, and revenue. In India, the climate for tobacco advertising, marketing, and promotional activities in the last few decades has changed dramatically several times. In the process, tobacco advertising campaigns in India have become much more youth-focused, and surrogate promotions have increased in recent years.

Weak regulation of all forms of media offers considerable potential for continued indirect tobacco advertising despite the ban. The fact that newer forms of media and technology as well as social networking sites are used more by youth presents a serious challenge and underlines the need for a purposeful monitoring and implementation mechanism for social media.

Cross-border advertising presents a major challenge in South and South-East Asian countries[57]. While COTPA restricts tobacco advertising, promotion, and sponsorship (TAPS), Indian citizens continue to be exposed to tobacco advertising from across international borders in various forms. Satellite television channels in countries like Nepal, Bhutan, Bangladesh, and Sri Lanka continue to advertise SLT brands indirectly. There is a two-way flow of tobacco promotion in Bangla and Nepalese channels across India's borders. The only way to restrict cross-border advertising is to sensitise the Ministry of Information and Broadcasting in both the country of origin and the countries receiving the broadcast, and specifically prohibit cross-border tobacco advertising and promotion strategies by law, develop a mechanism for monitoring and reporting at regional and international levels, and enlist the support of WHO–SEARO, ASEAN, and other organisations.

The Internet presents a totally unregulated platform to promote tobacco products. Indirect or even direct tobacco advertising can take the form of promotional emails, websites, blogs, and social networking groups. Because the Internet is most used by youth, strong regulatory mechanisms must prevent tobacco companies from reaching their potential customers.

Industry appears to circumvent the recent ban on any food product containing tobacco, and uses the ban to its advantage by continuing to sell pan masala and loose tobacco in separate pouches at higher prices. This is the biggest challenge to efforts to control smokeless tobacco in India today, and the government as well as law enforcers are at a loss as to how to address it.

India has implemented pack warnings on all tobacco products, including SLT, but there is still a long way to go in terms of implementation and impact. Public health advocates in India can argue for bigger, more graphic picture warnings, while also putting the case forward for plain packaging[58]. In view of the recent FSSA Rules implementation, the Government should amend Sections 5 and 7 accordingly.

CONCLUSIONS

The smokeless tobacco industry has astutely used marketing strategies to promote its products, adapting them to different tobacco control environments over the years and taking advantage of weak law enforcement.

The marketing of new areca nut and tobacco mixtures in the mass media from the 1970s helped popularise these new products. The innovation of offering these products packaged in single-portion sachets gave a strong impetus to sales and to diffusion of the products to the masses.

The government's promotion of areca nut provided a stimulus to the SLT industry. Adding areca nut has been a means of creating new products (e. g., pan masala, gutka) that appeal to high-end and busy customers looking for novelty, taste, convenience, and status symbols. The association of the products with social status appears to have motivated people at all social levels to acquire and use the products. Low-end products (e.g., mawa, kharra), made and promoted by pan vendors, and locally manufactured products (Mainpuri tobacco and local brands of gutka) have also been popular, probably due to their novelty, slightly lower cost compared to betel quid, taste, addictive power, and mental associations both with tradition (areca nut) and high-end products.

Because areca nut is classified as food, it has enabled the SLT industry to evade tobacco control laws and engage in brand stretching and surrogate advertising. The SLT industry has cleverly found ways to evade the laws regulating marketing, either by ignoring them (the Cable Networks Television Amendment, 2000, did not permit any form of indirect marketing until 2008), or by filing Public Interest Litigations (PILs) in court resulting in stay orders (on COTPA Amendment Rules, 2005, on point-of-sale advertising). The tobacco industry has also found a way to have the law amended in its favour and make it possible to perform surrogate advertising in a legal manner (Cable Networks Television Act, Amendment in 2008).

In the current environment under the FSSAI, the SLT industry is promoting single areca nut products and offering tobacco on the side; it also utilises cross-border advertising and the Internet. The SLT industry can be expected to come up with new ways of circumventing the law and doing business as usual or better than before.

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Chapter 8

Women and Smokeless Tobacco: Special Considerations

Sreevidya Subramoney[1], Mira B. Aghi[2]

[1]Sahlgrenska Akademin, Goteborg, Sweden
[2]Consultant, Delhi

INTRODUCTION

In India smoking is not prevalent among women because of social disapproval, but smokeless tobacco (SLT) use has been widely accepted and is fairly common among women. About 18.4% of adult women age 15 and above, amounting to about 70 million adult women in India, use SLT. In the country as a whole, the prevalence of SLT use is higher among men than women, but in most of the states in three regions (Eastern, North-Eastern, and Southern), SLT use prevalence in women is about equal to or higher than in men (also see chapter 4). Women are more likely to use SLT products for oral application in some regions (Central, Eastern, and Western) than others, and prevalence of oral application is higher among women than men. In India, 24.1 million women use tobacco as a dentifrice or to alleviate oral problems[1].

Women's SLT use differs in some ways from men's SLT use. On average, women initiate SLT use earlier than men. Some women begin tobacco use during pregnancy for medicinal purposes[2]. Using SLT influences reproductive outcomes because it affects the health of both the mother and the fetus. High tobacco use in pregnant women[3,4] and lack of counseling against SLT use during antenatal care are of great concern[5].

Highest prevalence of SLT use has been reported among women in North-Eastern India[1] along with correspondingly high age-adjusted incidence rates of tobacco-related cancers[6,7]. Based on results from two large cohort studies, the risk of mortality due to SLT use, especially between the ages of 35 and 69, including the reproductive-age group, appears to be higher in women than in men[8,9]. About 25% of deaths among women SLT users in the 35–69 age group are attributable to SLT use[8].

Despite the dangers, SLT products are often cheaper than most food products[2] and easily available in shops selling food, which women frequently visit, creating a conducive environment for women to initiate and sustain the SLT use. Unpackaged raw tobacco is cheap and easily available and carries no health or cessation warnings; women use it in betel quids and when preparing dentifrices or other types of SLT at home[10].

At least 9–10 million women in India are engaged in underpaid or unpaid tobacco-related occupations[2,11], ensuring low production costs for tobacco companies[12] but suffering serious health consequences[12,13]. SLT receives relatively little focus in the current tobacco control scenario in India[14], which denotes lack of specific focus on women's issues[12]. Because SLT use and SLT production pose major issues for Indian women, it is important to carefully document the impact of this use and production, and design policies and strategies to combat them.

This chapter elaborates on SLT's health effects on women, including underweight and anaemia, oral diseases, cancers, reproductive outcomes, and mortality, and examines other issues related to SLT use by Indian women.

HEALTH EFFECTS

Underweight and Anaemia

SLT use has been associated with lower body weight in Indian women. Low body mass index (BMI) (i.e., body weight/square of height in meters) is an independent determinant of all-cause mortality, and low BMI interacts with SLT use to increase all-cause mortality, deaths due to tuberculosis, and cancer in women[15-17]. In a representative cross-sectional survey of 40,071 men and 59,527 women in Mumbai, after adjustment for age and education, the excess risk of underweight [BMI <18.5kg/m²] in women, expressed as odds ratio [OR=1.50 (1.43–1.59)] was higher than in men [OR=1.28 (1.19–1.38)] when comparing SLT users to non-users. ORs for underweight increased with daily frequency of SLT use, after adjusting for age and educational status. At every dose, women had a higher risk of being underweight than men. Use of two or more SLT types was associated with significantly higher risk of underweight than use of mishri or betel quid alone[18] (Table 8.1).

Table 8.1: Mean body weight, BMI; prevalence of underweight and OR for underweight (adjusted for age, education, mother tongue, and religion); by SLT use status, in the Mumbai Cohort Study

Variables	n	Weight kg ± SE	Mean BMI ± SE	Prevalence% of BMI <18.5	Adjusted OR for underweight (<18.5)
Never-users	23,965	52.5±0.07	23.7±0.03	13.2 (12.8 to 13.6)	1.00
Mishri	15,899	48.8±0.08	22.4±0.04	20.9 (20.3 to 21.5)	1.41 (1.32, 1.50)
Mishri + other	13,401	46.5±0.09	21.6±0.04	26.6 (25.9 to 27.3)	1.72 (1.61, 1.83)
Betel quid	3,844	49.3±0.18	22.5±0.08	21.4 (20.1 to 22.7)	1.46 (1.33, 1.60)
Other tobacco	942	47.7±0.36	21.8±0.16	27.0 (24.2 to 29.8)	1.80 (1.53, 2.11)
Areca nut	1,210	50.5±0.33	23.0±0.14	17.2 (15.1 to 19.3)	1.18 (1.00, 1.40)NS

Note: SE = standard error.
Source: Pednekar et al., 2006[18].

In a sample of 90,303 women ages 15–49 years from the 1998–1999 National Family Health Survey (NFHS) in 26 Indian states, lower BMI was significantly associated with chewing tobacco (p= 0.001)[19] (Table 8.2). In an unordered multinomial multivariable model (using BMI 18.5–22.9 kg/m^2 as the reference), OR for underweight (BMI <18.5kg/m2) was 1.15 [95% confidence interval (CI), 1.09–1.22], after adjusting for age, religion, number of children, current smoking, alcohol use, history of tuberculosis treatment, and malaria[19].

Table 8.2: Distribution of women ages 15–49 [n (%)] across 7 categories of BMI, by use of chewing tobacco, in the NFHS-2 sample from 26 Indian states

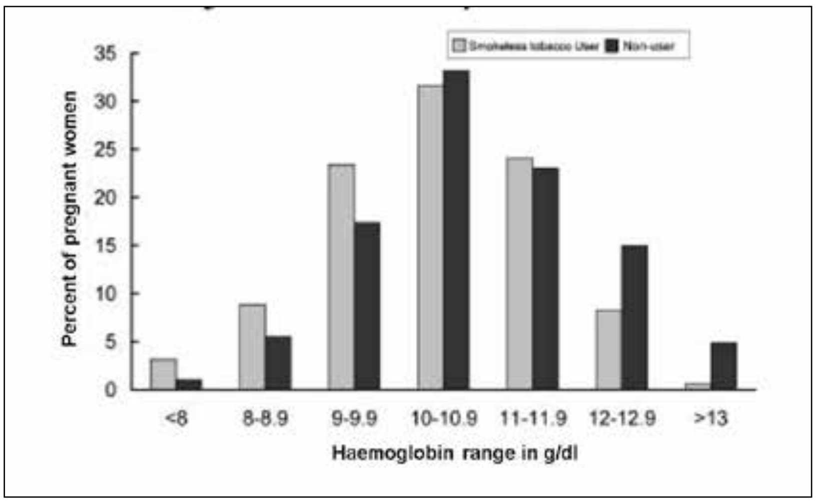
Variables	Sample size	BMI <16	BMI 16–16.9	BMI 17–18.49	BMI 18.5–22.9	BMI 23–24.9	BMI 25–9.9	BMI >30
Non-users	67,927 (88.0)	3,606 (5.3)	5,148 (7.6)	12,377 (18.2)	31,658 (46.6)	6,287 (9.3)	6,883 (10.1)	1,968 (2.9)
Tobacco chewers	9,293 (12.0)	818 (8.8)	852 (9.2)	1,960 (21.1)	4,444 (47.8)	590 (6.3)	523 (5.6)	106 (1.1)

Source: Reproduced from Subramanian and Smith, 2006[19].

Another study focused on 1,367 women who had live births in a hospital in Pune in 1978 and whose maternal weights were recorded at delivery. Among 1,205 middle and lower social class women, 46% chewers weighed <44kg, whereas 16% of the non-users weighed <44kg[20]. The conditional maximum-likelihood estimate (cMLE) odds ratio for weighing <44kg in women of lower and middle socioeconomic class who delivered between 37–38 weeks was 2.6 (1.7–4); for those who delivered at 39 weeks or later the cMLE was 7 (3.6–13.5)[20]. Similarly, in a population-based cohort study in Mumbai, 68% of SLT chewers and 61% of non-chewers weighed <50kg during 3–7 months of pregnancy ($p<0.05$)[21]. Unadjusted OR for BMI <19 in SLT users was 1.6 (1.1–2.3)[22].

SLT use is also associated with anaemia in pregnant and non-pregnant women. In a study using NFHS-3 data on 3,934 ever-married women ages 15–49 years from the state of Meghalaya, those who were tobacco users had a 1.2 times higher risk of anaemia (1.03–1.35) after adjustment for age, urban or rural residence, education, wealth index, pregnancy status, nutritional status, occupational status, and children ever born[23]. In a cohort study on pregnant women in Mumbai, mean haemoglobin levels were significantly lower in SLT users (10g/dl) in comparison with non-users (10.46g/dl, $p<0.001$). OR for maternal anaemia (Hb<10g/dl) associated with SLT use was 1.7, 95% CI (1.2–2.5), after adjustment for age of mother, education, socioeconomic status, type of residence, lower BMI, parity, vegetarian or non-vegetarian food intake, and haemodilution during pregnancy[22]. The whole distribution of haemoglobin was shifted towards the left in SLT users in comparison with non-users (Figure 8.1)[22].

Figure 8.1: Distribution of haemoglobin level by SLT use status



Source: Subramoney and Gupta, 2008[22].

NFHS-3 reported that, among 116,849 women surveyed (ages 15–49), the prevalence of mild (10.0–11.9 g/dl), moderate (7.0–9.9 g/dl), and severe (<7.0 g/dl) anaemia was 41.6%, 18.8%, and 2.9%, respectively, in women using tobacco; and 38.2%, 14.5%, and 1.6% in women who did not use tobacco, after adjusting for altitude of residence (p<001). Risk ratios calculated for mild, moderate, and severe anaemia in SLT user women in comparison to non-users were 1.17 (1.14–1.19), 1.4 (1.36–1.46), and 2.2 (1.9–2.4), respectively[24].

Maternal anaemia and underweight in women of reproductive age are independent determinants of low birthweight[25], preterm birth, small for gestational age, and reduced fetal iron stores[26]. Experimental studies suggest biological plausibility of the association between SLT use, underweight, and anaemia. Nicotine in SLT affects hypothalamic dopamine and serotonin, which reduces hunger[27,28]. Tobacco use increases production of free radicals and systemic oxidative stress[29,30] and reduces antioxidant levels, potentially damaging red blood cell (RBC) viability. A direct haemolytic effect of nicotine and cotinine on RBCs has been demonstrated[31]. Social disadvantage in women SLT users can prevent access to nutritious food[32,33], and reduced plasma levels of several antioxidant vitamins have been reported in SLT users[34].

Oral Diseases

Although pan masala and tobacco products are often advertised as mouth fresheners, women who use these products have severe oral health problems in comparison with non-users (see also chapter 12). Users experience more plaque and inflammation in the oral cavity[35], recession of gums, exposed root surfaces of teeth, increased periodontal pockets, and tooth loss[36]. Clinical loss of attachment of periodontal fibres increases with duration of SLT use[37]. Oral inflammation from tobacco and areca nut use further increases the risk of oral cancer[38], probably because of an increase in endogenous nitration and the formation of toxins[34,39,40].

Women consuming tobacco products with areca nut can also develop an extremely debilitating and potentially malignant and precancerous condition called oral submucous fibrosis (OSF). Women may have more symptomatic difficulty associated with OSF than men—for example, difficulty opening the mouth, difficulty eating, burning sensation, altered taste sensation, and difficulty in swallowing[41,42].

Cancer

Women who use SLT or pan masala have an increased risk of oral and pharyngeal cancers[34], and this risk increases with the duration and frequency of SLT use[38,43]. Women appear to be more vulnerable to the carcinogenic effects of SLT and pan masala than men[38,42-46] (Table 8.3). In a meta-analysis that included 12 published studies of oral cancer, women had a substantially higher risk of oral cancer [OR=12.4 (5.7–27.1) compared to 4.7 in men (2.9–7.8)][47]. Women's greater risks of oral cancer may have a variety of causes, which can only be hypothesised at this time.

Adverse Reproductive Effects

The evidence shows that SLT use by pregnant women results in a significantly higher risk of complications for the woman and the fetus. An interventional study on pregnant women in rural Maharashtra found a higher risk of pregnancy complications—including fetal distress [RR=1.8 (1.06–3.06)], pregnancy-induced hypertension (PIH) [RR=5.5 (1.06–28.6)], antepartum haemorrhage, oligohydramnios, polyhydramnios, and post-partum haemorrhage [RR=2.1 (1.33–3.31)]—among users in comparison to non-users[3]. Higher risk of fetal distress [RR=1.8 (1.06–3.06)] and pregnancy-induced hypertension [RR=5.5 (1.06–28.6)] were also observed.

Table 8.3: Increased risk of oral cancer among SLT user women in comparison to SLT user men

Reference, location	Study details	Sample description	SLT type, risk comparison	Risk in SLT users in comparison to non-users		Adjustment for potential confounders
				Women	Men	
Nandakumar et al., 1990 [45] Population Based Cancer Registry, Kidwai Memorial Institute, Bangalore	Case control study	475 incident cases and 471 controls (cancer suspects)	Tobacco chewing	OR=25.3 (11.2–57.3, p<0.001)	OR=3.6 (1.7– 7.9, p< 0.001)	Matched by age, sex, residential status

Reference, location	Study details	Sample description	SLT type, risk comparison	Risk in SLT users in comparison to non-users		Adjustment for potential confounders
				Women	Men	
Jayalekshmi et al., 2011[46] Karunagapally, Kerala	Prospective follow-up study for children ages 7–14 years	78,140 women and 66,277 men ages 30–84	Current tobacco chewers vs. never-users	RR=5.5 (3.3–9.0)	RR=2.4 (1.7–3.3).	Age, education, income (and bidi smoking and alcohol use in men)
Muwonge et al., 2008[43] Trivandrum	Nested case control study in a randomised controlled trial	282 incident oral cancers, 1,410 controls	Betel quid chewers	OR=11.0 (5.8–20.7)	OR=3.1 (2.1–4.6)	Matched by age, panchayath, and response status to interview
Balaram et al., 2002[38] Bangalore, Madras, and Trivandrum	Case control study	591 cancer cases, 582 controls	Betel quid chewing	OR=42 (24–76)	OR=5 (3.4–7.8)	Age, study centre, education (and smoking and drinking in men)
Wahi 1968[44] Mainpuri district (near Agra),	Cancer registry study	34,971 individuals ages ≥35 in rural and urban areas	Chewing Mainpuri tobacco	Prevalence rate ratio in chewers = 90 (95% CI 39–206); in chewers who smoked = 183 (64–528)	Prevalence rate ratio in chewers = 8 (4.7–13.8); in chewers who smoked = 15.8 (9.5–26)	Not adjusted

Note: RR = relative risk.

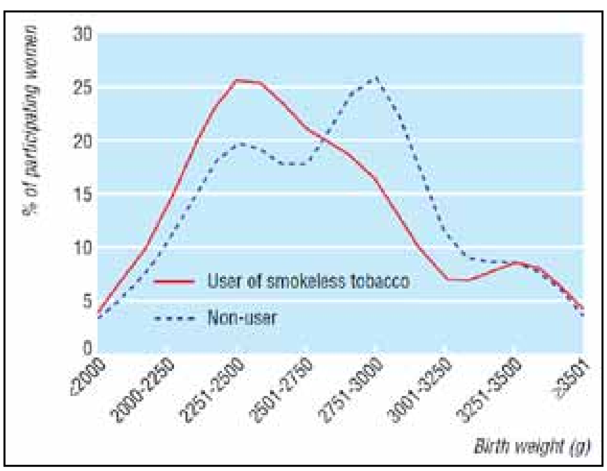
In a study of 48 SLT users and 48 non-users matched for age, socioeconomic status, literacy, parity, height and weight of mother, birth interval, and gender of baby, placental weight was increased by 70g in mothers who used tobacco with lime three or more times per day for a period of 6 years or more, in comparison to placentas of non-users ($p<0.001$)[48]. Mean surface area and number of cotyledons did not differ significantly[48]. (A cotyledon is one of the visible segments on the maternal surface of the placenta; typically a placenta may have 15 to 28 cotyledons.) However, this study did not match for gestational age at delivery, which is an important limitation.

Birthweight is an important determinant of neonatal and infant morbidity and mortality[49]. Highly significant and consistent birthweight reductions have been demonstrated with maternal SLT use in almost all Indian studies[3,4,21,50-52,56] after adjustment for a range of potential confounders (Table 8.4). In a study undertaken in Ahmedabad, SLT use was not associated with low birthweight in multivariate analysis, most likely because of over-adjustment by a variety of proximate variables[53]. In a cohort study of 1,217 pregnant women in Mumbai (Table 8.4), the whole distribution of birthweight was shifted toward the left in users compared to non-users (Figure 8.2) ($p=0.02$)[21]. Three studies have demonstrated significant dose–response effects of maternal SLT use on birthweight (Table 8.5)[3,21,87]. High levels of cotinine have been demonstrated in maternal blood, cord blood, and amniotic fluid in mishri users in a study in Mumbai (Figure 8.3)[54].

Table 8.4: Birthweight in relation to maternal SLT use in studies from India (2000–2013)

Study details	Sample	Results	Comments
Rural field practice area of medical college, Kolkata, West Bengal, 2013[4]	A simple random sample of 540 births selected from all births that had a valid address (n=2,229)	Adjusted RR for tobacco users = 2.7 (p<0.05) for low birthweight (LBW)	Adjusted for large number of potential confounders
Hospitals in Maharashtra, 2011[50]	274 term LBW babies and 274 term matched controls	Adjusted OR = 4.1, (95% CI 1.9–9)	Adjusted for large number of potential confounders
Hospital, rural Maharashtra, 2011[51]	200 LBW singleton live births and 200 normal weight singleton live births	11.5% of cases and 2% of control were tobacco users (p<0.0003), OR=6.4 (95% CI 2.2–19)	Only births between 37 and 42 weeks of gestation born to mothers 18–35 years of age
Nagpur, Maharashtra, 2011[52]	430 live LBW singletons and 430 matched controls	Maternal tobacco use not associated with LBW	Cases and controls differed significantly in place of residence, height, weight, birth interval
Intervention study, rural Maharashtra, 2010[3]	705 pregnant women including 218 mishri users	Mean birthweight of babies of 153 mishri users was 170g less than babies of non-users (p<0.05)	Users and non-users were compared
NFHS-3, women ages 15–45, 2005–2006[56]	Birthweight from 19,250 health cards. 34% of eligible births	Odds ratio for LBW was 1.2 (95% CI 1.07–1.36)	13% of all tobacco chewers smoked as well
Population-based, Mumbai, 2004[21]	1,217 women recruited during 3–7 months of gestation and followed up until delivery	Adjusted OR for LBW was 1.6 (95% CI 1.1–2.4).	Adjusted for several confounders

Figure 8.2: Distribution of birthweight by maternal SLT use status

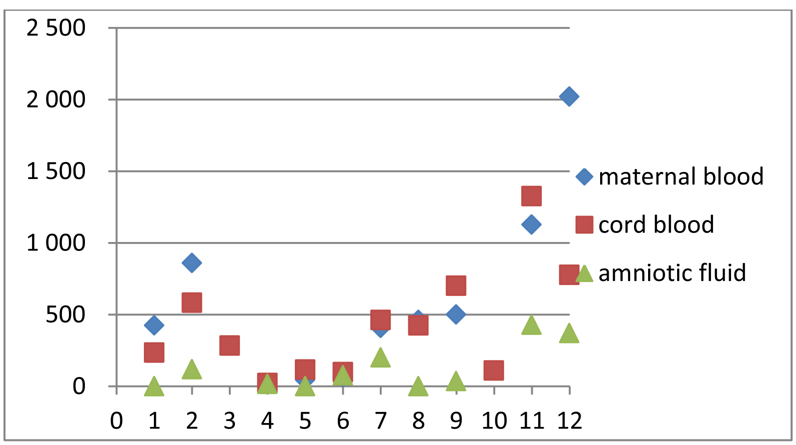


Source: Gupta and Subramoney, 2004[21].

Table 8.5: Impact of duration, quantity, frequency, or type of maternal SLT use on mean birthweight (BW) or low birthweight (LBW)

Study author/date	Type and location of study	Findings	
Pratinidhi et al., 2010[3]	Intervention study, rural Maharashtra	Mean birthweight by gestational age when mother stopped using mishri Non-user: 2,750 g Stopped at 28 wks: 2,736 g Stopped at 32 wks: 2,709 g Used throughout pregnancy: 2,580 g (F=10.9, p<0.000005)	Mean birthweight with years of mishri use Non-user: 2,699 g ≥6 yrs: 2,570 g p<0.05
Gupta and Subramoney, 2004[21]	Population-based cohort study, Mumbai	Reduction in mean birthweight with frequency of SLT use 1–4 times/day: 63 g ≥5 times/day: 189 g p=0.006	
Verma et al., 1983[87]	Jabalpur Medical College Hospital	Birthweight with quantity of SLT used Non-user: 2,842 g Used <200g/day: 2,576 g Used 200–299g/day: 2,476 g Used 300–399g/day: 2,372 g Used >400g/day: 2,402 g F=7.2, p<0.00005	

Figure 8.3: Cotinine levels in maternal blood, cord blood, and amniotic fluid of 12 mishri user mothers who delivered at a Ghatkopar Hospital in Mumbai, 1992 (numbered 1–12 on x-axis)



Source: Sarkar et al., 1992[54].

In an interventional study in rural Maharashtra, quitting SLT use during pregnancy improved the birthweight of infants delivered by these women. In this study, 13.3% of 209 mishri users stopped use by 28 weeks gestation, 16.5% reduced consumption or stopped at 32 weeks, and the remaining 70.2% did not change their practice of using mishri at all[3]. Birthweight reduction was greatest in those who continued use throughout pregnancy (Table 8.5)[54].

In a population-based study in Mumbai, SLT use was associated with average reduction in gestational age of 6.2 days (95% CI 3–9.4). Preterm deliveries were earlier by 11.6 days (95% CI 4.4–18.8 days). There was a dose–response relation between SLT use and gestational age; light SLT users and heavy SLT users delivered 4.9 and 8.9 days earlier than non-users, respectively (p=0.002). The percentage of infants delivered preterm by SLT users in comparison to non-users increased as gestational age decreased, from 37 weeks, 32–37 weeks, 28–32 weeks to <28 weeks (p<0.001)[21].

Similar to these findings, an intervention study with 705 pregnant women in rural Maharashtra showed that 6.4% of mishri users and 2.2% of non-users had previous preterm deliveries. The relative risk of preterm delivery among mishri users was 2.8 (95% CI 1.03–4.7)[3]. In the Pune study among 1,205 middle and lower socioeconomic women who had live births, SLT users had 4.8 times higher risk for delivery at 37–38 weeks (95% CI 3.3–7) and 16 times higher risk of delivering at 36 weeks or less (95% CI 9.2–29), in comparison with non-users[20].

Studies on stillbirth and spontaneous abortion in association with maternal SLT use are summarised in Table 8.6. A fetus born after at least 20 weeks of gestation that did not breathe or show any other evidence of life is defined as a stillbirth. Perinatal mortality refers to both late fetal (stillbirth) and early neonatal deaths (first week of life).

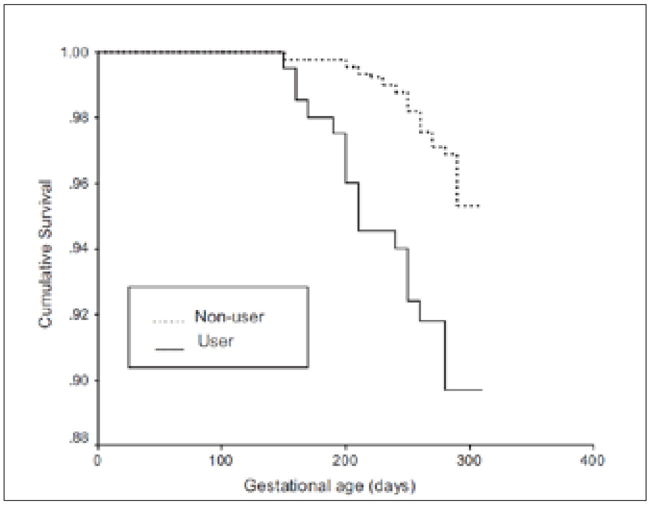
Unadjusted risk of stillbirth in SLT user women in epidemiological studies was 3–4.5 times higher than in non-users[55,56], and risk of spontaneous abortions and stillbirths combined was 1.1 times higher. A case control study across 38 centres revealed that the unadjusted OR of perinatal death in newborns of SLT users was 1.51 (95% CI 1.33–1.71)[55].

Table 8.6: Stillbirth and spontaneous abortion in relation to maternal SLT use (India)

Study, sample	Results	Comment
Population-based study, Mumbai, 2006[56]	HR_{adj} (for stillbirth) = 2.6 (95% CI 1.4–4.8) for SLT users	Dose–response effect with increasing frequency of daily use
Hospitals, Ahmedabad, 1991[85]	5.1% of mothers of stillborn babies used tobacco vs. 1.8% of live births [rate ratio=2.9 (95% CI 1.6–5)], p<0.0005	Over-adjustment by proximate factors attenuated the odds ratio in regression
76,699 currently married women who reported any fetal loss and tobacco use/non-use, from the NFHS-2, 1998–1999[86]	Spontaneous abortion and stillbirth rate was 32 per 100 in women who chewed tobacco, 25 per 100 in non-users [rate ratio=1.1 (95% CI 1.25–1.35; p=0.001)]	Chewers may include smokers and alcohol drinkers OR attenuated a little after adjustment
1,388 infants delivered in Pune hospital, 1978[20]	Rate ratio for stillbirth in chewers=2.9 (95% CI 1.4–6.1).	Antenatal care, parity were similar
Intervention study, rural Maharashtra, 2010[3]	6 out of 218 chewers had stillbirths vs 3 out of 487 non-users (rate ratio=4.5, 95% CI 1.1–18).	Users and non-users were comparable

In the cohort of 1,217 pregnant women in Mumbai, among 848 women who had had a previous pregnancy, the hazard ratio (HR) for stillbirth was 2.1 (95% CI 1.03–4.4) after adjustment for a range of potential confounders[56] (Figure 8.4).

Figure 8.4: Cumulative survival of babies born after 20 weeks to SLT users and non-users, by days of gestation at delivery



Source: Gupta and Subramoney, 2006[56].

Adverse Effects on Family Health

Tobacco users suffer increased episodes of hospitalisation and out-of-pocket expenditures for health care, which threaten their financial well-being and their ability to provide essential nutrition for their families, which adversely affects family health[57]. Mother's use of SLT is also associated with use of medical care: NFHS-3 reported that a significantly smaller proportion of users' infants were treated at a health facility for acute respiratory infections compared with non-users' infants (61% vs. 70%, respectively; $p<0.05$), although a significantly greater proportion of infants of tobacco user women had symptoms of acute respiratory infection in the two weeks preceding the survey compared to non-users' infants (7.3% vs. 5.6%; $p<0.001$)[25].

OTHER SLT-RELATED ISSUES IN WOMEN

Use of Multiple SLT Products

The Global Adult Tobacco Survey (GATS) 2009-2010 reported that 10–25% of all women in the states of Mizoram, Nagaland, Chattisgarh, Arunachal Pradesh, Odisha, Madhya Pradesh, and Manipur used SLT in multiple forms[1]. Kerala had a higher relative prevalence of multiple SLT use, although it had a lower overall prevalence. In a large population-based study in Mumbai, 21% of 59,527 women age 35 and above used multiple SLT products. Some 18% used mishri, and betel quid with tobacco, and 3% used other combinations[58]. A 2008 study of 202 female adolescents ages 15–19 years selected by simple random sampling from the 11 villages surrounding the Kasturba Rural Health Training Centre, Wardha, found that 12.4% had used SLT in the past 30 days, 72% used dry snuff to clean teeth, 32% used tobacco in the form of gutka, and 20% used tobacco and lime (one-fourth of users used two or more forms of SLT)[59]. In contrast, population-based surveys conducted during 1966–1969 and in 1976 found that use of multiple SLT products was rarely reported (0 to <0.5%); these studies surveyed more than 56,000 villagers in five widely different districts, representing a broad spectrum of the population of India (in the states of Andhra Pradesh, Bihar, Kerala, Gujarat, and Goa)[60].

These data suggest an increasingly clear trend toward use of multiple SLT products among women.

Determinants of SLT Use and Socioeconomic Status

Lower socioeconomic status—characterised by lower education, unemployment, manual occupations, rural residence, living in poorer or slum neighbourhoods, and other factors—was associated with higher prevalence of SLT use[58,60-63]. Social disadvantage was also associated with lower age at SLT initiation. According to GATS India 2009-2010, the mean age of initiation to SLT use was two years lower among those with no formal education, in comparison to those with secondary or higher education[1]. Some 23.4% of adults with no formal schooling initiated SLT before age 15, whereas only 8.4% of adults with secondary education and above initiated SLT before age 15[1].

Socioeconomic differentials in SLT use are significantly steeper in women than in men (GATS India 2009-2010). In the Mumbai Cohort Study of over 8,000 people, the odds ratios for SLT use after adjustment for age and occupation among illiterate women and men in comparison with the college educated were 21.02 (95% CI 16.63–26.56) and 7.75 (95% CI 6.55–9.18), respectively. For women and men who had only primary education, the adjusted odds ratios (AOR) in comparison to those with college education were 9.18 (95% CI 7.27–11.60) and 5.25 (95% CI 4.59–6.01), respectively; and for those with middle-school education, the AORs were 5.50 (95% CI 4.34–6.97) and 2.90 (95% CI 2.54–3.31), respectively[64].

SLT Use, Hunger, and Psychosocial Stress

Indian women report using SLT to improve oral hygiene[3], ease gastric problems[65], reduce menstrual pain[66], freshen breath, alleviate fatigue[65], and for manifold other medicinal or imaginary benefits. However, use of SLT by women seems to have deeper underpinnings. Indeed, for women who face economic difficulties, SLT can be a great value for the money. It is scientifically proven that use of tobacco and/or areca nut causes a biological suppression of hunger and reduces caloric intake[27-28,67-68]. Women report that they use SLT to alleviate hunger and help them skip a meal or two[65]. (It should be noted that food is far more expensive than SLT.) In fact, a study of Mumbai pavement dwellers highlighted the fact that the poor choose tobacco over food[69]. These conclusions are substantiated by local[18,20] and national-level studies[19] that have found a significantly higher prevalence of underweight among women using SLT in comparison with non-users, after adjusting for a variety of confounding factors.

Psychosocial stress is an important contributor to SLT use by Indian women. Women in India often lack equality with the men in the family, may have low levels of control over their lives, and may be frequently abused. Some 19% of ever-married women reported physical or emotional abuse in the family in an analysis of the NFHS-2 in 1998–99, and these women were more likely to use SLT than women who did not experience domestic violence (OR=1.36, 95% CI 1.28–1.44) after accounting for age, standard of living, caste, religion, residential and living environment, body mass index, employment, and pregnancy status in multilevel models[70].

Further, in an in-depth interview in Delhi, disadvantaged women reported that they tried to handle psychological threats or tried to control anger by withdrawing to chew tobacco[71]. Women also reported that SLT use helps them forget their worries and difficulties, and gives them a peer group with which to relate[65]. In fact, about 54% of women in NFHS-3 reported that wife-beating and threatening was justified for a variety of reasons[25]. Therefore, tobacco control for women in India also implies overcoming social inequalities and gender disparities, making healthy nutrition affordable to poor women, providing equitable health care, and raising women's self-esteem.

Positioning SLT as an Essential Household Commodity

In the multitude of retail stores that dot every Indian locality, strips of SLT sachets are conspicuously hung adjacent to sachets of washing powder, fruit jelly, hair oil, shampoo, mint, and snacks (Figure 8.5), in a display that is visible from a distance[72]. By placing their product in the midst of groceries and other essential household goods, SLT companies have effortlessly accomplished the critically important task of product positioning and promotion to millions of Indian women. The message that '*SLT is an essential household commodity*' is unsaid, but is automatically perceived by women[73].

Figure 8.5: Positioning of smokeless tobacco strips ['Gai' (cow brand) and 'Singham' (lion brand)] in stores among essential daily use commodities such as 'Rin' washing powder, 'Kissan' jam, and Pantene' shampoo

Source: Chaudhry and Chaudhry, 2007[72].

Almost all shops, including milk outlets, which are frequented by women to buy daily use items and groceries, stock varieties of SLT products[10,72,74]. A spatial analysis in a typical low-income community in Mumbai documented that all residents could reach a tobacco outlet within 30–100 feet of their homes[10]. This study also documented that, in general, grocery shops selling SLT were much more numerous in the community than shops that only sold tobacco products. GATS India 2009-2010 showed that 64% of women (compared to 50% of men) purchased SLT products from stores that sell daily use commodities[1].

In addition, tobacco-based toothpastes, toothpowders, and herbal dentifrices that contain tobacco[75] are commonly available in 'medical' or pharmaceutical shops, along with stocks of other toothpastes, toothbrushes, health drinks, muscle-building foods, and medicines.

Women Face More Problems Stopping SLT Use

SLT cessation seems more difficult for women than men. Women appear to be less interested in quitting SLT use than men are. According to GATS India 2009-2010, about 50% of SLT user women were not interested in quitting, compared with the 40% of males who were not interested in quitting. About 29% of daily SLT user women had made an attempt to quit in the past 12 months, in contrast to 39% of males[1].

Women also experience more anxiety and stress than men while trying to quit. They worry whether they will be able to continue their chores when they quit because they believe that using

SLT gives them energy and motivation and compensates for lack of food[65]. They fear how difficult it could be to control the urge to chew when feeling depressed or depleted of all energy[65]. Women need support to manage their lives without SLT.

Withdrawal symptoms together with trying to managing life's extreme stresses make it doubly difficult for disadvantaged women to quit[65]. Designing cessation strategies for disadvantaged women is therefore a challenging task that can only be accomplished with dedicated formative research involving the users and fully addressing their concerns, and having an inbuilt element of self-motivation[65]. With these women, focused behavioural intervention[76-78] should be combined with coping strategies for handling stress[65]. In addition, randomised controlled clinic and community trials show that SLT quit ratios can be higher when behavioural intervention is combined with examination for oral health problems, such as gum inflammation, tooth loss, or precancerous conditions, in the clinic or community setting[79-83]. Ideally, a combination of these strategies should be used to achieve the best results.

Women and Tobacco-Related Occupations

Tobacco farming is commonly thought to provide much higher returns than alternative crops. However, a detailed gender-based analysis of the dynamics of tobacco cultivation, production, and marketing concluded that the net returns of tobacco farming are smaller than returns for many other crops because of the high costs of pesticides and fertiliser, as well as the non-realisation of the costs of labour of the women in the family[12]. Tobacco farming is extremely labour intensive and relies heavily on the labour of women, and often of girls. Women and girls make up 80–90% of the workers employed by the Indian tobacco industry[2]. This underpaid or unpaid family labour produces a large, cheap supply of commodities for the contractors, increasing their profits[11,12].

High frequencies of tobacco-farming-related illnesses, deaths, and birth defects have been observed in communities that work with tobacco, including higher risks of developing cancers and liver cirrhosis[12]. Bio-monitoring studies have shown that workers' frequent inhalation of tobacco flakes and dust results in exposure to nicotine and carcinogens, just as it does in actual users of tobacco products[34,83]. In women bidi rollers, cotinine levels were several times higher than in unexposed individuals[13]. Pregnant women who work long hours in tobacco production without proper facilities are the worst affected and suffer frequent miscarriages and abortions[84]. Tobacco plants require large and frequent applications of pesticides, which are highly toxic and have been associated with respiratory, nerve, skin, liver, and kidney damage in women, and toxic pollution of natural waters and soils. The hazards of chronic exposure to pesticides range from birth defects to childhood deaths from aplastic anaemia. Children exposed to the pesticides used on tobacco frequently experience stunted growth. The longer the duration of tobacco use or engagement in tobacco farming and other processing activities, the greater the disadvantage and poverty in women[12].

Women carry their infants along when working[83], and take their work home[11], so their infants and children are also exposed to tobacco flakes and other chemicals used during farming, processing, and manufacture. Girls drop out of school and assist their mothers in rolling bidis or in preparing, curing, picking or other tobacco-related jobs[83]. Infants and young workers are at greater risk of becoming ill from exposure to pesticides and toxic substances, and women in tobacco farming need guidance and support with economically viable alternative occupations.

CONCLUSIONS

The burden of SLT use and SLT-related occupations on women and their families presents a disturbing picture. Stringent women-centred policies are urgently required to curb and regulate the availability and positive positioning of commercially packaged products and their constituents and to control the sale and production of raw tobacco. Even though SLT user women are lower on the socioeconomic ranking, tobacco is still affordable for them. Reducing their demand for tobacco will require strong price increases, the provision of equitable health care, and poverty reduction measures. Banning women's employment in tobacco-related industries, along with integrating them into alternative occupations, is essential to improving women's health and family health. Women-specific tobacco control policies are urgently required to enable India to reach its Millennium Development Goals of poverty reduction and improvement of the health status of its women and children.

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Chapter 9

Smokeless Tobacco and All-Cause Mortality

Mangesh S. Pednekar[1], P. Gangadharan[2]

[1]Healis-Sekhsaria Institute for Public Health, Navi Mumbai
[2]Amrita Institute of Medical Sciences and Research Centre, Cochin

INTRODUCTION

Population-based evidence for elevated risk of all-cause mortality in tobacco users has been examined by large-scale studies, mainly from Western countries. However, most of these studies only examine mortality related to tobacco smoking[1-6]. In India, where the nationally representative Global Adult Tobacco Survey 2009-2010 (GATS) reported that 25.9% of adults (15 years and older) use smokeless tobacco (SLT), it is important to know the impact of smokeless tobacco use on mortality[7]. The earliest systematic studies on the health effects of SLT use were conducted in India from the early 1950s through the 1980s[1, 8-14]. In this chapter, we present a review of the available evidence on SLT and all-cause mortality derived especially from Indian studies.

MORTALITY STUDIES

Effects of SLT Use

During the 1980s, cohort studies on tobacco users were reported from three different parts of India[12-14]. In all these areas together, 122,217 people age 15 and above were interviewed, and the type of tobacco used was recorded. This section describes the results of these and other cohort studies, which are summarised in Table 9.1.

In the first and largest of these studies, conducted between 1968 and 1971, a total of 101,761 individuals above the age of 15 years were interviewed about tobacco use and examined for oral precancerous lesions in a house-to-house survey in Ambegaon and Junnar *talukas* in rural Maharashtra[12]. The participants were followed up for 8 years. The age-adjusted mortality rate among male chewers was 29 deaths per 1,000, and for bidi smokers the rate was higher, at 47 per 1,000. Comparing all-cause mortality among male bidi smokers and tobacco chewers diagnosed with leukoplakia over the 8-year period, the age-adjusted annual mortality rate among tobacco chewers was 39; the rate among bidi smokers was 75. In this cohort study, the mortality rate among non-users of tobacco was not recorded[12].

Another cohort study, involving 10,287 individuals above the age of 15 years from Ernakulam district in Kerala, reported the mortality experienced by tobacco chewers and smokers after a 10-year follow-up from the baseline survey in 1966[13]. In this cohort, over 81% of men and over 39% of women were users of tobacco in any form, and of these, 14% of males and 38% females were tobacco chewers. The first follow-up was conducted 3 years after entry into the cohort, with subsequent follow-ups conducted annually. Examining a total of 83,822 person-years (40,312 for males, and 43,510 for females), this study found that the age-adjusted relative risk (RR) of mortality for women SLT users compared to non-users (1.3) was significant[13]. It was elevated among men SLT users also (1.2) but not significant.

Table 9.1: Results of cohort studies on SLT use and all-cause mortality

Study population	Number of Participants	Years of follow-up	Age (years)	Male SLT users	Female SLT users	Adjustments
				Risk ratio parameter (95% CI or p value)		
India: Kerala, Ernakulam[13]	10,287	10	≥15	RR=1.2 RR=1.4, dual users	RR=1.3	Age
India: Andhra, Srikakulam[14]	10,169	10	≥15	RR=1.96 RR=1.20, dual users	RR=1.24 (mainly chewers)	Age
India: Maharashtra, Mumbai[15]	99,570	5.5	35–69	RR=1.2 (1.1–1.3)	RR=1.3 (1.2–1.4)	Age, education
India: Kerala, Trivandrum[17]	167,343	6.5	≥34	HR= 1.75 (1.67–1.83) HR=0.93 (0.89–0.98) HR=0.90 (0.86–0.94)		Unadjusted Age Multivariate
			34–39 40–59 60–84	HR=1.15 (0.88–1.51) HR=1.01 (0.93–1.10) HR=0.90 (0.85–0.94)		Multivariate Multivariate Multivariate
Sweden[18]	135,036 men	12	35–65 35–54 55–65	RR=1.4 (1.3–1.8) RR=1.9 (1.6–2.4) RR=1.2 (1.0–1.3)	—	Age, region
Sweden[19]	9,976 men	29	≥15	HR=1.10 (1.01–1.21)	—	Multivariate
USA: CPS-1[20]	77,407 men	12	≥30	HR=1.17 (1.11–1.23)	—	Multivariate
USA: CPS-2[20]	114,809 men	18	≥30	HR=1.18 (1.08–1.29)	—	Multivariate

RR=relative risk; HR=hazard ratio; CI=confidence interval.

In a more recent study in Mumbai, tobacco-associated mortality was reported in a cohort of 99,570 men and women age 35 years and above recruited during the years 1991 to 1994. This cohort was followed up for an average of 5.5 years between 1997 and 2003, when 7,531 deaths were recorded[15]. Of a total of 210,129 person-years observed for men, 46.1% were among SLT users, 27.4% among smokers, and 26.5% among non-users. For women, in 323,316 person-years of observation, 59.3% were among SLT users, 0.4% among smokers, and 40.3% among non-users. Among the women SLT users, the adjusted relative risk (RR) of all-cause mortality was 1.25 (95% CI 1.15–1.35) for all ages, and 1.30 (95% CI 1.18–1.43) for the age group 35–69 years; for men, these RR were 1.16 (95% CI 1.06–1.26) and 1.14 (95% CI 1.03–1.26), respectively (Table 9.1)[15]. The interim results reported after a follow-up of 52,568 individuals were quite similar[16]. Additionally, the age-specific mortality rates among female SLT users were reported to be higher than those among non-users in all age groups[16].

A cohort study initiated in 1996 in a rural area of Kerala also investigated all-cause mortality in relation to SLT use[17]. Some 167,343 adults aged 34 years and older were recruited into the study and were regularly followed up for a mean duration of 6.5 years. In this study, betel quid with tobacco was the most commonly used chewing preparation (65%), and only 1% of chewers used commercial preparations. Although hazard ratios (HR) for specific causes, such as cancer, were significantly higher in SLT users (tobacco chewers), apparently there was reversal of risk for all-cause mortality among SLT users ('chewing with tobacco') after adjustments. The crude HR was 1.75 (95% CI 1.67–1.83); the age-adjusted HR was 0.93 (95% CI 0.89–0.98); and the multivariate-adjusted HR was 0.89 (95% CI 0.84–0.93). When stratified for age, this risk reversal effect was significant only for the oldest age group (60–84 yrs.)[17]. In this study, the HRs for death due to cancer among tobacco chewers were all significantly elevated, as were those for non-tobacco chewers (betel quid without tobacco)[17].

SLT Product-Specific Mortality

SLT product-specific mortality risks are available only from research by Gupta and colleagues that is known as the Mumbai Cohort Study (2005)[15]. While the most commonly used SLT products in the cohort were mishri and betel quid, relative risks were highest among users of other SLT products, which mainly included tobacco with lime (i.e., khaini) (among men, 1.24, 95% CI 1.08–1.41; among women 1.37, 95% CI 1.09–1.73). Among women, relative risk was almost the same for those who reported using mishri along with other tobacco products (1.36, 95% CI 1.24–1.48). Interestingly, relative risks were not significant for areca nut and for betel quid (Table 9.2).

Table 9.2: Relative risks for all-cause mortality by type of SLT used, from the Mumbai Cohort Study

	Person-years	Deaths	Age-adjusted mortality rate*	RR**	95% CI
Women					
Mishri	88,002	743	12.3	1.21	1.10–1.34
Mishri + other	71,817	1,323	14.1	1.36	1.24–1.48
Betel quid	20,153	236	9.8	0.96	0.83–1.11
Other tobacco†	5,020	80	14.1	1.37	1.09–1.73
Areca nut	6,633	88	9.9	1.05	0.84–1.31
Never used tobacco	130,294	907	8.9	1.00	—
Men					
Mishri	14,658	226	16.1	1.14	0.97–1.33
Mishri + other	38,981	782	18.3	1.18	1.07–1.31
Betel quid	24,368	436	16.2	1.10	0.98–1.24
Other tobacco	17,039	316	18.5	1.24	1.08–1.41
Areca nut	1,838	27	11.5	0.83	0.56–1.21
Never used tobacco	55,717	854	13.6	1.00	—

Notes: *per 1 000 person-years. **Age- and education-adjusted relative risk (RR) by using Cox model. †Generally tobacco plus lime
Source: Gupta et al., 2005[15].

Only one study in an Indian population examined mortality related to specific products. Some important studies from other parts of the world provide additional evidence for higher mortality among SLT users, even though the SLT products used are quite different.

A study of a large population of male Swedish construction industry workers (n=135,036) who attended a health examination during 1971–1974 presents data on cause-specific mortality during a 12-year follow-up period[18]. Among the entire cohort of snus users, the age-adjusted RR of dying from all causes was 1.4 (95% CI 1.3–1.8) compared with non-users. Among men aged 35–54 years at the start of follow-up, the RR of dying from all causes was 1.9 (95% CI 1.6–2.4) for SLT users, and the RR for those aged 55–65 years was 1.2 (95% CI 1.0–1.3)[18] (see Table 9.1).

A population-based study followed a cohort of 9,976 Swedish men from a 1973-1974 baseline survey until early 2002. Based on the 200,000 person-years studied, a slight increase in mortality was found, with an adjusted hazard ratio (HR) for snus use of 1.10 (95% CI 1.01–1.21) apart from elevated HRs for oral and pharyngeal cancer[19] (Table 9.1).

Two large prospective studies were reported from the U.S. population[20]. Health effects, especially mortality resulting from chronic use of chewing tobacco or snuff, were evaluated using a cohort study of 77,407 men enlisted in the 1959 Cancer Prevention Study 1 (CPS-1) and 114,809 men enlisted in the 1982 Cancer Prevention Study 2 (CPS-2). Men who currently used snuff or chewing tobacco at baseline had higher death rates from all causes than men who did not, as shown by both the CPS-1 (HR=1.17, 95% CI 1.11–1.23) and the CPS-2 (HR=1.18, 95% CI 1.08–1.29)[20] (Table 9.1).

Joint Effects

In studies of all-cause mortality among SLT users, confounding risk factors may be extremely important, such as low body mass index (BMI), alcohol use, hypertension, and tobacco smoking, and an interaction between SLT and these other risk factors may affect mortality. This section describes studies of possible joint effects on mortality of SLT and potential risk factors.

SLT and Body Mass

The joint effect of tobacco use and body mass on mortality was investigated in a cohort study of 148,173 men and women aged ≥ 35 years in Mumbai[21]. This cohort contributed 774,129 person-years of follow-up, and 13,261 deaths were recorded. Tobacco use increased the risk of death across different categories of body mass, with particularly high risks in both extreme ends of body mass categories. Never-users of tobacco who had a BMI of 25.0 to more than 30.0 were used as a reference category. In comparison with the reference group, an elevated risk of death was observed across SLT users in different BMI categories in men (RR ranging from 1.17 to 2.75) and women (RR ranging from 1.20 to 2.22). The study concluded that body mass and all forms of tobacco use, including SLT, had independent as well as multiplicative joint effects on mortality. Thus, obesity, which is independently emerging as a serious public health problem, will interact with any form of tobacco use, including SLT[21].

Alcohol and SLT Use

All-cause mortality related to alcohol use as well as alcohol and tobacco use was examined in the Mumbai Cohort Study[22]. A total of 35,102 men age 45 years and older reported their tobacco use and alcohol drinking status. A synergistic joint effect of all forms of tobacco and alcohol on mortality was observed, with HR in drinkers who had never used tobacco being 1.02 (95% CI 0.83–1.25); in SLT users who drank, HR was 1.37 (95% CI 1.21–1.56); and among mixed tobacco user–drinkers (drinkers who used both smoked and smokeless tobacco), HR was highest, at 1.79 (95% CI 1.58–2.03). This study thus clearly demonstrated a synergistic interaction of SLT with alcohol on mortality risk[22].

Hypertension and SLT Use

Hypertension has also been suspected to cause higher mortality among tobacco users. The Mumbai Cohort Study reported the association of blood pressure categories with various causes of deaths stratified by tobacco use. Hypertension levels were defined as Stage I (systolic 140–159 and/or diastolic 90–99 mm Hg), and Stage II (systolic =160 and/or diastolic 100 mm Hg). At Stage II hypertension, all-cause mortality among SLT users had a higher adjusted HR (HR=1.43, 95% CI 1.27–1.62) than among non-tobacco users with normal blood pressure. Again, among Stage II hypertensive individuals, for deaths due to all circulatory system diseases (ICD-10 codes I00–99), the adjusted HR was much higher among SLT users (HR=2.49, 95% CI 1.93–3.29) than among non-users (HR=1.43, 95% CI 1.07–1.90). Looking at subgroups of circulatory system diseases, the difference in risk level for people with Stage II hypertension was largest for cerebrovascular diseases (ICD-10 codes I60–69): HR among SLT users was 5.01 (95% CI 2.79–8.99) compared to an HR of 1.04 (95% CI 0.53–2.03) among non-users who also had Stage II hypertension. These findings are highly relevant for India, where the prevalence of both tobacco use and hypertension is high[21].

CONCLUSIONS

Three large cohort studies from India have shown a significantly higher age-adjusted relative risk of death among SLT users. Corroborating this finding, four large studies in Western countries—two from Sweden and two from the United States—have also shown significantly higher mortality among smokeless tobacco users. In studies where women participated, the relative risk of death in women SLT users was higher than that in men.

These results call for a research response. Because available studies have indicated that female SLT users were at higher all-cause mortality risk than males, it would be important to further study gender differences in age-specific all-cause mortality among SLT users. Such studies should record the specific products being used by each participant. Consideration should also be given to assessing the health impact of SLT use, the simultaneous use of other tobacco products and alcohol, and other potentially confounding factors, such as BMI, blood pressure, and duration of SLT use, and adjustments for socioeconomic background should be made.

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Chapter 10

Smokeless Tobacco Use and Cancer

Surendra Shastri[1], Pankaj Chaturvedi[1], Sourav Datta[1],
Aditi Shastri[2]

[1]Tata Memorial Centre, Mumbai
[2]Albert Einstein College of Medicine, Bronx, NY, USA

INTRODUCTION

The cancer burden in India is large, with 2 to 2.5 million cancer patients at any given time and about 0.7 million new cases diagnosed every year. Nearly half of all cancer cases in India die every year. An estimated 34% cancers in the country are tobacco related[1]. Among these, cancers of the oral cavity and pharynx are important public health problems, with nearly 85,000 new cases among men and 34,000 among women in India each year. The mortality rates for these cancers in India are also high compared to the rest of the world (Table 10.1)[2]. The burden of cancers on the health system is such that existing treatment facilities and financial allocations are inadequate to treat the current load[3].

Table 10.1: Incident cancers of lip, oral cavity, and pharynx in India and in high-income and low- and middle-income countries of the world

Cancer site	India				High-income countries				Low- and middle-income countries			
	Incidence		Mortality		Incidence		Mortality		Incidence		Mortality	
	M	F	M	F	M	F	M	F	M	F	M	F
Lip and oral cavity	45,445	24,375	31,102	16,551	62,757	28,391	21,878	8,811	10,7739	64,133	61,231	35,734
Pharynx	39,191	9,413	34,207	7,551	4,4978	10,464	22,853	4,846	121,462	44,159	89,589	29,871
Total	84,636	33,788	65,309	24,102	107,735	38,855	44,731	13,657	229,201	108,292	150,820	65,605

Source: GLOBOCAN 2008 (Ferlay et al., 2010)[2].

In India, about 275 million adults use tobacco in one form or another. Of this number, 206 million use smokeless tobacco (SLT) in various formulations[4]. The most common forms of SLT use include khaini, betel quid (pan), and gutka[4] (as described elsewhere in the monograph). The International Agency for Research on Cancer (IARC) stated that there is *sufficient* evidence that SLT is carcinogenic and that it causes cancers of the oral cavity and pancreas[5]. In 2004, the IARC also concluded that betel quid with or without tobacco causes oral, pharyngeal, and oesophageal cancers[6]. Voluminous data demonstrates the carcinogenic and other toxic effects of SLT (see chapter 13)[5]. In this chapter we present the recent epidemiological evidence primarily from Indian sources linking SLT use with all cancers and with cancers in specific sites.

ASSOCIATION WITH CANCER

All Cancers

Information on the relationship between smokeless tobacco use and all cancers combined is available from two cohort studies. In a cohort study of 99,570 individuals in Mumbai, India, with 97.7% follow-up after an average of 5.5 years from the baseline house-to-house survey, the age- and education-adjusted relative risk (RR) for mortality from all cancers (neoplasms) for women SLT users was 1.57 [95% confidence interval (CI) 1.16–2.13]. For men SLT users, the corresponding RR was 1.4 (95% CI 0.95–2.06) [7]. The RRs were stratified and computed only among non-smokers—that is, no participant who used both SLT and smoked was included among the SLT users (Table 10.2).

Table 10.2: Number of deaths and relative risks* by cause of death and tobacco use

Cause of death (ICD-10 code)	Never used tobacco	Used smokeless tobacco
Men		
Neoplasms [C00–C97]		
Deaths	40	91
RR (95% CI)	1.0	1.40 (0.95–2.06)
Oral and pharynx neoplasms [C00–C14]		
Deaths	1	7
RR (95% CI)	1.0	3.72 (0.46–30.26)
Respiratory neoplasms [C30–C39]		
Deaths	6	19
RR (95% CI)	1.0	2.23 (0.82–6.04)
Women		
Neoplasms [C00–C97]		
Deaths	65	177
RR (95% CI)	1.0	1.57 (1.16–2.13)
Oral and pharyngeal neoplasms [C00–C14]		
Deaths	1	11
RR (95% CI)	1.0	2.74 (0.60–12.40)

* Age- and education-adjusted relative risk (RR) by using Cox model

Source: Gupta et al., 2005[7].

In another cohort of 87,222 men in Mumbai, with 649,228 person-years of observation, the incidence of all types of cancers was calculated by matching the cohort members with the database of the Population Based Cancer Registry, Mumbai. The adjusted hazard ratio (HR) for association of SLT use with the incidence of all cancers among non-smokers was 1.20 (95% CI 1.03–1.41), adjusted for age, education, religion, mother tongue, and body mass index[8] (see Table 10.3).

Table 10.3: Adjusted* site-specific HRs and 95% CIs by SLT use, based on incidence cancers in the Mumbai Cohort Study, 1991–2003

Cancer site	Non-users	SLT users
Neoplasms (C00-99)		
n	273	476
HR (95%CI)	1.0	1.20 (1.03–141)
Lip, oral cavity, and pharynx (C00–14)		
n	44	107
HR (95%CI)	1.0	1.48 (1.03,2.13)
Digestive organs (C15–26)		
n	76	159
HR (95%CI)	1.0	1.43 (1.07,1.90)
Oesophagus (C15)		
n	7	36
HR (95%CI)	1.0	3.65 (1.59,8.38)
Stomach (C16)		
n	16	31
HR (95%CI)	1.0	1.28 (0.67,2.43)
Liver and intrahepatic bile ducts (C22)		
n	9	31
HR (95%CI)	1.0	2.35 (1.08,5.10)
Pancreas (C25)		
n	5	15
HR (95%CI)	1.0	1.95 (0.68,5.54)
Respiratory and intrathoracic organs (C30–39)		
n	27	64
HR(95%CI)	1.0	1.71 (1.08,2.73)
Larynx (C32)		
n	9	26
HR (95%CI)	1.0	1.86 (0.85,4.06)
Bronchus and lung (C34)		
n	17	34
HR (95%CI)	1.0	1.59 (0.87,2.90)
Male genital organ (C60–63)		
n	33	26
HR (95%CI)	1.0	0.71 (0.41,1.23)

* Hazard ratios (HRs) were adjusted for age, education, religion, mother tongue, and body mass index (BMI).

Source: Pednekar et al., 2011[8].

Oral Cancer

Since the beginning of the 20th century, betel quid chewing with tobacco (pan) has been suspected of causing oral cancer[9]. During the decades since then, numerous case reports, case series, case control studies, and cross-sectional and prospective studies have established a causal relationship between tobacco use and oral cancer. It has been estimated that 90% of oral cancer cases in India are attributable to tobacco use of any kind (smoking and smokeless)[10]. A review by Boffeta and colleagues (2008) estimated that more than half of all oral cancers in India are caused by smokeless tobacco use: 52.5% among men, and 51.6% among women. This study also estimated the number of oral cancer cases attributable to SLT use per year in India to be 27,304 among men and 8,827 among women[11].

Cohort Studies

A cohort of 10,287 individuals in Ernakulam district was examined for oral cancer annually for 10 years. This examination found that the annual age-adjusted incidence rates of oral cancer were 23 per 100,000 person years among betel quid chewers, and 32 per 100,000 in dual users. No case of oral cancer occurred in those who did not use tobacco[12].

A cohort study of 99,570 individuals in Mumbai looked at the age-adjusted RR for mortality from oral and pharyngeal cancer. With 97.7% follow-up after 5.5 years in a house-to-house study, this study found that the RR for mortality from these cancers among women SLT users was 2.74 (95% CI 0.6–12.4), and for men SLT users the RR was 3.72 (95% CI 0.46–30.26) (Table 10.2)[7].

In the Mumbai cohort of 87,222 men, the hazard ratio calculated for incident cases (i.e., new cases) in the cohort for cancer of the lip, oral cavity, or pharynx was 1.48 (95% CI 1.03–2.13) (Table 10.3)[8].

In another large cohort of 78,140 women in Karungapally, Kerala, the age- and income-adjusted RR of oral cancer was 5.5 for current chewers (95% CI 3.5–9.0) and 9.2 for former chewers (95% CI 4.6–18.1). The dose–response relationship between pattern of use (daily frequency of tobacco use, duration of tobacco use, and age of initiating use) and cancer cases was highly significant[13].

Case Control Studies

Many case control studies on oral cancer have been conducted in parts of India where betel quid chewing is the predominant form of tobacco chewing. The first case control study on oral cancer and betel quid chewing was reported in 1933[14]. A dose–response relationship was computed from the data in this study. The odds ratio (OR) increased from 4.9 when betel quid was chewed once or twice per day, to 68.0 when chewed six or more times per day; when betel quid was held in the mouth while sleeping, the OR increased to a phenomenal 212.5[15].

In 2003, a case control study in two cancer hospitals in Southern India examined 1,563 oral cancer cases in men in comparison with 3,638 controls (1,711 disease controls with non-tobacco-related cancer, and 1,927 healthy male hospital visitors). The adjusted odds ratio (OR) was 5.1 (95% CI 4.3–6.0) for chewing betel quid with tobacco, and 2.2 (95% CI 1.6–3.0) for chewing betel quid without tobacco (Table 10.4). Dose–response relationships were found for the number of quids consumed per day, duration of the practice in years, and cumulative exposure. In a stratified analysis, smoking and drinking in addition to chewing increased the risk further[16].

In a large cross-sectional study in the Mainpuri district in northern India[17], two forms of SLT use were investigated: plain sun-cured tobacco (Pattiwala) and Mainpuri tobacco, which is a mixture of tobacco with finely cut areca nut, lime, and flavourings such as sandalwood powder, cardamom, cloves, and in one version, camphor. In this population-based study of 349,710 adults, a total of 346 oral and oropharyngeal cancer cases were detected. Chewers of Mainpuri tobacco had the highest prevalence ratio (defined as the number of confirmed oral cancer cases diagnosed during the study period, March 1964 to September 1966, per 100,000 population): 21.8. The unadjusted prevalence ratios were 3.3 for chewers of Pattiwala tobacco, and 11.5 for chewers of both forms of tobacco. A strong dose–response relationship was found with the frequency of chewing per day, age at initiation, duration of tobacco use, and exposure time in the mouth[17].

Table 10.4: Smokeless tobacco–related cancers in India: case control studies

Reference and location	Disease	Exposure category	Cases	Controls	Odds ratio	95% CI	Comments
Znaor et al., 2003[16] Men from Chennai and Trivandrum	Oral cancer	Never-users	711	3,079	1.0	—	Male controls were hospital patients and hospital visitors from Chennai, not matched for age Adjusted for smoking or chewing and drinking
		Chewing without tobacco	88	181	2.2	1.6–3.0	
		Chewing with tobacco	757	374	5.1	4.3–6.0	
		Among non-smokers only					
		Chewing without tobacco	24	83	3.4	2.0–5.7	
		Chewing with tobacco	159	123	9.3	6.8–12.7	
Wahi, 1968[17] Men and women from Mainpuri District	Oral cavity cancer	Chewing without tobacco	90	251,120	1.00	—	A cross-sectional study with follow-up component in a large population
		Pattiwala tobacco	84	71,526	3.28	+	
		Mainpuri and pattiwala	37	8,913	11.58	+	Univariate (unadjusted)
		Mainpuri tobacco	134	17,026	21.96	+	ORs calculated for this report
		Other tobacco	1	759	3.68	+	
Wasnik et al., 1998[18] Men from Nagpur, Maharashtra	Oropharyngeal cancer	Non-chewers	2	153	1.0	—	
		Tobacco	24	11	15.9	6.9–36.7	
		Areca nut	5	14	2.6	0.9–7.7	
		Tobacco + betel nut	14	10	10.2	4.1–25.5	Univariate (unadjusted)
		Betel quid + areca nut	7	18	2.8	1.1–7.4	
		Tobacco + betel quid + areca nut	52	40	9.5	5.1–17.5	Hospital patient controls matched on sex and age
		Dentifrice not containing tobacco	90	231	1.0	—	
		Dentifrice containing tobacco	33	15	5.7	3.0–10.8	

Reference and location	Disease	Exposure category	Cases	Controls	Odds ratio	95% CI	Comments
Nandakumar et al., 1990[19] Bangalore	Oral cavity cancer	Men					Hospital controls matched on area of residence, age, sex Adjusted for smoking and drinking
		Never-users	68	89	1.0	—	
		Chewing betel quid without tobacco	15	15	1.5	0.6–3.8	
		Chewing betel quid with tobacco	32	11	4.0	1.8–8.9	
		Women					
		Never-users	19	144	1.0	—	
		Chewing betel quid without tobacco	9	30	2.2	0.7–6.5	
		Chewing betel quid with tobacco	205	59	30.4	12.6–73.4	
Balaram et al., 2002[20] Bangalore, Madras, and Trivandrum	Oral cavity cancer	Men					Hospital controls, frequency matched with cases by age and gender Adjusted for demographic variables For men only, adjusted for smoking and drinking as well
		Never-users	127	232	1.0	—	
		Chewing betel quid without tobacco	15	6	4.2	1.5–11.8	
		Chewing betel quid with tobacco	139	37	6.1	3.8–9.7	
		Women					
		Never-users	29	251	1.0	—	
		Chewing betel quid without tobacco	14	5	16.4	4.8–56.5	
		Chewing betel quid with tobacco	222	31	45.9	25.0–84.1	
Znaor et al., 2003[16] Men from Chennai and Trivandrum	Pharyngeal cancer	Never-users	424	3,079	1.0	—	Hospital patient and visitor controls Adjusted for smoking and drinking Stratified among non-drinkers
		Chewers without tobacco	34	181	1.4	0.9–2.1	
		Chewers with tobacco	178	374	1.8	1.4–2.3	
		Among non-smokers only					
		Chewing without tobacco	5	83	1.6	0.6–4.2	
		Chewing with tobacco	25	127	3.7	2.5–4.9	

Reference and location	Disease	Exposure category	Cases	Controls	Odds ratio	95% CI	Comments
Znaor et al., 2003[16]	Oesoph-ageal cancer	Never-users	371	3,079	1.0	—	Hospital patient and visitor controls
		Chewing without tobacco	33	181	1.6	1.1–2.5	Adjusted for smoking and drinking
Men from Chennai and Trivandrum		Chewing with tobacco	160	374	2.1	1.6–2.6	
		Among non-smokers only					Stratified among non-drinkers
		Chewing without tobacco	9	83	3.3	1.5–7.1	
		Chewing with tobacco	35	127	5.7	3.5–9.4	
Phukan et al., 2001[22]	Oesoph-ageal cancer	Men					Hospital visitors selected randomly as controls
		Non-chewers	30	249	1.0	—	
Dibrugarh, Assam		Chewing betel quid with leaf tobacco	40	62	3.1	1.3–6.7	Adjusted for smoking and drinking
		Chewing betel quid with fermented areca nut + leaf tobacco (Dhapat)	82	54	7.1	3.5–6.7	
		Plain tobacco (Chadha)	68	84	4.9	2.8–11.6	
		Women					
		Non-chewers	34	153	1.0	—	
		Betel quid with leaf tobacco	25	14	4.3	1.5–9.7	
		Betel quid with fermented areca nut + leaf tobacco (Dhapat)*	25	16	3.6	1.4–9.2	
		Plain tobacco (Chadha)	15	8	3.4	1.3–5.6	
Phukan et al., 2005[24] Aizawl, Mizoram	Stomach cancer	Non-chewers	131	388	1.0	—	Hospital patient controls matched on age, sex and ethnicity
		Chewing tobacco with lime	25	20	2.6	1.1–4.2	
		Chewing betel quid and tobacco	54	54	2.0	1.3–5.3	Adjusted for drinking, tuibur, chewing, smoking and demographics, as appropriate
		Non-tuiber users	236	557	1.0	–	
		Tuibur users (current)	56	55	2.1	1.3–3.1	

Reference and location	Disease	Exposure category	Cases	Controls	Odds ratio	95% CI	Comments
Rajkumar et al., 2003[25] Women in Chennai	Cervical cancer	Never-users	167	198	1.0	—	Age-matched hospital patient and visitor controls Adjusted for demographics, age at marriage, number of pregnancies, husband's extramarital relationships
		Chewing betel quid without tobacco	10	6	2.6	0.7–9.8	
		Chewing betel quid with tobacco	28	9	2.1	0.8–5.9	
		Chewing < 5 betel quid per day	16	9	1.4	0.5–4.1	
		Chewing ≥5 betel quid per day	22	6	4.0	1.2–13.3	
Kaushal et al., 2010[27] Women - Population Based Cancer Registries of Northeast India	Breast cancer Mean age: 45.5 ±12.9 yrs	Non-chewers	32	112	1.0	—	Women hospital visitors matched on age Adjusted for smoking, tobacco chewing, and drinking
		Chewing betel quid	85	62	4.8	2.9–8.0	
Harish and Ravi, 1995[28] Men in Madras (Chennai)	Penile cancer	Non-users	+	+	1.0	—	Hospital controls matched on age Univariate analyses
		Chewing tobacco or areca nut or both	171	78	3.1	2.2–4.4	
		Chewing tobacco or areca nut or both ≤ 10 years	26	21	1.8	0.9–3.3	
		Chewing > 10 years	145	57	3.6	2.5–5.3	
		Use of snuff	27	8	3.4	1.5–7.4	

+ = Not Available

A case control study conducted in three hospitals in Nagpur, Maharashtra, identified 123 cases of oropharyngeal cancer[18]. Cases were matched for age and sex, with two hospital controls. In a multivariate analysis, tobacco chewing conferred the highest excess risk: OR=8.0 (95% CI 4.1–13.6), followed by smoking OR=2.3, (95% CI 1.2–3.7). A high risk of oral cancer was associated with use of tobacco dentifrices: OR=5.7 (95% CI 3.0–10.8)[18].

In a case control study in Bangalore with 348 cases and an equal number of matched controls, the OR for women was 30.4 (95% CI 12.6–73.4), and the OR for men was 4.0 (95% CI 1.8–8.9)[19].

In a multicentric study in Southern India with 591 cases of oral cancer and 582 hospital controls, the OR for chewing pan (betel quid) with tobacco among women was 45.8 (95% CI 25.0–84.1), and the OR among men was 6.1 (95% CI 3.8–9.7). Chewing pan without tobacco also posed an elevated risk for women [OR=16.4 (95% CI 4.8–56.5)] and for men [OR=4.2 (95% CI 1.5–11.8)]. Among women, chewing and poor oral hygiene accounted for 95% of oral cancers, while in men, 49% of oral cancers were ascribed to chewing, with most of the rest attributed to smoking, drinking, and poor oral hygiene[20].

SLT Use and the Increase in Oral Cancer Among Younger Individuals

Although the incidence of oral cancer in general may be declining, evidence of an increase in oral cancer case among individuals younger than age 50 was found over an 11-year period in Ahmedabad, Gujarat. This increase corresponded to a decrease in the age of occurrence of oral submucous fibrosis (OSF), a high-risk precancerous condition related to gutka use[21].

In South-East Asia, and especially in India, the relationship between smokeless tobacco use and oral cancer has been consistent. A summary of epidemiological studies in Asia and the United States gives an overall relative risk of oral cancer of 2.6 (95% CI 1.3–5.2) for smokeless tobacco use[11].

Pharyngeal Cancer

A large case control study with 636 male pharyngeal cancer patients and 3,638 male controls found that chewers of betel quid with tobacco had an adjusted OR of 1.8 (95% CI 1.4–2.3). The risk for chewing betel quid without tobacco was slightly elevated, but not significant (1.4; 95% CI 0.9–2.1). In a stratified analysis, chewers with tobacco who did not smoke or drink had an OR of 3.7 (95% CI 2.5–4.9). Smoking and drinking increased the OR to 13.4 (95% CI 8.9–20.3). Dose–response relationships were seen for number of quids per day, duration of use in years, and cumulative exposure[16].

Oesophageal Cancer

Cohort Study

In the Mumbai cohort of 87,222 men, the adjusted HR for association between SLT use and incidence cancers of oesophagus among non-smokers was 3.65 (95% CI 1.59–8.38) (Table 10.3)[7].

Case Control Studies

In a case control study of 566 oesophageal cancer patients from Southern India, chewers of betel quid with tobacco had an OR of 2.1 (95% CI 1.6–2.6), and the OR of those who chewed betel quid without tobacco was 1.6 (95% CI 1.1–2.5). Odds ratios were adjusted for age, institution where the disease was diagnosed, smoking, and drinking. Dose–response relationships were seen for number of quids per day, duration of use in years, and cumulative exposure[16].

A case control study in the state of Assam, with 358 male and 144 female oesophageal cancer patients and two matched controls per patient from among the hospital visitors, chewers of betel quid with tobacco and fermented areca nut (tamol) had the highest risk, with adjusted OR for males of 7.1 ($p<0.001$) and for females, 3.6 ($p<0.001$). Chewers of plain tobacco (chadha) had adjusted ORs of 4.9 for males and 3.4 for females, both with $p<0.001$. Thus, chewing tobacco by itself was quite carcinogenic, but when the tobacco was combined with areca nut, especially if fermented, the combination was highly carcinogenic[22].

Pancreatic Cancer

Pancreatic cancer is comparatively rare in India. In the Mumbai cohort of 87,222 men, the incidence was calculated by matching the cohort members with the database of the Population Based Cancer Registry, Mumbai. Although the number of pancreatic cancers identified was small, it did indicate an elevated HR of 1.95 (95% CI 0.68–5.54) in relation to SLT use, but this HR was not statistically significant (Table 10.3)[8].

The IARC evaluation of *sufficient* evidence of the relationship between SLT use and pancreatic cancer was based on Western studies. For example, a prospective cohort study in Norway, begun in 1966, found that 31.7% of 10,136 men used snus. Participants who had ever used snus regularly had an elevated relative risk of 1.7 (95% CI 1.1–2.5), adjusted for age and smoking[23].

Cancer of the Stomach and Other Digestive Organs

Cohort Study

In the Mumbai cohort of 87,222 men, the adjusted hazard ratio, based on incident cancers, for association between SLT use and cancer of the stomach was 1.28 (95% CI 0.67–2.43); for cancer of the liver and intrahepatic bile ducts, the HR was 2.35 (95% CI 1.08–5.10); and for all digestive organ cancers, the HR was 1.43 (95% CI 1.07–1.90)[8] (Table 10.3).

Case Control Study

A case control study with 372 cases of stomach cancer in Mizoram registered during 3 years (2001–2004)[23] showed an elevated risk for using tobacco with lime, with an OR of 2.6 (95% CI 1.1–4.2). For chewing betel quid with tobacco, the OR was 2.0 (95% CI 1.8–4.4). In Mizoram, tobacco-smoke-infused water, tuibur, is widely used; this product is retained in the mouth for some time before being spat out. The adjusted OR for current tuibur use was 2.1 (95% CI 1.3–3.1)[24]. A dose–response relationship was also found. Quitting tuibur use was associated with a reduced OR that was close to unity after 20 years of non-use. The fact that stomach cancer cases represented more than one-third (35.1%) of all cancer cases seen at the hospital indicates an even larger contribution of SLT use to cancer cases in Mizoram[24].

Respiratory Cancers

In the Mumbai cohort of 87,222 men, the adjusted HR, based on incidence cancers, for association between SLT use and cancers of the respiratory and intrathoracic regions was 1.71 (95% CI 1.08–2.73). The HRs for larynx and lung cancers, however, were only slightly elevated and not significant[8] (Table 10.3).

In the cohort study of 99,570 individuals in Mumbai, the RR for mortality from respiratory neoplasms among men SLT users was 2.23 (95% CI 0.82–6.04)[7] (Table 10.2). This association is noteworthy because animal experiments have shown that the target organ for SLT, including its main carcinogens NNN and NNK, is the lung [NNN = N'-nitrosonornicotine; NNK = 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone].

Results for Other Cancers Based on Single Studies

Cervical Cancer

Among 205 women with invasive cervical cancer and 213 age-matched control women in Chennai, India, pan chewing showed a dose-dependent direct association with invasive cervical cancer. For using ≥5 pan per day, the OR was 4.0 (95% CI 1.2–13.3), adjusted for demographic characteristics, marital status, age at marriage, number of pregnancies, and husbands' extramarital relationships[25].

A study of precancerous conditions of the cervix suggests an elevated risk of cervical cancer in women who chew pan with or without tobacco. In a study of 1,990 women attending rural cancer detection clinics in West Bengal, dysplastic cervical smears were found in 311 women, and cancer was found in 2 (for a total of 313 cases); 1,647 women (the controls) were without dysplasia. The unadjusted odds ratio for cervical dysplasia and cancer was 28.8 for betel quid chewing with or without tobacco, and 26.3 for betel quid with tobacco, suggesting mutagenic changes associated with prolonged use of betel quid[26].

Breast Cancer

In a multicentric study in North-Eastern India with 117 cases of breast cancer and 174 controls, betel quid chewing emerged as a major risk factor, with a nearly fivefold elevated risk [OR=4.8 (95% CI 2.9–8.0)] [27]. Further research is needed to shed more light on this apparent association of betel quid chewing with this very important cancer.

Penile Cancer

In a study of 503 penile cancer patients and 503 age-matched controls from Chennai, a significant association was found for chewing tobacco (OR=3.1; $p<0.001$) and snuff use (OR 3.4; $p=0.004$) after adjusting for tobacco smoking and other confounders[28]. This association however, was not confirmed in the Mumbai cohort (adjusted HR 0.71; 95% CI 0.41–1.23) (Table 10.4).

CONCLUSIONS

The evidence for relationship between the use of SLT and cancers in some anatomic locations is conclusive, whereas in other locations it seems suggestive. The most frequently affected site is the oral cavity, which is understandable because of the intimate contact of SLT with the oral mucosa. Studies conducted around the world have produced very strong data in support of this relationship, ranging from no increased risk in some studies in Sweden[29], to a 61-fold excess risk in women using snuff in the United States[30]. Different levels of carcinogens in tobacco products in different countries, caused by varying methods of curing, processing, and storing tobacco, may be largely responsible for these differences[29]. In general, tobacco used in India contains high levels of carcinogens, and it is also often used with areca nut in some form, which contains carcinogens of its own.

Cancers in other contiguous sites such as the pharynx, oesophagus, and stomach have also showed some association with SLT use. A link is also emerging between SLT use and cancer in areas of the body distant from the site of SLT use, such as the cervix uteri, breast, penis, and pancreas. While such relationships are biologically plausible, considering the carcinogenicity and toxicity of SLT products, more extensive epidemiologic studies are needed to understand the development of cancers in these sites.

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Chapter 11

Cardiovascular Diseases and Other Health Consequences of Smokeless Tobacco Use

Salman Salahuddin[1], Sailesh Mohan[2],
Ambuj Roy[1], K. Srinath Reddy[2]

[1]All India Institute of Medical Sciences, New Delhi
[2]Public Health Foundation of India, New Delhi

INTRODUCTION

Tobacco use is well known to increase the risk of developing cardiovascular disease (CVD). Tobacco use accelerates atherosclerosis, increases myocardial workload, causes coronary vasoconstriction, reduces the oxygen-carrying capacity of the blood, increases catecholamine release, and induces a hypercoagulable state, leading to an increased risk for acute coronary syndromes. Accelerated atherosclerosis due to tobacco smoking is mediated by various mechanisms including an adverse effect on lipid profiles, endothelial dysfunction, oxidative stress, neutrophil activation, increased fibrinogen levels, and increased thrombosis[1,2].

According to an analysis of data from the Global Adult Tobacco Survey (GATS) 2009-2010, it is estimated that 247 million people out of 3 billion people from 16 countries surveyed use smokeless tobacco (SLT). Nearly 83% (206 million) of these SLT users live in India[3]. In most countries, cigarette smoking is responsible for most of the tobacco-attributable burden of CVD, but in India the very high rate of SLT use—which is much more prevalent than smoking, particularly among women—requires scrutiny to determine if it causes a significant proportion of tobacco-attributable CVD[4,5]. This chapter will review the association between SLT use and CVD and other diseases.

COMPONENTS OF TOBACCO AND THEIR ROLE IN CARDIOVASCULAR DISEASE

SLT products have been shown to contain a large array of chemical compounds, including nicotine, aldehydes, hydrocarbons, nitrosamines, polycyclic aromatic hydrocarbons (PAHs), alkaloids, and metals[6,7]. Because of the variety of SLT products and their diverse preparation techniques, these products differ widely in their nicotine and chemical content. Nicotine is the major addictive alkaloid in tobacco. Other minor alkaloids include anatabine, nornicotine, and anabasine[8]. Detailed reviews of the various components of smokeless tobacco are presented in other chapters of this report.

It has been demonstrated that peak levels of nicotine are similar after a single exposure to either SLT or cigarette smoking[9]. SLT use causes more prolonged and sustained nicotine levels, often lasting for an hour, unlike cigarette smoking, which produces peaks and troughs in nicotine levels. The rate of nicotine absorption may vary with different forms of SLT depending on the pH level of the product, the amount of nicotine, and size of the tobacco cutting. Benowitz and colleagues (1988)[9] showed that all the different brands of SLT produced higher venous concentrations of nicotine than those observed with cigarette smoking (see Table 11.1).

Table 11.1: Bioavailability and amount of nicotine absorbed per unit dose and time to maximum venous blood concentration of nicotine

Product	Bioavailability per dose	Time to maximum concentration
Cigarette	1–2 mg	5 minutes
Nicotine gum	1 mg, 2 mg	30 minutes
Nicotine inhaler	2 mg/cartridge	20–30 minutes
Nicotine nasal spray	0.5 mg	10 minutes
Nicotine patch	15–22 mg	4–9 hours
Smokeless tobacco	3.6–4.5 mg	20–30 minutes

Sources: Benowitz et al., 1988[9] and Fant et al., 1999[10].

PATHOPHYSIOLOGICAL MECHANISMS IN THE DEVELOPMENT OF CARDIOVASCULAR DISEASE

Acute cardiovascular effects, similar to those caused by cigarette smoking, are seen with the use of SLT. They include an increase in heart rate and blood pressure levels, with maximum cardiovascular effects preceding maximum blood nicotine levels[10]. Although the blood nicotine levels remain high, an acute tolerant effect to nicotine is seen after 15 minutes, with a decrease in heart rate. Martin and colleagues[11] examined the acute effect of a single dose of SLT on central aortic blood pressure and wave reflection characteristics. An acute dose of SLT was associated with a significant increase in heart rate, central aortic systolic and diastolic blood pressure, peripheral brachial systolic and diastolic blood pressure, and aortic augmentation index normalised to a fixed heart rate of 75 beats per minute.

Tobacco exerts its adverse effects on atherothrombosis and progression of atherosclerosis through several pathophysiological pathways. These include vascular and endothelial dysfunction, inflammation, induction of a prothrombotic state, derangement of lipid profile, and insulin resistance[12]. Most of the data for these pathobiologic mechanisms are derived from studies of cigarette smoking and its effect on CVD. Pathophysiological explanations for links between SLT use and cardiovascular disease are limited.

Tobacco contains *N*-nitrosamines and other alkaloids, which form highly reactive electrophiles and increase oxidative stress. Free-radical-mediated oxidative stress may play a central role in development of atherosclerosis. SLT extract has been shown to be more toxic in vitro than pure nicotine and to increase oxidative stress as a result of reactive oxygen free radicals[13], and SLT users tend to have lower levels of α- and β-carotene in the body. Similarly, smokers also have been shown to have lower levels of antioxidant vitamins than nonsmokers. Overall, increased oxidative stress may promote lipid peroxidation and increase deposits of atherosclerotic plaques in SLT users, and may be responsible for progression of atherosclerosis[12,13].

CARDIOVASCULAR MORTALITY

Overall, mortality rates related to tobacco have increased significantly over the past decade, as demonstrated by the Global Burden of Disease Study 2010. Tobacco was responsible for 6.3 million deaths worldwide in 2010, as compared to 5.3 million deaths in 1990, although these data reflected mortality primarily from smoking and exposure to secondhand smoke[14]. It is projected that tobacco deaths in India will increase from the current number of about 1 million each year and exceed 1.5 million annually by 2020[15,16]. However, mortality estimates attributable to SLT use are limited; only a few studies have addressed cardiovascular mortality and SLT use.

Among the Indian studies, a large cohort study in Mumbai reported increased relative risks (RR) of death for both men and women who used SLT (mainly in the forms of mishri and betel quid). Interim results were based on 52,000 study participants who were followed up for 5–6 years. The age-adjusted RR for SLT users when compared with non-tobacco users was 1.2 for men and 1.4 for women, with a suggestion of a dose–response relationship for daily frequency of use[17]. Gupta and colleagues studied a cohort of 10,287 individuals age 15 years and older in Ernakulam, Kerala, who were followed for 10 years. The relative risk of death for men who were chewers (mainly pan with tobacco) was 1.2 (non-significant), and among women chewers it was 1.3 ($p<0.05$). For men who smoked (mainly bidis) the relative risk was 1.5 ($p< 0.05$)[18]. In another cohort study in Srikakulam district, Andhra Pradesh, 10,169 individuals were followed for 10 years. The predominant habit was reverse chutta smoking, but some of the men were tobacco chewers; 41 deaths were recorded during 1,460 person-years of observation, which indicated an age-adjusted relative risk of 2.0[19].

Bolinder and colleagues studied about 135,000 Swedish construction industry employees and followed up with them over a 12-year period. SLT users had an age-adjusted relative risk of 1.4 [95% confidence interval (CI) 1.2–1.6] of dying from CVD compared with non-tobacco users, whereas the relative risk of death among smokers was 1.9 (95% CI 1.7–2.2)[20]. The authors concluded that both SLT and smoking increase the risk of dying from CVD, the risk being lower in SLT use than in smoking.

Data from two prospective American studies offer evidence that SLT use may increase cardiovascular-related mortality. The hazard ratio (HR) of mortality from coronary heart disease (CHD) in Cancer Prevention Study-I (CPS-I) was 1.1 (95% CI 1.03–1.2), and in CPS-II it was 1.3 (95% CI 1.1–1.5)[21]. Accortt and colleagues evaluated 20-year mortality data from the First National Health and Nutrition Examination Survey and Epidemiologic Follow-Up Study and found no association between SLT and cardiovascular mortality (HR=1.1, 95% CI 0.8–1.5) or between SLT and mortality from all causes (HR=1.1, 95% CI 0.9–1.3). Furthermore, the combined use of SLT and cigarettes did not increase overall mortality beyond that expected from use of the individual product alone[22].

These studies collectively indicate that the cardiovascular mortality associated with the use of SLT is significant when compared with that of non-tobacco users, emphasising the need for effective tobacco control policy interventions.

CARDIOVASCULAR MORBIDITY

Because the term ‘smokeless tobacco’ covers such a wide array of products, describing epidemiological associations between SLT use and disease is difficult[23]. Smokeless tobacco as used in Sweden has been linked to pancreatic cancer[24,25] and cardiovascular disease[26,27], but does not appear to be linked with other malignancies[28,29]. In North America, use of moist snuff and chewing tobacco is associated with oral malignancies, as well as cancers at other sites, and with cardiovascular disease[30]. For SLT products used in South Asia, there is considerable evidence for oral cancer and other adverse health effects[31,32]. Previously, SLT use was considered a possible alternative to cigarette smoking that could lessen the harm associated with tobacco smoking.

However, enough data exist to show that all forms of tobacco cause harm, and the quantum of harm differs depending on the product used. The various cardiovascular effects of SLT are summarised below.

Myocardial Infarction

Data from the Indian subcontinent come from the large international INTERHEART study. This study demonstrated that the use of SLT, especially chewing tobacco, was most common in the Indian subcontinent. The odds ratio (OR) of acute myocardial Infarction (MI) was 2.2 among those who used only SLT compared with those who never used any tobacco. This OR was similar to that of current cigarette smokers (OR=2.9) when compared with those who used no tobacco. The highest risk related to tobacco use was the risk for acute MI among smokers who also used SLT (OR=4.1), suggesting that some of the toxicants involved in the elevated cardiovascular risk could be contained in both smoking and smokeless products[33].

Smaller studies have shown similar results. Ram and colleagues, studying 135 patients with coronary artery disease, observed a significant association between smokeless tobacco consumption and coronary artery disease (OR=2.1)[34]. Rahman and colleagues showed that smokeless tobacco consumption in Bangladesh was strongly associated with CHD after adjusting for smoking and other confounders (adjusted OR=4.0, 95% CI 2.0–8.1)[35]. Zhang and colleagues, in a meta-analysis involving eight studies from South and East Asia, showed an association between betel nut chewing with or without tobacco and the risk of CVD, with a RR of 1.3 (95% CI 1.1–1.4)[36]. A 2012 case control study in Bangladesh reported no association between SLT use and CHD in general, but found a significant increase in CHD risk (OR 2.9, 95% CI 1.3–6.7) among users of gul, a local SLT product made with tobacco powder, molasses, alkaline modifiers, and other ingredients, which has a high nicotine content[37].

In a small clinic-based study in Jodhpur, measures of arterial stiffness, which predict CVD events, were found to be higher in women SLT users compared with non-users. Both average pulse wave velocity and arterial stiffness index were elevated in women SLT users compared with their non-user counterparts[38].

Several international population-based studies, most of which were done in Sweden, have investigated the risk for fatal and nonfatal CHD events in SLT users and produced somewhat heterogeneous results. In the Vasterbotten Intervention Program and the WHO-MONICA (Monitoring of Trends and Determinants in Cardiovascular Disease) study in northern Sweden, Wennberg and colleagues evaluated risk of first MI and sudden cardiac death among male snuff users and demonstrated no increased risk for current snuff users compared with non-tobacco users[39]. Other case control studies found no increase in the risk for fatal or nonfatal MI among snuff users living in Sweden[40-42]. However, a study by Hergens and colleagues evaluating long-term cardiovascular outcomes suggests that snus use is associated with an increased risk of fatal MI. During a 19-year follow-up of Swedish construction workers, Hergens and colleagues found an increased risk of fatal MI among people who had ever used snuff [past snuff users + current users (RR=1.3, 95% CI 1.1–1.6)], but no increase in the RR of nonfatal MI (RR=0.9, 95% CI 0.8–1.0) in ever snuff users[43].

In Cancer Prevention Study I (CPS-I) (subjects were enrolled in 1959 and followed up in 1972) and Cancer Prevention Study II (CPS-II) (subjects were enrolled in 1982 and followed up in 2000), current SLT use was associated with an increased hazard ratio for mortality related to

CHD and cerebrovascular disease[21]. Another study, the Atherosclerosis Risk in Communities (ARIC) study, examined whether current use of smokeless tobacco was associated with increased incidence of CVD. Among the 14,498 male and female participants ages 45–64 years, there were 2,572 incident CVD events during a median of 16.7 years of follow-up. Current use of smokeless tobacco at baseline was associated with an incidence of CVD that was 1.3 times greater (95% CI 1.1–1.5) than that associated with non-use, independently of demographic, socioeconomic, lifestyle, and other tobacco-related variables[44].

Two meta-analyses have systematically reviewed the risk of CVD in SLT users. In a review of eight studies, Lee and colleagues found that SLT use was associated with an increased risk of heart disease (RR=1.1, 95% CI 0.9–1.3)[45]. Boffetta and colleagues analysed 11 studies conducted in the United States and Europe and reported that ever use of SLT products was associated with an RR of 1.1 (95% CI 1.1–1.2) for fatal MI[26].

To summarise, data derived from the majority of the Swedish studies, where snuff/snus is the major form of SLT, have not demonstrated significant increase in risk of MI. However, data from the large INTERHEART study, the CPS-I and CPS-II studies, the Bangladesh study by Rahman and colleagues, and the meta-analyses mentioned above indicate an increased risk of development of MI. This heterogeneity reported in the risk of MI among SLT users in these different studies is likely to be attributable to the use of different types of SLT products and/or different patterns of SLT use in the various study groups or countries, as well as different research designs and methods.

Hypertension

Some evidence indicates that SLT may be a risk factor for hypertension and dyslipidemia, though perhaps to a lesser extent than smoking. Because of the sympathicoadrenal-activating properties of nicotine and the relatively high sodium content as well as the presence of licorice in some products, SLT has the potential to affect blood pressure. Licorice inhibits the mineralocorticoid metabolism and indirectly causes sodium retention, thereby increasing blood pressure (BP) levels[46]. Wolk and colleagues found that in healthy young men, SLT use increased mean BP by 10±1 mm Hg and heart rate by 16±2 beats per minute. These authors concluded that SLT is a powerful autonomic and haemodynamic stimulus[47]. In a study of ambulatory 24-hour blood pressure monitoring in healthy middle-aged participants, ambulatory daytime diastolic blood pressures were significantly elevated, on average by 5 mm Hg, in both smokeless tobacco users and smokers ($p < 0.001$) compared with non-users[48].

A study of Assam tea garden workers found that the consumption of locally prepared alcohol, intake of extra salt, and the habit of using khaini independently increased the risk of hypertension[49]. Another study found a statistically significant increase in heart rate and BP following the chewing of betel quid with tobacco for 15–30 min, whereas no significant differences were found after chewing betel quid without tobacco[50]. Pandey and colleagues, in a community-based cross-sectional study in Faridabad, India, showed that the mean systolic and diastolic blood pressure was significantly higher in exclusive SLT users as compared with non-users[51]. In a small case control study in Bikaner in North-Western India, Gupta and colleagues found a significantly greater prevalence of hypertension, hypercholesterolemia, hypertriglyceridemia, radiographic cardiomegaly, and positive stress test results in tobacco chewers as compared to controls[52]. Pednekar and colleagues found that mortality was significantly higher among SLT users with stage 2 hypertension than among non-users and normotensives from different categories of CVD such as circulatory diseases (HR=2.5, 95% CI 1.9–3.2), hypertensive diseases (HR=3.0, 95% CI 1.4–6.5), ischaemic heart disease (HR=2.0, 95% CI 1.4–2.9), and cerebrovascular diseases (HR=5.0, 95% CI 2.8–9.0)[53].

Dyslipidemia

Khurana and colleagues, in a study comparing serum lipid profile in 30 smokers, 30 tobacco chewers, and 30 controls without any tobacco habit, found that high-density lipoprotein cholesterol was lower in both smokers ($p<0.01$) and tobacco chewers ($p<0.001$) compared with the controls. This study also found that both smokers and tobacco chewers had higher values for total cholesterol, low-density lipoprotein cholesterol, very low-density lipoprotein cholesterol, and triglycerides as compared with controls. Thus, both smoking and tobacco chewing demonstrated comparable adverse effects on lipid profile and could be responsible for increasing cardiovascular risk[54]. In a study of U.S. adults, Tucker found that both SLT use and smoking play a part in causing hypercholesterolemia. Hypercholesterolemia was 2.5 times more common among SLT users, 2 times more common among heavy smokers, and 1.5 times more common among mild-to-moderate smokers compared with non-users[55].

Stroke

Henley and colleagues found that SLT use could increase mortality from stroke in the CPS-I (HR=1.5, 95% CI 1.3–1.6) and CPS-II studies (HR=1.4, 95% CI 1.1–1.8)[21]. However, a Swedish study by Asplund and others showed no association between SLT use and stroke[56]. SLT use was found to be associated with an increased risk of fatal stroke in meta-analyses by Lee[45] (RR=1.4, 95% CI 1.3–1.6, n=5 studies) and by Boffetta[26] (RR=1.4, 95% CI 1.3–1.5, n=5 studies). In another study, current use of snuff increased the risk of fatal ischaemic stroke (RR=1.7, 95% CI 1.1–2.8), but not haemorrhagic stroke among Swedish construction workers[57]. Data from India that could demonstrate an association between use of smokeless tobacco and an increased risk of stroke, if any, are scarce.

SMOKELESS TOBACCO USE AND OTHER DISEASES

Diabetes

A substantial body of scientific evidence has accumulated over the past two decades about a possible role of tobacco smoking in the development of diabetes. The health risks of smoking are reported to be higher for people with diabetes than for the general population. Multiple epidemiological studies (both case control and cohort) have identified smoking as a potential risk factor for diabetes[58,59]. However, the evidence linking SLT to diabetes is limited; it is mostly related to snuff use and largely derived from studies in the United States and Sweden. These studies have reported on SLT use and its impact on diabetes, glucose intolerance, glucose levels, insulin levels, and insulin resistance[45]. A Swedish study, one of the few to report an association, found that current snuff users who never smoked had higher diabetes prevalence (OR=3.9, 95% CI 1.1–14.3) compared to never-users[60]. In 2012, prospective data from Sweden provided evidence linking high snus use with development of diabetes. Weekly snus use of >5 boxes was associated with increased risk (OR=3.3, 95% CI 1.4–8.1) of developing diabetes over a 10-year period among men without diabetes at baseline[61].

Evidence from India on this question is limited. Among 444 males with diabetes attending public sector hospitals and belonging to low and middle socioeconomic groups in Kerala, 10% reported current SLT use, which was little more than half the current smoking prevalence (23%) in this sample. About 2% shifted from smoking to SLT use as a form of harm reduction. Associations were not examined in this study[62].

Tuberculosis

While the relationship between smoking and tuberculosis (TB) is now well established, the link between smokeless tobacco use and TB is less clear. A 2005 analysis of the Bombay Cohort Study reported an increased risk of death from TB among SLT users compared with never tobacco users, but this risk was lower than that among smokers. The RR of death from TB among SLT users of all ages was 1.5 (95% CI 1.1–2.0) compared with never tobacco users, and 1.6 (95% CI 1.1–2.2) at ages 35–69 years. But among women SLT users, this risk was not statistically significant (RR=1.4, 95% CI 0.9–2.0)[53]. In a 2012 analysis of this study that examined the joint effects of tobacco use and body mass, using smokeless tobacco and being underweight was associated with mortality from TB: 22% of TB deaths among men and 37% among women were attributable to using SLT and being underweight[63].

Few Indian studies have reported SLT use among TB patients. Among 215 male TB patients in Kerala who underwent assessment for tobacco use at different time points in their TB diagnosis and treatment trajectory, 22% used SLT 6 months before TB diagnosis, a percentage that decreased to 10% one week after diagnosis and increased to 13% after treatment[64]. Recent data from Karnataka indicate that 44% of TB patients used SLT 6 months prior to being diagnosed, which decreased to 8% during treatment and increased to 27% after completion of treatment. The relapse rate at 6 months post-treatment was higher for SLT users (52%) than for smokers (36%). Notably, patients advised to quit smoking continued using SLT and resorted to harm reduction by shifting from smoking to SLT use[65]. This perhaps indicates the need for TB control programmes to address cessation requirements not only of smokers but of SLT users as well to improve health outcomes.

Asthma

Patients with asthma who chew areca nut have been reported to exacerbate their condition, probably due to the broncho-constricting effect of the arecoline contained in the nut[66,67]. Few studies have investigated this relationship, however, particularly in India.

Other Respiratory Diseases

In the Bombay Cohort Study the RR of death from respiratory diseases among men who used SLT was 1.5 (95% CI 1.1–2.0) compared with non-users, but among women the risk was not elevated[53]. An investigation of snuff use in South African women aged ≥25 years indicated that compared with non-users, heavy snuff users (>8 times daily) had a higher risk (OR=2.9, 95% CI 1.2–7.0) of chronic bronchitis; they also had lower peak expiratory flow rates, an indicator of sub-optimal respiratory function[68].

Cataract

Tobacco smoking has been reported to be a risk factor for various eye disorders such as cataract, age-related macular degeneration, and glaucoma[69], but the relationship between SLT use and cataract development has not received much research attention. A study that examined this question among 3,924 people in Chennai, India, found an association between SLT use and the development of cataract. The adjusted OR for developing cataract among SLT users was 1.5

(95% CI 1.2–2.0), and the OR for developing nuclear cataract was even higher, at 1.7 (95% CI 1.2–2.4). The prevalence cataract was markedly higher among SLT users (74%) compared to smokers (53%) and non-tobacco users (51%)[70].

Infertility in Men

Lifestyle habits such as tobacco smoking have been reported to influence fertility by impacting sperm concentration, function, and quality[71]. The impact of smokeless tobacco use on fertility is less clear. In a clinic-based cross-sectional study of 638 infertile men in Mumbai, SLT use was associated with a decrease in sperm count, motility, morphology, and viability[72].

RESEARCH GAPS

Despite the fact that India is home to more than 80% of the world's SLT users, limited research has been conducted in India on the links between SLT use, CVD, and other diseases. Indian SLT products are vastly different from those used in Western countries, where most of the research on the association between SLT use, CVD, and other diseases has been performed. In addition, SLT use is much less prevalent in Western countries and is concentrated in specific population groups, whereas SLT use in India is widespread and increasing across different population groups; these factors increase the likelihood that SLT use in India is a major cause of death and disease.

However, population estimates of morbidity and mortality attributable to smokeless tobacco use are unavailable. Establishing such estimates should be a major research priority. Large, well-designed studies with representative samples are required to determine epidemiological associations between commonly used forms of SLT and development of CVD and other diseases in India. Research is also needed on cessation strategies that can help SLT users quit, as well as policy research on advancing tobacco control strategies to reduce SLT use. Such data can contribute to evidence-informed advocacy and tobacco control efforts to combat SLT use in India.

CONCLUSIONS

SLT use was previously thought to be free of significant adverse effects and was advocated as a harm reduction strategy in cigarette smokers. Current evidence refutes this assumption, however, and suggests that SLT use is associated with cardiovascular disease. Most studies suggest that cardiovascular risk is lower among SLT users than among smokers, but higher than among non-users of tobacco. Studies from the Indian subcontinent related to smokeless tobacco and its effects on the cardiovascular and other systems are limited. India's position as one of the largest consumers of smokeless tobacco necessitates more robust research to elicit the linkages between smokeless tobacco use and adverse health effects.

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Chapter 12

Oral Health Consequences of Smokeless Tobacco Use

Vijay Mathur[1], Tanupriya Gupta[2], Manu Raj Mathur[3],
Paluri Rama Murti[4]

[1]All India Institute of Medical Sciences, New Delhi

[2]Jamia Millia Dental College, New Delhi

[3]Public Health Foundation of India, New Delhi

[4]Formerly with the Basic Dental Research Unit and WHO Collaborating Centre for Oral Cancer Prevention, Tata Institute of Fundamental Research, Mumbai, and (Retired) Professor of Oral Pathology; Former Director, School of Dentistry, Faculty of Medical Sciences, The University of the West Indies, St. Augustine, Trinidad and Tobago, West Indies

INTRODUCTION

As of 2010, 206 million people in India use a great variety of smokeless tobacco (SLT) products (see Appendix 1) of which khaini, gutka, and betel quid with tobacco (pan) are the most frequently used[1]. Thus, SLT users represent a vast pool susceptible to adverse oral and general health consequences. SLT is often used in combination with other ingredients, including areca nut (*Areca catechu*), which also has important consequences for oral health. Both SLT and areca nut deliver many deleterious carcinogenic and toxic products (see chapter 13), collectively endangering oral health. This chapter discusses the health consequences of the whole SLT product, rather than its tobacco content alone.

The most serious oral health implication of SLT use is oral cancer, which is discussed along with other cancers in chapter 10. This chapter gives an overview of other serious outcomes such as precancerous lesions and conditions, currently called potentially malignant disorders by the World Health Organization (WHO) Working Group (2007)[2], which include other mucosal lesions that are less likely to become cancers[3], and the impact of SLT use on periodontal health and other dental effects.

ORAL PRECANCEROUS LESIONS AND CONDITIONS (POTENTIALLY MALIGNANT DISORDERS)

Various terms are used in the literature to denote this category. The term *precancer* refers to apparently benign mucosal alterations that can in the long run undergo malignant transformation[2]. Primary prevention of oral cancer consists of recognising and managing these potential malignancies, which highlight the need for curbing SLT use. Extensive pioneering long-term studies on these lesions in India[4] have produced valuable information on the natural history of precancer.

In 1978 the WHO Working Group distinguished between precancerous lesions and conditions[5]. The Working Group defined a *precancerous lesion* as a morphologically altered tissue in which cancer is more likely to occur than in its apparently normal counterpart. Examples included leukoplakia, erythroplakia, and palatal keratosis in reverse smokers. A *precancerous condition* was defined as a generalised state associated with a significantly increased risk for cancer. Precancerous conditions included submucous fibrosis, actinic keratosis, lichen planus, and discoid lupus erythematosus. The consensus view of another WHO Working Group, in 2007, was 'to refer to all clinical presentations that carry a risk of cancer under the term "potentially malignant disorders"[2]. Leukoplakia, erythroplakia, palatal lesions in reverse smokers, oral submucous fibrosis, lichen planus, discoid lupus erythematosus, and a few other hereditary disorders were from then onwards considered potentially malignant disorders. These disorders and their relation to SLT use are described in the sections below.

Leukoplakia

Definition

Leukoplakia was defined by the WHO (1978) as 'a white patch or plaque that cannot be characterised clinically or pathologically as any other disease'[5]. International Working Groups have amended this definition several times since. In 2007 the WHO Working Group redefined leukoplakia as 'white plaques of questionable risk, having excluded (other) known diseases or disorders that carry no increased risk for cancer'[2]. Leukoplakia is a clinical term and carries no histologic connotation. The most important microscopic feature of prognostic value, however, is the presence of epithelial dysplasia.

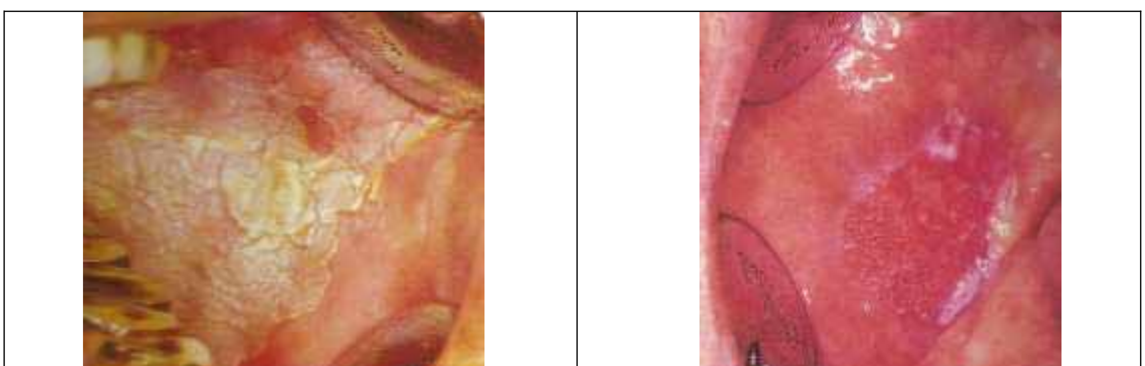
Epidemiology of SLT Use and Leukoplakia

The use of a mixture of tobacco and lime (e.g., khaini) is widespread in Maharashtra. In a large epidemiologic survey among 101,761 villagers in that state, the prevalence of leukoplakia among tobacco chewers (mostly tobacco-lime, or khaini users) was 11.8 per 1,000, whereas its prevalence in mishri users was 1 per 1,000[6]. In a case series report of 2,920 leukoplakia cases in Odisha in 2005, 28% occurred among betel quid chewers, 16% among khaini users, 10% among gudhaku users, and 8% among gutka users[7]. An older study from North India showed that the use of Mainpuri tobacco increased the risk for leukoplakia considerably[8]. In a random sample of 10,169 villagers in Ernakulum district, Kerala, the prevalence of leukoplakia among betel quid chewers was 18 per 1,000, and the prevalence among dual users was 61 per 1,000[9]. A 10-year follow-up study of the same population in Ernakulum district showed that the age-adjusted incidence rates (AAIR) among betel quid chewers were 2.5 per 1,000 person-years among men, and 3.0 among women[10]. Dual use (betel quid chewing and smoking) showed the highest AAIR: 6.0 per 1,000 person-years. No new leukoplakia cases were observed among non-users of tobacco.

Clinical Aspects

Leukoplakia is diagnosed under two categories, homogeneous and non-homogeneous, depending upon the patient's clinical appearance[2]. This distinction provides the clinician with behavioural/ management perspectives because the two types have different likelihoods of malignant transformation (see Natural History, below). Homogeneous leukoplakia lesions are uniformly flat and thin and may exhibit shallow cracks in the surface keratin (Figure 12.1A). Non-homogeneous types, such as the nodular types (also known as speckled leukoplakia), show mixed white and red areas, but retain a predominantly white character[2] (Figure 12.1B). Some leukoplakia lesions, often seen in bidi smokers, are marked by an ulcerated area surrounded by keratinised areas and are called ulcerated leukoplakias[4].

Figure 12.1: Homogenous leukoplakia (A) and nodular leukoplakia (B) in the buccal mucosa



(A)	(B)

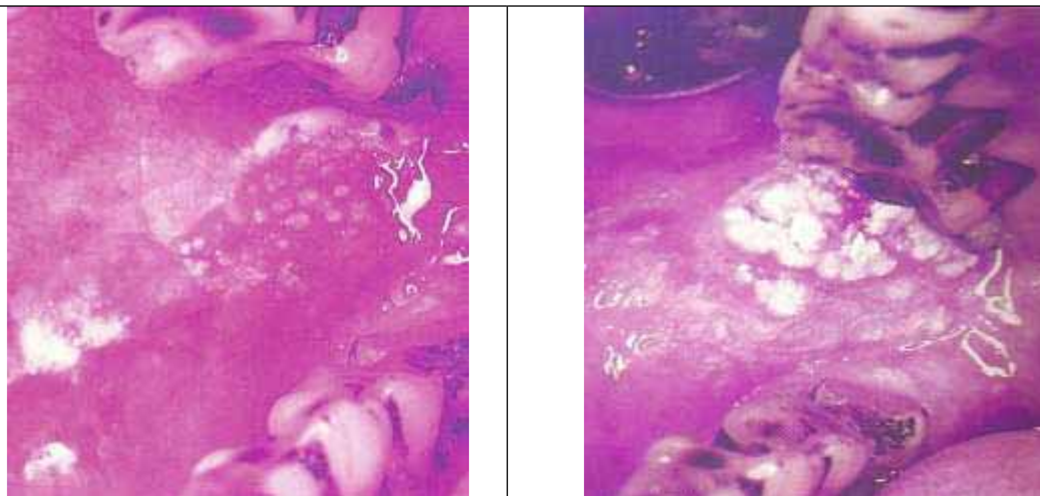
Photograph courtesy of Dr. Vijay Mathur.

Leukoplakias generally are correlated with a particular oral site and type of use. For example, leukoplakia among betel quid chewers occurs more often on the buccal mucosa where the betel quid is placed, whereas leukoplakia associated with khaini use occurs more in the anterior region where the khaini is habitually held[3].

Natural History

In a 10-year follow-up study among Indian villagers, 7% of the 94 cases found among betel quid chewers progressed to cancer, in contrast to 4% of the 85 leukoplakia cases observed among dual users[10]. Leukoplakia lesions associated with betel quid use were less persistent (25%) and regressed spontaneously more often (57%). Homogeneous leukoplakia showed malignant transformation in 2% and nodular leukoplakia, in 21% of cases (Figure 12.2).

Figure 12.2: (A) Nodular leukoplakia in the buccal mucosa at the site of placement of betel quid; and (B) showing cancer development after two years



(A) (B)

Photograph courtesy of Dr. Vijay Mathur.

The relative risk (RR) for malignant transformation of homogeneous leukoplakia was 25.6, whereas the RR for malignant transformation of nodular leukoplakia was 3,243, when compared with people who practiced some kind of tobacco use but did not have any lesions (Table 12.1)[11].

Table 12.1: Relative risk for malignancy associated with various precancerous lesions and conditions

Precancer lesion / condition	Total no.	Average follow-up period (years)	No. of oral cancers	Transformation per 100,000 per year	Relative risk
Nodular leukoplakia	13	2.8	6	16,216.2	3,243.2
Submucous fibrosis	25	6.0	3	1,986.7	397.3
Others*	26	2.6	1	1,515.2	303.0
Ulcerated leukoplakia	105	4.4	1	218.8	43.8
Homogeneous leukoplakia	489	4.8	3	128.1	25.6
Lichen planus	344	3.7	1	78.9	15.8
None of the above	10,145	7.8	4	5.0	1.0

*Nonspecific diagnoses such as ulcers, benign growths, red areas.
Source: Gupta et al., 1989[11].

Management

Detection and management of leukoplakia prevent progression to oral cancer. Specific management protocols have been suggested[2]. Gupta and colleagues (1986) found that counselling leukoplakia patients about tobacco use cessation is an effective preventive step, as it can lead to regression of the lesion [12]. Several biomarkers have been described[13], but the presence of epithelial dysplasia, which can be ascertained by biopsy, seems to be a reasonable predictor of malignant potential. Precancerous lesions showing epithelial dysplasia are 15 times more prone to malignant transformation[10].

Erythroplakia

Definition

Erythroplakia was defined as 'a fiery red patch that cannot be characterised clinically or pathologically as any other definable condition'[5].

Epidemiology

A 1971 study in India described erythroplakia as a rare lesion[4]. An oral cancer screening trial in India conducted in the year 2000 reported 100 erythroplakia cases among 47,773 people[14]. About 74% of the erythroplakia cases occurred in the 45- to 64-year-old age group. The adjusted odds ratio (OR) for erythroplakia was 19.8 (CI 9.8–40) for individuals who had ever chewed tobacco, after controlling for age, sex, education, body mass index, smoking, and drinking. There was a strong dose–response relationship, including high risk for chewers who swallowed the juice compared to those who did not. Chewers who kept the quid in the mouth overnight also showed higher risk compared to those who did not retain the chewing quid overnight.

Precancerous Nature

Erythroplakia carries high malignant potential. Microscopically, 91% of erythroplakia lesions in case series from the United States showed either squamous cell carcinoma or moderate to severe epithelial dysplasia[15]. In an Indian series of nine cases, four showed epithelial dysplasia[4].

Management

A biopsy is mandatory in all cases of erythroplakia. Depending on the microscopic features, the preferred management option would be surgery and regular follow-up with habit cessation. Erythoplakia should be treated soon after diagnosis.

Oral Submucous Fibrosis

Definition

Oral submucous fibrosis (OSF) is a chronic disorder characterised by fibrosis of the lining mucosa of the upper digestive tract involving the oral cavity, oropharynx, and frequently the upper third of the oesophagus.[2] The oral mucosa becomes stiff due to fibrosis of the *lamina propria* resulting in a limited oral opening (Figure 12.3). This condition is a high-risk, potentially malignant disorder[16].

Figure 12.3: (A) Limited oral opening and (B) fibrous bands (arrow) in the buccal mucosa in oral submucous fibrosis

	
(A)	(B)

Photograph courtesy of Dr. Vijay Mathur.

Epidemiology

OSF is associated with use of products that contain areca nut, such as betel quid (pan), gutka, mawa, and pan masala[17]. Prevalence and incidence of OSF have been shown to be higher in South India, specifically in the Ernakulam district of Kerala, compared to other areas of the country. A 1980 study in Ernakulam reported that the prevalence of OSF was 350 per 100,000 person-years[18]. The annual age-adjusted incidence rate was 7 per 100,000 person-years among men, and 17 per 100,000 person-years among women. All new cases were observed among betel quid chewers (35 per 100,000 person-years in men, and 29 per 100,000 in women)[10].

Trends

OSF has assumed epidemic proportions corresponding with the increase in use of various areca nut preparations, such as gutka, mawa, and pan masala[19-21]. A hospital-based study of 1,000 OSF cases found that the prevalence of OSF among outpatients was 2.42 per 1,000 in the year 2000, and 6.42 per 1,000 in 2004[20].

Aetiology

Although various factors have been postulated as possible causal factors, overwhelming epidemiologic and experimental evidence[17] implicates areca nut use independently or with SLT in causing OSF. This evidence is derived from case series, cross-sectional, cohort, and even intervention studies (see chapter 13)[17]. Tables 12.2 and 12.3 demonstrate evidence of this relationship and of a dose–response effect[22].

Table 12.2: Association of submucous fibrosis with areca nut chewing

Product use	Cases		Controls		Relative risk
	No.	%	No.	%	
No product use	1	2%	39	65%	1.0
Areca nut (not mawa)	5	8%	7	12%	29.9*
Areca nut (not including tobacco)	4	7%	2	3%	78.0*
Mawa	30	50%	11	18%	106.4*
Mawa and other products	20	33%	1	2%	780.0*
Overall	60	100%	60	100%	109.6*

Source: Gupta et al., 1998[21]. *p<0.01

Table 12.3: Relationship between duration of chewing (in years), frequency of chewing (per day), and occurrence of submucous fibrosis

Chewing frequency	Cases		Controls		Relative risk
	No.	*%*	*No.*	*%*	
Duration (in years)					
1–5	*17*	*29%*	*10*	*47%*	*1.0*
6–10	*16*	*27%*	*5*	*24%*	*1.9*
≥11	*26*	*44%*	*6*	*29%*	*2.5*
Frequency (per day)					
1–5	*16*	*27%*	*10*	*47%*	*1.0*
6–15	*37*	*63%*	*10*	*48%*	*2.3*
≥16	*6*	*10%*	*1*	*5%*	*3.8*
Total	*59*	*100%*	*21*	*100%*	

Source: Gupta et al., 1998[21].

A 2011 study found that 79% of 205 OSF cases were pan masala and gutka users[19]. Pan masala users developed OSF within one year of starting use; in contrast, betel quid chewers took twice as long to develop OSF. In a case control study of 220 OSF cases in 2009, the relative risk of developing OSF in gutka users was 1,142.4, with a strong dose–response relationship[23].

Clinical Aspects

OSF is a debilitating disease causing stiffening of the mucosa, which leads to progressive difficulty in opening the mouth. In earlier epidemiologic studies (1968 and 1980) this disease was more often seen in middle-aged adults and women[10,18]. Currently, OSF is occurring more often in younger people[19--21]. In a report of 1,000 participants in 2007, OSF cases predominantly occurred among younger age groups (78% at ages 20–29) and among men (83%)[20]. In a 2009 study of 220 respondents, 60% occurred in ages 10–24, and 25% in ages 25–34[23]. A similar shift was also observed in a large 1998 study of 21,852 individuals (including 5,018 tobacco/areca nut chewers) in whom 164 OSF cases were diagnosed[21]. Of these, 85% occurred in among people younger than 35 years. The authors of this study felt that this increase in OSF cases among younger people might result in an increase in the occurrence of oral cancer in younger individuals[24].

OSF occurs in all oral locations, sometimes extending into the pharynx and oesophagus[2], but location of the condition in the body varies by geographical region depending on the type of areca nut use practiced[25]. Clinically, OSF shows marked mucosal blanching, especially in the early stages[3]. Presence of palpable fibrous bands in the buccal mucosa and in the lips is the diagnostic feature. OSF patients might experience a burning sensation and hyper- or diminished salivation and speech defects.

Natural History

A long-term study did not report any spontaneous regression of OSF[10]. The most serious consequence is the development of oral cancer. Initially the malignant potential was suspected on observations of co-existence of oral cancer and leukoplakia, a higher frequency of epithelial dysplasia with OSF, histologic diagnosis of oral cancer among OSF patients, and the malignant transformation in OSF over time[26]. In a 17-year follow-up study of 66 patients, malignant transformation was observed in 0.4% of cases at the end of 10 years[10], which increased to 4.5% at the end of 15 years[26], and to 7.6% at the end of 17 years[16]. In an 8-year follow-up study, the RR for OSF to develop oral cancer was 397.3 compared with that for tobacco users who had no oral lesions (Table 12.1)[11].

Management

OSF is difficult to manage. Although several treatment modalities have been suggested, including surgical options, there does not seem to be any consensus treatment that helps restore the normal texture of the oral mucosa and reduce the risk for cancer development. Discontinuation of SLT products may prevent further progression in severity and lower the risk for malignant potential, and limiting use of SLT with areca nut results in a lower incidence of OSF[27].

Oral Lichen Planus

Definition

Lichen planus is primarily a dermatologic disorder in which various mucosal surfaces may be involved independently, concurrently with cutaneous (skin) involvement, or one after the other. The oral mucosa, however, is more frequently affected than other mucosal sites. The cause of lichen planus is probably related to immune system functioning. Interestingly, tobacco use seems to play a role in its natural history. The malignant potential of this condition is unclear.

Epidemiology

The prevalence of oral lichen planus in random population samples in India has varied from 0.1 to 1.5%.[4,28] Some 92% of individuals with oral lichen planus were tobacco users; 52% chewed betel quid, and many smoked as well. The prevalence of this lesion was 3.2% among betel quid chewers and 3.7% among dual users, compared to 7% among non-users. The annual age-adjusted incidence rate per 1,000 person-years was 2.1 among men and 2.5 in women who chewed betel quid, compared to 0.6 for men and 0.9 in women who were not tobacco users[10]. The RR for oral lichen planus among betel quid chewers was 6.2 for men and 4.9 for women[29]. Oral lesions thus showed a strong association with betel quid chewing, although tobacco use is not regarded as an aetiologic factor for oral lichen planus. SLT use, however, is a matter of concern in view of some malignant potential in this lesion. Nevertheless, the association between tobacco use and oral lichen planus may be indirect[28,29].

Clinical Aspects

Oral lichen planus is generally diagnosed on the basis of the presence of a pale, reticular, or lace-like pattern of *striae* on the oral mucosa or tongue. Several clinical forms of this disorder are recognised; the erosive or ulcerative type, which constitutes 20% of the oral lesions[28], seems to have more malignant potential. In a cohort study in India, oral lichen planus occurred predominantly among women[28,29], and the buccal mucosa was the most favoured location.

Natural History

A long-term follow-up (mean, 5.1 years) of 722 oral lichen planus cases showed cancer development in only three patients (0.4%) who had erosive lesions; of these three, two were betel quid chewers[30]. In another 8-year follow-up study of 344 individuals with oral lichen planus, the RR for malignant transformation was 15.8 (Table 12.1), which was not significant ($p>0.05$)[11]. Oral lichen planus often regressed and sometimes recurred; the regression rates were highest in non-users of tobacco and lowest in people who used both chewing and smoking products[10].

OTHER MUCOSAL EFFECTS

Betel Chewer's Mucosa

Definition

Betel chewer's mucosa (BCM) or (pan chewer's encrustation) is a benign condition characterised by a thick, brownish-black coloured encrustation on the buccal mucosa and mandibular groove, which are the usual sites where the quid is placed[3,31]. This encrustation can easily be scraped off with gauze and disappears when betel quid chewing is discontinued.

Epidemiology

The annual age-adjusted incidence of betel chewers' mucosa was 28.0 per 1,000 male betel quid chewers, and 17.4 per 1,000 among women betel quid chewers, according to the 1980 study by Gupta and colleagues[10]. BCM was also observed in 0.84% of 1,190 patients examined in a dental hospital set up in Manipal, Karnataka[32].

Natural History

BCM does not seem to carry any malignant potential. Of the 532 lesions followed up over a 3-year period by Gupta and colleagues, none progressed to cancer, 26% were persistent, 45% regressed, and 29% recurred[10].

Tobacco–Lime User's Lesion

Definition

A thick, yellowish-white lesion, occasionally with loose tags of tissue, occurs where tobacco–lime (e.g., khaini) is held in the mouth. A 1979 study by Bhonsle and colleagues found that prevalence of this lesion among 101,761 villagers in Maharashtra was 2.9%, more often among men[33]. As it is similar in appearance to leukoplakia, tobacco–lime user's lesion may be misdiagnosed. Unlike leukoplakia, this lesion can be scraped off, and it will disappear if use of tobacco-plus-lime is discontinued. Histological characteristics include pale, parakeratin-like surface layers of epithelium containing round nuclear remnants, ballooning vacuolated cells, and epithelial hyperplasia. Tobacco–lime user's lesion as a specific entity appears to be a counterpart of the betel chewer's mucosa described above; it does not show any malignant potential.

Mucosal Staining

Betel quid chewing inevitably stains the mucosa bright red as a result of the formation of o-quinone from water-soluble polyphenols, notably leucocynidins, at an alkaline pH of 8 to 9 via secondary reactions. These stains can be washed clean or will disappear if the habit is discontinued. It is not uncommon, however, to find habitual chewers with perpetually stained mucosa[3].

EFFECTS ON PERIODONTAL TISSUES

Few Indian studies have examined the link between SLT use and periodontal health[34-37]. Table 12.4 summarises the findings of some of these studies.

Table 12.4: Studies of the effect of SLT use on periodontal health

Type of study	Author, year	Study population	Findings
Cross-sectional	Singh et al., 2011[33]	n=2,045 n=1,069 tobacco users n=122 smokers n=657 smokeless tobacco users n=290 using both smokeless tobacco as well as tobacco in smoking form	The impact of SLT use was significantly higher on all the periodontal health indicators such as plaque index, gingival index, calculus, clinical attachment loss, gingival recession, mobility, furcation, lesion, and pocket depth. Both duration and frequency of SLT use significantly affected periodontal health.
Cross-sectional	Nagarajappa and Prasad, 2010[34]	42 SLT chewers and 42 non-chewers (age 20–60 years)	Chewers experienced a slightly higher incidence of periodontal disease than non-chewers, but the difference was not significant.
Case control	Parmar et al., 2008[35]	365 subjects (168 chewers and 197 non-chewers) with a mean age of 32.5 ± 0.7 and 30.4 ± 0.8 years, respectively	A significantly higher number of quid chewers suffered bleeding from the gums. Oral hygiene status of quid chewers was significantly deteriorated. The effect of quid chewing on the periodontium—i.e., the occurrence of periodontal pockets, gingival lesions, and gum recession—was significantly higher in quid chewers than in non-chewers.

Type of study	Author, year	Study population	Findings
Cross-sectional	Sumanth et al., 2008[36]	300 subjects (150 subjects were pan + tobacco chewers, and 150 subjects used pan without tobacco)	Higher incidence of periodontal diseases was found in pan chewers who used tobacco compared with pan chewers who did not use tobacco. It was concluded that, although betel nut has deleterious effects on the periodontium, the synergistic effect created by adding tobacco to betel nut results in a more severe impact on the periodontal tissues.

These studies have also shown SLT use to be associated with gingival inflammation and attachment loss, and a dose–response relationship has been found between SLT use and periodontal disease. A 2008 review of three studies noted an association between gutka consumption and periodontal inflammation (ORs for these studies were 1.64 [CI: 1.2–2.1], 2.20 [CI: 1.1–4.9], and 3.56 [CI: 1.9–5.5])[37].

EFFECTS ON DENTAL TISSUES

Dental Caries

The effect of SLT use on dental caries is not clearly understood, because findings have been contradictory. A study by Javed and colleagues (2010) documented that chewing tobacco and smoking can present significant risk factors for dental caries[38]. DMFT values (from the Decayed, Missing, Filled Teeth index, which measures the level of dental caries) of tobacco chewers, regular smokers, and ex-smokers were significantly higher than those of non-tobacco users. The mean number of decayed and filled teeth was highest in tobacco chewers. In contrast, Vellappally and colleagues (2008) found significantly fewer caries among chewers compared to non-chewers[39]. The paucity of studies makes the nature of this relationship unclear.

Other Dental Effects

Use of SLT with areca nut has also been recognised to lead to tooth wear, dental sensitivity, and halitosis[30,39- 41].

CONCLUSIONS

Oral precancer has been estimated to be a source for 70% of the oral cancers in India[3]. SLT use is strongly associated with various oral lesions, including several with the potential to become malignant. A matter of great concern is the upsurge in use of gutka and other SLT products with areca nut, such as mawa, and the corresponding increase in OSF cases among youth. The increasing incidence of the high-risk condition OSF is likely to continue to lower the age profile of oral cancer in India. Thus, it is vital to curb the use of SLT products implicated in causing these disorders.

Intervention efforts lead to lower incidence rates of leukoplakia[42], as shown by studies of betel quid chewers. The incidence of leukoplakia among women who had stopped betel quid chewing was 72 per 100,000 person-years compared to 239 per 100,000 among those who had not stopped the habit[43]. Among men who had stopped betel quid chewing, the incidence was 272 per 100,000 compared to 337 per 100,000 in those who had not stopped. This reduction in the incidence implies a decreased risk for cancer development. Important priorities for oral and general health are: educating the public on the oral health consequences of SLT use, enlisting continued support of relevant agencies for this purpose, involving oral health professionals in curbing SLT use, and developing appropriate infrastructure and support to manage the potentially malignant conditions.

Limited data from Indian studies have shown SLT use might be responsible for gingival inflammation, attachment loss, and tooth wear. Studies evaluating the association of SLT and dental caries remain inconclusive.

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Chapter 13

Chemistry and Toxicology of Smokeless Tobacco

Rajani A. Bhisey[1], Stephen B. Stanfill[2]

[1](Retired) Head, Carcinogenesis Division, Cancer Research Institute, Advanced Centre for Treatment, Research and Education in Cancer, Kharghar, Navi Mumbai

[2]Centers for Disease Control and Prevention, Atlanta, GA, USA

INTRODUCTION

In India, unburnt or smokeless tobacco (SLT) products range in complexity from simple tobacco-only products to elaborate products with numerous chemical ingredients and, in some cases, substantial amounts of other plant material[1-5]. Air- or sun-cured tobacco is the primary constituent of various smokeless tobacco products. Although most tobacco in SLT is *Nicotiana tabacum*, it is estimated that 35–40% of SLT products contain *Nicotiana rustica*, a tobacco species grown in several states of India[6], which contains much higher levels of nicotine and tobacco-specific *N*-nitrosamines (TSNAs)[7]. The International Agency for Research on Cancer (IARC) has classified smokeless tobacco as a Group 1 carcinogen[4].

Smokeless tobacco products may be used for chewing, sucking, gargling, sniffing, and as a dentifrice[7]. Zarda, khiwam, betel quid, gutka, Mainpuri tobacco[5], and kharra[8] are chewed. Khaini is held in the mouth and sucked. SLT products used as dentifrice include gudakhu, mishri (also called masheri), bajjar, and lal dant manjan (red tooth powder). Tuibur is water through which tobacco smoke is passed; this is the only product that is gargled. Snuff is used nasally or orally[7]. Tobacco, alkaline agents such as lime, and areca nut are the three key ingredients of SLT products; catechu, sweetening, and flavouring agents may be present in some products. In work environments where tobacco is processed, tobacco dust is involuntarily inhaled[9].

Unprocessed and processed forms of tobacco used in various products contain a number of toxic, mutagenic, or carcinogenic chemicals that can contribute to the onset of noncommunicable diseases including cancer, heart disease, diabetes, adverse reproductive effects, and oral pathologies[2-5]. It is therefore essential to consider the chemical composition of tobacco and non-tobacco ingredients of SLT products, and to understand their contribution to adverse health effects.

This chapter is divided into two parts:

- **Part I** focuses on the chemistry of green and dry tobacco leaves, processed tobacco, and SLT products.
- **Part II** presents data on specific exposure to tobacco constituents, mechanisms through which toxic effects are imposed, and the nature of genotoxicity, carcinogenicity, and adverse health effects resulting from SLT exposure.

PART I: CHEMICAL COMPOSITION OF SLT AND SLT PRODUCT INGREDIENTS

Chemical Complexity of Tobacco

A 1988 study found that tobacco contains 3,044 constituents[10]. In 2001, the number was extended to 3,095[4], and a review in 2009 reported the presence of 4,200 chemicals in unburnt tobacco[11]. Chemical composition of tobacco undergoes substantial changes as the plant grows and during curing, fermentation, processing, and storage[12-16]. In the process of curing, the starch content of the leaves declines. The content of polyphenols and carbohydrates in the leaves diminishes during the fermentation of dry tobacco leaves[4].

Broadly, chemicals in tobacco include alkaloids such as nicotine, nornicotine, cotinine, anabasine, anatabine, aliphatic hydrocarbons present in the leaf coating, and hundreds of isoprenoids that produce the aroma typical of tobacco leaves. The alkaloid content of tobacco leaves varies depending on soil conditions, use of fertilisers, and the degree to which the plant is ripened[17]. Tobacco also contains a number of phytosterols such as campesterols, as well as cholesterol, alcohols, phenolics, chlorogenic acid, rutin, carboxylic acids, terpenes, polyphenols, alkanes, aromatic hydrocarbons, aldehydes, ketones, amines, nitriles, *N*- and *O*-heterocyclic hydrocarbons, pesticides, alkali nitrates, and at least 30 metallic compounds and several free amino acids[18]. Toxic metals including mercury, lead, chromium, and other trace elements have also been detected[2].

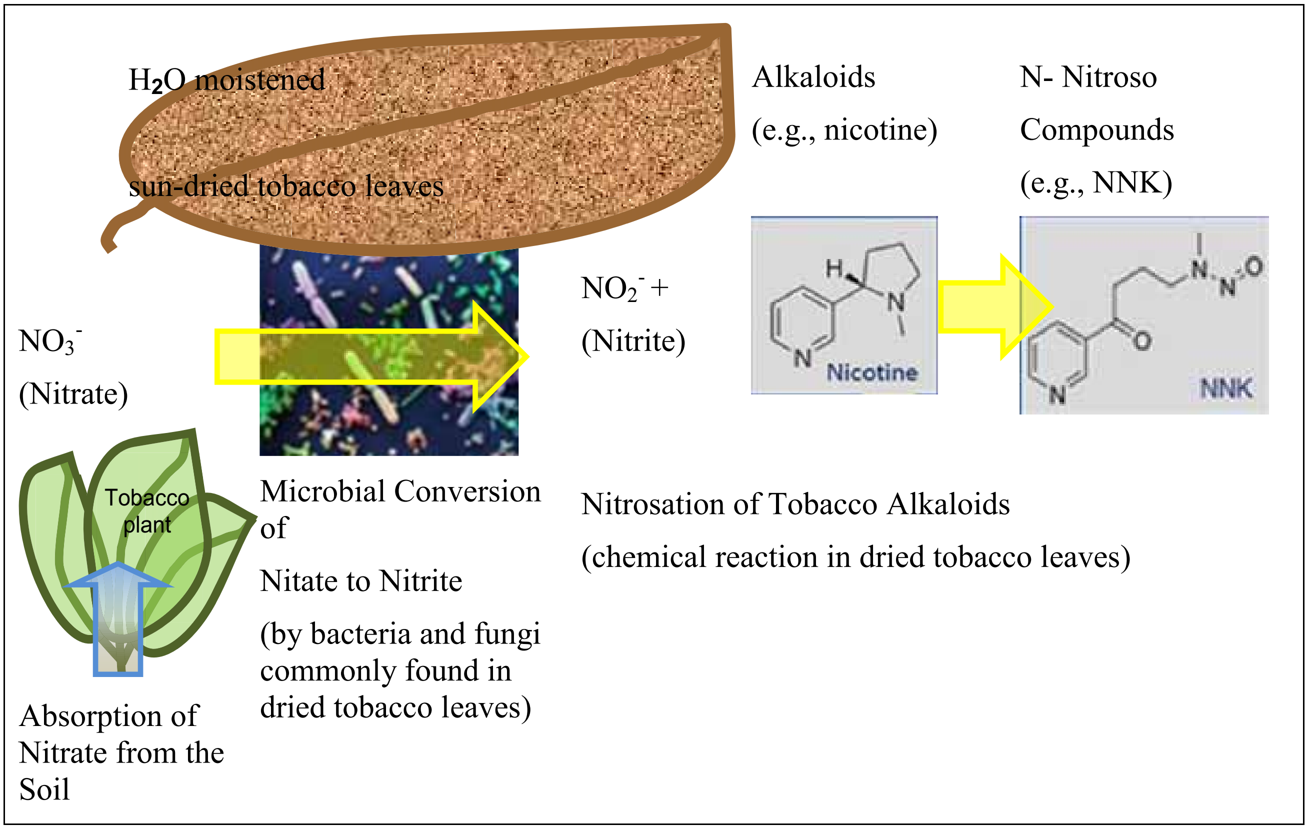
Nicotine is the known addictive substance in tobacco. It exists in two forms, acid (bound) and base (free). Free nicotine is the form of nicotine most rapidly and easily absorbed in the mouth[19]. Many SLT products contain slaked lime or other alkaline agents which are responsible for the high alkaline pH and increased amount of free nicotine delivered to the user[20].

Types of Carcinogens and Other Toxins in SLT

Between 1992 and 2007 researchers listed as many as 28 carcinogens that had been identified in SLT[4,18]. As of this writing (2013), the list has grown to approximately 36 carcinogens[21,22], including TSNAs, volatile *N*-nitrosamines, nitrosamino acids, volatile aldehydes, ethyl carbamate, polycyclic aromatic hydrocarbons, metals/metalloids such as radioactive polonium-210[2,4,21,22] and mycotoxins[23]. Any product that contains fire-cured tobacco, tobacco that has had contact with smoke, or tobacco that has been pyrolysed or burned (mishri) during its preparation is likely to contain PAHs. Detectable levels of benzo[*a*]pyrene (B[*a*]P, a PAH compound), an IARC Group 1 carcinogen, have been reported for several products, including gutka, khaini, creamy snuff products, and several mixtures of zarda and areca nut (supari)[4]. Areca nut, a constituent of a number of other SLT products/preparations produced and used in India, is also classified by IARC as a Group 1 carcinogen[3,5].

Among the listed carcinogens, the TSNAs *N'*-nitrosonornicotine (NNN) and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) are quantitatively the most abundant strong carcinogens. 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL) is also carcinogenic[18,24], while *N'*-nitrosoanabasine (NAB) is a weak carcinogen, and *N'*-nitrosoanatabine (NAT) is generally considered inactive[11]. Both NNK and NNN have been classified by the IARC as carcinogenic to humans (Group 1)[4]. Carcinogenic TSNAs are formed by nitrosation of tobacco alkaloids in tobacco leaves[25,26], as depicted in Figure 13.1.

Figure 13.1: Plant-related, microbiologic, and chemical steps in the formation of tobacco-specific N-nitrosamines



NNK = 4--(methylnitrosamino)-1-(3-pyridyl)-1-butanone

Nitrate and nitrite are classified as carcinogens when ingested, because of their potential for endogenous formation of carcinogenic nitroso compounds. SLT users swallow saliva and also may ingest products containing significant amounts of nitrate and nitrite and secondary amines that can be nitrosated. Studies of in vitro nitrosation of extracts of betel quid with tobacco at pH conditions existing in the oral cavity and stomach showed that nitrosation of extracts at pH 2.1 increased the NNN level by 4–64 times. Higher levels of NAT were detected following nitrosation of samples at pH 7.4, and very high concentration (>2,000 ng/g) was obtained at pH 2.1, which suggests that *N*-nitroso compounds may be formed in the body from tobacco-derived nitrosatable precursors during tobacco chewing and as a result of swallowing the juice[27]. For this reason, nitrate and nitrite are important constituents contributing to the carcinogenicity of SLT.

Carcinogens identified in various SLT products, listed in Table 13.1, include those that can be absorbed from the soil, result from microbial contamination, form chemically, or are added.

Table 13.1: List of IARC carcinogens that have been identified in various smokeless tobacco products*

Compound/substance	IARC Group	Compound/substance	IARC Group
Tobacco-specific N-nitrosamines (TSNAs)		Polycyclic aromatic hydrocarbons	
N'-nitrosonornicotine (NNN)	1	Benzo[*a*]pyrene (B[a]P)	1

Compound/substance	IARC Group	Compound/substance	IARC Group
4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)	1	Benz[a]anthracene (B[*a*]A)	2B
Volatile N-nitrosamines		Dibenz[a,h]anthracene (DB[*ah*]A)	2A
N-nitrosodimethylamine (NDMA)	2A	Benzo[b]fluoranthene (B[*b*]F)	2B
N-nitrosopyrrolidine (NPYR)	2B	Benzo[j]fluoranthene (B[*j*]F)	2B
N-nitrosopiperidine (NPIP)	2B	Benzo[k]fluoranthene (B[*k*]F)	2B
N-nitrosomorpholine (NMOR)	2B	Indeno[1,2,3-cd]pyrene (IcdP)	2B
N-nitrosodiethanolamine (NDELA)	2B	Naphthalene (NAP)	2B
Nitrosamino acids		Metals/metalloids	
N-nitrososarcosine (NSAR)	2B	Arsenic	1
Inorganic compounds		Beryllium	1
Nitrate (due to nitrosation activity in the body)	2A	Cadmium	1
Nitrite (due nitrosation activity in the body)	2A	Lead	2B
Volatile aldehydes		Nickel	1
Formaldehyde	1	Polonium-210	1
Acetaldehyde	2B	Chromium	1,3
Fermentation-related compound		Mycotoxins	
Ethyl carbamate (urethane)	2A	Aflatoxins (mixtures of)	1
Plant Material		Ochratoxin A	2B
Areca nut (Ingredient of betel quid)	1	Sterigmatocystin	2B

*Substances are grouped according to available evidence on their carcinogenicity:

Group 1 = Carcinogenic to humans

Group 2A = Probably carcinogenic to humans (limited evidence); sufficient evidence for carcinogenicity to animals

Group 2B = Possibly carcinogenic to humans as regarding evidence in humans and animals

Group 3 = Not classifiable as to its carcinogenicity to humans

Group 4 = Probably not carcinogenic to humans

Sources: WHO, IARC Monograph Vol. 37 (pp. 62–78)[2]. WHO, IARC Monograph Vol. 89 (pp. 57–60, 427, 432, 553)[4]. WHO, IARC Monograph Vol. 100E (pp. 268–269)[5]. Varma et al., 1991[23]. IARC 2014[117].

Quantities of Carcinogens in Tobacco Leaves and SLT Products

Tobacco Leaves

One study[28] reported trace amounts of NNK and NNN in green leaves of the *N. tabacum* and *N. rustica* species, while levels of these substances in dry tobacco were several times higher. In one season, mature green leaves of *N. rustica* grown in India were found to contain up to 2,340 ng/g of NNK, 5,200 ng/g of NNN, and 23,700 ng/g of NAT (all measured in dry weight of tobacco), while in sun-dried tobacco the levels of NNK and NNN were 25,800 ng/g and 15,000 ng/g tobacco, respectively. In comparison, levels of NNK and NNN in sun-dried *N. tabacum* were 37 ng/g and 49 ng/g tobacco.

Mishri

The levels of preformed NNN and NAT in aqueous extracts of mishri were higher than in tobacco used in the preparation of mishri[29]. At pH 3, concentrations of NNN in mishri and in the tobacco used to prepare it were 1,131 and 707 ppb, respectively, while an increase in NNK level was not observed. B[*a*]P was not detected in tobacco used for making mishri, but B[*a*]P levels were higher in all mishri samples. Nicotine level was lower in mishri than in the unburnt tobacco from which it was prepared. Hydrogen cyanide (HCN) was detected in all mishri samples, and the levels of phenols shown to have tumor-promoting and co-carcinogenic activities were also higher. Moreover, HCN is metabolised in the liver to thiocyanate which acts as a catalyst in the formation of *N*-nitrosamines at acidic pH, suggesting that HCN metabolism may contribute to increased levels of *N*-nitrosamines in mishri. High levels of NNK and NNN and the presence of co-carcinogenic polycyclic aromatic hydrocarbons including B[*a*]P were also reported[30].

Chewing Tobacco Products

The presence of preformed NNN and NAT in different chewing tobacco products sold in India has been widely reported[31-33]. High levels of NNN (15.3–24.4 µg/g) and NNK (2.7–6.5 µg/g) were found in chewing tobacco; dry snuff contained 137–1,356 µg/g of NNN and 110–245 µg/g of NNK[33]. Other researchers have reported a high level of NNN in khaini[34]. A comprehensive study of the amount of TSNAs found in 32 smokeless tobacco products revealed high levels of NNN, NAT, NAB, and NNK in these products[35] (see Table 13.2).

Table 13.2: Tobacco-specific nitrosamines, nitrate, nitrite, and nicotine in Indian smokeless tobacco and related products

Product/ brand	TSNAs (µg/g)[b]				Nitrate (µg/g)[c]	Nitrite (µg/g)[c]	Nicotine (mg/g)[d]
	NNN	NAT	NAB	NNK			
Khaini							
Raja	76.9	13.8	8.83	28.4	705	1,020	21.3
Hans Chhap	39.4	4.83	3.78	2.34	1,090	1,410	19.6
Zarda							
Goa 1000	8.36	1.98	0.48	3.09	966	2.20	14.6
MoolchandSuper	6.47	0.64	0.46	1.64	1,320	ND	15.0
Sanket 999	7.77	1.51	0.36	1.99	1,910	2.08	65.0
Baba120	4.81	1.40	0.19	1.07	1,700	1.63	44.2
Shimla	19.9	1.53	1.19	2.61	1,360	2.53	13.8
Other tobacco							
HathiChhap	2.75	1.53	0.23	0.85	2,760	1.97	39.5
GaiChhap	19.2	11.9	1.57	2.61	2,950	8.40	47.8
Miraj	1.74	0.35	0.12	0.08	1,420	13.6	15.6
Mishri							
Shahin	4.21	2.55	0.15	0.87	1,720	5.18	21.0
Gutka							
Star 555	0.47	0.07	0.02	0.13	417	1.61	6.77

Product/ brand	TSNAs (µg/g)[b]				Nitrate (µg/g)[c]	Nitrite (µg/g)[c]	Nicotine (mg/g)[d]
	NNN	NAT	NAB	NNK			
Manikchand	0.38	0.05	0.01	0.12	43.9	2.00	3.22
Zee	0.32	0.05	0.01	0.08	62.3	3.42	3.31
Tulsi Mix	0.69	0.07	0.02	0.31	184	2.58	5.67
Wiz	0.31	0.04	0.02	0.13	215	2.82	1.67
Kuber	0.32	0.03	0.01	0.12	47.3	4.50	1.23
Pan Parag	0.44	0.06	0.02	0.12	332	2.84	2.67
Zatpat	1.09	0.08	0.05	0.43	171	1.99	5.48
Vimal	0.09	0.01	ND	0.04	268	1.58	6.82
Josh	0.49	0.08	0.03	0.20	252	1.74	11.4
Supari							
Goa	ND	ND	ND	ND	7.5	4.71	NA
Moolchand	ND	ND	ND	ND	8.5	2.48	NA
Rajnigandha	ND	ND	ND	ND	8.8	3.34	NA
Sanket	ND	ND	ND	ND	8.5	4.27	NA
Shimla	ND	ND	ND	ND	8.0	6.56	NA
Creamy snuff/toothpaste							
IPCO	3.32	0.53	0.11	1.31	580	ND	4.71
Dentobac	2.52	1.49	0.07	2.16	232	ND	7.71
Snuff							
Click	0.56	0.38	0.02	0.24	2,260	ND	71.4
Tooth powder							
Baidyanath	0.04	ND	ND	ND	48.6	ND	0.72
New Roshanjyot	ND	ND	ND	ND	11.6	1.25	0.25
Dabur	0.04	ND	ND	ND	27.6	ND	0.58
Reference snuff							
Kentucky IS3	3.39	3.15	0.25	0.94	3.86	6.35	36.2

ND = Not detected. NA = Not analysed.

Source: Stepanov et al., 2005[35].

Another study[36] estimated levels of moisture, pH, nitrite, nitrate, nicotine, and other tobacco-specific alkaloids in a brand of unprocessed chewing tobacco, zarda, and three brands of mishri and processed bidi tobacco. Nicotine content was highest in unprocessed chewing tobacco and second highest in zarda. These two products also showed high content of nornicotine, which is converted to carcinogenic NNN during curing of tobacco leaves (Table 13.3).

Table 13.3: Comprehensive data on moisture, pH, and alkaloid content of chewing tobacco products

Tobacco product	Mois-ture %	pH	Nitrate (mg/g)	Nitrite (µg/g)	Nico-tine* (mg/g)	Nico-tine† (mg/g)	Nor-nico-tine† (mg/g)	Ana-basine † (mg/g)	Anat-abine† (mg/g)	Cotinine† (mg/g)
Pandharpuri	3.99	5.15	4.66	23.05	55.25	54.77	17.11	0.31	0.63	0.37
Zarda	11.58	5.02	5.00	30.80	25.79	26.20	10.23	0.09	0.92	0.15
Mishri brand 1	7.69	6.33	6.49	11.07	5.52	6.02	0.46	0.05	0.04	0.10
Mishri brand 2	5.80	7.12	2.26	9.25	18.90	23.08	3.66	0.07	0.38	0.43
Rawa tobacco‡	9.52	5.18	8.56	9.01	14.35	16.91	4.23	0.72	0.91	0.09
Rawa mishri§	4.29	5.89	4.49	16.40	5.60	4.99	0.34	0.74	0.09	0.11
Bidi tobacco	10.26	5.09	1.15	13.43	37.70	35.15	3.41	0.10	1.53	0.16

* As detected by ultraviolet spectrophotometry (UV-SP).
†Detected by gas chromatography–flame ionisation (GC-FID)
‡ Rawa tobacco is unmanufactured tobacco in the form of a coarse powder made mostly of shredded ribs that is used in making bidis. § Rawa mishri is roasted tobacco in a coarse powder form.
Source: Pakhale et al., 1997[36].

Another study examined the chemical composition of 10 different SLT products used in India and found that zarda had the highest pH, Raja Khaini had the highest nicotine content, Dabur red tooth powder (lal dant manjan) had the highest nitrate level, and Click Eucalyptus (formerly sold in India) had the highest cadmium and arsenic levels[37].

Table 13.4 provides information on the minimum and maximum values for pH, ammonia, total carbonate, nicotine, NNN, NNK, B(a)P, cadmium, arsenic, and nitrate content in various tobacco products.

Snuff

One study on snuff detected a number of carcinogenic and co-carcinogenic PAHs[30], and another study reported the presence of preformed TSNA in snuff samples used for inhalation[33]. Levels of NNN and NNK in dry snuff were 137–1,356 mg/g and 110–245 mg/g, respectively.

Creamy Snuff

High levels of NNN and NNK were detected in creamy snuff[33,35,37], and a high nicotine content was also reported[35].

Table 13.4: Chemical composition of smokeless tobacco products used in India

Constituent	Minimum value	Brand	Maximum value	Brand
pH	5.21	Baba Zarda 120	10.1	Lime Mix–Miraj Tobacco
Ammonia (µg/g)	4.04	Baidyanath Red Tooth Powder	5,280	GaiChhap Zarda

Constituent	Minimum value	Brand	Maximum value	Brand
Total carbonate (µg/g)	140	Dabur Red Tooth Powder	2,040	Baba Zarda 120
Nicotine (mg/g)	1.24	Raja Khaini	10.16	Dentobac Creamy Stuff
NNN (µg/g)	ND	Click Eucalyptus	7.36	Baba Zarda 120
NNK (µg/g)	ND	Click Eucalyptus	4.88	IPCO Creamy Stuff
Benzo[*a*]pyrene (µg/g)	< 0.0001	Click Eucalyptus	0.94	IPCO Creamy Stuff
Cadmium (µg/g)	0.03	Click Eucalyptus	0.5	Baba Zarda 120
Arsenic (µg/g)	0.07	Click Eucalyptus	1.53	Shahin Mishri
Nitrate (µg/g)	<0.01	Dabur Red Tooth Powder	13.85	Lime Mix–Miraj Tobacco

ND = not detected. NNK = 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone. NNN = N'-nitrosonomicotine.
Source: Gupta, 2004[37].

Tuibur
One analysis found that the NNN concentration in tuibur was 19.7 to 20.1 ng/g[37].

Tobacco Used for Bidi Manufacture
A study that measured moisture content, pH, nitrite, nitrate, nicotine, and other tobacco-specific alkaloids in bidi tobacco found high levels of nicotine, TSNA, nitrite, and nitrate (Table 13.3)[36].

Betel Quid with Tobacco
One study[27] estimated the levels of *N*-nitroso compounds in extracts of betel quid with tobacco before and after nitrosation at pH 7.4 and pH 2.1 to simulate pH in the oral cavity and stomach respectively. At pH 7.4 there was no substantial increase in the level of NNN after in vitro nitrosation of betel quid with tobacco. At pH 2.1, however, a 4- to 64-fold increase in NNN levels was observed upon nitrosation. NAT levels increased moderately following nitrosation of samples at pH 7.4, while at pH 2.1 a very high concentration (>2,000 ng/g) was obtained. The study established that additional *N*-nitroso compounds may be produced endogenously from tobacco-derived nitrosatable precursors in the oral cavity and stomach of tobacco chewers. Nitrosation of arecoline and areca nut alkaloids also occurs in the saliva of chewers of areca nut, leading to the formation of *N*-nitroso compounds such as nitrosamines due to the presence of nitrite and thiocyanate[3].

Toxic Metals in Smokeless Tobacco Products

One study detected the toxic metals arsenic (As), cadmium (Cd), lead (Pb), copper (Cu), mercury (Hg), and selenium (Se) in all 25 samples of gutka, zarda, creamy snuff, khaini, mishri, and other chewing tobacco preparations studied[38]. Levels of Pb, As, Cd, and Cu exceeded the permissible daily average consumption of these metals. Of these toxic metals, arsenic and cadmium are Group 1 carcinogens (carcinogenic to humans) and lead is a Group 2A carcinogen (carcinogenic in experimental animals and probably carcinogenic in humans).

Chemistry of Non-Tobacco Ingredients in SLT

Areca Nut

Areca nut, the seed from the areca palm (*Areca catechu*), is an ingredient in several commonly used SLT products such as betel quid, gutka, mawa, Mainpuri tobacco, and some forms of zarda. The major constituents of areca nut are carbohydrates, fats, proteins, crude fibre, polyphenols, alkaloids, and minerals[39-41]. The main alkaloids in areca nut are arecoline, arecaidine, guvacine, and guvacoline[39,42,43]. Auto-oxidation of polyphenols in areca nut and catechu produces toxic reactive oxygen species; this reaction is enhanced by iron and copper and alkalinity. Elements such as sodium, magnesium, chlorine, calcium, vanadium, manganese, bromine, and copper have been reported in areca nut, pan masala, and other areca nut chewing products[44]. Areca nut has been classified as a Group 1 carcinogen[3].

Arecoline is absorbed through the buccal mucosa and is measurable in the blood plasma of areca nut consumers[3]. In vitro studies have showed that *N*-nitrosation of arecoline resulted in the formation of *N*-nitrosoguvacoline (NGL), 3-(methylnitrosamino)propionitrile (MNPN), and 3-(methylnitrosamino)propionaldehyde (MNPA)[45]. NGL, *N*-nitrosoguvacine (NGC), and MNPN were detected in the saliva of chewers of betel quid with or without tobacco[27,29,46,47].

Slaked Lime

Slaked lime, a common alkaline agent, is composed mainly of calcium hydroxide but also contains iron, magnesium, and a number of trace elements[48].

Catechu

Catechu is the residue resulting from the hot water extraction of heartwood from the *Acacia catechu* tree. The main constituents of catechu are catechu-tannic acid, quercetin, and catechu red. Several trace elements have also been detected[48].

Silver Foil

Flakes of silver foil are added to some products to convey a sense of added worth or desirability to the product. Ingestion of both metallic silver and silver compounds in small doses over periods of months to years can result in a condition called argyria, or argyrosis, in which the skin or eyes take on a blue or bluish-grey colour[49].

Betel Leaf

Betel leaf contains betel oil, which contains phenols including chavicol, hydroxychavicol, and eugenol. Betel leaf also contains vitamin C and carotenes[50]. Trace elements such as iron, mangenese, and sodium are also present[48].

Magnesium Carbonate

Magnesium carbonate, commonly found in gutka and pan masala, is an alkaline as well as an anti-caking agent. In India, use of magnesium carbonate is permitted only in specific food items under Rule 3.1.7 of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011. Tobacco and nicotine are also prohibited as ingredients in any food item under Rule 2.3.4 of these regulations, 2011. Under these regulations and under Section 30 (2)(a) of the Food Safety and Standards Act, 2006, the Commissioner of Food Safety of a state is empowered to prohibit (for one year in the interest of public health) the manufacture, storage, distribution, or sale of any article of food in the entire state. In this manner, pan masala and gutka have been repeatedly banned in Maharashtra.

PART II: TOXICOLOGY OF SLT

Epidemiological studies have established that use of SLT is associated with development of a number of noncommunicable diseases, including cancer. It is therefore necessary to understand how tobacco-specific chemicals are absorbed by users of SLT. Tobacco-specific chemicals such as nicotine, its metabolite cotinine, and TSNAs in body fluids are used as markers of SLT-specific exposure. Ingestion of tobacco constituents leads to induction of detoxifying enzymes, and deficient detoxification is known to result in DNA damage and mutagenic lesions that play a major role in causing cancer.

Part II of this chapter provides the available information on indicators of specific tobacco exposure, exposure to tobacco mutagens, alterations in levels of xenobiotic-metabolising enzymes, mutagenicity of SLT in body fluids, chromosomal alterations, genetic factors, adverse physiological effects of exposure, and animal data on carcinogenicity of SLT and SLT products, which are most important for an understanding of SLT as a human carcinogen.

An additional source of exposure to smokeless tobacco is through respiration of tobacco dust by workers who roll bidis or process dry tobacco. Studies of this kind of exposure are included here to enhance understanding the toxicity of SLT.

Indicators of Exposure to Smokeless Tobacco and Ingredients of Smokeless Tobacco Products

Tobacco-Specific Exposure: Detection of Tobacco Components and Their Metabolites in Body Fluids

Chewing tobacco, betel quid with tobacco, and mishri users: Nicotine and/or cotinine have been detected in the saliva and urine samples of chewers of tobacco, betel quid, and mishri[9,27,51,52]. Among tobacco chewers, cotinine levels in gastric fluid ranged from 0.4 to 13.64 µg/ml, with a mean of 3.78±1.39 µg/ml[53]. The presence of NNN, NAT, and NNK has been demonstrated in saliva samples of chewers of betel quid with tobacco and in chewers of tobacco alone[27,46,54].

Bidi workers: Urinary cotinine was detected in samples of bidi rollers (0.07±0.02 µg/ml[55]) and tobacco processors (3.46±0.95 mM/M creatinine[52]). The level of inspirable dust in the breathing zone of workers was 7 times higher than in a control environment (6.74±2.96 vs. 0.99±0.60)[56,57].

Non-Specific Markers of Exposure to Potential Genotoxic Agents in Tobacco

Detoxification products as exposure indicators to toxic compounds: Many foreign chemicals are metabolised enzymatically to produce soluble, inactive conjugates of glutathione and glucuronic acid that are excreted in urine as thioethers and glucuronides, respectively. Hence, levels of urinary thioethers and glucuronides serve as non-specific indicators of exposure to toxic compounds. Increase in the levels of these conjugates denotes elevated exposure to toxic compounds.

In a solitary study, tobacco exposure was found to elevate urinary thioethers and glucuronides among bidi rollers[55].

Urinary mutagenicity as an indicator of exposure to mutagenic compounds: The Ames assay is used to evaluate mutagenic properties of chemicals by converting *Salmonella typhimurium* strains deficient in histidine synthesis to those that can synthesise histidine in the presence or absence of microsomal enzymes or sodium nitrite.

SLT users: Urine samples from female users of mishri or both mishri and betel quid with tobacco were found to be mutagenic in *Salmonella typhimurium* strain TA100 directly and upon nitrosation with sodium nitrite[57], and in strains TA98 and TA102 upon metabolic activation with rat liver microsomal fraction (S9)[52]. Gastric fluid (GF) samples from chewers of tobacco and lime exhibited direct mutagenicity in *S. typhimurium* strains TA98, TA100, and TA102[53].

Bidi industry workers: Urine samples from female bidi rollers who were not tobacco users were directly mutagenic in strain TA98 and also upon treatment with β glucuronidase in one study[57], and were directly mutagenic to strains TA98, TA100, and TA102 in another study[52].

Modulation of Levels of Xenobiotic-Metabolising Enzymes as Indicators of Exposure to Toxic Agents

Metabolism of toxicants occurs in vivo mainly through reactions catalysed by enzymes belonging to cytochrome P450 and glutathione-S-transferase (GST) families. Hence, their levels indicate cellular exposure to toxic agents.

SLT users: An increase in the activity of cytochrome P450 and cytochrome b5 enzymes and a decrease in GST activity were reported in the liver of mice fed an extract of chewing tobacco[58,59]. A significant reduction in GST activity (9.40±0.98 nmoles/min/mg protein vs 12.20±1.00 nmoles/min/mg protein, $p<0.05$[60]) and GSH level (8.92±0.99 pg/cell vs 10.87±1.26 pg/cell[61]) were observed in the lymphocytes of male tobacco chewers and female mishri users with respect to controls who did not use tobacco.

Bidi workers: A significant reduction with respect to controls was noted in lymphocyte GST activity in workers who did not use tobacco or those who used mishri[61].

Toxic Effects on Cells

Exposure of Syrian golden hamster tracheal epithelial cells to a non-toxic dose of an aqueous extract of tobacco led to cellular hypertrophy and widening of intercellular spaces; it also stimulated ornithine decarboxylase activity and significantly increased the rate of DNA synthesis (5.5-fold with respect to control cultures), but slowed down cellular growth and increased cell doubling time (29.4±0.3 hr vs 14.0±3.75 hr; $p<0.001$). Reduction in cell number was associated with blocking of cells in S phase[62].

In an in vivo study in hairless mice that were initiated with dimethylbenz[*a*]anthracene (DMBA), application of an aqueous extract of tobacco induced increased epidermal mitotic activity (6.9±1.6 vs 4.1±0.4; $p<0.05$) and mild epidermal hyperplasia, and increased epidermal and dermal thickness[63].

Genetic Damage Caused by SLT Products

Mutagenicity of SLT Products

Crude ethanolic extracts of mishri were found to be mutagenic in *Salmonella typhimurium* strain TA98 in the presence of rat liver S9 fraction[64,65] and upon nitrosation in strains TA100 and 102[65].

The nitrosated extract of chewing tobacco elicited significant mutagenic response in strains TA98 and TA100, and the extract of chewing tobacco and lime (CTLE) was directly mutagenic in strains TA98, TA100, and TA102. Upon nitrosation, CTLE elicited strong mutagenic response in strain TA102.

Organic extracts of bidi tobacco were mutagenic in strains TA98 and TA100 while the aqueous: ethanolic extract was directly mutagenic in strain TA98[66].

Micronucleus Assay

The micronucleus assay detects chromosomal damage that results in the formation of micronuclei or small membrane-bound DNA fragments in the cytoplasm of interphase cells following exposure to genotoxic agents. This test alone indicates that an SLT product was toxic at the place where it was kept in the mouth, which is the target site for oral cancer.

Frequency of Micronucleated Cells in SLT Users

One study found that the frequency of micronucleated cells (MNC) in exfoliated buccal epithelial cells from chewers of tobacco and lime was significantly elevated (5.20±0.66 vs 2.59±0.37) with respect to controls[67]. Other studies obtained similar results from oral cancer patients[69] and users of betel quid with tobacco [68], khaini[34], gudakhu[70], mishri alone[9], or mishri plus betel quid with tobacco[9].

Increase in MNC frequency was also observed in oral mucosa cells from healthy individuals who chewed a mixture of tobacco and areca nut, and from those with oral submucous fibrosis. MNC frequency was 0.740±0.064 in unaffected tobacco chewers, 0.753±0.097 in patients with oral submucous fibrosis, and 0.193±0.022 in controls (non-users of tobacco)[71]. Similar results were obtained in regular users of areca nut, mawa, tamol (fermented areca nut), tobacco with lime, dry snuff, or mishri[72].

MNC frequency was also high in cultured peripheral blood lymphocytes of subjects who used mishri as a dentifrice[61], and a stepwise increase in MNC frequency was reported from the non-user group, to the tobacco users, and then the patients with oral leukoplakia[73].

MNC Frequency in Bidi Industry Workers

MNC frequency in exfoliated oral mucosal cells of bidi rollers (0.68±0.06) and tobacco processors (0.66±0.07) who did not use tobacco in any form was significantly elevated when compared to controls (0.45±0.05) with no occupational or other exposure to tobacco ($p<0.02$)[9,61].

Cytogenetic Alterations

Allium Cepa Assay

In a study that assessed toxic effects of tuibur in *Allium* (onion) bulbs, reduction in root growth and mitotic index were observed. Onion root tip cells exhibited formation of micronuclei, lagging chromosomes, and c-mitosis[74].

Chromosomal Aberrations in Peripheral Blood Lymphocytes

Peripheral blood lymphocytes (PBL) are cultured in the presence of a mitogen to delineate chromosomal aberrations induced by a chemical incorporated in the culture medium or those caused in individuals by toxic chemicals.

Smokeless tobacco users: The mean frequency of chromosomal aberration was significantly elevated in the PBL of tobacco, areca nut, and lime chewers (0.097±0.007), patients with oral submucous fibrosis (0.127±0.009), and patients with oral cancer (0.144±0.009), when compared to the mean frequency of chromosomal aberration in people who were not tobacco chewers (0.050±0.004; $p<0.01$)[71,75]. One study of cultured peripheral blood lymphocytes from male and female tobacco chewers reported sister chromatid exchanges (SCE), increased frequency of chromatid breaks, gap-type aberrations, and an increase in SCE for males and females (males: 9.80±1.30 vs 3.84±0.40; $p<0.025$; females: 5.18±0.20 vs 4.00±0.20; $p<0.20$)[69]. SCE frequency was also elevated in the PBL of female mishri users as compared to controls (6.1±0.31 vs 4.29±0.11)[61] and in tobacco, areca nut, and lime chewers[75].

Bidi workers: A high proportion of bidi workers who did not use tobacco in any form and a high proportion of mishri users both exhibited a significantly elevated frequency of chromatid breaks and deletion fragments as compared with their respective controls[76]. SCE frequency was also elevated (5.77±0.16 vs 4.29±0.11; $p< 0.001$) in the PBL of tobacco processors who did not use tobacco compared with non-user controls who had no occupational exposure to tobacco[61]. A significant increase in the frequency of chromosomal aberrations was observed in PBL from all tobacco processors regardless of their tobacco smoking status[77], and the frequency increased with the number of years of occupational exposure to bidi tobacco.

Carcinogenicity of SLT and SLT Products in Animal Studies

Oral Administration

Swiss mice fed an extract of chewing tobacco as part of their diet developed lung adenocarcinoma and hepatocellular carcinoma[58], and mice feeding on a diet containing gutka developed tumors of the lung, stomach, liver, testis, ovary, and adrenal gland[78]. In another study, Swiss mice, Sprague-Dawley rats, and hamsters fed mishri in their diet developed forestomach papillomas[79].

Gavage Feeding

Gavage feeding of extracts of chewing tobacco or gutka alone induced forestomach and oesophageal papillomas in a small number of animals, while the increased tumor yield in animals initiated with diethylnitrosamine indicated that the extracts promoted tumor development. Histopathology showed the presence of microscopic papilloma in oral mucosal tissues of some tobacco- or gutka-treated animals[80].

Application to the Cheek Pouch

Topical application of an extract of chewing tobacco to the cheek pouch mucosa of Syrian golden hamsters resulted in leukoplakia. In hamster cheek pouches treated with snuff, no tumors were observed[81], but another study found forestomach tumors following application of snuff to the hamster cheek pouch[82].

Skin Application

Skin papillomas were induced following application of mishri extract to the back skin of Swiss mice[64]. Similar treatment resulted in skin papilloma in hairless Bare mice, and the extract promoted skin papilloma in Swiss mice that were initiated with 7,12-dimethylbenz[*a*]anthracene[83].

Prolonged application of an aqueous extract of chewing tobacco and lime or gutka failed to induce skin tumors in Swiss Bare mice, indicating that chewing tobacco extract did not promote skin tumor development or progression. On the other hand, the gutka extract's tumor-promoting potential was evident from the increased yield of papillomas in DMBA-initiated mouse skin, and the extract's progressor potential was indicated by the increase in the conversion rate of papilloma to carcinoma in the mouse skin[80]. Topical application of an extract of tobacco in DMBA-initiated Swiss Bare mice increased the yield of papillomas and increased the rate of conversion of papilloma to carcinoma[63].

Physiological Toxicity of SLT and SLT Products in Experimental Systems

Reproductive, Prenatal, and Postnatal Toxicity of SLT

Exposure of pregnant CD-1 mice to aqueous extracts of moist snuff during gestation days 7–14 led to a significant reduction in the body weight of dams and fetuses. Increased incidence of haemorrhages and supernumerary ribs in fetal mice and a significant delay in ossification of the supraoccipital bone, the sacrococcygeal vertebrae, and the bones of the feet were observed[84]. An increase in maternal death, fetal resorption, and the incidence of minor heart defects were also observed in pregnant females receiving the snuff extract[85]. Similar treatment of Sprague-Dawley rats led to a reduction in fetal weight[86]. Higher snuff concentrations were found to cause reduction of pup weight and maternal weight gain, and infant mortality was found to increase with increasing exposure to tobacco extract. A decreased success rate for the surface-righting reflex was noted for pups exposed to tobacco extract[87]. Increase in sperm head abnormalities, degenerative changes in seminiferous tubules and interstitial tissue, and impaired liver function were observed in Swiss mice fed gutka in their diet[88].

Genetic Determinants of Oral Cancer Risk Associated with Tobacco Use

Human susceptibility to cancers caused by tobacco carcinogens is believed to be affected in part by polymorphisms in genes involved in metabolism of carcinogens and repair of damaged DNA.

In a study on polymorphism[89], GSTM1 null genotype was a major risk factor for development of oral cancer among tobacco chewers; this finding was later substantiated[90]. Further studies revealed that, in addition to GSTM1 null genotype, GSTT1 null, rs2031920, rs3813867 (CYP2E1), and rs13181 genotypes were associated with oral cancer[91].

In a pooled analysis, an association was found in tobacco users between head and neck cancer risk and variations in MGMT and XRCC1 genes involved in DNA repair, alcohol dehydrogenase gene variants, and GSTM1 null genotype[92]. In a meta- and pooled analysis, people with GSTM1 null genotype and the CYP1A1 m1m2 variant allele were reported to be at greater risk for oral and pharyngeal cancer[93]. Polymorphism of angiotensin I-converting enzyme gene was also found to be associated with increased susceptibility to oral cancer and lymph node metastasis[94].

Physiological Effects of SLT and Ingredients in SLT Products

Physiological Effects of SLT Consumption

Smokeless tobacco can lead to dependence and addiction, created by nicotine. SLT use also causes a significant acute increase in heart rate, and elevation of blood pressure, which is directly related to the plasma level of nicotine[4] and may affect lipid metabolism[1].

Reproductive, Prenatal, and Postnatal Toxicity of Areca Nut and Other Ingredients in SLT Products

An increase in the percentage of resorption, as well as dead, macerated fetuses and a dose-related decrease in the average total body weight per litter were observed when extracts of areca nut were administered to pregnant mice[95]. Injection of areca nut extract in chick embryos led to reduced body size, sparse feathering, everted viscera, shortened lower beak, and arthrogryposis[96]. Suppression of compensatory ovarian hypertrophy was observed in animals receiving arecoline[97]. Intraperitoneal injections of arecoline resulted in sperm abnormalities in mice[98]. An increase in the frequency of micronucleated polychromatic erythrocytes in fetal mouse blood was also observed[99]. Morphological sperm abnormalities[100], decrease in the weight of testes, and impaired liver function[101], have been reported in mice and rats fed pan masala.

Effect of Pan Masala, Arecoline, and Arecaidine on Oral Soft Tissue

A study in Wistar rats whose oral cavity was painted with pan masala paste reported morphological changes such as moderate loss of nuclear polarity, increase in keratoses, parakeratoses, inflammatory cell infiltration, increased mitotic figures and vascularity, and an increase in submucosal collagen indicative of submucous fibrosis[102]. Similar results were not obtained in two other studies that used arecoline[103] and arecaidine[104], respectively. Oral submucous fibrosis is a precancerous condition observed only in the users of SLT products that contain areca nut.

Effects of Areca Nut and Betel Quid Without Tobacco on the Gastrointestinal Tract

Feeding albino rats a diet containing areca nut or betel quid containing areca nut caused splenomegaly, fatty liver changes, stunted skeleton, necrosis of buccal and intestinal mucosa[105], increased gastric mucosal acid back-diffusion, and reduced mucous secretion[106]. A decrease in alkaline phosphatase was observed after oral administration of areca nut to rats[107].

Effect of Areca Nut on Lipid Metabolism

Four studies have reported a marked decrease in plasma cholesterol and triglyceride concentrations, as well as a decrease in the intestinal pancreatic esterase activity involved in the cholesterol absorption process[108-110].

Diabetogenic Effects of Areca Nut and Arecoline

F1 offspring of animals fed areca nut, especially males, were found to develop diabetes in various litters. Feeding of areca nut resulted in development of permanent diabetes in a small percentage of CD1 mice[111]. However, subcutaneous injection of arecoline into diabetic male rabbits reduced blood sugar levels for only 4–6 hours[112].

Effect of Arecoline on Collagen Production

Arecoline was found to stimulate collagen production by fibroblasts[113], but catechin, flavonoid, and tannin compounds in areca nuts cross-linked collagen fibres, making them less susceptible to collagenase degradation[114]. Upregulation of lysyl oxidase by copper in areca nut has been implicated in excessive cross-linking and accumulation of collagen in patients with OSF[115]. Very high levels of copper were detected in four gutka products (237–656 μg/g)[38], and a definitive dose-dependent relationship between the frequency and duration of chewing areca nut without tobacco and the development of OSF in users has been demonstrated[116].

CONCLUSIONS

All smokeless tobacco products contain the alkaloid nicotine, which is the addictive substance in tobacco products. SLT products/preparations used in India, whether they contain tobacco only or tobacco and other ingredients, are complex chemical mixtures, many of which are toxic, mutagenic, and carcinogenic, and are thus associated with a number of noncommunicable diseases including cancer. Other ingredients (for example, areca nut) contain additional toxic chemicals.

During the processes leading to the finished tobacco product (cultivation, curing, product formulation, storage, etc.) and during use, toxic agents can be accumulated (heavy metals), formed (nitrite, nitrosamines), or added (areca nut).

Evidence from animal carcinogenicity data (on mice, rats, and hamsters) and on biological fluids and cells from tobacco users plays a major role in the designation of a compound or a mixture of compounds as carcinogenic to humans. This evidence has provided support for categorising tobacco and a number of its constituents as carcinogenic.

Assessment of SLT products in terms of their potential harm to human health should include not only tobacco but all other product ingredients and constituents that can be toxic or result in the formation of toxic/carcinogenic agents.

Every effort should be made to reduce the use of SLT products among new users and to limit the harmful agents in products used by people who are unable to quit. Testing products and labelling them with the toxic chemical present is another strategy to inform potential consumers of the risks they would be taking by consuming these products.

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Chapter 14

Smokeless Tobacco: Addiction, Withdrawal, and Cessation

Raj Kumar[1], Nitin Goel[1]

[1]Vallabhai Patel Chest Institute, New Delhi

INTRODUCTION

According to the Global Adult Tobacco Survey (GATS) 2009-2010[1], 25.9% of adults in India use smokeless tobacco (SLT) products, and more men (32.9%) than women (18.4%) use SLT. Amongst daily tobacco users, 60.2% consume tobacco within half an hour after waking up[1].

The survey also found that 45.2% of SLT users planned to quit or at least thought of quitting. This breaks down into 14.6% of SLT users planning to quit within the next month, 12.8% within the year, and 17.8% someday but not within the year. Some 26.7% of SLT users had been advised to quit by a health care provider[1], while 35.4% of people who had ever used SLT had made a quit attempt in the past year. Nevertheless, the quit ratio for smokeless tobacco remains low, at 4.8% of former daily SLT users among people who had ever used smokeless tobacco daily[1].

Smokeless tobacco use is also disturbingly common amongst adolescent students in India, of whom 9% were users in 2009[2].

Because of the toll that smokeless tobacco use exacts on human health, as described in other chapters of this report, this high rate of SLT use is a problem that needs to be addressed on an urgent basis. This chapter gives an overview of smokeless tobacco addiction and cessation activities in India.

TOBACCO ADDICTION

The high prevalence of SLT use and the consequent occurrence of tobacco-related diseases are associated with tobacco addiction. According to the World Health Organization (WHO), addiction is defined as:

Repeated use of a psychoactive substance or substances, to the extent that the user (referred to as an addict) is periodically or chronically intoxicated, shows a compulsion to take the preferred substance (or substances), has great difficulty in voluntarily ceasing or modifying substance use, and exhibits determination to obtain psychoactive substances by almost any means. Typically, tolerance is prominent and a withdrawal syndrome frequently occurs when the substance use is interrupted. The term addiction also conveys the sense that such substance use has a detrimental effect on society, as well as on the individual.[3]

By virtue of possessing all the above qualities except intoxication, tobacco can be considered a highly addictive substance, like other substances of addiction.

The 1986 U.S. Surgeon General's report, *The Health Consequences of Using Smokeless Tobacco*[4], concluded that the use of smokeless tobacco products can lead to nicotine dependence or addiction and that the overall magnitude of nicotine exposure is similar for both smoking and smokeless tobacco.

The 1988 U.S. Surgeon General's report *The Health Consequences of Smoking: Nicotine Addiction*[5] had three major conclusions about addiction to nicotine: (1) cigarettes and other forms of tobacco are addictive, (2) nicotine is the chemical in tobacco that causes this addiction, and (3) the pharmacological and behavioural processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine.

Like all addictions, tobacco addiction also includes interactions among many factors: pharmacology, individual genetic make-up, conditioned responses, as well as social and environmental factors such as product marketing[6]. Whether smoked or smokeless forms of tobacco are used, nicotine produces the same kind of psychoactive effects: stimulation, arousal or relaxation, mood modulation and enhancement of the sense of well-being, reduction of anxiety, and improvement of cognitive functioning[5,6,7]. Tobacco is consumed repeatedly to obtain these reinforcing effects[8].

The Diagnostic and Statistical Manual IV (DSM-IV)[9] and the International Classification of Diseases, 10th revision (ICD-10)[10] have given criteria for nicotine dependence (the diagnostic term that includes both addiction and the outdated term *habituation*). Although developed for smoking, these criteria for nicotine dependence are applicable to smokeless tobacco as well (see textbox). Smokeless tobacco delivers nicotine to the user, which leads to addiction, also referred to as physical dependence.

Box 14.1: Criteria for nicotine dependence, adapted from two sources

DSM-IV criteria for nicotine dependence

Three or more of the following at any time in the same 12-month period:

- Tolerance: Smoker/SLT user needs increased amounts of nicotine to achieve the desired effect, or experiences diminished effect with continued use of the same amount
- Experience of withdrawal symptoms
- Nicotine often taken in larger amounts or over a longer period than intended
- Persistent or unsuccessful efforts to cut down or control use
- Spending a great deal of time in activities necessary to obtain nicotine or recover from its effects
- Important social, occupational, or recreational activities given up or reduced because of nicotine use
- Nicotine use continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by it

ICD-10 criteria for nicotine dependence

A cluster of behavioural, cognitive, and psychological occurrences that develop after repeated use of tobacco/nicotine:

- Increased tolerance
- Sometimes physical withdrawal symptoms
- A strong desire to take nicotine
- Difficulty controlling use
- Higher priority given to nicotine use than to other activities and obligations
- Persisting use despite harmful effects

Sources: DSM-IV criteria from American Psychiatric Association, 1994[9]; ICD-10 criteria from World Health Organization, 2010[10].

Dependence is used to signify both the clinical manifestations (denoted as addiction) as well as the biological mechanisms responsible for these manifestations when intake of the drug/ substance of abuse is stopped (physical dependence).

Because of the addictive nature of tobacco, any attempt by users to stop may lead to the manifestation of distressing withdrawal symptoms which make tobacco cessation difficult. WHO defines withdrawal syndrome as:

A group of symptoms of variable clustering and degree of severity which occur on cessation or reduction of use of a psychoactive substance that has been taken repeatedly, usually for a prolonged period and/ or in high doses The syndrome may be accompanied by signs of physiological disturbance. A withdrawal syndrome is one of the indicators of a dependence syndrome. It is also the defining characteristic of the narrower psycho-pharmacological meaning of dependence.[3]

Criteria for Assessing Nicotine Dependence

The Fagerström Test for Nicotine Dependence is a standardised instrument for assessing the intensity of physical addiction to tobacco/nicotine. The higher the Fagerström score, the greater the intensity of tobacco dependence. Originally developed for smoking, this test was modified to assess addiction to SLT in the United States[11], asking questions such as 'How soon after you wake up do you place your first chew?', 'Do you chew more frequently during the first hours after waking up than during the rest of the day?' as well as questions on swallowing of tobacco juice and quantities of SLT used per week. This modified Fagerström Test addresses only chewing forms of tobacco. In India, using some forms of tobacco first thing in the morning may have more to do with use of these forms as a dentifrice or mouth freshener than with the user's level of addiction. The test therefore would require further refinement and validation for use in India. Because the array of smokeless products used in this country varies so widely, a unique test could be required for each type of product.

Another scale that could be adapted for assessing smokeless tobacco dependence in India is the Smokeless Tobacco Dependence Scale[12]. This scale asks about the quantity of SLT consumed per week and the frequency of use per day, intentional swallowing of juices, presence of mouth sores, concomitant smoking, and difficulty in not using smokeless tobacco where it is prohibited. This test is clearly based on American products and hence would require considerable modification to make it relevant for India.

The role of these scales for determining and treating SLT dependence has not yet been fully established for either clinical or research settings[13]. In addition, these scales may not address the important issues of psychological and social characteristics of dependence[13,14]. Moreover, no Indian studies validating these scales are available at present. Therefore, the existing scales may be used only as a crude guide to the level of dependence in programmatic management, pending their validation in Indian scenarios.

Pathophysiology of Smokeless Tobacco Addiction

Nicotine, one of the 3,000 chemicals found in smokeless tobacco[15], is the primary addictive constituent of tobacco and demonstrates the properties of a drug of abuse. All commercially successful tobacco products deliver psychoactive levels of nicotine to users. As described by Benowitz[16]. 'Nicotine is a tertiary amine composed of a pyridine and a pyrrolidine ring. In its non-ionized form, nicotine freely permeates membranes, including the buccal mucosa and the blood–brain barrier'. To facilitate absorption of nicotine, slaked lime is added to SLT products to buffer to an alkaline pH. Nicotine is absorbed more slowly from SLT than from tobacco smoke, but peak venous levels are similar, if not higher. Blood levels of nicotine fall rapidly after smoking, but they level off slowly after SLT use, indicating that nicotine continues to be absorbed even after the tobacco is consumed[16,17]. A study of Indian products would be required to accurately characterise the product-specific absorption patterns that would be relevant to India.

Nicotine targets nicotinic-acetylcholine receptors in the peripheral and central nervous systems[8,18]. Nicotine binding to these receptors found on neurons in the reward pathway (where other drugs of abuse also act) causes dopamine release. Dopamine release gives a pleasurable feeling and is the major contributor to the reinforcing effects of nicotine (i.e., promoting self-administration). Evidence shows that these effects are regulated predominantly by the α4β2 and α6β2 receptors in addition to other subclasses of nicotinic acetylcholine receptors[19-21]. Ongoing research in this field has discovered other neuronal mechanisms responsible for nicotine dependence. Nicotine administration also increases the extracellular noradrenaline in specific parts of the brain, in addition to other peptides and neurotransmitters[22] (Figure 14.1). The release of these various neurotransmitters leads to the pleasure sensation, arousal, performance enhancement, and analgesic and weight-loss effects associated with tobacco use[8]. Because of all these psychoactive effects, smokeless tobacco becomes such a highly addictive substance that users find it difficult to give up.

Figure 14.1: Nicotinic cholinergic receptor activation promotes the release of a variety of neurotransmitters, which mediate various psychoactive effects in tobacco users

Nicotine

- Dopamine----------Pleasure, appetite suppression
- Norepinephrine---Arousal, appetite suppression
- Acetylcholine-----Arousal, cognitive impairment
- Glutamate---------Learning, memory enhancement
- Serotonin----------Mood modulation, appetite suppression
- β-endorphin-------Reduction of anxiety and tension
- GABA--------------Reduction of anxiety and tension

GABA = Gama-aminobutyric acid.
Source: Adapted from Gotti et al., 2006[22].

SLT Withdrawal Symptoms

Tobacco use, like other dependence-inducing substances, leads to withdrawal symptoms on stopping intake[8] . Total abstinence or even decreasing the amount of consumption of tobacco product leads to a constellation of withdrawal symptoms which may vary amongst different individuals, but can be marked and distressing. SLT use has been found to cause withdrawal symptoms that show higher prevalence with greater frequency of previous use[23]. The withdrawal symptoms after SLT cessation have been found to be similar to those encountered in smoking cessation, although in SLT users the symptoms are fewer in number and less severe[7,24] .These withdrawal symptoms include: craving, difficulty concentrating, irritability, insomnia, feeling hungry more often/increased eating, restlessness, and feeling depressed or sad. It has been also suggested that withdrawal symptoms in younger SLT users (who have used smaller amounts of SLT and for a shorter time) may be less evident than withdrawal symptoms among smokers[7,24], whereas in older SLT users (with greater duration and amount of SLT use) the degree and intensity of physical dependence is comparable to that in smokers. Withdrawal symptoms in SLT users have been found to peak within 1 week and decrease to baseline after 4 weeks[24].

The addictive properties of SLT and the occurrence of withdrawal symptoms on stopping use highlight the difficulty of SLT cessation.

SMOKELESS TOBACCO CESSATION

SLT cessation requires dispelling the misconception that SLT use is 'normal' or 'safe' as well as managing nicotine addiction by behavioural intervention or pharmacotherapy—for example, nicotine replacement therapy (NRT) or bupropion. Behaviour counselling, especially by physicians and other professionals, has been found to significantly increase quit rates, and pharmacotherapy can help when counselling is not sufficient[25,28]. Several studies and public health guidelines have described evidence-based treatment approaches[26-29]. Studies in India have also found counselling with pharmacotherapy to be better than counselling alone[30,31].

Early Tobacco Cessation Efforts in India

Community-based, primary care interventions for tobacco cessation were started in India as early as the 1980s and 1990s in the context of cancer control. One of the evaluated interventions was conducted in three rural areas and used both interpersonal and mass media communication[32]. It involved home visits in which social scientists who interviewed adults about tobacco use and dentists who examined the tobacco users for oral precancerous lesions explained the dangers of using tobacco to them in an interactive fashion. An educational film was developed and screened in the community on this topic, and later another film on strategies for quitting tobacco was shown, based on the needs expressed by the intervention group. The intervention carried out in Ernakulam, Kerala, showed five-year quit rates among chewers in the intervention group of 10.2% for men and 14.9% for women[32], for an overall rate of 13.9%, compared with 4.2% overall in the control group. After five years, the intervention was found most helpful to men, chewers, and those with a long duration of tobacco use[33]. As the intervention continued, further progress was achieved. After 10 years, quit rates among the tobacco chewers were 15.1% for men and 18.4% for women, while the corresponding quit rates for chewers in the control group were 2.3% for men and 7.8% for women[34].

In a case control study of an anti-tobacco community education programme carried out in Karnataka for two years[35], health education was imparted in a community where smokeless tobacco use (chewing) constituted a major part of all tobacco use. Health workers educated the community about the harmful effects of tobacco use by showing them short films and exhibits (handbills, display boards, photo albums, etc.), and by having group discussions and personal contact with tobacco users. After three years, the quit rates for smokeless tobacco users (chewers) were 30.2% for men and 36.7% for women (almost exclusively chewers). In contrast, in the two control areas the corresponding quit rates were 1.1% for men in both areas and 0.5% and 1.5% for women. Among men, a higher proportion of tobacco users participating in the intervention had given up chewing (30.2%) compared with smoking (20.4%)[35].

Recent Targeted Campaigns at Workplaces

Various government and non-governmental organisations have also carried out targeted tobacco cessation campaigns at workplaces. One such programme was conducted for one year at an industrial chemical unit in Ratnagiri District, Maharashtra, among 104 employees, of whom 50 were tobacco users; 33 of these used SLT exclusively and 10 used both smoking and smokeless forms[36]. Programme activities included lectures, oral screening, small-group discussions, professional counselling with individuals, and involvement of the family and the on-site occupational health team. Quit rates were 51.5% among SLT users, 14% among smokers, and 20% among dual users[36].

In another example, a campaign was directed toward tobacco workers amongst the 739 workers at a confectionary factory in Mumbai[37]. This structured, three-stage intervention consisted of education on the harmful effects of tobacco, oral cancer screening, and behaviour therapy for tobacco cessation at the worksite. The study concluded that an integrated approach for worksite-based tobacco use prevention with oral cancer screening results in good acceptance and participation, and is also an effective method of addressing the problem of tobacco consumption at workplaces[37].

Tobacco Cessation Centres—A Clinic-Based Approach

The National Tobacco Control Cell was established in 2001 as part of the initiative of the Government of India and the World Health Organization on tobacco control in India. In 2002, WHO supported the establishment of 12 tobacco cessation clinics (TCCs) in medical colleges, specialised and general hospitals, and non-government organisations[38]. Six Regional Cancer Centres (RCCs) were added by 2005, and another TCC was set up in 2009 in a general hospital setting. All these centres were provided with infrastructure resources such as computer equipment and human resources such as a clinical psychologist and medical social worker[38].

The smokeless tobacco cessation efforts at these centres, which were modelled on smoking cessation programmes, consist of initial assessment, three steps of intervention, and evaluation at regular intervals, with estimation of urinary cotinine levels as an objective measure of cessation. To involve the public in a large-scale cessation activity, these centres have organised extensive community interaction programmes. Establishing smokeless cessation clinics within major hospitals helped to draw SLT-using patients and hospital staff into the programmes. Intake and follow-up procedures for these TCCs have been standardised. The operation and results of these centres are monitored, and any required mid-course corrections are made.

Tobacco dependence treatment guidelines were developed in 2011 by the Ministry of Health and Family Welfare, Government of India, under the National Tobacco Control Programme, and made freely available on the Internet[39]. These guidelines proposed the following suggestions for scaling up and strengthening the programme:

- All health care providers must provide brief counselling for tobacco cessation as part of routine health care, and levels of dedicated tobacco cessation services can be set up in primary, secondary, and tertiary health care settings.
- Specialist care may be provided particularly to help people with more severe tobacco dependence.
- Tobacco cessation services can be set up in various departments of a hospital or medical college, such as dentistry, medicine, surgery, ENT, psychiatry, community medicine, tuberculosis and chest diseases, paediatrics, obstetrics, and gynaecology.
- A specialised setting can be run by a team consisting of a trained physician, counsellor, or social worker attendant. A trained nurse, pharmacist, or health worker can also provide counselling services.

The TCCs have also developed modules for tobacco cessation in Indian languages used in various locations.

Evaluation of the TCC programme has shown that effective tobacco cessation services are workable in Indian settings[39]. Behaviour change counselling has resulted in satisfactory quit rates, which allow room for improvement. Counselling, the most practicable option, is also cost-effective and the least expensive treatment option for expanding services[38]. The overall quit rate at 6 weeks was 15.1% among SLT users and 12.2% for smokers. For smokers and SLT users combined, adding pharmacotherapy improved quit rates (from 12.5% with counselling alone to 17.2%)[40]. Unfortunately, no data are available so far for individual TCCs, but combined data from all TCCs have been published[40].

Results from the TCCs: The First Five Years

Results from the TCCs have been encouraging and support the conclusion that an effective tobacco control programme can be carried out in India by judiciously using the existing health care infrastructure. In the first five years of the programme, the 18 TCCs based in health care facilities registered 34,741 tobacco users for tobacco cessation, with baseline information available for 23,320 of them (92% were men)[40]. Of cases seen at the TCCs, 65.5% were SLT users (chewers), and an additional 5.3% were smokers as well (dual tobacco users). Among men, 64% of the attendees were SLT users and 5.6% were dual users. Among women participants in the programme, 83.5% were SLT users and an additional 2.2% also smoked. Quit rates at 6 weeks for SLT users were 15.1% overall, 15.7% for men, and 9.5% for women. For dual tobacco users the corresponding quit rates were 9.4%, 9.3%, and 10.0%[40].

Behaviour counselling is a cornerstone of the tobacco cessation programme in India and was utilised effectively at these TCCs. In 68.9% of all cases attending the TCCs (including smokers and SLT users), behaviour counselling was the primary strategy for cessation intervention. Pharmacotherapy in the form of nicotine replacement therapy was also administered to about 10.1% of cases, while 20.0% received some other form of pharmacotherapy (mostly bupropion). Of men attending the programme, 31.1% quit tobacco, and 49.5% reported that they had reduced their tobacco usage by 50% or more (in cases with 6 weeks of follow-up available—that is, about 44.9% of the entire group). An analysis of the data for the entire cohort found that, even if those lost to follow-up are considered ‘not improved’, 36% were in the improved group, and of these, 14% had quit and 22% had reduced their use by 50%. Not all TCCs had maintained long-term follow-up data. Nevertheless, the overall data provided important insight into the management of tobacco dependence, including the finding that a significant number of cases who were in the ‘no change’ category after 6 weeks had moved into the improved category. This observation can be heartening for the counsellors at these centres, and it indicates that longer term retention of SLT users in these cessation programmes leads to better outcomes[40].

The data show that not only are TCCs in diverse clinical settings feasible, they are also effective. These results have important implications for future policy regarding both smoked and smokeless forms of tobacco consumption. The results also have contributed to the development of intervention models that have been extended to surrounding communities and have the potential to be extended on a large scale (scaled up). Limitations of the clinic-based approach in the form of TCCs are that it reaches a relatively small number of predominantly urban and educated users, treatment used has been heterogeneous, and use of pharmacotherapy has been limited.

THE EVOLVING NATIONAL TOBACCO CONTROL PROGRAMME

The Ministry of Health and Family Welfare, Government of India, launched the National Tobacco Control Programme (NTCP) in 2007–2008[41]. Currently, the programme is under implementation in 21 out of 35 States/Union Territories in the country, covering 42 districts. The

NTCP has raised awareness of the need to increase the areas covered by this programme to all the States/Union territories in India[41].

Under the NTCP, the National Tobacco Control Cell (NTCC) is responsible for overall policy formulation, planning, monitoring, and evaluation of the different tobacco cessation activities to be performed under the programme. The NTCC functions under the direct guidance and supervision of the head of the programme in the Ministry of Health and Family Welfare. Every identified state and Union Territory is required to set up a State Tobacco Control Cell (STCC) which is responsible for overall planning, implementation, and oversight of the different activities, and for reaching the state programme's physical and financial targets[41].

Taking into account the widespread use of tobacco and tobacco users' needs for assistance in quitting, the NTCC called for establishing tobacco cessation facilities at the district hospitals. The District Tobacco Control Cells (DTCCs) have been made responsible for all NTCP activities in their districts. This provision was a major step forward in bringing tobacco cessation facilities close to communities. In addition to setting up cessation facilities in medical and dental institutions and all district hospitals, the focus of the DTCCs is to build every state's capacity in tobacco cessation by training health professionals and establishing TCCs. National Guidelines for Tobacco Dependence Treatment[39], published in 2011, included smokeless tobacco cessation along with a focus on smoking cessation. Training modules for doctors and health workers, also developed in 2010–2011, emphasise 'brief advice' for tobacco cessation[40].

For the first time, tobacco cessation assistance was also incorporated in the training modules of doctors under the Revised National Tuberculosis Control Programme (RNTCP)[40]. All tuberculosis hospitals, general hospitals, and medical and dental colleges have been encouraged to set up tobacco cessation programmes as part of caregiving[40].

Strengthening of the tobacco control programme will require increasing the availability of nicotine replacement therapy (NRT), making counselling as well as pharmacotherapy available to patients free of cost, and finally, incorporating a dedicated performance review mechanism into tobacco cessation services.

Establishment of one apex laboratory and five tobacco testing laboratories in the country has also been approved under the NTCP[41], but this has not yet been implemented[42]. To completely implement the legal requirement of displaying nicotine and tar levels on tobacco product labels, the country may require more than five peripheral labs. Once operational, these laboratories could give further insights into mechanisms of tobacco addiction in India and thus contribute to the development of new and better cessation interventions.

CONCLUSIONS

By initiating the National Tobacco Control Programme in 2007, India has made commendable progress toward providing evidence-based interventions to help SLT users quit. This programme has given further momentum and direction to the tobacco cessation movement initiated by the establishment of TCCs with the help of the World Health Organization in 2002. Calling for the establishment of cessation services in all district hospitals and in medical and dental institutions is a move in the right direction by the NTCP, but good implementation and coverage will be required to accomplish this goal. Further research into the practical aspects of SLT cessation should also be carried out to elucidate the behavioural and social aspects of SLT use in India.

This research will help in formulating better targeted, more evidence-based policies for SLT cessation.

To summarise, widespread tobacco cessation efforts in India have been initiated and are being implemented, but services must be further developed and offered to more of the population, and the public must be better informed about the availability and relevance of such services. Services must more actively target young tobacco users, women users, rural populations, and the economically underprivileged. In addition, further research is needed on developing pharmacotherapies that are not only cost-effective, but can also deal with withdrawal from tobacco and be well tolerated and safe (with the fewest and most acceptable side effects).

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Chapter 15

Advocacy and Policy Measures

Monika Arora[1], Deepti Singh[1],
Raghvendra Madhu[1], Shekhar Salkar[2]

[1]Public Health Foundation of India, New Delhi
[2]National Organization for Tobacco Eradication (India)

INTRODUCTION

Smokeless tobacco (SLT) is a multifactorial issue requiring a multisectoral response. In the past two decades, the country has witnessed a rampant increase in consumption of SLT in industrially manufactured forms, especially gutka. Gutka was originally available as areca nut, slaked lime, catechu, condiments, and powdered tobacco custom-mixed by pan vendors. This dry preparation, which contains around 3,000 chemicals, has undergone major commercialisation since 1975[1]. These alternative tobacco products have often been advertised as mouth fresheners, and advertisements for them have misled consumers by highlighting their expensive ingredients. Surrogate advertising has led to a much higher frequency of use by younger chewers, who constitute an alarming cohort for a new epidemic of oral cancer[2].

The Global Adult Tobacco Survey (GATS) India report for 2009-2010 noted that there are four times as many SLT users as smokers. This report also revealed that the SLT initiation rate before the age of 15 is higher among users who are poorer and have no formal education, adding to their existing burden[3]. Between 2005-2006 and 2009-2010 the percentage of women SLT users has more than doubled, from 8.4% to 18%[4,5]. Children as young as 14 years have been diagnosed with precancerous lesions resulting from smokeless tobacco use. The Global Youth Tobacco Survey of 2009 revealed that 6% of school-going girls (13–15 years) use smokeless tobacco compared to 3.7% who smoke[6]. Surveillance estimates have provided evidence that SLT use is high among adolescents and adults, particularly impacting vulnerable population groups, thus making a case for active public health advocacy and policy. SLT is unique because it is available in myriad varieties, and it is easy to access and affordable, especially for adolescents. Research has shown that SLT is a gateway product (i.e., it facilitates initiation of other tobacco products)[7].

Preventing SLT use had policy support early on. The Cigarettes and Other Tobacco Products Act (COTPA) of 2003 aims to regulate trade of all tobacco products[12]. Despite this policy support, tobacco use has increased considerably in India. Since the 1980s, many policy and legislative developments have attempted to regulate SLT use but failed to reduce prevalence. In 2002 Maharashtra[8] and subsequently a few other states (Goa[9],Tamil Nadu[10], West Bengal[11]) invoked the provisions of the Prevention of Food Adulteration Act (PFA, 1954) to impose a ban on gutka and pan masala (containing tobacco) in the interest of public health. Despite these attempts to control SLT, its use and related health burden have continued to rise. The challenges and gaps in enforcing these policy measures, which have led to unregulated SLT consumption and the rising SLT-related disease burden in India, underscore the need for stronger and concerted public health advocacy and appropriate policy treatment to tackle the problem of SLT in India.

These challenges spurred the organisation of the first National Consultation on SLT in April 2011 by the Ministry of Health and Family Welfare (MoHFW) and the World Health Organization (WHO) in collaboration with the Public Health Foundation of India (PHFI), which highlighted the magnitude of the problem of SLT use and recommended a complete ban[12].

This chapter will describe and give a chronology of the advocacy and policy initiatives undertaken in India with reference to SLT to update the readers about events that led to current prohibition in 17 states of India (until October 2012). In addition to discussion of these initiatives, this chapter describes lessons learnt throughout this process, challenges to SLT regulations, and recommendations for future action.

ADVOCACY STRATEGIES

Smokeless tobacco is a multifaceted challenge that supports the economic interests of a few over the indirect cost borne by the society as a whole and the government in the form of disease, health care costs, and environmental pollution. To deal with this challenge, multilevel advocacy efforts were undertaken in India to curb the ill effects of SLT and bolster control and prohibition policies. These efforts, described below, fall into three categories: civil society–led campaigns, government-driven initiatives, and government–NGO partnership.

Civil Society–Led Campaigns

Civil society in India has been demonstrating a steely resolve to curb SLT use through a comprehensive advocacy strategy that includes both demand and supply reduction measures[13].

NGO Coalitions

In 2001, nine national NGOs working in tobacco control advocacy and research in India formed the Advocacy Forum for Tobacco Control (AFTC). Currently, the AFTC has 65 NGO members and is a nationwide network. The AFTC was instrumental in passage of the COPTA bill in 2003, vigorously advocating for it with members of Parliament and supporting MoHFW during debate on the bill in Parliament in April 2003. The bill had been introduced in Parliament in 2001 and was referred to a Standing Committee for review. At that stage COTPA addressed only cigarettes and no other tobacco products, but during public hearings and through civil society representation, the scope of the bill was expanded to include all forms of smoking and smokeless tobacco products. The AFTC designed and implemented informative messages and a multisectoral advocacy campaign directed toward key members of Parliament that clarified the benefits of having a comprehensive tobacco control law in India[13]. The bill got clearance from both the houses of Parliament and, with the assent of the President, became an Act on 18 May 2003, which is a landmark in the history of tobacco control efforts in India.

Other similar efforts have arisen, such as the Tobacco Free India Coalition (Chandigarh) and state-specific coalitions like the Rajasthan Coalition for Tobacco Control (Jaipur) and the Tamil Nadu Tobacco Control Coalition (Chennai). These organisations function to boost tobacco control advocacy efforts at the state level.

More recently, the PHFI, as a part of its Strengthening of Tobacco control Efforts through innovative Partnerships and Strategies (STEPS) project, organised state-level consultations in Gujarat to support implementation of the gutka ban there, and to advocate for an SLT ban in Andhra Pradesh. These coalitions aim to monitor and support tobacco control initiatives in these tobacco-producing states, with the long-term vision of achieving Tobacco Free Andhra Pradesh and Gujarat (see Box 15.1).

Box 15.1: Coalition for Tobacco Free Gujarat

A state-level stakeholder consultation on tobacco control in Gujarat was organised by PHFI's Project STEPS in partnership with the Government of Gujarat and the Indian Institute of Public Health–Gujarat and held on 26 September 2012. The objective of the consultation was to ensure better implementation of the gutka ban and achieve the broader goal of making Gujarat tobacco free. Stakeholders from government, civil society, and the media attended the meeting. Based on the discussions at the consultation, all the stakeholders agreed to form a coalition of NGOs and other stakeholders (the Coalition for Tobacco Free Gujarat [CTFG]) to support and advance tobacco control activities in the state, including implementation of tobacco control law and the gutka ban.

Right-to-Information Advocacy Campaigns

India implemented pictorial health warnings on product packaging in 2009 after six years of intense advocacy campaigns. To learn the cause of the delay in implementing pictorial warnings, the Voluntary Health Association of India (VHAI), a pan-India NGO working on tobacco control in most of the states and in Delhi[14], filed a Right to Information (RTI) application in 2010, which revealed that pictorial warnings on tobacco packs were deferred because of pressure from the tobacco industry. The Group of Ministers had also deferred implementation of pictorial warnings from 30 November 2008, to 31 May 2009, which a similar RTI filed by VHAI showed was also caused by continuous industry interference.

Delhi Metro Rail Corporation's (DMRC) policy permitting surrogate advertisements of SLT products was also investigated by means of an RTI application filed by HRIDAY (Health Related Information and Dissemination Amongst Youth), a Delhi-based NGO working on chronic disease prevention and health promotion issues countrywide. The RTI response from DMRC highlighted significant gaps specific to prohibiting surrogate advertising of tobacco products and policy conflict between COTPA and the Ministry of Information and Broadcasting (MoIB) notification on advertising. Further, the response also exposed the fact that the surrogate advertisements were providing social space and acceptance for pan masala[15]. RTI has proven to be an efficient tool to unveil tobacco industry interference in public health policy decisions, which aids in media advocacy and promotes transparency in policy decisions.

NGO Advocacy for Strong Pictorial Warnings

In May 2009, under a Group of Ministers directive, a set of mild and diluted warnings were introduced by the Directorate of Advertising and Visual Publicity (DAVP) (Figure 15.1). These warnings were not field tested, and an independent evaluation by public health research organisations found them to be ineffective[16,17]. Through strategic advocacy campaigns, HRIDAY, VHAI, Healis, and AFTC alerted the government about the ineffectiveness of the warnings and about violations of health warnings policy. As a result of consistent advocacy by NGOs in India, the current set of warnings on SLT products have been improved (Figure 15.2).

Figure 15.1: Stronger pictorial warnings as notified in 2006 (on left) and later diluted in 2009 (on right). Enforced from 31 May 2009.

Photographs courtesy of Ministry of Health and Family Welfare Notification G.S.R. 985(E), December 20, 2010

Figure 15.2: Current warnings for smokeless tobacco product packages, as notified from 1 December 2011

Photographs courtesy of Ministry of Health and Family Welfare
Notification G.S.R. 724(E), September 27, 2012

NGOs and Litigation

Litigation is a powerful advocacy strategy that paved the way for development of the current laws on smokeless tobacco.

In the 1980s, the Consumer Education and Research Centre (CERC), before the Monopolies and Restrictive Trade Practice Commission, compelled tobacco-based toothpaste manufacturers to label their products in English and the local languages with information on their composition and tobacco content and to include a statutory health warning stating that tobacco is injurious to health in their advertisements. In 1992, the Central Government and Supreme Court (SC) upheld this decision under the Drugs and Cosmetics Act of 1940 (for details, see Table 15.3).

The Prevention of Food Adulteration Act banned food items that fall below the prescribed standards of purity or quality. Between 2001 and 2004, states used PFA provisions to impose a blanket ban on gutka. In the *Godawat* lawsuit in 2004, the SC considered tobacco a 'food item', acknowledged that any ban on these products may come only with a central legislation, and struck down bans on SLT at the state level. Although this ruling appeared to be unfavourable to the cause of tobacco control, this landmark judgement laid the foundation for current SLT prohibition in the country.

Packaging

The courts in India have played a major role in the implementation of pictorial warnings on packaging. The process of implementing pictorial warnings on all tobacco packages in India was initiated through a Public Interest Litigation (PIL) in the High Court (HC) of Himachal Pradesh in 2004. Health for Millions (HFM), an NGO, filed an intervention application in an existing transfer petition on pack warnings in the Supreme Court, pleading for early and effective implementation of pictorial warnings. The SC hearing the petition ordered the implementation of pictorial health warnings, as approved by the Group of Ministers, starting on 31 May 2009. Rotations of these warnings were constantly delayed during 2010. HFM's petition brought this rotation delay to the notice of the SC, and as a result the Government of India implemented the Packaging and Labelling Rules, 2011, but the rotation period was extended from 12 months to 24 months.

Plastic Packaging

In 2010, gutka manufacturers filed an appeal in the SC challenging a Rajasthan High Court order that had directed them to pay a fixed amount of 'pollution fine' to their state governments in proportion to their gross sales revenue[18]. The SC *suo moto* included the Ministry of Environment and Forests (MoEF) also and directed MoHFW to assess the hazardous health effects of SLT products and packages, and other similar products such as pan masala, on human health. To curtail the environmental ill effects of tobacco product packages, directions were issued to ban the sale of tobacco products like gutka, tobacco, and pan masala in plastic pouches. The MoEF was asked to finalise the Plastic Management and Disposal Rules, 2009, and these were enforced beginning in March 2011[19].

Removing Subsidies for SLT Production

In the case of *Bejon Mishra v. Union of India and Others,* the civil society VOICE (Voluntary Organization in Interest of Consumer Educaton) had advocated for quashing the notification before Delhi High Court whereby the Executive Authority in Delhi restored subsidies and exemptions to the manufacturers of gutka and chewing tobacco products. As a result of this timely advocacy effort, the Delhi Government withdrew the impugned notification.

PILs to Implement Food Safety and Standards Regulations in the States

In response to a PIL filed by a group of doctors *('Doctors for you' v. State of Delhi*) for implementation of Regulation 2.3.4 of the Food Safety and Standards Act (FSSA), 2006, the Government of the National Capitol Territory of Delhi assured that steps would be taken to implement the regulation. The Government of Delhi complied and passed orders imposing a complete ban on gutka and pan masala in the state. Similar PILs were filed by NGOs in High Courts in Andhra Pradesh and Uttar Pradesh, and the HCs ordered the state governments to enforce this FSS regulation (see chapter 16 for details).

Voice of Tobacco Victims (VoTV)

The Voice of Tobacco Victims (VoTV) campaign, founded in 2008, gives patients suffering from tobacco-related cancers a platform from which to raise public awareness about the public health menace of tobacco. This campaign has contributed to existing litigation against the tobacco industry and has lobbied with Legislative Assembly Members and policy makers to implement stronger policies on tobacco, particularly smokeless tobacco, in their states. VoTV has worked for stronger pictorial warnings, higher taxation, a ban on indirect advertising, and effective enforcement of Section 6(b) of COTPA, 2003 (i.e., ban on sale of tobacco products within 100 yards of educational institutions)[20-22]. In 2011, VoTV effectively advocated for state-level bans on gutka and pan masala. A charter of demands and petitions was given to the Chief Ministers and Health Ministers of various states calling for formation of an inter-ministerial task force to implement FSSA Rule 2.3.4[23].

Media Advocacy

NGOs and the media have worked in tandem to highlight SLT as a health menace. In the last two to three years, leading magazines and newspapers have published well-researched articles on the ill effects of SLT use; some of these publishing efforts were supported by NGOs. In 2011, *Down to Earth* magazine published a detailed report on banning gutka which stated that these SLT products were highly toxic and contained waste from perfumeries and tanneries as additives.

Counter-Campaigns

Since April 2012, when states started enforcing bans on gutka and pan masala, the SLT industry has conducted a nationwide paid media campaign declaring this ban unjust. To counter the SLT industry's misleading advertising campaign, PHFI, in collaboration with VHAI and MoHFW, organised a joint press conference in October 2012 (Figure 15.3). The press conference presented the scientific and legal justification for the ban, highlighted tactics used by the industry to subvert the landmark legislation, discussed implementation and enforcement of the ban, and described steps to take toward a nationwide ban. This NGO-led advocacy earned media space in seven respected national newspapers, national wire agencies, and on five major television news channels.

Figure 15.3: Press conference on the SLT industry's misleading ads

Photographs courtesy of Photobank PHFI

Youth as Messengers

An exhibit titled 'Pictures save lives: Choose and save millions', launched at the India International Trade Fair on Children's Day, 14 November 2010, is an example of advocacy by young people on behalf of reducing smokeless tobacco use. This campaign was developed by youth health advocates from schools in Delhi, in collaboration with HRIDAY, PHFI, and the Campaign for Tobacco-Free Kids (U.S.). Its goal was to introduce effective pictorial warnings on tobacco products in India. The two-week interactive exhibit (Figure 15.4) highlighted the weak health warnings displayed on tobacco product packages in India during 2010 and showcased powerful warnings used on tobacco product packages in other countries. Through signature campaigns, opinion polls, warnings on walls, media advocacy, and informative education and communications materials, the exhibit garnered public and political support for strengthening health warnings in India. Fifteen members of Parliament lent their support to the campaign (Figure 15.5).

Figure 15.4: Students' interactive exhibit about SLT warning labels

Figure 15.5: Students meet with a member of Parliament

Photographs courtesy of Photobank HRIDAY.

According to the opinion poll conducted at the exhibition, nearly 80% of respondents (13,020 people) stated that mouth cancer warnings are effective in conveying the health hazards of tobacco use. An appeal calling for timely implementation of effective pictorial health warnings was signed by 12,531 people and sent to the Prime Minister and President of India. Such advocacy events along with other efforts by civil society resulted in replacing earlier, ineffective pictorial health warnings (depicting a scorpion, a lung x-ray, and diseased lungs) displayed on tobacco product packages in India with strong, effective graphic warning images, such as the gruesome picture of 'oral cancer' introduced on SLT products on 1 December 2011.

Social Media Optimisation

Tobacco control advocates in India have increasingly used social media to sensitise youth and engage a wider audience. An online mass awareness campaign titled 'Chew on this' [http://www.chewonthis.in/chewonthis/] highlighted the dangers of SLT use (Figure 15.6).

Figure 15.6: Webpage of the 'Chew on This' online campaign

Photograph courtesy of Photobank HRIDAY.

Social media were also used as part of the other SLT-related campaigns directed at youth. Opinion polls on the 'Youth for Health' Facebook page (www.facebook.com/youthforhealth) generated support for gruesome pictorial warnings on tobacco products. Social media were also a crucial part of the ‘Pictures save lives: Choose and save millions’ campaign (Figure 15.7)[22].

Figure 15.7: Facebook campaign to ban SLT in all states

Photograph courtesy of Photobank HRIDAY.

Curbing Surrogate Advertisement of SLT Products

Regular monitoring found that surrogate advertisements of tobacco products were displayed at many busy Delhi metro stations in 2012. Health advocates from HRIDAY wrote letters urging the Managing Director of Delhi Metro Rail Corporation (DMRC) to remove all indirect or surrogate advertisements of pan masala[21] (Figure 15.8). This incident brought to light the fact that DMRC advertising guidelines permitted surrogate advertising in DMRC stations with approval from Ministry of Information and Broadcasting.

Figure 15.8: SLT advertisements in DMRC buses

Photograph courtesy of Photobank HRIDAY.

Another noteworthy effort to curb surrogate advertisements was carried out by an NGO based in Gujarat, the Faith Foundation, which runs a project called ‘Indirect Advertisement Free Gujarat by 2012’ that led to the removal of about 80 hoardings of pan masala and gutka in Vadodara district. Such violations of prohibitions against surrogate advertisements at events have been reported to the State and District Level Steering Committee for Tobacco Control in Gujarat and Vadodara.

Government Efforts That Support Advocacy and Policy Initiatives

Surveillance and Monitoring

Several surveillance efforts led by the government—the Global Adult Tobacco Survey (GATS), the Global Youth Tobacco Survey, the National Sample Survey, the National Family Health Survey, and others—have advanced the understanding of tobacco consumption and its costs to households. Most survey data in India show that gutka and SLT are driving the tobacco epidemic. The use of SLT is especially high among women and children and is socially accepted, whereas smoking is still taboo. This important information has helped the government and public health advocates to make reducing SLT use a priority for immediate policy action that would show larger population-level health benefits.

National Consultation on SLT (April 2011) and Intradepartmental Coordination

The GATS India 2009-2010 report revealed that smokeless tobacco use was the most widespread form of tobacco used by Indians, which led MoHFW to convene experts from around the country to deliberate on the policy response to SLT proliferation in India. Also invited were representatives from the Food Safety and Standards Authority of India (FSSAI), an autonomous department within MoHFW. This National Consultation on SLT, held in April 2011, was the first such meeting ever held on SLT in India. It was attended by more than 80 tobacco control experts from across India and around the world (Figure 15.9). These experts deliberated on the available evidence on the constituents of SLT, the harmful health effects and economic costs of SLT use, and existing policies and laws that regulate SLT products.

Figure 15.9: Experts at the National Consultation on SLT, 2011

Photograph courtesy of Photobank PHFI.

The expert group recommended a complete ban on SLT production, supply, and distribution countrywide by notifying FSS regulation. Immediately after this consultation, organisations like PHFI worked with the media and government to get the FSS regulation notified in August 2011. The consultation further recommended developing a comprehensive plan to deal with the social and economic implications of a total ban on smokeless tobacco, including tobacco cessation, and loss of revenue and livelihood; they also made recommendations for tackling illicit trade[12].

Implementing FSSA Regulation 2.3.4

Regulations banning SLT required intradepartmental coordination, and MoHFW steered these discussions successfully to achieve the desired notification moved by FSSAI in August 2011. The process of implementing FSSA Regulation 2.3.4 consisted of the following:

- On 2 August 2011, the FSSAI CEO wrote a letter alerting all food commissioners to the urgent need for states to take action before 5 August to ensure correct implementation of the FSS Rules and Regulations.
- In response to queries from various states with regard to implementation of the regulations under FSSA, the Special Secretary, MoHFW, issued a letter on 8 May 2012, directing the states in implementing the ban.
- PHFI also sent letters with supporting government documents to Chief Ministers, Health Ministers, and food commissioners of all the states requesting them to implement the SLT ban. Other organisations such as AFTC, VHAI, and VoTV held meetings and public events with state food commissioners and other officials and urged various state administrations to implement the ban; they also supported the ban by drafting state orders.
- The VoTV campaign and civil society meetings raised awareness among the Chief Ministers, bureaucrats, and key administrators of some states about the scourge of SLT use. Some states involved key Ministries like Home, Health, Finance, Agriculture, Food and Drug Administration, and Education and coordinated with the Principal Secretary of those states to obtain legal approval and pass the orders.
- At the request of state governments that were considering enforcement of this notification, PHFI provided technical support by formulating a Standard Operating Procedure document to implement the ban.

Table 15.1 provides notification and implementation dates of FSS Regulation 2011 by states as of October 2012. It also indicates whether the tobacco industry challenged these notifications in these states.

Table 15.1: Notification and implementation of FSS Regulations, 2011, Rule 2.3.424, by states

Order of notification	State	Date of notification/declaration	(1) Challenged by industry litigation or (2) a PIL was filed to implement the ban*
1	Madhya Pradesh	Notification dated 31 March 2012 Implemented from 1 April 2012 Order passed by state Commissioner of Food Safety	Yes
2	Kerala	Notification dated 22 May 2012 Order passed by state Commissioner of Food Safety	Yes
3	Bihar	Notification dated 30 May 2012 Order passed by state Commissioner of Food Safety/Secretary of Health	Yes

Order of notification	State	Date of notification/declaration	(1) Challenged by industry litigation or (2) a PIL was filed to implement the ban*
4	Rajasthan	Notification dated 18 July 2012 Order passed by state Commissioner of Food Safety	Yes
5	Maharashtra	Notification dated 19 July 2012 Order passed by state food safety commissioner, FDA	Yes
6	Haryana	Declaration passed on 20 July 2012	No
7	Chhattisgarh	Notification dated 25 July 2012 Order passed by state Commissioner of Food Safety	No
8	Chandigarh	Notification dated 25 July 2012 Order passed by Secretary of Health/ Commissioner of Food Safety	No
9	Haryana	Implemented from 15 August 2012 Order passed by state Commissioner of Food Safety	No
10	Jharkhand	Notification dated 25 July 2012 Order passed by Commissioner of Food Safety	Yes
11	Gujarat	Notification dated 28 August 2012 Order passed by Commissioner of Food Safety Implemented from 11 September 2012	No
12	Himachal Pradesh	Notification dated 13 July 2012 Implemented from 2 October Order passed by state Commissioner of Food Safety	No
13	Mizoram	Notification dated 22 August 2012 Order passed by Secretary/Food Safety Commissioner	No
14	Punjab	Notification dated 5 September 2012 Order passed by Commissioner of Food Safety/Secretary of Health and Family Welfare	No
15	Delhi	Notification dated 11 September 2012 Order passed by Commissioner of Food Safety	Yes
16	Sikkim	Notification dated 17 September 2012	No

Order of notification	State	Date of notification/declaration	(1) Challenged by industry litigation or (2) a PIL was filed to implement the ban*
17	Uttar Pradesh	Declaration passed on 4 October 2012 Implemented from 1 April 2013 Order passed by state Food Safety Commissioner	Yes
18	Nagaland	Notification dated 12 October 2012 Order passed by Commissioner of Food Safety/Commisson/Secretary to the government of Nagaland	No

*For details of litigations, see chapter 16.

Judicial Coordination

Regulation 2.3.4 of the Food Safety and Standards Act, 2006 (specifically, the Prohibition and Restrictions on Sales Regulations, 2011[24]) prohibits sale of products that contain any substance injurious to health and prohibits using tobacco and nicotine as ingredients in any food products. FSSA Regulation 3.1.7 [of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011] restricts use of anti-caking agents like carbonates of calcium and magnesium in foods. This law has been challenged in various industry petitions. The government filed a transfer petition—namely, *Union of India & Another v. Dharampal Satyapal Ltd. and Others*—for transfer of cases pending before various HCs to the Honourable SC, to avoid any adverse orders being passed against the enforcement of FSS regulation. At the same time, industry petitions challenging an earlier PFA rule (Rule 44J), which was transferred to the SC during 2009, will also be heard in addition to the *UOI v. Dharampal* transfer petition (described in more detail in chapter 16).

Government–NGO Partnerships

In addition to laws banning SLT use, NGOs have worked closely with state and Central Government to support other tobacco control measures in India.

Tobacco Taxation

The Additional Secretary (MoHFW) in a letter to the Chief and Finance Secretaries of all states, urged that the value-added tax (VAT) be increased on all tobacco products to deal with the growing tobacco epidemic. Such an increase was intended to prevent new initiation into tobacco use and encourage existing tobacco users to quit. Government efforts to advocate with state governments through inter-ministerial coordination complemented ongoing civil society advocacy with the state governments, and a few Indian states increased the VAT on SLT products up to 40% (Table 15.2). Efforts to raise the VAT in Rajasthan started in April 2010 with an initiative undertaken by the Rajasthan Cancer Foundation directly with the Chief Minister who was also the Finance Minister. The Rajasthan Cancer Foundation's partners in the Resource Centre for Tobacco Control (RCT) supported their initiative by effectively persuading the Chief Minister and the state departments of Finance and Medical and Health to increase the VAT on all retail tobacco products from 20% to 40% in the year 2010-2011. In the subsequent fiscal year, 2011-2012 the VAT was raised to 50%, and in 2013-2014 it was increased to 65%—

the highest rate in the country. Similarly, Jammu and Kashmir increased the VAT from 30% to 40% in the 2013-2014 fiscal year. However, advocacy efforts should be stepped up to raise SLT taxes to the recommended 70–80% of retail price in India.

Table 15.2: Value-added tax (VAT) on all forms of tobacco (as of October 2012)

State/UT	Previous VAT (2010-11) (%)	VAT for 2011-12 (%)
Andhra Pradesh	14.5	20
Bihar	13.5	20
Gujarat	12.5	25
Jammu and Kashmir	25	30
Jharkhand	14	20
Kerala	20	22.5
Rajasthan	40	50
Uttar Pradesh	12.5	30

Community Mobilisation: Tobacco-Free Villages

In order to test a model of using self-help groups to create demand for tobacco cessation at a community level, a downstream advocacy campaign involving local influencers was initiated in Andhra Pradesh and Gujarat in 2011-2012 (Box 15.2). The existing informal groups for social benefit were identified as resources to provide sustainability to this campaign. As a part of PHFI's STEPS project, village-level self-help groups were mobilised. These groups consisted of youth representatives, former tobacco users, Accredited Social Health Activists (ASHAs), Auxiliary Nurse Midwives (ANMs), religious leaders, and Anganwadi workers. (Anganwadi workers are women selected from local communities as frontline honorary workers in child development programmes; they are also agents of social change, mobilising community support for better care of young children, girls, and women.) Self-help group members were trained in motivational interviewing (see Figure 15.10 for a picture of their handbook). The members have social meetings and provide tobacco users with brief advice on quitting (Figure 15.11). This community-level advocacy involving village and panchayat leaders has led to dynamic policy changes, sowing seeds for 'Tobacco Free India' and helping to change social norms to no tobacco use.

Box 15.2: Tobacco-free villages in India

The administration of Pongalipakka village in Visakhapatnam, Andhra Pradesh, declared themselves ‘tobacco free’ on World No Tobacco Day 2012 as a result of systematic community efforts through PHFI’s STEPS project[25]. Alternate livelihoods were arranged for tobacco-selling vendors. Ten to 12 other neighbouring villages are also becoming tobacco free.

The local self-governments (Panchayati Raj Institutions) in Sarfabad village (Noida) observed that its youths were suffering from serious illness caused by using gutka and other forms of tobacco. The elders in the village supporting the ban reported that they observed that an increasing number of youth were becoming addicted to tobacco use[26] which led them to declare their village tobacco free.

The Jorhat village in Assam reportedly succeeded in becoming tobacco free in 2012[27].

Also in 2012, the Government of Tamil Nadu worked to make about 86 villages tobacco free, including Pudupetty in Madurai, Pachaimalaian Kottai in Dindigul, and Varanavasi in Kancheepuram (the remaining 83 villages were in Villupuram district)[22].

Shankapura village in Haryana has an age-old tradition of no tobacco use, as the village population are predominantly Sikh[28].

Figure 15.10: Self-help group handbook

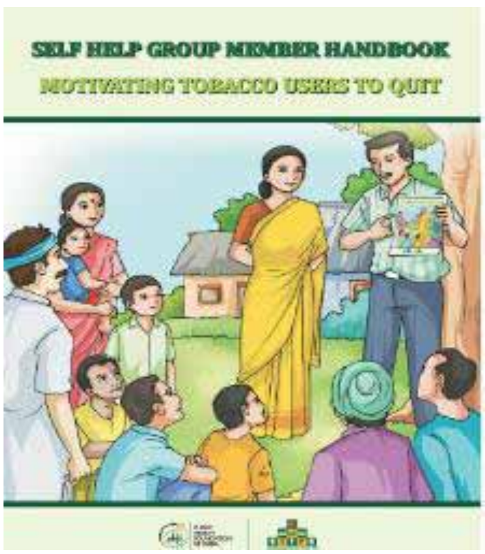

Figure 15.11: Self-help group meeting on SLT cessation

Photographs courtesy of Photobank PHFI.

POLICY INITIATIVES

Because of the ample evidence that smokeless tobacco causes severe health effects, Central and state initiatives have repeatedly regulated SLT production and sale. Table 15.3 briefly describes, in chronological order, the notable existing policies to regulate and ban SLT use that have been formulated and enacted at the Central and state levels.

Table 15.3: Policies and orders to regulate smokeless tobacco use In India

Year implemented	Name	Description
1987	Bombay Police Act (1951)[40]	Notification under cancer control programme. Section 116 of this Act prohibited smoking and spitting on government premises in Maharashtra.
1990	Prevention of Food[29] Adulteration Act (1954)	Required warnings on all chewing forms of tobacco.
1992	Drugs and Cosmetics Act (1940) and amendment rules, 1992[30]	By this amendment, the Central Government banned the manufacture and sale of toothpastes and toothpowders containing tobacco. The Supreme Court supported the ban, invoking Article 19 (6) of the Constitution in the public interest.
1995	School policy for all Central Board of Secondary Education (CBSE), Navodaya, and Kendriya Vidyala (KV) Schools[31]	Use of tobacco on school premises by students, teachers, parents, and visitors was banned in all CBSE Schools starting in 1995. All the Central Schools and Navodaya schools were instructed by the Central Government to ban sales of tobacco and tobacco products within a distance of 100 metres. In 2011, an order declared all Kendriya Vidyalayas in the country tobacco free to prevent youth access and exposure to tobacco use. The order was extended to prevent use of tobacco on school premises by students, teachers, and non-teaching staff during and after school hours.
1998	Central Committee for Food Standards (CCFS) under Directorate General of Health Services[29]	This committee recommended the appointment of a special Expert Committee at the Central Government level to ban chewing tobacco on health grounds.
2000	Cable Television Networks (Regulation) Act (1994)[32]	The Central Government amended the advertisement codes to prohibit the direct or indirect advertisement of cigarettes and other tobacco products on cable television.
2001	Indian Railways (Executive Order)[33]	The railway authorities banned the sale of gutka on railway station premises, concourses, and trains, and in reservation centres.
2001-2003	Prevention of Food Adulteration Act (1954)[29]	Under provision section 7 (iv), 9 states prohibited gutka and pan masala *(*starting with Tamil Nadu, followed by Maharashtra, Uttar Pradesh, Bihar, Madhya Pradesh, Andhra Pradesh, Goa, Gujarat, and Kerala). According to section 7 (iv), the sale of any article of food can be prohibited by the Food (Health) Authority in the state in the interest of public health.
2003	Cigarettes and Other Tobacco Products Act (COTPA)[34]	This Central-level comprehensive legislation was intended to regulate the sale and consumption of all tobacco products. It prohibits sale to anyone under 18 years old (S.6); requires that packages show pictorial health warnings about the harmful effects of smokeless tobacco (S.7); and prohibits all direct and indirect advertisements of these smokeless forms of tobacco products (S.5).

Year implemented	Name	Description
2004	Godawat Pan Masala Products I.P. Ltd. & Another v. Union of India & Others[35]	In this court case, the SC held that gutka is a food product, and that only the Central Government can ban gutka, and only by framing rules under Section 23 of the PFA.
2005	Goa Public Health Amendment Act[36]	The state of Goa banned all SLT products, declaring them injurious to health. Box 15.3 presents a case study of Goa as an example of best practices in policy formation and enforcement.
2006-2007	Prevention of Food Adulteration Act (1954)[29]	The Central Government amended the PFA Act, 1954 and introduced Rule 44J: 'Product not to contain any substance which may be injurious to health: Tobacco and nicotine shall not be used as ingredients in any food products'. Tobacco industry litigations challenging the amendment were transferred to the SC in 2009. No decision has been pronounced on pending petitions until 2012.
2007	Ankur Gutkha and Others v. Indian Asthma Care Society and Others (2007)[37]	Invoking the principle of 'the polluter pays' for environmental pollution, the High Court of Rajasthan (2007) gave a verdict banning the use of plastic packaging for gutka sachets in the state. This verdict was upheld by the SC and rules enforced from 2011 to be complied with by all the states.
2011	Ministry of Environment and Forests amendment of Plastic Waste (Management and Handling) Rules (2011)[19]	MoEF amended rules to prohibit use of plastic materials in sachets for storing, packing, or selling gutka, tobacco, and pan masala. This prohibition has been in force since March 2011.
2011	Indian Railways executive order dated 15 September 2011[38]	This executive order banned the sale of gutka and other tobacco products, including bidis and cigarettes, on trains and on Indian railway platforms; the order required strict compliance.
2011-2012	Food Safety and Standards Act (FSSA) (2006) and Regulations (2011) repealed the PFA Act[39]	The FSSA effectively bans all food products that contain nicotine and tobacco. A few states have issued orders to prohibit magnesium carbonate as an ingredient in food products (Regulation 3.1.7 of the FSS Regulations, 2011). Sixteen states and the National Capital Territory of Delhi have begun to implement this policy by passing a state notification to enforce the ban as of October 2012. (See Table 15.1 for the current status of implementation in each state and territory.)

Box 15.3: State law to prohibit SLT: Goa case study

Goa is the only state in the country to enforce a ban on SLT since 2005. Under the Goa Public Health Act 1985, the Government of Goa promulgated the Goa Public Health Ordinance 2004 to ban the manufacture, sale, distribution, stocking, storing, or conveying of any injurious food article containing tobacco or tobacco extracts. In 2005, with the approval of the Legislative Assembly, the Goa Public Health (Amendment) Act was enacted and implemented. This Act empowers officials from the FDA, police, and health services, as well as the Collectorate staff to conduct search and seizure operations and to prosecute defaulters dealing in prohibited food articles containing tobacco. Punishment prescribed in case of conviction is imprisonment of up to 6 months and a fine of Rs 10,000. During the course of enforcement of this ban, SLT manufacturers challenged the validity of the Act before the HC of Bombay at Goa bench. The HC dismissed the manufacturers' plea. This petition was moved to the SC by the manufacturers, but no specific relief of any nature was granted, and the gutka ban in the State of Goa remains in effect. (For details, see chapter 16.)

As indicated by Table 15.3, policies begun in the years 1987–2001 included regulating SLT use through statutory warnings on SLT products and prohibiting spitting in public places, Central Committee for Food Standards recommendations against use, and administrative orders from railways, school authorities, and the Ministry of Industry and Broadcasting regulating promotion and advertising (direct and indirect) of SLT products. Between 2001 and 2004, many states passed orders against the sale, manufacture, storage, and distribution of gutka, invoking provisions of the PFA, 1954. Maharashtra's gutka ban was upheld by Bombay High Court. However, the *Godawat* lawsuit (2004), in which the SC struck down the notifications issued under the PFA, 1954, represented a setback for the states. The strong policies and legislative actions summarised in this table have been a decisive development in the Indian tobacco control movement.

SUCCESSFUL ADVOCACY: LESSONS LEARNT

This section presents lessons learnt about successful advocacy with regard to SLT regulation in India. Current bans in the states (through FSS regulations) are a result of an Act that strengthens efforts to ban and control SLT, in contrast to earlier state-specific, disjointed efforts. Active engagement of civil society in use of multipronged advocacy strategies has greatly supported policy initiatives and boosted their effectiveness.

Effectiveness of Public Interest Litigations (PILs) in Strengthening Implementation of SLT-Related Laws

The experiences of PILs like the *Ankur Gutkha* lawsuit and the *Bejon Mishra* lawsuit, as well as VoTV intervention applications in several tobacco control issues, and results like the Packaging and Labelling Rules (Health for Millions)—all clearly indicate that PILs are an effective advocacy tool. The courts in India have pronounced positive judgements and reinforced the Right to Health in the public interest. (For further details, see chapter 16.)

Supreme Court Directive on Transfer of All Cases Pertaining to SLT Bans to the Apex Court

One powerful action of government has been the transfer of industry petitions challenging Regulation 2.3.4 of the FSS Regulations, 2011, to the apex court. This decision resulted from the lawsuit *Union of India & Anr. v. Dharampal Satyapal Ltd. & Ors.* Transferring these petitions to the SC was an attempt to avoid decisions by HCs in various parts of the country which would adversely affect enforcement of the FSS regulation banning gutka. In addition, in 2009, industry petitions that challenged earlier PFA rules (Rule 44J) were transferred to the SC. These transfer petitions are being heard together, which ensures similar treatment of the issue across the whole country as of November 2012 (see chapter 16).

Community Empowerment: Demand Reduction Strategy to Complement Supply-Side Action

Experiences in India's tobacco-free villages such as Pongalipakka in Visakhapatnam, Sankhapura in Haryana, and Sarfabad in Noida affirm that empowering local self-governments (Panchayat) with knowledge of tobacco harms can lead to positive policy outcomes and make SLT bans an acceptable norm. In addition to bans and community education, it is important to provide cessation support and opportunities to tobacco users who want to quit this addiction; these supports should be offered at the sub-district level.

Increased Vigilance and *Suo Moto* Crackdown Campaigns on Food Business Operators

Raids carried out by the food safety officers and other enforcement agencies in Jharkhand, Gujarat, and Rajasthan between July 2012 and September 2013 proved to be an effective awareness and advocacy activity that also curbed cross-border smuggling and illicit trade. Food and drug departments in many states reportedly raided several districts and seized banned gutka products.

Banning Gutka and Other SLT Products: Best Practices from Maharashtra

Maharashtra is an example of best practices with regard to enactment of FSS Regulations, 2011. Maharashtra's order noted the prevalence of SLT and the harmful effects of gutka and pan masala and gave examples of adulteration (magnesium carbonate). The state government banned the manufacture, storage, distribution, and sale of all pan masala and gutka products, as well as other food products containing tobacco, nicotine, and magnesium, or any products marketed separately to be combined to produce SLT or pan masala as final products. Regulation 3.1.7 of the FSS Regulations, 2011, restricts use of anti-caking agents like carbonates of calcium and magnesium in foods except where specifically allowed, and empowers the government to ban pan masala containing magnesium carbonate. Maharashtra's adoption of this restriction and ban will aid in plugging the loophole which allows manufacturers to sell various ingredients of gutka and tobacco powder separately in different sachets.

CHALLENGES TO SLT POLICIES

As described in this chapter, considerable challenges have obstructed enforcement of SLT policies. The FSS Regulations, 2011, addressed some of these challenges, but enforcing current regulations also poses numerous new challenges for state governments.

Enforcing National Bans and Laws Preventing Smuggling and Tax Avoidance

It is crucial that bans, other tobacco control laws, and tobacco taxation laws are enforced nationwide and that all states comply with these policies uniformly. If one state allows trade in gutka and pan masala, smuggling of these products to neighbouring states becomes a huge challenge.

The tobacco industry is increasingly adopting practices such as selling pan masala and tobacco powder separately under the same brand name in states where currently only gutka is banned

(Figure 15.12). This tactic is in direct conflict with the spirit of Section 2.3.4 of the FSS Regulation, because the consumer is able to mix these two separate packets and continue consuming gutka. The improvement in public health that is the goal of the FSS rules will not be achieved if this circumvention of law is not checked.

Figure 15.12: Pan masala and tobacco packaged separately

Photograph courtesy of Photobank HRIDAY.

Surrogate Advertising of SLT Products

Although Section 5 of COTPA imposes a total ban on all advertisement of tobacco products, the FSSA allows advertising of pan masala and other products. The tobacco industry attempts to take full advantage of this inconsistency; they engage in misleading surrogate advertising, marketing tobacco-containing products and non-tobacco-containing products (pan masala) under the same brand name (as explained in detail in chapter 7). While FSSA also prohibits misleading advertisements, the inadequacy of its strategies to monitor such violations limits the scope of this Act.

Another legislative barrier is that, for trading purposes, manufacturers are able to register their products under the Trademarks Act, 1999, with identical names. Thus, surrogate advertising flourishes, with both banned products and non-banned products sold by the same manufacturer and carrying the same name. Laws should be amended to empower provisions of FSSA and COTPA to address the challenge of surrogate advertising, and advocacy efforts on this issue should be directed toward the FSSAI, the Ministry of Commerce, and the Ministry of Industry and Broadcasting.

Ban on Export-Oriented Units Allowed by States

Currently, Gujarat is the only state in India which has notified a gutka ban but has allowed one manufacturer to produce SLT for export, although several civil society bodies and public health experts had lobbied for a complete ban on manufacture of gutka and pan masala in Gujarat. Such discriminatory measures by states jeopardise state governments' ability to ensure that these products do not leak into the local market.

CONCLUSIONS

Advocacy and policy efforts have contributed to successful notification and enforcement of current SLT prohibition and regulation in India, which will reduce the incidence of oral cancer in the long run. The current political consensus upholding the interest of public health over trade is a remarkable achievement which strengthens India's position as a leader in tobacco control at the global level.

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Chapter 16

Litigation and Judicial Measures

Amit Yadav[1], Ranjit Singh[2], Arpita Singh[3], Deepti Singh[1]

[1]Public Health Foundation of India, New Delhi
[2]Ministry of Health and Family Welfare, Government of India, New Delhi
[3]Healis-Sekhsaria Institute for Public Health, Mumbai

INTRODUCTION

Litigation helps institutionalise law by bringing about a judicial interpretation and sanction. It helps elucidate the diverse components of a comprehensive law and facilitates analysis of these components. Judicial review lies at the heart of effective implementation of any legislation and provides much-needed clarity on a law. Among the many angles from which the tobacco epidemic in India must be tackled, litigation and judicial measures are fast emerging as effective tools to protect people from the morbidity and mortality attributable to tobacco use. Since about 2004, much fruitful litigation has provided protection for the population at large and has strengthened the hands of various groups fighting the tobacco epidemic. This chapter gives an overview on the role of litigation and judicial measures in curbing tobacco use in India. Inevitably, due to the nature of available cases, there will be some overlap between litigation as it relates to tobacco in general and to smokeless tobacco (SLT) in particular.

BACKGROUND OF LITIGATION AND JUDICIAL MEASURES

The Supreme Court of India's direction to curb sexual harassment in the workplace[1] and their direction to provide emergency medical care to accident victims[2] are illustrations of judicial actions to protect public health and well-being. Tobacco control laws also fall into the category of actions to protect the public, as seen when the Hon'ble Supreme Court prohibited smoking in public places[3], which preceded the enactment of the same prohibition under the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003, known as COTPA. Over time it has been evident that most of the key provisions of Indian tobacco control laws have been strengthened for effective implementation by rulings of the Hon'ble High Court of States in India or by the Hon'ble Supreme Court of India. Litigation brought about by the efforts of a strong civil society has become an effective means to enforce tobacco control laws in India, and a responsive judiciary has not only delivered strong judgments but has also followed through with monitoring enforcement of such pronouncements.

The initial efforts in tobacco control both globally and in India focused on dealing with the hazards of smoking and preventing public exposure to secondhand smoke. In India, the first tobacco control law, the Cigarettes (Regulation of Production, Supply and Distribution) Act, 1975, informed people only about the harmfulness of smoking cigarettes. The law failed to regulate all non-cigarette tobacco products, including bidis, cheroots, cigars, gutka, khaini, and other SLT products used across diverse social, linguistic, economic, and demographic groups. Early tobacco control efforts were mostly restricted to curbing smoking in public places, as directed by the Hon'ble High Court of Kerala in 1999[4] and the Hon'ble Supreme Court of India in 2002[5], which further directed the Union of India, state governments, and the Union Territories to effectively prohibit smoking in public places, since it adversely affects both smokers and those who are not smoking. Consequently, breathing air free of tobacco smoke was recognised as a fundamental right to life guaranteed under the Constitution of India.

As early as 1948, Sardar Bhopinder Singh Man proposed inserting the word 'tobacco' between the words 'drinks' and 'drugs'[6] in Article 47[7] of the Constitution of India, during the debates of the National Constituent Assembly (his motion was rejected by the Assembly). Before the enactment of COTPA, some Central and state enactments sought to protect the public from the hazards of SLT by imposing limits on manufacture, storage, distribution, and sale in order to reduce consumption of SLT. These legislations included but were not restricted to the

Constitution of India, 1949, the Cinematograph Act, 1952, the Prevention of Food Adulteration Act, 1954, the Drugs and Cosmetics Act, 1940, the Consumer Protection Act, 1986, the Child Labour (Prohibition and Regulation) Act, 1986, the Indian Penal Code, 1860, and the Code of Criminal Procedure, 1973.

A comprehensive law on tobacco control, the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 was enacted by the Indian Parliament only in 2003. COTPA completely prohibited advertisements of all tobacco products and provided the framework for regulating production, marketing, and sale of both smoking and SLT products.

Tobacco control has gained momentum over the years, with public health policy and legislation mandating increasingly strict tobacco control measures in a bid to make the use of tobacco less attractive and less accessible, particularly amongst youth. While many tobacco control objectives are achieved through legislation, the reach and ultimate impact of such laws is highly dependent on their effective enforcement. Enforcement of a law is a major challenge which may involve effective administrative measures (such as cancellation/suspension of license, imposing fines) and judicial measures (such as litigation against violators or demands for compliance with law). Most of the litigation to control tobacco is filed or defended by tobacco control activists under the writ jurisdiction and public interest litigations, largely to seek enforcement of the laws and rules framed thereunder by the authorities and to defend the constitutional validity and applicability of the law.

Challenging laws and attempting to prevent tobacco control efforts by the government and civil society are tactics commonly used by the tobacco industry. The early history of tobacco control litigations in India reveals that on numerous occasions the tobacco industry has been able to halt implementation of laws. In many other instances the tobacco industry has succeeded in delaying and diluting provisions of tobacco control laws with the help of protracted litigation.

It is only in recent times (since around 2004) that petitions to seek implementation of existing laws have been filed by tobacco control activists. Activists also file caveats (i.e., application to a court to be considered as an interested party in a matter expected to come before the court) to preempt any hasty petition from the tobacco industry to thwart implementation of a law. Over the last decade, several judgments and orders pronounced by the Courts in India have had a strong impact on the tobacco control movement. This chapter will only discuss the litigation and judicial pronouncements related to prevention and control of SLT in India. Specific matters in various courts will be analysed in terms of their policy implications for regulating SLT in the country. Both successful and adverse judicial pronouncements will be examined in order to recommend strategic responses against the tobacco industry's tactics before the Hon'ble Courts. Thus, this chapter aims to outline the role of litigation as a successful tool used by civil society in advancing tobacco control in India as it relates to SLT.

IMPORTANT LITIGATION IN INDIA RELATING TO THE REGULATION OF SLT

Litigations concerning SLT products feature prominently in the Indian tobacco control movement. The judicial verdicts from these cases have had a major impact on governmental policies and have affected the behaviour of the tobacco industry as well. The major cases considered by the Hon'ble Courts arose either from petitions filed by tobacco control activists pleading for strong regulatory measures for the protection of the fundamental right to health (embodied under Article 21 of the Constitution of India, which guarantees a person right to life), or from the tobacco industry challenges to regulatory efforts as an infringement of their fundamental right to carry on any trade or business [under Article 19(1)(g)] and as an infringement of their fundamental right to freedom of speech and expression [under Article 19(1)(a) of the Constitution of India, 1949].

In a number of instances judicial interventions have played a positive role in achieving stronger implementation of tobacco control laws. In a few instances the tobacco industry with the help of protracted litigation has succeeded in delaying and diluting the laws. The extensive litigation relating to regulation of SLT in India can be categorised as follows:

- Litigation under COTPA
- Public interest litigation
- Litigation by the tobacco industry
- Litigation under other Acts
- Litigation under the Consumer Protection Act, 1986
- Litigation under the Drugs and Cosmetics Act, 1940
- Litigation under the Prevention of Food Adulteration Act, 1954 (PFA)
- Litigation under the Food Safety and Standards Act, 2006 (FSSA)

(See Appendix 3 for a table summarising the litigations under these Acts.)

Litigation Under COTPA

Public Interest Litigation

Public interest litigation (PIL) is an innovative approach adopted by the Indian judiciary and activists to compel the courts to review matters of public interest. Under a PIL, the traditional rule of *locus standi*, that only a person whose right is infringed can file a petition, has been considerably relaxed by the Hon'ble Supreme Court of India[8]. A PIL can be filed by any individual or organisation on behalf of the public, or the court *suo motu* can take up a matter for judicial scrutiny. The Hon'ble Courts permit public interest litigation at the instance of public-spirited citizens for the enforcement of constitutional or legal rights. Any public-spirited citizen can move the Hon'ble Courts for a public cause (in the interests of the public or public welfare) by filing a petition under:

- Article 32 of the Constitution in the Hon'ble Supreme Court (the right to move the Supreme Court);
- Article 226 of the Constitution in an Hon'ble High Court (the right to move a High Court); and
- Section 133 of the Criminal Procedure Code in the Magistrate's Court (a police or government official may approach a Magistrate about a public nuisance).

The following paragraphs describe PILs and the resulting interventions by the Hon'ble Courts that have helped to combat the menace of tobacco in general and SLT in particular.

Protection of Minors (Not Limited to SLT) (Under COTPA, Section 6)

In *Jammu and Kashmir Voluntary Health and Development Association v. State and Others (2010)*[9], the Hon'ble Jammu and Kashmir High Court issued directions to the appropriate authorities in various departments and municipal corporations to take necessary steps to implement the provisions of COTPA, in particular Section 4 (prohibition on smoking in public places) and Section 6 (prohibition on sale of tobacco products to minors and near educational institutions).

In *Sumaira Abdulali v. Union of India* (2007)[10] the Hon'ble Bombay High Court directed Ministry of Health and Family Welfare, Government of India, to notify the implementation of Section 6(b) of COTPA with respect to the prohibition of sale of tobacco products within 100 yards of an educational institution. As a result, Section 6(b) of COTPA was notified and came into force on 18 September 2009.

In *World Lung Foundation South Asia v. Ministry of Health and Family Welfare* (2012)[11] the Hon'ble Delhi High Court issued directions to the enforcement agencies for stricter enforcement of the prohibition on sale of tobacco products within 100 yards of educational institutions, as stipulated under Section 6(b) of COTPA.

In *Cancer Patients Aid Association v. State of Karnataka & Another (2009)*[12] the Hon'ble Karnataka High Court issued the directions for implementation of Section 6(b) of COTPA and further directed the monitoring of such implementation on a monthly basis.

The Hon'ble Kerala High Court in *Kerala Voluntary Health Services v. Union of India* (2010)[13] issued directions to all concerned authorities for implementing the provisions prohibiting the sale of cigarettes and other tobacco products as per the Educational Institutions Rules, 2004, framed under COTPA. The Court gave directives for setting up school protection committees in each school in the state and a district-level monitoring committee in each district of the state to periodically supervise the functioning of the school protection committee. Further directive was given to establish a state-level monitoring committee chaired by the Secretary, Home Department, which would meet at least once in six months to ensure effective compliance with the Hon'ble Court's directives.

The case of *Naya Bans Sarv Vyapar v. Union of India and Others* (2011)[14] was initiated by an association of wholesale traders of tobacco products seeking exemption from Section 6(b) of COTPA on the pretext that they do not sell their products to end users. The Hon'ble Delhi High Court dismissed the petition and ordered the tobacco association to pay costs to both the Central and state governments, which would be utilised for anti-tobacco initiatives. An appeal [LP(C)No(s).39271-39272/2012] was filed against the High Court order on 1 February 2013, and the Hon'ble Supreme Court *ex parte* stayed the High Court judgment with the condition that the petitioners would transact their wholesale business only after 2:00 p.m., and they would not engage in any retail business.

Pictorial Health Warnings on All Tobacco Products (Under COTPA, Sections 7, 8, 9)

The implementation of pictorial health warnings on all tobacco products in India was only possible due to writ petitions filed by public-spirited groups. The Government of India notified the pictorial health warnings as a result of a PIL filed by Ruma Kaushik (2007)[15] before the Hon'ble Himachal High Court in the year 2006. Subsequently, in the writ petition *Health for Millions Trust v. Union of India and Others* (2008)[16] filed before the Hon'ble Supreme Court of India, the government after extensive delay and dilution of pictorial warnings finally gave an undertaking on 6 May 2009 in the Hon'ble Court that pack warnings would be implemented from 31 May 2009. While this litigation is still pending before the Supreme Court, in subsequent hearings of the case, civil society, even after the initial victory in 2009, has been able to compel implementation of new health warnings by the Indian government. (The warnings are changed after 1–2 years; this pending litigation helps in monitoring the implementation of the new warnings.)

Point-of-Sale Advertisements of All Tobacco Products (Under COTPA, Section 5)

The Ministry of Health notified certain restrictions on advertisements at the point of sale, but the Bombay High Court stayed enforcement of these regulations in an *ex parte* proceeding in 2005[17]. Only in response to civil society intervention through a special leave petition filed by the Health for Millions Trust did the Hon'ble Supreme Court of India set aside the Bombay High Court stay order, which paved the way for implementation of the rules[18].

Display of Tar and Nicotine Contents [Under COTPA, Section 7(5)]

In *Puneet Gupta v. Union of India and Others* (2004)[19], at the direction of the Hon'ble Delhi High Court, the Government gave an undertaking that they will create the requisite institutional capacity to test the nicotine and tar contents of tobacco products by setting up tobacco testing laboratories to enforce the provisions of COTPA, Section 7(5), which mandates display of tar and nicotine contents on the packs containing tobacco products.

Restrictions on the Tobacco Industry Regarding Tobacco Advertising, Promotion, and Sponsorship (TAPS) (Under COTPA, Section 5)

The Hon'ble High Court of Gujarat in *Amarsinh Z Choudhari v. Union of India* (2009)[20] issued directions to the Gujarat State Road Transport Corporation and Ahmedabad Municipal Transport Services for removal of advertisements of gutka and pan masala displayed on the public transport vehicles.

The Hon'ble Karnataka High Court in the writ petition *Institute of Public Health v. The State Government of Karnataka and Others* (2010)[21] directed the Government of India to withdraw sponsorship extended by the Tobacco Board of India to a tobacco industry–sponsored event in October 2010, in compliance of Section 5 of COTPA. Further, on 8 February 2011 an undertaking was given by the Government that they would strictly adhere to and implement the provisions of COTPA. The Government also assured that it would consider the Petitioner's proposal of a code of conduct for public officials to prevent interference from the tobacco industry, whilst developing and implementing public health policies and programmes pertaining to tobacco control, in accordance with Article 5.3 of the World Health Organization Framework Convention on Tobacco Control (FCTC), which states that tobacco control policies should be protected from commercial and vested interests[22].

In *Bejon Mishra v. Union of India and Others* (2006)[23] the petitioner filed a PIL in the Hon'ble Delhi High Court for quashing the notification, whereby subsidies and exemptions to the manufacturers of gutka and chewing tobacco products were restored. This notification was thereafter withdrawn by the Government.

Litigation by the Tobacco Industry

In several instances the tobacco industry, through front groups or industry-based associations or by itself, has filed writ petitions to delay implementation of tobacco control legislation, rules, and notifications, and have succeeded in diluting these measures. Some of these litigations that have impacted the SLT industry are as follows:

Against Pictorial Health Warnings (Under COTPA, Sections 7, 8, 9)

The tobacco industry has filed more than 50 court cases in various High Courts in India to challenge the rules notifying the pictorial health warnings which *inter alia* required the pictorial depiction of the ill effects of tobacco use on all tobacco packages. The industry contended that besides COTPA, 2003, the Rules were *ultra vires* Articles 14, 19(1)(a) and 19(1)(g) of the Constitution of India, 1949[24]. However, the Government, while defending the Rules, submitted that the Rules did not violate the fundamental right to practice any profession or to carry on any occupation, trade, or business under Article 19(1)(g) of the Constitution. Pictorial health warnings on tobacco products are merely a reasonable restriction, imposed by the Rules in the interest of the general public. The Ministry of Health and Family Welfare also filed a transfer petition to avoid any inconsistency in orders passed by different Hon'ble High Courts on the same matter. Hearing the petition in *Union of India v. Gopal Corporation Ltd. & Others* (2008)[25], the Hon'ble Supreme Court transferred 31 writ petitions pending before different Hon'ble High Courts before itself for a conclusive and final decision. Pursuant to the directive of the apex court, the Pictorial Health Warning Rule, 2008, is in force, and all tobacco products in India were required to display the specified pictorial health warnings starting on 31 May 2009[26].

In the matter of *M/S Raj Products v. State (Govt of NCT of Delhi) and Another* (2010)[27], the High Court of Delhi upheld the order of the Additional District Judge for confiscation of gutka pouches on the grounds that the packets (packaging) did not conform with the provisions of the Packaging and Labelling Rules, 2008, notified for implementation of Section 7 of COTPA, 2003.

Against Depiction of Tobacco Use in Films (Under COTPA, Section 5)

In 2005, the Government of India notified the Rules under COTPA imposing restrictions on display of tobacco products or their use in films and television programmes. However, the Rules were challenged in *Mahesh Bhatt v. Union of India and Another* (2009)[28] and *Kasturi and Sons v. Union of India* (2008)[28]. When the Hon'ble Delhi High Court quashed the Rules, the Government went in appeal to the Hon'ble Supreme Court of India, which stayed implementation of the High Court's Order. In the meantime the Government of India, after making some modifications of the Rules, re-notified the Rules *vide* notifications dated 27 October 2011, which went into force on 14 November 2011[29]. After subsequent litigations and a series of discussions between the Ministry of Health, the Ministry of Information and Broadcasting, and the Ministry of Law and Justice, a compromise was arrived at requiring amendment of the rules. Amended rules were notified on 21 September 2012 and went into effect beginning on 2 October 2012[30].

The amended rules have been considered an example of global best practices in tobacco control.

In *Kerala Voluntary Health Services v. Union of India* (2010)[31] the Hon'ble Kerala High Court directed the Central Government through the Ministry of Information and Broadcasting to ensure that no scenes are depicted in films, tele-serials, or other visual media which would violate the provisions of COTPA.

Against Regulation of Point-of-Sale Advertisement of Tobacco Products (Under COTPA, Section 5)

In *Namdeo Kamathe v. Union of India* (2005)[32] and *Sridhar Kulkarni v. Union of India* (2005)[33] filed before the Hon'ble Bombay High Court, distributors of tobacco products petitioned the court to challenge Rules 4(1) to (5) notified *vide* GSR No. 137, dated 25 February 2004 and amended *vide* GSR No. 345 dated 31 March 2005, which proposed the regulation of point-of-sale (POS) advertising. The petitioners alleged that the notified Rules violate their fundamental right to freedom of speech and expression under Article 19(1)(a) and fundamental right to trade under Article 19(1)(g) of the Constitution, and thus *ultra vires* the Constitution of India. In an *ex parte* hearing the Court stayed implementation of these Rules, and the matter has been *sub judice* since 2006.

A public interest litigation was also filed before the Hon'ble Kerala High Court seeking implementation of the Rules pertaining to point-of-sale advertisements. The Court issued notice to the Government seeking its response on the matter[34]. In the meanwhile, the Supreme Court of India in *Health for Millions v. Union of India and Others* (2012)[35] set aside the Bombay High Court Order that acted as an impediment to implementation of the Point-of-Sale Rules notified under COTPA, 2003. Once again, active litigation by a civil society organisation has made possible the implementation of an essential law on tobacco control.

In *Rajiv Kumar Gupta and Others v. the State of Maharashtra* (2006)[36] the Hon'ble Bombay High Court upheld the First Information Report (FIR), which is the first level of formal complaint to police, registered against the manufacturer of Rajnigandha Pan Masala for creating misleading advertisements and failing to mention the presence of magnesium carbonate in their products. The Hon'ble Bombay High Court held that the petitioners misled the Food (Health) Authorities, and the petition was dismissed.

Litigation Under Other Acts

Litigation Under the Consumer Protection Act, 1986

A consumer organisation filed a complaint against the tobacco industry in 2005 before the National Consumer Disputes Redressal Commission (NCDRC) in the matter of *Consumer Education Research Society and Others v. Dharampal Satyapal and Others* (2005) [37]. The petitioners claimed compensation of more than Rs 1 crore (Rs 10 million) only for and on behalf of identified and unidentified victims of oral cancer caused by chewing of tobacco products. They also contended that selling gutka, a hazardous product, without any warning suitable for people who are unable to read and with only feeble warnings for those who can read also amounts to deficiency in the product and thus should be compensated. The litigation is currently *sub judice* before NCDRC.

Litigation Under the Drugs and Cosmetics Act, 1940

In the matter of *Kastoori Udyog and Others v. The Union of India and Others* (1993)[38] the Hon'ble Rajasthan High Court upheld the Central Government`s Notification GSR 443(E), dated 30 April 1992, prohibiting the use of tobacco in toothpastes/toothpowders under Section 33(EED) of the Drugs and Cosmetics Act, 1940. The Hon'ble High Court also issued direction to the Central Government to appoint a committee of experts to study the use of tobacco in pan masala, gutka, and other products, and its effect on public health. In the event the committee determined that such products were injurious to public health, appropriate steps should be taken to prohibit its manufacturing.

In *Laxmikant v. The Union of India and Others* (1997)[39] the Hon'ble Supreme Court upheld the above notification prohibiting the use of tobacco in toothpastes/toothpowders, taking into account that tobacco is an ingredient that may cause cancer, with the observations that imposition of a total ban is in the public interest.

Litigation Under the Prevention of Food Adulteration Act, 1954 (PFA)

The Prevention of Food Drug Adulteration Act, 1954, was enacted to protect the health of the people of India from food that is adulterated and injurious to health. The PFA defines 'food' as: 'Any article that is used as food or drink for human consumption and includes any article that ordinarily enters into or is used in the composition or preparation of human food'. Courts have elaborated on this definition, declaring that constituents such as areca nut (supari) used in SLT products such as gutka, zarda, khaini, and others are food products. Litigations on this issue include the following:

- In *P.K. Tejani v. M.R. Dange* (1970)[40] the Constitutional Bench of the Hon'ble Supreme Court observed that the word 'food' under the PFA is a very general term and applies to all that is eaten by human beings for nourishment, and includes ingredients in food items. As supari, or areca nut, is eaten for taste and nourishment, it is food within the meaning of Section 2(v) of the Act.
- In *State of Tamil Nadu v. R. Krishnamurthy* (1980)[41] the Supreme Court held that all that is required to classify a product as food is that it be commonly used for human consumption or in preparing human food.
- In *M/s. Khedal Lal & Sons v. State of U.P) Allahabad High Court,* FAC 1981 (1) 262, the Hon'ble Allahabad High Court held that chewing tobacco (i.e., zarda) is a food article.
- In *Manohar Lal v. State of Uttar Pradesh,* Criminal Revision No. 318 of 1982, the Hon'ble Allahabad High Court held that tobacco is something that is consumed by human beings and is food under Section 2(v) of the PFA.
- In *Sri Krishan Gopal Sharma and Another v. Government of N.C.T. of Delhi* (1996)[42] the Supreme Court held that pan masala and mouth freshener are food under Section 2(v) of the PFA.

Box 16.1: Gutka Banned in Goa Since 2005

In 2005 the Government of Goa amended the Goa Public Health Act to prohibit consumption, manufacture, sale, and distribution of any article of food containing tobacco within the State of Goa. The tobacco industry challenged this provision on the grounds of being in violation of COTPA and PFA. In *Sai Traders v. State of Goa and Others* (2006(4) BomCR1) the Bombay High Court held that COTPA and PFA had different objectives from that of the Amendment Act, which is to ensure maintenance of public health, and upheld the amendment to the Goa Public Health Act.

Under the PFA, the Commissioner, Food and Drug Administration and Food (Health) Authority for the State of Maharashtra, issued a notification dated 23 July 2002 banning the manufacture, sale, storage, and distribution of gutka and pan masala (containing tobacco) for five years beginning 1 August 2002. In *Dhariwal Industries Ltd. and Another v. Union of India and Others*

(2003)[43] the Appellants challenged the validity of the ban notification before the Hon’ble Bombay High Court. The Hon’ble Court dismissed the writ petition and upheld the validity of the notification. Several other states also prohibited the manufacture, sale, storage, and distribution of pan masala and gutka within their borders under the provisions of the PFA at that time. However, the tobacco industry challenged the judgment of the Hon’ble Bombay High Court and other such State Orders by moving the matter to the Hon’ble Supreme Court of India.

In *Godawat Pan Masala Products I.P. Ltd. & Another v. Union of India & Others* (2004)[44] the issue raised before the Hon’ble Supreme Court was the validity of notifications issued by the State Food (Health) Authority under Section 7(iv) of the PFA, by which the manufacture, sale, storage, and distribution of pan masala and gutka were banned in different states. The Hon’ble Court concluded that Section 7(iv) of the PFA[45] was not an independent source of power for the state authority and that the State Food (Health) Authority has no power to prohibit the manufacture, storage, sale, or distribution of any article not used as food. Consequently, the Hon’ble Court quashed all such notifications issued by state governments, but the Hon’ble Court held that gutka is a food product, and the power of banning an article of food because it is injurious to health belonged appropriately to the Central Government under Section 23(1A)(f) of the PFA[46]. Therefore, all such notifications issued by the state governments were quashed.

Notably, the tobacco industry itself referred to chewing tobacco as an edible commodity regulated under the PFA when the industry challenged the Packaging and Labelling Rules before the Tamil Nadu High Court[47].

SCIENTIFIC AND TECHNICAL INFORMATION FOR TOBACCO CONTROL LITIGATION

Scientific and technical information submitted before the Hon’ble Court plays a vital role in litigation outcomes. The tobacco industry bases its arguments on the technical and scientific claim that tobacco products are not as harmful as asserted by the regulators. The industry challenges decisions to regulate tobacco on the grounds that they will adversely affect the economy and render millions of people unemployed. The facts are that tobacco use itself adversely affects the health and economy of a country, and the jobs generated by tobacco companies are temporary and seasonal with little or no economic security for those engaged in such work.

The tobacco industry opposed prohibiting the sale of SLT products under the PFA in 2004, suggesting that all tobacco products must be ‘regulated’ under COTPA (because COTPA only prohibited sale to a person below the age of 18 years). However, it is interesting to note that the same industry retracted its submissions and came to challenge the very constitutionality of COTPA and the Rules notified therein. The tobacco industry has challenged almost every notification under COTPA as being unconstitutional for one reason or another. Manufacturers of SLT products challenged the implementation of pictorial health warnings on packaging as discriminatory and argued for softer warnings than those appearing on packages of smoked tobacco products, suggesting that SLT products were less harmful.

In addition to the constitutional and scientific challenges, the tobacco industry also protracted implementation of the pictorial health warnings on the erroneous technical ground that printing of ‘coloured pictograms’ as graphic health warnings would be costly for the manufacturers of

SLT products. However, the Hon'ble Supreme Court's verdict compelled the smokeless industry to display the warnings beginning 31 May 2009.

As the tobacco industry raises scientific and technical arguments to challenge and avoid compliance with laws, litigation provides an opportunity for the governments, non-governmental organisations (NGOs), and civil society to intervene and establish the need for effective measures for tobacco control. It was the expert committee constituted as a result of the Hon'ble Supreme Court's directive in a PIL that revealed the presence of 3,095 chemicals in SLT products, 28 of which were found to be carcinogenic. In the same matter, the Hon'ble Supreme Court prohibited the sale of certain tobacco products in plastic sachets, based on the available scientific and technical information[48].

LITIGATION INFLUENCING THE CURRENT POLICY ENVIRONMENT FOR REGULATION OF SLT

Step I: Prohibition on Sale of Gutka, Pan Masala, and Other SLT Products in Plastic Sachets

A local NGO, the Indian Asthma Care Society, filed a PIL before the Hon'ble Rajasthan High Court for restriction of sale and imposition of fines on the manufacturers of pan masala, gutka, and other forms of chewing tobacco because of the environmental hazards caused by littering of its plastic sachets, which is a major toxic pollutant. The High Court, *vide* its order dated 29 July 2007, agreed with the petitioners and gave directions restraining the manufacturers of gutka and pan masala from selling their products in plastic sachets. The Hon'ble Court also ordered exemplary fines against the manufacturers on the basis of the 'polluter pays' principle used for enforcement of environmental laws. The manufacturers were also directed to comply with the provisions of COTPA[49].

Gutka manufacturers appealed the Order of the Hon'ble Rajasthan High Court before the Hon'ble Supreme Court of India in *Ankur Gutka v. Indian Asthma Care Society and Others* (2007)[50]. The Hon'ble Supreme Court, *vide* its order dated 7 December 2010, directed the Ministry of Health and Family Welfare to undertake a comprehensive analysis and study of the contents of gutka, pan masala, and similar SLT products manufactured in the country and the harmful effects of their consumption. The Ministry of Environment was also directed to finalise, notify, and enforce the Plastics (Manufacture, Usage and Waste Management) Rules, 2009, which *inter alia* banned the sale of gutka and pan masala in plastic sachets. In compliance with the Hon'ble Supreme Court's direction, the Plastic Waste (Management and Handling) Rules, 2011, were notified on 4 February 2011, with Rule 5(d) banning the storing, packing, or selling of gutka, tobacco, and pan masala in plastic sachets. The manufacturers of gutka, tobacco, and pan masala were restrained from using plastic sachets beginning on 1 March 2011. Subsequently, when the Ministry amended the above Rules, 2011, exempting plastic pouches or sachets meant exclusively for export, the Hon'ble Supreme Court once again intervened to ensure that this concession was withdrawn. Subsequently, the Ministry, *vide* GSR No. 1527(E) dated 2 July 2011, introduced Rule 5(g)[51] which prohibited the use of plastic in any form for packing of gutka, tobacco, and pan masala.

Step II: Complete Prohibition on Sale of Gutka

Subsequent to the judgment in the *Godawat Pan Masala Products I.P. Ltd. & Another v. Union of India & Others* (2004)[52] that held gutka to be a food product which the Central Government has the right to ban because it is injurious to health, the PFA Rules, 1955, were amended to incorporate Rule 44J of 1986, which prohibited the use of tobacco and nicotine as ingredients in any food products. However, the manufacturers challenged this Rule in various Hon'ble High Courts, and the Courts have stayed the implementation of this provision; the matter is *sub judice* before the Supreme Court of India, *vide* the Transfer Petition *Union of India v. Central Arecanut Marketing Co-Operative and Others* (2007)[53]. In the meantime, the Government enacted the Food Safety and Standards Act, 2006 (FSSA) to replace the PFA. The objective of FSSA is to establish food standards and regulate/monitor the manufacturing, import, processing, distribution, and sale of food to ensure the safety of food intended for human consumption. The FSSA overrides all food-related laws and defines the word 'food' more broadly than PFA did.

In another development, the Ministry of Health and Family Welfare, Government of India, in partnership with the Public Health Foundation of India (PHFI) and the World Health Organization (WHO), organised a National Consultation on SLT in April 2011 to highlight the magnitude of the problem of SLT use and possible policies to regulate and control SLT use in India. After deliberations, the Consultation *inter alia* recommended:

- Imposing a complete ban on SLT products
- Considering all forms of chewing tobacco products as food items
- Reviving and implementing Rule 44J, which prohibits use of tobacco and nicotine as ingredients in any food products.

Four months later, in August 2011**,** *the PFA Act 1954 was repealed by the Food Safety and Standards Act, 2006,* and Rule 44J of the PFA Act was re-notified as the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation 2.3.4 under the Food Safety and Standards Act (FSSA), 2006, which went into force beginning 5 August 2011. (The statement in Regulation 2.3.4 that 'tobacco and nicotine shall not be used as ingredients in any food products' is taken verbatim from and in *pari materia* with Rule 44J of the PFA.)

Based on FSS Regulation 2.3.4 and the fact that Hon'ble Courts have held that gutka, zarda, chewing tobacco, and pan masala are a food products, 33 states and Union Territories have banned the manufacture and sale of gutka and pan masala containing tobacco and nicotine, and a few states have also extended the ban to zarda and pan masala. (See Appendix 4 for a table summarizing the status of the states relative to the FSSA.)

Since Regulation 2.3.4 was implemented by the states and Union Territories, the tobacco industry has challenged the regulation in various High Courts including in Delhi, Kerala, Jabalpur, Gwalior, Allahabad, Patna, Rajasthan, Bombay, and Karnataka. All the Courts have refused any relief to the tobacco industry in the matter and have upheld the law. Litigations for implementation of this provision of FSSA have also been filed, and the High Courts of Allahabad, Jammu and Kashmir, Delhi, and Andhra Pradesh have directed the state governments to consider enforcement of the Regulation banning gutka.

Litigations Under the Food Safety and Standards Act, 2006 (FSSA)

The first ban under the FSSA regulation was imposed by the state of Madhya Pradesh, and at the very first instance, *Ghoi Foods Private Limited* (2012)[54] went to the Gwalior Bench of the Madhya Pradesh High Court challenging the state notification. Similarly, the notification of the Government of Kerala was challenged by the *All Kerala Tobacco Dealers' Association* (2012)[55]. The notification of the Government of Bihar was challenged before the Hon'ble Patna High

Court by *Lal Babu Yadav* (2012)[56]; in the same year, the notifications of the Delhi[57], Rajasthan[58], Bombay[59], and Karnataka governments were also challenged, and many other similar cases were filed one after another across the country challenging the decisions of the governments. However, all the Hon'ble High Courts rejected the gutka manufacturers' pleas for a stay of the state governments' notifications imposing the ban.

The Indian Dental Association of the state of Uttar Pradesh filed in the Allahabad High Court for issuance of an order similar to that imposed by the state government of Madhya Pradesh, calling for implementation of the FSSA Regulation 2.3.4 banning gutka[60]. The Hon'ble High Court of Allahabad directed the state governments to take steps to enforce the Regulation banning gutka. Similar orders were passed by the Hon'ble High Court of Delhi[61], the Hon'ble High Court of Jammu and Kashmir, and the Hon'ble High Court of Andhra Pradesh. Though the matters are *sub judice*, the governments of Delhi, Uttar Pradesh, Jammu and Kashmir, and Andhra Pradesh have already enforced the ban in their states.

Considering the volume of litigations regarding this Regulation, the Government of India, through the Ministry of Health and Family Welfare, filed a transfer petition—*Union of India & Another v. Dharampal Satyapal Ltd. and Others* (2012)[62] and *Food & Safety Authority of India Etc. v. M/s Kaipan Panmasala Pvt. Ltd. and Others* (2012)[63]—requesting the Hon'ble Supreme Court to transfer all the cases and hear the matter itself to avoid the passing of inconsistent and conflicting decisions by different High Courts and to avoid adverse orders against the enforcement of the Regulation. The Hon'ble Supreme Court, *vide* an order dated 3 March 2012, has allowed the transfer petition *Union of India & Another v. Dharampal Satyapal Ltd. and Others* (2012), which will be heard along with the earlier transfer petitions in the matter of *Union of India v. Central Arecanut Marketing Co-Operative and Others* (2007).

The Bombay High Court, *vide* an order dated 21 January 2013, dismissed a petition seeking exemption from the ban on gutka manufactured for export[64]. Hearing a special leave against this order, the three-judge bench of the Hon'ble Supreme Court dismissed the petition[65].

On 3 April 2013 the Hon'ble Supreme Court directed the Health Secretaries of the state governments that had banned gutka and pan masala with tobacco under FSSA Regulation 2.3.4 to file a compliance report on the status of the implementation of this ban. The Health Secretaries of the states that have not issued orders to ban gutka and pan masala with tobacco are required to file an affidavit giving their reasons for not implementing the ban[66].

CHALLENGES AND OPPORTUNITIES

Lack of comprehensive tobacco control legislation before COTPA and the adoption of the WHO FCTC was a challenge for tobacco control litigations. However, enactment of COTPA in 2003 and its protracted implementation in subsequent years resulted in increased litigation both in the public interest and by the tobacco industry. The public interest litigation sought to ensure early and effective implementation of the law, whilst the tobacco industry litigated to delay and dilute the law. The tobacco industry has challenged most tobacco control legislation before the Courts at all levels and remains the greatest challenge to effective tobacco control.

One industry tactic has been to challenge tobacco control laws in multiple High Courts only to increase the burden on the responding agencies. In matters where more than one department is impleaded as respondent, lack of coordination among the respondents weakens the tobacco control stand before the Courts. The gap in coordination between the Ministry of Health and Family Welfare, the Ministry of Information and Broadcasting, and the Ministry of Law and Justice contributes to the delay in implementing the law and restricting the use of tobacco. Moreover, lack of coordination between the Central Governments and its authorised representatives in the states often results in stays in implementation of the law before the Government responds to the challenges.

Prolonged judicial proceedings further delay the implementation of effective tobacco control measures. The Hon'ble Supreme Court has yet to take a final decision in the matter of *Union of India v. Central Arecanut Marketing Co-Op and Others* (2007), which involved a challenge to Rule 44J of the Prevention of Food Adulteration (Amendment) Rules, 2006, dated the 21 August 2006, which prohibited the use of tobacco and nicotine as ingredients in any food products. In another instance of prolonged litigation, enforcement of rules on point-of-sale advertising has been kept in abeyance by the Hon'ble Bombay High Court since 2005[67].

In contrast, litigations initiated by tobacco control activists and favourable judicial pronouncements have thwarted the tobacco industry's efforts to delay and dilute tobacco control measures. A notable example is the pictorial health warning notified by MoHFW (Ministry of Health and Family Welfare) in compliance with the directive of the Hon'ble High Court of Himachal Pradesh in response to a public interest litigation. The tobacco industry filed more than 50 cases in various Hon'ble High Courts of the country against the pictorial warning rules framed between 2006 and 2009. Although the rules have been implemented since 31 May 2009 after the Hon'ble Supreme Court's directions, these litigations are still pending before the Hon'ble Supreme Court for final disposal.

The order in *Ankur Gutka and Others v. Indian Asthma Care Society and Others* (2007) has been helpful in restricting the sale of SLT products in plastic sachets. The Court also directed commissioning of a report which helped to reveal the hazardous, carcinogenic nature of the chemical components in SLT products.

The findings of the Hon'ble Supreme Court in *Godawat Pan Masala Products I.P. Ltd. & Another v. Union of India & Other* (2004)—that gutka is a food product and that the power to ban food products that are injurious to health belongs to the Central Government—paved way for the Central Government to enact a regulation imposing a complete ban on use of tobacco in any food products under the Food Safety and Standards Act, 2006, thus banning the sale of gutka.

It is important to build upon the progress achieved by the 33 states and Union Territories in imposing a ban on the sale of gutka and pan masala containing tobacco. Enforcement agencies must give grassroots implementation of such regulations and court orders the highest priority in order for India to derive the utmost public health benefit from these decisions.

CONCLUSIONS

Tobacco control litigation in India has a long history, with hundreds of cases in several courts across the country in the last decade and half. Most of these court cases focused on smokeless tobacco as well as smoked tobacco, or have an impact on regulation of SLT. It is encouraging to note that tobacco control NGOs and civil society have increasingly taken the lead, through public interest litigations, in challenging the tobacco industry and taking the relevant government departments to court to ensure implementation of effective tobacco control measures. These litigations demonstrate the effectiveness of judicial intervention in thwarting tobacco industry tactics.

However, in almost every case, the tobacco industry, which violates the human rights of millions, protests tobacco control regulations saying that they violate the industry's fundamental constitutional rights, and the industry flouts these regulations without punitive action or damages. It is high time that the Indian courts look beneath this insidious industry and allow both criminal and civil suits for injury to person, community, consumer, and environment, and award exemplary damages against the tobacco industry, something that other progressive jurisdictions (e.g., the United States, Canada, and Australia) are already doing successfully.

Petitions from civil society groups to be part of particular litigations as intervener or as amicus curiae assist the courts by providing the latest scientific evidence and consensus on the matter in question. Civil society efforts also help by revealing the sinister and mercenary nature of the tobacco industry's claims. Civil society actions prevent the tobacco industry from negatively affecting the implementation of tobacco control policy initiatives. There is a need to raise the judicial system's awareness of the public health imperatives behind tobacco control litigation and legislation. Free legal aid through the legal services committees at every court should be available for any intervener, amicus curiae, and caveat applications. Young lawyers should be trained in public health law as part of their law school curriculum.

Most successful tobacco control cases have illuminated the hazards of tobacco and the tactics used by tobacco companies in addition to compelling governmental action and strengthening effective compliance with the provisions of the tobacco control laws. These cases align with WHO FCTC Article 19[68], which encourages parties to strengthen legal procedures to fix criminal and civil liability, including compensation where appropriate, against the tobacco industry. An intensive study of progressive legal systems that implement effective public health laws and judicial pronouncements that emphasise the right to health should be undertaken in order to assist courts in taking a universal approach to tobacco control. A holistic assessment of litigation and judicial pronouncements must be considered in order to implement stronger and more effective tobacco control policies.

Box 16.2: Definitions of Legal Terms

Locus standi – A place of standing; standing in court. A right to appear in a court of justice, or before a legislative body, on a given question.

Ex parte proceedings – The legal procedure in which only one side is represented.

Sub judice – Under or before a judge or court; under judicial consideration.

Caveat – An application filed by a legal person in a particular court of civil nature against one or more legal persons, seeking to be heard before passing any ex parte order against him in any proceedings that may be filed by those persons in that court.

'Polluter pays' principle – In environmental law, **the polluter pays principle** is enacted to make the party responsible for producing the pollution responsible for paying for the damage the pollution has done to the natural environment.

Inter alia – Among other things. A term long used in pleading, especially in reciting statutes, where the whole statute was not set forth at length.

***Suo motu* –** *Suo motu* describes an act of authority taken without formal prompting from another party. The term is usually applied to actions by a judge taken without a prior motion or request from the parties.

Pari materia – Of the same matter; on the same subject. This phrase is used to refer to two laws relating to the same subject matter that must be analysed with each other.

Amicus curiae – A friend of the court. A bystander (usually a counsellor) who interposes and volunteers information upon some matter of law in regard to which the judge is doubtful or mistaken. A person with strong interest in or views on the subject matter of an action, but not a party to the action, may petition the court for permission to file a brief, ostensibly on behalf of a party but actually to suggest a rationale consistent with its own views. Amicus curiae briefs are commonly filed in appeals concerning matters of a broad public interest, such as civil rights cases.

Ultra vires – Beyond the legal power or authority. Any act that lies beyond the authority to perform or falls outside the powers that are specifically listed.

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6. Sardar Bhopinder Singh Man (East Punjab: Sikh) while moving his amendment motion in the Constituent Assembly on November 24, 1948, said, 'Mr. Vice-President I would like that where these words, namely, "Drinks and drugs" occur, the word "tobacco" also be added between them. Mr. Vice-President, I am aware that in moving this amendment, I would be incurring the displeasure of the influential members of this House and I also feel that I am going against the temper of the majority. In reminding Mr. Tyagi regarding this omission I am submitting it after judging it according to the test laid down by him. He has made out two points, namely, to prohibit those intoxicants that are bad and dangerous for health. Judging by this test we should see whether it can be classified as an intoxicant or not, or whether it is harmful to health. I have no doubt that tobacco is an intoxicant and is more harmful to health than liquor. This is the considered opinion of the medical men that tobacco has nicotine—a poison—most harmful to health. Take the villagers; they get liquor only off-and-on, but they smoke tobacco day and night, and due to their indolence they let suffer even their important tasks. As far as the economic aspect is concerned, I can assure you that much greater loss is incurred on account of tobacco than by liquor. Not only lakhs but crores of rupees annually flow out of the country on this account. When it is realised that tobacco is in fact a dangerous intoxicant, then I do not see why Mr. Tyagi has left out tobacco while mentioning liquor and other drugs. It is probably because it is consumed by the majority but that is no reason. It is said that cigarette or bidi, if consumed in small quantity, would not be harmful to health. But this leads to another controversy of "too much or too less". Even if a useful thing is consumed in excess, it might prove harmful. My point is that when you are dead against an innocent thing like liquor then why don't you prohibit tobacco also?' Available at http://parliamentofindia.nic.in/ls/debates/vol7p12.htm (accessed on 21-11-12).
7. Article 47 of the Constitution of India, 1949 states 'Duty of the State to raise the level of nutrition and the standard of living and to improve public health. The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavor to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health'.
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10. Sumaira Abdulali v. Union of India, PIL/182/2007, High Court of Bombay (Date of judgment/order_09.07.2009)
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15. Ms Ruma Kaushik v. UOI CWP No. 1259 of 2007, High Court of Himachal Pradesh (Date of judgment/order 07.06.2006 and 06.07.2006)
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20. Amarsinh Z Choudhari v. Union of India, Special Civil Application (SCA) /4848/2009 2/2, High Court of Gujarat (Date of judgment/order 22.12.2010)
21. Institute of Public Health v. The State Government of Karnataka and Others, Writ Petition 27692/2010, High Court of Karnataka (Date of judgment/order 08.02.2011)
22. Article 5.3: 'In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law'.
23. Bejon Mishra v. Union of India and Others, Writ Petition (Civil) 7789/2006, High Court of Delhi (Date of judgment/order 10.05.2007)
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25. Among the rights specified in Article 19(1) are the rights (a) to freedom of speech and expression; and (g) to practice any profession, or to carry on any occupation, trade or business.
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47. Section 23 (1-A) (f) of the PFA reads as 'Power of the Central Government to make rules:- The Central Government may, after consultation with the Committee and after previous publication by notification in the Official Gazette, make rules to carry out the provisions of this Act,
48. 1-A In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely,
49. (f) Prohibiting the sale or defining the conditions of sale of any substance which may be injurious to health when used as food or restricting in any manner its use as an ingredient in the manufacture of any article of food or regulating by the issue of licences the manufacture or sale of any article or food'.
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71. Article 19: Liability
    a. For the purpose of tobacco control, the Parties shall consider taking legislative action or promoting their existing laws, where necessary, to deal with criminal and civil liability, including compensation where appropriate.
    b. Parties shall cooperate with each other in exchanging information through the Conference of the Parties in accordance with Article 21 including:
        i. information on the health effects of the consumption of tobacco products and exposure to tobacco smoke in accordance with Article 20.3(a); and
        ii. information on legislation and regulations in force as well as pertinent jurisprudence.
    c. The Parties shall, as appropriate and mutually agreed, within the limits of national legislation, policies, legal practices and applicable existing treaty arrangements, afford one another assistance in legal proceedings relating to civil and criminal liability consistent with this Convention.
    d. The Convention shall in no way affect or limit any rights of access of the Parties to each other's courts where such rights exist.
    e. The Conference of the Parties may consider, if possible, at an early stage, taking account of the work being done in relevant international fora, issues related to liability including appropriate international approaches to these issues and appropriate means to support, upon request, the Parties in their legislative and other activities in accordance with this Article.

Chapter 17

Health Communication for Smokeless Tobacco Control in India

Nandita Murukutla[1], Tahir Turk[1], Sandra Mullin[1], Vineet Gill Munish[2], Praveen K. Sinha[3]

[1]World Lung Foundation, New Delhi/New York
[2]World Health Organization, New Delhi
[3]Ministry of Health and Family Welfare, Government of India, New Delhi

INTRODUCTION

Effective control of smokeless tobacco (SLT) use depends on adoption of evidence-based, affordable health communication strategies. These strategies must address the current gaps in public awareness, attitudes, and practices related to SLT. In this chapter we summarise the available information, present possible health communication strategies, and discuss their efficacy.

COMMUNICATION CAMPAIGNS FOR SLT CONTROL IN INDIA (1970s –2012)

There have been very few campaigns in India to inform and influence the public's knowledge, attitudes, and behaviours (KAB) around SLT use. In the 1990s, campaigns were typically part of cancer prevention efforts, and most health communication programmes tended to be local in nature, conducted at the interpersonal and community levels.

More recently, an increasing emphasis has been placed on health communication campaigns focused on SLT harms. Tobacco control is recognised as a critical public health priority in India, and policy, programmatic, and legal efforts are seen as key interventions. These include the World Health Organization's Framework Convention on Tobacco Control (FCTC)[1], the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (COTPA)[2], and the National Tobacco Control Programme (NTCP)[3]. The Government of India (GOI) and partner organisations have invested in comprehensive tobacco control programmes which have incorporated health communication, including population-level mass media campaigns, as a key intervention.

Through these investments, a comprehensive surveillance tool, the Global Adult Tobacco Survey (GATS)[4] was implemented in 2009-2010, which has resulted in wide recognition of SLT as the primary tobacco threat to public health in India. GATS India 2009-2010 has also yielded information about the profiles of SLT users and patterns of usage that is critical to the development of effective health communication interventions.

Another factor in the development of health communication campaigns on SLT has been the rapid evolution in the economic and media landscape in India in the last two decades[5-9]. These economic and communications changes have generated greater opportunities for effectively disseminating tobacco control and other health campaign messages through mass media to populations which heretofore had been difficult to reach.

Thus, in recent years, there have been a greater number of SLT communication campaigns, which increasingly use population-level approaches. In this section, we discuss the history and types of interventions that have been designed to educate, inform, or otherwise influence KAB regarding SLT use. Only interventions published in peer-reviewed journals between 1970 and 2012 are included.

INTERPERSONAL AND COMMUNITY CHANNELS OF COMMUNICATION

Community Programmes

One of the earliest demonstrations of SLT health education and communication comes from a 10-year controlled prospective intervention trial for primary prevention of oral cancer. Although it was implemented in three districts in India, the impact of the intervention on tobacco chewers was only fully analysed in Ernakulam, Kerala, owing to the small number of SLT users in the other locations[10-12]. The intervention cohort included 12,212 tobacco users 15 years of age and older who received the health communication programme for 10 consecutive years between 1977 and 1988. This health education programme included interpersonal communication channels (IPC) and community media approaches, which involved significant time, knowledge, and resource investment from implementers. Specifically, the harms of SLT use were discussed individually with tobacco users, using photographs and pictorial booklets as aids. With the involvement of the community, two documentary films were made and shown during home visits. Additionally, cinema slides, posters, folk dramas, local radio programmes, and newspaper articles were used in the intervention areas. Cessation camps were also conducted, including a few days of regular daily counselling. The intervention group was interviewed annually to track their tobacco behaviours; at the same time, they also received a physical evaluation to monitor the presence and development of precancerous oral lesions. A non-concurrent control group was formed from data gathered in a different survey conducted in the same area, with the same methodology, between 1966 and 1977. Although the non-concurrent control group did not receive the health education intervention, they did receive counselling by physicians to stop SLT use, especially if they indicated precancerous lesions.

Analysis of the five-year follow-up data revealed greater quitting rates for SLT use in the intervention group than the control group (14% vs. 4%). Additionally, incidence of precancerous lesions was lower in the intervention than control group: at five-year follow-up, the age-adjusted incidence rate of leukoplakia per 1,000 men was 22.6 in the intervention group versus 44.6 in the control cohort; for women it was 6.2 versus 33.5 per 1,000 women. Reductions in prevalence and changes in biological markers are strong indicators of effectiveness, and analysis of the results of this intervention provided promising early evidence of the potential efficacy of health communication programmes as cancer prevention strategies. Results at 10-year follow-up were similar[11]. Limitations of the study design made it difficult to identify causal relationships between the intervention and its SLT-related outcomes. Specifically, by using a control group that was based on data gathered 10 years prior to the intervention, the influence of extraneous confounding factors on the findings observed in the intervention group could not be accounted for. Additionally, impact assessments did not study the reach and relative efficacy of the different forms of communication used in this study.

Following the Ernakulam intervention, another controlled intervention as part of a cancer prevention programme was implemented in the Kolar district of Karnataka between 1987 and 1990[13]. One hundred and seventeen villages (population = 60,447) under the purview of Primary Health Centres (PHC) participated in the intervention. The health education programme was time- and labour-intensive, utilising 25 junior workers and 3 senior health workers from the local PHC who would visit each village weekly/monthly to educate users on the harms of tobacco by engaging in discussions with individuals and groups and using visual aids and a film titled ‘Cancer is curable’.

The impact of the intervention was assessed with concurrent baseline, midline, and end-line surveys in the intervention area and two sociodemographically matched control sites. The baseline survey indicated that about 17% of the population in the intervention area were SLT users. At end-line, a significant reduction in prevalence was found among male smokeless users in the intervention area (5%) compared to the control areas (0–1%). Likewise, there was a significantly greater quit rate for SLT use in the intervention than in the control areas. Three different forms of health messages used in this intervention were evaluated for their impact—written, interpersonal, and audiovisual communication—and exposure to each among quitters and non-quitters was assessed. No differences were found between quitters and non-quitters in exposure to the written and interpersonal communication forms. However, a greater number of quitters than non-quitters of either gender reported exposure to the audiovisual form of the message, suggesting that this medium may have been relatively more effective in encouraging cessation than the other communication message types.

The intervention also underscored the intense degree of commitment, time, and effort required over a significant period of time to ultimately affect a small area. The authors noted that the efficacy of this intervention hinged on characteristics that may or may not be scalable, including the leadership of the medical officer and many characteristics related to the health workers—the feasibility and logistical capability for health workers to take on an additional programme of health education for tobacco control; their educational qualifications, professional responsibility, and commitment; additional training required; and most importantly, their natural skill at building rapport and executing this kind of intervention.

In the National Rural Health Mission, health workers who work at the community level have been provided with a Health Worker's Guide[14] to discuss tobacco harms in the communities. An evaluation of the implementation and impact of this programme has not been conducted to date.

School-Based Programmes

Currently, school-based health education programmes are a component of the National Tobacco Control Programme. The objective is that in addition to preventing the uptake of tobacco among students, school-based education will also educate parents and other adults in the children's homes and communities on the harms of tobacco use.

The earliest recorded school-based intervention was implemented in 46 villages in the Northern and Central zones of Goa in 1987 and 1988; villages in the Southern zone of Goa served as a control[15]. The goal of the intervention was to inform children in grades 4 through 9, and, through them, to influence adults at home and in the community. The intervention included booklets on the harms of tobacco and ways to quit, which were taught during the academic year by teachers who had been trained as part of the intervention. Multipurpose health workers and Anganwadi (rural) health workers also communicated the information. Post-intervention evaluations suggested that attitudes toward tobacco became more negative and that quit rates increased in the intervention compared to the control sites. These conclusions were significantly weakened, however, by analyses that did not account for a priori sociodemographic differences between the intervention and control sites, and the outcome evaluation did not differentiate between SLT and smoking products.

Two school-based randomised controlled intervention trials have been reported in recent years (2002 and 2009)[16,17]. One was designed to prevent cardiovascular disease; it was conducted from

1996 to 1998 with 7th grade students (n > 4,500) from 30 schools in Delhi[16]. Ten schools were randomly assigned to the following: (1) a school-based curriculum; (2) a school-based curriculum plus home-based activities; or (3) a control with no specific intervention. The school-based curriculum included an awareness and advocacy package that was delivered by teachers and peer leaders. The home-based curriculum included activity-based booklets designed to encourage healthy lifestyles, which were completed by students and their families together. The evaluation reported greater acceptance by schools of the need for healthy lifestyle–related interventions, as well as greater resistance among students to consuming tobacco in the future. It is unclear whether these effects were primarily related to smoking or SLT forms of tobacco.

Another randomised controlled trial, implemented between 2002 and 2007, involved 16 schools each in Delhi and Chennai[17]. The project was designed to target social-environmental and intra-personal factors (knowledge, values, meanings, beliefs, skills) that contribute to tobacco use among adolescents. Intervention components included: (1) classroom curricula, (2) school posters, (3) parent postcards, and (4) peer-led health activism. Evaluation of the programme using baseline, midline, and end-line surveys indicated that the intervention was effective for smoking behaviours, but of limited efficacy for SLT behaviours, because there was no difference between the groups on SLT usage through the intervention period. Greater emphasis on smoking than SLT was possibly one explanation for this differential impact.

MASS MEDIA INTERVENTIONS

Many mass media interventions have been implemented, the bulk of them designed in support of World No Tobacco Day, but these have not been evaluated and are not described here.

The earliest national mass media intervention, Radio-DATE[18], was designed to educate the public on drugs, alcohol, and tobacco. The campaign aired on the only radio station in 1990, All India Radio, in 30 Sunday morning episodes broadcast in 16 languages from 84 stations. Ten of these episodes focused on tobacco. This programme was evaluated through community-based surveys in Goa and Karnataka. Among potential listeners, 27% and 32% had heard at least one episode on tobacco, and 4% and 6% users had stopped tobacco use in Goa and Karnataka, respectively, after listening to the programme[10].

The first comprehensive pan-national mass media campaign specifically targeting SLT harms was developed and aired in 2009[18,19]. This campaign was guided by evidence that graphic anti-tobacco messages depicting the health harms of tobacco are more effective in prompting quitting and reducing uptake. The message was targeted toward priority audiences including women, rural residents, and low-income groups. A 30-second documentary-style public service announcement (PSA), referred to as *'Surgeon,'* was developed and pre-tested. It features an oral cancer surgeon from a tertiary care cancer hospital with one of the busiest cancer wards in the world, as he describes and presents the serious illnesses and disfigurement of his patients, which have been caused by cancers resulting from the use of SLT.

The *Surgeon* campaign aired for six weeks from November to December 2009. Television coverage included state-owned and private national and regional channels, with 81% of television exposures occurring during 'prime time' (56% on weekday evenings, 20% on weekend evenings, and 5% on weekend mornings) and 19% outside of prime time (11% on weekday mornings and 8% on weekend afternoons). In addition, the campaign also aired nationally on popular radio stations.

The *Surgeon* campaign was evaluated with a nationally representative household survey of male and female SLT users (n = 2,898), ages 16 to 50 years, who were recruited randomly from over 15,000 households[20]. Reflecting the demographic characteristics of SLT users, about 80% of the study participants resided in rural areas and were from the lowest socioeconomic class. The evaluation found that 63% of smokeless-only users and 72% of dual users (i.e., those who consumed both smoking and smokeless forms) recalled the campaign advertisement, primarily through television channels. The vast majority (over 70%) of those aware of the campaign said that it made them stop and think, was relevant to their lives, and provided new information. The majority of smokeless-only users (75%) and of dual users (77%) said that it made them feel concerned about their habit. Campaign awareness was associated with better knowledge, more negative attitudes towards SLT, and greater cessation-oriented intentions and behaviours among SLT users. This overall pattern of findings was consistent across urban and rural settings, among men and women, and among both youth in their late teens and older adults.

Following the success of the *Surgeon* campaign, a tragic event provided the impetus for a second SLT mass media campaign[19]. A 24-year-old SLT user named Mukesh, who was featured in the *Surgeon* campaign PSA, died soon after the campaign was aired. Following discussions with and encouragement from Mukesh's parents, his attending physicians at the Tata Memorial Hospital, and other key advisors, the *Surgeon* PSA was re-cut to feature Mukesh's story more prominently for a subsequent wave of media activity. The *Mukesh* campaign was aired by the GOI from February through April 2011. In addition to informing and influencing the public on the harms of SLT usage, the *Mukesh* campaign was used to support and intensify advocacy and policy efforts by providing a powerful face and story to the issue of SLT harms. Media activities including a Voices of Tobacco Victims (VoTV) campaign were used to synergise and highlight the tragic consequences of SLT use.

A ban on gutka, the second most prevalent form of SLT, was being considered in the Supreme Court of India at the time. Emotive images from the *Mukesh* campaign featuring the image of Mukesh with the words: 'Mukesh would support the ban on gutka' were strategically placed, including outside the courts, to highlight the seriousness of the SLT issue. The social and electronic media were leveraged, with a website called 'Chewonthis' (www.chewonthis.in), which provided additional opportunities for social networking. The campaign also employed an SMS mobile phone strategy, with two million SMS messages disseminated across the country.

The *Mukesh* campaign was evaluated using street intercept surveys with tobacco users in five states, representing five zones of the country[20]. Evaluation findings revealed that 71% of smokeless users recalled the campaign, and the majority rated the PSA as easy to understand (77%), believable (80%), personally relevant (79%), and making them feel concerned about the health effects of their SLT use (77%).

Surveillance data from GATS India 2009-2010[4] provides similar findings about anti-tobacco messaging campaigns. All respondents were asked whether they noticed any anti-SLT messages during the 30 days prior to the survey. Two-thirds of adults in India (66%) had noticed anti-SLT information in the 30 days before the survey, with a marginal variation between SLT users (69%) and non-users of SLT (66%). Television was the most frequently cited source of anti-SLT messaging (40%), followed by newspapers/magazines (32%), billboards (24%), and radio (21%). Sources other than these accounted for 2% of recall. Television and radio combined accounted for over half (52%) of exposures to anti-SLT messaging. This pattern of recall by medium was consistent among current users and non-users of SLT. Although a higher proportion of young, urban, male respondents ages 15–24 years noticed anti-SLT messages compared to their respective rural counterparts, the differentials were 8% points or less.

PACK WARNINGS: A POLICY-LEVEL INTERVENTION FOR PUBLIC AWARENESS

This section describes pack warnings and, in particular, the synergies between pack warnings and population-level mass media campaigns (for more detail on pack warnings, see chapter 15).

Using Pack Warnings to Warn About Tobacco Harms

Strong picture-based health warnings on all tobacco product packages (smoking and smokeless forms) deliver information directly to the users. The message is repeated and reinforced every time a tobacco user reaches for a tobacco product. Article 11 of the FCTC[1] and the guidelines framed thereunder require the Parties to implement large, clear, and visible pictorial health warnings that occupy at least but preferably much more than 30% of the pack. The 'W' of the MPOWER strategy[21] also calls nations/ parties to implement 'effective package warning labels' on all tobacco product packs.

Effective warning labels increase knowledge about risks associated with smoking and can influence future decisions about smoking[22,23]. Large, graphic warning labels can motivate smokers to quit, discourage non-smokers from starting[24], and keep former smokers from starting again[23]. Warning labels that combine pictures with text are particularly important and relevant in India, where a substantial proportion of the population is illiterate, particularly those who use SLT.

In addition to the direct impact of pack warnings, the impact of pack warnings is amplified when they are synchronised with a mass media campaign. Two studies in Australia[25] found a complementary and reinforcing relationship between exposure to pack warnings and mass media advertising.

Efficacy of Pack Warnings and Opportunities for Synergies with Mass Media Campaigns

The earliest mandate for health warnings on tobacco products and advertising in India dates to 1975, when the GOI passed legislation requiring the 'text only' health warning 'cigarette smoking is injurious to health'[26]. However, this legislation exempted non-cigarette tobacco products, including bidi, cheroot, cigar, gutka, and chewing tobacco from textual warnings.

In 2003 a law was enacted that mandated the display of a skull and crossbones pictorial health warning on smoking as well as smokeless forms of tobacco products. After a long struggle, the weak and poorly communicative pictorial health warnings were finally implemented in 2009[27]. The warnings covered only 40% of the principal display area and on the front panel of the pack only, with the option of alternating the message every 12 months. The image of a scorpion was mandated for all SLT products. When independently field-tested in cross-sectional surveys of tobacco users, these warnings were determined to be largely ineffective[28,29].

Since rotation of warnings was notified every 12 months for subsequent rounds[30], efforts were made to improve the pack warnings. In a test of 11 sets of images in 7 states, 98% of the respondents voted that the 'mouth cancer' pictorial warning was the most effective. In March 2010 a notice was issued to replace the earlier message with the mouth cancer warning as of 1 June 2010. Implementation of the new message, however, was rolled back and, in a further weakening, the period of rotation was increased from 12 months to 24 months. In May 2011, a new set of four warnings deleting the text message was notified to be implemented from 1 December 2011. Since there is no compulsion on rotating the warnings, the industry chose to use the one that it considered the least effective.

Continued advocacy from tobacco control advocates and the public for the implementation of strong, tested pack warnings is required. Effective mass media campaigns are required to support stronger pack warnings by graphically presenting the health effects and human costs of SLT use.

GAINS, CHALLENGES, AND OPPORTUNITIES

Our review of interventions targeting SLT usage from the 1970s to the present has identified a preponderance of community-level and interpersonal interventions[11,13]. These interventions took the traditional 'Information Education Communication' (IEC) perspective such as sensitisation campaigns, advocacy, and training, with the expectation that providing information will result in behaviour change. This perspective was also the basis of the earliest school-based programmes, which sought to transmit information through students to adults in the family and community. Nonetheless, the early randomised intervention trials—specifically, the ones in Ernakulam district and in Kolar—did report reduced prevalence in the intervention compared to the control sites, and they demonstrated how reductions in SLT use could actually reduce the risk of the development of precancerous lesions.

Since that time, health communication programming has evolved into a more strategic, participatory, and interactive approach that seeks to understand target audiences and address their needs and motivations. This approach is guided by behavioural theories that address the various factors that motivate or hinder the desired behaviour change.

One of the most significant recent developments in anti-SLT health communication programming has been the use of population-level approaches, specifically through mass media. With the application of social marketing approaches, and informed by behavioural theories, recognition is growing that anti-SLT mass media campaigns can impact social norms and beliefs, and create fertile ground for effective public policy. The *Surgeon* and *Mukesh* communication campaigns[19] reflected this evolved approach to health communication programming. The wide reach of mass media illustrated by these campaigns, including among rural areas, was corroborated by GATS India 2009-2010, which found that television and radio were the media through which over half of Indian adults obtained their information about SLT harms.

Interpersonal approaches—until recently, the most popular channels for communicating the harms of SLT use—are limited in terms of scalability due to their highly resource-intensive nature. Ultimately, the numbers reached through IPC approaches are small, rendering interpersonal communication a relatively cost-inefficient approach. Community media, particularly when using audiovisuals, have shown greater potential. The outcome evaluation of the Kolar intervention[13] found that quitters had had greater exposure to audiovisual community media than non-quitters, suggesting that this communication channel is more effective than written text and IPC communications.

Ultimately, the strongest evidence for behavioural impact and cost-efficiency is for best practice tobacco control mass media campaigns. Although the immediate cost of airing national mass media campaigns may be high, they are the most cost-efficient in terms of the numbers reached and the immediacy of their behavioural impact.

Finally, pack warnings offer governments an easy and inexpensive channel for communication that has broad population reach and must be part of a comprehensive communications approach. Once implemented, pack warnings have negligible costs to governments and can be highly effective in motivating users to quit. However, in order to be effective, pictorial warnings must be hard-hitting and blunt and must include graphic images, a particularly important consideration for India, which has large populations that have low levels of literacy.

CONCLUSIONS

The growing tobacco epidemic in India calls for strong and quick action. The science of effective health communication, particularly for tobacco control, has evolved significantly, with proven theories and approaches for informing and influencing tobacco-related behaviour, social norms, and public policy. While all communication approaches have their merits and drawbacks, the evidence to date is strongest for population-level tobacco control campaigns utilising mass media channels of communication. A comprehensive tobacco control communication approach in India must harness the power of mass media to quickly and forcefully reach large numbers, while synergising with community media and interpersonal channels of communication, to achieve the broadest and deepest behavioural impact. It is also critical that these campaigns adhere to an evidence-based approach that evaluates the intended and unintended consequences of interventions, and favours those approaches that can achieve the greatest behavioural impact and cost-efficiencies.

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Chapter 18

Strategic Partnerships and Integration

Rajmohan Panda[1], Monika Arora[1], Divya Persai[1]

[1]Public Health Foundation of India, New Delhi

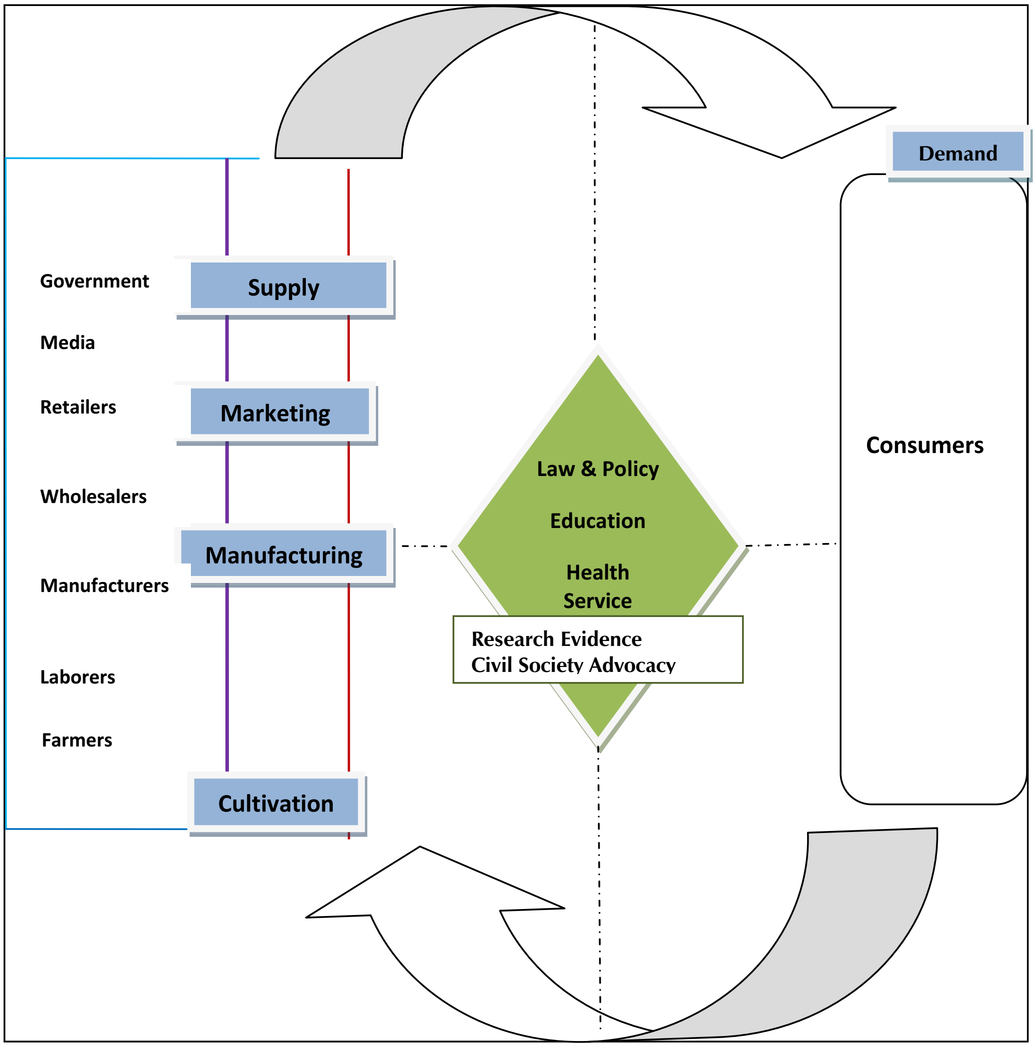
INTRODUCTION

Comprehensive smokeless tobacco (SLT) control is only possible through a holistic approach involving health, education, law, and other sectors of national life. Reaching out effectively to key stakeholders is essential to any strategic plan. The holistic approach consists of proven demand and supply reduction strategies which include treating tobacco addiction by providing services to help tobacco users quit tobacco[1]. Preventive and promotive measures are needed, such as health education to help reduce demand for SLT products, and legal–policy actions, such as a ban on sale of tobacco products to minors, to help reduce supply.

Tobacco control has both short-term and long-term benefits for the community. Integrating tobacco control interventions in health systems helps to build providers' knowledge and skills in counselling patients who are smokeless tobacco users. Appropriate counselling and pharmacotherapy are cost-effective steps that will help increase quit rates. These interventions have immediate health benefits and could reduce not only long-term morbidity and mortality from tobacco use but the short-term tobacco death burden as well[2,3].

The strategic approaches described in the chapter focus on the different stages of the smokeless tobacco life cycle and suggest ways of reducing supply and demand of the products. The life cycle of an SLT product extends from growing the tobacco plant to getting the final product into the hands of the consumer. This cycle has deleterious effects on health, the environment, and the economy, but these steps in the life cycle also can be seen as opportunities for interventions to regulate and reduce smokeless tobacco use (see Figure 18.1). Interventions at suitable entry points in the life cycle can reduce both supply and demand for smokeless tobacco products.

Figure 18.1: The strategic partnership and integration model for smokeless tobacco control



LIFE CYCLE APPROACH TO SMOKELESS TOBACCO CONTROL

Tobacco is a cash crop that is promoted by organised government machinery, the tobacco industry, and financial institutions[4]. These institutions collaborate to promote direct and indirect subsidies and tax-based incentives to facilitate the production and supply of tobacco. Tobacco farmers are an important supply lifeline for the tobacco manufacturing industry. If this link is broken, which can only be done through encouragement of alternative, equally lucrative cash crops, the supply of tobacco products would be reduced. Evidence-based solutions that encourage tobacco farmers to divert to alternative crops and/or other livelihoods should figure prominently in a holistic tobacco control movement.

At the macro level, incentives for tobacco growing (like subsidies, easy loans, doorstep delivery of tobacco plants for cultivation, assurance for postproduction purchase), which are offered by financial institutions and the government should cease and or be gradually withdrawn. At the same time, policy-level measures should be introduced to encourage production of alternative cash crops. These measures require strong advocacy, administrative initiatives, and political commitment. Thus, political establishments, the bureaucracy, and the farmers are all stakeholders whose engagement is an essential ingredient for a comprehensive shift in tobacco control.

At the micro level, the supply chain for procurement and sale of alternative crops should be strengthened to encourage tobacco farmers to shift to cultivation of alternative crops. Civil society and environmental groups should advocate for viable alternatives for the tobacco farmer by using evidence-based solutions generated from operations research in these areas. The collective efforts of the agricultural, environmental, trade, and commerce sectors, as well as civil societies and development programmes are required to decrease tobacco production and ultimately shift from tobacco cultivation to equally lucrative cash crops.

Raw tobacco is converted into consumable smokeless tobacco products and marketed to the community by the manufacturers of tobacco. The large number of unregistered manufacturers who produce myriad varieties of SLT and market them locally is well out of the reach of the regulatory bodies. This is a major obstacle for interrupting the life cycle of the smokeless tobacco product. Empowering and engaging local law enforcers, student and worker unions, and vigilant civil society groups can help in monitoring the regulation of such manufacturers and products; this monitoring is currently being done in a growing number of states[5,6] (see the section 'Strategic Partnership for Law and Policy Interventions' in this chapter). This is a vital linkage for success of the prohibition and production of smokeless tobacco.

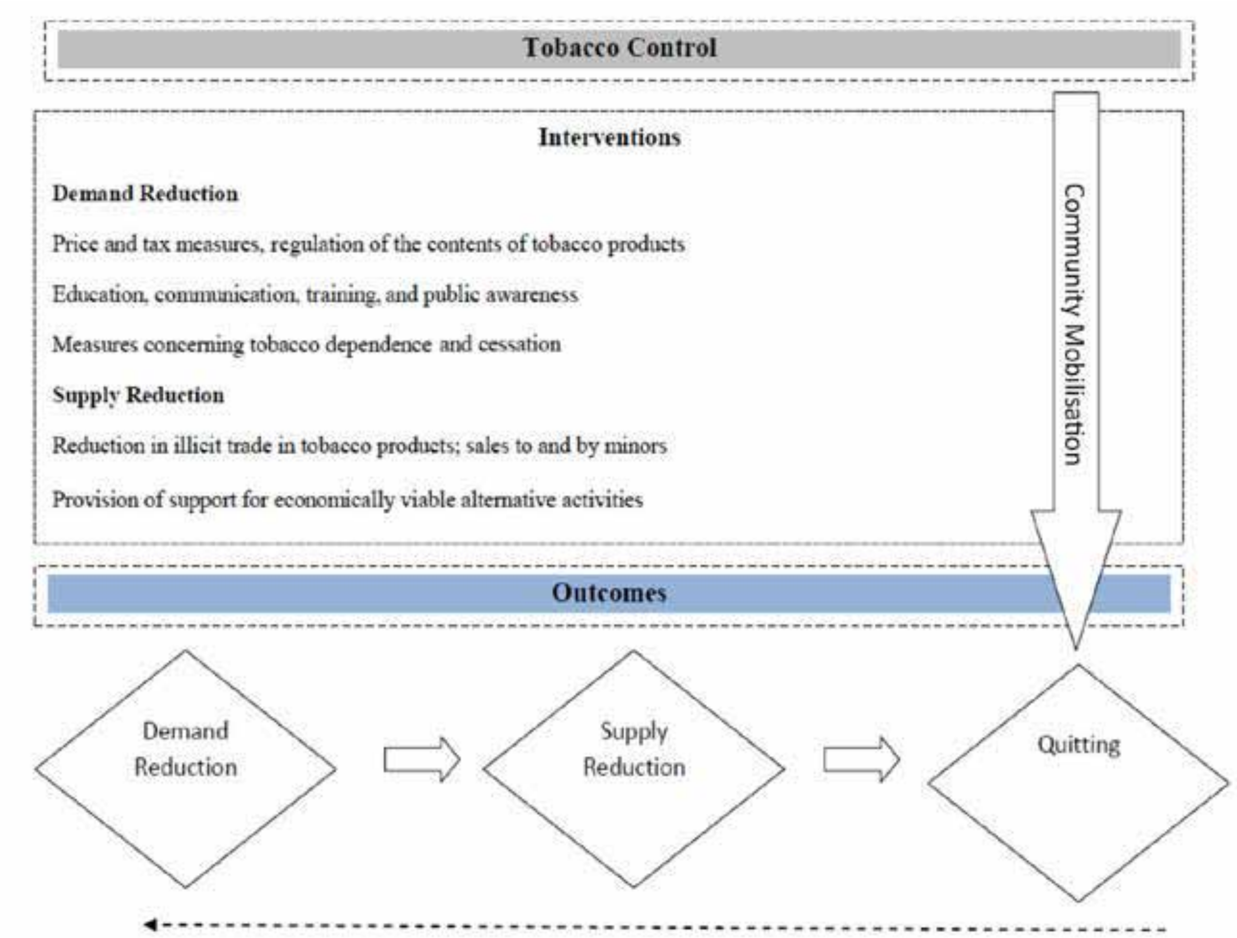
The tobacco industry uses aggressive promotion strategies and employs a novel supply chain to lure people to consume tobacco products. This strategy of easy access through promotion and sale at every possible point helps maintain an uninterrupted supply of tobacco products, which ensures continuous demand from consumers[7], which in turn helps the tobacco industry to thrive and flourish. It is thus important to intervene in the marketing and promotion of smokeless tobacco, which can be accomplished through (1) policy-level regulation of promotion through the media and point-of-sale and surrogate advertisement; and (2) sale restriction, health warnings, and community education.

The entire process from cultivation of tobacco to its final use by the consumers involves multiple stakeholders who promote, regulate, or counter the product and its use. Maximum benefit from tobacco control interventions can only be realised when the complex interactions between these diverse stakeholders are understood and suitably addressed. One major obstacle to intervention is the lack of empirical data on both the demand side and the supply side. For example, there are very few well-documented sources of improvement in morbidity, mortality, and cost-effectiveness of tobacco control interventions in the country, especially in relation to smokeless tobacco. Lack of such empirical evidence hinders the development of evidence-based policy decision for engaging multiple stakeholders.

The solution then is to create and strengthen existing networks and partnerships amongst researchers and tobacco control advocates. This is an essential and required step in establishing a comprehensive tobacco control strategy in which smokeless tobacco is suitably addressed. Where should such networks be created, fostered, and strengthened? Key elements for such a comprehensive tobacco control strategy include measures involving various sectors, such as law and justice, finance and treasury, customs and excise, trade and commerce, consumer affairs, agriculture, external affairs and international trade, labour, transport and public service, health, education, environment, defence, culture and sports, and religion[8]. In this chapter we discuss the various stakeholders in relation to three major interventions:

- Law and policy interventions (demand and supply reduction)
- Educational interventions (demand reduction)
- Health system interventions targeted at tobacco use cessation (see Figure 18.2).

Figure 18.2: Multipronged approach for smokeless tobacco control



One common tactic would be to create linkages between these interventions so that incremental benefits are realised over time. The interventions discussed here are supported and strengthened by evidence generated from various research studies as well as advocacy work done by tobacco control advocates and civil society organisations. The aim of adopting a systems approach toward an effective tobacco control system is to integrate tobacco control interventions into health and developmental programmes so as to make these interventions sustainable.

STRATEGIC PARTNERSHIP FOR LAW AND POLICY INTERVENTIONS

Legislation forms the foundation of successful tobacco control activity[9]. Legislation serves specific social objectives: It helps to recognise, reinforce, reassess, and reconcile certain societal values. India's history spans centuries, and it is only in the recent past that legal actions against smokeless tobacco have been initiated and that legislation has come to the forefront in the fight against smokeless tobacco. The first major impetus for a multisectoral approach to tobacco was the 22nd Report of the Indian Parliament's Committee on Subordinate Legislation, published in 1995. In this report, the committee made wide-ranging recommendations and called upon the medical, scientific, and legal sectors to collaboratively form a national-level nodal agency for the comprehensive control of tobacco[10]. It also called for engaging parliamentarians and policy makers in creating a favourable climate for effective legislation for smokeless tobacco laws and policies.

Comprehensive tobacco control in India requires the collaborative efforts of both the Central Government and the states. The implementation of the Cigarettes and Other Tobacco Products Act, 2003, (COTPA) is the responsibility of the State Governments. Some states not only have formulated strong, independent laws to address specific components of tobacco control strategy, but have also used existing laws like COTPA and other laws to curb smokeless tobacco use in their respective states. COTPA, an amended version of the draft bill of 2001, completed its passage through Parliament on 30 April 2003 and was assented to by the President of India on 18 May 2003. The states of Tamil Nadu, Andhra Pradesh, Maharashtra, Goa, and Bihar have banned the use of smokeless forms of tobacco such as gutka and pan masala. These practices are good examples of the partnerships between various ministries as well as the Central and State Governments, which came together to formulate and implement legislation to curb the smokeless tobacco epidemic. It is important to note here that many of these legislations would not have been possible without the activism of civil society advocates and dynamic partnerships between health and developmental programmes. Evidence provided by these groups in the form of studies, anecdotes, case studies, and media briefings has been instrumental in stimulating legislative bodies and policy makers to formulate and enact acts to tackle the menace of smokeless tobacco.

In order to protect youth from unnecessary exposure to tobacco usage through films and television programmes and to regulate the depiction of tobacco products and their use in films and TV programmes, the Government of India notified the COTPA [amendment] Rules in 2005. These rules could not, however, be implemented due to litigation. In 2011, after due deliberation and inter-ministerial consultations, the Government amended the original Rules and notified the COTPA [2nd amendment] Rules 2011 vide GSR 786 dated 27 October 2011[11]. These amended rules are still robust and go a long way toward protecting people from exposure to tobacco use.

Champions in the NGOs sector have initiated many judicial interventions through litigation, and NGOs have advocated for a tobacco-free society. Tobacco control efforts are being monitored at the grassroots level through the formation of local volunteer groups. Panchayats (elected bodies of government operating at the village level) are raising social awareness and mobilising their communities against the ills of smokeless tobacco. In 2011 and 2012 many such village committees banned sales of tobacco (including gutka) in an attempt to make their villages tobacco free[12].

It is well known that tobacco cultivation is responsible for loss of biodiversity and land pollution through the use of pesticides, as well as soil degradation, deforestation, and water pollution. Tobacco plants consume soil nutrients at a higher rate than most other crops. In addition, smokeless tobacco manufacturing uses plastic and paper for packaging which further degrades the environment when the packaging material is disposed of after use. Spitting during SLT use has a detrimental effect on environmental sanitation and hygiene. Therefore, advocacy and legislation to protect the environment should aim at curbing cultivation of tobacco crops, use of plastics in manufacturing of tobacco products, and littering. As a good example of how the law can be used to prevent environmental damage, the Supreme Court of India banned plastic pouch packaging of tobacco products beginning 1 March 2011, a ban that has far-reaching implications for environmental safety. Similar efforts to involve environmental groups are also needed to prevent spitting of tobacco on roads, in buildings, open places, and public places.

Many Government ministries are involved in tobacco control: the Ministry of Health and Family Welfare (MoHFW), the Ministry of Information and Broadcasting, the Food and Drug Administration, the Ministry of the Environment, the Home Ministry, the Ministry of Labour, the Ministry of Industry, and the Ministry of Excise. As we have seen, there are already many examples of synergies for tobacco control, in that some ministries make the legal provisions and others take measures to implement them. Much remains to be done, however, especially with regard to the largest burden—that is, addressing smokeless tobacco.

STRATEGIC PARTNERSHIPS FOR EFFECTIVE IMPLEMENTATION OF TOBACCO CONTROL LAWS

Implementation of these laws requires strong partnerships at various levels. In India, legal and policy decisions are taken at the levels of the Union and the States, while implementation is done at district and sub-district levels or at the organisational or institutional level. The Union and the States make Acts, levy taxes, issue executive orders, and provide recommendations.

Taxes on smokeless tobacco products should be increased and the generated revenue spent to strengthen the tobacco control programme, with particular consideration given to addressing smokeless tobacco. As tobacco production and consumption exacerbate poverty and undermine sustainable development, tobacco control should be adequately addressed as a component of development assistance programmes in the country[13].

Many good examples of strong partnership models for tobacco control, led by various organisations, exist both within and outside India, as described in the following paragraphs.

The Framework Convention Alliance

The Framework Convention Alliance (FCA)[14] is a civil society alliance made up of 350 organisations from more than 100 countries aimed at developing and implementing the World Health Organization's Framework Convention on Tobacco Control (FCTC) to curb the tobacco menace. This organisation has influenced countries to implement the FCTC, kept government officials and the media updated on measures regarding the FCTC, provided grants for tobacco control activities, and helped compile evidence for tobacco control measures. It has also improved accountability of governments. Thus the FCA has catalysed global tobacco control efforts. The FCTC has established that international law has a vital role in preventing disease and promoting health[1].

The Bloomberg Initiative

The Bloomberg Initiative[15], funded by Bloomberg Philanthropies, has five partners: the U.S. Centers for Disease Control and Prevention, World Health Organization, Johns Hopkins Bloomberg School of Public Health, World Lung Foundation, and Campaign for Tobacco-Free

Kids. These stakeholders perform different functions, such as monitoring and surveillance, country-level coordination, capacity building, advocacy, and grants management. These efforts have helped scale up tobacco control efforts in developing countries in a coordinated manner. As a result, many developing countries have been able to produce country-specific evidence that has influenced policies for effective tobacco control interventions.

The National Organisation for Tobacco Eradication

The National Organisation for Tobacco Eradication (NOTE), established in Goa in 1992, is an alliance of 20 Indian NGOs that has brought together multiple organisations/institutions for anti-tobacco policy changes, community mobilisation, and campaigns against tobacco industry tactics. NOTE was the major impetus behind the Goa Prohibition of Smoking and Spitting Act, 1997. NOTE analyses and assesses public policy and publishes journal articles and official reports.

The Advocacy Forum for Tobacco Control

The Advocacy Forum for Tobacco Control (AFTC)[16] is a coalition of organisations and individuals working in tobacco control in India. Since 2001, it has been pivotal in coordinating and uniting individuals, professionals, and institutions for tobacco control advocacy, awareness, and research in India. AFTC aims to create mass support for tobacco control policies through evidence-based, scientifically validated, and concerted advocacy targeted at policy makers through involvement of media, youth, and the general population to create a tobacco free India.

Academic Institutions

The Post Graduate Institute of Medical Education and Research, Chandigarh (PGI Chandigarh)[17] runs one of the 19 tobacco cessation centres established by the Government of India and WHO. The PGI psychiatric department has shown leadership by producing manuals for tobacco control counselling and treatment and also offers a one-day training programme for doctors on tobacco dependence treatment. Another academic institution, the National Institute of Mental Health and Neurosciences (NIMHANS) at Bengaluru, has pioneered training manuals and developed strong cessation partnership linkages with the state health department.

The Resource Material Development Partnership Model

Tobacco control in India has advanced over the last decade (since 2004). Previously, the lack of information and expertise in this field was a deterrent to implementation of tobacco control activities. With the help of technical expertise from international agencies such as the Centers for Disease Control and Prevention (U.S.) and WHO, India, the Government of India was able to produce resource materials for tobacco control in India (see Table 18.1). During this process, knowledge from Western countries such as the United States was extended to the Indian context with the involvement of Indian academic and research organisations such as the All India Institute of Medical Sciences (AIIMS), International Institute for Population Sciences (IIPS), National Institute of Health and Family Welfare (NIHFW), Tata Memorial Centre (TMC), Public Health Foundation of India (PHFI), Healis-Sekhsaria Institute for Public Health, and NIMHANS. Government of India also involved its apex educational research body, the National Council of Educational Research and Training (NCERT), to develop resource materials for training and education of schoolteachers and students in tobacco control.

Table 18.1: Resource material developed by MoHFW in partnership with international and national agencies, civil societies, and academic institutes

Resource Material
Bidi Smoking and Public Health (2008)[18]
Report on Tobacco Control in India (2004)[1]
GATS India Report (2009-2010)[19]
Training Manual for Doctors NTCP (2011)[20]
NTCP – A Guide for Teachers (2011)[21]
Tobacco Dependence Treatment Guidelines (2011)[22]

All of these examples of effective partnership models for tobacco control have utilised the strengths of various stakeholders to maximise tobacco control efforts and programme implementation.

STRATEGIC PARTNERSHIP FOR EDUCATIONAL INTERVENTION

Health education is a ‘social vaccine’; it has been suggested as an effective measure to prevent and reduce the smokeless tobacco epidemic, which affects school-going children as young as 10 years[22–27]. Evidence from community intervention research led by the Indian Council of Medical Research (ICMR) which, with the involvement of schoolchildren, established the feasibility and effectiveness of school-based tobacco control programmes[28]. Evidence generated from this study helped the Ministry of Education in Goa to promote tobacco education as a co-curricular activity for classes 5 and above. The MYTRI and Salaam Bombay projects are also successful projects that produced evidence for school-based tobacco control intervention including smokeless tobacco[29–31]. These interventions succeeded primarily because of strategic partnerships between stakeholders, as summarised in Table 18.2. While these pilot programmes were successful in generating evidence for integrating such models into the physical or health education school curriculum, issues remain to be addressed, especially around integration into an already ‘heavy’ school curriculum.

Table 18.2: Tobacco control interventions in educational institutions: success stories

Model Interventions	Partners	Outcomes
Classroom teaching and community activism by students in anti-tobacco community project **(ICMR)**	Research organisation, government, educational institutes, schoolchildren, teachers, and community	1. Reduced initiation of tobacco use 2. Reduced tobacco use in the community
Classroom teaching, community outreach, and peer-led activism **(MYTRI)**	Research and funding organisation, civil society, government, educational institute, schoolchildren, teachers, and community	1. Increased knowledge 2. Decreased tobacco use 3. Decreased intention to use
Classroom teaching and exposure to tobacco control programme **(Salaam Bombay)**	Funding organisation, civil society, government, educational institute, schoolchildren, teachers, NTCP implementers, and community	1. Increased knowledge 2. Decreased tobacco use 3. Increased tobacco control activism

Abbreviations: ICMR: Indian Council of Medical Research; MYTRI: Mobilising Youth for Tobacco-Related Initiatives in India; NTCP: National Tobacco Control Programme

In 2011, the Department of Health and Family Welfare, in partnership with the Department of Human Resource Development, directed all educational institutions to establish boards in accordance with Section 6 of COTPA, and asked district administrations to ensure that no tobacco products are sold within 100 yards of educational institutions. Further supporting the efforts of COTPA, the state of Odisha's State Programme Managers in the Department of Human Resource Development direct schools to ensure compliance with Section 6 of COTPA.

As far as college and university students are concerned, best practices like Youth Unite for Victory on AIDS (YUVA) and Red Ribbon Club for HIV/AIDS control could be adapted to engage students in tobacco control efforts. Partnering with higher educational institutes, state and university departments—such as sports, youth and cultural affairs, adult education, open schooling, vocational training, and community education will engage more youth in smokeless tobacco control and can also extend the coverage of NTCP in India. Furthermore, the educational institutes have social and legal obligations regarding tobacco control because they are both social institutions as well as public places.

The majority (74–97%) of students in the health professions (medical, dental, pharmacy, and nursing) believe that health professionals are role models for their patients in tobacco control, but only a few (10–37%) amongst them have been exposed to tobacco cessation approaches[32]. At present, training in delivering treatment for tobacco dependence is limited to postgraduate courses in psychiatry and medicine in the country. Training in tobacco cessation must be given in the undergraduate and postgraduate professional curriculum[33]. A strategic partnership with regulatory bodies engaged in health professional education such as the Medical Council of India, Dental Council of India, Pharmacy Council of India, and Indian Nursing Council would be a starting point for advocating for the inclusion of a comprehensive tobacco control–related curriculum in both undergraduate and postgraduate medical, nursing, and allied health education. Engaging educational departments in disciplines such as law, economics, and development is important to building a critical mass of champions who will be future opinion leaders and policy influencers. Tobacco taxation and related policies as a postgraduate assignment in development studies will equip development and public health professionals with the necessary tools to aid in tobacco control.

PARTNERSHIPS WITH LAWMAKERS AND LAW ENFORCEMENT PERSONNEL

Legal preparedness is a critical component of a comprehensive public health programme[34]. The law can be used as an instrument to take proactive steps to improve public health[35]. Unfortunately, many lawyers who provide legal support to public health departments do not have the time or resources to develop a thorough and up-to-date understanding of public health laws. Therefore, tobacco control law must be introduced into the course curriculum of law students both at the undergraduate and postgraduate levels. Most prominent law schools in India have related courses like medical law and ethics.

Efforts taken by the Government of Bihar have been effective in sensitising the Department of Home in the state to tobacco control issues. In 2011, the Secretary of Home, Government of Bihar, sent directions to all senior superintendents of police and the superintendents of police in Bihar's 38 districts to ensure effective implementation of COTPA in the state. To build capacity among police officials, the State Health Society, in association with NGOs, presented an

Advocacy Workshop on Effective Implementation of Indian Tobacco Control Law (COTPA) for police personnel on 2 December 2011. Senior police officials from five intervention districts (Vaishali, Bhojpur, Darbangha, Samastipur, and Katihar) and two NTCP districts (Patna and Munger) were trained on the implementation of Indian tobacco control law. Senior officials of the police and health departments directed police personnel to effectively enforce the provisions of COTPA.

STRATEGIC PARTNERSHIPS FOR HEALTH SYSTEM INTERVENTIONS

Tobacco prevention and cessation services at health facilities at different levels in the primary health care system would greatly benefit patients. The central health ministry has a tobacco control cell that coordinates the National Tobacco Control Programme (NTCP) and plans to integrate tobacco control into various programme divisions such as RNTCP (Revised National Tuberculosis Programme), RCH (Reproductive Child Health), MH (Mental Health), NCD (Non-Communicable Disease), and Oral Health, ensuring synergy while mainstreaming tobacco control efforts. It is also recommended that tobacco cessation treatment should be included as an essential service in Indian Public Health Standards guidelines. Health care providers still do not see smokeless tobacco is still not seen as a significant risk factor for many diseases[36]. To engage clinicians requires development of evidence-based and context-specific training material with emphasis on smokeless tobacco use. A portion of the tax revenue levied on smokeless tobacco should be dedicated to raising resources for the long-term sustainability of such endeavours.

Different approaches, like counselling and pharmacotherapy, have been advocated for helping users quit smokeless tobacco. Increased capacity for individual assessment of tobacco dependence, especially dependence on smokeless tobacco, is needed for treatment purposes at the primary and secondary care levels. There are still huge gaps in knowledge and practice among health care practitioners regarding issues of mortality, morbidity, and the economic burden associated with smokeless tobacco use. Partnership between academia, research organisations, and policy makers will facilitate the development and implementation of evidence-based cessation measures for smokeless tobacco. Creating a formal network amongst the country's researchers in tobacco control will make it possible to collect and analyse evidence and share resources. Resources and the training of a generation of health professionals skilled in tobacco cessation and dependence treatment are essential not only to build capacity but also to produce more robust evidence of the effectiveness of treatments for smokeless tobacco.

Partnerships with experts both within and outside the country are required for the development of suitable courses for training a large number of professionals. Training a critical number of master trainers will only be possible through partnerships with existing networks of training institutes across this huge country. The private sector can play an essential role in this area, and a strong public–private partnership will enable the building of a network of proficient cessation experts across the country who can offer evidence-based therapy for cessation.

Within the existing public health system there is a need for diagonal integration of tobacco control programmes at the district and sub-district levels. Diagonal integration for tobacco control would mean integrating both preventive and treatment approaches into existing health programmes. Because tobacco users present as clients of all the health specialties and also as clients at primary care centres, it is important to equip all cadres of health professionals in tobacco control interventions. The capacity to perform 'brief interventions' and 'behaviour change counselling' that are feasible, adaptable, and affordable in these settings is greatly needed. When clients are motivated to quit, they should be referred to quitting clinics that are embedded in the secondary health care system. Establishing such a referral across both public and private sectors will help tap into 'missed opportunities' that currently exist in clinical practice[37] in India. Addressing vulnerable groups like pregnant women in ANC facilities, and adolescents in adolescent-friendly health clinics, is necessary for ensuring equity of smokeless tobacco prevention and treatment. At the state and national levels, tobacco control should be made an integral part of other health programmes like Reproductive and Child Health, the National Cancer Control Programme (NCCP), and other non-communicable disease programmes.

In addition to the conventional modern system of medicine, AYUSH (Ayurveda, Unani, Sidhha, and Homeopathy) systems of medicine are practiced in India. The AYUSH system embedded within the culture of rural communities is sensitive to the needs of the local population and is more affordable and accessible; hence it has more acceptability among vulnerable groups such as women and children in rural areas. AYUSH should be suitably engaged both for creating demand as well as effectively scaling up smokeless tobacco control treatment in the country.

Multipronged approaches should be undertaken to promote tobacco cessation. Eventually, the World Health Organization's inclusion of nicotine replacement therapy (NRT) as an essential drug in its 16th WHO Model List of Essential Medicines, along with other cessation pharmaceutical products, will serve as a major impetus for universal access to this clinical treatment option for tobacco use. Despite the fact that India has the highest burden of smokeless and smoking tobacco in the world, quitting services still remain out of reach for people who want to quit. This is partially due to the limited availability and accessibility of the drugs for quitting, which will become more important if the efforts by several states to ban smokeless tobacco are successful. In that case, individuals will need a variety of quitting treatments, and pharmacotherapies have been shown to be successful in enabling quitters to cope with withdrawal symptoms.

Outside the health system, other developmental sectors play an important role in the initiation or continuation of tobacco use. Public education on the hazards of tobacco helps prevent initiation of use and promotes cessation of SLT use[38]. Educating and raising the awareness of the public can also help in creating environmental and social support for quitting, and these measures complement health system efforts for tobacco control. Other programmes like poverty alleviation, rural development, women's and children's welfare, and tribal welfare have extensive influence and should be engaged because they can be a suitable platform to reach large vulnerable populations like rural residents, women, and children.

CONCLUSIONS

Effective smokeless tobacco control relies on efforts both at the macro level (education, and law and policy) and at the micro level (individual tobacco cessation). These complementary interventions require partnerships between various social and developmental sectors, and these partnerships will work better if they are facilitated by building the research evidence and engaging civil society in advocacy efforts. Interactions between the relevant stakeholders are as numerous and complex as smokeless tobacco products and patterns of use.

An effective strategy will address the convergence of the various sectors identified in this chapter and help to integrate tobacco control into mainstream health and developmental programmes. Such integration would result in effective and efficient implementation of multiple tobacco control interventions with synergistic outcomes and reduction of the smokeless tobacco burden. Of paramount importance are a firm political endorsement and inter-sectoral coordination between government and non-government agencies and other stakeholders at various levels of tobacco control intervention planning and implementation. Within the health department, different health programmes should cover coordination between various health-related sectors. Tobacco control should also be integrated into routine clinical practice in order to strengthen and build a holistic health system approach for effective tobacco control intervention.

RESEARCH PRIORITIES

Before large-scale programme implementation, evidence is needed about the effectiveness of integrating tobacco control into different health and development programmes. Experiences with various interventions should be shared in order to guide policy development and implementation. Current evidence available mostly on cigarette use in Western populations cannot be copy-pasted into the Indian context, where bidi and smokeless tobacco use predominate. A local base of evidence is vital. Health system intervention models should be indigenous, acceptable, and address the needs of all sections of the Indian population. Research should focus on the feasibility of multiple options and the cost-effectiveness of different approaches to integrating brief interventions into health systems and building capacity in cessation treatment. Research should generate cost-effective treatment options and model interventions to meet the needs of multiple population groups using a wide variety of tobacco products.

NOTE

This chapter has been prepared using a review of the existing literature and consultation with experts in the field. PubMed and Google Scholar search engines were used to identify appropriate literature, using keywords such as tobacco control, partnership, integration, life cycle, cessation interventions, India, and tobacco cessation centres. However, it should be noted that the literature examining partnership and integration models for smokeless tobacco control is limited.

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Recommendations

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.

Addendum

Information Published During 2013-2015

Update: Studies on the Impact of the Gutka Ban

- After one year of enforcement of the gutka ban, an evaluation of the ban's impact conducted in seven states of India revealed that support for the ban was very high (92%) across various study sites. There was almost universal agreement (99%) that gutka bans are good for the health of India's youth. Of the respondents who continued to use pre-packaged gutka, half (49%) reported they consume less since the bans. Approximately half of respondents reported attempting to stop using gutka in the previous year. Approximately 80% of respondents agreed that the gutka bans will help people quit[1].
- A focus group discussion was conducted among 11 male current and former gutka users from different professions in the city of Mumbai, Maharashtra. Three out of the 11 respondents completely stopped using gutka and other tobacco products after the ban went into effect, and the rest switched to other tobacco products. All the respondents were aware of the ban but felt that it had not been enforced effectively and properly in Maharashtra[2].

Chapter 2: Economics of Smokeless Tobacco in India

- Between 2008 and 2014, taxes on smokeless tobacco (SLT) products have gradually increased. However, the price rise is less than per capita income growth, indicating that affordability has also increased[3].
- An analysis of data from the Global Youth Tobacco Survey (GYTS) showed that higher prices can be an effective deterrent to youth tobacco use, regardless of the form of tobacco used. Bidis have the highest price elasticity of participation (–2.70), followed by gutka (–0.58), and cigarettes (–0.40)[4].
- Analysis of Global Adult Tobacco Survey (GATS) 2009-2010 data showed that SLT advertising is more likely to influence SLT consumption by women than men, while men are more likely to respond to changes in SLT price. No strong direct evidence on the economic substitutability or complementarity of smoked and smokeless products was found[5].
- For value added tax data for smokeless tobacco, see the following table[6].

Value Added Tax Data for India, by State and Union Territory (percent)

State/UT	VAT 2010-11	VAT 2011-12	VAT 2012-13	VAT 2013-14	VAT 2014-15	VAT 2015-16
Andhra Pradesh	12.5	20.0	20.0	20.0	20.0	20.0
Arunachal Pradesh	12.5	12.5	12.5	12.5	20.0	20.0
Assam	13.5	20.0	20.0	20.0	Ban	Ban
Bihar	12.5	13.5	20.0	30.0	30.0	30.0
Chandigarh			12.5	12.5	20.0	20.0
Chhatisgarh	21.5	21.5	21.5	21.5	21.5	21.5
Delhi	20.0	20.0	20.0	20.0	20.0	20.0
Goa	Ban	Ban	Ban	Ban	Ban	Ban
Gujarat	20.0	25.0	25.0	25.0	25.0	25.0
Haryana	21.0	21.0	21.0	21.0	21.0	21.0
Himachal Pradesh	13.75	16.0	18.0	36.0	36.0	36.0
Jammu & Kashmir	13.5	25.0	30.0	40.0	40.0	40.0
Jharkhand	12.5	24.0	30.0	30.0	30.0	30.0
Karnataka	15.0	15.0	17.0	17.0	17.0	17.0
Kerala	12.5	20.0	22.5	22.5	22.5	22.5
Madhya Pradesh	38.0	38.0	38.0	38.0	52.0	52.0
Maharashtra	20.0	20.0	20.0	25.0	25.0	25.0
Manipur	13.5	13.5	13.5	13.5	13.5	13.5
Meghalaya	20.0	20.0	20.0	20.0	20.0	27.0
Mizoram	12.5	12.5	12.5	13.5	13.5	13.5
Nagaland	12.5	15.0	15.0	18.0	18.0	18.0
Odisha	12.5	25.0	25.0	25.0	25.0	25.0
Punjab	13.75	14.3	14.3	14.3	14.3	14.3
Rajasthan	20.0	40.0	50.0	65.0	65.0	65.0
Sikkim	12.5	12.5	12.5	20.0	20.0	20.0
Tamil Nadu	12.5	20.0	20.0	20.0	20.0	20.0
Tripura	12.5	13.5	13.5	35.0	35.0	35.0
Uttar Pradesh	13.5	13.5	31.0	31.0	31.0	31.0
Uttrakhand	13.5	13.5	20.0	20.0	20.0	20.0
West Bengal	13.5	20.0	20.0	35.0	35.0	35.0

Chapter 3: Smokeless Tobacco Use Among Youth in India

- A study of the effect of tobacco advertisement on tobacco use among 1,533 students in Mumbai showed that tobacco advertisement density within 100 m of schools was associated with ever use (odds ratio [OR]=2.01; 95% confidence interval [CI] 1.00–4.07), current use (OR=2.23, 95% CI 1.16–4.28), and current smokeless tobacco use (OR=2.01, 95% CI 1.02–3.98). Tobacco vendor density within 200, 300, 400, and 500 m of schools was associated with current tobacco use and current smokeless tobacco use, but not ever use[7].
- Analysis of two different rounds of GYTS data from a multi-country study revealed that prevalence of SLT use was significantly higher among boys (11.1%) than girls (6.0%), and that prevalence of among youth in India did not decrease between 2006 and 2009[8].
- In India, nearly 4.4 million young people (ages 15–17 years) are daily tobacco users, according to GATS India 2009-2010 data, and approximately 6.6% of the population in this age group are current daily users of SLT. Underage users spend nearly US$270.8 million on chewing tobacco products[9].
- A study of the demographic profile of 4,759 smokeless tobacco users from Gujarat and Andhra Pradesh showed that women were less likely than men to report ‘peer pressure’, ‘fashion statement’, and ‘stress/coping’ as motivating factors for SLT use. Older age groups had lower odds of citing ‘peer pressure’ than 15- to 24-year-olds. Respondents with 11 or more years of education were more likely to report ‘stress/coping’ as a determinant of SLT use than those with no education (OR=2.82, 95% CI 1.06–7.48), after adjusting for age and gender. Women were less likely than men to mention ‘relaxation’, and ‘distance from family’ as important factors (OR=0.50, 95% CI 0.32–0.80; OR=0.20, 95% CI 0.06–0.65) in continuing SLT use[10].

Chapter 4: Smokeless Tobacco Use Among Indian Adults

- A study analysing data from Demographic and Health Surveys in nine countries found that smokeless tobacco (recorded mainly as chewable tobacco) was used in diverse forms, particularly in India, and its use was associated with higher age, lower education, and poverty[11].
- A study analysing GATS India 2009-2010 data to assess the prevalence of nasal snuff inhalation showed that prevalence was higher among females (1.2%) than males (0.5%), and higher in rural areas (1.0%) compared with urban (0.5%). Prevalence increased with age (0.3% for the 15–24 years age group and 2.0% of those 65+) and decreased with increase in educational level (1.4% among those without formal education to 0.2% among those with secondary level education or above)[12].
- Another analysis of GATS India data showed that adults from poor households were at significantly higher risk of using smokeless tobacco[13].
- Prevalence of current tobacco use decreased from 77.4% to 53.9% among schoolteachers in Bihar between the years 2000 and 2008 after the implementation of the Cigarettes and Other Tobacco Products Act (COTPA) of 2003[14].
- Based on data from 70 countries representing 70% of world’s population, nearly three-fourths of SLT users (approximately 220 million users) lived in India in 2010[15]. Another

recent study analysing data from 121 countries, which represented 88% of world's population, showed that 237.4 million (67.4%) SLT users lived in India[16].

- A significantly increasing trend of SLT use was observed among men (27.1% to 33.4%, p<0.001) and women (10.1% to 15.7%, p<0.001) between 1998 and 2010. The overall trend in both sexes combined also showed an increasing trend (18.7% to 24.8%, p≤0.001) in this time period[17].

Chapter 5: Dual Use of Tobacco

- In India, 20.6% of the population used SLT only, and 5.3% used both smoking and smokeless forms—that is, were dual users. SLT use increased among males and with increasing age, and decreased with higher education and wealth[18].

Chapter 6: Determinants of Smokeless Tobacco Use

- Analysis of socioeconomic inequalities in smokeless tobacco use as revealed by data from GATS India 2009-2010 showed a higher prevalence of smokeless tobacco consumption in the medium wealth quintiles. Risk of smokeless tobacco consumption was 3.1 times higher among the poorest compared to the richest quintile. Declining odds ratios of SLT consumption with rising education were found across different regions of India. Poverty was a strong predictor of smokeless tobacco use in all regions[19]. In another study analysing GATS data, prevalence of current SLT consumption varied from 1.7% (richest quintile in Jammu and Kashmir) to 59.4% (poorest quintile in Mizoram)[20].
- Analysis of GATS India 2009-2010 data for 69,030 adults revealed inverse associations between wealth and smokeless and dual tobacco use. Significant interactions were observed for gender and area in the association between smokeless tobacco use with wealth and education. The probability of smokeless tobacco use and of dual use was higher for those with lesser wealth and education[21].
- Smokeless tobacco use was more prevalent in the lowest education, wealth, and occupation (among men only) groups compared to higher SES groups in a study of 16,288 males (≥20 years) representative of Chennai and Delhi, India, and Karachi, Pakistan[22].

Chapter 7: Advertising and Marketing of Smokeless Products

- Data from GATS showed that with even a low level of exposure to SLT marketing, adults were more likely to be current users of SLT (OR=1.24, 95% CI 1.1–1.4). For SLT, the ORs showed an increasing trend (P for trend < 0.001) with greater level of exposure (moderate, OR=1.55, 95% CI 1.1–2.2; high, OR=2.05, 95% CI 0.8–5.1)[23].
- According to a pilot survey conducted in Mumbai and Patna by the Tobacco Control Project India, 74% (n=562) of respondents reported seeing some form of pro-tobacco advertising in the last six months, with no differences observed between smokers (74%), smokeless tobacco users (74%), and non-smokers (73%). Smokers were more likely to perceive tobacco use as harmful to their health compared with smokeless tobacco users and non-users (p<0.01)[24].

Chapter 8: Women and Smokeless Tobacco: Special Considerations

- A survey of 409 women SLT users (ages 18–40 years) and 42 in-depth interviews showed that 64% used only one type of SLT; of these, 30% used mishri, 32% used pan with tobacco, and the rest used chewing tobacco (11%), gul (17%), or gutka (10%). Thirty-six percent used more than one type of SLT. Consumers of multiple SLT products used 50% more tobacco than single users (mean consumption of tobacco per day: 9.54 vs. 6.49 grams; p<0.001). Women were more likely to be poly-SLT users if they: (1) were illiterate rather than literate (adjusted odds ratio [AOR]=1.67, 95% CI 1.07–2.71); (2) had lived in Mumbai for 10 years or more, compared with less than 10 years (AOR=1.67, 95% CI 1.03–2.71); and (3) were married to a poly-SLT user rather than someone who did not use SLT (AOR=2.78, 95% CI 1.63–4.76)[25].

Chapter 9: Smokeless Tobacco and All-Cause Mortality

- A meta-analysis to estimate the number of deaths attributable to SLT use in India showed that among those ages 35 years and older, the relative risk (RR) of mortality for females was 1.34 (95% CI 1.27–1.42) and for males, 1.17 (95% CI 1.05–1.42). The number of deaths attributable to SLT use in India was estimated to be 368,127 (217,076 women and 151,051 men)—that is, nearly three-fifths (60%) of these deaths occurred among women[26].

Chapter 10: Smokeless Tobacco Use and Cancer

- A study of an urban population (Ahmedabad) with mouth cancer across four time periods showed that the age-specific incidence rates of mouth cancer among men increased over the 25-year period of the study, while lung cancer rates showed a net decrease. Using a cohort approach for mouth cancer, a rapid increase among younger age cohorts was found. Mouth cancer incidence increased markedly among men in urban Ahmedabad between 1985 and 2010[27], especially among lower age groups.
- A case-control study conducted in urban (Chennai city) and rural areas (Villupuram district) in Tamil Nadu state in South India showed that, when controlling for age, gender, education, and study area, the adjusted mortality odds ratio was 30% higher (RR=1.3, 95% CI1.2–1.4) in ever tobacco chewers compared to never chewers. The adjusted mortality odds ratio was significant for deaths from respiratory diseases combined (RR=1.5, 95% CI 1.4–1.7), respiratory tuberculosis (RR=1.7, 95% CI 1.5–1.9), cancers of all sites combined (RR=1.5, 95% CI 1.4–1.7), and stroke (RR=1.4, 95% CI 1.2–1.6). Of the cancers, the adjusted mortality odds ratio was significant for upper aero-digestive, stomach, and cervical cancers. Chewing tobacco caused 7.1% of deaths from all medical causes[28].

Chapter 11: Cardiovascular Diseases and Other Health Consequences of Smokeless Tobacco Use

- Meta-analyses of prospective studies of smokeless tobacco users in Europe reported the relative risk for fatal stroke in Asian countries as 1.26 (95% CI 1.12–1.40). Case-control studies reported significantly greater risk for acute coronary events in smokeless tobacco users (RR=2.23, 95% CI 1.41–3.52) and smokers (RR=2.89, 95% CI 2.11–3.96), and the greatest risk among those who both chewed and smoked (RR=4.09, 95% CI 2.98–5.61).

Hypertension and metabolic syndrome were more prevalent in users of smokeless tobacco. Like smoking, smokeless tobacco use leads to accelerated atherothrombosis[29].

Chapter 12: Oral Health Consequences of Smokeless Tobacco Use

- A study with 1,500 schoolchildren ages 12–15 from Chhatisgarh showed that 15.8% used tobacco in the chewable form and 25.3% used betel/areca nuts. The OR for calculus formation was highest for gutka chewers (OR=14.32), and pan masala chewers had the highest odds of developing bleeding on probing[30].
- A review of Indian studies on the relationship between smokeless tobacco and various cancers of head and neck region found a significant association between SLT use and cancer of the oral cavity. The association was stronger for the buccal mucosa than the tongue, and for females compared to males. Significant association was observed between SLT use and cancer of the hypopharynx and oropharynx, but no definitive association was noted for cancer of the larynx and nasopharynx. Some dental disease and oral premalignant conditions were also associated with SLT use[31].
- A case-control study of 350 cases and 350 controls was conducted in Pune for 19 months in 2005-2006 to investigate the association of tobacco and poly-ingredient oral dip products with oral cancer. Use of chewing tobacco ($p < 0.0001$, OR=8.3, 95% CI 5.4–13.0), mishri ($p < 0.0001$, OR=3.3, 95% CI 2.1–5.4), gutka ($P < 0.0001$, OR=12.8, 95% CI 7.0–23.7) and supari ($P < 0.0001$, OR=6.6, 95% CI 3.0–14.8) was strongly associated with oral cancer after adjusting for various covariates[32].

Chapter 13: Chemistry and Toxicology of Smokeless Tobacco

- A study estimating the nicotine content in smoked and smokeless products showed significant variations in nicotine content across different products. Nicotine content varied from 1.01 to 13.0 mg/cigarette in smoked products, and from 0.8 mg/g to 50.0 mg/g in smokeless products. Moisture content varied from 9% to 21%[33].
- A review of 62 studies on the systemic effect of areca nut showed that areca nut affects almost all organs of the human body, including the brain, heart, lungs, gastrointestinal tract, and reproductive organs. It causes or aggravates pre-existing conditions such as neuronal injury, myocardial infarction, cardiac arrhythmias, hepatotoxicity, asthma, central obesity, type II diabetes, hyperlipidemia, and metabolic syndrome. Areca nut affects the endocrine system, leading to hypothyroidism, prostate hyperplasia, and infertility. It affects the immune system leading to suppression of T-cell activity and decreased release of cytokines. Areca nut has harmful effects on the foetus when used during pregnancy[34].

Chapter 14: Smokeless Tobacco: Addiction, Withdrawal, and Cessation

- A double-blind placebo-controlled randomized trial of varenicline (12 weeks, 1mg, twice per day) with 237 smokeless tobacco users was conducted in New Delhi. Self-reported abstinence 12 weeks after the end of treatment was significantly greater for varenicline (43%) versus placebo (31%; AOR=2.6, 95% CI 1.2–4.2, $p = .009$). Biochemically confirmed end-of-treatment abstinence was greater for varenicline versus placebo (25.2% vs. 19.5%), but this was not statistically different (AOR=1.6, 95% CI 0.84–3.1, $p = .15$).

Compared with placebo, varenicline did not reduce the risk for a lapse (hazard ratio [HR]=0.86, 95% CI 0.69–1.1, p = .14), but it did increase the likelihood of recovery to abstinence (HR=1.2, 95% CI 1.02–1.4, p = .02). Greater adherence increased end-of-treatment cessation rates for varenicline (39% vs. 18%, p = .003) but not for placebo (28% vs. 14%, p = .06). There were no significant differences between varenicline and placebo in the rate of side effects, serious adverse events, hypertension, or stopping or reducing medication[35].

Chapter 17: Health Communication for Smokeless Tobacco Control in India

- A school-based intervention designed to promote tobacco control was carried out among teachers from 72 randomly selected rural and urban schools in the Indian state of Bihar. The intervention consisted of educational efforts, tobacco control policies, and cessation support and was tailored to the local social context. Immediately after the intervention, the 30-day quit rate was 50% in the intervention and 15% in the control group (p = .001). At the 9-month post-intervention survey, the adjusted 6-month quit rate was 19% in the intervention and 7% in the control group (p =.06). Among teachers employed for the entire academic year of the intervention, the adjusted 6-month abstinence rates were 20% for the intervention group and 5% for the control groups (p = .04)[36].
- A cross-sectional study of knowledge about warning labels on tobacco products was conducted in the city of Ahmedabad. Of the 776 tobacco users participating, 561 (72.3%) had ever noticed warnings on the tobacco products. Among those who did notice warning labels, 64.4% were aware of the health effects, and 66% had thought of quitting tobacco. Tobacco users of younger age groups were more aware of the warning labels, and females were less aware[37].

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Appendix 1

Factsheets on Smokeless Tobacco Products in India

BETEL QUID WITH TOBACCO

Figure: Making betel quid. *Source:* Dr. Gaurav Kumar, PHFI, Delhi

Common Name

Pan or paan

Brands

None. Product is assembled from ingredients at the user end, either by the vendor (panwala) or by user himself.

About the Product/Ingredients

Betel quid with tobacco consists of four main ingredients: betel leaf (*Piper betle*), areca nut (*Areca catechu*), slaked lime [Ca (OH_2)], and catechu (extract from *Acacia catechu*). Betel leaves contain volatile oils such as eugenol and terpenes, nitrates, and small quantities of sugar, starch, tannin, and several other substances. In a betel quid, other ingredients and flavouring agents such as menthol, camphor, sugar, rosewater, aniseed, cardamom, clove, mint, or other spices may also be added according to regional practices and individual preferences[(1)].

Different forms of tobacco, both raw and processed, are added as constituents to pan. Forms used and their names vary from place to place.

Zarda and kiwam are commercially manufactured processed forms that are popular especially in North India.

Kaddipudi and hogesoppu are used in state of Karnataka. Kaddipudi means ‘powdered sticks’ in Kannada (local language in Karnataka). It is made by crushing stalks and petioles of tobacco plant into a fine powder. It is used either as powder or processed into bricks/blocks made with jaggery and water. Hogesoppu is leaf tobacco used frequently by women in Karnataka, either by itself or with pan(2).

Unprocessed tobacco sold as bundles of long strands in Kerala. A small piece is cut from the strand to use with betel quid(3). It is marketed in bundles containing several strands, each about 115 cm long and 5 cm thick. A regular user consumes one 15-cm piece of the strand per day(4).

Gundi is mixture of cured tobacco, coriander seeds, and other spices. Each constituent is fried separately, powdered coarsely, mixed, and scented with resinous oil. It is known as ‘kadapan’ in Orissa and Bengal. It is also used in Gujarat(2).

Pattiwala is sun-dried flaked tobacco used with or without lime(5). It is used mainly in Maharashtra and many north Indian states including Uttar Pradesh(3, 5).

Processing/Manufacturing

Betel quid can be prepared by the vendor or at home by the user. Vendors are mostly small roadside kiosks that can be seen at every nook and corner in India. The quid is assembled by smearing slaked lime and catechu on the betel leaf, covering that with areca nut and other ingredients of personal choice, including tobacco, and folding the leaf in a funnel shape. The top of the funnel is folded over to close the open end, and the whole assembly is secured by inserting something like a clove or a toothpick in the quid. The method of folding the betel leaf into a quid varies regionally and from person to person, thus the shape and size of the finally assembled product varies (see the figure “Making betel quid”).

Pattern of Use

The prepared product is placed in the mouth and chewed.

Mode of Absorption

Oral

Geographical Distribution of Usage

Betel quid with tobacco is used in Central, East, South and South-East Asia, in the western Pacific, and in migrant communities from these regions(6).

Betel quid with tobacco is used in all Indian states. Prevalence is, however, much higher in the North-Eastern states of Tripura (32.2%), Manipur (29.5%), Nagaland (25.0%), Assam (14.7%), Arunachal Pradesh (14.3%), and Meghalaya (14.3%). Use is also high in Odisha (17.7%), West Bengal (9.2%), Karnataka (9.9%), and Kerala (7.6%)(7).

Prevalence and Demographics

Approximately 200 million people chew betel regularly throughout the western Pacific basin and South Asia(8). In India, approximately 31 million men and 19 million women chew betel quid with tobacco regularly, which represents 6.2% of the total adult population (over 15 years of age). Betel quid use is more common in rural areas and among people with lower education levels. Among women, use is much more common in older age groups(7).

Cultural Aspects of Use

Betel quid (pan) chewing as a habit has existed in India and South-East Asia for over 2,000 years(1). In Hindu culture (the predominant religion in India), pan chewing has been referred to as one of the eight *bhogas* (enjoyments) of life and was known as *tambula* in Sanskrit(2). Tobacco in the betel quid became popular sometime after Europeans introduced it in India as smoking product in the 16th century. It should be noted that pan is itself not a tobacco product but acts as a carrier of smokeless chewing tobacco. Most of betel quid chewing in India now, however, contains tobacco(1).

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CHEWING TOBACCO (PLAIN)

Figure: Chewing tobacco. *Source:* Dr. Gaurav Kumar, PHFI, Delhi

Common Name

Tambakoo. Some customers ask for it just by the locally prevalent brand name.

Brands

There are some locally well-recognized brands. It is also available as a loose grocery item from shops.

About the Product/Ingredients

Finely or coarsely shredded tobacco leaves[(1)]

Processing/Manufacturing

Like other smokeless tobacco products, plain chewing tobacco is available in sachets. Also in the sachet a few manufacturers pack slaked lime in miniscule plastic containers (2 or 3 ml in size) which the user can mix with the plain chewing tobacco.

Pattern of Use

Plain chewing tobacco is used for chewing or sucking. It is most commonly used with added lime; this product is called khaini[(1)].

Mode of Absorption

Oral

Geographical Distribution of Usage

All over India

Prevalence and Demographics

No statistics available

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CREAMY SNUFF

Figure: Creamy snuff sold in toothpaste-like tube. *Source:* Dr. Gaurav Kumar, PHFI, Delhi

Common Name

Creamy snuff. Customers often ask for the product by brand name.

Brands

There are a few well-recognized brands in the market.

About the Product/Ingredients

Creamy snuff is a tobacco-based paste consisting of finely ground tobacco mixed with clove oil, glycerin, spearmint, menthol, camphor, salts, water, and other hydrating agents[1, 2] .

Processing/Manufacturing

Creamy snuff is commercially manufactured from finely ground tobacco mixed with other ingredients into a paste form. The preparation is sold in tubes similar to those used for toothpaste[1] .

Pattern of Use

Creamy snuff is rubbed on the gums and teeth with finger or toothbrush. Manufacturers recommend rubbing it for 3 to 4 minutes before rinsing mouth with water. Manufacturers advertise it as a way to enjoy tobacco without the harms associated with tobacco smoking or chewing[3]. Though not marketed as a toothpaste, creamy snuff is advertised as antibacterial (due to the nicotine content), good for the gums and teeth (due to other ingredients like clove oil), and as something that cleanses and freshens the mouth[3, 4]. In fact, manufacturers recommend using it in the morning and before going to bed.

Mode of Absorption

Oral

Geographical Distribution of Usage

Varying degree of usage all over India

Prevalence and Demographics

The Global Youth Tobacco Survey of 2000-2002 found that 2% to 32% of children (ages13–15 years) used creamy snuff in the 18 states sampled. The highest prevalence was in Nagaland (32%), followed by 25% each in Manipur and Tripura, 23% in Arunachal Pradesh, 18% each in Meghalaya and Uttaranchal, and 10% each in Bihar, Orissa, and Uttar Pradesh[(5)]. In Goa, 46% of boys and 47% of girls have been found using creamy-snuff[(6)]. No data are available on use among adults.

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DOHRA

Figure: Dohra. *Source:* School of Preventive Oncology, Patna

Common Name
Dohra

Brands
Dohra is a non-branded product prepared by individual vendors for sale.

About the Product/Ingredients
Dohra is a wet mixture of tobacco, slaked lime, areca nut, and other ingredients like catechu (kattha), peppermint, and cardamom (ilayachi)(1).

Processing/Manufacturing
Dohra is prepared by a vendor at the user end. It is packaged for sale in two different ways: (1) in two packets, a packet containing tobacco (often zarda or surti) to be mixed with a separate packet of areca nut, catechu, and other flavourings; or (2) as a ready-made mixed tobacco product. Users consume tobacco (surti/zarda) with dohra according to their level of addiction(2). The product is normally sold in small amount (about 200 mgs) wrapped in a plastic bag tied with a rubber band. One packet is sold for as little as 1 rupee (about US$0.02)(1).

Pattern of Use
Chewed and sucked

Mode of Absorption
Oral

Geographical Distribution of Usage
Dohra is popular in Allahabad and adjoining districts of Jaunpur and Pratapgarh in Uttar Pradesh and is unique to this region(1).

Prevalence and Demographics

Little data are available on prevalence of use. One study that surveyed an all-male group of power-loom workers in Allahabad district in 2007 and found that 3.12% of workers used it[(3)].

Cultural Aspects of Use

'Dohra' means 'double' in the local language, Hindi, probably because of its packaging in two packets.

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GUDAKHU

Figure: Gudakhu. *Source:* Dr. Direndra N. Sinha, WHO-SEARO

Figure: Gudakhu sold in packaging of different sizes. *Source:* www.Katkigudakhu.com.

Common Name

Gudakhu, gurakhu

Brands

There are some well-recognized brands in the market.

About the Product/Ingredients

Gudakhu is a paste-like tobacco preparation made using fine tobacco leaf dust, sheera (molasses), lime, and geru mati (red soil).

Processing/Manufacturing

Gudakhu is commercially manufactured using the ingredients listed above, though users can also make it themselves(1). The proportion of various constituents as reported by one of the manufacturers is 1 kg of tobacco powder, 2 kg. of molasses, 150 grams of lime, and 50 grams of red ochre(2). In the market, it is available in tube packs (e.g., of 50 g and 100 g), in containers (e.g., of 40 g, 100 g, 200 g), and in bucket packs of 3 kg and 5 kg(3).

Pattern of Use

During use, gudahku (about 2 g) is rubbed over the teeth and gums with a fingertip for 10–15 minutes. Some users swallow the saliva-mixed extracts, whereas others spit it out[4]. After use, the mouth is rinsed with water. Being a tobacco product, gudakhu is addictive. Some users are known to have applied it for more than 40 years and as many as 20 times a day[4].

Mode of Absorption

Oral

Geographical Distribution of Usage

Gudakhu is mainly used in the states of Bihar, Chattisgarh, Orissa, West Bengal, Uttar Pradesh and Uttaranchal[5].

Prevalence and Demographics

In the GYTS (2000-2002), prevalences in Bihar, Chattisgarh, Orissa, West Bengal, Uttar Pradesh, and Uttaranchal ranged from 4% to 16%[5]. It is used predominantly by rural women[1]. In a survey in the Singhbhum district of Bihar (now in Jharkhand) published in 1969, 1% of men and 16% of women used gudhaku[6]. Due to use as toothpaste, children as young as 10 years old have been found using it[4].

Interesting Facts

Although gudakhu is applied to teeth and gums like toothpaste, whether gudakhu meets the definition of toothpaste has been a contentious issue in the courts in India. Interestingly, one manufacturer himself contended that although gudakhu is intended to be rubbed against human teeth, it does not cleanse teeth but is actually used for its narcotic effect[2]. Other manufacturers have also contended that gudakhu is not a toothpaste but a tobacco product[7]. In fact, manufacturers' advertisements claim that "the effect generated is one of freshness and soothing effects associated with tobacco products"[3].

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GUL

Figure: Gul. *Source:* Dr. Gaurav Kumar, PHFI, Delhi

Common Name
Gul

Brands
There are some well-recognized brands in the market

About the Product/Ingredients
Gul is a pyrolysed, powdered tobacco product that is marketed in small tin cans or sachets as a dental care product[1]. Ash of tendu leaves is the other ingredient in the product.

Processing/Manufacturing
Gul is commercially manufactured using very fine tobacco dust. According to one of the manufacturers, ash of tendu leaves and ‘motihari leaf tobacco’ are its only constituents. Ash of burnt and refined bidi leaf is mixed with the dust of motihari tobacco to prepare gul[2]. Its characteristic strong flavour and aroma are used in marketing the product.

Pattern of Use

Users apply gul to teeth and gums as a dentifrice and then rinse the mouth with water. Being a tobacco preparation, gul is addictive, and users are known to apply it several times a day. Highly addicted users can apply it 40 to 50 times a day[(3)].

Mode of Absorption

Oral

Geographical Distribution of Usage

Gul is used in Uttar Pradesh, Uttaranchal, Bihar, Jharkhand, and Orissa in India, as well as in the eight North-Eastern states of India. Gul is also used in neighbouring Bangladesh.

Prevalence and Demographics

In the Global Youth Tobacco Survey (GYTS) of 2000-2002, gul use was reported by 6% in Bihar, 3% each in Arunachal Pradesh and Nagaland, and 2% each in Assam, UP, and Uttaranchal[(4)]. Use is higher among rural females[(5)]. A recent survey of tobacco use among females in a village of Eastern UP in 2010 found 7.9% using gul[(6)].

In the 2001 Global School Personnel Survey (GSPS), females reported significantly higher gul use than males in most states: Assam (13.5% vs. 0.1%), Meghalaya (25% vs. 1.9%), Nagaland (6.2% vs. 1.4%), and Sikkim (46.5% vs. 3.9%). In Mizoram, however, 9.8% females reported gul use as compared to 19.2% males. Manipur also had higher use among men[(7)]. Similarly, a cross-sectional survey (2001-2003) in Bangladesh found more men (2.2%) using gul than women (1.5%). In Bangladesh, urban residents were 3.6 times more likely to use gul[(8)]. The more recent Global Adult Tobacco Survey conducted in Bangladesh in 2009 found 5.5% males and 5.1% females using gul (overall: 5.3%)[(9)].

Cultural Aspects of Use

As claimed by a manufacturer, gul was first prepared in or about 1932 by Shah Hussain Baksh Khan in Howrah. When he shifted to Ranchi and settled there, he started selling gul under the trade name 'gulab marka gul'[(10)].

Although smoking by females is largely unacceptable in South Asian culture, use of tobacco in the form of gul is socially acceptable, Gul makes it possible for people to use tobacco in the guise of cleaning their teeth[(3)].

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GUTKA

Figure: Gutka. *Source:* Dr. Gaurav Kumar, PHFI, Delhi

Common Name
Gutka or gutkha

Brands
Many big brands of gutka are well known nationally as well as internationally, and there are numerous smaller and local brands.

About the Product/Ingredients
Gutka contains almost all the ingredients that go into the making of a pan, but these are dehydrated so that the final gutka product is not perishable. Ingredients consist of areca nut, slaked lime, catechu, and sun-dried, roasted, finely chopped tobacco, which are mixed together with several other ingredients such as flavourings and sweeteners. A similarly packaged mixture without tobacco, often with an identical brand name, is called pan masala[1-3].

Processing/Manufacturing
This dehydrated, non-perishable pan substitute is commercially manufactured and sold in tins as well as in small easy-to-carry sachets that can be used at any place or time[4].

Pattern of Use
Gutka is held in the mouth, sucked, and chewed. It is retained in the mouth for longer periods of time, after which saliva is generally spit out but is sometimes swallowed. Small portions of gutka can be ingested while chewing and sucking[1].

Mode of Absorption
Oral

Geographic Distribution of Usage
Gutka is popularly used in South Asia, including the Indian subcontinent, and by Asian expatriates in several parts of the world, especially Canada, the United Kingdom, and the United States(1).

In India, use of gutka is common in all states. The highest prevalence is in the states of Madhya Pradesh (17%), followed by Arunachal Pradesh (15.9%), Gujarat (12.8%), Chattisgarh (11.9%), Rajasthan (11.5%), Uttar Pradesh (10.5%), Jharkhand (9.7%), and Odisha (9.4%)(5).

Prevalence and Demographics
In India, 8% adults use gutka. Although, overall, khaini is the most popular smokeless product in India, gutka is the most popular product in certain groups such as adolescents males (ages 15–24 years), urban males, males with secondary education or higher, and male students and in some states [Madhya Pradesh (gutka, 17% vs. khaini, 14%), Gujarat (gutka, 12.8% vs. khaini, 5.3%), Rajasthan (gutka, 11.5% vs. khaini, 7.3%), Delhi (gutka, 8.2% vs. khaini, 3.1%)](5).

Prevalence of use among women is less than men in all states (overall, 3% vs. 13%) except in Mizoram where women use it three times more than men (6.2% vs 2.1%), Meghalaya (1.4% vs. 1.1%) and Kerala (2.1% vs. 1.6%). Highest use among women has been reported from North-Eastern states of Arunachal Pradesh (11.4 %) and Nagaland (7.4%)(5).

Additional Facts
Originally available freshly mixed at the pan shop according to the user's specification, gutka is now a commercial preparation, manufactured industrially since 1975(2). Initially sold as pan masala in tins (in weights of 100 g, 250 g, etc.) and preferred among people of high socioeconomic status living in urban areas, gutka gradually came to be sold in small sachets (1.5 g, 2 g, 3.5 g, 4 g, etc.) priced as little as 1 or 2 rupees (~US$0.02–0.05). These sachets were aggressively marketed and made widely available from metropolitan areas to remotes villages, a practice that was pioneered in 1985 by Pan Parag to market its pan masala in India(6). Easy accessibility and availability, very low price, ease of carrying, and lack of social stigma attached to its use (unlike with smoking products) led to use of gutka not only by men, but also by women and children, and in rural and financially weak sections of the community in addition to well-to-do communities. Currently, gutka use is more prevalent in rural areas and among people with lower education(5). Its popularity can be gauged by the production figures: according to commercial estimates, the Indian market for gutka/pan masala sold in sachets costing only few rupees is worth several hundred million US dollars in aggregate(3).

Brands of gutka often have the same names and almost the same packaging as pan masala (which does not contain tobacco) and are produced by the same manufacturer(7). Although the Cigarettes and Other Tobacco Products Act, 2003, in India banned advertisement of tobacco products, gutka has been aggressively marketed in India in the guise of pan masala advertisements, leading to widespread usage.

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KHAINI

Figure: Khaini prepared on palm. *Source:* Dr. R. B. Bhonsle, Dr. P. R. Murti, TIFR

Figure: Ready-made khaini. *Source:* Dr. Gaurav Kumar, PHFI, Delhi

Common Name

Khaini (khoinee in Bangladesh)

Brand Names

Many big national brands as well as local brands are available in the market.

About the Product/Ingredients

Khaini basically consists of sun-dried or fermented, coarsely cut tobacco leaves mixed with slaked lime. Khaini is the most popular smokeless tobacco product used in India.

Processing/Manufacturing

Khaini can be prepared by the user at the time of use, but is also available commercially as ready-made. A regular khaini user may carry a double-ended metal container, one side of which is filled with tobacco and the other with slightly moistened slaked lime. A small quantity of tobacco is taken in the palm and a little slaked lime is added. The ingredients are then mixed vigorously with the thumb of other hand. Ready-made khaini comes with tobacco leaves crushed into smaller pieces and mixed with lime. It may have other flavours added as well.

Pattern of Use

The user places khaini in the right, left, and central upper or lower mouth. Khaini is generally not chewed but is retained in place and sucked slowly for 10–15 minutes. Occasionally, it is left in the groove overnight. In Maharashtra and Gujarat, khaini is placed in the premolar region of the mandibular groove, whereas in Bihar and Uttar Pradesh, it is generally held in the lower labial groove. In the Singhbhum district of Bihar, khaini is often kept on the dorsum of the tongue(1).

The average weight of this mixture for a single use is about 0.2 g. A user's frequency of use varies widely, ranging from 3 to 30 times per day(1).

Mode of Absorption

Oral. Addition of lime makes the mixture alkaline. The pH of the khaini (or any other chewing tobacco products) is important, because nicotine most readily crosses the oral mucosa in the non-protonated form. Smokeless tobacco products tested in volunteers were found to deliver high doses of nicotine to the bloodstream rapidly, depending on the pH of the product in aqueous solution(2).

Geographical Distribution of Usage

Khaini is popular in India, Nepal, and Bangladesh(1).

Khaini is used throughout India. It is extremely popular in the states of Jharkhand (32.6%), Bihar (27.6%) and Chhattisgarh (21.2%), and also in north-eastern states of Nagaland (26.2%), Mizoram (24.5%), and Manipur (19.2%). It is also quite popular in the states of Maharashtra, Madhya Pradesh, Uttar Pradesh, Arunachal Pradesh, Sikkim, and Assam(3).

Prevalence and Demographics

On average, one in eight adults chews khaini in India, making it the most popular smokeless tobacco product. Chewing khaini is more common among men (18%) than women (5%). In states with high khaini usage (see previous paragraph), khaini is used by every third to every fifth person. Considering only men, every second person is a khaini user in Jharkhand and Bihar. Khaini use among females is remarkably higher in Mizoram, where every third woman uses it (34.3%), and prevalence among women is twice that of men. On the other hand, in Tamil Nadu prevalence is negligible, and in the states of Punjab, Chandigarh, and Goa it is less than 5 in 1,000(3).

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KHARRA

Figure: Making kharra. *Source:* Dr. Gaurav Kumar, PHFI, Delhi

Common Name
Kharra

Brands
None. Product is prepared from ingredients at the user end.

About the Product/Ingredients
Kharra is a combination of tobacco, areca nut, lime (chuna), and catechu (kattha) with additional ingredients that vary by person and location.

Processing/Manufacturing
A panwala (vendor) mixes the ingredients on a plastic sheet, folds the mixture into a small bag, and rubs it vigorously against palm or a hard surface to mix the contents uniformly. Small portions of this mixture are then sold to customers. Kharra costs from Rs 4 to Rs 10 a dose. Being locally made, it is a largely unregulated product[(1)].

Pattern of Use
Like gutka, kharra is held in the mouth, sucked, and chewed. It is retained in the mouth for longer periods of time, after which saliva is generally spit out but is sometimes swallowed. Small portions sometimes are ingested while chewing and sucking.

Mode of Absorption
Oral

Geographical Distribution of Usage
Especially popular in the state of Maharashtra

Prevalence and Demographics
A cross-sectional study in an urban health centre in Mumbai in 2010 reported that 28.6% of youth (15–24 years) used kharra (M: 30.8%, F: 20.7%)[(2)]. Another survey in villages of Wardha district in Maharashtra found kharra to be the most popular tobacco product among male adolescents ages15–19 years. They preferred freshly prepared kharra (54.09% in last 30 days),

supposing it to be less strong than gutka (31.69%) and khaini (21.86%). Prevalence of use by female adolescents was quite small (only 2 in a sample of 202)[3].

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KIWAM

Figure: Kiwam sold in a jar. *Source:* Dr. Dhirendra N. Sinha, WHO-SEARO

Common Name

Kiwam, khiwam, qiwam, qimam, khimam

Brands

Manufactured by some big national brands

About the Product/Ingredients

Kiwam is a thick paste prepared from tobacco leaf extract, spices (e.g., saffron, cardamom, aniseed), and additives such as musk.

Processing/Manufacturing

The tobacco used for kiwam is from *N. rustica* and/or *N. tabacum*[(1)]. Tobacco leaves are processed by removing their stalks and stems, and the resulting material is then boiled and soaked in water flavoured with spices (e.g., saffron, cardamom, aniseed) and additives such as musk. The resulting pulp is mashed, strained, and allowed to macerate until it becomes a paste. It is also available as granules or pellets[(2)].

Pattern of Use

Kiwam is placed in the mouth and chewed or used as an optional tobacco ingredient in betel quid.

Mode of Absorption

Oral

Geographical Distribution of Usage

Kiwam is used in South Asia, mainly in north India, Pakistan, and Bangladesh[(1, 3)]. It is used mostly by upper socioeconomic groups.[(2)]

Prevalence and Demographics

Little information is available on prevalence and demographics of use.

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LOOSE TOBACCO LEAF

Figure: Loose tobacco leaf folded, packed and sold in plastic pouch. *Source:* Dr. Gaurav Kumar, PHFI, Delhi

Common Name
'Tobacco leaf' translated into the local language, sada patta

Brands
There are some locally recognized brands.

About the Product/Ingredients
This product is simply air-cured loose tobacco leaf used for chewing as well as for smoking purposes.

Processing/Manufacturing
The manufacturing process consists of air curing loose tobacco leaves, then folding them into a manageable size, which is then packed in a pouch for sale[(1)]. In Kerala, loose tobacco leaf is marketed in bundles containing several strands, each about 115 cm long and 5 cm thick[(2)].

Pattern of Use
When used for chewing, a piece of tobacco leaf 0.75 to 1 inch in diameter is either chewed or held in place in the mouth. Saliva is usually spit out, but it can also be swallowed[(1)].

A piece taken from the leaf may also be added as the tobacco ingredient in betel quid. A regular user consumes one 15-cm piece of the strand per day[(2)]. Low-income people in rural and urban areas of Bangladesh and Myanmar often put tobacco leaf in their betel quid[(2)].

Mode of Absorption
Oral

Prevalence and Demographics
There are no statistics specifically on the prevalence of loose leaf tobacco use.

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MAINPURI TOBACCO

Figure: Mainpuri tambakoo. *Source:* Dr. R. B. Bhonsle, Dr. P. R. Murti, TIFR

Common Name

Mainpuri tambakoo. One variant is called kapoori.

Brands

There are some local brands.

About the Product/Ingredients

Mainpuri tambakoo is a specialty product of the Mainpuri district in Uttar Pradesh (UP) state. It is a mixture of finely cut betel nut and small pieces of tobacco leaves treated in slaked lime and other ingredients such as powdered cloves, cardamom (elaichi) seeds, kewara (extract from the fragrant flower of *Pandanus odoratissimus*), and sandalwood powder. Catechu *(*kattha) is an infrequent ingredient[(1)].

A locally popular variant of it, 'kapoori', is camphor flavoured *(*Camphor called as *kapoor* in Hindi) and has peppermint as a regular ingredient, but contains no sandalwood powder[(1)].

Processing/Manufacturing

Manipuri tambakoo is manufactured commercially in small-scale units. Newspapers report three major producers of Mainpuri alone manufacturing 5 to 6 quintals a day (2012)[(2)].

Pattern of Use

Mainpuri tambakoo is held in mouth, chewed, and sucked. It is retained in the mouth for longer periods of time, after which saliva is generally spit out but is sometimes swallowed. Small portions are sometimes ingested while chewing and sucking.

Mode of Absorption

Oral (chewed and sucked)

Geographical Distribution of Usage

Mainpuri tambakoo is extensively produced and consumed in the Mainpuri district of Uttar Pradesh(1).

This product is also used in neighbouring Pakistan, where it is quite popular. The Sindh province, however, recognizing its deleterious health effects, imposed a ban on Manipuri tambakoo under section 144 (power to issue order absolute at once in urgent cases of nuisance or apprehended danger) of their Criminal Procedure Code in December 2011(3).

Prevalence and Demographics

A survey of 34,997 people ages 35 years and older in 139 villages in Mainpuri between March 1964 and September 1966 found that 7.5% of the sampled population used Manipuri tambakoo. Users had a 21.7 times higher risk of getting oral and oropharyngeal cancers compared to non-users(1). No recent data is available.

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MAWA

Figure: Mawa. *Source:* Dr. R. B. Bhonsle, Dr. P. R. Murti, TIFR

Common Name
Mawa

Brands
None. Product is assembled from ingredients at the user end.

About the Product/Ingredients
Mawa is a mixture of thin shavings of areca nut with some tobacco flakes and slaked lime.

Processing/Manufacturing
It is sold by vendors in cellophane paper tied into a small ball. This is prepared by placing 5–6 grams of areca nut shavings on cellophane, adding about 0.3 grams of tobacco, and then sprinkling a few drops of slaked lime on top. The resulting mixture is about 95% areca nut(1). The contents are then tied into a ball with thread. At the time of use, the ball is rubbed vigorously on the palm to homogenize the contents.

Pattern of Use
Mawa is placed in mouth and chewed for 10 to 20 minutes(1). A person may chew as many as 5–25 times a day(2).

Mode of Absorption
Oral

Geographical Distribution of Usage
Especially popular in the state of Gujarat and to some extent in adjoining areas in Maharashtra

Prevalence and Demographics

Mawa chewing is very popular in the state of Gujarat, especially among young men. It's prevalence has increased tremendously in recent years(3). A house-to-house survey conducted in 20 villages of Bhavnagar district in 1993-1994 found 18.9% men and 0.07% women using mawa(4). Another cross-sectional survey conducted recently (2007-2008) in the urban area of Jamnagar district in Gujarat found mawa to be the most popular smokeless tobacco product (20.96% prevalence of current use); 63.7% of current tobacco chewers used mawa-masala, followed by 57.6% who chewed gutka. Most users initiate in late adolescence and chew 6 to 8 times a day(5).

Additional Facts

The magnitude of mawa use is indicated by the fact that the Bhavnagar city administration appealed to its citizens not to litter the streets with the cellophane mawa wrappers, as they clogged the city drains(3).

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MISHRI

Figure: Mishri. *Source:* Dr. Shastri, Tata Memorial Hospital

Common Name

Mishri, masheri, misheri

Brands

Mishri is mainly a homemade preparation, but is also available in the market under different brand names.

About the Product/Ingredients

Mishri is roasted and powdered tobacco with no other ingredients[(1)].

Processing/Manufacturing

Mishri is made by baking tobacco on a hot metal plate until it is uniformly black, and then making it into a powder[(2)].

Pattern of Use

Mishri is applied to the gums using a finger, often for the purpose of cleaning the teeth. Users then tend to hold it in their mouths (due to the nicotine addiction). People initially use mishri as a dentifrice but soon become addicted to its nicotine content and apply it multiple times a day.

Mode of Absorption

Oral

Geographical Distribution of Usage

Mainly in Maharashtra and in adjoining Goa[3-7]

Prevalence and Demographics

Mishri use is popular in Maharashtra and in adjoining Goa, especially among women[3-7]. It is more common in lower socioeconomic groups. A prospective cohort study done in Mumbai (1992–1999) found as many as 44.5% women used mishri, which accounted for most tobacco use among women. Mishri was less commonly used by men (22.7%), among whom betel quid chewing was more popular[3].

Table A1: Prevalence of use of different tobacco products in Mumbai (Maharashtra)

Tobacco Product	Prevalence of Use	
	Women	Men
Mishri	26.5%	10.3%
Mishri + betel quid with tobacco	18.0%	12.4%
Betel quid with tobacco	5.9%	14.7%
Other smokeless products	6.9%	18.2%
Smoking	0.4	23.6%

Source: Adapted from Gupta 1996[3].

Uniquely, mishri users start the practice at a much younger age than users of other smokeless tobacco products—50% of them even before they are 10 years old, and 80% before they are 20 years old. This early age of initiation is perhaps due to the fact that, as a common household item used as a dentifrice, mishri is readily available to children. Easy, free access and social acceptability of use lead to widespread adoption of mishri at an early age and continued use throughout the lifespan. Frequency of use in a day is relatively low, mostly less than 3 times a day, consistent with use as a dentifrice[3].

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TAPKEER

Figure: Tapkeer sold in plastic container and sachet. *Source:* Dr. Gaurav Kumar, PHFI, Delhi

Common Name

Tapkeer, tapkir, dry snuff

Known as "bajar" in the Saurashtra region of Gujarat state, where it is applied to teeth and gums like toothpowder.

Brands

There are some well-recognized brands in the market.

About the Product/Ingredients

Tapkeer is dry powdered tobacco for oral or nasal use. It is a form of dry snuff. Tapkeer is available in the market in unscented plain, mentholised, and scented (perfumed) varieties. Other ingredients like lime, musk, essential oils, and flavours are also added(1). Manufacturers claim to use perfumes extracted from natural herbs and flowers(2).

Processing/Manufacturing

In Europe and the United States, tobacco is fire-cured, then fermented and processed into a dry, finely powdered form known as dry snuff. The moisture content of the finished product is less than 10%. It is packaged and sold in small metal or glass containers(3).

In India it is available in the market in sachets, in plastic or tin containers as well as in large buckets in weight options ranging from 5 grams to 10 kilograms.

Pattern of Use

In the United States, a pinch (called a 'dip') is held between the lip or cheek and gum. In Europe, a small quantity of it is commonly inhaled into the nostrils, where it is absorbed through nasal mucosa(3).

In India, dry snuff, though once commonly used nasally, is now mainly used orally(4). Some users rub it on the teeth and gums, often several times a day, while others suck a pinch of it(3).

Although rubbed on teeth and gums as a toothpowder, tapkeer is positioned in the market as a tobacco product rather than a dentifrice.

Mode of Absorption

Oral or nasal

Geographical Distribution of Usage

Tapkeer is mainly used in Gujarat, Maharashtra, Goa, and eastern parts of India[4].

Prevalence and Demographics

In a survey of adolescents in 11 villages of the Wardha district in Maharashtra in 2008, 17.48% of boys and 8.91% of girls were found to use tapkeer. It was the preferred form of tobacco use among girls (72% used it)[5] .

Bajar is popular among older women in rural areas. In a house-to-house survey of 20 villages in the Bhavnagar district of Saurashtra region in 1993-1994, prevalence of bajar use was 11.6% among females and 0.2% among males. In this region, bajar use accounted for 97.31% of all forms of tobacco use by females[6]. An earlier survey in the same district found prevalence rates of 14% among women and 1% among men[7]. A 2007-2008 survey in the urban area in the Jamnagar district found that 5.8% of adults used tapkeer[8] .

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TOBACCO-CONTAINING TOOTHPOWDERS AND TOOTHPASTES

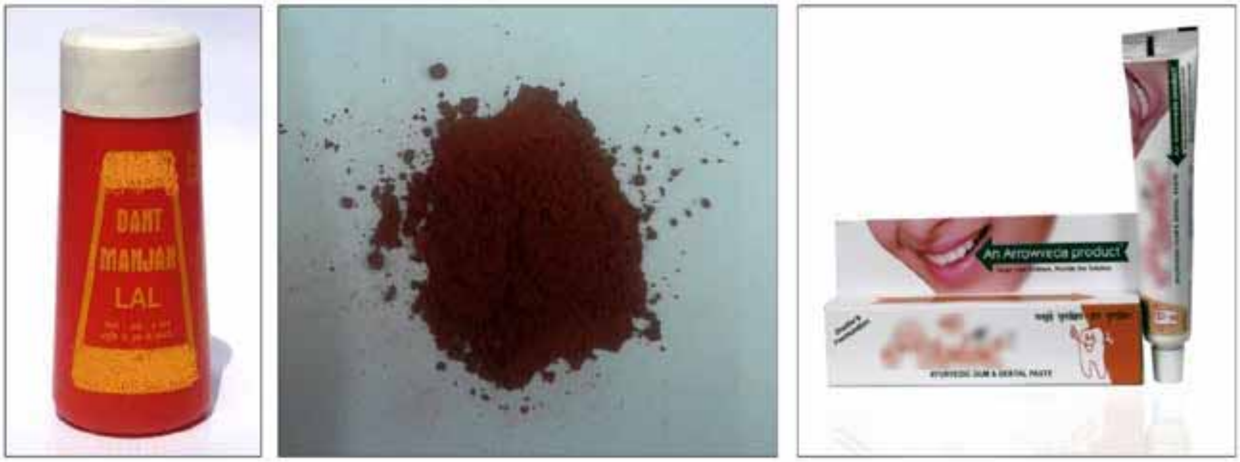

Figure: Red toothpowder bottle, red toothpowder, and herbal toothpaste. *Source:* Dr. Gaurav Kumar, PHFI, Delhi

Common Name

Lal dantamanjan, red toothpowder, red toothpaste

Brands

No red toothpowder or toothpaste brand acknowledges having tobacco as an ingredient, as tobacco in these products is outlawed in India. Various lab investigations have, however, detected nicotine in some brands[(1)] .

About the Product/Ingredients

While gul and mishri are used as tobacco toothpowder and gudakhu and creamy snuff as tobacco toothpaste, these are '*mainly* tobacco products'. They are used to get the effects of tobacco. Many herbal toothpowders and toothpastes in the market contain small amounts of tobacco as an ingredient and are used for the purpose of cleansing teeth.

Lal dantmanjan or red toothpowder is notable among these products. It contains many additional ingredients including herbs and flavouring agents. It is manufactured commercially and marketed as herbal toothpowder and paste[(2)].

Processing/Manufacturing

Commercially manufactured in factories

Pattern of Use

Most consumers of these tobacco-containing herbal toothpowders and toothpastes may be unaware that they are using a product with tobacco in it. Because these products are considered dentifrices, consumers tend to use them only once or twice a day (unlike gul, mishri, gudakhu, and creamy snuff).

Mode of Absorption

Oral. For regular oral hygiene a person uses 2–3 g of toothpowder/toothpaste each day[3]. Thus, between 4.18 mg and 38.85 mg of nicotine could enter the oral cavity of users of the above brands of herbal toothpowder/toothpaste (calculated using data from the chemical analysis described below). In the case of gul and creamy snuff, nicotine exposure would be 10 times higher. Adults remove most of the tooth powder/toothpaste from the oral cavity by rinsing, but children may retain and ingest a much greater amount of dentifrice than adults because of incomplete rinsing[3].

Geographical Distribution of Usage

Brands of red toothpowder/toothpaste found to contain tobacco include well-known, popular national brands that are used throughout India.

Prevalence and Demographics

Tobacco-containing herbal toothpowders/toothpastes are used by men, women, and children of all ages throughout India[4]. More concerning is the fact that children age 10 and younger use these products without knowing they are using tobacco or understanding its effects. The 2000-2002 Global Youth Tobacco Survey of school students ages 13–15 years found that red toothpowder (lal dantmanjan) was used by 49% in Bihar; 29% each in UP and Uttaranchal; 25% in Orissa; 9% in Mizoram; 5% in Nagaland; 4% each in Arunachal, Assam, and Meghalaya; 3% in Tripura; and 2% each in Goa, Maharashtra, Manipur, and Sikkim[5]. Another study conducted in a village in Bihar found that children in all age groups (0–4 years, 5–9 years, 10–14 years) were exposed to tobacco through red toothpowder use[6] .

Additional Facts

Gul, mishri, gudakhu, and creamy snuff are sold as tobacco products, and many brands come with pictorial health warning on their packages, as mandated by law (see the factsheets for these products). However, manufacturers of herbal toothpowders and toothpastes that have tobacco in them do not disclose it on the package or even admit that they contain any tobacco[7, 8].

This is not surprising, since the Government of India has banned use of tobacco in toothpowder and toothpaste since 1992 through legislation[5,9]. An amendment as made in Drugs and Cosmetics Act, 1940 vide notification published in the Gazette of India vide G.S.R. 443(E) and 444(E) dated 30 April 1992 prohibits the manufacture and sale of all cosmetics and all Ayurvedic drugs licensed as toothpowders or toothpastes containing tobacco[1]. After passage of the law, manufacturers stopped listing tobacco as an ingredient[10]. A manufacturer from Madhya Pradesh, however, challenged the notification. The State High Court upheld the ban, which was appealed in the Supreme Court, which observed, 'the view taken by the Government of India imposing total prohibition on the use of tobacco in the preparation of tooth powder and tooth paste **is well justified in the public interest** covered by Article 19(6) of the constitution, though it offends the right to carry on trade guaranteed under Article 19(1) of the constitution. The imposition of total ban is in the public interest'. On 11 April 1997, the matter was ultimately decided in favour of the total ban on use of tobacco in toothpowder/toothpaste[11].

Before the prohibition and litigation in the 1990s, efforts had been made to control tobacco in toothpowders/toothpastes. In the eighties, the Consumer Education and Research Centre (CERC) took Indian manufacturers of tobacco-based toothpaste to the Monopolies and Restrictive Trade

Practice Commission and compelled them to provide labelling information in English and the local language regarding the composition of the toothpaste, its tobacco content, and a warning about tobacco being injurious to health. Publication of similar information in both languages was also a part of directions for the advertisement(12).

Chemical Analysis

Although outlawed since 1992, some manufacturers still add tobacco as an ingredient in herbal toothpowder/toothpastes. In a British Medical Journal article in 2004, Sinha and colleagues stated, 'A laboratory test of five samples of red tooth powder that did not declare tobacco as an ingredient found tobacco content of 9.3–248 mg/g of tooth powder'(5). In a laboratory study published as recently as 2012, nicotine was detected in 1 out of 7 brands of herbal toothpowders (12.95 mg/g) and in 2 out of 6 brands of herbal toothpastes (5.752 mg/g, 2.093 mg/g). A brand of gul and two brands of creamy snuff were also tested and, as expected, were found to have very high nicotine content (216.10 mg/g, 123.82 mg/g, and 119.13 mg/g, respectively)(1). An earlier study (2009) by same the researchers had detected nicotine in 3 out of 7 brands of commonly used herbal toothpowders (dant manjan) and in the sole brand of gul that they tested(13).

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TUIBUR (TOBACCO WATER)

Figure: Tobacco water sold in the marketplace. *Source:* Sinha, DN, Gupta PC, Pednekar M. Tobacco water: a special form of tobacco use in the Mizoram and Manipur states of India. Natl Med J India. 2004;17(5):245-7.

Common Name

Tuibur in Mizoram, hidakphu in Manipur

Brands

None. Made locally in very small units.

About the Product/Ingredients

Tobacco water is tobacco-smoke-infused water. It is a unique smokeless product that is liquid.

Processing/Manufacturing

Tobacco water is made by passing smoke, generated by burning tobacco, through water until the preparation turns cognac in colour and has a pungent smell. The preparation is stored and sold in bottles at many places such as stationery shops and daily or weekly markets (see the figure above).

Tobacco water was traditionally produced at home in small quantities for household consumption. Women would smoke a specially designed pipe with a receptacle for water through which tobacco smoke was passed. Later, small-scale manufacturing units were set up (usually near a water source like a rivulet, waterfall, or fountain) for commercial production in larger quantities. One iron oven with a few pipes and containers is all that is required, at a cost of around Rs 3000 (in 2001). A space of 8′ x 8′ is sufficient for a small production unit, usually in bamboo-thatched structures in Mizoram. A typical factory may produce 500 liters of tobacco water in one month[1]. Production is largely unregulated, and there are no health warnings on the tuibur bottles sold.

The quality of tobacco water is graded according to the concentration of tobacco smoke in the water, which is based on the quantity of tobacco used and the time taken for production—the higher the concentration, the better the quality (see table A2)[1].

Table A2: Grades of tobacco water

Grade of tobacco water	Amount of tobacco required (kg)	Processing time (hrs)	Amount of water used (L)	Amount of tobacco water produced (L)	Price in Rs/L (in 2001)
First	21	18	20	20	38
Second	14	12	20	20	15
Third	7	6	20	20	12

Pattern of Use

Users sip 5 to 10 ml tuibur and gargle or keep it in the mouth for 5 to 10 minutes, then spit it out[2]. The frequency of use of tobacco water varies from 1 to 30 times a day. Some 92.1% of users in Churchandpur and 36.7% in Aizawl sipped it more than 5 times a day[1].

Mode of Absorption

Oral

Geographical Distribution of Usage

Tobacco water is popular in the North-Eastern states of Mizoram and Manipur.

Prevalence and Demographics

A 2001 survey conducted in 25 randomly selected villages in Aizawl district of Mizoram and in Churchandpur district of Manipur found that 7.2% of residents of the Mizoram villages and 6.5% of the Manipur villagers used tobacco water[1]. Prevalence rates are similar among men and women (see table A3), although in the past this product was said to be used predominantly by women.

Table A3: Prevalence of use of tobacco water in surveyed districts of Mizoram and Manipur

Location	Prevalence of Tobacco water use		
	Men	Women	Total
Aizawl district, Mizoram	7.7%	6.6%	7.2%
Churchandpur district, Manipur	6.2%	6.9%	6.5%

Cultural Aspects of Use

In Mizoram and Manipur, tobacco water use has been integrated with the social and cultural rituals of communities for a long time. Definite records of its use are available since 1907[3].

Women as producers of tobacco water. In the traditional Mizo society in northeast India, tobacco and women have been associated as part of a social custom which requires the housewife to serve tobacco water to the husband as well as to visitors.

Figure: A Mizo woman is smoking pipe called tuibur. *Source:* www.shahnazkimi.com

Traditionally, tobacco water was offered to guests and visitors both at family and social levels, and it was considered very rude to omit this greeting. Tobacco water was one of the essential items especially in rural parties. A family generally owned three tobacco water flasks, one carried by the husband, one by the wife, and a spare one kept in the house. No grown man or woman went around without a flask. This custom was common among the Lakhers, a tribal community in Mizoram, in both urban and rural areas. Today, men as well as women smoke tobacco using different types of pipes (called vaibel and tuibur).The tuibur pipe has a water receptacle through which smoke is drawn. The nicotine-rich tobacco water that remains in the bowl after a woman smokes her pipe is used as a favoured beverage to serve family members and visitors. Women are, therefore, expected to smoke frequently to produce sufficient quantities of the tobacco water. Tobacco water meant for visitors is stored in a hollow gourd, from which sips are offered.

The reputation of a woman as a housewife and as a hostess often depends on her ability to serve adequate amounts of nicotine water. During the process of courting, the girl offers tobacco water to the boy. If the boy refuses, it is understood that he has no interest in the girl. Indeed, the ability of a young woman to make and serve tobacco water has been an important criterion during bride selection. For that reason, even young girls are taught to smoke to attain a desired level of proficiency in making and serving tobacco water. Education among the Mizos, now a highly literate society, and the commercial availability of bottled tobacco water are making this custom less common now[3].

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ZARDA

Figure: Zarda sold in tin and sachets. *Source:* Dr. Dhirendra N. Sinha, WHO-SEARO

Figure: Zafrani Zarda. *Source:* Dr. Gaurav Kumar, PHFI

Common Name

Zarda

Brands

Manufactured by some big national brands

About the Product/Ingredients

Zarda is flavoured chewing tobacco flakes mixed with aromatic spices, menthol, herbs, fragrances, saffron, raw kimam*,* silver flakes, and sandalwood oil in combinations unique to different manufacturers. Manufacturers claim their blends give a pleasing aroma and taste that will linger in the mouth for some time[1, 2]. When flavoured with saffron, zarda is often called Zafrani Zarda (in Persian, '*zafran'* means 'saffron'). Areca nut is not a regular ingredient in zarda, but some manufacturers have been found adding it as well[3]. Some other manufacturers provide lime separately in the zarda packaging. Most zarda preparations are dried, but some are wet (called *vizapatta* in Bangladesh)[4].

Zarda is used in two forms: pilapatti and kalipatti. Pilapatti looks yellow in colour and its granules are fine; kalipatti is black and its granules are loose. Pilapatti is considered mild, and Kalipatti is supposed to be "harder' (i.e., stronger)[4]

Processing/Manufacturing

Zarda is manufactured by blending tobacco with different perfumes and flavouring agents. Finely cut tobacco leaves (tobacco flakes) are boiled in water with slaked lime and spices until evaporation. The residual particles are then dried, and colouring and flavouring agents are added[4].

Zarda in the market comes in various grades (labelled as 120, 160, 600, etc. by a leading zarda brand in India) according to the strength of the flavour. It is sold in small pouches as well as metal cans in different weight options, such as 0.45 g, 5 g, 10 g, 50 g, 200 g[2].

Pattern of Use

Primarily used as the tobacco ingredient in betel quid (pan), zarda is also chewed alone or mixed with lime and/or chopped areca nut.

Mode of Absorption

Oral

Geographical Distribution of Usage

Zarda is commonly used in India, Bangladesh, Pakistan, Nepal, and Myanmar and in migrant populations from these countries[4].

Prevalence and Demographics

Specific prevalence rates for zarda use are not available. It is often used by men and women of middle and upper socioeconomic groups[4].

Cultural Aspects of Use

As claimed in an anecdote by Dharampal Satyapal (DS) group, the leading zarda manufacturer in India, the recipe for making their brand of zarda was discovered accidentally in 1948 by Satyapal, son of founder Dharampal. While experimenting and blending perfumes at the small perfumery opened by his father at Old Delhi's Chandni Chowk in 1929. Satyapal tasted one of his blends and found it unique, as it left a very good taste lingering in the mouth for a long duration of time. Satyapal combined the perfume mixture with the plain zarda that his father consumed and found that his family members and friends raved about the new taste, prompting Satyapal's father to launch commercial production of zarda using this recipe, which became an instant hit with consumers. The product's market expanded exponentially from a small shop at Delhi's Chandni Chowk area in 1948 to a corporate house by the turn of the century, with a turnover of a few billion rupees in zarda manufacturing. This product is currently distributed all over India as well as abroad. Other business houses also came in zarda manufacturing by experimenting with their own blends[5].

References

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Appendix 2

Smokeless Tobacco Intervention Programs for Youth

As described in chapter 3 of this report, use of smokeless tobacco (SLT) is well-known as a cause of oral cancer and other chronic diseases, which are increasing at an alarming rate in India. The early age of onset of these diseases indicates the early age at which use of SLT begins in India. Preventing initiation of SLT use requires intervention at these early ages, before young people begin to experiment with different types of tobacco. This appendix reviews two tobacco use prevention programs, one community-based and one school-based, that are targeted towards Indian adolescents. This review discusses the outcomes and impact of these interventions on behaviours and intentions in regard to smokeless tobacco use.

These intervention programs were intended to advance knowledge about tobacco, change sociocultural norms surrounding tobacco, and modify intentions to use tobacco. These programs were conducted among youth between 2004 and 2011. Project MYTRI was a multicomponent intervention focused on students in grades 6–10. Project ACTIVITY was a community-based intervention among youth and adults ages 10–19 in a lower SES community.

PROJECT MYTRI

Project MYTRI (Mobilizing Youth for Tobacco Related Initiatives in India) was a group-randomised, school-based, prevention trial in 32 schools in Delhi and Chennai over two academic years. The survey was implemented first in 2004 with 6th and 8th graders as the two beginning cohorts, and the end line survey was conducted in 2006 with the students in the 8th and 10th grades. The goal of the intervention was to positively influence social-environmental and intrapersonal factors that predict tobacco use among urban Indian youth and reduce tobacco usage among this age group[1].

Components

Intervention strategies included classroom activities, school posters, parent postcards, and peer-led health activism. The intervention model is based on the social influences model[2] and social cognitive theory, as well as other evidence-based smoking prevention programs modified for this setting[3].

Outcomes

Results of the MYTRI program were measured in terms of two outcomes: (a) tobacco use behaviours and (b) tobacco use intentions. In both areas, significant differences were seen between the intervention and control groups after the two-year program[3]. Overall, tobacco use increased by 68% in the control group and decreased by 17% in the intervention group. The two groups showed significant differences in intentions to chew ($p<0.03$) and smoke ($p<0.01$) tobacco, with the intervention students decreasing their intentions more than the control. Intentions to smoke tobacco increased by 5% in the control group and decreased by 11% in the intervention group. Intervention-related changes in knowledge, advocacy skills, and normative beliefs were responsible for changes in tobacco use behaviours[4].

Impact on SLT

There were no significant between-group differences in the trajectories of chewing tobacco use ($p>0.10$). Intentions to chew tobacco decreased in both the control and intervention groups (12% and 28%, respectively). Baseline data revealed that the prevalence rate for ever-use of SLT by girls and boys was 12% and 16%, respectively[5]. In the intervention schools, girls' adoption of

SLT use decreased marginally over time compared to initiation of SLT use by girls in control schools, where there was no change[4]. Project MYTRI was not successful in reducing rates of chewing tobacco among adolescents in the study schools. Though the intervention tackled both smokeless and smoking forms of tobacco, an emphasis was placed on smoking-related consequences and policies. The study showed a high prevalence of chewing tobacco in the sample and thus highlighted the need for targeted SLT interventions among youth[3]. Policies around prohibiting smoking in public places influence adolescents' knowledge and normative beliefs about smoking, but no such equivalent policy measure existed for SLT use, which could have contributed to this outcome.

PROJECT ACTIVITY

Project ACTIVITY (Advancing Cessation of Tobacco In Vulnerable Indian Tobacco consuming Youth) was designed as a community-based, group-randomised trial to test the efficacy of an intervention aimed to reduce tobacco use among youth ages 10–19 years residing in low-SES communities in Delhi. Whereas MYTRI used a school-based approach, ACTIVITY focused on communities in lower SES settings. In low- and middle-income countries like India, community-based interventions may prove more effective because they capture youth who may not be attending school and thus have higher tobacco use rates than school students[6].

Fourteen slum communities taken from a list of registered resettlement colonies and nearby Jhuggi Jhopris (slum) were randomised to intervention and control groups. The study surveys focused on youth (n=6,954) with an average age of 14.4 years. The intervention was designed to meet the community's needs as a community-based, low-cost, multiple-strategy program to promote awareness and skills surrounding prevention and cessation of tobacco use. Similar to MYTRI, the intervention was based on social cognitive theory and on qualitative research that identified cultural factors relevant to the design and implementation.

Components

The four components of the intervention included (1) training workshops for project staff, partner NGOs, youth peer leaders, and adult community leaders; (2) community-based interactive activities and outreach programs; (3) community-based tobacco cessation camps; and (4) enforcement of key provisions of the Indian tobacco control law (COTPA), with a focus on tobacco-free public places and a prohibition of sale of tobacco to anyone under 18 years of age[7]. Peer and adult leaders from the community along with NGO personnel were identified and trained to facilitate delivery of the intervention program. Activities during the first year included films, street plays, rallies, and role plays, while the second year encouraged youth to be agents of change through the formation of community support groups and leadership education.

Outcomes

ACTIVITY produced a strong community response, including the formation of 54 youth support groups across 7 communities. The intervention was successful in significantly increasing young people's knowledge about the harmful effects of tobacco use and about tobacco control policies, while also changing normative beliefs and strengthening the efficacy of advocacy skills. The baseline survey reported 3.32% prevalence of current use of chewing tobacco in the intervention community and 4.32% use in control communities.

The main outcome variables included (a) behaviour: current use of any of three forms of tobacco (smoking, chewing, or smokeless) in the past 30 days, and (b) intention to smoke or use smokeless tobacco. Overall, current tobacco use decreased more in the intervention group than in the control group, though the results were not significant.

Differences between the control and intervention groups were significant among the resettlement colonies but less so among the JJs, perhaps because the latter community was characterised by very low SES, and thus was an even more hard-to-reach population (unpublished data from Stigler et al., 2014).

Impact on SLT

The intervention prompted a statistically significant decline in the prevalence of *smoking* (i.e., bidis and cigarettes) tobacco. Though a slight decline was noted with the use of SLT, the decline was the same in both the intervention and control groups and thus was not statistically significant. These findings mirror those from MYTRI in terms of the intervention's ability to reduce use of smoking tobacco products among youth.

CONCLUSION

Both the school- and community-based intervention programs had a clear impact on smoking tobacco use and intentions to use, but their impact on smokeless tobacco was low. The missing link is the support of public policy in curbing access and supporting higher taxation of SLT. Easy access and affordability of SLT products for adolescents seem to be important challenges to influencing SLT use behaviours through health promotion interventions. Project ACTIVITY showed that the norms for SLT in lower SES communities surround family, cultural traditions, socialisation, and medicinal use. Health education and awareness must act in concert with public policy in order for behaviour change to be successful at the population level.

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Appendix 3

Compilation of Litigations

Compilation of Litigations

Sl. No.	Petitioner/ Respondent	Name of Court	Legislation in Question	Tobacco Products in Question	Brief Order of the Court	Judgment	Citation
1	Jammu and Kashmir Voluntary Health & Development Association v. State & Others	High Court of Jammu and Kashmir	COTPA	Both	Directed various state departments/ municipal corporations to ensure enforcement of the provisions of COTPA	Favourable	OWP(PIL) No. 406/2010
2	Sumaira Abdulali v. Union of India	High Court of Bombay	COTPA	Both	Notify and implement Section 6(b) of COTPA	Favourable	Writ Petition No. 182 of 2007
3	World Lung Foundation South Asia v. Ministry of Health and Family Welfare	High Court of Delhi	COTPA	Both	Direction to the enforcement agencies for stricter enforcement of Section 6(b) of COTPA	Favourable	MANU/DE/2692/ 2012 WP(C)7540/2013
4	Cancer Patients Aid Association v. State of Karnataka & Another	High Court of Karnataka	COTPA	Both	Direction to the enforcement agencies for stricter enforcement of Section 6(b) of COTPA	Favourable	Writ Petition No. 17958 of 2009
5	Kerala Voluntary Health Services v. Union of India	High Court of Kerala	Cinematograph Act, Constitution of India, COTPA	Both	Direction to CBFC and other enforcement agencies to ensure compliance with COTPA and its advertisement Rules	Favourable	Writ Petition No. 38513 of 2010
6	Ms Ruma Kaushik v. Union of India	High Court of Himachal Pradesh	COTPA	Both	Direction for notification of pictorial health warnings for all tobacco products	Favourable	Writ Petition No. 1223 of 2004
7	Health for Millions Trust v. Union of India & Others	Supreme Court of India	COTPA	Both	Government assured the Supreme Court that the pack warnings will be implemented from 31 May 2009.	Favourable	Writ Petition No. 549 of 2008
8	Indian Asthma Care Society & Anr. v. State of Rajasthan & Ors.	High Court of Rajasthan	"Polluter pays" principle of Indian Environmental laws and COTPA	Smokeless	Direction for restraining the manufacturers of gutka, pan masala from selling their products in plastic sachets and for payment of pollution fine. Also directed to comply with COTPA.	Favourable	Writ Petition No. 1966 of 2003

Sl. No.	Petitioner/ Respondent	Name of Court	Legislation in Question	Tobacco Products in Question	Brief Order of the Court	Judgment	Citation
9	Ankur Gutkha v. Indian Asthma Care Society & Ors.	Supreme Court of India	Contempt of Courts Act, Plastic Waste (Management and Handling) Rules; Plastics (Manufacture, Usage and Waste Management) Rules, COTPA	Smokeless	Directed MoHFW to undertake a comprehensive analysis and study of the contents of smokeless tobacco and harmful effects of its consumption Directed MoEF to finalize, notify, and enforce the Plastics (Manufacture, Usage and Waste Management) Rules, 2009, that inter-alia banned the sale of gutka, tobacco and pan masala in plastic sachets from 1 March 2011	Favourable	Special Leave Petition No. 16308 of 2007
10	Amarsinh Z Choudhari v. Union of India	High Court of Gujarat	COTPA	Both	Directions issued to Gujarat State Road Transport Corporation and Ahmedabad Municipal Transport Services for removal of advertisements for gutka/pan masala displayed on public conveyances	Favourable	Special Civil Application No. 4848 of 2009
11	Institute of Public Health v. The State Government of Karnataka & Ors.	High Court of Karnataka	COTPA	Both	Tobacco Board of India withdrew sponsorship from a tobacco industry event. Government assured that it will strictly adhere to and implement the provisions of COTPA and agreed to consider a code of conduct for public officials to prevent tobacco industry's interference in developing and implementing public health policies and programmes related to tobacco control.	Favourable	Writ Petition No. 27692 of 2010
12	Bejon Mishra v. Union of India & Ors.	High Court of Delhi	Notification No. 69/2003 – Central Excise (N.T)	Smokeless	The notification restoring the subsidies and exemptions to the manufacturers of gutka and chewing tobacco products was challenged. The petition was disposed of, as the notification challenged was withdrawn by the Government.	Favourable	Writ Petition No. 7789 of 2006

Sl. No.	Petitioner/ Respondent	Name of Court	Legislation in Question	Tobacco Products in Question	Brief Order of the Court	Judgment	Citation
13	Sai Traders v. State of Goa & Ors.	High Court of Bombay (Goa Bench)	The Goa Public Health Amendment Act	Smokeless	Upheld the amendment to the Goa Public Health Act that prohibited consumption, manufacture, sale, and distribution of any article of food containing tobacco in the entire State of Goa	Favourable	Writ Petition Nos. 396 and 397 of 2005
14	M/S Raj Products v. State (Government of N.C.T. of Delhi) & Anr.	High Court of Delhi	COTPA, Code of Civil Procedure, Code of Criminal Procedure	Smokeless	Upheld the order of the Additional District Judge, for confiscation of the gutka pouches as not being in conformity with the provisions of Packaging and Labelling Rules, 2008	Favourable	MANU/DE/2920/ 2010 F.A.O. 61/2010
15	Avinash v. Union of India & Ors.	High Court of Madhya Pradesh (Jabalpur Bench)	COTPA	Both	Direction issued to the Government to consider whether the rules prescribing the maximum permissible limits of nicotine and tar in cigarettes and other tobacco products could be made and testing laboratories could be established and recognized as early as possible	Favourable	2008 (4) MPLJ 49
16	Dhariwal Industries Ltd. & Anr. v. Union of India & Ors.	High Court of Bombay, Karnataka, Tamil Nadu, Andhra Pradesh	PFA, Constitution of India, Code of Civil Procedure	Smokeless	All petitions challenging the ban on sale of gutka were dismissed by the respective courts and the validity of state notifications upheld.	Favourable	Writ Petition Nos. 1982, 2001, 2002, 2024, 2251 of 2002

Sl. No.	Petitioner/ Respondent	Name of Court	Legislation in Question	Tobacco Products in Question	Brief Order of the Court	Judgment	Citation
17	Godawat Pan Masala Products I.P. Ltd. & Anr. v. Union of India & Ors.	Supreme Court of India	PFA, COTPA, Constitution of India, The Industries (Development and Regulations) Act, Tobacco Board Act, Essential Commodities Act, Food and Drugs Act	Smokeless	State notifications imposing ban on sale of gutka held ultra vires and bad in law. They were unconstitutional and void as abridging the fundamental rights of the appellants guaranteed under Articles 14 and 19 of the Constitution. Therefore, the notifications were quashed.	Adverse (however, gutka and pan masala considered 'food')	AIR 2004 SC 4057
18	Tirupati Products and Haji Shah v. State of Jharkhand and Ors.	High Court of Jharkhand	PFA, COTPA, Drugs and Cosmetics Act, Constitution of India	Smokeless	Relying on the Godawat judgment notification imposing ban on production, manufacture and sale of 'gutka' or 'pan masala' or 'gul', containing tobacco or without tobacco, quashed	Adverse	MANU/JH/0081/2005 WP(C) 4093/4026/2004
19	K.P. Sugandh Limited & Etc. v. State of Chhattisgarh & Ors.	High Court of Chhattisgarh	Constitution of India, PFA	Smokeless	As above	Adverse	MANU/CG/0032/2008
20	Union of India v. Gopal Corporation Ltd. & Ors.	Supreme Court of India	COTPA	Smokeless	Transferred to itself more than 31 Writ Petitions challenging pictorial warnings in different high courts across the country	Favourable	T.P. (Civil) 457-485 of 2008
21	Laxmikant v. Union of India & Ors.	Supreme Court of India	Drugs and Cosmetics Act, Constitution of India	Smokeless	The notification prohibiting manufacture and sale of toothpastes/tooth powders containing tobacco upheld	Favourable	Civil appeal No. 3000 of 1997

Sl. No.	Petitioner/ Respondent	Name of Court	Legislation in Question	Tobacco Products in Question	Brief Order of the Court	Judgment	Citation
22	Mr. Mahesh Bhatt and Kasturi and Sons v. Union of India & Ors.	High Court of Delhi	COTPA, Cinematograph Act, Cable TV Network (Regulation) Act, Constitution of India	Both	The rules imposing restrictions on display of tobacco products or their use in films and television programmes stayed	Favourable Order in appeal	MANU/DE/0185/2008
23	Union of India v. Mahesh Bhatt and Kasturi & Sons	Supreme Court of India	COTPA, Constitution of India	Smoking	Interim stay on the impugned orders of the High Court of Delhi till further date. The stay order has been made absolute vide order dated 27 April 2012.		SLP (Civil) 8429-8431 / 2009
24	Mahesh Bhatt v. Union of India	High Court of Delhi	COTPA	Both	The new rules restricting depiction of smoking scenes in movies and television programmes have been challenged before the Hon'ble court which is pending consideration.	Pending	Writ Petition No. 1475 of 2012
25	Namdeo Kamathe v. Union of India; & Sridhar Kulkarni v. Union of India	High Court of Bombay	COTPA	Both	Ex-parte stay on the rules regulating point-of-sale advertisement	Adverse	Writ Petition Nos. 8763 and 6151 of 2005
26	CERS & Ors. v. Dharampal Satyapal & Ors.	National Consumer Disputes Redressal Commission (NCDRC)	Consumer Protection Act	Smokeless	Class action complaint for compensation to identified and unidentified victims of oral cancer invoking the provisions of the Consumers Protection Act, 1986	Pending	Complaint No. 116 of 2005
27	Deepak Kumar v. ITC Ltd, Maharashtra State Consumer Dispute Redressal Commission	Consumer Disputes Redressal Commission, Maharashtra	Consumer Protection Act	Smoking	The Commission, by an order dated 3 March 2012, dismissed the case on the ground that complaint is barred by the limitation and thus not maintainable.	Adverse	Complaint No. 201 of 2009

Sl. No.	Petitioner/ Respondent	Name of Court	Legislation in Question	Tobacco Products in Question	Brief Order of the Court	Judgment	Citation
28	Union of India v. Central Arecanut Marketing Co-Operative & Ors.	Supreme Court of India	PFA	Smokeless	Rule 44J of the Act was challenged before various high courts. Some of the petitions transferred to the Supreme Court vide order dated 01.10.09.	Pending	Transfer Petition Nos.940-946 of 2007
29	Ghoi Foods Private Limited v. Union of India	High Court of Madhya Pradesh	FSSA and PFA	Smokeless	Upheld the state notification banning sale, manufacture, distribution of gutka in the state	Favorable	Writ Petition No. 3131 of 2012
30	Lal Babu Yadav v. State of Bihar & Ors.	High Court of Patna	FSSA and PFA	Smokeless	Dismissed the petition filed by gutka company and upheld the state notification banning gutka in the state.	Favourable	Writ Petition No. 10297 of 2012
31	All Kerala Tobacco Dealers' Association v. State of Kerala	High Court of Kerala	FSSA and PFA	Smokeless	Dismissed the petition filed by gutka company and upheld the state notification banning gutka in the state	Favourable	Writ Petition Nos. 12352/12932/13271/13580 of 2012
32	Indian Dental Association of the State of Uttar Pradesh	High Court of Allahabad	FSSA and PFA	Smokeless	Issued notice to the state government to consider the enforcement of the regulation in the state	Favourable	PIL No. 19126 of 2012
33	Doctors for You v. Union of India	High Court of Delhi	FSSA and PFA	Smokeless	Directed the Delhi government to pass appropriate orders within 2 weeks for the implementation of the Regulation 2.3.4 of Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011, in Delhi	Favourable	W.P.(C) 5103 of 2012, CM No.10447 of 2012
34	M/s. Dhariwal Industries Limited & Anr. v. The State of Maharashtra & Ors.	High Court of Bombay	Constitution of India, FSSA, and PFA	Smokeless	Upheld the notification banning sale etc. of gutka and pan masala in Maharashtra and ordered government not to destroy the seized gutka pouches till September 25, so as to enable the petitioners to seek relief from the Supreme Court	Favourable	MANU/MH/1519/2012 Writ Petitions No. 1631/1632/1633/1634/1635/2012 7592/2012 8800/2012

Sl. No.	Petitioner/ Respondent	Name of Court	Legislation in Question	Tobacco Products in Question	Brief Order of the Court	Judgment	Citation
35	Union of India & Anr. v. Dharampal Satyapal Ltd. & Ors.	Supreme Court of India	FSSA	Smokeless	The Court ordered to transfer and hear petitions on implementation of FSS rules, 2011	Favourable	Transfer petition No. 683 of 2012
36	Manohar Lal v. State of Uttar Pradesh	High Court of Allahabad	PFA	Smokeless	The Court held that tobacco is something which is consumed by human beings and is eaten, hence it is food.	Favourable	Criminal Revision No. 318 of 1982
37	M/s. Khedan Lal & Sons v. State of Uttar Pradesh & Anr.	High Court of Allahabad	Constitution of India, PFA	Smokeless	The Court held that chewing tobacco (i.e., zarda) is a food article.	Favourable	Writ Petition No. 4613 of 1975
38	Naya Bans Sarv Vyapar v. Union of India & Ors.	High Court of Delhi	Constitution of India	Both	The case was dismissed by the Hon'ble court by an order dated 9 November 2012 and upheld the validity of the provisions in the interest of the society at large.	Favourable	W.P. (C) No. 7292/2011 and W.P.(C) No. 4392/2012
39	Puneet Gupta v. Union of India & Ors.	High Court of Delhi	COTPA	Both	Government gave an undertaking to create institutional capacity to test nicotine and tar contents of tobacco products by setting up tobacco testing laboratories to enforce the provisions of COTPA, section 7(5)	Favourable	W.P. (C) No.18440 of 2004
40	Kastoori Udyog & Ors. v. Union of India & Ors.	High Court of Rajasthan (Jaipur Bench)	Constitution of India, Drugs and Cosmetics Act	Smokeless	The notification prohibiting the use of tobacco in toothpaste and tooth powder was upheld and the petition was dismissed.	Favourable	D.B. Civil Writ Petition No. 3354 of 1993
41	Pyarali K. Tejani v. Mahadeo Ramchandra Dange & Ors.	Supreme Court of India	Constitution of India, PFA	Smokeless	Because men eat supari or arecanut for taste and nourishment, it is food within the meaning of Section 2(v) of the Act.	Favourable	Criminal Appeal No. 20 of 1973 and Writ Petition No. 29 of 1973

Sl. No.	Petitioner/ Respondent	Name of Court	Legislation in Question	Tobacco Products in Question	Brief Order of the Court	Judgment	Citation
42	State of Tamil Nadu v. R. Krishnamurthy	Supreme Court of India	PFA	Smokeless	Supreme Court held that all that is required to classify a product as food is that it be commonly used for human consumption or in preparing human food.	Favourable	Criminal Appeal No. 236 of 1973
43	Sri Krishan Gopal Sharma Another v. Government of N.C.T. of Delhi	Supreme Court of India	PFA	Smokeless	Supreme Court held that pan masala and mouth freshener are food under Section 2(v) of the PFA.	Favourable	1996(2) RCR 591

List of Legislation:

1. Cable TV Network (Regulation) Act, 1995
2. Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003
3. Cinematograph Act, 1952
4. Code of Civil Procedure, 1908
5. Code of Criminal Procedure. 1973
6. Constitution of India, 1950
7. Consumer Protection Act, 1986
8. Contempt of Courts Act, 1971
9. Drugs and Cosmetics Act, 1940
10. Essential Commodities Act, 1955
11. Food Safety Standards Act, 2006
12. Plastic Waste (Management and Handling) Rules, 2011
13. Plastics (Manufacture, Usage and Waste Management) Rules, 2009
14. Prevention of Food Adulteration Act, 1954
15. The Goa Public Health Amendment Act, 2005
16. The Industries (Development and Regulations) Act, 1951
17. Tobacco Board Act, 1975

Appendix 4

FSSA:

States' Status

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
1	Madhya Pradesh	Notification dated March 31, 2012 Implemented from April 1, 2012 Order passed by Commissioner of Food Safety, M.P.	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Bans all food products containing tobacco and nicotine	All districts are issued the directives by state notification to ban the manufacture and sale of all food products containing tobacco and nicotine. Gutka and similar products to be included.	In case storage of such goods are found, to confiscate such products and violators should be punished according to the law. No license or registration or any relaxation in rules given to such manufacturers and sellers who deals with such prohibited food products.	
2	Kerala	Notification dated May 22, 2012 Order passed by Commissioner of Food Safety, Kerala	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Bans all food products containing tobacco and nicotine, Section 26 and Section 92 2(i) & Section 30	Ban manufacture, sale, storage, distribution, gutka and pan masala or by whatsoever name called, being food products in which tobacco and nicotine are used as ingredients. As injurious to health	Invoked Section 26 (Responsibility of food safety operators) and Section 92 2(i) (limits of contaminants) & Section 30 (power of food commissioner) of FSS regulations	-In the interest of public health

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
3	Bihar	Notification dated May 30, 2012 Order passed by Commissioner of Food Safety cum Secretary Health, Bihar	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Bans all food products containing tobacco and nicotine, Section 26 and Section 92 2(i) & Section 30	Ban on manufacture, sale, storage, distribution, gutka and pan masala as ingredients by whatsoever name available in the market, being food products in which tobacco and nicotine are used as ingredients. As injurious to health	Invoked Section 26 (Responsibility of food safety operators) and Section 92 2(i) (limits of contaminants) & Section 30 (power of food commissioner) of FSS regulations Section 30 Food commissioners to impose the ban for a year	-In the interest of public health -Prohibited for one year from date of order
4	Rajasthan	Notification dated July 18, 2012 Order passed by Commissioner Food Safety, Rajasthan	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Bans all food products containing tobacco and nicotine	All districts are issued the directives by state notification to ban the manufacture, storage, distribution and sale of all pan masala, gutka and other food products containing tobacco and nicotine.	Violators should be punished according to the FSSA (2006) No license or registration issued under the Act to food business operators	

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
5	Maharashtra	Notification dated July 19, 2012 (most elaborative) Order passed by Food Safety commissioner, FDA, Maharashtra	Notification quoted the prevalence of SLT, harmful effects of gutka and pan masala and examples of adulteration (Magnesium) in these. To ban the manufacture, storage, distribution and sale of all pan masala, gutka and other food products containing tobacco and nicotine & magnesium or any products marketed separately to constitute as gutka and pan masala etc as final products are prohibited.	Invokes Regulation 2.3.4 which prohibits sale of products that contain any substance injurious to health and prohibits tobacco and nicotine as ingredients in any food products & Regulation 3.1.7, restricts use of anti-caking agents like carbonates of calcium and magnesium in foods except where specifically allowed like in table salt, onion powder, fruit powder and soup powder, but not more than 2%.	Section 30 (power of food commissioner) empowered to impose the ban for a year	-In the interest of public health -Prohibited for one year from date of order
6	Chhattisgarh	Notification dated July 25, 2012 Order passed by Commissioner Food Safety, Chattisgarh	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) To ban manufacture and sale of all food products containing tobacco and nicotine	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits articles of food containing tobacco and nicotine as they are injurious to health, Section 26 and Section 92 2(i) & Section 30		-Prohibited for one year -In the interest of public health

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
7	Chandigarh	Notification dated July 25, 2012 Order passed by Secretary Health cum Commissioner Food Safety, Chandigarh Admin	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) The competent authority has prohibited the use of tobacco and nicotine as ingredients in any food products injurious to health.		The designated officers to create public awareness and implement regulations ensuring that tobacco & nicotine not used in food products. Initiate action under FSSA, 2006 & rules made under, no separate orders of implementation required.	
8	Haryana	Declaration passed on July 20, 2012 implemented from August 15, 2012 Order passed by Commissioner Food Safety, Haryana	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits articles of food containing tobacco and nicotine as they are injurious to health, Section 26 and Section 92 2(i) & Section 30		Section 30 (power of food commissioner) empowered to impose the ban for a year	-In the interest of public health -Prohibited for one year with effect from August 15, 2012
9	Jharkhand	Notification dated July 25, 2012 Order passed by Commissioner Food Safety, Jharkhand	Cited FSSA 2006 to ban the manufacture, storage, distribution and sale of all food products containing tobacco and nicotine.	Initiate action under FSSA, 2006 against violators. Plan comprehensive mass awareness campaigns.	The ban has come after permission from state council of ministers. This clearly outlines the fact that state government is serious about this issue.	-To invoke provisions under FSSA & exercise authorized powers to ensure implementation.

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
10	Gujarat	Notification dated August 28, 2012 (most elaborative) Order passed by Commissioner of Food Safety, Gujarat Implemented from September 11, 2012	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) to ban the manufacture, storage, distribution and sale of all food products containing tobacco and nicotine.	Section 30 (2)(a) power of food commissioner to impose the ban for a year	Cited reports and research on harmful effects of gutka and pan masala.	-In the interest of public health -Prohibited for one year with effect from September 11, 2012 -Ban on other products marketed separately to constitute as gutka or pan masalaas final products. -Said prohibition not applicable in respect of 100% export oriented units.
11	Himachal Pradesh	Notification dated July 13, 2012 implemented from October 2, 2012 Order passed by Commissioner Food Safety, H.P.	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits use of tobacco and nicotine as ingredients in any food products, in exercise of powers under Section 26 and Section 92 (2) under FSSA.	In view of provision 2.3.4 (FSS), storage, sale or distribution of gutka, pan masala, masheri, khaini becomes illegal.	If such prohibited products are being manufactured or sold, such persons will be proceeded against as per provisions of FSSA, 2006. Such food business operators should neither be registered nor issued a licence.	-Order disclosed that gutka and pan masala, masheri and khaini are articles of food in which tobacco and nicotine are widely used.

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
12	Mizoram	Notification dated August 22, 2012 Order passed by Secretary cum Food Safety Commissioner, Mizoram	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) To impose a complete ban on sale of gutka/pan masala/zarda/or other cheweable products			-In the interest of public service
13	Punjab	Notification dated September 5, 2012 Order passed by Commissioner Food Safety cum Secretary Health and Family Welfare	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) to ban the manufacture, storage, distribution and sale of any articles of food containing tobacco and nicotine.	Section 30 (2)(a) power of food commissioner to impose the ban for a year		-In the interest of public health -Prohibited for one year with effect from September 5, 2012
14	Delhi	Notification dated September 11, 2012 Order passed by Commissioner Food Safety, Delhi	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits use of tobacco and/or nicotine as ingredients in any food products, in exercise of powers under Section 26 and Section 92 (2) under FSSA.		To prohibit the manufacture, the storage, the transportation, the display, the distribution and sale of all food products containing tobacco and nicotine, being food products in which tobacco and/or nicotine is widely used.	-In the interest of public health -Order disclosed that gutka and Pan masala (containing tobacco and nicotine) are articles of food in which tobacco and/or nicotine are widely used.

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
15	Sikkim	Notification dated September 17, 2012	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits use of tobacco and/or nicotine as ingredients in any food products, in exercise of powers under Section 26 and Section 92 (2) under FSSA.			-It bans all food items containing gutka and nicotine (Notification cannot be obtained.)
16	Uttar Pradesh (U.P.)	Declaration passed on October 4, 2012 implemented from April 1, 2013 Order passed by Food Safety Commissioner, U.P.	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits use of tobacco and/or nicotine as ingredients in any food products, in exercise of powers under Section 26 and Section 92 (2) under FSSA.		To prohibit the manufacture, the storage, the sale or distribution of gutka and panmasala containing tobacco and nicotine as ingredients, by whatsoever name it is available is prohibited.	-In the interest of public health
17	Nagaland	Notification dated October 12, 2012 Order passed by Commissioner Food Safety Commissioner cum Commissioner and Secretary to the government of Nagaland	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits articles of food in which tobacco and/or nicotine are used as ingredients in any food products, in exercise of powers under Section 26 and Section 92 (2) under FSSA.	To impose a complete ban on manufacture, the storage, the distribution and sale of chewing tobacco such as zarda etc.	Under Section 30, the manufacture, the storage, the distribution and sale of gutka and pan masala containing tobacco or nicotine as ingredients by whatsoever name, is hereby prohibited for one year from the date of issue of Order.	-Prohibits articles of food in which tobacco and/or nicotine are used as ingredients as they are injurious to health -Prohibition applicable for one year

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
18	Andaman & Nicobar	Notification dated November 1, 2012 Order passed by Commissioner Food Safety	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits article of food in which tobacco and nicotine are used as ingredients in any food products, in exercise of powers under Section 26 and Section 92 (2) under FSSA.		To prohibit the manufacture, the storage, the distribution and sale of any article of food in the whole of the state.	-Ban on gutka and pan masala in which tobacco and nicotine are widely used as ingredients -Ban with immediate effect in the interest of public health
19	Uttarakhand	Declaration passed on December 12, 2012 implemented from January 1, 2013 Order passed by Joint Food Safety Commissioner	Cited FSSA 2006 and related regulations under the act.		To prohibit the sale or distribution of gutka and panmasala containing nicotine.	-Special campaign to be launched under this notification to oversee the implementation of ban on gutka and first weekly report to be submitted on January 7, 2013.
20	Orissa	Notification dated January 3, 2013 Order passed by Commissioner cum Secretary to Govt.	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits use of tobacco and/or nicotine as ingredients in any food products, in exercise of powers under Section 26 under FSSA.		To prohibit the manufacture, the storage, the distribution and sale of gutka & pan masala containing tobacco or nicotine as ingredients, by whatsoever name available in the market, from the date of notification.	-In the greater interest of public

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
21	Andhra Pradesh	Notification dated January 9, 10 and 11, 2013 Commissioner Food Safety, A.P. (most elaborative)	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits use of tobacco and/or nicotine as ingredients in any food products, in exercise of powers under Section 26, Section 30 (2)(a) and Section 92 (2) under FSSA.		Ban on sale of gutka/ pan masala/other cheweable products containing tobacco and/or nicotine in the state of A.P. To prohibit the manufacture, the storage, the distribution and sale of gutka & pan masala containing tobacco or nicotine as ingredients.	-There is a ban as they are injurious to health (scientific studies) -In the interest of public health -The departments mentioned in the notification for effective enforcement and instructions given to information and public relations department & commissioner, civil supplies and consumer affairs to create consumer awareness. -The enforcers shall be placed on regular vigil on inter-state check posts. -Commercial tax department shall check the banned items and inform the enforcement authorities of food safety for taking action. -Ban for a period of one year

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
22	Manipur	Notification dated February 23, 2013 Order passed by Commissioner of Food Safety & Principal Secretary (Health and FW)	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits article of food in which tobacco and nicotine are used as ingredients in any food products	Complete ban on the manufacture, the storage, transportation, distribution, display, sale and purchase of gutka, khaini, zarda, pan masala and other chewable, smokeless tobacco products containing tobacco or nicotine food ingredients as unsafe food injurious to health, by whatsoever name available in the market	Resultant of state cabinet decision taken on 14.2.2013	-In the interest of public health
23.	Dadar & Nagar Haveli	Notification dated March 06, 2013 implemented from March 15, 2013 Order passed by Commissioner of Food Safety	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Bans all food products containing tobacco and nicotine, Section 92 2(i) & Section 30 2(a)		Research has shown that due to consumption of zarda (chewing tobacco) there are chances of oral cancer. Zarda (chewing tobacco or known by any name) are articles of food which contain tobacco and nicotine as ingredients and consumption of such products are injurious to health.	-To prohibit in the interest of public health the manufacture, the storage, the distribution and sale of (zarda) chewing tobacco

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
24	Jammu & Kashmir	Notification dated March 06, 2013 Order passed by Commissioner of Food Safety	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits article of food in which tobacco and nicotine are used as ingredients in any food products, in exercise of powers under Section 26 and Section 92 (2) under FSSA.	To prohibit the manufacture, the storage, transportation, the display or distribution and sale of gutka & pan masala containing and or/ nicotine being food product in which tobacco and/or nicotine are used as ingredients	Prohibit gutka by whatever name and pan masala/zarda containing tobacco or nicotine in an article of food in which tobacco and/or nicotine are used as ingredients	-Under section 30 (2) commissioner of food safety J&K named in the notification as an empowered authority to implement the said notification in the state.
25.	Assam	Notification dated March 08, 2013 Order passed by Commissioner of Food Safety	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits articles of food containing tobacco and nicotine as they are injurious to health, Section 26 and Section 92 2(i) & Section 30	To prohibit the manufacture, the storage, transportation, the display or distribution and sale of gutka & pan masala containing tobacco or nicotine as ingredients,	Gutka by whatever name and pan masala containing tobacco or nicotine by whatever name as available in the market are prohibited	-The ban is for the period of one year as per clause a of sub-section 2 of Section 30 of FSSA, 2006 -In the interest of public health
26.	West Bengal	Notification dated May 01, 2013 By the commissioner of food safety	FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits articles of food containing tobacco and nicotine as they are injurious to health, Section 26 and Section 92 2(i) & Section 30 2(a)	Ban on the manufacture, sale of gutka, pan masala or any other product containing tobacco or nicotine		-The ban is imposed for one year -In the interest of public health

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
27.	Tamil Nadu	Notification dated May 23, 2013 Order passed by Commissioner of Food Safety	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits article of food in which tobacco and nicotine are used as ingredients in any food products, in exercise of powers under Section 26 and Section 92 (2) under FSSA.	To prohibit the manufacture, the storage, distribution or sale of gutka & pan masala containing tobacco or nicotine as ingredients	Prohibit gutka and pan masala, being food products in which tobacco or nicotine are used as ingredients	-Section 30 2(a), commissioner of food safety in the interest of public health impose this ban -Ban for a period of one year
28.	Karnataka	Notification dated May 30, 2013 Order passed by Food Safety Commissioner	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits article of food in which tobacco and nicotine are used as ingredients in any food products, in exercise of powers under Section 26 and Section 92 (2) under FSSA.	To prohibit the manufacture, the storage, distribution or sale of gutka & pan masala containing tobacco or nicotine as ingredients, by whatsoever name available.	Prohibit gutka and pan masala, being food products in which tobacco or nicotine are used as ingredients	- Food Safety Commissioner is appointed by the state government for the effective implementation of food safety and requirements laid down -All the said products under the regulations prohibited in the interest of public health
29.	Daman & Diu	May 2013	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) for banning gutka and pan masala			-Notification not available

Sl. No	STATE	Date of Notification/Declaration	Main Provisions	Similarities	Differences	Analysis
30.	Goa	Goa public health amendment act, 2005 dated 16.3.2005	The state banned all tobacco products, under articles injurious to health			-The state banned all tobacco products, under articles injurious to health
31	Puducherry	Notification dated June 18, 2013 Order passed by Commissioner of Food Safety	Cited FSSA 2006 and provision 2.3.4 (FSS regulations) Prohibits article of food in which tobacco and nicotine are used as ingredients in any food products, in exercise of powers under Section 26 and Section 92 (2) under FSSA.	To prohibit the manufacture, the storage, distribution or sale of gutka & pan masala containing tobacco or nicotine as ingredients	Prohibit gutka and pan masala, being food products in which tobacco or nicotine are used as ingredients	-Section 30 2(a), commissioner of food safety in the interest of public health impose this ban -Ban for a period of one year

सत्यमेव जयते

Ministry of Health and Family Welfare
Government of India