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No More Loosies: A Mixed-Methods Study on the Implementation and Enforcement of the Loose Cigarette and Bidi Sale Ban in India

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NO MORE LOOSIES: A MIXED-METHODS STUDY ON THE IMPLEMENTATION AND ENFORCEMENT OF THE LOOSE CIGARETTE AND BIDI SALE BAN IN INDIA

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DEDICATION

To my parents for always believing in me, and for being my pillars of strength and source of motivation; to my brother who took on the responsibility of looking after our parents and ensuring their well-being while I was away; and to my wife for going on this journey with me from start to finish, for being with me during my good and bad phases, and for being my biggest support.

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ABSTRACT

Background: Sale of loose cigarettes and bidis (loosies) is widely accepted as a key factor in promoting the tobacco epidemic in India. This mixed-methods study aimed to broaden understanding around the sale and purchase of loosies addressed three aims: 1) To determine the prevalence and correlates of loosies purchase in India; 2) To examine the association between purchase behavior and health warning labels (HWLs) exposure and responses, and 3) To conduct a stakeholder analysis regarding the ban on the sale of loosies in India. **Methods:** Data from the 2018-19 Tobacco Control Policy (TCP) India survey (643 current cigarette users and 730 current bidi users) and 82 in-depth interviews with smokers (n=28), tobacco vendors (n=28), and policymakers and implementers (n=26) from two Indian cities, Mumbai (where ban on the sale of loosies was implemented) and Delhi (without the ban) were analyzed. Ordinal and logistic regression models were used to analyze the survey data and open and axial coding was done to analyze the interview data. **Results:** Survey findings suggest that about 75% of cigarette smokers and 12% of bidi smokers bought loose cigarettes and bidi, respectively, at their last purchase. Those with low education levels, unemployed, from urban neighborhoods, occasional smokers, and unsuccessful quitters were significantly more likely to purchase loosies. Those who purchased loosies less often noticed HWLs on cigarette packs. Interview findings suggest that financial and social restrictions, and

limiting cigarette consumption, were the main reasons for purchasing loosies. Awareness regarding the ban was poor among smokers, vendors, and implementers in Mumbai. Participants described that the ban would reduce their cigarette consumption and assist in quitting. Policymakers and implementers discussed potential barriers, such as unclear implementation guidelines and lack of a monitoring and evaluation mechanism, and facilitators for effective policy implementation, such as need for tobacco vendor licensing, and effective coordination between multiple stakeholders.

Conclusion: Loose tobacco prevalence remains widespread in India. Poor awareness of the policy among stakeholders signals inadequate implementation of the ban. Banning loose cigarettes will promote cessation and prevent initiation and should be included as part of the overall approach to tobacco control in India.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF ABBREVIATIONS

COTPA .....Cigarettes and Other Tobacco Products Act

FCTC .....Framework Convention on Tobacco Control

HWL.....Health Warning Labels

RQ.....Research Question

TCP .....Tobacco Control Policy

WHO..... World Health Organization

CHAPTER 1

INTRODUCTION

Tobacco use is one of the top causes of preventable deaths globally. Tobacco consumption is associated with several types of chronic illnesses including cancers, cardiovascular diseases, lung disease, and stroke (Gakidou et al., 2017). Even though smoking prevalence has decreased globally, there has been an increase in the absolute number of smokers both globally and in India due to increasing population (Reitsma et al., 2021). Despite decrease in smoking prevalence, about 20% of the global population are current tobacco smokers (Reitsma et al., 2021), and approximately 29% of the Indian population aged 15 years and above consume tobacco products in some form. Among Indian tobacco users, 11% are current tobacco smokers (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). Tobacco consumption is attributed to 7.7 million deaths globally (Reitsma et al., 2021), of which 1.3 million deaths (16.9%) are from India (Jha et al., 2008; World Health Organization), one of the top producers and consumers of tobacco products both smoked and smokeless tobacco (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). It also contributes to approximately 6% of disability adjusted life years in India (Gakidou et al., 2017). In addition to loss of life, tobacco use also imposes a huge economic burden due to increased healthcare costs, both direct and indirect (Mohan, Lando, & Panneer, 2018). It

costs the global economy about USD 1.4 trillion every year (World Health Organization, 2021), and contributed to around USD 27.5 billion in total healthcare costs to India for the year 2017-18 (R. M. John, Sinha, Munish, & Tullu, 2021).

To reduce tobacco prevalence and tobacco-related morbidity and mortality, the Government of India enacted the Cigarettes and Other Tobacco Products Act (COTPA) (Ministry of Health and Family Welfare Govt. of India) in 2003 and became a signatory to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) (International Legal Consortium at the Campaign for Tobacco-Free Kids, 2020) that recommends demand and supply reduction measures to decrease tobacco prevalence. At the national level, COTPA ensures pictorial health warnings on cigarette packs, increased taxes on tobacco products, prohibits completely tobacco product marketing (advertisements, promotion, and sponsorships of any kind, both direct and indirect), and regulates tobacco production and distribution (Ministry of Health and Family Welfare Govt. of India). Despite these policies, the widespread availability of loose cigarettes and bidis (hand-rolled, flavored, or unflavored cigarette made of unprocessed tobacco wrapped in tendu leaves) in Indian markets may impede the effectiveness of these policies.

Loose cigarette and bidi sale in the unregulated, informal economy in India is widely accepted as a key factor in promoting the tobacco epidemic in India (Reddy & Gupta, 2004; Yadav et al., 2020). About 75% of all cigarettes sold are loose (Lal et al., 2015), which goes against Article 16 of the WHO-FCTC recommendations to ban the sale of loose cigarettes (International Legal Consortium at the Campaign for Tobacco-Free

Kids, 2020). Smokers perceive loose cigarettes to be more affordable (per purchase) compared to the price of the whole pack (International Legal Consortium at the Campaign for Tobacco-Free Kids, 2020), resulting in easy access to disadvantaged population groups (Gemson et al., 1998) and potentially acting as a gateway to addiction (Forster & Wolfson, 1998). Loose cigarette sales also potentially neutralize the expected benefits from evidence-based strategies, such as increased taxes on tobacco products, and pictorial health warnings on cigarette packs. Since loose cigarettes and bidis are perceived to be relatively affordable (per purchase) compared to the price of a whole cigarette pack, it undermines the greater benefits of higher taxed cigarettes (Hanewinkel, Radden, & Rosenkranz, 2008). Similarly, loose cigarette and bidi sale defies the purpose of displaying health warning labels (HWLs) by potentially diminishing their visibility and legibility (Peiris, 2018; Thrasher, Villalobos, Barnoya, Sansores, & O'Connor, 2011; Yadav et al., 2020).

The issue of loose cigarette and bidi sales has received little consideration from the policy makers and implementers and is understudied by public health researchers in the context of India. There are no published studies that have examined the correlates of loose cigarette and bidi use, and its association with exposure to and effects of health warning labels in India. Additionally, a few Indian states have recently prohibited loose cigarette and bidi sales (The Indian Express, 2020; Times of India, 2020; Yadav et al., 2020). There are no studies, however, that have examined the perceptions of key stakeholders regarding the loose cigarette and bidi sale ban in any low-and-middle

income country. For the policy ban to be effectively implemented and enforced, it is crucial to understand the perceptions of all relevant stakeholders.

Therefore, this project aimed to broaden understanding regarding loose cigarette and bidi sales in India. Specifically, this project involved a secondary analysis of the Tobacco Control Policy (TCP) (International Tobacco Control Policy Evaluation Project) India survey to understand the prevalence and correlates of loose cigarette and bidi purchase and to examine the association between purchase behavior and HWL exposure and responses. Additionally, the qualitative component of the project examined perceptions of the three key stakeholder groups: (a) policymakers, policy implementers, and law enforcement officials, (b) loose cigarette and bidi vendors), and (c) loose cigarette and bidi users, regarding the ban on the sale of loose cigarette and bidis. The qualitative interviews were guided by the health policy implementation framework developed by Balane and colleagues (2020) (Balane, Palafox, Palileo-Villanueva, McKee, & Balabanova, 2020). The framework integrates key concepts from stakeholder analysis approaches to studying policy implementation and is focused on assessing knowledge, interest, power, and position while conducting this type of stakeholder analysis.

Specific Aims

This study was designed to deepen scientific understanding around the issue of loose cigarette and bidi purchase in India and stakeholder perceptions of the loose cigarette and bidi sale ban in India. In doing so, I addressed the following specific aims:

Aim 1

<u>To determine the prevalence, correlates, sources, and prices paid for loose cigarette and bidi purchases among Indian adult smokers.</u>

RQ1. What is the prevalence of loose cigarette and loose bidi purchase in India?

RQ2. What are the prices paid for loose cigarettes and bidis?

RQ3. Who are the vendors from whom smokers most often purchase loose cigarettes and bidis?

RQ4. What are the correlates of loose cigarette/bidi use among Indian smokers?

Aim 1 Methods. I conducted a secondary data analysis using the 2018-19 TCP India survey to answer RQ1, RQ2, RQ3, and RQ4. Using descriptive analysis, I first examined the prevalence of loose cigarettes and loose bidi sale. Second, I analyzed the prices paid for loose cigarettes and bidis separately where I calculated the average prices paid for an individual cigarette and bidi stick, and the average number of loose cigarettes and bidis purchased. Third, I used chi-square tests to determine if there were any differences in the types of vendors from whom survey respondents bought their last cigarette/bidi and compared it at the neighborhood level (urban vs rural). Finally, I calculated odds ratios using logistic regression models (crude and adjusted) to determine socio-demographic and tobacco-related correlates of loose cigarette and bidi purchase by Indian adult smokers. All regression models were adjusted for socio-demographics including sex, age groups, marital status, education level, occupation, and

neighborhood and tobacco-related correlates including tobacco status, smoking frequency, past quit attempt, and intentions to quit. Findings from aim 1 are presented in Manuscript 1 (see Chapter 4) and will be submitted to the journal *Tobacco Control.*

Aim 2

To examine the association between purchase behavior and exposure to and effects of HWLs on cigarette/bidi packs.

RQ5. What is the association between bidi purchase behavior (loose vs bundle) and HWL exposure and responses?

RQ6. What is the association between cigarette purchase behavior (loose vs packs) and HWL exposure and responses?

Aim 2 Methods. I analyzed the 2018-19 TCP data by treated survey questions measuring HWLs exposure and responses (noticing HWLs; reading or loosing closely at HWLs; forgoing a cigarette/bidi because of HWLs; thinking about the health risks of smoking because of HWLs; and thinking about quitting smoking cigarettes/bidi because of HWLs) as dependent variables, and cigarette purchase behavior (loose vs pack) as the main independent variable. I used ordinal regression analysis and models were fit separately for cigarettes and bidis, whereby HWL variables were regressed on purchase behavior. I adjusted all the models for age, sex, education, smoking frequency, and intentions to quit. I also used data from the qualitative interviews conducted with smokers for Specific Aim 3. I conducted semi-structured, in-depth interviews with 28 smokers from two Indian cities, Mumbai and Delhi. Data specifically about their perceptions regarding

noticing HWLs at the time of purchasing loose cigarettes was analyzed and used for this aim. I analyzed the qualitative data using inductive open and axial coding (Corbin & Strauss, 2014; Miles & Huberman, 1994). Findings from aim 2 are presented in Manuscript 2 (see chapter 4) and will be submitted to the journal *BMJ Global Health.*

Aim 3

To conduct stakeholder analysis regarding loose cigarette and bidi sale ban in India.

RQ7. Why do cigarette users purchase loose cigarettes?

RQ8. What is the awareness regarding the ban on the sale of loose cigarettes and what are cigarette users, tobacco vendors, and policymakers, implementers, and law enforcement officials' perceptions about the status of policy implementation in Mumbai?

RQ9. What are cigarette users and tobacco vendors' perceptions regarding the impact of the ban on the sale of loose cigarettes on users' purchase behavior?

RQ10. What are the potential barriers in the implementation and enforcement of the ban on the sale of loose cigarettes?

RQ11. What are the facilitators for the implementation and enforcement of the ban on the sale of loose cigarettes?

RQ12. How have stakeholders contributed or can potentially contribute to the implementation and enforcement of the ban on the sale of loose cigarettes?

Aim 3 Methods. I conducted semi-structured, in-depth interviews with the three stakeholder groups in two cities, one where loose cigarette sale was banned (Mumbai) and one without the ban (Delhi). Using a systematic recruitment and interview protocol, I interviewed 28 cigarette smokers, 28 tobacco vendors and 26 policymakers, implementers, and law enforcement officials. I performed thematic analysis used open and axial coding (Miles & Huberman, 1994). I also examined emergent themes across stakeholder groups using a constant comparison method (Boeije, 2002). Findings from aim 3 focused on the interviews conducted with smokers and vendors are presented in Manuscript 3 (see Chapter 4) and will be submitted to the journal *Frontiers in Public Health.* Findings from aim 3 focused on the interviews conducted with policymakers, implementers, and law enforcement officials are presented in Manuscript 4 (see Chapter 4) and will be submitted to the journal *Global Health Research and Policy.*

CHAPTER 2

BACKGROUND AND SIGNIFICANCE

Smoking burden and prevalence in India

Tobacco consumption is an important public health issue that causes significant morbidity and mortality across the world (Reitsma et al., 2021). It is the leading preventable cause of deaths that kills an estimated 7 million people globally (Reitsma et al., 2021). India is the third largest producer and second largest consumer of tobacco products (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). An estimated 1.3 million Indians die annually from tobacco-related diseases (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences; World Health Organization). Of those 1.3 million, nearly 1 million deaths are attributed to tobacco smoking (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences).

Nationally representative surveys indicate that approximately 29% (267 million) of the Indian population aged 15 years and above consume tobacco in some form (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences), and about 11% are current tobacco smokers

(Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). Among smoked-tobacco products, bidis are the most used product (7.7%) followed by cigarettes (4%) (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). However, by age groups, cigarettes are most preferred and smoked among young adults aged 15-24 years as compared to bidis (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). In terms of neighborhood, prevalence of bidi smoking was higher in rural areas (9.3%) (vs urban (4.7%)), and the prevalence of cigarette smoking was higher in urban areas (4.4%) (vs rural (3.8%)).

The two focus cities for this proposed research, Mumbai, and Delhi, are diverse in terms of tobacco use prevalence and patterns. As per the second round (2016-17) of Global Adult Tobacco Survey, 17.8% of adults in Delhi and 26.6% adults in Mumbai consumed tobacco in some form (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). About 3.8% of tobacco users in Mumbai consumed smoked tobacco in the form of cigarettes and bidis (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). By contrast 11.3% of adults in Delhi were current tobacco smokers, which was higher than the national average (10.7%) (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). About 4.9% and 8.2% of adults in Delhi smoked cigarettes and bidis respectively, whereas 1.9% of adults in Mumbai smoked each cigarette and bidi (Ministry of Health

and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences).

Even though there has been a reduction in the prevalence of tobacco use In India, increasing population has led to an increase in the total number of tobacco users both globally and in India (Reitsma et al., 2021) with tobacco consumption rates growing annually between 2-3% (Mohan et al., 2018). Tobacco use not only result in loss of lives, but also places enormous burden on an economy through increased healthcare costs, both direct and indirect (World Health Organization). Tobacco associated morbidity and mortality in India contributed to USD 27.5 billion in total economic costs for the year 2017-18 (World Health Organization).

Tobacco prevention policies in India

To reduce tobacco use prevalence, the Government of India enacted the Cigarettes and Other Tobacco Products Act (COTPA) in 2003 that focused on prohibiting advertisement or marketing of tobacco products (advertisements, promotion, and sponsorships of any kind, both direct and indirect), and regulation of tobacco production and distribution (Ministry of Health and Family Welfare Govt. of India). It was amended later in 2006 that 50% area on the front and back of cigarette packs and other tobacco products must have pictorial health warnings (Arora & Yadav, 2010). The most recent amendment in 2014 related to pictorial health warnings required at least 85% area on front and back of cigarette packs and other tobacco products to have pictorial health warnings (Campaign for Tobacco-Free Kids, 2020; Chahar, Karnani, &

Mohanty, 2019). Despite these policies, the tobacco industry continues to hold out against tobacco control measures in India. One such tactic of the tobacco industry is the availability and sale of loose cigarettes and bidis, which is also a neighborhood level determinant that remains a hurdle to effective policy implementation, including health equity concerns (Crosbie, Defrank, Egbe, Ayo-Yusuf, & Bialous, 2021).

Loose cigarette sale in India

Cigarettes are generally sold loose in many low- and middle-income countries such as India, Bangladesh, Brazil, Thailand, Uruguay, Vietnam, Guatemala, Mexico, and Philippines (de Ojeda, Barnoya, & Thrasher, 2012; Elf, Modi, Stillman, Dave, & Apelberg, 2013; Hall, Fleischer, Reynales-Shigematsu, Arillo-Santillán, & Thrasher, 2015; Kostova et al., 2014) and in the lower socio-economic status neighborhoods of developed countries such as the United States (Baker, Lee, Ranney, & Goldstein, 2015; Latkin, Murray, Smith, Cohen, & Knowlton, 2013; Stillman et al., 2007; Stillman, Bone, Milam, Ma, & Hoke, 2014). Prevalence of purchase and availability of loose cigarettes has increased in low-and-middle income countries (de Ojeda et al., 2012; Hall et al., 2015). People living in neighborhoods with higher deprivation levels have higher access to loose cigarettes compared to those living in neighborhoods with lower deprivation levels (Hall et al., 2015; Latkin et al., 2013). Higher prevalence of loose cigarettes has also been found to be positively associated with illegal sales of tobacco to minors, thus potentially contributing to the growing population of adult smokers (Kuri-Morales, Cortés-Ramírez, & Cravioto-Quintana, 2005).

A study using GATS data from 15 low-and-middle income countries found that the majority of the cigarettes sold and purchased in India were loose cigarette sticks (Chaturvedi, Sarin, Seth, & Gupta, 2017; Kostova et al., 2014). Nationally representative surveys conducted in India have found that about 67% of cigarette smokers, and 17% of bidi smokers purchased loose cigarettes and bidis, respectively, at their last purchase (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). In the unregulated tobacco markets of India, most cigarette vendors continue to sell individual cigarette sticks which have been taken out from the commercially packed cigarette box. Selling loose cigarettes is in contrast of Section 7 of the COTPA which states that "no person shall, directly or indirectly, produce, supply or distribute cigarettes or any other tobacco products unless every package of cigarettes or any other tobacco products produced, supplied or distributed by him bears thereon, or on its label, the specified warning including a pictorial depiction of skull and cross bones and such other warnings as may be prescribed" (Ministry of Law and Justice, 2003). Lal and colleagues (2015) found that of all cigarettes sold in India, nearly 75% were sold loose (Lal et al., 2015).

A study by Eshwari and colleagues (2020) used cross-sectional surveys to examine perceptions and practices, and awareness regarding the implemented ban on the sale of loose cigarettes among tobacco vendors and smokers in Karnataka, India (Eshwari et al., 2020). It was found that 95.5% of the tobacco vendors (primarily general stores and small shops) reported selling loose cigarettes (Eshwari et al., 2020). Vendors also reported that loose cigarettes were most frequently purchased by adult men and

college students and that cigarette smokers (95%) preferred loose cigarettes over cigarette packs (Eshwari et al., 2020). Only half of the cigarette vendors were aware of the loose cigarette sale ban and only a quarter of them reported that the ban had been implemented (Eshwari et al., 2020). Most vendors also reported that if the ban on the sale of loose cigarettes was properly enforced, they would stop selling loose cigarettes (Eshwari et al., 2020). Widespread availability and lower cost of loose cigarettes (at the time of purchase) as compared to the cost of whole pack were the most common reasons cited by smokers for their preference for loose cigarettes (Eshwari et al., 2020). Awareness of the ban on sale of loose cigarettes was found to be low among cigarette smokers. A small proportion of current smokers (22%) reported that if the ban was strictly enforced, they would reduce the number of cigarettes they smoked, 16% reported that they would think about quitting, and 9.5% reported to completely give up smoking (Eshwari et al., 2020).

A multi-centric study by Goel and colleagues (2021) examined loose cigarette prevalence as well as the factors associated with the sale of loose cigarettes at points of sale by tobacco vendors in four Indian states (Goel et al., 2021). Out of 2044 points of sale, 93% were found selling loose cigarettes (Goel et al., 2021). Most of the points of sale (~60%) that were selling loose cigarettes were in urban areas and about one-third were permanent kiosk kind of establishments (Goel et al., 2021). Results revealed that loose cigarettes were significantly more likely to be available and sold at points of sale in urban areas, points of sale selling tobacco products to minors, and points of sale selling smoking aids and flavored chewable tobacco to customers (Goel et al., 2021). Points of

sale in urban areas selling loose cigarettes were two times more likely to be street/mobile vendors and six times more likely to be those who offered other services in addition to selling tobacco (Goel et al., 2021). At the neighborhood level, it was found that urban points of sale as compared to rural points of sale had significantly more advertisements outside the shop and displayed tobacco products. However, urban points of sale compared to their rural counterparts were also less likely to sell tobacco to/by minors, and less non-compliant to tobacco pack health warnings (Goel et al., 2021). Additionally, tobacco vendors at urban points of sale were more likely to be non-compliant in enquiring age of customers before selling tobacco products (Goel et al., 2021).

Loose cigarettes and perceptions related to affordability and accessibility

It has been established that availability and sale of loose cigarettes makes tobacco affordable (per purchase compared to the cost of the whole pack) and accessible for minors (Goel et al., 2021). Studies that examined smokers' perceptions have found that they perceived loose cigarettes to be more affordable (per purchase) than the cost of the whole pack (Stillman et al., 2007; Stillman et al., 2014). Qualitative studies among African American urban youth smokers in the United States found that those who purchased loose cigarettes cited 'convenience' and 'less expensive' as the most common reasons for purchasing loose cigarettes (Stillman et al., 2007). Youth smokers who purchased loose cigarettes were also found to be daily smokers (Stillman et al., 2007). On the other hand, studies have also showed that purchase of loose cigarettes was linked to non-daily smoking (Sacks, Coady, Mbamalu, Johns, & Kansagra,

2012) indicating lack of clarity on the relationship between loose cigarette consumption and quitting behavior as smokers who purchased in loose were no more likely to make an attempt to quit smoking compared to those who did not purchase in loose (Thrasher et al., 2011). Additionally, loose cigarettes are most often purchased by individuals with lower socio-economic status and young adults indicating that those with lower income levels and limited money were more likely to purchase loose cigarettes (Thrasher et al., 2009). Further, easy availability and affordability (per purchase) of loose cigarettes create disparities by putting disadvantaged population groups, such as minors, at high risk of experimenting with cigarettes and eventually getting addicted (Hall et al., 2015).

Loose cigarettes and dependence

There is mixed literature on whether loose cigarettes are used as strategies to limit cigarette consumption and quitting or perceived as nudges to smoke for potential smokers. The affordability and availability of loose cigarettes has been linked with smoking initiation and progression among among the youth (de Ojeda et al., 2012; Jarvis & McNeill, 1990). A survey among adult smokers in four Mexican cities also reported that the sight of loose cigarette sales cues smoking behavior, which could potentially lead to addiction (Thrasher et al., 2009). Results from the ITC Mexico Survey analyzed by Thrasher and colleagues found that about one-quarter of the smokers smoked loose cigarettes to be able to cut down their cigarette consumption (Thrasher et al., 2011). Thrasher and colleagues also found that sale of loose cigarettes in the neighborhood was associated with smokers reporting cravings to smoke after seeing availability of loose cigarettes (Thrasher et al., 2011). Further, frequency of cravings was found to be

positively associated with purchase and consumption of loose cigarettes (Hall et al., 2015; Thrasher et al., 2011). Even though some studies have reported loose cigarette purchase among smokers as a means to limit cigarette consumption, the evidence is not conclusive (Stillman et al., 2014).

Loose cigarettes and exposure to warning labels

Health warning labels on cigarette packages are among the most effective and credible means of communicating health information with both cigarette smokers and non-smokers (Cecil, Evans, & Stanley, 1996; Moodie, MacKintosh, & Hammond, 2010). Cigarette packages offer frequent exposure to warning labels as smokers who purchase cigarette packs are potentially exposed every time they smoke, leading thousands of exposures each year (Slade, 1997; Wakefield, Morley, Horan, & Cummings, 2002). Additionally, cigarette pack labels communicate health information at the time when people are considering smoking, potentially deterring this decision (Wakefield et al., 2002). The World Health Organization Framework Convention on Tobacco Control recommends that at least 50% of the principal display area of cigarette packs carry clear, large and rotating health warning messages (International Legal Consortium at the Campaign for Tobacco-Free Kids, 2020). The anti-tobacco law in India, COTPA, goes beyond this minimum recommendation, requiring that warnings cover 85% of the principal display areas of cigarette packs and other tobacco products (Campaign for Tobacco-Free Kids, 2020).

Numerous studies have focused on examining the effectiveness of health warning labels in different countries and on different population groups. Cohort studies conducted globally have found more cigarette smokers reporting to have received health information about the risks associated with tobacco consumption from cigarette packs than from any other communication source (G. Fong, 2009). The majority of smokers perceived cigarette packs with large pictorial health warnings as a source of health information (G. Fong, 2009), whereas findings also suggest that small sized text warnings that do not include pictorial graphics are associated with poor recall and low levels of awareness (Noar et al., 2016). Several characteristics of health warning labels such as size, type, and position influence its effectiveness. Studies have showed that both young and adult population groups were more likely to recall health warnings that were larger in size and relate them to having greater impact (Créatec, 2008; Environics Research Group, 1999). Experimental studies conducted in developed countries such as Canada and Australia have also found that increasing the size of health warning labels significantly enhances their effectiveness among adult and young smokers as well as vulnerable non-smokers (David Hammond, 2011).

Health warning labels convey health information through text, graphics, or a combination of both. Studies that evaluated enhancement of text warning labels found that larger text-based warnings are associated with higher risk perceptions, increased knowledge, and awareness regarding harms from tobacco use, and has a greater potential to enable smokers to quit smoking (Brewer et al., 2016; Fathelrahman et al., 2009; David Hammond et al., 2007; Noar et al., 2016). Research has also shown that

using graphics, such as pictures and imagery, are very effective in communicating health information as they are more noticeable, improve information processing and memory for the message, and can aid in promoting smoking cessation (Braun, Mine, & Silver, 1995; David Hammond, 2011; Levie & Lentz, 1982; Sherman, Cialdini, Schwartzman, & Reynolds, 1985; Strahan et al., 2002). Picture-based warnings are also effective in acting as a barrier for new smokers to initiate smoking as well as a means to promote cessation among current cigarette smokers (Kees, Burton, Andrews, & Kozup, 2006, 2010; O'Hegarty et al., 2006; Vardavas, Connolly, Karamanolis, & Kafatos, 2009). They are also more noticeable and more frequently viewed by smokers and help generate firmer beliefs about the harms of smoking (G. T. Fong et al., 2010; David Hammond et al., 2007; Davis Hammond, Fong, McDonald, Cameron, & Brown, 2003; David Hammond, Fong, McNeill, Borland, & Cummings, 2006; Hassan, Shiu, Thrasher, Fong, & Hastings, 2008; Liefeld, 1999; O'Hegarty et al., 2006; Thrasher, Hammond, Fong, & Arillo-Santillán, 2007; White, Webster, & Wakefield, 2008).

Text and pictorial warnings have been reported to have assisted in cessation behavior. Both adult and young population have reported that large health warnings have lowered their consumption levels, increased their motivation and likelihood to quit and remain abstinent after quitting (Borland & Hill, 1997; David Hammond, Fong, McDonald, Brown, & Cameron, 2004; Davis Hammond et al., 2003; David Hammond et al., 2006; M. C. Willemsen, 2005). Additionally, longitudinal studies conducted with adult and young population have also found an association between reading and thinking about warning labels and cessation behavior (Borland et al., 2009; Davis

Hammond et al., 2003; White et al., 2008; Yong et al., 2016). Health warnings have not just enabled smokers to lower their consumption level and make quit attempts but have also led to an increase in the usage of cessation services. Studies have indicated significant increase in the call volumes to smoking cessation helpline indicated on health warnings on cigarette packs (Miller, Hill, Quester, & Hiller, 2009; M. Willemsen, Simons, & Zeeman, 2002; Wilson, Li, Hoek, Edwards, & Peace, 2010). Overall, evidence till date suggests that large, clear, and comprehensive health warning labels are the most effective means of motivating cessation behavior and preventing smoking initiation.

Studies that have examined the perceived impact of health warning labels in preventing tobacco uptake in the context of India found that college students reported that having both pictorial and text warnings on cigarette packs discouraged them from smoking (Mullapudi et al., 2019). After viewing pictorial warnings on cigarette packs, most felt scared and reported that they would not initiate tobacco consumption, or would reduce/quit smoking (Mullapudi et al., 2019). The most recent second round of the Global Adult Tobacco Survey (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences) India also found that there has been a significant increase in health warning label salience and its impact on quit intentions among Indian smokers.

Where large pictorial health warnings on cigarette packs make smoking appear less attractive through repeated exposures at the time of purchase and at each time a smoker takes out a cigarette from a cigarette pack (Cohen et al., 2016; David Hammond, 2011), availability of loose cigarettes potentially reduces the effectiveness of pictorial

warnings as loose cigarette smokers are less likely to be exposed to health warning labels (Latkin et al., 2013). Even though smokers may still be exposed at the point of sale, as loose cigarettes are usually displayed to the buyer in a pack that has warnings, one cannot rely on the fact that every point of sale or every vendor is depicting the warning, in the prescribed format, and is not masking it. As per the 2016-17 GATS India survey, about 48% of the current smokers purchased their last cigarette from a small tobacco kiosks or street vendors (Tata Institute of Social Sciences , Health, & Family Welfare, 2018), and a substantial percentage of tobacco vendors, especially small vendors displayed advertisement boards without health warnings and had a higher non-compliance rate to the presence of health warnings (Goel et al., 2015; Joseph et al., 2021).

Loose cigarettes and taxation

Increasing taxes and prices of tobacco products have proved to be a very effective strategy in reducing tobacco prevalence as it encourage current smokers to reduce/quit tobacco consumption and discourage potential smokers from initiating tobacco consumption (Chaloupka, Straif, & Leon, 2011; von Lampe, Kurti, & Johnson, 2018). Higher tobacco taxes and prices are significantly associated with quitting behavior through increased rates of quit attempts and lower cigarette consumption (Chaloupka et al., 2011; Dinno & Glantz, 2009; Gallus, Schiaffino, La Vecchia, Townsend, & Fernandez, 2006). Studies that have examined association between tobacco prices and smoking initiation in India found that higher prices for smoked tobacco products such as cigarettes and bidis were significantly associated with reduced risk of cigarette

and bidi smoking initiation (Shang, Chaloupka, Gupta, Pednekar, & Fong, 2019). Another study that examined the association between state-imposed value added taxes on tobacco products and tobacco use also found that a 10% increase in value added taxes significantly reduced dual use of cigarettes and bidis by 6.5% (Shang, Chaloupka, Fong, Gupta, & Pednekar, 2018). However, the sale and purchase of loose cigarettes defies the whole purpose of increasing the price of tobacco products for consumers as smokers find the up-front costs of loose cigarettes to be attractive as they are lower than the cost of the whole cigarette pack. Even though the immediate cost of a loose cigarette stick is perceived to be lower (Thrasher et al., 2009) (as compared to the price of the whole cigarette pack), the true cost of a loose cigarette is still higher (de Ojeda et al., 2012; Smith et al., 2007). Studies that have analyzed price responsiveness for consumers' purchasing power demonstrated that availability of loose tobacco products undermined the greater benefits of higher taxed cigarettes (Hanewinkel et al., 2008), meaning that widespread sale and purchase of loose cigarettes challenges the effectiveness of tobacco control policies, especially tax policy, because of which countries are recommended to opt for large tax increases (vs incremental increases) to ensure the full effect of the policy (Gallien, Occhiali, & Ross, 2023).

Loose cigarettes and quitting behavior

Availability of loose cigarettes potentially encourages smoking and decreases the likelihood of making quit attempts (Baker et al., 2015). However, some studies also suggest that smokers purchase loose cigarettes to be able to cut down their cigarette consumption (Hall et al., 2015; Smith et al., 2007; Thrasher et al., 2011). Hall and

colleagues (2014) found that smokers who lived in a neighborhood where loose cigarettes were easily accessible were less likely to make an attempt to quit cigarette smoking and were more likely to switch back to smoking (Hall et al., 2015). Additionally, smokers who purchased loose cigarettes with the intention to limit their smoking were not more likely to quit smoking than those who did not purchase single cigarettes with the intention to reduce their cigarette consumption (Thrasher et al., 2011). A mixed-methods study among adult smokers in four Mexican cities reported that a sighting of loose cigarette sale acts as a cue to smoking and prevents smokers from successfully quitting (Thrasher et al., 2009). Another study conducted in the US in an African-American population also found that prevalence of loose cigarettes in the neighborhood was a risk factor for relapse (Phan et al., 2021).

Gaps in the current research

Availability and consumption of loose cigarettes can potentially act as a gateway to tobacco addiction resulting in loss of lives. It is a critical public health issue that needs immediate attention from policy makers, law enforcers, and public health researchers. Acknowledging it as an important public health issue, WHO-FCTC has recommended in Article 16 to form comprehensive policies and enforcement strategies to combat loose cigarette sales (International Legal Consortium at the Campaign for Tobacco-Free Kids, 2020). Sales of loose cigarettes are very prevalent in low-and-middle income countries, pointing to the ineffective implementation and enforcement of tobacco control policies (de Ojeda et al., 2012; Hall et al., 2015). The most recent amendment to the Legal Metrology Act by the Department of Consumer Affairs, Government of India, can be

interpreted as banning the sale of loose cigarettes (Press Trust of India, 2016). In addition to that, the Government of India also amended Section 7 of the COTPA stating that cigarettes/bidis or any other tobacco products can only be sold and purchased in their sealed, intact, and original packing (Goel et al., 2021). Following these amendments, several Indian states such as Maharashtra, Punjab, Himachal Pradesh, Karnataka, and Chhattisgarh banned loose cigarette sales (The Hindu, 2015; The Indian Express, 2020; Times of India, 2020; WHO Framework Convention on Tobacco Control Knowledge Hub, 2020; Yadav et al., 2020). Since health being a state issue in India, many of the remaining states that represent densely populated regions with high smoking prevalence were yet to implement the ban.

Despite the strong recommendation by the FCTC for banning loose cigarette sales (International Legal Consortium at the Campaign for Tobacco-Free Kids, 2020), studies that have measured compliance with India's tobacco control laws have shown low adherence to the provisions of COTPA (Goel et al., 2015; Panda et al., 2012; Sharma et al., 2019) and have pointed to the inadequacies in the enforcement of such laws and provisions (Mullapudi et al., 2021). Mullapudi and colleagues (2021) specifically assessed compliance to section 7, 8, and 9 of COTPA which relate to health warning requirements on tobacco packs (Mullapudi et al., 2021). Overall compliance for the three sections was achieved only by 6% and 34% of bidis and cigarette packs respectively indicating low compliance with respect to the size of text and pictorial warnings, legibility, and language requirements for warning labels on tobacco packs (Mullapudi et al., 2021). There was a need to conduct a stakeholder analysis to collect scientific data regarding

loose cigarette/bidi sales and its effect, and disseminate findings with the goal of increasing the implementation and enforcement of COTPA's provisions banning the sale of loose cigarettes and bidis. In-depth interviews with the key stakeholders (policy implementers and law enforcement officials, tobacco vendors, and smokers) in states both with and without bans would help identify the barriers and gaps to effective policy implementation and enforcement.

There was also limited information on the prevalence of the purchase and availability of loose cigarettes in India. Studies have discussed several potential explanations for the availability of loose cigarettes in the markets. In Mexico, selling loose cigarettes was profitable for cigarette vendors as they were sold at a much higher price than the per-unit cost of packaged cigarettes (Hall et al., 2015). Additionally, lack of clarity regarding which government bodies were responsible for effective implementation and enforcement of tobacco control policies was also potentially associated with the continued prevalence of loose cigarettes (Hall et al., 2015). Policy implementation and enforcement is the responsibility of multiple stakeholders who could have a direct or indirect influence on implementation-related decision making and processes (Balane et al., 2020). Exploring policy implementation with key stakeholders is important to understand their inter-relations, interests, and to assess the influence and resources and skills they bring to affect decision making or implementation processes (Varvasovszky & Brugha, 2000). In policy implementation research, stakeholder analysis can be used to understand stakeholders' roles and potential contributions in policy processes or inform future directions for policy implementation (Varvasovszky &

Brugha, 2000). There was a need to conduct an in-depth analysis to examine the knowledge, position, power, and interest of stakeholders regarding the implementation and enforcement of the ban on the sale of loose cigarettes and bidis. Knowledge regarding the prevalence, sources, prices, and correlates of loose cigarette purchases among Indian smokers was limited as well. Further, the association between cigarette/bidi purchase behavior (loose vs pack) and HWLs exposure and responses among Indian smokers also needed more clarity.

Significance

India has amended COTPA in the last several years, including increasing excise duties on tobacco products, increasing the size of pictorial warnings to 85% of principal display areas of cigarette packs and all other tobacco products, and banning smoking in public places. Assessing the prevalence of loose cigarette purchases in India would help in understanding how cigarette smokers were responding to the tobacco control policies in India. It would also help understand the extent to which India has complied with Article 16 of the WHO-FCTC that focuses on banning loose cigarette sales. This research would advance knowledge regarding the prevalence, correlates, prices, and sources for loose cigarette/bidi purchase in India and assess how loose cigarette/bidi may decrease the effectiveness of health warning labels through reduced exposure. Ban on loose cigarette sale in other low and middle income countries has not been effectively implemented and has often been ignored by cigarette vendors and enforcement agencies (Hall et al., 2015). It was therefore important for effective implementation and enforcement to conduct a stakeholder analysis regarding the loose cigarette/bidi sale

ban in India, which would not only evaluate the existing policy in Mumbai but also help advance and apply the project's findings in states where the ban was yet to be implemented. A stakeholder analysis would help identify gaps and barriers, and motivations and facilitators to effective policy implementation and enforcement.

Innovation

This research was innovative as it explored an under-studied and under-researched topic of loose cigarette and bidi sales in India, which is the second largest consumer of tobacco products in the world. Further, only a few Indian states had implemented the policy ban, and the majority of the remaining states were yet to implement it which made this work very timely. It was also the first mixed-methods study that examined the perceptions of three stakeholder groups (policy implementers and law enforcement officials, tobacco vendors, and smokers) regarding loose cigarette and bidi sale ban in India.

Guiding conceptual framework

Figure 2.1 depicts the conceptual framework that guided the three aims of this study. It depicts the core constructs that describe how implementation and enforcement of tobacco control policy influence loose cigarette prevalence which is linked to increased tobacco consumption and tobacco-related morbidity and mortality. The quantitative part that involved a secondary data analysis, covered specific aims 1 and 2 and focused on determining the prevalence, correlates, prices, and sources of loose cigarette purchase and its association with HWL exposure and responses. Loose

cigarette purchase behavior is influenced by several sociodemographic and tobacco-related correlates such as neighborhood, sex, age, education, occupation, SES, marital status, smoking frequency, and quitting behavior including quit attempts and intentions to quit smoking. People living in urban neighborhoods, low SES groups, college students, young unemployed population groups, are more likely to purchase loose cigarettes and bidis (Eshwari et al., 2020; Goel et al., 2021; Thrasher et al., 2009). Loose cigarette prevalence potentially acts as a gateway to nicotine addiction and potentially reduces the exposure to health warning labels on cigarette and bidi packs (Latkin et al., 2013). It enables smokers to smoke a cigarette without having to purchase the whole cigarette pack, and can act as a cue to smoking (Hall et al., 2015). Smokers purchasing loose cigarettes and bidis were also less likely to make quit attempts and perceives lower risk from cigarette smoking (Baker et al., 2015; Hall et al., 2015; Phan et al., 2021; Thrasher et al., 2011; Thrasher et al., 2009). There is a bilateral relation between loose cigarette purchase and gateway to addiction and cessation success as smokers not only reported to use loose cigarettes to be able to cut down their cigarette consumption (Thrasher et al., 2009) but were also less likely to intend to quit smoking (Thrasher et al., 2011).

Prevalence of loose cigarettes may be reduced through effective implementation and enforcement of COTPA provisions banning the sale of loose cigarettes. Thus, the qualitative part (specific aim 3) of this research aimed to understand the perceptions of key stakeholders regarding the ban on the loose cigarette sale in India. Varvasovszky and Brugha (2000) define stakeholders as “actors who have an interest in the issue under consideration, who are affected by the issue, or who – because of their position –

have or could have an active or passive influence on the decision making and implementation processes" (Varvasovszky & Brugha, 2000). Core constructs (knowledge, interest, position, power) that guided our examination of stakeholders' perceptions were adapted from the health policy implementation framework developed by Balane and colleagues (2020) (Balane et al., 2020). Knowledge has been defined in terms of stakeholders' understanding and knowledge of the health policy in consideration (Balane et al., 2020). Interest has been defined as perceived impact and motivation of the stakeholders in implementing the health policy in consideration in their own organization (Balane et al., 2020). Balane and colleagues (2020) defined power as the potential ability of the stakeholder to influence or affect policy implementation (Balane et al., 2020). Finally, position was operationally defined as whether the stakeholder opposes, supports, or was neutral about implementing the policy in consideration (Balane et al., 2020). All four constructs intersect with one another. Knowledge and awareness levels about the policy in consideration was linked to the level of interest. Stakeholders who had limited/no knowledge about the policy may be perceived as less interested in implementing the policy in their organization. That pointed to the opportunity of measuring stakeholders' interest and stakeholders' knowledge together. Further, stakeholders' interest was linked to stakeholders' position. Stakeholders' motivations and perceived impact of the policy controls stakeholders' position of supporting, opposing, or being neutral about policy implementation. For the last possible intersection between power and position, the framework suggests that there was more value in analyzing power (potential power based on resources) and position

(actual exercise of power ascertained by stakeholders' actions) separately as it would give an opportunity to identify those stakeholders who have high potential power but were not putting sufficient efforts in implementing the health policy. These constructs informed my conceptualization and data collection efforts to understand the implementation and enforcement of COTPA provisions regarding the ban on the sale of loose cigarettes and bidis. Based on this conceptualization, lower levels of knowledge, interest, and power, and weak support from the stakeholders should lead to poor implementation and monitoring of loose cigarette and bidi sales ban and thus increase loose cigarette sale and purchase. A complete list of the domains to be studied for each of the four characteristics has been provided in the "measures" section of the next chapter.

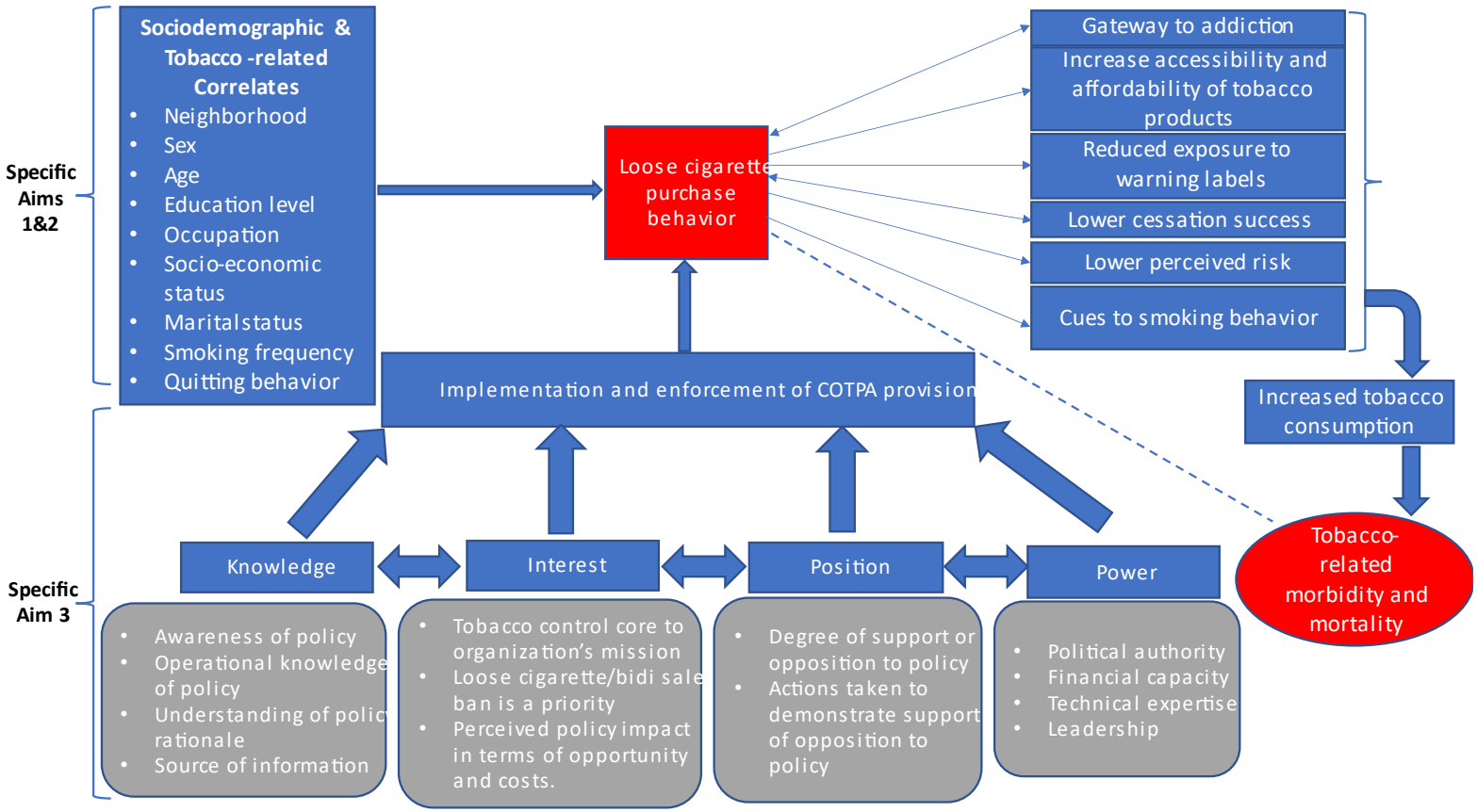

Figure 2.1: Conceptual framework guiding mixed-methods study on loose cigarette use

CHAPTER 3

RESEARCH DESIGN AND METHODS

Overview of research design

This research work employed a mixed-methods design that involved data from the third wave (2018-19) of the Tobacco Control Policy (TCP) Evaluation Project India survey and qualitative data from a stakeholder analysis, which involved smokers, tobacco vendors, policymakers, implementers, and law enforcement officials, regarding the loose cigarette and bidis sale ban in India. The TCP dataset was analyzed to determine the prevalence, correlates, sources, and prices paid for loose cigarette and bidi purchase in India and to examine the association between cigarette and bidi purchase behavior (loose vs pack) and HWL exposure and responses. Findings from the in-depth interviews served a dual purpose: (1) evaluated the existing loose cigarette and bidi sale ban in Mumbai, and (2) identified the implementation barriers and facilitators in Delhi, where loose cigarette and bidi sale ban was not implemented. I obtained all the required approvals for the study protocol and documents from the University of South Carolina (Pro00120549) and partner's (IRB00007340; FWA00019699) Institutional Review Boards prior to secondary data analysis and primary data collection.

Study sample

For specific aims 1 and 2, I had requested for the 2018-19 administration of the TCP Evaluation Project India survey from the Healis Sekhsaria Institute for Public Health and the University of Waterloo. TCP India survey data is part of the larger International Tobacco Control (ITC) Policy Evaluation Project (ITC Project, 2021) that has conducted 180 waves of cohort surveys in 31 countries. The TCP India Project has conducted three rounds of prospective cohort surveys of both tobacco users and non-users aged 15 years and above in four Indian states including Maharashtra, West Bengal, Bihar, and Madhya Pradesh. The most recent third wave of the TCP Evaluation Project India, the data source for specific aims 1 and 2, was carried out between July 2018 to December 2019, and included 8046 participants. Of those participants, 1097 smoked tobacco users (those who smoke cigarettes and/or bidis), and 1848 mixed tobacco users (those who smoke both cigarettes and/or bidis and smokeless tobacco) were considered for the analysis. Current tobacco smokers were asked about their last purchase whether they had purchased cigarettes or bidis in loose or in packs / bundles. The final analytic sample included those who reported having purchased smoked tobacco (either loose or in pack/bundle) at their last purchase. A total of 643 tobacco users reported having bought cigarettes for themselves (either loose or in pack or carton) at their last purchase, and 730 reported having bought bidis for themselves (either loose or a bundle) at their last purchase.

For specific aim 3, study sample included cigarette smokers (who had purchased loose cigarettes at least once in the last 30 days), tobacco vendors (permanent tobacco

shops, small tobacco kiosks, street vendors, and grocery stores), and policymakers, implementers, and law enforcement officials. Policymakers, implementers, and law enforcement officials included all the personnel who were authorized to enforce the provisions of Sections 6 and 7 of the COTPA act. I also interviewed officials from the state, national, and international foundations/non-governmental organizations who were directly involved in tobacco control. A list of all the stakeholders as authorized by the COTPA is presented in Table 3.1:

Table 3.1: List of stakeholders authorized to enforce the COTPA provisions.

Authorized persons to enforce sections 6 and 7
Vice Chancellor or Director or Procter or Principal or Headmaster or In-charge of an Educational Institution.
Assistant Labor Commissioner from the Department of Labor.
All officers of the rank of Sub- Inspector in State Food and Drug Administration from the Department of Food and Drugs
All officers of the rank of Inspectors from the Department of Education.
All Police officers of the rank of Sub- Inspector of Police and above.
Municipal Health Officers.
Representatives of Panchayati Raj Institutions (Chairperson or Sarpanch or Panchyat Secretary).
District Program Manager or Finance Manager - District Health Society (National Rural Health Mission).

Civil Surgeon or Chief Medical Officer at District Hospital or Medical Officer at Primary Health Centre (PHC).
Block Development Officer, Block Extension Educator (BEE).
Director or Joint Director Department of Health, and Department of Education in the State Government.
Nodal Officers of State and District Tobacco Control Cell under National Tobacco Control Program.
All officers of the level of Superintendent and above from the Department of Revenue.
Officials from Department of Home Affairs.

Study setting

TCP Evaluation Project India data was collected from the urban and rural areas of four Indian states including Maharashtra, Bihar, West Bengal, and Madhya Pradesh. Data was collected in 2018-19 before Maharashtra implemented a ban on the sale of loose cigarettes in 2020. Primary data collection for the stakeholder analysis was conducted in two Indian urban cities: one where loose cigarette and bidi sale was banned, and one where loose cigarette and bidi sale was not banned. Mumbai, a city in the western part of India, had banned the sale of loose cigarettes and bidis, and Delhi, a city in the northern part of India, and the national capital of India was yet to implement the ban. Both the cities were diverse with respect to their geographic location and

tobacco use prevalence. Smoking prevalence in Mumbai, Maharashtra, as per the second round (2016-17) of Global Adult Tobacco Survey (Tata Institute of Social Sciences et al., 2018), was the least among all Indian states at 3.8%, whereas smoking prevalence in Delhi (11.3%) was higher than the national average (10.7%).

Recruitment

Recruitment was conducted primarily for specific aim 3 that included multiple stakeholder groups, including smokers, vendors, policymakers, implementers, and law enforcement officials. Healis Sekhsaria Institute of Public Health, our collaborator in India, assisted and advised in recruiting policy implementers and law enforcement officials through their established connections. Policymakers, implementers, and law enforcement officials were either visited in their offices or were reached out via emails, telephone calls, and professional social media platforms, such as LinkedIn. I interviewed a combined total of 26 individuals who were associated with the implementation of tobacco control provisions in Mumbai and Delhi and included officials from the government departments, such as the Department of Health, Department of Police, Food and Drug Administration, Municipal Corporation Department, heads of educational institutions, and officials from the state, national, and international non-governmental organizations.

To interview tobacco vendors and smokers, I developed a recruitment/walking protocol which was followed in both the cities. Within each city, based on discussions with in-country partners, economically and socially diverse neighborhoods were

selected. Within each identified neighborhood, more distinctive neighborhoods such as tourist places, university areas, urban villages, shopping malls, prominent landmarks, public or private schools, metro stations, shopping complexes, prominent government buildings, hospitals, commercial office places, etc. were further identified. Following a systematic walking protocol around each identified distinctive neighborhood, I recruited four types of tobacco vendors: permanent tobacco shops, small tobacco kiosks, street vendors, and grocery stores. To ensure that the vendors sold loose cigarettes, I observed from a distance if the vendor provided loose cigarettes to any customer. I interviewed 13 vendors from Delhi and 15 vendors from Mumbai.

Loose cigarette/bidi smokers were primarily identified at the tobacco shops that were visited for recruiting vendors (Latkin et al., 2013). After completing the recruitment and interview procedure with the vendor, I observed customers that bought loose cigarettes/bidis from the vendor. If any customer purchased a loose cigarette/bidi and smoked near the vendor's shop, I would approach them and invite them to participate in the study. In addition to recruiting smokers from tobacco shops, I also used a snowball sampling approach (Parker, Scott, & Geddes, 2019) where after having interviewed a participant, I asked them to recommend others, they knew who smoked cigarettes and/or bidis. The recommended participants were later reached out and were asked if they had purchased loose cigarette/bidi at their last purchase or in the last 30 days, to determine if they met the inclusion criteria. I interviewed 15 smokers from Delhi and 13 smokers from Mumbai.

Measures

Measures for specific aims 1 and 2

Demographic and tobacco-related covariates

Sociodemographic variables were assessed on the TCP India survey by asking questions regarding participant's age, sex, neighborhood (urban/rural), marital status, level of education, and occupation. Level of education was categorized as "illiterate", "literate, no formal education", "up to primary school", "middle school", "secondary school", "graduate", "postgraduate degree", and "above post graduate degree". I re-coded education into three levels – low, moderate, and high. Participant's primary occupation was categorized into "professional, technical, and related workers", "administrative, executive, and managerial workers", "clerical and related workers", "sales workers", "service workers", "farmers, fisherman, hunters, and related workers", "craft and related trades", "plant and machine operators", "elementary occupations", "student", "currently have no job", and "housewife". I re-coded occupation into being employed in an organized sector, being employed in an unorganized sector, and not employed.

Tobacco-related covariate included smoking frequency, which was measured by asking "*On average, how often do you smoke cigarettes/bidis*: less than once a week, once a week, twice a week, 3-5 times a week, every day or almost every day, and more than once a day". The first four categories were coded as "non-daily" smoking, and the last two categories were coded as "daily" smoking.

Cigarette/bidi purchase behavior

Cigarette/bidi purchase behavior was measured by asking "*The last time you bought cigarettes/bidis for yourself, did you buy them as loose (single) cigarettes, by the pack, or by the carton?*" Questions that followed type of purchase included "How many loose (single) cigarettes/bidis did you buy?", "How much did you pay for one loose cigarette/bidi?", and "How much did you pay for all loose cigarettes?"

Health warning label response – Noticing warning labels

Exposure to health warning labels was measured by asking "In the last 30 days, how often have you noticed warning labels on cigarette/bidi packages?". Response options included "Whenever I smoke cigarettes/bidis", "Often", "Once in a while", "Never", and "Don't know".

Health warning label response – Reading or looking closely at warning labels

Respondents were asked "In the last 30 days, how often have you read or looked closely at the warning labels on cigarette/bidi packages?". Response options included "Regularly", "Often", "Once in a while", "Rarely", "Never", and "Don't know".

Health warning label response – Forgoing a cigarette/bidi

Respondents were asked "In the last 30 days, have the warning labels stopped you from having a cigarette/bidi when you were about to smoke one?", and the response categories included "Many times", "Once in a while", "A couple of times", "Never", and "Don't know".

Health warning label response – Thinking about the harms of cigarette/bidi smoking

This measure was assessed by asking "To what extent do the warning labels on cigarette/bidi packages make you more likely to think about the health risks of smoking cigarettes/bidis?" with the response categories, "A lot", "A little", "Not at all", and "Don't know".

Health warning label response – Thinking about quitting smoking

Finally, respondents were asked "To what extent do the warning labels on cigarette/bidi packages make you more likely to quit smoking cigarettes/bidis?". Response categories included "A lot", "A little", "Not at all", and "Don't know".

Quit attempts and intentions

Quit attempts were examined by asking respondents if they had ever made a serious attempt to stop smoking cigarettes/bidis in the past (Yes/No). Quit intentions were assessed by asking "Are you planning to quit smoking cigarettes (1) within the next month (2) within the next 6 months (3) sometime in the future, beyond 6 months (4) not planning to quit, and (5) don't know".

Guiding constructs for specific aim 3

Measures for the stakeholder analysis were adapted from the health policy implementation framework developed by Balane and colleagues (2020) (Balane et al., 2020). A detailed description of the four constructs including operational definition, main domains and sample questions is provided in Table 3.2.

Table 3.2: List of guiding constructs and domains adapted from (Balane et al., 2020) for specific aim 3

Construct	Operational Definition	Domains	Sample Questions
Knowledge	Stakeholders' knowledge and understanding of the policy	1. Awareness of policy 2. Operational knowledge of policy 3. Understanding of policy rationale 4. Source of information	Q1. What is your awareness of the policy ban on sale of loose cigarettes and bidis in your state? Q2. What do you think about the ban on selling loose cigarettes and bidis? Q3. What kind of information or evidence are you aware of that shows whether or not the policy ban is/will be effective?

Interest	Stakeholder's motivations and perceived impact of policy implementation to their own organization.	1. Tobacco control core to organization's mission 2. Loose cigarette and bidi sale ban is a priority for organization 3. Perceived policy impact in terms of opportunities and costs to the stakeholder	Q1. In your opinion, what are the potential barriers that you could face in implementing and enforcing the policy ban? Q2. In your opinion, what are the facilitators/strengths that you have for effective policy implementation and enforcement? Q3. Why do you think that banning the sale of loose cigarette/bidis is a public health priority?

Power	The potential ability of the stakeholder to affect policy implementation	1. Political authority - Direct: Derived from hierarchy, legal mandate, regulatory regimes. - Indirect: Ability to create incentives and constraints for other actors. 2. Financial capacity: Possession and control of financial resources 3. Technical expertise: Technical capacity to	Q1. What types of resources do you have or might need to be able to effectively implement and enforce the ban on loose cigarette/bidi sale? Q2. How confident are you that you will be able to implement/enforce the policy ban? Q3. What kind of technical expertise do you have for generating and disseminating implementation findings?

		produce, interpret, and disseminate knowledge and information 4. Leadership - Ability to build partnerships, motivate other stakeholders and/or shape opinion for or against policy implementation. - Personal attributes of individuals within the organization which can include charismatic	Q4. What types of support do you have from the local, state, or national bodies for policy implementation and enforcement?

		authority, personal commitment, and motivation	
Position	Whether the stakeholder supports, opposes or is neutral about policy implementation	1. Degree of support or opposition to policy expressed through use of potential power (sources of power) 2. Actions taken to demonstrate support or opposition to policy	Q1. How have you contributed so far in reducing the prevalence of loose cigarette in your area? Q2. What influence do you have to be able to effectively implement and enforce the proposed policy ban?

Data collection tool

For specific aims 1 and 2, the data from the TCP Evaluation Project India was collected in four Indian states including Maharashtra, Bihar, West Bengal, and Madhya Pradesh. Surveys were conducted face to face with respondents aged 15 years and above in both urban and rural areas of the four states. A total of 8046 respondents were surveyed for the third wave of the TCP Evaluation Project India data.

For specific aim 3, three open-ended semi-structured interview guides were developed for conducting in-depth interviews with the three stakeholder groups – smokers, tobacco vendors, and policymakers, implementers, and law enforcement officials. Interview questions for smokers primarily focused on understanding reasons for purchasing loose cigarettes/bidis, awareness regarding the ban on the sale of loose cigarettes and policy implementation status (for smokers in Mumbai), thoughts on the necessity of banning loose cigarettes, and the perceived impact of the policy ban. Interview questions for vendors focused on reasons why individuals purchased loose cigarettes, preference for selling loose/packed cigarettes, awareness regarding the ban on the sale of loose cigarettes and policy implementation status (for vendors in Mumbai), and how would the policy ban impact the vendor, and customer's buying behavior. Finally, the interview guide for policymakers, implementers, and law enforcement officials that comprised of 20 questions explored their knowledge, awareness, and understanding of the policy ban on the sale of loose cigarettes; role in tobacco control; reasons for purchasing loose cigarettes; perceived impact of the policy;

how they had contributed / might contribute to its implementation and enforcement; and barriers and facilitators for effectively implementing and enforcing the policy.

Data Management

For specific aims 1 and 2, I used Microsoft Excel to clean the secondary dataset received from the University of Waterloo and Healis Sekhsaria Institute of Public Health. I kept the data for participants who had self-reported themselves as exclusive smokers and mixed users. I then deleted the data for non-users and quitters. Finally, I maintained the variables of interest and deleted those not to be used in the analysis. The final dataset comprising 643 current cigarette smokers and 730 current bidi smokers was analyzed using SPSS 28.0 (IBM Corp.).

For specific aim 3, I used the NVivo 14 qualitative software (QSR International) to organize the interview transcripts from different stakeholders.

Data Analysis

For specific aims 1 and 2, I conducted a secondary analysis of the most recent third wave of the TCP Evaluation Project India data, which is a prospective cohort survey of participants aged 15 years and above. For both aims 1 and 2, analysis was conducted using SPSS version 28 (IBM Corp.).

For specific aim 1, descriptive analysis (frequencies, percentages) was conducted to calculate the prevalence of loose cigarettes and bidis, prices paid for loose cigarettes and bidis, and the type of vendor where the last purchase was made. Crosstabulations

were performed to calculate the prevalence of purchasing loose cigarettes and bidis among key subgroups. I also ran Chi-square tests to determine if there were any differences in the types of vendors from whom respondents bought their last cigarette/bidi and compared it at the neighborhood level (urban vs rural). Finally, I build crude and adjusted logistic regression models separately for cigarettes and bidis in which purchase behavior (loose vs pack/bundle) was regressed on socio-demographic factors, tobacco use patterns (i.e., non-daily/daily; smoked tobacco only/mixed use), having ever tried to quit cigarette/bidi smoking (yes/no), and intentions to quit cigarette/bidi smoking in the next six months (yes/no).

For specific aim 2, I performed descriptive analysis (crosstabulations, frequencies, percentages) between purchase behavior (loose vs pack/bundle) and HWL variables (noticing HWLs; reading or looking closely at WLs; forgoing a cigarette/bidi because of HWLs; thinking about the health risks of smoking because of HWLs; and thinking about quitting smoking cigarettes/bidi because of HWLs). I conducted ordinal regression analysis and models were fit separately for cigarette and bidis, whereby HWL variables were regressed on purchase behavior. All models were adjusted for age, sex, education, smoking frequency, and intentions to quit. Data from the qualitative interviews conducted with smokers was also analyzed to answer specific aim 2. I did a thematic analysis for the qualitative data which is explained in the next section.

For specific aim 3, I analyzed the data from in-depth interviews by performing a thematic analysis. First, all the interview recordings were translated from regional Indian languages to English by a professional transcription service provider based in India. I

then reviewed all the 82 transcripts to ensure no information was missed from the interviews. Based on the three interview guides, I developed three preliminary codebooks to guide the analysis of the transcripts. Two of my committee members and I independently coded three individual transcripts (one from each stakeholder group) keeping the preliminary codebook as a reference. We met to discuss the codes and the meanings of each code to further refine the preliminary codebook. After this initial analysis, I uploaded all the remaining transcripts into NVivo 14 (QSR International), a qualitative software for organizing and interpreting qualitative data. As each additional transcript was being reviewed, I followed an open coding process where I did a line-by-line analysis and added new codes to the existing codebook based on newly identified codes (Corbin & Strauss, 2014). Once open coding was completed and all transcripts were individually coded, I followed an axial coding process where I made meaningful connections between the codes that were developed in the open coding process (Miles & Huberman, 1994). Codes were then organized and grouped into common themes for interpretation. Using a constant comparison method, I also examined the emergent themes from the axial coding process across stakeholder groups (Boeije, 2002). I stopped the analysis when no additional themes and categories were emerging, meaning data saturation was reached (Saunders et al., 2018).

CHAPTER 4

RESULTS

4.1 Manuscript 1

Prevalence and correlates of single-unit / loose cigarette and single-unit / loose bidi purchase in India: Findings from the Tobacco Control Policy India Project[1]

[1]Sakhuja, M., Thrasher, J.F., Macauda, M.M., Hebert, J.R., Pednekar, M.S., Gupta, P.C., Fong, G.T., & Friedman, D.B. To be submitted to *Tobacco Control.*

Abstract

Background: Easy access to loose smoked tobacco (loosies) among minors and disadvantaged groups may promote smoking initiation and addiction. This study aims to determine prevalence, sources, prices, and correlates of loose cigarette and bidi purchase among Indian smokers.

Methods: Data from the 2018-19 Tobacco Control Policy (TCP) India survey were analyzed, limiting the analytic sample to those who reported buying either loose/packed cigarettes (n=643) or loose/bundled bidis (n=730) at their last purchase. The prevalence of purchasing loose cigarettes and bidis was calculated, including among key subgroups. Chi-square tests were run to determine differences in types of vendors for purchase behavior (loose vs pack). Crude and adjusted logistic regression models were fit separately for cigarettes and bidis, whereby purchase behavior (loose vs pack/bundle) was regressed on socio-demographic factors, tobacco use patterns (i.e., non-daily/daily; smoked tobacco only/mixed use), having ever tried to quit cigarette/bidi smoking (yes/no), and intention to quit cigarette/bidi smoking in the next six months (yes/no).

Results: Most respondents were male (98.3%), married (86.1%), from urban neighborhoods (71.4%), had low education (62%), smoked daily (81.3%) and exclusively (72.3%), had no intention to quit in the next 6 months (93.9%), and had never made a quit attempt (81%). About 75% of smokers, who purchased cigarettes for themselves at their last purchase, reported having bought them loose; only about 12% smokers who purchased bidis for themselves at their last purchase bought loose bidis. More than 80%

of loose cigarette and bidi purchases were made from tobacco stores and small tobacco kiosks. In adjusted logistic models, non-daily smokers [adjusted odds ratio (OR)=9.36], smokers with low education level (OR=1.86), and smokers who had ever made a quit attempt (OR=2.30) were more likely to purchase loose cigarettes, and exclusive smoked tobacco users were less likely (OR=0.56) than mixed product users to purchase loosies. In adjusted models for loose bidi purchase, females (OR=2.99), smokers from urban neighborhoods (AOR=5.54), non-daily smokers (OR=2.47), and unemployed smokers (vs smokers in unorganized sector (OR=0.43)) were more likely to purchase loose bidis.

Conclusions: Most cigarettes purchased were in the form of loosies and the prevalence was higher among disadvantaged populations with lower educational attainment and with no employment. The high prevalence of loosie purchases calls for adoption and enforcement of a complete ban on the sale of loosies as a potential strategy to reduce smoking initiation and consumption.

Introduction

Cigarettes and bidis are the most commonly consumed combustible tobacco products in India (World Health Organization). In contrast to a cigarette, which is a roll of processed and cut tobacco leaves enclosed in a thin paper, a bidi is made of unprocessed tobacco and hand-rolled in tendu leaves (type of leaf used for wrapping bidis). About 11% of Indian population smoke tobacco in the form of cigarettes or bidis, where 4.0% are current cigarette smokers, and 7.7% are current bidi smokers (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences).

The World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) recommends demand and supply reduction measures to decrease tobacco prevalence, including Article 16 that recommends banning the sale of loose tobacco products such as cigarettes and bidis (International Legal Consortium at the Campaign for Tobacco-Free Kids, 2020). Loose cigarette and loose bidi sale refers to the sale of individual cigarette/bidi sticks which are taken out from their commercial pack (usually of 10 or 20) and then sold individually. Cigarettes are sold loose in many low- and middle-income countries such as India, Bangladesh, Brazil, Thailand, Uruguay, Vietnam, Guatemala, Mexico, and Philippines (de Ojeda et al., 2012; Elf et al., 2013; Kostova et al., 2014) and in the lower socio-economic status neighborhoods of developed countries such as the United States (Baker et al., 2015; Latkin et al., 2013; Stillman et al., 2007; Stillman et al., 2014). The purchase and availability of loose

cigarettes has increased in some low-and-middle income countries, like Mexico (Hall et al., 2015).

Sale of loose cigarettes and loose bidis is highly prevalent in the unregulated and informal tobacco markets of India. Majority of the cigarettes sold and purchased in India are loose cigarette sticks (Chaturvedi et al., 2017; Kostova et al., 2014). As per the 2016-17 Global Adult Tobacco Survey (GATS) in India, about 67% of cigarette smokers, and 17% of bidi smokers purchased loose cigarettes and bidis, respectively, at their last purchase (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). Lal and colleagues (2015) found that of all cigarettes sold in India, nearly 75% were sold loose (Lal et al., 2015).

Loose cigarette and bidi sale in the unregulated Indian market is widely accepted as a key factor in promoting the tobacco epidemic in India (Reddy & Gupta, 2004; Yadav et al., 2020). Community-based cross-sectional studies among tobacco vendors in India have found that 93% of tobacco vendors reported selling loose cigarettes, whereby 60% of tobacco vendors selling loose cigarettes were located in urban neighborhoods (Goel et al., 2021).

Goel and colleagues (2021) found that 7.3% of vendors selling loose cigarettes sold tobacco products to minors, and 2.5% of loose cigarette vendors were themselves minors. This widespread availability of loose cigarettes and bidis allows minors and disadvantaged population groups to purchase loose tobacco products without having to purchase the whole pack, and thus makes tobacco products more affordable to

purchase. Studies conducted among youths have pointed to the affordability of loose cigarettes, meaning smokers found it less expensive to pay for loose cigarette sticks, even if loose sticks were sold at a higher price (compared to what they would have cost per unit when sold as a whole pack) (Stillman et al., 2007; Stillman et al., 2014).

There is inconclusive evidence regarding how the purchase of loose cigarettes is related to quitting behavior. Some studies with youth smokers found linkage between purchase of loose cigarettes and frequent daily smoking (Stillman et al., 2007), whereas other studies found loose purchase to be linked with non-daily smoking (Sacks et al., 2012). Evidence from other countries suggest that prevalence and easy access to loose cigarettes encourages smoking and lowers the odds of making quit attempts (Baker et al., 2015). Even though smokers have reported purchasing loose cigarettes to be able to cut down their cigarette consumption (Hall et al., 2015; Smith et al., 2007; Thrasher et al., 2011), there is evidence that smokers who lived in a neighborhood where loose cigarettes were easily accessible were less likely to make an attempt to quit cigarette smoking and were more likely to switch back to smoking (Hall et al., 2015).

Most studies have focused on the purchase of loose smoked tobacco products have been conducted with youth smokers and it is unclear what correlates are associated with loose purchase of smoked tobacco products among adult Indian smokers and whether loose purchase is associated with quitting behavior. This study, therefore, aims to examine the prevalence and correlates of loose cigarette and loose bidi purchase among Indian adult cigarette and bidi users and also examine the sources, and prices paid for loose cigarettes and loose bidis.

Methods

Data

Data were obtained from the 2018-19 administration of the International Tobacco Control Policy Evaluation Project in India (TCP India), an international collaborative effort of 31 countries aimed to assess the impact of tobacco control policies among adult tobacco users. Data for the third wave (2018-19) of the TCP India project were collected from the urban and rural neighborhoods of four Indian states: Bihar, Madhya Pradesh, Maharashtra, and West Bengal (ITC Project, 2021). A total of 8046 respondents were part of the third wave of data collection, which included smokers, smokeless tobacco users, mixed tobacco users, quitters, and non-users. Because cigarettes and bidis are the most sold loose smoked tobacco products, only smokers and mixed tobacco users were considered for the analytic sample of this study. Smokers comprised individuals who only used smoked tobacco, including cigarettes and/or bidis. Mixed tobacco users comprised of individuals who consumed both smoked tobacco (cigarettes and/or bidis) and smokeless tobacco.

Sample

Respondents who were younger than 18 years of age were excluded, resulting in a sample of 2945 tobacco users that included 1097 (37.2%) smoked tobacco users and 1848 (62.8%) mixed tobacco users. Current tobacco smokers were asked about their last purchase whether they had purchased cigarettes or bidis in loose or in packs / bundles. The final analytic sample included those who reported having purchased smoked

tobacco (either loose or in pack/bundle) at their last purchase. A total of 643 tobacco users reported having bought cigarettes for themselves (either loose or in pack or carton) at their last purchase, and 730 reported having bought bidis for themselves (either loose or a bundle) at their last purchase. Of the final analytic sample of 1373 tobacco users, 992 (72.3%) were smoked tobacco users and 381 (27.7%) were mixed tobacco users.

Measures

Purchase behavior

The main dependent variable was purchase behavior for cigarettes or bidis. Respondents were asked to answer the question "The last time you bought cigarettes/bidis for yourself, did you buy them as loose (single) cigarettes/bidis, or by the pack/bundle or carton?" Responses were coded as buying either loose cigarettes or bidis (1) or a pack/bundle or carton (0). Those who reported having bought loose cigarettes or bidis also were asked how many units of loose cigarettes or bidis they had bought and how much they paid per unit for cigarettes or bidis. Participants also were asked where they had purchased most recently, and responses were categorized into street vendors, small tobacco kiosks, grocery stores, and tobacco stores.

Socio-demographic correlates

Respondents were asked to report their sex, age, marital status, education level, and occupation. Neighborhood (urban/rural) from where the respondent belonged was also coded. Age was recoded into four categories: 18 – 30, 31 – 40, 41 – 50, and 51 years

and older. Marital status was categorized into those who were married, those who were single and those who were widowed or divorced. Those who were illiterate or had no formal education or had completed primary or middle school were categorized as having a low education level. Those who had completed secondary school were categorized as having a moderate education level. Finally, those who had at least an undergraduate degree or higher were categorized as having a high education level. Occupation was recoded into those employed in organized sectors, those employed in unorganized sectors, and those who were unemployed. Organized sectors included individuals who were professional / managerial / clerical / sales / service workers. Individuals engaged in farming, crafts or related trades, plant or machine operators, or other elementary occupations were all categorized as working in unorganized sectors.

Tobacco-related correlates

Tobacco-related correlates included tobacco use status, smoking frequency, if the smokers had ever made any quit attempts, and if smokers intended to quit cigarette/bidi smoking in the next six months. For tobacco use status, we coded for smoked tobacco users and mixed tobacco users. For smoking frequency, smokers were categorized into daily and non-daily smokers. Smokers also responded if they had ever made any attempt to quit cigarette/bidi smoking (yes/no), and if they intended to quit cigarette/bidi smoking in the next six months (yes/no).

Statistical analysis

Analysis was conducted using SPSS, version 28. Descriptive analysis (frequencies, percentages) was conducted to calculate prevalence of loose cigarettes and bidis and the type of vendor where the last purchase was made. Crosstabulations were performed to calculate the prevalence of purchasing loose cigarettes and bidis among key subgroups. Chi-square tests were used to determine if there were any differences in the types of vendors from whom respondents bought their last cigarette/bidi and comparing it at the neighborhood level (urban vs rural). Crude and adjusted logistic regression models were fit separately for cigarettes and bidis in which purchase behavior (loose vs pack/bundle) was regressed on socio-demographic factors, tobacco use patterns (i.e., non-daily/daily; smoked tobacco only/mixed use), having ever tried to quit cigarette/bidi smoking (yes/no), and intention to quit cigarette/bidi smoking in the next six months (yes/no).

Results

Sample characteristics

The sample comprised almost all males (98.3%) with an average age of 41.4 years (see Table 4.1). Most (86.1%) respondents were married; 71.4% were from urban neighborhoods; and 62% had low educational attainment. An almost equal number of respondents were employed in organized (39.8%) and unorganized sectors (40.7%), and 19.5% were unemployed. More than two thirds (72.3%) were exclusive smoked-tobacco users and 81.3% were daily smokers. Eighty-one percent of respondents had never

made an attempt to quit cigarette/bidi smoking and 93.9% reported having no intentions to quit cigarette/bidi smoking in the next six months.

Prevalence of loose cigarette and loose bidi purchase

Among cigarette users, 74.3% reported purchasing loose cigarettes, whereas only 11.8% of those who last purchased bidis purchased them as loosies. The average number of individual cigarette and bidi stick purchased were 2 and 4 respectively, and the average price per individual cigarette and bidi stick paid was INR 7 (~ $0.085) and INR 1.20 (~ $0.014), respectively. About two-thirds of cigarette users who reported loose cigarette purchase were in the age groups 18 – 30 years (35.6%) and 31 – 40 years (31.8%), and majority of loose cigarette purchase was made by those who had low (46%) and moderate (34.7%) education levels. Of those who reported having bought loose bidis, 94.2% were male; 94% had low to moderate education level; and 89.5% were from urban neighborhood. The prevalence of loose cigarette and loose bidi purchase among key subgroups is presented in Table 4.1.

Table 4.1: Prevalence of loose purchase among key subgroups and sample characteristics

Characteristics, n (%)	**Cigarettes**		**Bidis**		**Total Sample**
	Loose	**Pack/Carton**	**Loose**	**Bundle**	
Sex, n (%)					
Female	4 (0.8%)	1 (0.6%)	5 (5.8%)	13 (2%)	23 (1.7%)
Male	474 (99.2%)	164 (99.4%)	81 (94.2%)	631 (98%)	1350 (98.3%)
Age groups, n (%)					
18 – 30	170 (35.6%)	47 (28.5%)	12 (14%)	119 (18.5%)	348 (25.3%)
31 – 40	152 (31.8%)	45 (27.3%)	18 (20.9%)	161 (25%)	376 (27.4%)
41 – 50	86 (18%)	42 (25.5%)	24 (27.9%)	195 (30.3%)	347 (25.3%)
51+	70 (14.6%)	31 (18.8%)	32 (37.2%)	169 (26.2%)	302 (22%)
Marital status, n (%)					
Married	391 (82.3%)	139 (84.2%)	69 (80.2%)	580 (90.1%)	1179 (86.1%)
Other	16 (3.4%)	5 (3%)	9 (10.5%)	38 (5.9%)	68 (5%)
Single	68 (14.3%)	21 (12.7%)	8 (9.3%)	26 (4%)	123 (9%)
Education level, n (%)					
Low	219 (46%)	63 (38.7%)	60 (71.4%)	504 (78.5%)	846 (62%)
Moderate	165 (34.7%)	55 (33.7%)	19 (22.6%)	107 (16.7%)	346 (25.3%)
High	92 (19.3%)	45 (27.6%)	5 (6%)	31 (4.8%)	173 (12.7%)
Occupation, n (%)					
Unemployed	49 (17.3%)	12 (15%)	17 (32.7%)	78 (20.2%)	156 (19.5%)
Unorganised sector	89 (31.4%)	27 (33.8%)	18 (34.6%)	192 (49.7%)	326 (40.7%)
Organised sector	145 (51.2%)	41 (51.3%)	17 (32.7%)	116 (30.1%)	319 (39.8%)
Neighborhood, n (%)					
Urban	399 (83.5%)	143 (86.7%)	77 (89.5%)	361 (56.1%)	980 (71.4%)
Rural	79 (16.5%)	22 (13.3%)	9 (10.5%)	283 (43.9%)	393 (28.6%)

Tobacco status, n (%)					
Smoked users	316 (66.1%)	128 (77.6%)	62 (72.1%)	486 (75.5%)	992 (72.3%)
Mixed users	162 (33.9%)	37 (22.4%)	24 (27.9%)	158 (24.5%)	381 (27.7%)
Smoking frequency, n (%)					
Non-daily	170 (35.7%)	10 (6.1%)	17 (20%)	59 (9.2%)	256 (18.7%)
Daily	306 (64.3%)	155 (93.9%)	68 (80%)	584 (90.8%)	1113 (81.3%)
Quit attempts ever, n (%)					
Yes	92 (19.7%)	39 (23.6%)	14 (16.3%)	113 (17.7%)	258 (19%)
No	374 (80.3%)	126 (76.4%)	72 (83.7%)	527 (82.3%)	1099 (81%)
Intention to quit in next 6 months, n (%)					
Yes	41 (8.8%)	7 (4.3%)	7 (8.1%)	26 (4.2%)	81 (6.1%)
No	424 (91.2%)	155 (95.7%)	79 (91.9%)	599 (95.8%)	1257 (93.9%)

Location of last purchase

We used Pearson chi-square tests to assess different types of vendors from whom people purchased their last cigarette or bidi and compared those who bought loose cigarette/bidi with those who bought packs/bundles. For cigarettes, there was no statistically significant difference between vendor types. Tobacco stores (65.6%) and small kiosks (22.9%) were the top sources for purchasing loose cigarettes. Respondents also reported to have purchased loose cigarettes from street vendors (9.2%) and grocery stores (2.1%). For bidis, there was a significant association ($p = 0.046$) between vendor types and purchase behavior (loose vs bundle). Most loose bidis were purchased from a tobacco store followed by small kiosks. We also adjusted for neighborhood to determine any significant differences across vendor types between urban and rural neighborhoods. No statistically significant differences were found for loose cigarette or loose bidi purchase across vendor types at the neighborhood level. However, the majority (> 80%) of the loose cigarette and loose bidi purchases across all vendor categories were in urban neighborhoods.

Correlates of purchasing loose cigarettes

Crude and adjusted logistic regression models were fit to assess the characteristics associated with purchasing loose cigarettes (see Table 4.2). Purchase behavior (loose (1) vs pack/carton (0)) was regressed on socio-demographic correlates (sex, age, marital status, education level, occupation, neighborhood), and tobacco-related correlates (tobacco status, smoking frequency, having ever made any quit

attempt, and intention to quit in the next six months). In the crude model, smokers with lower education level (OR 1.70; 95% CI 1.08 to 2.67), non-daily smokers (OR 8.61; 95% CI 4.42 to 16.76), and mixed tobacco users (compared to smoked tobacco users, OR 0.56; 95% CI 0.37 to 0.85), were all more likely to purchase loose cigarettes.

In the adjusted logistic regression model, smokers with lower education levels (AOR 2.35; 95% CI 1.05 to 5.25), those who smoked less regularly (non-daily smokers) (AOR 8.61; 95% CI 3.34 to 22.15), and those who had ever made an attempt to quit cigarette smoking (AOR 2.30; 95% CI 1.02 to 5.20), were all more likely to purchase loose cigarettes than their counterparts.

Table 4.2: Crude and adjusted logistic regression models for purchasing loose cigarettes at last purchase

Independent Variables	**Crude OR (95% CI)**	**P**	**Adjusted OR (95% CI)**	**P**
Sex				
Female	1.38 (0.15 – 12.47)	0.77	0.14 (0.00 – 4.53)	0.27
Male	ref		Ref	
Age				
18 – 30	1.60 (0.94 – 2.72)	0.08	1.33 (0.48 – 3.70)	0.57
31 – 40	1.49 (0.87 – 2.56)	0.14	1.02 (0.37 – 2.82)	0.96
41 – 50	0.90 (0.51 – 1.58)	0.73	0.54 (0.20 – 1.47)	0.23
51+	ref		Ref	
Marital status				
Married	0.86 (0.51 – 1.47)	0.60	0.93 (0.39 – 2.22)	0.87
Other	0.98 (0.32 – 3.02)	0.98	4.23 (0.40 – 44.73)	0.23
Single	ref		Ref	
Education level				
Low	**1.70 (1.08 – 2.67)**	**0.02**	**2.35 (1.05 – 5.25)**	**0.03**
Moderate	1.46 (0.91 – 2.34)	0.10	1.69 (0.77 – 3.69)	0.18
High	ref		ref	
Occupation				
Organised sector	0.86 (0.42 – 1.78)	0.69	1.01(0.39 – 2.59)	0.97
Unorganised sector	0.80 (0.37 – 1.73)	0.58	0.99 (0.35 – 2.80)	0.99
Unemployed	ref		ref	
Neighborhood				
Urban	0.77 (0.46 – 1.29)	0.33	1.16 (0.50 – 2.64)	0.72
Rural	ref		ref	

Tobacco status Smoked tobacco user Mixed tobacco user	 0.56 (0.37 – 0.85) ref	 **0.006**	 0.52 (0.25 – 1.08) ref	 0.08
Smoking frequency Non-daily Daily	 **8.61 (4.42 – 16.76)** ref	 **<0.001**	 **8.61 (3.34 – 22.15)** ref	 **<0.001**
Quit attempts ever Yes No	 0.79 (0.51 – 1.21) ref	 0.29	 **2.30 (1.02 – 5.20)** ref	 **0.04**
Intention to quit in next 6 months Yes No	 2.14 (0.94 – 4.87) ref	 0.07	 1.56 (0.43 – 5.65) ref	 0.49

Correlates of purchasing loose bidis

In the crude logistic regression model (see Table 4.3) for bidi smokers, females (OR 2.99; 95% CI 1.04 to 8.62), smokers whose marital status was single (compared to married, OR 0.38; 95% CI 0.16 to 0.88), those who were unemployed (compared to those employed in unorganized sectors, OR 0.43; 95% CI 0.21 to 0.87), smokers from urban neighborhoods (OR 6.70; 95% CI 3.30 to 13.61), and non-daily smokers (OR 2.47; 95% CI 1.36 to 4.48) were positively associated with the odds of purchasing loose bidis. In the adjusted models, smokers from urban neighborhoods (AOR 5.18; 95% CI 2.12 to 12.66) and non-daily smokers (AOR 3.76; 95% CI 1.66 to 8.50) had higher odds of purchasing loose bidis than their counterparts.

Discussion

This is the first study that uses the most recent TCP India (2018-19) data to examine the prevalence, sources, prices, and correlates of loose cigarette and loose bidi purchase among adult Indian smokers. Study findings suggest an overall high prevalence of loose cigarette purchase (74.3%) among Indian adult smokers. This is similar to but higher than the GATS 2016-17 results, which estimated 67% of cigarette smokers bought loose cigarettes at their last purchase (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences).

Table 4.3: Crude and adjusted logistic regression models for purchasing loose bidis at last purchase

Independent Variables	**Bivariate OR (95% CI)**	**P**	**Multivariate OR (95% CI)**	**P**
Sex				
Female	2.99 (1.04 – 8.62)	**0.04**	0.94 (0.14 – 5.98)	0.94
Male	ref		ref	
Age				
18 – 30	0.53 (0.26 – 1.07)	0.07	0.59 (0.15 – 2.20)	0.43
31 – 40	0.59 (0.31 – 1.09)	0.09	1.01 (0.38 – 2.67)	0.97
41 – 50	0.65 (0.36 – 1.14)	0.13	0.83 (0.36 – 1.89)	0.66
51+	ref		ref	
Marital status				
Married	0.38 (0.16 – 0.88)	**0.02**	0.50 (0.11 – 2.33)	0.38
Other	0.77 (0.26 – 2.25)	0.63	1.42 (0.24 – 8.09)	0.69
Single	ref		ref	
Education level				
Low	0.73 (0.27 – 1.97)	0.54	0.61 (0.13 – 2.85)	0.53
Moderate	1.10 (0.38 – 3.18)	0.85	0.85 (0.17 – 4.26)	0.84
High	ref		ref	
Occupation				
Organised sector	0.67 (0.32 – 1.39)	0.28	0.78 (0.29 – 2.10)	0.63
Unorganised sector	0.43 (0.21 – 0.87)	**0.02**	0.94 (0.36 – 2.45)	0.91
Unemployed	ref		ref	

Neighborhood Urban Rural	**6.70 (3.30 – 13.61)** ref	**<0.001**	**5.18 (2.12 – 12.66)** ref	**<0.001**
Tobacco status Smoked tobacco user Mixed tobacco user	0.84 (0.50 – 1.39) ref	0.49	1.16 (0.52 – 2.58) ref	0.71
Smoking frequency Non-daily Daily	**2.47 (1.36 – 4.48)** ref	**0.003**	**3.76 (1.66 – 8.50)** ref	**0.001**
Quit attempts ever Yes No	0.90 (0.49 – 1.66) ref	0.75	0.89 (0.36 – 2.19) ref	0.80
Intention to quit in next 6 months Yes No	2.04 (0.85 – 4.85) ref	0.10	1.72 (0.47 – 6.34) ref	0.41

We found that the prevalence of purchasing loose bidis was lower (~12%). The majority of smokers in the study reported having bought a bundle versus a loose bidi perhaps because of the significantly lower costs of purchasing a whole bundle of bidi vs a pack of cigarettes. This points to the issue of unequal taxation on tobacco products in India. Taxes in India vary by the type and characteristics of tobacco products. Different tax rates make some tobacco products affordable for smokers, such as the case of bidis (DNA India, 2022). Bidis are taxed at a lower rate compared to cigarettes, thus making bidis more affordable than cigarettes; therefore driving bidi prevalence higher in India compared to cigarettes (Kostova et al., 2014).

Tobacco vendors from which smokers bought loose cigarettes or loose bidis were generally the same. Tobacco stores and small kiosks were the top sources of loose cigarettes in addition to street vendors and grocery stores. Most of these vendors operate within the informal economy and sell tobacco products illegally without possessing a license to sell tobacco products. The informal economy comprises the majority of the Indian economy and is mostly unregulated, which poses serious challenges in the implementation of tobacco control policies. Our study found that the majority of all vendor types from whom smokers last purchased loose cigarettes and bidis were in urban neighborhoods, similar to a cross sectional study conducted among tobacco vendors in India that documented high prevalence of loose cigarettes with tobacco vendors in urban areas (Goel et al., 2021). Analysis of GATS 2016-17 India survey also found that prevalence of loose cigarette purchase was higher in urban neighborhoods (Singh, Dogra, Kumar, & Kumar, 2017a). Studies conducted in high-

income countries such as the United States also found high prevalence of the sale of flavored and loose cigarettes in urban communities (Laws, Whitman, Bowser, & Krech, 2002).

We found that disadvantaged population groups, such as smokers with lower education levels and smokers who were unemployed (in the crude model), were more likely to purchase loose cigarettes and loose bidis respectively. Our findings are consistent with the studies conducted in high-income countries and low-middle income countries. Azagba and colleagues (2020) found that being employed and having some college education were inversely associated with purchasing loose cigarettes among US adult smokers, meaning those who did not have employment and those who had low education levels were more likely to purchase loose cigarettes (Azagba et al., 2020). Likewise, Thrasher and colleagues (2009) found that smokers in Mexico who had higher income levels and those who had greater than a high school education (compared to those who had less than middle school level education) had lower odds of purchasing loose cigarettes. However, education lost significance in the adjusted model (Thrasher et al., 2009). These findings support the notion that the prevalence of loose tobacco products potentially keeps disadvantaged population groups, such as those with lower incomes and lower education levels, smoking.

Consistent with other studies (Singh et al., 2017a), we also found that non-daily cigarette and bidi smokers had higher odds of purchasing loose cigarettes and bidis. Because of the availability of loose cigarettes in the neighborhood, non-daily smokers could choose to buy loose cigarettes or bidis whenever they had an urge to smoke,

instead of buying a pack to maintain supplies. Evidence from Mexico suggests that smokers reported an urge to smoke whenever they saw sale of loose cigarettes and such urges were positively associated with odds of purchasing loose cigarettes (Thrasher et al., 2011). It is therefore important to reduce the availability of loose cigarettes through proper vendor licensing and through a curb on sale of loose cigarettes which would limit the number of vendors selling tobacco products in a neighborhood and aid those who smoke occasionally from having sudden urges to smoke.

In our adjusted model for correlates of purchasing loose cigarettes, those who had ever attempted to quit cigarette smoking were more likely to purchase loose cigarettes. This means that despite having tried to quit sometime in the past, smokers still reported having purchased loose cigarettes. This may mean that availability of loose cigarettes in the neighborhood might have been the reason for smokers to relapse. Even though occasional smokers may intend to quit in the future, loose cigarette prevalence may keep them away from making successful quit attempts for longer periods. Findings are consistent with the studies conducted in high-income and low-and-middle income countries. Guillory and colleagues (2015) found that young adults in the US who intended to quit or had attempted to quit in the past were more likely to purchase loose cigarettes (Guillory, Johns, Farley, & Ling, 2015). A mixed-methods study among adult smokers in four Mexican cities reported that a sighting of loose cigarette sale acts as a cue to smoking and prevents smokers from successfully quitting (Thrasher et al., 2009). Another study conducted in the US in an African-American population also found that prevalence of loose cigarettes in the neighborhood was a risk factor for relapse (Phan et

al., 2021). Findings in this study strongly support the notion that loose cigarette/bidi prevalence acts as cues to smoking, evokes cravings to smoke and restricts Indian adult smokers from making successful quit attempts as these measures have not been assessed in the third wave of the TCP Evaluation India survey. We recommend adding environmental / neighborhood-level factors (such as how often do smokers see single cigarettes for sale in their neighborhood, and how often it evokes a desire to smoke) as measured in other ITC surveys, such as ITC Mexico, in the future waves of TCP India data collection to better understand the relationship between loose purchase and quitting behavior and whether loose tobacco prevalence acts as a cue to smoking and evokes cravings among Indian adult smokers.

There are limitations to this study. The cross-sectional nature of the analytical data makes it challenging to determine causality between study variables. To establish causality, longitudinal analysis in which temporal relationships can be established will be required to answer whether those who purchase loose cigarettes and bidis actually quit at higher rates than those who purchase packs. It also will be important to examine the relapse behavior to be able to confidently say that loose cigarette and bidi prevalence restricts smokers from successfully quitting (Hall et al., 2015). Similar studies also need to be conducted with youth to determine if loose tobacco prevalence encourage smoking initiation among minors. Finally, findings from our study cannot be generalized to the whole of India as the data were collected from four Indian states only, or to female smokers, because most of the smokers in the analytical sample were males.

Despite these limitations, this study provides clear evidence that there is widespread prevalence of loose tobacco purchase in India which makes it easily accessible and affordable for disadvantaged population groups, such as those with low education levels and those who are unemployed, to consume tobacco products. It also touched upon the notion that loose cigarette prevalence may act as cue to smoking and potentially restricts smokers from successfully quitting. Future work should aim to assess causality between loose consumption and quitting behavior by including environmental / neighborhood level variables.

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4.2 Manuscript 2

Examining the association between cigarette/bidi purchase behavior (loose vs pack) and health warning label exposure and responses: Findings from the Tobacco Control Policy (TCP) India Project and In-depth interviews with smokers[2]

[2]Sakhuja, M., Friedman, D.B., Macauda, M.M., Hebert, J.R., Pednekar, M.S., Gupta, P.C., Fong, G.T., Cohen, J.E. & Thrasher, J.F. To be submitted to *BMJ Global Health.*

Abstract

Background: Sale of loose cigarette/bidi defies the purpose of displaying health warning labels (HWL) on cigarette packs/bidi bundles by diminishing their visibility and legibility. This study examines the association between purchase behavior (loose vs pack/bundle) and health warning label (HWL) exposure and responses among Indian adult smokers.

Methods: Data from the 2018-2019 India Tobacco Control Policy (TCP) Project survey and 28 in-depth interviews with Indian smokers were analyzed. The analytic sample for the TCP survey was limited to those who reported buying either loose/packed cigarettes (n = 643) or loose/bundled bidis (n = 730) at their last purchase. Ordinal regression models were fit separately for cigarette and bidis, whereby HWL variables (noticing HWLs; reading / looking closely at HWLs; forgoing a cigarette/bidi because of HWLs; thinking about health risks of smoking; and thinking about quitting smoking cigarettes/bidi because of HWLs) were regressed on purchase behavior. Participants for in-depth interviews were recruited following a standardized protocol and included those from Delhi and Mumbai who had purchased loose cigarettes at least once in the last 30 days. Interview data were analyzed using thematic analysis.

Results: Survey findings indicated that about 75% of cigarette users and 12% of bidi users reported having bought loose sticks at their last purchase. Those who purchased loose cigarettes or bidis noticed HWLs less often. Purchase behavior was unassociated with other HWL responses for cigarettes. Interview findings indicated that exposure to

HWL was lower among those who primarily purchased loose cigarettes. In addition to keeping the cigarette boxes out of the sight of smokers, small tobacco vendors did not post mandatory health warnings at the point of sale, further reducing potential exposure to health warnings. Smokers also reported not paying attention to HWLs as they were already aware of the warning messages.

Conclusion: Main themes emerging from the interviews aligned with the survey findings. Those who purchased loose cigarettes noticed HWLs less often. Loosie purchase decreased the likelihood of delivering constant reminders about harmful effects of smoking through reduced exposure, thus reducing HWLs effectiveness.

Introduction

Tobacco use is one of the top causes of preventable deaths in India, accounting for 1.3 million deaths every year (Jha et al., 2008; World Health Organization). Pictorial health warning labels (HWLs) on all tobacco products are a promising strategy for reducing the mortality and morbidity associated with tobacco use. Article 11 of the World Health Organization Framework Convention on Tobacco Control recommends that every country should mandate that at least 50% area of tobacco product packages should depict large, clear, and rotating HWLs and messages that convey the harmful effects of tobacco use (International Legal Consortium at the Campaign for Tobacco-Free Kids, 2020). Since 2014, the Cigarettes and Other Tobacco Product Act in India requires that at least 85% area of the front and back of tobacco product packs must have pictorial HWLs (Campaign for Tobacco-Free Kids, 2020; Chahar et al., 2019).

HWLs are low-to-no cost and have broad, population-level reach for communicating health information with both smokers and non-smokers (Cecil et al., 1996; David Hammond, 2011). Cigarette packages are an effective medium for reaching smokers who purchase cigarette packs because they are potentially exposed to HWLs every time they reach for a cigarette (Slade, 1997; Wakefield et al., 2002). Moreover, exposure to warning labels are also associated with higher risk perceptions, increased knowledge and awareness regarding harms from tobacco use, and has a greater potential to enable smokers to quit smoking (Brewer et al., 2016; Fathelrahman et al., 2009; David Hammond et al., 2007; Noar et al., 2016).

The availability of loose cigarettes potentially reduces the effectiveness of HWLs as people who use loose cigarettes do not carry them around in the packaging on which health warning labels are printed (Latkin et al., 2013; Peiris, 2018; Thrasher et al., 2011; Yadav et al., 2020). According to the 2016-17 Global Adult Tobacco Survey (GATS) in India, about 67% of cigarette smokers and 17% of bidi smokers purchased loose cigarettes and bidis, respectively, at their last purchase (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). Lal and colleagues (2015) found that of all cigarettes sold in India, nearly 75% were sold loose (Lal et al., 2015).

However, no study of which we are aware has evaluated whether purchase of loose cigarettes and bidis reduces HWL effectiveness. This mixed methods study examines associations between cigarette/bidi purchase behavior and self-reported responses to HWLs among Indian adult smokers.

Methods

Data sources

This paper uses data from two sources. First, data from the 2018-19 India administration of the Tobacco Control Policy (TCP) Evaluation Survey were used (ITC Project, 2021). Data were collected from the rural and urban areas of four Indian states: West Bengal, Maharashtra, Madhya Pradesh, and Bihar (ITC Project, 2021). Multi-stage cluster sampling of households was done to get representative samples at the level of the four states (ITC Project, 2021). Respondents in the 2018-19 wave of TCP data

collection included smokers, smokeless tobacco users, mixed-tobacco users, quitters, and non-users (ITC Project, 2021). Second, as part of a qualitative project focused on the implementation and enforcement of the ban on the sale of loose cigarettes and bidis, data from in-depth interviews of people who smoke were also used in this study. Individuals were recruited and interviewed using a standardized protocol in two Indian cities, Delhi, and Mumbai. Users who purchased loose cigarettes/bidis were reached out at the points of sale across different regions in both the cities and were interviewed either outside, near the point of sale where they were approached, or online via zoom. Snowball sampling was also used where interviewed individuals were asked to recommend other potential participants (Parker et al., 2019).

Study sample

A total of 1373 respondents from the TCP survey data were included in the analytic sample. Of those, 643 were cigarette users who reported buying either loose or packaged cigarettes at their last purchase, and 730 were bidi users who reported buying either loose or bundled bidis at their last purchase. Qualitative interviews were conducted with 28 individuals in Mumbai (where the ban on the sale of loose cigarettes was implemented) and Delhi (where the ban was not implemented) who had purchased loose cigarettes at least once in the last 30 days.

Measures

The main independent variable was purchase behavior, determined by asking individuals to report whether they purchased cigarettes/bidis in loose or in

packs/bundles at their last purchase. Dependent variables included variables related to HWL effectiveness including noticing HWLs (whenever I smoke cigarettes/often/once in a while/never, and don't know); reading or looking closely at WLs (regularly, often, and once in a while/rarely/never, and don't know); forgoing a cigarette/bidi because of HWLs (many times, and once in a while/a couple of times/never, and don't know); thinking about the health risks of smoking because of HWLs (a lot/a little/not at all, and don't know); and thinking about quitting smoking cigarettes/bidi because of HWLs (a lot/a little/not at all, and don't know).

Interview questions focused on assessing smokers' knowledge and awareness regarding the policy ban on the sale of loose cigarettes and bidis and how the policy has/might impact their smoking behavior. Individuals were also asked to describe their most recent experience of visiting a tobacco vendor to purchase loose cigarettes for which they were probed how often did they notice warning labels at the vendor's establishment and on cigarette packs at the time of purchase. Their perceptions regarding exposure to warning labels have been analyzed in this study.

Data analysis

We performed descriptive analysis (crosstabulations, frequencies, percentages) between purchase behavior (loose vs pack/bundle) and HWL variables (noticing HWLs; reading or looking closely at WLs; forgoing a cigarette/bidi because of HWLs; thinking about the health risks of smoking because of HWLs; thinking about quitting smoking cigarettes/bidi because of HWLs). We conducted ordinal regression analysis and models

were fit separately for cigarette and bidis, whereby HWL variables were regressed on purchase behavior. All models were adjusted for age, sex, education, smoking frequency, and intentions to quit. Regression analysis was performed using SPSS V.28 (IBM Corp.).

Thematic analysis was performed for the qualitative interviews and all data were organized using the NVivo® qualitative software (QSR International). A preliminary codebook was developed to guide the analysis. Three authors independently coded one transcript to further refine the codebook. Line-by-line analysis was conducted on each additional transcript and new codes were added to the existing codebook (Corbin & Strauss, 2014). Codes were then organized and grouped into common and meaningful themes for interpretation (Miles & Huberman, 1994).

Results

Sample characteristics

Survey respondents

The sample consisted mainly of males (98.3%); married (86.1%) individuals, those from urban neighborhoods (71.4%), and those with low educational attainment (62%). About 72.3% were exclusive tobacco smokers; 81.3% smoked daily; 81% had never attempted to quit cigarette / bidi smoking; and 94% had no intentions to quit cigarette / bidi smoking in the next six months. Slightly less than two-thirds (74.3%) of cigarette users reported purchasing loose cigarettes at their last purchase, whereas only 11.8% of bidi users purchased loose bidis at their last purchase.

Interview participants

The mean age of the 28 individuals (15 from Delhi and 13 from Mumbai) interviewed was 26.4 years (SD = 6.2 years). All purchased cigarettes at their last purchase and 85.7% (n=24) purchased them loose. About 61% smoked daily; 89% were exclusive smoked-tobacco users; and 71.4% had no intentions to quit smoking in the next six months. Most were male (67.9%) and had high education attainment (64.3%).

Survey findings

Association between HWL responses and purchase behavior

About 15% of cigarette users (vs 7.6% of bidi users) reported never noticing HWLs on cigarette packages. Thirty-four percent of cigarette users (vs 41.2% of bidi users) reported never reading or looking closely at HWLs on cigarette packages; 81.5% cigarette users (vs 73.2% bidi users) reported that the HWLs never stopped them from having a cigarette when they were about to have one. Crosstabulations between HWL responses and purchase behavior (pack vs loose) for both cigarettes and bidis are presented in Table 4.4.

Table 4.4: Crosstabulations between HWL responses and purchase behavior for cigarettes and bidis.

Measure	Cigarette users		Bidi users	
	Pack (n=165)	Loose (n=478)	Pack (n=644)	Loose (n=86)
In the last 30 days, how often have you noticed WL on cigarette/bidi packages?				

Whenever I smoke cigarettes/bidis	25.9%	12.0%	20.6%	13.0%
Often	52.5%	49.2%	57.6%	52.1%
Once in a while	10.5%	22.6%	14.4%	23.9%
Never/Don't know	11.1%	16.2%	7.3%	10.9%
In the last 30 days, how often have you read/looked closely at WL on cigarette/bidi packages?				
Regularly / Often / Once in a while	33.3%	32.8%	36.0%	46.3%
Rarely	34.0%	32.6%	20.7%	34.1%
Never/Don't know	32.6%	34.6%	43.3%	19.5%
In the last 30 days, have the WL stopped you from having a cigarette/bidi when you were about to have one?				
Many times / Once in a while	8.0%	6.0%	15.1%	13.0%
A couple of times	11.7%	12.1%	10.8%	23.9%
Never/Don't know	80.2%	81.9%	74.2%	63.0%
To what extent do the WL make you more likely to think about health risks of smoking?				
A lot	11.7%	15.5%	14.2%	30.4%
A little	37.0%	41.7%	45.6%	52.2%
Not at all/Don't know	51.2%	42.8%	40.2%	17.4%
To what extent do the WL make you more likely to quit smoking?				
A lot	8.7%	17.4%	14.5%	28.3%
A little	31.7%	33.3%	37.7%	43.5%
Not at all/Don't know	59.6%	49.2%	47.8%	28.3%

Individuals who purchased cigarette packs noticed HWLs more often compared to those who purchased loose cigarettes at their last purchase. Other HWL responses for cigarette smoking did not have any significant association with purchase behavior. Estimate values and 95% confidence intervals for association between HWL responses for cigarettes and purchase behavior are presented in Table 4.5.

Table 4.5: Ordinal regression models for HWL responses and cigarette purchase behavior

Variable		Estimate	Sig.	95% Confidence Interval
Noticed warning labels	Whenever I smoke cigarettes			
	Often			
	Once in a while			
	Never / Don't know (Ref.)			
Purchase behavior	Pack	-0.846	**<0.001**	-1.212 to -0.479
	Loose (Ref.)	-	-	-
Read / looked closely at warning labels	Regularly / Often / Once in a while			
	Rarely			
	Never / Don't know (Ref.)			
Purchase behavior	Pack	0.045	0.813	-0.331 to 0.421
	Loose (Ref.)	-	-	-
Forgoing a cigarette	Many times / Once in a while			
	A couple of times			
	Never / Don't know (Ref.)			
Purchase behavior	Pack	-0.162	0.513	-0.649 to 0.324
	Loose (Ref.)	-	-	-
Think about health risks of smoking	A lot			
	A little			

	Not at all / Don't know (Ref.)			
Purchase behavior	Pack	0.246	0.187	-0.119 to 0.611
	Loose (Ref.)	-	-	-
Think about quitting smoking	A lot			
	A little			
	Not at all / Don't know (Ref.)			
Purchase behavior	Pack	0.343	0.073	-0.032 to 0.719
	Loose (Ref.)	-	-	-

No association was found between purchase behavior and noticing HWLs on bidi bundles. Bidi pack purchasers also had an increased likelihood of not thinking about health risks of bidi smoking and quitting bidi due to HWLs on bidi packs. Estimate values and 95% confidence intervals for association between HWL responses for bidis and purchase behavior are presented in Table 4.6.

Table 4.6: Ordinal regression models for HWL responses and bidi purchase behavior

Variable		Estimate	Sig.	95% Confidence Interval
Noticed warning labels	Whenever I smoke bidis			
	Often			
	Once in a while			
	Never / Don't know (Ref.)			
Purchase behavior	Pack	-0.473	0.115	-1.061 to 0.115
	Loose (Ref.)	-	-	-
Read / looked closely at warning labels	Regularly / Often / Once in a while			
	Rarely			
	Never / Don't know (Ref.)			

Purchase behavior	Pack	0.519	0.103	-0.105 to 1.143
	Loose (Ref.)	-	-	-
Forgoing a cigarette	Many times / Once in a while			
	A couple of times			
	Never / Don't know (Ref.)			
Purchase behavior	Pack	0.286	0.386	-0.361 to 0.934
	Loose (Ref.)	-	-	-
Think about health risks of smoking	A lot			
	A little			
	Not at all / Don't know (Ref.)			
Purchase behavior	Pack	0.961	**0.001**	0.373 to 1.549
	Loose (Ref.)	-	-	-
Think about quitting smoking	A lot			
	A little			
	Not at all / Don't know (Ref.)			
Purchase behavior	Pack	0.673	**0.022**	0.096 to 1.250
	Loose (Ref.)	-	-	-

Qualitative Findings

In-depth interviews were conducted with loose cigarette users in two Indian states, Mumbai, and Delhi. Even though the policy ban on the sale of loose cigarettes in Mumbai was already proposed at the time of data collection, the implementation and awareness regarding the ban was poor and study participants reported no issues in accessing loose cigarettes in the city. We therefore present the results of both the cities together as there were no differences in accessing loose cigarettes. In the following sections, we have presented participant's perceptions about noticing HWLs on cigarette

packs and at the point of sale at the time of purchasing loose cigarettes. Exposure to the warning messages was dependent on type of purchase (loose vs pack), number of cigarettes purchased (one vs more than one), type of tobacco vendor (big tobacco shop vs small tobacco kiosk), and use of foreign-made cigarettes. We also present participants' reactions to noticing warning labels.

Noticing health warning labels at the time of purchase

Interview participants were asked if they were exposed to or noticed HWLs at the time of purchasing loose cigarettes. Exposure to the warnings was lower among those who primarily purchased loose cigarettes as they did not frequently notice warnings on cigarette packs as the vendor directly handed out single cigarette sticks in the respondent's hands rather than showing them the cigarette pack.

"*I would say, not very frequently because what happens is that the shop owner gives us the cigarette in our hands if I am buying one or two cigarettes. So, we don't get to touch the cigarette packet, so we don't get to see the label over it also.*"

It was reported that loose cigarettes were usually kept in separate containers which the buyers did not have access to and as a result did not get to notice HWLs on cigarette packs at the time of purchase.

"*No, I cannot see at that time. Obviously, if someone is buying one [cigarette] then he will not see the box. Sometimes it is there down in his drawers. So, he takes it directly*

from there and gives it to me. So, I cannot see the box."

"*He actually takes it out from the box and then gives it to us. He doesn't show that he is taking it out from the box in front of us. Usually, they have it in a container as such.*"

Smokers were aware that cigarette packs depicted health warnings. Even though the vendor opened the cigarette pack in front of the buyers to hand out loose cigarettes, buyers themselves tended not to notice health warnings on the cigarette packs at the time of purchase.

"*I think....I will tell him to give me an Indie Mint, so he just takes one packet, takes it out and gives it to me. I don't really notice what's written on the packet. I know what's written on the packet. But I don't really notice the health warning that's on them.*"

However, some participants also mentioned noticing HWLs on cigarette packs stating that the vendor took out the loose cigarette from the pack in front of them because of which they were able to notice both pictorial and text warnings.

"*Yeah, I mean, he pulled it out from a box. So obviously I saw that, like smoking kills and that graphic image of I don't know..... I don't even know what.*"

Exposure to HWLs was not just limited to cigarette packs. Participants also

reported noticing health warnings at and around the point of sale from where they purchased cigarettes. Buyers were able to notice warnings through warning boards that were put up at the vendor's establishment.

"*It is always visible, because if you go to a proper pan [tobacco] shop, they have this huge signboards,,,,,so suppose cigarette company is sponsoring him or something, they will put up the ad, there will be this statutory warning and stuff.*"

In addition to the warnings that the vendors are required to put up at their establishment, few cigarette users reported seeing pictorial warnings on cigarette packs that were on display inside the vendor's establishment and through the empty cigarette packs that were thrown out around the establishment.

"*Yes [could see health warnings], because he [the vendor] keeps everything on display, so you can clearly see that.*"

"*The used boxes that were empty, that were thrown out. They had those images.*"

Not all tobacco vendors put up statutory warnings inside their establishments or are able to display cigarette packs due to limited space inside their establishment. Participants who purchased cigarettes from small vendors such as street vendors or small tobacco kiosks usually did not get exposed to health warnings as those vendors

did not put up any statutory warnings.

"*No, street vendors do not put any warnings on their setup. Because late night vendors do not have at all, and not only this type, but then there are other people also who sell in the midnight like boost, coffee, and tea on their cycles, so they have this milk and tea in the thermos but then they carry cigarette packets in plastic bag.*"

"*So no, they have not displayed the packets anywhere because it is also a tea shop so they keep it in a drawer. It is not visible.*"

Participants mentioned that noticing HWLS on cigarette packs also depended on the number of loose cigarettes being purchased by the buyer. Those who bought multiple loose cigarettes did notice HWLs on cigarette packs as they tended to ask for an empty cigarette box in which they could keep secure their loose cigarettes.

"*Sometimes he even gives the six cigarettes in the box. We cannot keep it just like that. Cigarettes are very delicate. They break. So, he puts it in a box and gives it. It is obvious. I ask for six cigarettes and he puts them in the box and gives it to me. It is written on the box that tobacco causes cancer.*"

However, participants who preferred foreign made cigarette brands did not notice HWLs on cigarette packs at all as foreign brands do not have the mandatory

pictorial warnings on their cigarette packs.

"*Actually, the cigarettes that I smoke don't have any pictorial representation. It [pictorial warning] is not there on the Esse Lights box. They don't have that because it's a foreign brand. They have it written, like.. not in a very big way. It's written in a very tiny font, I should say.*"

"He took the box in front of me, but the picture was not there, so it was not seen clearly."

To reduce the exposure to health warning messages, tobacco vendors tried different tactics so that buyers could not read warning messages. Participants mentioned that the vendors would blur the warnings, decrease their size, or change the lighting around it so that it was not clearly visible.

"*It's like,,,,, so the thing is everybody reads it..... but it is so ignorant in that way that....they are placing the warnings with the tobacco company's advertisement.... like a big image of a cigarette is advertised and below that it is written "tobacco kills", nobody is going to focus on that, right!*"

"*Shopkeepers do hang them (warnings) but it is so dull, means where the warning is mentioned, they won't put a light next to it, so that people cannot see the warning,..... I have never noticed it, even if I had, nobody put warnings of big enough size.*"

"*But nobody notice that, they either blur the warning or make it dark, so that no one notices them. There is no sense of putting the warning, people do not pay attention to them.*"

Reactions to getting exposed to health warning labels on cigarette packs

Participants described an avoidance behavior regarding noticing HWLs. They mentioned that they tended to avoid seeing or noticing HWLs because they did get exposed to them frequently.

"*No, it does not really always happen that I get to view pictorial warnings, because like I said most of the times I smoke because I am stressed or like I really want to easen up. That's when I smoke. So, now I'm just used to seeing-seeing all of those things. So, like memory chooses to avoid it, rather than you know, keeping on watching it every now and then. So, that's what it is.*"

Even though participants avoided noticing HWLs, they were still aware of the message as a smoker who last bought a cigarette pack found the labels to be awful which made them think of the harmful effects of cigarette smoking.

"*It just makes you think that, you know, what if ….of course what they show is like very*

extreme but like at times they make me think that "can this really impact this bad?" but then I think, then we just end up ignoring that because for example liquor for that matter, we know that in the long run it does impact the liver but we still do. I think a part of us just becomes ignorant and we just start ignoring those because of course they are awful to look at. And I often try and flip the pack so that I don't see it but on the other side also it is there. So, I just put it in the bag. I don't just carry the entire box everywhere, every time. It is generally in the bag, I don't really see it all the time. So I think I have just had that ignored..... I think we are very self or we are very selective for that matter, I think all of us women we take in what we really want to hear or see and we tend to ignore the rest. So, I think that's something that I do now. But the thought that I told you has crossed my mind a couple of times but yeah."

Participants offered that HWLs on cigarette packs helped keep health messages vividly in the minds of the people who smoke. Even though purchase of loose cigarettes reduces the frequency of noticing HWLs, people who purchased loose cigarettes did get exposed to them at least once which kept the health message alive in their minds.

"*Yes, everyone knows, all get exposed to the warnings on the cigarette packet. If I have seen once, that there is a picture depicting cancer, that if we smoke cigarette, we can get cancer, now even if I go to purchase cigarettes 10 times and not get exposed to the warnings those 10 times, but I would still know that I can get cancer if I smoke. So, out of 10 times, people do get exposed at least once, that they can get cancer from it.*"

They believed that the purchase of loose cigarettes also decreased the likelihood of pictorial warnings delivering constant reminders about the harmful effects of cigarette smoking due to the reduced exposure.

"*If somebody has a box with him or her, if they are carrying the box with them, then that will act as a constant reminder to them. They would keep looking at it and think it's very ugly. Like if you see that poster (with pictorial warnings), it's very… you tend to feel disgusting when you see that. And then you tend to think that the same thing can happen with us as well. In loose cigarettes, yes, there is a difference. In that case you will see such a warning maybe just once max to max, and that too if the vendor takes it out from the cigarette pack in front of you.*"

Discussion

Survey findings and the findings from the qualitative interviews with smokers complement one another by highlighting that availability of loose tobacco products reduces the exposure to HWLs. Where survey findings highlighted that those who purchased loose cigarettes noticed HWLs less often, interview findings explained the specific mechanisms through which the exposure gets reduced such as packs not being visible, the avoidance behavior of the smokers, tobacco vendors not putting up statutory warnings at the point of sale, and demand and availability of foreign made cigarettes that do not carry the required HWLs on their cigarette packs.

We found that those who purchased loose cigarettes were less likely to be exposed to HWLs. To our knowledge, this is the first study that provides evidence that exposure to HWLs reduces due to the sale and purchase of loose cigarettes and explains the specific mechanisms through which the exposure gets reduced. For those who purchased bidi bundle at their last purchase, we found that they less often thought about the health risks of bidi smoking and quitting bidi due to HWLs on bidi packs. This can be attributed to the poor compliance to the HWL law on bidi in India. A recent study by Saraf and colleagues (2021) that examined the extent of compliance of HWLs on bidis in India found that none of the bidi packs were compliant with the law requirements (Saraf et al., 2021). Non-compliance issues pertained to non-standardized packaging, incomplete HWLs, poorly printed HWLs, and old HWLs (Saraf et al., 2021). Consistent with that, another study based in India found that about 94% of bidis were not compliant with the COTPA sections 7,8, and 9 meaning they either did not have warnings on both sides of the pack, or did not meet the minimum stipulated height and width requirement, or the language of the text warning was different than that of the pack (Mullapudi et al., 2021).

There has been an increasing prevalence of foreign made cigarettes which are sold illegally in India which not only reduces exposure to HWLs but also violates the provisions of the COTPA. Qualitative findings from our study found that those who were users of foreign made cigarettes never noticed HWLs as packs of foreign made cigarettes do not have HWLs on them as required by the Indian law. Findings are

consistent with other studies conducted in India. Chahar and colleagues (2019) found that there was a poor compliance to the sections 7,8, and 9 of COTPA among the foreign cigarette brands (Chahar et al., 2019). Only 11% of the foreign made cigarettes depicted pictorial health warnings on their cigarette packs, significantly reducing the exposure of foreign made cigarette users to HWLs (Chahar et al., 2019).

In addition to noticing HWLs on cigarette packs, interviewed participants also described noticing health warning messages at the point of sale as vendors were required by the government to put up statutory health warnings at the entrance of their establishments. Some participants reported seeing statutory warnings or pictorial health warnings on cigarette packs which were displayed inside big tobacco stores. Statutory warnings do not have the pictorial component and one can easily choose to ignore to read it depending on how direct or strong the text only warning is. Studies have shown that pictorial graphic warnings (compared to text only warnings) demonstrated more negative implicit attitudes among smokers (Macy, Chassin, Presson, & Yeung, 2016). However, one cannot rely on the fact that every point of sale or every vendor is depicting the warning, in the prescribed format, and is not masking it. As per the 2016-17 GATS India survey, about 48% of the current smokers purchased their last cigarette from a small tobacco kiosks or street vendors (Tata Institute of Social Sciences et al., 2018). Findings from our study indicate that vendors like street vendors and small tobacco kiosks did not put up any statutory warnings at their establishments nor did they display cigarette packs, thus reducing smoker's exposure to health warning messages. Our finding is consistent with the prior literature highlighting substantial

percentage of tobacco vendors displaying advertisement boards without health warnings (Goel et al., 2015) and a higher non-compliance to the presence of health warnings especially among small vendors (Joseph et al., 2021).

Even though the paper primarily focused on exposure to HWLs, exposure is also considered as a gateway to other effects of HWLs. Exposure influences warning reactions, knowledge and beliefs about cigarette smoking, and perceived effectiveness of the warnings (Francis, Hall, Noar, Ribisl, & Brewer, 2017). Those who purchase loose cigarettes are less likely to have complete knowledge of the harms of smoking. Elton-Marshall and colleagues (2018) found that smokers who purchased loose cigarettes (compared to packs) had lower knowledge about the health effects of smoking (Elton-Marshall, Wijesingha, Kennedy, & Hammond, 2018). With the plans to update the content of HWLs in India (Ministry of Health and Family Welfare, 2022), reduced exposure due to loose sale of cigarettes could deter the dissemination of new knowledge through the updated HWLs. Exposure generates various warning reactions and we found loose cigarette users described an avoidance behavior in which they ignored the health warnings because they were already exposed to them and did not like seeing them. Literature on warning avoidance is inconsistent. The Extended Parallel Process Model states the avoidance behavior as a defensive reaction which could deter quitting (Witte, 1992), whereas other studies have found that warning avoidance does not likely restrict cessation (Borland et al., 2009; David Hammond et al., 2004) and may be associated with more quit attempts (Brewer et al., 2019; Cho et al., 2016; Thrasher et al., 2016). However, interview participants described avoiding health warnings to be

able to continue with their smoking behavior. Finally, the purpose of HWLs is to increase the frequency of exposure so that they can generate firmer beliefs about the harms of smoking and aid in promoting smoking cessation (G. T. Fong et al., 2010; Hassan et al., 2008; Thrasher et al., 2007). Even though exposure to HWLs at least once makes the users aware of its content, the subsequent avoidance behavior fails to deliver constant reminders necessary for firmer beliefs about the harmful effects of cigarette smoking. Interview findings reveal that those who purchased loose were less likely to have beliefs about the chances that smoking will cause health related harms and about the seriousness of the threat, thus reducing the overall effectiveness of HWLs.

Limitations

This study has limitations. Survey findings cannot be generalized to the entire country as the survey was conducted in only four Indian states and is not nationally representative. Interviews with the smokers were conducted only in the urban neighborhoods of two metropolitan cities; so, qualitative findings cannot be generalized to the rural context or other cities/states. Most participants purchased loose cigarettes at their last purchase so no comparison could be made with pack purchasers who could potentially have more exposure to HWLs.

Conclusion

Our study provides evidence that purchase of loose cigarettes reduces the exposure to HWLs. Those who purchased bidi bundles were less likely to think about the harms of bidi smoking and think about quitting bidi smoking. Participants were generally aware of the content of HWLs and intentionally avoided seeing them. Loose cigarette

purchase reduced the opportunity to deliver constant reminders to smokers about the harmful effects of cigarette smoking due to reduced exposure. There is a need to strengthen laws around displaying warning labels on bidis and strictly implementing and enforcing the prohibition on selling loose cigarettes and adhering to the Section 7 of COTPA that recommends that all tobacco products should be sold intact in their commercial packs covered with pictorial health warnings. We also strongly recommend that strict efforts should be made to increase the awareness regarding the ban on the sale of loose cigarettes in Mumbai to be able to assess the true impact whether the loose cigarette users are less likely to be exposed to warning labels compared to only pack purchasers.

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4.3 Manuscript 3

"The ban is there, but it is not there": Perceptions of cigarette users and tobacco vendors regarding ban on the sale of loose cigarettes in India[3]

[3] Sakhuja, M., Macauda, M.M., Thrasher, J.F., Hebert, J.R., Pednekar, M.S., Gupta, P.C., Cohen, J.E. & Friedman, D.B. To be submitted to *Frontiers in Public Health.*

Abstract

Introduction: Prevalence of loose cigarettes in India violates Article 16 of the World Health Organization – Framework Convention on Tobacco Control that recommends banning the sale of loose cigarettes. This study aims to understand the perceptions of cigarette users and tobacco vendors regarding the ban on the sale of loose cigarettes in India.

Methods: Using a systematic recruitment and interview protocol, we interviewed cigarette users (n = 28) and tobacco vendors (n = 28) from two Indian cities, Mumbai (where the ban on the sale of loose cigarettes was implemented), and Delhi (where the ban was not implemented). We developed two open-ended, semi-structured interview guides. Interview questions focused on reasons for purchasing loose cigarettes, preference for buying and selling loose vs packs, thoughts on the necessity of banning loose cigarettes, and the perceived impact of the policy ban for vendors and cigarette users. We performed thematic analysis and used NVivo for organizing the transcripts.

Results: Main reasons for purchasing loose were financial constraints, social restrictions, and limiting cigarette consumption. Awareness regarding the ban in Mumbai was poor among both users and vendors. Those who were aware mentioned that the policy was not being implemented. Cigarette users reported that loose cigarettes were associated with smoking initiation, and prevented them from making successful quit attempts. Both users and vendors reported that a ban on loose cigarettes would reduce cigarette

consumption and promote quit attempts as it would not be possible for everyone to purchase packs.

Conclusion: Loose cigarettes were widely available in both the cities as users reported easy access. Awareness regarding the ban in Mumbai was poor among both users and vendors, implying inadequate enforcement efforts. A country-wide ban on the sale of loose cigarettes would prevent smoking initiation, and promote quit attempts among cigarette users.

Introduction

Tobacco consumption is attributed to 1.3 million deaths each year in India (Jha et al., 2008; World Health Organization) and about 11% of Indian population aged 15 years and above are current tobacco smokers (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). Despite several tobacco control provisions in India (Ministry of Law and Justice, 2003), availability of loose cigarette sale in the unregulated Indian markets continues to promote the tobacco epidemic in the country (Reddy & Gupta, 2004; Yadav et al., 2020).

Chaturvedi and colleagues (2017) found that the majority of cigarettes sold and purchased in India are in the loose form (Chaturvedi et al., 2017). According to the 2016-17 Global Adult Tobacco Survey (GATS) in India, about 67% of cigarette users reported having purchased loose cigarettes at their last purchase (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). Most tobacco vendors in India continue to sell loose cigarettes which have been taken out from their commercially packed cigarette box. A study conducted by Lal and colleagues (2015) to estimate the sale of loose cigarettes found that about 75% of total cigarettes sold in ten jurisdictions, representing the four regions of India, were in loose (Lal et al., 2015). Another cross-sectional study based in India found that 95.5% of the tobacco vendors reported selling loose cigarettes and that loosies were most frequently purchased by adult men and college students (Eshwari et al., 2020). Similarly, Goel and colleagues (2021) found that 93% of the tobacco vendors were selling loose cigarettes

and most of them were located in urban neighborhoods and sold tobacco products to minors (Goel et al., 2021).

Availability of loose cigarettes is significantly associated with the sale of tobacco products to minors, and thus potentially contributing as a gateway to addiction (Kuri-Morales et al., 2005). Smokers perceived loose cigarettes to be more affordable (per purchase) compared to the cost of the whole cigarette pack (Stillman et al., 2007; Stillman et al., 2014). Studies conducted among adult Mexican smokers found that a sight of loose cigarette sale acted as a cue to smoking and that the sale of loose cigarettes in the neighborhood was associated with smokers reporting cravings to smoke, which was found to be positively associated with the purchase and consumption of loose cigarettes (Thrasher et al., 2011; Thrasher et al., 2009).

Prevalence of loose cigarettes in the Indian markets contradicts Article 16 of the World Health Organization Framework Convention on Tobacco Control (WHO-FCTC) that recommends banning the sale of loose cigarettes (International Legal Consortium at the Campaign for Tobacco-Free Kids, 2020). Additionally, loose cigarettes also violate several central legislations in India such as the Central Excise Act, 1944, that imposes taxes on harmful goods on pro rata basis, the Legal Metrology Act, 2009, that prohibits sale of products without their commercial packaging, and Section 7 of the Cigarettes and Other Tobacco Products Act (COTPA), 2003 that requires 85% area of the cigarette packs be covered with health warning labels (Kapoor, Mehra, Yadav, Lal, & Singh, 2021). The most recent amendment by the Government of India to Section 7 of COTPA requires

that cigarettes/bidis and other tobacco products must be sold and purchased in their sealed, intact, and original packaging (Kapoor et al., 2021).

Following these amendments, many Indian states have banned loose cigarette sales (The Hindu, 2015; The Indian Express, 2020; Times of India, 2020; WHO Framework Convention on Tobacco Control Knowledge Hub, 2020; Yadav et al., 2020), whereas many of the remaining states that represent densely populated regions with high smoking prevalence are yet to implement the ban. Since India is now considering a national ban on the sale of loose cigarettes as per the recent recommendations of the Parliamentary Standing Committee on Health and Family Welfare to the Government of India (The Hindu, 2022), it becomes more important to understand perceptions of key stakeholders regarding the policy ban on the sale of loose cigarettes and generate evidence for policy effectiveness and implementation. This study, therefore, aimed to evaluate perceptions of cigarette users and tobacco vendors in two Indian cities, Mumbai, where the ban was already implemented, and Delhi, where the ban was not implemented – to not only evaluate the existing policy but also generate evidence for its implementation across the country.

Methods

Study setting

Two major urban cities were selected, one where sale of loose cigarette was banned (Mumbai), and one where sale of loose cigarette was not banned (Delhi). Within each city, based on discussions with in-country partners, we selected economically and

socially diverse neighborhoods. Within each identified neighborhood, we further identified more distinctive neighborhoods such as tourist places, university areas, urban villages, shopping malls, prominent landmarks, public or private schools, metro stations, shopping complexes, prominent government buildings, hospitals, commercial office places, etc., where recruitment and interview protocol were followed.

Operational definitions

Permanent tobacco shops: A shop enclosed in a permanent building structure which sells multiple types of tobacco products.

Small tobacco kiosks: A small shop, which is not enclosed in a permanent structure, rather built like a small booth made of aluminium/steel/tin with an open window, which sells cigarettes, bidis, pan masala, paan, candies, and mouth fresheners.

Street vendor: An individual who does not have a permanent place of business or an establishment, and primarily sells cigarettes, bidis, and pan masala on streets on a moving cart/vehicle or on foot.

Grocery store owners: A shop enclosed in a permanent building structure which sells grocery items, general items, cleaning supplies, and tobacco products.

Recruitment protocol for tobacco vendors

To recruit tobacco vendors who sold loose cigarettes and/or loose bidis in Mumbai and Delhi, a systematic protocol was followed. Our plan was to interview four different types of tobacco vendors: a) permanent tobacco shops, b) small tobacco

kiosks, c) street vendors, and d) grocery store owners. Within each distinctive neighborhood, we aimed to identify, recruit, and interview at least one vendor of each of the four types. MS, who was the primary data collector, visited the identified distinct neighborhood. On the first visit, MS explored the neighborhood by foot or by public/private conveyance to understand the area better and would also speak with locals like shop owners, pedestrians, or drivers of public transport to learn more about the neighborhood and the areas where commercial activities took place within and around that distinct neighborhood. On the next visit to that neighborhood, MS would arrive at a randomly chosen fixed point. From that fixed point, MS walked towards the area of commercial activity where multiple shops were present.

Facing towards the area of commercial activity, MS would first look for a permanent tobacco shop. If a permanent tobacco shop was present, MS approached the first available shop. Before initiating any discussion, MS observed from a distance, transactions between the vendor and customers. Observation was done to determine if the vendor was selling loose cigarettes or loose bidis to its customers, which was the inclusion criteria for tobacco vendors. Once inclusion criteria was met, MS followed the interview protocol described in the next section.

If that specific vendor did not agree to participate, MS looked for another nearest permanent tobacco shop within the same commercial area and approached the vendor in the same way as described above. If none of the permanent tobacco shop vendors agreed to participate, MS then looked for small tobacco kiosks within the same commercial area.

If a small tobacco kiosk was available, then MS would approach the vendor in the same way as described above, and if not, then MS would look for grocery store owners in the same commercial area. If no grocery store was found in the commercial area, then MS also travelled to a nearby residential area since grocery stores are usually located around residential colonies.

Since street vendors do not have a permanent location to do business and do not have a proper establishment like other vendor types, MS looked out for street vendors in all neighborhoods he visited. If any street vendor was identified and any other type of vendor was already interviewed from that neighborhood, MS still approached the street vendor for the interview since it was difficult to locate them because of their continuous mobility or small establishment structure.

If none of the vendor types were able to be interviewed, MS then travelled towards the other potential commercial area within that neighborhood. On reaching the second commercial area, MS would look for the first available permanent tobacco shop (if permanent tobacco shop vendor was not interviewed in the previous commercial area). However, if a permanent tobacco shop vendor was interviewed in the first commercial area, then MS looked for a small tobacco kiosk in the second commercial area. If a small tobacco kiosk was not found, MS then looked for a grocery store. MS followed this process until all four vendor types were interviewed or MS had covered four commercial areas in the identified distinct neighborhood. A similar process was followed in other distinct neighborhoods as well.

Interview protocol for tobacco vendors

If it was observed that the vendor did sell loose cigarettes and/or loose bidis, MS would then approach the vendor and spend considerable time building rapport before introducing anything about the research project. Once MS felt that the vendor was not hesitant in continuing the conversation, he then introduced himself as a doctoral student working on a research project focused on loose cigarettes. MS would then describe the purpose of the study and asked the vendor if he would like to participate in a brief conversation on the topic. If the vendor agreed, then he was asked for a suitable time to have a conversation. Those who agreed to participate either spoke at the same time or asked MS to come at a specific time depending on their availability and customer load. Before starting the interview, MS completed a brief quantitative survey described in the following section. All interviews were conducted in-person and outdoor at the vendor's shop and were audio-recorded after receiving consent from the vendor. Once the interview was over, MS himself completed an observational checklist described later. Finally, MS took pictures of the vendor's shop after getting permission from the vendor.

Survey instrument for vendors

The brief survey instrument included questions about vendor's age, type of store, and buying behavior of customers for cigarettes and bidis with five response options (only singles / mostly singles / singles and packs equally / mostly packs / only

packs). Vendors were also asked, “Of 100 daily customers, how many of them visited to purchase singles”.

Observational checklist for vendors

After the interview, MS observed and noted other items being sold by the vendor; whether tobacco products were displayed and if yes, whether pictorial warnings on those displayed products were clearly visible from the entrance of the shop; availability of smoking aids such as lighters, ashtrays; whether statutory warnings were present and if they clearly depicted the ill effects of tobacco; and whether the vendor advertised any tobacco product.

Recruitment protocol for smokers

Loose cigarette/bidi smokers were primarily identified at the tobacco shops that were visited for recruiting vendors. After completing the recruitment and interview procedure with the vendor, MS would observe customers that bought loose cigarettes/bidis from the vendor. If any customer purchased a loose cigarette/bidi and smoked near the vendor’s shop, MS would then approach the customer and introduce himself. MS then described the purpose of the research project and invited the individual for a brief interview. MS assured the individual it would be a brief conversation and that they did not need to answer any question with which they felt uncomfortable. Some agreed to be interviewed on the spot whereas others who could not participate immediately shared their contact number or email and asked to

schedule a later time for the interview. They were later reached out again via call or email to determine their availability.

In addition to recruiting smokers from tobacco shops, we also used a snowball sampling approach (Parker et al., 2019) where MS after having interviewed a participant asked them to recommend others, they knew who smoked cigarettes and/or bidis. The recommended participants were later reached out and were asked if they had purchased loose cigarette/bidi at their last purchase or in the last 30 days, to determine if they met the inclusion criteria.

Interview protocol for smokers

Smokers who agreed to participate on the spot were interviewed outdoors, somewhere near the vendor's shop where they were initially approached. Interviews with others were conducted online, via zoom. All interviews were audio recorded and consent was received from all the participants. Prior to the interview, participants answered a brief survey focused on capturing their socio-demographic information and their tobacco use status, such as smoking frequency, and quit intentions.

Data collection tools

Two open-ended semi-structured interview guides were developed for conducting interviews with smokers and vendors. Interview questions for smokers primarily focused on understanding reasons for purchasing loose cigarettes/bidis, awareness regarding the ban on the sale of loose cigarettes and policy implementation status (for smokers in Mumbai), thoughts on the necessity of banning loose cigarettes,

and the perceived impact of the policy ban. Interview questions for vendors focused on reasons why individuals purchased loose cigarettes, preference for selling loose/packed cigarettes, awareness regarding the ban on the sale of loose cigarettes and policy implementation status (for vendors in Mumbai), and how would the policy ban impact the vendor, and customer's buying behavior.

Data analysis

All audio files were organized in NVivo (QSR International), and thematic analysis was performed. A codebook was developed using the original interview guide and three authors independently coded one transcript each of smoker and vendor to further refine the preliminary codebook. Additional codes were added while reviewing every transcript line by line (Corbin & Strauss, 2014). Final codebook was analyzed, and codes were grouped together into meaningful themes (Miles & Huberman, 1994).

Results

We conducted 28 semi-structured, in-depth interviews with cigarette users and 28 interviews with tobacco vendors in Delhi and Mumbai. Participant characteristics for cigarette users are presented in Table 4.7, and participant characteristics for tobacco vendors are presented in Table 4.8. In the following sections, we present the findings comparing perceptions of cigarette users and tobacco vendors by three major themes: a) reasons for purchasing loose cigarettes; b) awareness of the policy and policy implementation status; and c) perceived impact of the policy.

Table 4.7: Cigarette users' characteristics (N = 28)

Variable	**N (%)**
City	
- Delhi	15 (53.6%)
- Mumbai	13 (46.4%)
Sex	
- Male	19 (67.9%)
- Female	9 (32.1%)
Education	
- Low	4 (14.3%)
- Moderate	6 (21.4%)
- High	18 (64.3%)
Occupation	
- Organized sector	12 (42.9%)
- Unorganized sector	5 (17.9%)
- Unemployed	7 (25%)
- Self-employed	4 (14.3%)
Marital status	
- Married	4 (14.3%)
- Unmarried	23 (82.1%)
- Divorced	1 (3.6%)
Age (Mean $\pm$ SD)	26.4 $\pm$ 6.2
Last product purchased	
- Cigarette	28 (100%)
Last purchase type	
- Loose	24 (85.7%)
- Pack	4 (14.3%)
Smoking frequency	
- Less than once a week	4 (14.3%)
- Once a week	-
- Twice a week	1 (3.6%)
- 3 – 5 times a week	6 (21.4%)
- Everyday or almost everyday	2 (7.1%)
- More than once a day	15 (53.6%)
Tobacco use status	
- Smoked tobacco user	25 (89.3%)
- Mixed tobacco user	3 (10.7%)
Quit intentions	
- Within the next month	4 (14.3%)
- Within the next 6 months	4 (14.3%)
- Sometime in the future, beyond 6 months	7 (25%)
- Not planning to quit	13 (46.4%)

Table 4.8: Tobacco vendors' characteristics (N = 28)

Variable	**n (%)**
City	
- Delhi	13 (46.4%)
- Mumbai	15 (53.6%)
Vendor type	
- Permanent tobacco shop	10 (35.7%)
- Small tobacco kiosk	9 (32.1%)
- Grocery store	6 (21.4%)
- Street vendor	3 (10.7%)
Do your customers buy	
- Only singles	5 (17.9%)
- Mostly singles	18 (64.3%)
- Singles and packs equally	2 (7.1%)
- Mostly packs	3 (10.7%)
- Only packs	-
Of 100 daily customers, how many of them visit to purchase loose?	
- Mean	76.6
- Range	20 – 95
For bidis, do customers buy	
- Only singles	-
- Mostly singles	-
- Singles and packs equally	-
- Mostly packs	7 (25%)
- Only packs	16 (57.1%)
- Did not sell bidis	5 (17.9%)
Display of cigarettes/bidis	
- Yes	16 (57.1%)
- No	12 (42.9%)
Pictorial warnings on displayed cigarettes/bidis visible	2 (12.5%)
- Yes	14 (87.5%)
- No	
Availability of smoking aids	
- Yes	27 (96.4%)
- No	1 (3.6%)
Warning board stating “sale of tobacco products to a person below the age of 18 years is a punishable offence”	
- Yes	6 (21.4%)
- No	22 (78.6%)
Tobacco advertisement at the entrance	

- Yes - No	16 (57.1%) 12 (42.9%)
Tobacco advertisement accompanied by warning - Yes - No	 15 (93.8%) 1 (6.2%)

Findings from interviews with cigarette users and tobacco vendors

Reasons for purchasing loose cigarettes

- *Perceptions of cigarette users*

We asked participants "how would they rather buy cigarettes – loose or in packs?". Most participants reported that they would prefer purchasing loose cigarettes. Major reasons mentioned for purchasing loose cigarettes were to limit consumption, intending to quit smoking, financial constraints, and social restrictions.

Cigarette users from both the cities mentioned that they purchased loose to moderate their cigarette consumption as they felt that they would smoke more if they purchased and carried a pack with them.

"I would not like to buy them in whole packs because when you have more, you are going to smoke more. So the idea behind buying them loose is I would reduce the number because I will have to go out and buy it every single time. So the effort is more, so I will try not to make that much of effort for cigarettes and not buy an entire pack." – Smoker from Delhi

"Because...see if I buy a packet I know that I have it with me and I can smoke it at any point of time. I just have to take it out and smoke. But I have it in loose, you know, if I

have like one with me or two with me, I know that...you know..that this will get over and I have to physically go out and get one for me and then smoke it. So, that involves a bit of effort. So, that sort of reduces the tendency of smoking for me." – Smoker from Mumbai

Users from both the cities also mentioned that they purchased in loose because they smoked occasionally; did not get the urge to smoke frequently; or were intending to quit cigarette smoking.

"I don't really smoke very often, so that doesn't make any sense to buy a whole packet and keep it. And also, when I want to, I can just get like a loose one. And especially because I have it just once in a month, so it makes more sense." – Smoker from Mumbai

Many cigarette users stated monetary reasons for purchasing loose cigarettes. They mentioned that it was more economical for them per purchase to spend on loose cigarettes than spending on an entire pack and that they did not have enough money to purchase a whole pack.

Finally, users from both the cities described that they purchased loose because they stayed with their families who were unaware of their smoking status or were staying in a hostel where cigarette smoking was prohibited. Some mentioned that cigarette smoking was prohibited at their workplaces or offices because of which they could not keep a pack.

"And one more major reason is that I don't smoke at home. I can't. I'm obviously scared of my parents. So, I don't bring back cigarettes home, ever." – Smoker from Delhi

- *Perceptions of tobacco vendors*

We asked tobacco vendors "why did customers purchase loose cigarettes?" Main reasons stated by vendors from Delhi and Mumbai were social restrictions (fear of getting caught at home; smoking restrictions in offices), financial constraints (loose cigarettes being affordable compared to the whole pack), and to limit cigarette consumption (perception that they will smoke more if they'll purchase a pack).

"According to me, they buy it like this because of money. Because a pack of cigarette is expensive. While one packet comes for around Rs. 100, a single cigarette comes for Rs. 10. So that is why, people buy single." – Grocery store owner from Mumbai

"Some are young and smoke without the knowledge of their parents. They cannot take it home so they buy loose and smoke and then they go." – Small tobacco kiosk from Delhi

"One more reason to buy loose cigarettes is if they have a pack in the pocket there is a chance that they might smoke more." – Small tobacco kiosk from Delhi

Vendors from both the cities mentioned similar reasons as cigarette users for purchasing loose cigarettes. They stated that some users had limited capacity to smoke, like smoking just one cigarette a day, so they only purchased loose; some could not take packs at home so preferred purchasing loose; while some found purchasing loose to be pocket-friendly and helpful in limiting their consumption. Tobacco vendors also reported that since tobacco shops were spread throughout the country, it offered cigarette users an easy access to loose cigarettes. Table 4.9 presents the major reasons

provided by cigarette users and tobacco vendors for purchasing loose cigarettes by cigarette users.

Table 4.9: Reasons for purchasing loose cigarettes by cigarette users

Themes	**Cigarette users**	**Tobacco vendors**
Reduce consumption - Limit overall consumption	*"I buy them loose because I used to buy them as packets. But my experience is that when you buy packets, you smoke more. So, that's why I intentionally don't buy packs."* – Smoker from Delhi	*"People's mentality is that if they smoke loose cigarettes then they'll smoke 3 a day, but if they buy a packet then they might smoke 10 cigarettes, that's why people buy single only."* – Permanent tobacco shop from Mumbai
- Intending to quit smoking	*"It is only sometimes, you know, when it comes in your mind to stop cigarette smoking, so I don't buy a pack and buy loose cigarettes."* – Smoker from Delhi	
- Low smoking frequency	*"I always prefer to buy them loose because it keeps my habit in check as in I don't get the frequent rush of having a cigarette or anytime I am going outside I don't feel like I should smoke a cigarette now or anything like that because I don't have a habit so I always prefer to buy cigarette in loose, preferably one in number because that actually keeps my habit in check."* – Smoker from Mumbai	*"And those people who have to smoke only one or two cigarettes in the entire day, they buy loose cigarettes for this reason."* – Grocery store owner from Delhi
Financial restrictions		

- Economical to spend on loose cigarettes - Limited budget	*"Suppose there is just me and one friend, and we are like okay let's meet for a walk, and we'll smoke a cigarette, and then we will go, so that is pocket friendly also, because if I buy a packet of cigarette, it will cost me between Rs. 180 to Rs. 200 and if I am buying loose cigarettes, it will cost me like 36 bucks."* – Smoker from Mumbai *"We generally make 10 or 20 rupees with which we can easily buy loose cigarettes but to purchase a pack, we would need 100 rupees which we generally do not have. So, buying loose cigarettes is easy for us."* – Smoker from Delhi	*"One major reason can be that they don't have to give the bulk amount."* – Permanent tobacco shop from Mumbai *"This is South campus [University] area. Students have limited money with them. So, the majority of the people will buy the cigarettes by looking at their pockets. Most of them will buy loose itself, they will not buy packs."* – Small tobacco kiosk from Delhi
Social restrictions - Hide from family / others	*"No one smokes, my parents or my sister or my brother. My cousins smoke. Everyone knows about them but no one knows about me. It is a kind of safety measure [to purchase loose cigarettes]."* – Smoker from Delhi	*"They mostly prefer loose cigarettes because if they buy a pack they might get caught at home. So that's why they buy a loose cigarette, smoke here and leave."* – Permanent tobacco shop from Mumbai
- Workplace / office restrictions on smoking	*"At work, if checking happens then I will be in a problem if they find cigarettes with me. But at home, I stay alone so there is no problem as such."* – Smoker from Delhi	*"The reason is they cannot smoke in the office. They will come and smoke on the roadside. That is one reason."* – Small tobacco kiosk from Mumbai
- Smoking restrictions at public places		*"They cannot buy packets because they have*

		problems at home also, in trains also, and traveling also so people mostly use loose." – Permanent tobacco shop from Mumbai
Widely and easily available		*"For addiction and also shops is everywhere. Shops are available throughout the country that is the reason people buy loose cigarettes."* – Street vendor from Mumbai

Awareness of the policy and policy implementation status

- *Perceptions of cigarette users*

Since Mumbai had adopted the ban on the sale of loose cigarettes, we asked users if they had heard about the ban. We also asked participants in Delhi if they were aware of the policy being implemented anywhere in the country. Only a few participants from Delhi were aware of the ban being implemented in some of the Indian states. Most participants in Mumbai had no knowledge of the ban on the sale of loose cigarettes and stated that they were easily available and accessible throughout the city.

"No, even if there is any such rule, I do not have any idea, because till date neither anyone has refused me a loose cigarette, nor I have heard of it." – Smoker from Mumbai

Only a few participants were aware of the ban and reported that nobody was following it and that loose cigarettes were widely available everywhere.

"I got to know about it through my friends and ofcourse in today's world, whatever happens, be it funny, be it serious, it is on memes everywhere, so yeah I got to know it

through that, I read a little about it but then of course, this being India, people do not take anything seriously,,,,, initially, it was there like you have to buy a packet etc, vendors were also like that, but then it is back to normal, you can take as much as you want, no need to buy a packet." – Smoker from Mumbai

We mentioned to the users in Mumbai about the policy ban and asked how easy or difficult did they think was to buy loose cigarettes since the policy was declared. Participants stated that they did not think the policy was implemented as buying a loose cigarette was very easy and was widely available at most stores and around educational campuses, and at tourist places in the city.

"I mean, I didn't even know that this was the rule. I mean only the reason that I didn't even know was that. Because it is so easily available. Doesn't seem like there is a ban. It's very easily available." – Smoker from Mumbai

"It is as easy as buying a chocolate or a pack of bread." – Smoker from Mumbai

"I have not been aware about this policy. I mean..you can just go to any shop in Mumbai and ask them for a loose cigarette. Even in Marine Drive if you go, the chaiwallah (tea-seller) is there selling tea and you can just ask them for a cigarette and they will give you a loose cigarette." – Smoker from Mumbai

- *Perceptions of tobacco vendors*

None of the tobacco vendors in Delhi were aware of the ban on the sale of loose cigarettes anywhere in the country. Most of the vendors in Mumbai were unaware of

the ban on the sale of loose cigarettes and mentioned that there was no such rule being implemented and enforced, and that anyone could sell loose cigarettes in the city.

"Nothing like that, selling loose is on. The government was about to ban it but did not. They have talked about it 5-6 times but have not banned." – Street vendor from Mumbai

"No, I have not heard about this. I only got to know about it when you told me that sale of loose cigarettes is banned. I didn't know it earlier." – Permanent tobacco shop from Mumbai

A few vendors mentioned that they had heard about the ban, but it was not being implemented. They also mentioned that there were talks that the tobacco companies would start producing cigarette packs of fewer cigarettes, but nothing was implemented.

"Yes, there was a ban on selling loose cigarettes. Maybe 6-8 months ago. It is still not allowed. I heard on news that there is a ban on selling loose cigarettes, It was there like 6-8 months ago, but then it was not followed. This happened in between, and the company also mentioned that they will start producing a pack of 3 cigarettes, you have to sell 3 cigarettes, but that also did not work out." – Permanent tobacco shop from Mumbai

"I just heard about it 4-5 years back, that only packets can be sold and not loose cigarette, but after that nothing happened, loose is openly sold." – Street vendor from Mumbai

Perceived impact of the policy

- *Perceptions of cigarette users*

Cigarette users from both the cities were asked whether the policy would promote or reduce their smoking consumption and were further probed if they would start purchasing packs, or think about making a quit attempt, or switch to other tobacco products such as cheaper cigarettes or bidis. Users' responses are presented into three major themes: perceptions regarding purchasing packs; perceptions around switching to other tobacco products; and perceptions about the policy leading to quitting behavior and reduced cigarette consumption.

Some users from Mumbai and Delhi mentioned that those who smoked more frequently or were habitual, and could afford to buy a cigarette pack would switch to purchasing packs. They also mentioned that switching to packs would increase their cigarette consumption.

"Yes, If there is a restriction on loose cigarettes and if I buy a pack and keep it with me then instead of smoking fourteen cigarettes a week, which I normally do, I may smoke twenty cigarettes. That means I will consume the complete pack within a week which used to get consumed within ten days earlier. That may get consumed in seven days." – Smoker from Delhi

"Those who are habitual won't mind buying a whole pack of cigarettes because they have their set habits and practices. They know how many cigarettes they want to have." – Smoker from Mumbai

However, users did mention that not everyone would be able to buy a pack due to monetary reasons and social norms and restrictions such as fear of smoking in front of parents or fear of getting caught by parents.

Even though some reported switching to packs, users from both the cities also mentioned that individuals would try to reduce their consumption despite purchasing packs as that would start having a psychological impact on them by making them think about the harmful effects of cigarette smoking and motivate them to gradually change their smoking habits.

"Because from the conversations I have had and the feelings I have had with smoking, when people have to buy packs, it kind of does hit them. That "Oh my God! I" and if they have a pack in their hand and they realize, "Okay, like I have smoked up the whole pack within a day or two days or three days." It does hit them much more and it does affects them more psychologically than when they keep walking to their paan [tobacco] shop and keep having conversations with their friends while they are there and smoke cigarettes and lose count of how much they have actually smoked. So, I think if people are buying packs, it impacts them psychologically more." – Smoker from Delhi

A few users from both the cities also described that they would buy packs and share them amongst their social circles as the ban was on buying loose and not on pack sharing.

"I would say that I would just look for my friends with whom I used to go for smoking and just go with them and buy a pack of cigarettes and share it amongst us. That's what

I would do. Regarding whether it would reduce my habit I really don't think so. If I want to get it I can still get it. So the policy would not affect me to that extent or that much." – Smoker from Mumbai

We probed users whether the ban would make them quit smoking or reduce their cigarette consumption and learned that they perceived that their consumption levels would reduce if loose cigarettes were not available as that would reduce the accessibility to loose cigarettes and in return help them forgo a cigarette.

"I feel it will reduce the smoking pattern of the people. It will be a hassle for a person to get one cigarette then. He would think before, you know, like should I buy it now? He will be like, you know, forced to buy only when he needs it so badly or he will have to depend on others, basically. He won't be independent in purchasing a loose cigarette. He will have to consider other factors." – Smoker from Mumbai

They also stated that banning loose cigarettes would help them in successfully quitting smoking as they won't be able to afford a whole pack. Some also showed concern that buying a pack would mean harming their own health so they would rather quit. Participants who have been trying to quit smoking mentioned that this policy would assist them in successful quitting.

"Yes, most likely I will try to quit smoking initially. If I won't be able to do so, then will quit gradually." – Smoker from Delhi

"If the policy gets enforced today then I will quit tomorrow because I feel that I should not pay so much money for a thing that is injurious to my health. Buy a 100 Rupees box and burn the lungs as well. I don't want that." – Smoker from Mumbai

"If the government completely bans loose cigarettes then it will help me in quitting. I keep trying to quit and this will be an additional factor which will help me to quit smoking cigarettes." – Smoker from Delhi

"It will be very relevant because I am trying to quit and seeing that it will be so difficult to quit, you know, like I would have to consider a lot and I don't think I will buy a whole packet of cigarettes. That is because that's not my smoking pattern right now and I don't want to increase it." – Smoker from Mumbai

Users from both the cities described that they would rather quit smoking as they were aware of its harmful effects and would not want to increase their consumption by purchasing a pack if loose cigarettes were not available.

Finally, it was perceived that the policy would prevent smoking initiation especially among children as they would then be less likely to notice smoking in open places which attracted young children to smoking. Additionally, due to their limited purchasing power, they wouldn't be able to purchase a whole pack.

"And it would help people reduce their consumption and it would ensure that we do not have like so many like starters for smoking." – Smoker from Delhi

"Children have less money. Anyone can buy a 10 Rupee cigarette but to buy a 100-200 Rupees packet will be something big for the children and they will not even think about trying, in case they have to buy a packet." – Smoker from Mumbai

We also inquired whether users would switch to other tobacco products such as bidis or cheaper cigarette packs if loose cigarettes were not available. Most users reported that it is less likely that those who smoked cigarettes would switch to smoking bidis as cigarette smoking was perceived to be a status symbol, whereas bidi was not. Bidis were also considered to be harsher than cigarettes.

"I doubt that. I doubt that because people who are smoking cigarettes, I don't think they will switch to beedis. Until and unless they are too much of brat. I doubt that." – Smoker from Delhi

"In your college when you are holding a cigarette in your hand, you think you look like a dude, or you look very smart and all. Most of it is show off part. And that show off is only limited to a cigarette and not to a bidi." – Smoker from Delhi

A few users from Delhi also reported that they would switch to other cheaper cigarettes which would only increase their cigarette consumption.

"There are cheap cigarettes available too. A packet for INR 40, 60. People will surely smoke." – Smoker from Delhi

Even though some responded that switching to cheaper cigarettes was a possibility, a few others stated that it was unlikely to switch to a different brand of cigarette if one has already acquired the taste of other brand.

Finally, a few users mentioned that they would consider quitting cigarette smoking but would also switch to using e-cigarettes.

"There are chances. Even I am seeing this trend nowadays in my friends that they are turning to this e-cigarette thing which is also very easily available." – Smoker from Mumbai

- *Perceptions of tobacco vendors*

We asked the vendors what changes they have observed (those who were aware of the ban in Mumbai) or anticipate observing in their customer's buying behavior and smoking patterns. They reported that if loose cigarettes were banned, most people would not purchase packs due to financial constraints.

One vendor from Mumbai described his experience of not selling loose cigarettes for a few days when he heard about the ban on the sale of loose cigarettes. He mentioned that cigarettes were still being sold but his sales got reduced as those who smoked occasionally did not purchase a pack when loose cigarettes were not available.

"Cigarettes were still being sold but the sales got reduced by 20-30%, because a person who smokes only single will not purchase a pack, so that affected our business." – Permanent tobacco shop from Mumbai

Some vendors from Delhi and Mumbai also reported that users would start purchasing packs. They stated that those who were habitual or highly addicted to smoking and had enough money to buy a pack would switch to purchasing packs and the policy would not impact them much but would rather increase their smoking consumption.

"All the high class and rich people will buy packets." – Permanent tobacco shop from Delhi

"The addict will buy a packet and smoke. If he has money, he will continue smoking." – Street vendor from Mumbai

However, when probed, they mentioned that not everyone would be able to purchase packs. Users would think a lot before buying a pack, and they would not buy it if they did not have the capacity to smoke a whole pack.

"It is difficult that everyone will be able to buy a pack because a person thinks even before buying a single cigarette. So, it is difficult to buy a box. If they don't have the capacity, then they will not buy a packet. They will go away." – Small tobacco kiosk from Mumbai

A few vendors also mentioned the possibility of pack sharing. However, they stated that smoking would reduce as not everyone from the group would always be available for contribution.

Vendors from both the cities reported that such a policy would benefit the upcoming generation as they would not be able to purchase packs which would reduce smoking among younger age groups. They also mentioned that individuals belonging to low SES, and occasional smokers would not be purchasing packs and would eventually quit smoking.

"It is good for youth; they will stop smoking. This policy, if it comes let's not say for us, but it would be very beneficial for the upcoming generation. Upcoming generation who are smoking under the influence of others, they'll not do it anymore. Yes, there will be an effect. Students will reduce or stop smoking, they'll not buy packets, and sales will decrease." – Permanent tobacco shop from Mumbai

"It will be beneficial for those who smoke occasionally because they won't get loose cigarettes and only packet, so that may make them quit smoking." – Permanent tobacco shop from Delhi

"The people from the lower strata will get impacted. They cannot invest at one time that they buy a full packet and consume it. If they want to do that then how will they pay for the other things? They don't get that much to pay for it. That is their problem. The people from the lower strata will have difficulty buying. They cannot buy a box for 100 or 120 Rupees and consume it throughout the day. They are not able to do that. Somewhere small people will get impacted because they have to watch their pockets." – Small tobacco kiosk from Mumbai

We later probed the vendors to see if smokers would switch to consuming other tobacco products such as bidis or cheaper cigarettes if loose cigarettes were not available. Most described that it was less likely that smokers would switch because they have got into the habit of smoking a particular brand of cigarette, and that bidis were harsher compared to cigarettes and were preferred only by the labor class or individuals belonging to the lower SES.

"Very less likely that people will switch to bidis. That is because of the beedi and cigarette, if we consider the filter then the beedi hits more, it is harsher and the cigarette is smooth. So, I don't think that people will prefer beedi." – Small tobacco kiosk from Mumbai

"They will not smoke bidis. Only the labor and people belonging to low income group smoke bidis. People who are of higher class smoke cigarette only." – Small tobacco kiosk from Mumbai

A few vendors also pointed to the possibility that buyers might switch to purchasing cheaper cigarettes which cost less than their usual brand. Table 4.10 presents the main themes regarding the perceived impact on cigarette users' buying behavior.

Table 3.10: Perceived impact of the ban on the sale of loose cigarettes on cigarette users' purchase behavior

Themes	**Cigarette users**	**Tobacco vendors**
Perceptions regarding purchasing packs		

- Users will switch to purchasing packs.	*"I have friends who smoke 1½ boxes daily. So, they will not get affected by this. If such a policy is implemented in India, sorry in Bombay, that will not make any difference to them because they anyway smoke 1½ cigarette box per day. So, if they don't get loose cigarettes then they will buy a box."* – Smoker from Mumbai	*"They will buy a box of course because as per habit of those people who smoke, they will purchase a box. Because their habit cannot be stopped immediately. They cannot stop the habit once they have started. It is not possible. They will purchase."* – Grocery store owner from Mumbai
- Users will not switch to purchasing packs because of financial and social restrictions.	*"No, even if I look, consider myself when I was in college, I never used to purchase a pack because I was scared, you know, where will I keep it, what if you know, my mother or my dad catch me, you know..."* – Smoker from Delhi	*"Sales would reduce by 50%. If they won't get loose cigarettes they won't smoke, because they will not have enough money to buy the pack."* – Permanent tobacco shop from Mumbai
- Users will switch to packs but also try to reduce consumption.	*"I will have to change my habit, because if I will not change my habit, then earlier where I was smoking 10 cigarettes, now I will start to buy 10 packets, it will be like that. Because it will then be in my pocket all the time, and I will smoke in every two minutes. So if I will not change my habit, then I would be at loss. If it gets implemented from tomorrow, it won't be possible for me to change my habit all at once at the starting, I will have to change my habits gradually. In the beginning it [smoking] will increase, but*	*"No matter how addicted they are they'll always try to control. Earlier they were stubborn about smoking but not anymore. Because of the corona, people have changed a lot."* – Permanent tobacco shop from Mumbai

	smokers will also realize that slowly, if he is sincere,,,,,,I am not talking about drunkards or heavily addicted, so moving forward they will reduce their consumption on their own. In the beginning, everyone will start smoking more, who used to smoke a single,,,,,,,, if he buys a packet, he will smoke more in the beginning, but afterward he will control slowly." – Smoker from Mumbai	
- Users will share packs.	*"See, I can buy a packet and I can share it with my friends, five friends, so I can also contribute with my friends that let's buy a packet of cigarettes and then we will split five in all, like that. So, you cannot. The ban comes on buying loose cigarettes but that doesn't include sharing the cigarettes. So, I don't think so, it's going to make any difference."* – Smoker from Delhi	*"All of them will come together, 4-5, if one packet costs 50 Rupees, then each one will pay 10 Rupees and they will buy and smoke again. That can also happen." – Small tobacco kiosk from Mumbai*
Perceptions regarding leading to quitting behavior - Users' cigarette consumption will reduce.	*"So, if something like that happens, it will definitely be a good thing. Because it happens that, if you are travelling, or if you are stepping out of Metro or you are on a bus stand or you step out of an auto rickshaw at some stand,*	*"It's easy for them. They will quit easily. Those who smoke for fun or occasionally, they will smoke once a week. If they won't find one in a week, they will plan for another week and gradually, quit*

	and you find a vendor adjacent to the bus stand or whatever. And you are waiting during that time for say 10 minutes, so you tend to think that since I am waiting for 10 minutes, let me smoke a cigarette till then. So that trend will start disappearing gradually. So, I would say that it would be really good for me." – Smoker from Delhi	*smoking."* – Permanent tobacco shop from Delhi
- Users will get assistance in successful quitting. - Potential users will be restricted to initiate smoking.	*"I will quit, because even if I somehow afford a packet, I cannot take it home with me, I cannot enter the home with it (cigarettes). When I was even outside, when I was in Dehradun, I was alone in hostel, then also I never bought a packet, now I am with family, I cannot take it home, I cannot hide it outside, so then I will have to quit."* – Smoker from Delhi *"They [youngsters] won't even start, quit will be the question if they start... there will be a major change in like, like in the next five-seven years, you know, they will see a majority of the people who are not even starting that bad habit."* – Smoker from Delhi	*"Many people would try to quit. Suppose poor people, he has Rs. 10, he will not be able to smoke because one packet costs Rs. 100, he will not smoke, slowly he has to quit."* – Street vendor from Mumbai *"It will become a compulsion or helplessness, you cannot buy a pack and you are not getting it in singles, then there is no option left at all. Then they have to automatically quit thinking about smoking, and the addiction will not happen. It will be very good for new generation."* – Small tobacco kiosk from Delhi
Perceptions regarding switching to other tobacco products		

- Users will not switch to bidis.	*"I think for me that will not happen. For some people that I know, especially men in India and in general I think. But I do feel like the middle class, upper middle class or the corporate, you know, going people, I don't think that they will switch to beedis and other tobacco products. Because it's also like a status thing."* – Smoker from Delhi	*"The person who is used to smoking cigarettes will smoke cigarettes till the time cigarette stops coming to the market, even if you give the box worth 200 for 500 or 1000."* – Small tobacco kiosk from Delhi
- Users will switch to cheaper cigarettes.	*"In some other way, people are going to buy it. So, if not this cigarette, I will go for another cheaper cigarette. There are packets of cigarettes available, even in 100 rupees, 150 rupees. There are packets of cigarettes, it's a small packet even. So, if you know that there is a pack of 10 cigarettes in 80 rupees even. 150 rupees packet is available. I'm going to buy cheap cigarettes but it's not going to stop the smoking. It's going to increase the smoking only."* – Smoker from Delhi	*"Everyone can buy, if not the expensive ones, then the cheap ones like Rs. 40 – Rs. 50 per pack. Earlier he was smoking a cigarette costing Rs. 20, now he'll ditch that and switch to a pack of cigarette costing Rs. 50 if he cannot buy loose cigarettes. He'll start smoking a low quality cigarette."* – Grocery store owner from Delhi
- Users will not switch to cheaper cigarettes.	*"If you started smoking with a particular type of cigarette or a particular type of tobacco. You can't switch it; your body is used to it. I had started with Marlboro. And I have tried all the types of cigarettes, I have not found a permanent replacement for*	*"I will tell you, my experience. If you come to me for the small Light Mint and I tell you that the small light mint is not available, only Gold Flake is available. You will say, leave it. You will go to another shop. That is because the person likes it and has got into the habit of smoking it. He will*

	it. I did try those low on nicotine, low on tobacco, the slim ones, but my body is not getting used to it." – Smoker from Mumbai	*not smoke something else. If their brand is not there, and if I tell them that, then they will not buy it. He will go to another shop. He will not smoke the cheaper one."* – Small tobacco kiosk from Mumbai
- Users will switch to e-cigarettes.	*"Um, I think I would consider quitting maybe, but before that, I would maybe try and switch to another product (e-cigarettes). Not a tobacco product. But maybe, I mean, I do use e-cigarettes. So, I'll just use more of that."* – Smoker from Mumbai	

Discussion

This paper focused on understanding in-depth the perceptions of cigarette users and tobacco vendors regarding the policy ban on the sale of loose cigarettes in India and the status of policy implementation in Mumbai, Maharashtra where the ban on the sale of loose cigarettes has been in place since 2020. Study findings offer insights into the reasons for purchasing loose cigarettes, awareness levels of cigarette users and tobacco vendors regarding the ban on the sale of loose cigarettes, and the perceived impact of the policy ban on cigarette users' buying behavior. We did not find any differences in the themes between the two cities as most cigarette users and vendors from Mumbai were unaware of the ban on the sale of loose cigarettes and stated that no such policy

was being implemented or enforced in Mumbai, which made findings from both the cities similar.

Both cigarette users and tobacco vendors in both the cities reported that the main reasons for purchasing loose cigarettes were to reduce smoking consumption, financial restrictions, and social restrictions. Participants reported purchasing loose cigarettes to regulate their smoking consumption as they felt that if they bought packs, they would start consuming more cigarettes. Study findings also suggest that occasional smoking, and intending to quit were also related to purchasing loose cigarettes. Our findings are consistent with the literature as studies have showed that purchase of loose cigarettes is linked to non-daily smoking (Sacks et al., 2012). Thrasher and colleagues (2011) also found that about one-quarter of the Mexican smokers smoked loose cigarettes to cut down their cigarette consumption (Thrasher et al., 2011). It is well established that the prevalence of loose cigarettes makes tobacco affordable and accessible for minors (Goel et al., 2021). Studies that examined smokers' perceptions have found that they perceived loose cigarettes to be more affordable than the cost of the whole pack (Stillman et al., 2007; Stillman et al., 2014). Qualitative studies among African American urban youth smokers in the United States found that those who purchased loose cigarettes cited 'less expensive' as the most common reason for their purchase (Stillman et al., 2007). Our study findings are consistent as participants reported that it was economical to spend on loose cigarettes and those with a low budget could easily purchase a loosie. Finally, participants mentioned that they feared getting caught by their parents which again aligns with the literature that smokers found

carrying cigarette packs to be socially unacceptable and purchased loose cigarettes to hide their smoking habits from others (Singh et al., 2017a).

One of the aims of this study was to assess the impact of the policy ban on the sale of loose cigarettes in Mumbai and how the impact differed between the two cities. However, we found that most of the cigarette users and tobacco vendors were not aware of the policy ban and rather stated that no such ban was being implemented or enforced and that loose cigarettes were widely available. These findings related to low awareness are similar to a study conducted by Eshwari and colleagues (2020) that used cross-sectional surveys to examine perception and practices, and awareness regarding the ban on the sale of loose cigarettes among cigarette users and tobacco vendors in Karnataka, a southern Indian state (Eshwari et al., 2020). They found that 95.5% of the tobacco vendors continued selling loose cigarettes; about half of them were aware of the ban; and only a quarter reported that the ban on the sale of loose cigarettes was implemented (Eshwari et al., 2020). Similarly, awareness of the ban among cigarette users was found to be low as well (Eshwari et al., 2020).

Both users and vendors reported that individuals would not switch to smoking bidis if loose cigarettes were banned as bidis were primarily consumed by individuals from low SES, whereas cigarettes were preferred by high SES groups and was considered a status symbol. Males, older age groups, and those with lower SES are significantly more likely to smoke bidis (Mbulo et al., 2020). Cigarettes, on the other hand, are associated with higher SES and sophisticated lifestyles (Nichter, Nichter, & Van Sickle, 2004). There is a lack of evidence suggesting that those who are used to cigarette

smoking would prefer switching to smoking bidis. However, participants mentioned that individuals could switch to purchasing packs of cheaper cigarette brands if loose cigarettes of their usual brand were not available. That transition could be possible due to the unequal taxes imposed on different types of cigarettes (R. M. John, Rao, R.K., Rao, M.G., Moore, J., Deshpande, R.S., Sengupta, J., Selvaraj, S., Chaloupka, F.J., & Jha, P., n.d.). Taxes in India vary by the type of tobacco products, and cigarettes are taxed based on their length, with longer cigarettes taxed at a higher rate compared to cigarettes with shorter lengths (R. M. John, Rao, R.K., Rao, M.G., Moore, J., Deshpande, R.S., Sengupta, J., Selvaraj, S., Chaloupka, F.J., & Jha, P., n.d.). We recommend that the taxation system should be simplified, and equal taxes should be imposed across all tobacco products. A higher and equal price would prevent users from switching to cheaper cigarettes.

Cigarette users and tobacco vendors described how a ban on the sale of loose cigarettes would impact the buying behavior of cigarette users. Findings were categorized based on perceptions related to switching to buying cigarette packs, leading to quitting behavior, and switching to other tobacco products. We found that cigarette users with high smoking frequency and those who were already purchasing packs would continue to purchase packs and even if they did purchase packs, they would certainly try to control their consumption. However, not everyone would be able to buy packs due to financial and social constraints. Most participants mentioned that the policy would assist users to quit cigarette smoking or reduce their consumption by forgoing a cigarette. Eshwari and colleagues (2020) found similar results from their cross-sectional

surveys with 22% users reporting that if loose cigarettes were banned, they would reduce the number of cigarettes they smoked; 16% would think about quitting; and 9.5% would completely give up smoking (Eshwari et al., 2020). Literature suggests that availability of loose cigarettes decreases the likelihood of making quit attempts (Baker et al., 2015). Hall and colleagues (2014) found that smokers who lived in a neighborhood where loose cigarettes were easily accessible were less likely to make an attempt to quit cigarette smoking and were more likely to switch back to smoking (Hall et al., 2015). Additionally, smokers who purchased loose cigarettes with the intention to limit their smoking were not more likely to quit smoking than those who did not purchase single cigarettes with the intention to reduce their cigarette consumption (Thrasher et al., 2011). Thus, our study findings align with the literature as participants felt that the policy ban would help them in successfully quitting cigarettes. We recommend that longitudinal studies are needed to examine how the policy ban on the sale of loose cigarettes would impact smoking behaviors of individuals with a focus on product switching, quit attempts, successful quitting, and relapse. Even though our study provides strong evidence about the effectiveness of the policy in reducing smoking prevalence, we still recommend that simulation studies should be conducted to further strengthen the evidence. Finally, future studies should also assess whether users would switch to products other than cheaper cigarettes and bidis, such as vapes, e-cigarettes, hookahs / waterpipe tobacco, and other emerging products.

This study has several limitations. First, findings from this study are based on a hypothetical situation. Because the policy was not properly implemented or enforced in

any of the two cities, participants would not have experienced the real impact of the policy. However, a tobacco vendor who was aware of the policy and did not sell loose cigarettes for some time reported a decline in his sale and cigarette consumption which aligns with the responses of both cigarette users and tobacco vendors. Second, since the policy was not implemented, this study could not measure the actual impact of the policy and thus hinders our ability to draw conclusions about real world effects. Third, participants were recruited from urban neighborhoods of two Indian cities, so, study findings cannot be generalized to rural neighborhoods or other parts of the country. Fourth, the sample size of tobacco vendors is not representative as we could not find many street vendors since they came out late in the night which was not always a convenient time for recruitment. Finally, the study findings could only be attributed to cigarette users as we did not find individuals who purchased loose bidis.

Conclusions

Main reasons reported for purchasing loose cigarettes were to control cigarette consumption, and financial and social restrictions. Loose cigarettes were widely available in both the cities and users reported easy access. Awareness regarding the ban on the sale of loose cigarettes was poor among users and vendors in Mumbai, implying inadequate implementation and enforcement. Participants in Mumbai reported that even if the ban was there, it was not being implemented. Our study findings demonstrate strong support for implementing a ban on the sale of loose cigarettes as it would reduce cigarette consumption, assist users in quitting cigarette smoking, and prevent potential users from initiating smoking.

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4.4 Manuscript 4

Barriers and facilitators for the implementation and enforcement of the ban on the sale of loose cigarettes in India: A qualitative stakeholder analysis[4]

[4] Sakhuja, M., Friedman, D.B., Macauda, M.M., Hebert, J.R., Pednekar, M.S., Gupta, P.C., Cohen, J.E. & Thrasher, J.F. To be submitted to *Global Health Research and Policy.*

Abstract

Introduction: Several Indian states have adopted a ban on the sale of loose cigarettes and India is now considering a national ban. This study aims to understand the perceptions of policymakers, implementers, and law enforcement officials regarding the implementation and enforcement of banning the sale of loose cigarettes.

Methods: Between May – October 2022, we conducted in-depth interviews (n = 26) with key stakeholders involved in tobacco control in two Indian cities, Delhi (ban not being implemented at time of data collection) and Mumbai (ban being implemented). Stakeholders belonged to various government departments such as the police, municipal corporations, food and drug administration (FDA), health department, and civil society organizations / non-governmental organizations such as Vital Strategies, World Health Organization, International Union against Tuberculosis and Lung Disease, and other local NGOs based in Mumbai and Delhi. Interviews explored participants' awareness of the policy, policy implementation status, and barriers, facilitators and potential role in implementation and enforcement of the ban on the sale of loose cigarettes.

Results: In Mumbai, awareness of the ban was poor among implementers and law enforcers such as officials from FDA, municipal corporations, and the police department, whereas awareness was greater among officials from the health department and civil-society/non-governmental organizations directly involved in tobacco control. Implementation and enforcement of the ban was poor and loose cigarettes were still

openly sold. Main barriers to policy implementation included unclear implementation guidelines, poor awareness among tobacco vendors, limited resources, and lack of stakeholders' commitment for tobacco control. Participants from Delhi and Mumbai stated the need for a vendor licensing system, imposing hefty penalties, imparting health education, and a multi-sectoral approach for effective policy implementation.

Conclusion: Limited awareness of the ban and continued sale of loose cigarettes indicates inadequate policy implementation and enforcement. For effective policy implementation, there is a need for increasing awareness regarding the policy, adopting a tobacco vendor licensing policy, and establishing clear implementation guidelines involving a multi-sectoral approach.

Introduction

About 11% of the Indian population aged 15 years and above exclusively smoke cigarette and/or bidis (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). Among those, 4% are current cigarette users (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). Loose cigarettes are common in India, where vendors take individual cigarette sticks from their commercial packs and sell them individually. According to the 2016-17 Global Adult Tobacco Survey (GATS) in India, about 67% of cigarette users purchased loose cigarettes at their last purchase (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences). Sale of loose cigarette sticks in the unregulated tobacco market of India, violates Section 7 of the Cigarettes and Other Tobacco Products Act (COTPA) that requires cigarette packs to depict pictorial health warnings on 85% of the total area (Ministry of Health and Family Welfare Govt. of India).

High prevalence of loose cigarettes poses major challenges to the effectiveness of COTPA provisions such as pictorial health warnings on cigarette packs, increased taxes on tobacco products. Loose cigarette sale is significantly associated with the sale of tobacco products to minors (Goel et al., 2021). The availability of loose cigarettes makes individual sticks highly affordable compared to the price of the whole pack, meaning smokers found it less expensive to pay for loose cigarette sticks, even if loose sticks were sold at a higher price (compared to what they would have cost per unit when sold as a whole pack) (Stillman et al., 2007; Stillman et al., 2014). Additionally,

loose cigarettes potentially reduce the impact of pictorial health warnings on cigarette packs since those who buy loose cigarettes are less likely to be exposed to such warnings (Peiris, 2018; Thrasher et al., 2011; Yadav et al., 2020).

Sales of loose cigarettes are very prevalent in low-and-middle income countries (LMICs), pointing to the ineffective implementation and enforcement of tobacco control policies (Hall et al., 2015). In 2015, the Government of India placed an amendment bill in the public domain as part of pre-legislative consultations and proposed amendments to Section 7 of COTPA stating that cigarettes and other tobacco products must be sold and purchased in their sealed, intact, and original packaging (Ministry of Health and Family Welfare). Following the proposed amendments, Maharashtra, Punjab, Himachal Pradesh, Karnataka, and Chhattisgarh have banned loose cigarette sales (The Hindu, 2015; The Indian Express, 2020; Times of India, 2020; WHO Framework Convention on Tobacco Control Knowledge Hub, 2020; Yadav et al., 2020). However, many of the remaining states that represent densely populated regions with high smoking prevalence are yet to implement the ban. Despite the strong recommendations in the Article 16 of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) that focuses on the necessity of banning the sale of loose cigarettes (International Legal Consortium at the Campaign for Tobacco-Free Kids, 2020), studies that have measured compliance with India's tobacco control laws have showed low adherence to COTPA, documenting the inadequacies in implementation and enforcement (Goel et al., 2015; Mullapudi et al., 2021; Panda et al., 2012; Sharma et al., 2019).

Policy implementation and enforcement is the responsibility of multiple stakeholders who could have a direct or indirect influence on implementation-related decision making and processes (Balane et al., 2020). Exploring policy implementation with key stakeholders is important to understand their inter-relations, interests, and to assess the influence and resources and skills they bring to affect decision making or implementation processes (Varvasovszky & Brugha, 2000). In policy implementation research, stakeholder analysis can be used to understand stakeholders' roles and potential contributions in policy processes or inform future directions for policy implementation (Varvasovszky & Brugha, 2000). Since India is considering a national ban on the sale of loose cigarettes (The Hindu, 2022), analysis of policy implementation stakeholders may help strengthen the implementation and enforcement of COTPA's provisions banning the sale of loose cigarettes.

Using a qualitative approach, this study aimed to understand the perceptions of key stakeholders in two cities, Delhi and Mumbai, regarding the implementation and enforcement of loose cigarette sale ban. The stakeholder analysis will not only aim to evaluate the existing policy ban in an Indian city but also help advance and apply the project's findings in cities where the ban is yet to be implemented.

Methods

Study design

We conducted in-depth interviews between May-October 2022 with 26 key stakeholders, including policymakers, implementers, and law enforcement officials from

two cities in India: Mumbai, where the ban on the sale of loose cigarettes and bidis was implemented in 2020, and Delhi, where the ban was yet to be implemented at the time of data collection. Both the states are diverse with respect to their geographic location and tobacco use prevalence. Smoking prevalence in Mumbai, as per the 2016-17 Global Adult Tobacco Survey in India, is the least among all Indian states at 3.8%. Whereas smoking prevalence in Delhi (11.3%) is higher than the national average (10.7%) (Tata Institute of Social Sciences et al., 2018). Another reason for choosing Delhi was that it is the national capital and national level health officials and national foundations were based in Delhi. Two cities were selected to compare the findings and assess any differences in implementation barriers and facilitators and to learn from the implementation experience for policy expansion.

Recruitment and interview protocol

We compiled a list of key stakeholders who were authorized as per the COTPA to enforce tobacco control provisions in India. The initial list of stakeholders included personnel from various government departments (e.g., Department of Health, Department of Police, Department of Food and Drugs), heads of academic institutions, and personnel from the municipal corporation bodies (department that provides civic services at the state level). The list of stakeholders was updated after discussion with in-country partners to identify key personnel from non-governmental organizations (NGOs), foundations, research institutions, and international organizations that were directly involved with tobacco control.

MS travelled in-person to the offices of policy implementers and enforcement officials including government officials, heads of academic institutions, and some NGO officials to interview them. MS also reached out to a few individuals over an email with an introduction of himself and the research project, and mentioned his intentions to speak with them and subsequently scheduled a call. Recruitment was also conducted using social media platforms (LinkedIn), where MS reached out to key officials working in international organizations. Upon meeting with the stakeholders, MS described the research project and would tell them that they were important stakeholders, and their opinions would help in effective policy implementation. Some agreed to be interviewed on the spot, whereas some asked to return later or on some other day. We also sent emails to other important stakeholders working at the national level of the Ministry of Health and Family Welfare but did not get any response. Follow-up emails were sent and those who did not respond were not contacted again.

Interviews with key personnel in this group were conducted either in their office premises, or virtually (over zoom or telephone call), based on their preference. However, one senior official from the municipal corporation in Delhi preferred to respond to interview questions in writing. All interviews conducted in-person or virtually were audio recorded after receiving consent from respective participant. Notes were taken during the interview and key points were noted post the interview.

Conceptual framework

To develop the interview guide, we used the policy implementation research framework developed by Balane and colleagues (2020) (Balane et al., 2020) that analyzes the characteristics of key stakeholders or policy actors and how those characteristics interact with one another. Interview questions were based on four broad themes: knowledge, interest, power, and position of stakeholders with respect to the policy ban on the sale of loose cigarettes. Knowledge was defined as "stakeholders' awareness and understanding of the policy"; interest referred to "stakeholders' motivations and perceived impact of policy implementation"; power was defined as the "potential ability of the stakeholders to affect policy implementation; and position meant "whether the stakeholder supports, opposes, or remain neutral about policy implementation".

Data collection tool

The interview guide comprised 20 questions to explore stakeholders' knowledge, awareness, and understanding of the policy ban on the sale of loose cigarettes; role in tobacco control; reasons for purchasing loose cigarettes; perceived impact of the policy and how they contributed / might contribute to its implementation and enforcement; and barriers and facilitators for effectively implementing and enforcing the policy.

Data analysis

All interviews were audio recorded after receiving consent from the participants. Audio files were then transcribed using services from a professional transcription

agency. All transcripts were organized and managed using NVivo® (QSR International) and thematic analysis was performed. A list of initial *a priori* codes was developed using the original interview guide to inform the analysis. Three authors (MS, DBF, MMM) independently coded one transcript and came together for a discussion to further refine the preliminary codebook and added relevant codes. Later, MS did a line-by-line analysis for every transcript and added emerging codes to the codebook (Corbin & Strauss, 2014). Once the codebook was finalized, axial coding was used in which thematic relationships among existing codes were identified (Miles & Huberman, 1994).

Results

In this paper, we only present findings related to participants' awareness of the policy, policy implementation status, barriers and solutions for effective implementation and enforcement. Finally, we discuss how participants have contributed or might contribute to the implementation process.

Key participants

A total of 26 interviews were conducted. Participants belonged to various sectors including government departments such as the Department of Health (n=2), municipal corporations (n=7), Police Department (n=4), heads of educational institutions (n=3), Food and Drug Administration (n=1), and various non-governmental organizations who were directly involved in tobacco control (n=7) such as the World Health Organization, Vital Strategies, and International Union against Tuberculosis and Lung Disease (see Table 4.11). Participants were asked about their association with tobacco

control and the specific role that they played in tobacco control policymaking, policy implementation and enforcement, or both. Policy implementers and enforcers included officials from the health department, police department, municipal corporations, and heads of educational institutions. Their primary role included undertaking field visits and penalizing violators of tobacco control laws such as smoking in public places and selling prohibited items, and regulating and issuing licenses to shopkeepers, including tobacco vendors. Those who were involved as a technical support partner/enabler/facilitator/action research scientist facilitated policymaking and policy implementation. They were primarily associated with non-governmental organizations / civil society organizations and were involved in generating and providing evidence for strengthening the policies, garnering support for stronger policies, ensuring multi-sectoral support is mobilized for robust enforcement, assisting in specific areas such as strategic health communications, and capacity building of implementers and enforcers.

Table 4.11: Participant characteristics (n=26).

Department / Organization type	**City**	**Type of organization**	**Role**	**Total (n=26)**
Health Department - Official 1 - Official 2	 Mumbai Mumbai	State Government	Policymaking / Implementation	 2
Hospital Research Centre - Official 1	Mumbai	Hospital Research Centre	Technical support	1
State Foundation 1 - Official 1	Mumbai	Civil society organizations / non-governmental organizations	Technical support	1
State Foundation 2		Civil society organizations /	Technical support	

- Official 1	Mumbai	non-governmental organizations		1
Police Department - Official 1 - Official 2 - Official 3 - Official 4	 Mumbai Mumbai Delhi Delhi	Government / law enforcement	Enforcement / Implementation	 4
Heads of Educational Institutions - School Principal 1 - School Principal 2 - University Director	Delhi Mumbai Mumbai	Educational Institutions	Implementation	3
Private Sector - Official 1	 Mumbai	Private Sector Company	Implementation	 1
Food and Drug Administration - Official 1	Mumbai	State Government	Enforcement	1
National Foundation 1 - Official 1	Delhi	Civil society organizations / non-governmental organizations	Action research scientist	1
International NGO 1 - Official 1	 Delhi	Non-governmental organizations	 Enabler	 1
Municipal Corporation Department - Municipal Health Officer - District Health Officer 1 - District Health Officer 2 - Medical Officer 1 - Public Health Inspector 1 - Public Health Inspector 2 - Medical Officer 2	 Delhi Delhi Delhi Delhi Delhi Mumbai	State Government	Enforcement / Implementation	 7
National Foundation 2 - Official 1	 Delhi	Civil society organizations /	Facilitator	 1

		non-governmental organizations		
International NGO 2 - Official 1	Delhi	Non-governmental organizations	Technical support	1
International NGO 3 - Official 1	Delhi	Non-governmental organizations	Technical support	1

Participant's awareness, and policy implementation status

Participants were asked if they knew anything about the ban on the sale of loose cigarettes and whether any such ban was implemented in their states or anywhere else in India. In Mumbai, officials from the health department, state foundations directly working in tobacco control, and a school principal were aware of the ban on the sale of loose cigarettes.

"But in September 2020 the additional chief secretary of the Maharashtra health department, Pradeep Vyas, issued a letter. I'll not call it a notification or a circular. They issued a small circular on the ban on loose cigarettes and cited and referred to the COTPA section 7 violation and that they [loose cigarettes] do not have a health warning." – State Foundation 1 official from Mumbai

"No, I cannot tell you anything specific about that rule, but there is a rule here which says that you cannot sell loose cigarettes. Maharashtra government has banned selling them, but still it is sold here." - School principal from Mumbai

However, awareness regarding the policy among the implementers and enforcement officials was found to be poor in Mumbai. Officials from the police,

municipal corporation, and food and drug administration, and a university director cited that they had never heard of such a policy.

"I have not come across as I said I'm not completely in this area. I don't know the finer details of the policy." - University director from Mumbai

In Delhi, only those officials working in non-governmental organizations were aware of the policy and of its implementation in Mumbai, Maharashtra.

"I think some of the states did ban it. I think Maharashtra was the first state that banned the sale of loose cigarettes." – Official from International NGO 2

"Well, the states have started to come up with these orders in addition to what the legal metrology and the central excise say but, the implementation is very mixed, and it goes in waves and it depends on, you know, just before a declaration of a smoke free or a tobacco free cities to be done, the ban on loose cigarette sale or its implementation comes around that time. So, there's some people who get picked up, if you had open packets of cigarettes, so they get caught, but, but again the signs are too minimal, and people are just let away with very small punitive measures on upon them, so there's really not much that happens." – Official from International NGO 1

Those in Mumbai who were aware of the policy were asked about how the policy was operationalized and implemented in the city. Only officials from the state health department stated that public awareness was created to sensitize the vendors regarding the ban and enforcement squads were created to penalize those who did not adhere to the ban.

"Regarding this, they have awareness. The functionaries of the National Tobacco Control programme at the district level, like the consultants, and the counsellors, so, whenever they go on the field for outreach, they give health education to the people selling on the handcarts etc. Public awareness is a separate thing. So there is also sensitisation of the people who sell. They are also told the penalties that are applicable by the law. They are told that there is a fine applicable if they sell it in loose. This is the awareness that we create." – Official 2 from health department

"Yeah, we have enforcement squads in 34 districts even at the taluka level we have those squads, but the enforcement squad is the combination of three departments, the health department, the police department, and the FDA. So, there exists the combination and contribution of these three departments. There exists only a little problem but otherwise, enforcement is very good, and the involvement of the police department is very nice as well. We have collected more than 5 crores as fines this year itself." – Official 1 from health department

Even though the policy was proposed in Mumbai, Maharashtra, perceptions about its implementation differed as officials from international NGO, state foundations, and heads of academic institutions mentioned that the policy was not being implemented and loose cigarettes were still easily available in the city.

"I don't think it's being implemented; you just go out and buy, try to buy. You will be able

to. I mean, if you ask for two Cigarettes you will get, so, I mean that can be the best example rather than just talking things." – Official from International NGO 3

"We cannot say that it is not applied. It is there, but it is not being implemented." – Official from State Foundation 2

Barriers to policy implementation and enforcement

Participants described multiple challenges in the implementation and enforcement of the ban. Seven main barriers emerged from the interviews conducted in both the cities, and they are presented in order from most discussed.

1. Unclear implementation guidelines

The most commonly mentioned barrier was unclear guidelines for implementing and enforcing the ban on the sale of loose cigarettes. Officials from the state foundations, hospital research system, private sector, and municipal department in Mumbai stressed that there was limited clarity regarding how the policy was supposed to be implemented and by whom, and whether training would be provided. Officials mentioned that even though the policy was announced, no standard operating procedures were developed or shared, and there was no clarity around what did the ban entail, how were the fines supposed to be levied, or what were the legal processes in case of any violation, and no trainings for such matters was provided to the implementers and enforcement officials.

"But the order on the ban on sale of loose cigarettes that was released in September 2020 is not clear. I mean how will it be implemented? How will it be monitored? Who will report to whom? Will the police take action? What will be the fine for violating it? Nothing is clear. For example, for the ban on gutka pan masala, it is clearly mentioned in the FSSAI amendment that there will be a fine of INR 10,000, and certain period in jail….. everything is clearly mentioned… but for loose cigarettes… the simple circular that was released showed that the policymaker was not provided with any training related to the policy, there is no awareness in the community. We have been working in this field for so many years now and that circular was incomplete. If you are releasing any circular, it is important that those officers should receive the necessary training, which was not the case, and you can easily find loose cigarettes everywhere. Even though you released the circular regarding banning the sale of loose cigarettes, the implementation is very poor."
–State Foundation 1 official from Mumbai

More specifically, there was lack of clarity regarding whose responsibility it was to implement and enforce the ban. On being asked whose responsibility it was to implement the ban, policy implementers and enforcers from both the cities mentioned that it was the responsibility of other departments, but theirs, to implement the ban. For example, municipal corporation officials from Delhi stated that it was the responsibility of the police, health, and education department to implement such a policy ban, whereas the head of an educational department in Mumbai perceived it be to be the responsibility of municipal corporation officials and was not sure if they could enforce the ban outside their academic institution.

"But under your nose, I mean, selling undercover or selling by dubious means, all that probably may happen around the campus, which may create problems of enforcing the ban, but there is little that we can do outside the institute. But certainly, we will, you know, make sure that this is enforced within the campus, but we don't know, I mean, the ban, the sale of loose cigarettes will not happen within the institute, but it can happen outside. So, I'm not really sure whether we can play any active role in that." – University Director in Mumbai

"No, not at all. We are not there at any level. We will not be there in monitoring. We don't have any supervisory role. We will not be there in implementation as well. We will not be involved with that. The health department as a whole is not coming under that department." – Medical officer in charge of a primary health centre in Mumbai

"Now for enforcing this, tell me who can take action on this? Don't bring the police into this. This act is not the job of police. It is the job of food and drugs. That act is majorly related to them. It is mainly their job." – Police official from Mumbai

Because of unclear guidelines, state foundation officials from Mumbai mentioned that policy implementers and enforcement officials from some departments placed responsibility on the other department, resulting in poor implementation and enforcement. Additionally, officials from national foundations in Delhi pointed that unclarity in implementing roles would be a major issue if a ban comes in place in Delhi.

"For loose cigarettes, there are no clear guidelines regarding who should implement and enforce this law. So, every department pushes it on each other that this is not our work,

who will do this? We already have lots of work to do, so this is the situation. So, someone should be nominated for this responsibility, they should designate this responsibility to someone, that you have to implement this policy. And if they want to take action, where should they take action? This should be also there. So, there is no proper management, and that's why there is no implementation of the law." – State Foundation 2 official from Mumbai

2. Lack of commitment for tobacco control

Policy implementers and enforcers from Mumbai, including officials from the police, FDA, municipal corporation, and head of an academic institution stated that tobacco control was not a priority in the city as much as it should be. Police officials stated that tobacco control was not a priority for their department as they had multiple other responsibilities, whereas municipal corporation official mentioned that their focus was more on treating non-communicable diseases than participating in activities related to tobacco control.

"I am telling you unofficially that it [priority] is not there. If they wanted it, then it could have been done 100% throughout India but it is not the case. It is not going to help if it is done only in Maharashtra. Now you are banning gutkha in Maharashtra but in neighboring Karnataka, it is allowed. In neighboring Goa, it is allowed. It is allowed in Gujarat. So, it comes through the border. Just asking the state authorities to implement it does not help. We are doing it because we have to do it. We cannot say no. But if you

want to do it then do it throughout India otherwise don't do it. They can do it, but they are not focusing on it." – FDA official from Mumbai

"It is not really a priority as per our department since we have to work on everything. We work on whatever comes our way. But this is necessary. This should be focused upon." – Police official from Mumbai

Additionally, officials from the state foundations in Mumbai also pointed out that tobacco control was not given proper importance and issues related to implementing the ban on the sale of loose cigarettes was being neglected by senior government officials.

Participants from Delhi shared similar opinions regarding low commitment for tobacco control. Policy implementers including municipal officials stated that their department did not make tobacco control a priority and that they were not directly involved in tobacco control. Officials from international NGOs felt that tobacco control was not prioritized at the national level as they considered that officials at the state and district level were more responsive to the issue of tobacco control. However, officials from national foundations expressed lack of efforts for tobacco control by the state government in Delhi.

"I think we have more faith in state and district, we don't really have much hope on national support. It's too complex and too politically compromised, so it's always best to go to States where you find some local champions who want to make a difference." – Official from International NGO 1

"At the level of Delhi Govt. while you know there is general support for public health measures, I mean I do not see too much happening at the state level in terms of tobacco control." – National Foundation 2 official from Delhi

Enforcement and NGO officials in Mumbai also stated that there was interference in policy implementation from local politicians which made implementation a challenge. It was also difficult for strong policies to pass due to policymakers' interests in the tobacco lobby. An FDA official also described how local politicians interfered during their field visits regarding prohibited items and coerced them to not take necessary action against the violators.

"After we go there on the field, there is local interference from the local politicians, who say that he is our person, they pressurize us so that is a problem. We anyway do our work, but it is a distraction." – Official from FDA in Mumbai

"If you will see, policy makers, especially politicians do give instructions to ban this, or ban gutkha pan masala, or ban loose cigarettes, so they do have that intention, but sometimes what happens is like the social justice department and politicians of other departments have interests in the tobacco lobby, and sometimes they are also tobacco users, so strong policies can't be passed." – State Foundation 1 official from Mumbai

3. Resource-related barriers

Resources such as money, infrastructure, and manpower were considered crucial for policy implementation and enforcement. Policy implementers including FDA and

police official in Mumbai described that there was lack of sufficient human resources. FDA official also mentioned that there were limited financial resources, and infrastructure, such as vehicles, to carry out the field visits by enforcement officials. Due to lack of infrastructure, they also referred to undertaking field visits as a risky task. As a result of lack of manpower, they described that they would collaborate with other departments, such as police, to carry out implementation and enforcement related activities.

"If you want to raid many places in Mumbai, then you will need that much manpower. To go there… There should be good management so that you can raid many places in one go. That won't be possible, right? If I go alone, then I will go to one stall and conduct a raid and then go to the other. This is Bandra. Here, there are so many cigarette stalls. So, these problems are bound to come." – FDA official from Mumbai

"That is always there [need for more personnel]. Even now it is less. Do you know what is the strength of one police station? I think 230-240 is the strength that is sanctioned, but only 156 people are working. Human resource is needed." – Police official from Mumbai

The lady FDA official described that they did not have any financial support for undertaking field visits to seize prohibited items. They had to incur expenses themselves which were not reimbursed to them. She also brought up that undertaking such visits without a vehicle and security was risky.

"See, we don't get any funds for all these things. The expenses incurred on the vehicle for going and coming back. The expense incurred for bringing the stock here, and also for

loading and unloading, we have to give it ourselves. We cannot claim it from the office. There is no mention of funds. It is just like that. It works this way." – FDA official from Mumbai

"We form a team and go there [for inspection]. We don't get a vehicle to go there. We don't get any security. So, we first go to the police station. We give them a letter and then get the security from them. One or two policemen come with us in the rickshaw. Then we go there. After reaching there, they [violators] will try to argue that they have not done it. Sometimes they run away from there. All these things happen. After that registering an FIR is also a problem. I am telling you about the prohibited articles and not about cigarettes. There are difficulties. After that, if the stock is more, then carrying the stock from that place where we have seized it to bring it here involves so many difficulties. We have to look for a vehicle. There is no infrastructure, so these difficulties are there. If I go at 9 in the morning, then I reach home by 2 or 3 in the night for one raid. There are many challenges." – FDA official from Mumbai

"I am telling you about my experience. I am telling about prohibited articles. I am a lady officer. To go there is a big thing for me, to go to the stall because they are criminal-minded. If they are selling banned products, then they have some connection. So, to go there is risky." – Official from FDA in Mumbai

Officials from the health department and state foundation in Mumbai also pointed to the difficulties in managing the tobacco control program related activities due to scarce manpower. They stated that for implementing the policy, there were

fewer resources at the district level and below. As a result of that, they focused on multi-sectoral coordination with other government departments such as the police, for implementing tobacco control related provisions.

"No, this policy is implemented because of the 2003 law. We are following the guidelines written in it. It talks about following a multi-sectoral approach and all. We involve other people in this because there are only 3 members in Tobacco Control Program, maximum posts in the tobacco control program are vacant. My district would not get monitored by 3 persons that's why I have included all the departments and we get information from them." – Official 1 from Health Department

Municipal corporation officials from Delhi also discussed issues around paucity of health staff and that no funds were allocated to them for implementing such policies.

4. System-level barriers

Officials from national foundations in Delhi and hospital research centre in Mumbai emphasized the lack of monitoring and evaluation mechanisms for loose cigarette sales. They referred to the high density of vendors selling tobacco products in the country which made monitoring a very challenging task. They mentioned lack of focus towards evaluating such policies as another potential barrier and that real-time tracing, real time evaluation or on-field evaluation for tobacco control policies was not being conducted.

"And the other thing also is, an initial challenge is about checking this loose sale. It is very very difficult to control because you know in a country like ours tobacco products are something which are available at every local corner and so checking something like loose sale will be definitely a challenge." – National Foundation 2 official from Delhi

"Another important thing is also about evaluation and that is again something which is not spoken as much in India as probably in some of the other countries is that when laws and legislations are enforced after a certain point in time, when reasonable period has been passed where you know that law has been in place, we don't evaluate the level of enforcement or the impact that it has brought about. So, I think for tobacco control policies in general and even for this new policy of ban on loose sales, evaluating the implementation of policy is very important." – National Foundation 2 official from Delhi

Health department officials and those from international NGOs stated that not having a proper licensing system for tobacco products and vendors was a challenge in the implementation of the ban as it made controlling and monitoring loose sales difficult as vendors without a license were able to freely sell tobacco products from any place in the city.

"They are freely sold in loose. They start selling anywhere. Maharashtra is struggling with the vendor license issue. Vendor licensing, we are trying to promote from our end at the state level. If willpower is raised amongst the policymakers and bureaucrats… See,

they sell it anywhere on the road on a handcart. They will take the handcart from one place to another. If the police come and takes action against them, then they shift their handcart from one place to another. We think that if vendor licensing is properly done, then they will get taxed. So, there will be control over the sale and the monitoring and supervision can be properly done." – Official 2 from health department

An official from Mumbai also stated that there was no working platform where complaints could be raised if someone was found selling loose cigarettes.

"Plus one more thing. The toll-free number which was given by the central government to raise complaints, that is not even operational. That's the whole thing. Where will the general public raise their complaints then? If there is a portal and I need to reach out to someone, it is just not possible. Everybody doesn't know about this that there is a National Tobacco Control Program in the district headquarter or state headquarter. They have no clue about it. There should be a platform available where people can raise complaints. That is the most important. There is no such platform available. It was there earlier administratively, but it even got shutdown administratively." – Official from Hospital Research Centre

5. Enforcement-related barriers

Policy implementers and enforcement officials from Delhi including municipal corporation and police officials, and a head of an academic institution from Mumbai described that if loose cigarettes were banned, there would be resistance from tobacco

vendors and they would continue to sell discreetly as the policy would impact their income, and livelihood.

"There will be arguments and fights between us and the public. Shopkeeper will argue with us. To impose any rule, we have to do that forcefully. No work can be done without being forceful. If I ask someone politely that you have loose cigarettes, give it to me, will he give it to me? Of course he won't. So, we have to forcefully implement it." – Public Health Inspector Official 2 from Delhi

Official from state foundation in Mumbai also mentioned that enforcement would also be affected if corruption were involved among policy implementers and enforcers.

"Secondly, law implementers themselves induce bias while implementing the law. Suppose they will go somewhere to enforce the law, and say them themselves smoke, so then they will ask the vendor to give them four, five or ten packets [referring to bribe]. So this is a big gap. First of all the government workers who smoke on duty should be fined, hundred percent. There should be a report against them in the service book and this should be forcefully implemented for every government official from top to bottom, from IAS officer up to the sweeper." – State foundation 2 official from Mumbai

6. Tobacco industry interference

Tobacco industry interference was described as a critical barrier in the implementation and enforcement of tobacco control provisions. Participants from international NGOs and state foundations stated several tactics that the tobacco

industry used to delay policy approvals and implementation. They funded political parties, offered gifts and bribes to policy officials, and would state that the livelihoods of tobacco vendors would be impacted if any strong policy was about to be brought in. They also mentioned that the policies government officials and civil society organizations worked on received a lot of pushbacks from the tobacco industry and that the ban on the sale of loose cigarettes would face similar pushback from the industry.

"And the interference of tobacco industry is so much like….at the time of new year…representatives from ITC company will gift new year calendars to these officials, and then that officer will never step forward to implement that tobacco control law. There is a lot of tobacco industry interference in Maharashtra, especially with ITC." – State foundation 1 official from Mumbai

7. Lack of awareness about the policy

Multiple stakeholders from the health department and state foundations in Mumbai pointed to the fact that awareness regarding the policy was poor among tobacco vendors and public; only those who work in tobacco control were aware of it since they advocated for it. They mentioned that it was not possible to assess the impact of policy as vendors were still selling loose cigarettes due to lack of awareness.

"From the perspective of loose cigarettes, I would say, the most important thing which I feel is that, the ban which has been implemented on loose cigarettes, that ban has not been portrayed that effectively from the government's side. As per COTPA, people cannot consume tobacco within the 100 yards radius of an educational institution, and

people are aware of it now. The thought or the severeness behind it is something that people do not know. But somewhere down the line what I feel is, this idea that loose cigarettes are banned, has not reached people properly. Like, this rule that you are not allowed to sell cigarettes to minors, tobacco vendors know about this, but the fact that loose cigarettes are banned, this is something that tobacco vendors do not know. And tobacco vendors are not aware about it because there is no vigilance authority supervising tobacco vendors which can inform and update them about these policies which are drafted." – Hospital Research Centre official from Mumbai

"We have launched the notification but if you go into the field then you would see that people are not aware of this, they still sell loose cigarettes. Specially paan shops, or any small shops sell it. So, our target is to make them aware. We should tell those who sell chocolate or any biscuit to not sell cigarettes because they [kids] would come to buy these products and they will notice that cigarettes are being sold so they may end up trying the cigarette and get into the habit of smoking. That is why awareness is important. These activities happen but we can't calculate the impact that has been there. But there has been some impact, not 100% but some for sure." – Health Department official 1 from Mumbai

Facilitators for policy implementation and enforcement

We asked the participants about the potential facilitators or solutions for effectively implementing and enforcing the ban on the sale of loose cigarettes. Several key facilitators such as imposing heavy fines and penalties, issuing tobacco licenses to vendors, reducing tobacco industry's interference, promoting health education about

the harmful effects of smoking, and multi-sectoral coordination between implementing departments were described:

1. Stricter implementation and enforcement

Participants strongly emphasized that strict implementation of the ban on the sale of loose cigarettes was needed. Policy implementers from both the cities including municipal officials, police officials, heads of academic institutions, and officials from the health department stated that heavy fines and penalties must be imposed on tobacco vendors only then the policy would have an impact and sales would reduce. Without the presence of fines, tobacco vendors would continue to sell loose cigarettes. Additionally, participants mentioned that the policy must be implemented with full force and not half-heartedly. Strictness should be enforced by increasing the amount of fines and penalties with the intention of increasing tobacco vendors' fear of the consequences from breaking the law. Participants also cited examples of how stricter enforcement of running a red light and smoking in the Delhi metro [public transport] were highly effective as it significantly reduced the number of violations.

"If it is to be done then it has to be stringent. If it is a non-cognisable offence then it will not have any impact. The person will easily go by. He will pay the fine and again open the shop and start selling again. He should have that fear that he cannot sell loose." – Police official from Mumbai

"The law should be quite stringent for this. There should be hefty fines. If somebody gets

caught then there should be a hefty fine. The way if someone jumps a red light then nowadays there is a huge fine. Fewer people jump. Similarly, if there is a fine of Rs.200/- and if there is a fine of Rs.2000/-, if you sell loose cigarettes then there should be a fine of Rs.2000/- on you or Rs.5000/- fine. Then the shopkeeper will think that I don't want to get into this mess. Why should I sell? I will lose all the profit that I made on that day. This is also there. The fine and the punishment should be at a deterrent level." – District health official from Delhi

2. Vendor licensing

Participants from both the cities emphasized the need for having a vendor licensing system for selling tobacco products. They stated that vendors must acquire a separate license for selling tobacco products, just like a liquor store or a gas station had a license to operate. Policymakers and implementers from the health department in Mumbai stressed that it was difficult to put a check on vendors if they were selling tobacco products without having a license. They mentioned that vendor licensing would ensure that not every shop owner would be able to sell tobacco products but only those who had a valid permit. And those with a valid permit would not be allowed to sell anything except tobacco and would need to operate from a specific geographic location only.

"I want to say that vendor licensing should be compulsory and ban on loose cigarettes and licensing is required because those who sell chocolate, biscuits, and chips, they should not sell these kinds of tobacco products and if they want to sell tobacco products…like there is a license for alcohol, similarly a license for tobacco too, then they

must have a license then only it would get controlled." – Health Department Official 1 from Mumbai

"I feel that vendor licensing should be universal. That is because we can ask whether the vendor is selling loose cigarettes or not, only when he has the license. If they sell without a license like the food products then it is difficult to put checks on them. If we catch him at one place, tomorrow he will go to some other place with his handcart and start doing business. If we do the vendor licensing as we do for liquor, then it gets controlled. Similarly, if we control the sale of tobacco as well with proper licensing then there will be proper checks." – Health Department Official 2 from Mumbai

Implementers from Delhi also asserted that licenses should be seized from those who violated the law and discussed that a proper vendor licensing system would ensure that tobacco products were not being sold in the informal economy such as by those who sold tobacco products on the roadside or on handcarts that could be moved from one place to another.

"I will get connected to the licensing branch that issues the license to them. If a person is found violating the act, his license should be revoked. The second thing is some people work without a license so they have to be cleared from that place. You might see many of them selling on the roadside." – District health official from Delhi

3. Reduce tobacco industry's interference in policymaking

State foundation officials in Mumbai said that to effectively implement the ban on the sale of loose cigarettes, interference by the tobacco industry needed to be

reduced. Proper guidelines needed to be established that would define how policymakers and implementers should meet the representatives of the tobacco industry.

"I believe that interference should be reduced and for that instructions should be given at the department level, that if you want to meet the representative of the tobacco industry then there should be a proper guideline from the department, or those guidelines should be made at the CM or the chief secretary level. And those guidelines are currently not there. Because anyone will then go and meet the FDA commissioner or the director of the health department and then there is interference. So, all that will not happen and yes, behind this, there is a political agenda, and we have seen that it delays the implementation and enforcement of any new policy. To ban gutka pan masala, it took a lot of time." – State Foundation 1 official from Mumbai

4. Health education and awareness

Stakeholders from both the cities stressed that the ban on the sale of loose cigarettes would not be highly effective if implemented as a standalone provision, rather it should be complemented with imparting health education and awareness. Instead of making the implementation of this policy ban only enforcement driven, participants suggested that health education about the harmful effects of cigarette smoking be promoted at a larger scale and should be the ultimate objective.

"If you want to ban it then, realistically, social awareness is most important. You have to make people aware that what is the harm of cigarette smoking and what are the

diseases that you may suffer from. They should make the law stringent. A combination of the two is required – awareness and law." – District health official from Delhi

5. Dedicated nodal officer for tobacco control

Participants from the health department and non-governmental organizations in Mumbai stated the need for appointing a nodal officer specifically for the tobacco control program which would assist in implementing the tobacco control provisions more effectively.

"There is a need for a nodal officer, if you have to collect fines from every district then there should be a proper mechanism for that. Monitoring is usually a challenge for COTPA implementation, so there should be a proper monitoring team and monitoring officers, which is currently missing." – State Foundation 1 official from Mumbai

"Yeah, special enforcement is needed, power is also required, and enforcement too. But for the health department, more than enforcement and power, we need a dedicated person. See, I look after 9 programs, and tobacco is one of the small programs. So, if there are separate State Program Officers for every program, the programs could be implemented more effectively." – Health Department official 1 from Mumbai

6. Coordination and collaboration between multiple stakeholders

Participants strongly emphasized the need for and importance of a multi-sectoral approach for implementing and enforcing the ban on the sale of loose cigarettes. Due to stakeholders' multiple responsibilities and limited human and financial resources, health

department officials, state and national foundation officials and policy implementers from both the cities emphasized collaboration between government departments as crucial. Implementers believed that implementation could be improved if all government departments were involved and there was coordination between them.

"Yes, it can be done. Definitely, it [better implementation] is possible. The police have a lot of information. They have more informers. So, the raid can be done collectively taking along other departments." – FDA official from Mumbai

Policy implementers also believed that not only the government departments, but other institutions and associations such as resident welfare associations, schools, and the public at large should play a crucial role in enforcing tobacco control provisions. Moreover, state foundation officials from Mumbai believed it was equally important to involve and engage with civil society organizations for their expert guidance on policymaking and implementation. Policymakers and implementers also suggested that the power to impose fines should be disseminated among other stakeholder groups, such as school teachers, municipal officials, and resident welfare associations, as at that time only the police officials had the power to penalize or impose fines on those who violated tobacco control provisions.

"If a teacher in school is good, he should be given permission that he can fine someone. Some officer from health centre should be permitted to implement fine. So many control measures can be implemented. The reason why there is a problem now is that only a

police officer is putting fine. If we have 10,000 people and 10 people are controlling them, then how would things work." – School principal in Mumbai

"I take the report from the inspectors to know how many people were issued challan [fines]. In that matter as well they do not have any power as such. If I am an inspector and I catch hold of you while you are smoking then in a way I will have to request that you don't smoke or there will be a challan issued. Either the policeman should be there. They can take you to the police station and make you sit for four hours. There was no power or support of this type. We have not been much successful till now with this." – District health official from Delhi

"There are many societies. Suppose there is a society where there are 500 residents, 500 families are residing. There will be an RWA in that society who looks after the day-to-day administration. They look after the housekeeping. They look after the electrical problems. They should ensure that such type of activity, they do not get sold loose, around society, they can approach the police or they can stop them from selling. This type of public mobilization is required." – District health official from Delhi

Municipal corporation officials from Delhi and officials from International NGOs stressed that to ensure efficient collaboration and coordination between multiple stakeholders, capacity building was considered crucial where each stakeholder would have the opportunity to learn their specific responsibilities to avoid confusions or lags in policy implementation. Implementers from Delhi mentioned that if they received proper guidance from the state or central government and worked as a team with other

departments, then they would not face any difficulties in implementing the ban.

Contributions to the implementation and enforcement of the policy

We asked the participants to describe how they and their organizations have contributed / could potentially contribute specifically to the implementation and enforcement of the ban on the sale of loose cigarettes. Only officials from the state health department in Mumbai mentioned that they had contributed in capacity building and enforcement, whereas all other stakeholders shared how they could potentially contribute in the future. Non-governmental organizations offered that they would be able to support in capacity building and generating scientific evidence through monitoring and evaluation. They also offered support for advocating for the policy and garnering support for it. Enforcement officials such as the police offered to provide security to other officials and conduct investigations, and educational institutions could potentially contribute to imparting health education and undertaking advocacy campaigns. Detailed description of potential contributions of various stakeholders is described in Table 4.12.

Table 4.12: Participants' ideas about potential contributions to policy implementation and enforcement

Department	**Contribution**	
	Mumbai	**Delhi**
Health Department	Capacity building and enforcement	-
Hospital Research Centre	Capacity building of enforcement officials with the objective of health education.	-
State Foundation 1	Advocate and follow up with the ministry for policymaking;	-

	Involve school children in advocacy activities.	
State Foundation 2	Capacity building of enforcement officials.	-
Police Department	Public awareness – discuss the issue with schools and colleges; Conduct investigations into case of violations; Provide security to other enforcement officials	Conduct inspections
Heads of Educational Institutions	Impart health education to children and through them to the community; Undertake advocacy campaigns; Encourage postgraduate students to undertake research studies for generating more evidence for supporting the policy.	Impart health education through school children via street plays and public rallies.
Private Sector	Advocate for the policy; capacity building of communities and enforcement officials.	-
Food and Drug Administration	Conduct inspections; issue challans / fines	-
National Foundation 1	-	Improve public awareness by sensitizing the community members; Monitoring and evaluation.
International NGO 1	-	Provide technical support for vendor licensing.
Municipal Corporation Department	Medical officer in charge of a primary health centre takes no responsibility.	Undertake field visits for inspections and issue challans/fines or seal the shop if violations are caught; Seize loose cigarettes; Control vendors through regulating license issuance; IEC activities.
National Foundation 2	-	Garner support for the policy; Sensitize young people and vendors on the

		policy; Monitoring and evaluation.
International NGO 2	-	Design and sustain health communication campaigns; Messaging on social media around the policy targeted towards policymakers; Create support through public agenda setting.
International NGO 3	-	Generate and disseminate scientific evidence.

Discussion

Our in-depth interviews with stakeholders in two Indian cities regarding the ban on the sale of loose cigarettes identified a number of key issues around policy implementation in Mumbai, Maharashtra, a state where the ban on the sale of loose cigarettes has been in place since 2020. Stakeholders identified several barriers to policy implementation, which we categorized into: (1) unclear implementation guidelines, (2) lack of commitment for tobacco control, (3) resource-related barriers, (4) system-level barriers, (5) enforcement-related barriers, (6) tobacco industry interference, and (7) lack of awareness. Finally, the main facilitators or solutions for policy implementation that stakeholders identified were (1) stricter implementation and enforcement, (2) vendor licensing, (3) reduce tobacco industry's interference in policymaking, (4) health education and awareness, (5) dedicated nodal officer for tobacco control, and (6) coordination and collaboration between multiple stakeholders.

Our study found that even though the policy ban on the sale of loose cigarettes was proposed in 2020 in Mumbai, awareness among policy implementers and

enforcement officials was found to be low. Participants from Mumbai mentioned that the policy was not being implemented and that loose cigarettes were still widely available in the city. Other studies conducted in India have found that awareness and understanding of COTPA provisions among implementers and law enforcement officials have generally been poor which is considered a major impeding factor in effective policy implementation (Kaur & Jain, 2011; Persai, Panda, & Gupta, 2016). Poor awareness levels also signifies lack of training and capacity building opportunities for implementers and enforcers which eventually results in failure or delay in initiating action for violations (Kaur & Jain, 2011). Literature suggests that awareness and knowledge about the policy was linked to the stakeholders' level of interest in the policy, where policy implementers who were unaware of the policy may have lower interest in its implementation (Balane et al., 2020). A similar stakeholder analysis focused on understanding perceptions of stakeholders regarding a universal health insurance policy in Ghana also suggested that lack of stakeholder's understanding of the policy acted as a hindrance in successful policy implementation as low awareness levels affected stakeholders' interest in the policy (Abiiro & McIntyre, 2013).

Participants from Mumbai mentioned unclear implementation guidelines as the most common barrier to the implementation of the ban on the sale of loose cigarettes. Unclear implementation guidelines led to lack of clarity about implementation roles of various stakeholders and lack of knowledge about how the policy was supposed to be operationalized. Study findings are consistent with the global literature on tobacco control policy implementation. Study conducted by Mohamed and colleagues (2018) to

assess facilitators and barriers in the formulation and implementation of tobacco control policies in Kenya stated unclear roles among members of the tobacco control unit as a barrier in tobacco policy formulation and implementation (Mohamed, Juma, Asiki, & Kyobutungi, 2018). Similar findings were reported by Astuti and colleagues (2020) that unclear roles and responsibilities of tobacco control stakeholders in Indonesia led to delays in effective policy implementation (Astuti, Assunta, & Freeman, 2020).

WHO-FCTC focuses on the importance of strong political commitment for successful tobacco control policy formulation and implementation (International Legal Consortium at the Campaign for Tobacco-Free Kids, 2020), which has been described as a barrier for implementing the ban on loose cigarettes. Participants from both the cities described that tobacco control was not prioritized by their organization and that political leaders interfered in the policy implementation process. Evidence suggests that tobacco control has always been a low priority issue not only in India but also in other developing and developed countries (Hamann, Mock, Hense, Charoenca, & Kungskulniti, 2012; Owusu-Dabo, McNeill, Lewis, Gilmore, & Britton, 2010; Persai et al., 2016; Robertson, Conigrave, Ivers, Usher, & Clough, 2012). Strong leadership and political commitment has been described as a key facilitator for tobacco policy formulation and implementation in Kenya (Mohamed et al., 2018). The significant decrease in the smoking rates in Turkey has also been attributed to Turkish government's sustained political commitment to tobacco control (Ozcebe et al., 2018). In addition to lack of prioritization for tobacco control (Persai et al., 2016), lack of resources, including

financial support, infrastructure and manpower, has been a long standing barrier for effective tobacco control policy implementation in India (Jandoo & Mehrotra, 2008; Persai et al., 2016) and in other low-and-middle income countries (Owusu-Dabo et al., 2010).

Stakeholders described that for implementing the ban on the sale of loose cigarettes, a strong monitoring and evaluation system was lacking. Loose cigarette sales could only be monitored if there was a robust tobacco vendor licensing mechanism. Not having a vendor licensing system in place meant that anyone, be it a grocery store or a street vendor, could sell tobacco products illegally without a license resulting in high density of tobacco vendors in the neighborhood. Studies conducted in India have found that tobacco vendor density was notably high (Pouranik et al., 2021). Easy access to tobacco retailers and the retail environment in a neighborhood significantly influences tobacco use, especially among youth (Mistry et al., 2022). A study found that school children in neighborhoods with high tobacco vendor density reported increased risk of consuming smokeless tobacco (Mistry et al., 2015). The government should prioritize and implement tobacco retail licensing and learn from the experiences of states, such as Himachal Pradesh, where tobacco retail licensing has already been institutionalized to complement the ban on the sale of loose cigarettes and has remarkably reduced the availability of tobacco products (Chauhan, 2018). Vendor licensing will prevent vendors from selling other food items with tobacco products and reduce vendor density and access to tobacco products.

Even though policy implementers described resistance from tobacco vendors as another potential barrier to effective policy implementation, cross sectional studies conducted in other states of India where loose cigarettes were banned found that most vendors admitted that if the ban on loose cigarettes was properly enforced, they would stop selling loose cigarettes (Eshwari et al., 2020). Finally, interference by the officials of tobacco industry in policymaking and implementation was another potential barrier that was explained. This finding aligns with the global policy implementation literature. Tobacco industry delayed implementation of tobacco control policies in Kenya through instituting legal suits or by bribing senior officials (Mohamed et al., 2018). Similar findings were reported from Argentina, Malawi, Colombia, and other low and middle-income countries (Lee, Ling, & Glantz, 2012; Mejia, Schoj, Barnoya, Flores, & Pérez-Stable, 2008; Otañez, Mamudu, & Glantz, 2009; Uang, Crosbie, & Glantz, 2018).

Study participants suggested that to overcome the barriers to implementing the ban on the sale of loose cigarettes, strict implementation and enforcement, tobacco vendor licensing, health education, reducing tobacco industry interference, and adopting a collaborative approach among various stakeholders was needed. Similar to our findings, Persai and colleagues (2016) emphasized that to strengthen the existing tobacco control policies, health education strategies in conjunction with community-based campaigns must be adopted to bring change in tobacco use (Persai et al., 2016). FCTC recommends participation of multiple stakeholders, including civil society organizations, for formulating and implementing tobacco control provisions (International Legal Consortium at the Campaign for Tobacco-Free Kids, 2020). Studies

focused on tobacco control in India have recognized the need for establishing a national coordination mechanism for tobacco control (Jandoo & Mehrotra, 2008). India can learn lessons from other low-and-middle income countries such as Brazil, who had established a similar model and had become a leader in controlling and regulating tobacco products (Jandoo & Mehrotra, 2008). Kenya too benefitted from a central coordination mechanism that was a facilitating factor in the tobacco control policy formulation process and ensured representation from multiple stakeholder groups (Mohamed et al., 2018). Such mechanisms would ensure collaboration and coordination among various stakeholders such as NGOs, civil society organizations, and government departments at the state and national levels authorized for enforcing COTPA provisions. A multisectoral approach will help in leveraging knowledge, reach, and resources, which has been described as an important barrier in implementation. Study participants suggested that to reduce tobacco industry interference in policymaking and implementation, guidelines must be drafted regarding how policymakers should meet with tobacco industry officials. Similar solutions have been suggested in other studies for advocating for adopting a code of conduct by government officials to minimize complicit connections with industry officials (Astuti et al., 2020).

Finally, participants also described how they may contribute to the implementation and enforcement of the ban on the sale of loose cigarettes. Participants' responses will help in the process of assigning specific and clear roles for policy implementation. For example, to increase awareness and understanding regarding the policy ban, NGOs which have expertise in strategic health communication

could step in. The government should bring together all these stakeholders and design detailed implementation guidelines for implementing and enforcing the ban on the sale of loose cigarettes.

This study has limitations. Findings from this study are not generalizable to non-urban areas and places in the South, Northeast or Northwest areas of the country, as participants were interviewed in Mumbai and Delhi. We also could not interview national level stakeholders working in the Ministry of Health & Family Welfare who could have provided more in-depth information regarding the operationalization of the policy. We also think that the sample is not representative as we could not interview officials from other departments such as the Excise and Home departments.

Conclusion

Even though Mumbai, Maharashtra is one of the early cities in India to legally propose a ban on the sale of loose cigarettes, awareness of the policy among implementers and law enforcement officials was found to be poor. Policy implementation status in Mumbai was similar to Delhi as loose cigarettes were still widely sold in Mumbai due to inadequate implementation and enforcement efforts in Mumbai. No significant differences in the findings were found between the two cities and the stakeholders in both the cities discussed similar barriers and facilitators to the implementation and enforcement of the ban on the sale of loose cigarettes. Unclear implementation guidelines, limited resources, and lack of commitment for tobacco control were the most discussed barriers to implementing the ban on the sale of loose

cigarettes. Since India is considering a national ban on loose cigarettes, it would be crucial to enforce the policy strictly, increase awareness among the vendors and general public with the ultimate objective of educating them about the harms of cigarette smoking through community-based campaigns, establishing systems for proper monitoring, and ensuring efficient multi-sectoral coordination between the enforcement agencies.

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CHAPTER 5

DISCUSSION

The overall goal of this research was to develop in-depth understanding of the issue around the sale of loose cigarettes and loose bidis in India. I was interested in determining the prevalence and correlates of loose cigarette and loose bidi purchase among Indian adult smokers. I also examined whether those who purchased loose cigarettes and bidis were less likely to be exposed to health warning labels on cigarette and bidi packs and if that reduced the overall effectiveness of health warning labels. Finally, since India is considering a national ban on the sale of loose cigarettes, I did a stakeholder analysis to understand the perceptions of cigarette users, tobacco vendors, policymakers, implementers, and law enforcement officials regarding the implementation and enforcement of the ban on the sale of loose cigarettes. This section discusses and summarizes the main research findings, and highlights study limitations, strengths, and implications for future research.

Summary of findings

Specific aim 1: To determine the prevalence, correlates, sources, and prices paid for loose cigarette and loose bidi purchases among Indian adult smokers.

RQ1. What is the prevalence of loose cigarette and loose bidi purchase in India?

The analytic sample from the TCP dataset included 643 cigarette users and 730 bidi users who reported buying either loose/packed cigarettes or bidis. About 75% of cigarette users reported that they had purchased loose cigarettes at their last purchase, and about 12% of bidi users reported that they had purchased loose bidis at their last purchase. These findings are similar to but higher than the GATS 2009-10 and GATS 2016-17 results. As per GATS 2009-10 results, about 57% of current cigarette smokers reported buying loose cigarettes (Singh, Dogra, Kumar, & Kumar, 2017b), whereas GATS 2016-17 found that about 67% of current cigarette smokers and 17% of current bidi smokers bought loose cigarettes and bidis respectively at their last purchase (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences).

However, our study found that the prevalence of purchasing loose bidis was lower (~12%). Most bidi users in the study reported having bought a bidi bundle at their last purchase versus a loose bidi. It can be attributed to the significantly lower costs of purchasing a whole bundle of bidi vs a pack of cigarettes (R. M. John, Rao, R.K., Rao, M.G., Moore, J., Deshpande, R.S., Sengupta, J., Selvaraj, S., Chaloupka, F.J., & Jha, P., n.d.). Different tax rates make some tobacco products affordable for smokers, such as the case of bidis (DNA India, 2022). Bidis are taxed at a lower rate compared to cigarettes, thus making bidis more affordable than cigarettes; therefore driving bidi prevalence higher in India compared to cigarettes (Kostova et al., 2014).

RQ2. What are the prices paid for loose cigarettes and bidis?

Our study found that current cigarette smokers purchased an average of 2 cigarette sticks and 4 bidi sticks at their last purchase. The average cost per cigarette stick was found to be INR 7 (~ $0.085), and the average cost per bidi stick was INR 1.20 (~ $0.014). The price of an individual cigarette stick was 483 percent higher than the price of an individual bidi stick. Similar findings have been reported in prior studies. Pawar and colleagues (2014) also found bidis to be much less expensive than cigarettes and the daily consumption was higher among bidi smokers compared to cigarette smokers (Pawar et al., 2014).

RQ3. Who are the vendors from whom smokers most often purchase loose cigarettes and bidis?

Survey respondents were asked about the type of vendor from whom they had purchased cigarettes or bidis at their last purchase. Vendors were categorized into permanent tobacco stores, small tobacco kiosks, street vendors, grocery store owners, and others. The Chi-square test results did not suggest any association between purchase behavior (loose vs pack) and type of vendor for cigarette smokers, meaning sources of loose and packed cigarettes were primarily the same. Permanent tobacco stores (65.6%) and small tobacco kiosks (22.9%) were the top sources for purchasing loose cigarettes, and some respondents also purchased their last cigarette from a street vendor (9.2%) and a grocery store (2.1%). When adjusted for neighborhood level (rural vs urban), we did not determine any significant differences across vendor types between urban and rural neighborhoods. Our study findings are similar to the GATS 2016-17 findings. As per GATS 2016-17, more than half (50.8%) current cigarette

smokers purchased their last cigarette from a permanent tobacco store; about 38.7% purchased from a small tobacco kiosk; and 9.2% purchased from a street vendor (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences).

With respect to bidis, there was a significant association between vendor types and purchase behavior (loose vs bundle), with most loose bidis being purchased from a permanent tobacco store followed by small tobacco kiosks. However, no significant difference was found for loose bidi purchase across vendor types at the neighborhood level. Findings from the GATS 2016-17 survey also suggest that a large proportion of current bidi smokers (60.4%) purchased their last bidi from a permanent tobacco store and slightly less than one-third (31.8%) purchased their last bidi from a small tobacco kiosk (Ministry of Health and Family Welfare Govt. of India; World Health Organization; Tata Institute of Social Sciences).

Most of the loose cigarettes and loose bidi purchases across all vendor types were in urban neighborhoods. A cross-sectional study by Goel and colleagues (2021) documented high prevalence of loose cigarettes with tobacco vendors in urban neighborhoods (Goel et al., 2021). Likewise, GATS 2016-17 survey also found higher prevalence of loose cigarette purchase in urban neighborhoods compared to rural neighborhoods (Singh et al., 2017a). Not just in India, but in high-income countries as well, such as the United States, sale of flavored and loose cigarettes is more prevalent in urban communities (Laws et al., 2002).

RQ4. What are the correlates of loose cigarette/bidi use among Indian smokers?

Logistic regression models revealed that smokers who had lower education levels and who were unemployed were more likely to purchase loose cigarettes and loose bidis respectively which was consistent with the studies conducted in high-income and low-and-middle income countries. Among adult smokers in the US, Azagba and colleagues (2020) found that being employed and having some college education were inversely associated with purchasing loose cigarettes among US adult smokers, meaning those who did not have employment and those who had low education levels were more likely to purchase loose cigarettes (Azagba et al., 2020). In low-and-middle income countries like Mexico, Thrasher and colleagues (2009) also found an association between higher education levels and lower odds of purchasing loose cigarettes (Thrasher et al., 2009) which support the notion that loose cigarette prevalence keeps disadvantaged population groups smoking.

Findings also revealed that those who smoked occasionally or non-daily had higher odds of purchasing loose cigarettes or loose bidis. Similar to our findings, a secondary analysis of the GATS 2009-10 survey found that the intensity of smoking was lower for those who reported having purchased loose cigarettes at their last purchase (Singh et al., 2017a). Availability of loose cigarettes in the neighborhood allowed non-daily smokers to buy loose cigarettes or bidis whenever they had an urge to smoke, instead of buying a whole pack. As a result of that, smokers may experience an urge to smoke on seeing loose cigarettes in the neighborhood. Evidence from Mexico suggests that smokers reported an urge to smoke whenever they saw sale of loose cigarettes and

such urges were positively associated with odds of purchasing loose cigarettes (Thrasher et al., 2011).

Finally, we also found that those who had ever made a quit attempt, or who were unsuccessful quitters were more likely to purchase loose cigarettes. It signifies that their smoking relapsed which could mean that loose cigarette prevalence potentially keeps smokers from successful quitting. Studies conducted among adult Mexican smokers found that smokers reported a sight of loose cigarette sale acted as a cue to smoking and prevented them from successful quitting (Thrasher et al., 2009). Another study conducted in the US in an African-American population also found that prevalence of loose cigarettes in the neighborhood was a risk factor for relapse (Phan et al., 2021). Findings in our study strongly support the notion that loose cigarette/bidi prevalence acts as cues to smoking, evokes cravings to smoke and restricts Indian adult smokers from making successful quit attempts.

Specific aim 2: To examine the association between purchase behavior (loose vs pack) and exposure to and effects of HWLs on cigarette/bidi packs.

RQ5. What is the association between bidi purchase behavior (loose vs bundle) and HWL exposure and responses?

Results from the adjusted ordinal regression models did not find any significant association between bidi purchase behavior and exposure to HWLs. However, the crude regression model found that those who purchased loose bidis at their last purchase less often noticed HWLs. Adjusted ordinal regression models for bidis found that those who

purchased bidi bundles at their last purchase, less often thought about the health risks of bidi smoking and quitting bidi due to HWLs on bidi packs. This can be attributed to the poor compliance to the HWL law on bidi in India. A recent study by Saraf and colleagues (2021) that examined the extent of compliance of HWLs on bidis in India found that none of the bidi packs were compliant with the law requirements (Saraf et al., 2021). Non-compliance issues pertained to non-standardized packaging, incomplete HWLs, poorly printed HWLs, and old HWLs (Saraf et al., 2021). Consistent with that, another study based in India found that about 94% of bidis were not compliant with the COTPA sections 7,8, and 9 meaning they either did not have warnings on both sides of the pack, or did not meet the minimum stipulated height and width requirement, or the language of the text warning was different than that of the pack (Mullapudi et al., 2021).

RQ6. What is the association between cigarette purchase behavior (loose vs pack) and HWL exposure and responses?

Adjusted ordinal regression models found that those who purchased loose cigarettes less often noticed HWLs on cigarette packs. Our survey findings provide evidence that loose purchase behavior significantly reduces exposure to HWLs and to our knowledge this is the first study that has examined such association. No other associations with other HWL variables were detected to be significant. The qualitative findings from the in-depth interviews complemented the survey findings as most participants explained the specific mechanisms through which their exposure to HWLs was limited. They described that cigarettes packs were not visible at the point of sale and the vendor usually keeps loose cigarettes in a separate container which could not

be seen by buyers. They also described that they themselves avoided noticing HWLs, some mentioned that vendors did not put-up statutory health warnings at point of sale, and some mentioned that the foreign made cigarettes that they preferred did not carry the HWLs on its packaging.

Foreign made cigarettes are illegally sold in the Indian markets as their cigarette packs do not depict the mandatory HWLs required by the Indian law. Our qualitative findings are consistent with other studies conducted in India. Chahar and colleagues (2019) found that there was a poor compliance to the sections 7,8, and 9 of COTPA among the foreign cigarette brands (Chahar et al., 2019). Only 11% of the foreign made cigarettes depicted pictorial health warnings on their cigarette packs, significantly reducing the exposure of foreign made cigarette users to HWLs (Chahar et al., 2019).

Even though some participants mentioned that they noticed health warning messages at the point of sale, it should be noted that those statutory warnings did not have a pictorial component and viewers could easily choose to ignore it. Studies have shown that warnings that have a pictorial component are more effective than the text-only warnings (Macy et al., 2016). Additionally, it should not be assumed that all vendors displayed statutory health warning messages at their point of sales. GATS 2016-17 results indicate that about 48% of the current smokers purchased their last cigarette from a small tobacco kiosks or street vendors (Tata Institute of Social Sciences et al., 2018). Findings from our study indicate that vendors like street vendors and small tobacco kiosks did not put up any statutory warnings at their establishments, thus reducing smoker's exposure to health warning messages. Our finding is consistent with

the prior literature highlighting substantial percentage of tobacco vendors displaying advertisement boards without health warnings (Goel et al., 2015) and a higher non-compliance to the presence of health warnings especially among small vendors (Joseph et al., 2021).

Even though no association was found between cigarette purchase behavior and other HWL responses from the survey findings, exposure is considered as a gateway to the other effects of HWLs. Literature that discusses how HWLs work, states that exposure influences warning reactions, knowledge and beliefs about cigarette smoking, and perceived effectiveness of the warnings (Francis et al., 2017). Studies have also found that those who purchased loose cigarettes were less likely to have complete knowledge of the harms of smoking (Elton-Marshall et al., 2018). With the plans to update the content of HWLs in India (Ministry of Health and Family Welfare, 2022), reduced exposure due to loose sale of cigarettes could deter the dissemination of new knowledge through the updated HWLs.

With respect to warning reactions, qualitative findings suggest that cigarette users described an avoidance behavior in which they ignored the health warnings because they were already exposed to them and did not like seeing them. Literature suggests that exposure generates various warning reactions and avoiding HWLs is one of them (Francis et al., 2017). Literature on warning avoidance is inconsistent, where some literature suggests that the avoidance behavior deters quitting (Witte, 1992), and some suggests that it does not restrict cessation (Borland et al., 2009; David Hammond et al., 2004) and may be associated with more quit attempts (Brewer et al., 2019; Cho et al.,

2016; Thrasher et al., 2016). However, interview participants described avoiding health warnings to be able to continue with their smoking behavior.

Finally, our qualitative findings reveal that loose cigarette purchase behavior reduces the overall effectiveness of HWLs. The purpose of HWLs is to increase the frequency of exposure so that they can generate firmer beliefs about the harms of smoking and aid in promoting smoking cessation (G. T. Fong et al., 2010; Hassan et al., 2008; Thrasher et al., 2007). Even though exposure to HWLs at least once makes the users aware of its content, the subsequent avoidance behavior fails to deliver constant reminders necessary for firmer beliefs about the harmful effects of cigarette smoking. Interview findings reveal that those who purchased loose were less likely to have beliefs about the chances that smoking will cause health related harms and about the seriousness of the threat, thus reducing the overall effectiveness of HWLs.

Specific aim 3: To conduct stakeholder analysis regarding loose cigarette and bidi sale ban in India.

RQ7. Why do cigarette users purchase loose cigarettes?

Cigarette users and tobacco vendors were asked about the reasons for purchasing loose cigarettes. Both users and vendors discussed similar reasons for purchasing loose cigarettes and those were to reduce cigarette consumption, financial restrictions, and social restrictions.

Both users and vendors reported that loose cigarettes were purchased to regulate smoking consumption as they felt that if they bought packs, they would start

consuming more cigarettes. Findings also suggest that non-daily smoking, and intending to quit were also related to purchasing loose cigarettes. These findings are consistent with the literature as studies have showed that purchase of loose cigarettes is linked to non-daily smoking (Sacks et al., 2012). Studies conducted among Mexican smokers also found that about one-quarter of them smoked loose cigarettes to cut down their cigarette consumption (Thrasher et al., 2011).

We know that availability of loose cigarettes makes tobacco affordable and accessible for minors (Goel et al., 2021). Smokers perceive loose cigarettes to be more affordable than the cost of the whole pack (Stillman et al., 2007; Stillman et al., 2014). Qualitative studies among African American urban youth smokers in the United States found that those who purchased loose cigarettes cited 'less expensive' as the most common reason for their purchase (Stillman et al., 2007). Our study findings are consistent with the literature as participants reported that it was economical to spend on loose cigarettes and those with a low budget could easily purchase a loosie.

Regarding social restrictions, participants mentioned that they feared getting caught by their parents which aligns with the literature that smokers found carrying cigarette packs to be socially unacceptable and purchased loose cigarettes to hide their smoking habits from others (Singh et al., 2017a).

RQ8. What is the awareness regarding the ban on the sale of loose cigarettes and what are cigarette users, tobacco vendors, and policymakers, implementers, and law

enforcement officials' perceptions about the status of policy implementation in Mumbai?

Mumbai had proposed a ban on the sale of loose cigarettes in 2020. Cigarette users, tobacco vendors, and policymakers and implementers were asked whether they were aware of any ban on the sale of loose cigarettes in Mumbai. Findings suggest that most of the cigarette users and tobacco vendors were not aware of the policy ban and rather stated that no such ban was being implemented or enforced. They mentioned that loose cigarettes were widely and easily available throughout the city. These findings are similar to a study conducted by Eshwari and colleagues (2020) that used cross-sectional surveys to examine perception and practices, and awareness regarding the ban on the sale of loose cigarettes among cigarette users and tobacco vendors in Karnataka, a southern Indian state (Eshwari et al., 2020). They found that 95.5% of the tobacco vendors continued selling loose cigarettes; about half of them were aware of the ban; and only a quarter reported that the ban on the sale of loose cigarettes was implemented (Eshwari et al., 2020). Similarly, awareness of the ban among cigarette users was found to be low as well (Eshwari et al., 2020).

Even though officials from the health department and state foundations were aware of the ban in Mumbai, awareness among policy implementers and enforcement officials from the police, FDA, and municipal corporation was found to be low. Participants from Mumbai mentioned that the policy was not being implemented and that loose cigarettes were still widely available in the city. Other studies conducted in India have found that awareness and understanding of COTPA provisions among

implementers and law enforcement officials have generally been poor which is considered a major impeding factor in effective policy implementation (Kaur & Jain, 2011; Persai et al., 2016). Poor awareness levels also signifies lack of training and capacity building opportunities for implementers and enforcers which eventually results in failure or delay in initiating action for violations such as in the case of the ban on the sale of loose cigarettes (Kaur & Jain, 2011).

RQ9. What are cigarette users and tobacco vendors' perceptions regarding the impact of the ban on the sale of loose cigarettes on users' purchase behavior?

Both users and vendors were asked whether users would switch to smoking other tobacco products, such as bidis or cheaper cigarettes, if loose cigarettes were banned and most of them reported that individuals would not switch to smoking bidis as bidis were primarily consumed by individuals from low SES, whereas cigarettes were preferred by high SES groups and was considered a status symbol. Males, older age groups, and those with lower SES are significantly more likely to smoke bidis (Mbulo et al., 2020). Cigarettes, on the other hand, were associated with higher SES and sophisticated lifestyles (Nichter et al., 2004). There is a lack of evidence suggesting that those who are used to cigarette smoking would prefer switching to smoking bidis. However, participants mentioned that individuals could switch to purchasing packs of cheaper cigarette brands if loose cigarettes of their usual brand were not available. That transition could be possible due to the unequal taxes imposed on different types of cigarettes (R. M. John, Rao, R.K., Rao, M.G., Moore, J., Deshpande, R.S., Sengupta, J., Selvaraj, S., Chaloupka, F.J., & Jha, P., n.d.). Taxes in India vary by the type of tobacco

products, and cigarettes are taxed based on their length, with longer cigarettes taxed at a higher rate compared to cigarettes with shorter lengths (R. M. John, Rao, R.K., Rao, M.G., Moore, J., Deshpande, R.S., Sengupta, J., Selvaraj, S., Chaloupka, F.J., & Jha, P., n.d.). We recommend that the taxation system should be simplified, and equal taxes should be imposed across all tobacco products. A higher and equal price would prevent users from switching to cheaper cigarettes.

Users and vendors were also asked if users would start purchasing packs as a result of the ban on the sale of loose cigarettes and found that cigarette users with high smoking frequency and those who were already purchasing packs would continue to purchase packs and even if they did purchase packs, they would certainly try to control their consumption. However, not everyone would be able to buy packs due to financial and social constraints.

We learned that the policy would assist users to quit cigarette smoking or reduce their consumption by forgoing a cigarette. Eshwari and colleagues (2020) found similar results from their cross-sectional surveys with 22% users reporting that if loose cigarettes were banned, they would reduce the number of cigarettes they smoked; 16% would think about quitting; and 9.5% would completely give up smoking (Eshwari et al., 2020). Literature suggests that availability of loose cigarettes decreases the likelihood of making quit attempts (Baker et al., 2015). Hall and colleagues (2014) found that smokers who lived in a neighborhood where loose cigarettes were easily accessible were less likely to make an attempt to quit cigarette smoking and were more likely to switch back to smoking (Hall et al., 2015). Additionally, smokers who purchased loose cigarettes with

the intention to limit their smoking were not more likely to quit smoking than those who did not purchase single cigarettes with the intention to reduce their cigarette consumption (Thrasher et al., 2011). Thus, our study findings align with the literature as participants felt that the policy ban would help them in successfully quitting cigarettes.

RQ10. What are the potential barriers in the implementation and enforcement of the ban on the sale of loose cigarettes?

Policymakers, implementers, and law enforcement officials from Delhi and Mumbai were asked about the barriers that they had faced or might face in implementing the ban on the sale of loose cigarettes. They discussed that the implementation guidelines were unclear and there was no clarity about the roles of various stakeholders in the implementation process. Stakeholders also did not have complete knowledge about how the policy was supposed to be operationalized. Findings are consistent with the global literature on tobacco control policy implementation. Similar barriers related to unclear roles in the implementation process have been faced by other low-and-middle income countries, such as Kenya (Mohamed et al., 2018) and Indonesia (Astuti et al., 2020), in formulating and implementing tobacco control policies that delayed the implementation process.

Policy implementers and foundation officials from both the cities described that tobacco control was not prioritized and was often neglected by senior government officials. There were also discussions about local politicians interfering in the implementation process. There is similar evidence in other developing and developed

countries where tobacco control received low priority (Hamann et al., 2012; Owusu-Dabo et al., 2010; Persai et al., 2016; Robertson et al., 2012). However, strong leadership and political commitment has been described as a key facilitator for tobacco policy formulation and implementation in Kenya (Mohamed et al., 2018). The significant decrease in the smoking rates in Turkey has also been attributed to Turkish government's sustained political commitment to tobacco control (Ozcebe et al., 2018).

Lack of financial, human, and infrastructural resources has been a long standing problem for tobacco control policy implementation in India (Jandoo & Mehrotra, 2008; Persai et al., 2016). Our study found that policy implementers reported lack of infrastructural resources for undertaking field visits, and lack of financial funds for enforcing tobacco control provisions. We also found that most participants described that there was limited manpower within their department and that they relied on coordinating with other government departments for enforcing tobacco control provisions. Similar resource related barriers have been reported by other low-and-middle income countries (Owusu-Dabo et al., 2010).

Regarding system level barriers, participants described that there was no provision for monitoring and evaluating the policy, which was only possible with a robust tobacco vendor licensing system. They mentioned that monitoring the sale of loose cigarettes was a challenging task due to the high density of tobacco vendors, and that there was no platform where complaints could be raised if someone was found selling loose cigarettes.

Even though policy implementers described resistance from tobacco vendors as another potential barrier to effective policy implementation, cross sectional studies conducted in other states of India where loose cigarettes were banned found that most vendors admitted that if the ban on loose cigarettes was properly enforced, they would stop selling loose cigarettes (Eshwari et al., 2020).

Interference by the officials of tobacco industry in policymaking and implementation was another potential barrier that was explained. Participants mentioned that the tobacco industry would delay policy approvals and implementation as they funded political parties and offered gifts and bribes to government officials. This finding aligns with the global policy implementation literature. Tobacco industry delayed implementation of tobacco control policies in Kenya through instituting legal suits or by bribing senior officials (Mohamed et al., 2018). Similar findings were reported from Argentina, Malawi, Colombia, and other low and middle-income countries (Lee et al., 2012; Mejia et al., 2008; Otañez et al., 2009; Uang et al., 2018).

Finally, participants from Mumbai stated that lack of awareness regarding the policy and incomplete knowledge about policy operationalization was another barrier that delayed policy implementation. Other studies conducted in India have found that awareness and understanding of COTPA provisions among implementers and law enforcement officials have generally been poor which is considered a major impeding factor in effective policy implementation (Kaur & Jain, 2011; Persai et al., 2016). Poor awareness levels also signifies lack of training and capacity building opportunities for implementers and enforcers which eventually results in failure or delay in initiating

action for violations (Kaur & Jain, 2011). Literature suggests that awareness and knowledge about the policy was linked to the stakeholders' level of interest in the policy, where policy implementers who were unaware of the policy may have lower interest in its implementation (Balane et al., 2020). A similar stakeholder analysis focused on understanding perceptions of stakeholders regarding a universal health insurance policy in Ghana also suggested that lack of stakeholder's understanding of the policy acted as a hindrance in successful policy implementation as low awareness levels affected stakeholders' interest in the policy (Abiiro & McIntyre, 2013).

RQ11. What are the facilitators for the implementation and enforcement of the ban on the sale of loose cigarettes?

Participants discussed several solutions to overcome the barriers to implementing the ban on the sale of loose cigarettes. Participants described that to overcome system-level barriers, tobacco vendor licensing was necessary. Loose cigarette sales could only be monitored if there was a robust tobacco vendor licensing mechanism. Not having a vendor licensing system in place meant that anyone, be it a grocery store or a street vendor, could sell tobacco products illegally without a license resulting in high density of tobacco vendors in the neighborhood. Tobacco vendor density in India was notably high (Pouranik et al., 2021), and easy access to tobacco retailers and the retail environment in a neighborhood significantly influences tobacco use, especially among youth (Mistry et al., 2022). It has been found that school children in neighborhoods with high tobacco vendor density reported increased risk of consuming smokeless tobacco (Mistry et al., 2015). The government should prioritize

and implement tobacco retail licensing and learn from the experiences of states, such as Himachal Pradesh, where tobacco retail licensing has already been institutionalized to complement the ban on the sale of loose cigarettes (Chauhan, 2018). Vendor licensing will prevent vendors from selling other food items with tobacco products and reduce vendor density and access to tobacco products.

Study participants also suggested other solutions including strict implementation and enforcement, health education, reducing tobacco industry interference, and adopting a collaborative approach among various stakeholders. Similar to our findings, Persai and colleagues (2016) emphasized that to strengthen the existing tobacco control policies, health education strategies in conjunction with community-based campaigns must be adopted to bring change in tobacco use (Persai et al., 2016). FCTC recommends participation of multiple stakeholders, including civil society organizations, for formulating and implementing tobacco control provisions (International Legal Consortium at the Campaign for Tobacco-Free Kids, 2020). Studies focused on tobacco control in India have recognized the need for establishing a national coordination mechanism for tobacco control (Jandoo & Mehrotra, 2008). India can learn lessons from other low-and-middle income countries such as Brazil, who had established a similar model and had become a leader in controlling and regulating tobacco products (Jandoo & Mehrotra, 2008). Kenya too benefitted from a central coordination mechanism that was a facilitating factor in the tobacco control policy formulation process and ensured representation from multiple stakeholder groups (Mohamed et al., 2018). Such mechanisms would ensure collaboration and coordination among various stakeholders

such as NGOs, civil society organizations, and government departments at the state and national levels authorized for enforcing COTPA provisions. A multisectoral approach will help in leveraging knowledge, reach, and resources, which has been described as an important barrier in implementation. Study participants suggested that to reduce tobacco industry interference in policymaking and implementation, guidelines must be drafted regarding how policymakers should meet with tobacco industry officials. Similar solutions have been suggested in other studies for advocating for adopting a code of conduct by government officials to minimize complicit connections with industry officials (Astuti et al., 2020).

RQ12. How have stakeholders contributed or can potentially contribute to the implementation and enforcement of the ban on the sale of loose cigarettes?

Participants also described how they may contribute to the implementation and enforcement of the ban on the sale of loose cigarettes. Officials from the health department in Mumbai stated that to implement the ban, they were involved in capacity building and enforcement, whereas all other participants described how they could potentially contribute to the implementation process. Non-governmental organizations, including state, national, and international foundations, offered support in capacity building, generating scientific evidence through monitoring and evaluation of the ban, advocating and garnering support for the policy, and assisting in specific areas such as vendor licensing and strategic health communication. Policy implementers and enforcement officials on the other hand offered to conduct investigations and provide security to other implementers. Participants' responses will help in the process of

assigning specific and clear roles for policy implementation. For example, to increase awareness and understanding regarding the policy ban among policy implementers and enforcement officials, NGOs which have expertise in strategic health communication could play an important role. The government should bring together all these stakeholders and design detailed implementation guidelines for implementing and enforcing the ban on the sale of loose cigarettes.

Study limitations

Several limitations should be considered with respect to this study. First, our survey sample was limited to the four states in India and is not nationally representative. Survey findings from the first paper and the second paper cannot be generalized to the whole of India. Second, survey sample included almost all males, so survey findings are not applicable to the female population.

Survey findings from the first paper states that unsuccessful quitters were more likely to purchase loose cigarettes. Even though this finding supports the notion that loose cigarettes acts as cue to smoking, and evokes cravings among smokers and keeps them away from successful quitting, however, these measures related to cue to smoking or experiencing cravings on seeing loose cigarettes, were not measured in the survey data. Moreover, survey findings are based on cross-sectional data, so it limits us to determine causality between the study variables and points to the need to conduct longitudinal studies.

Third, qualitative interviews with the smokers and tobacco vendors were conducted only in the urban neighborhoods of two metropolitan cities; so, qualitative findings cannot be generalized to the rural context or other cities/states. Similar studies should be conducted in other regions of India to ensure findings are consistent and generalizable.

Fourth, most smokers purchased loose cigarettes at their last purchase so no comparison could be made with pack purchasers who could potentially have more exposure to HWLs. We recommend future studies to include representative samples of pack purchasers to compare the impact of loose purchase behavior on HWL effectiveness among loose and pack purchasers. Only cigarette users were included in the qualitative sample as no loose bidi purchasers were found in any of the two cities. Qualitative findings can thus only be applicable to cigarette users. For tobacco vendors, we could not recruit representative samples of street vendors, as they were hard to find since they came out late in the night which was not always a convenient time for recruitment. I also could not interview national level stakeholders working in the Ministry of Health & Family Welfare who could have provided more in-depth information regarding the operationalization of the policy. We also think that the sample was not representative as we could not interview officials from other departments such as the Excise, Home, and Education departments.

Finally, findings from this study are based on a hypothetical situation. Because the policy was not properly implemented or enforced in any of the two cities, participants would not have experienced the real impact of the policy. Since the policy

was not implemented, this study could not measure the actual impact of the policy and thus hinders our ability to draw conclusions about real world effects.

Study strengths and implications for future research

A key strength of this study is that it focuses on the understudied issue around the sale of loose cigarettes and bidis in India and contributes important scientific evidence to the literature. Loose availability is a neighborhood level determinant that promotes tobacco use and is associated with smoking initiation. To my knowledge, this is the first study that determined that socio-demographic and tobacco-related correlates of loose cigarette and loose bidi purchase among Indian adult smokers. Several aspects of the analysis could be examined differently in future research. Since survey findings were based on cross-sectional data, it was challenging to determine causality between study variables. Even though we found that unsuccessful quitters were more likely to purchase loose cigarettes, however, to establish causality, we recommend that future studies should use a longitudinal design in which temporal relationships can be established to answer whether those who purchase loose cigarettes and bidis actually quit at higher rates than those who purchase packs. It also will be important to examine the relapse behavior to be able to confidently say that loose cigarette and bidi prevalence restricts smokers from successfully quitting (Hall et al., 2015). Similar studies also need to be conducted with youth to determine if loose tobacco prevalence encourage smoking initiation among minors in the context of India.

Another strength of this study is that it is based on a conceptual framework that was designed for conducting stakeholder analysis and was tested in a low-and-middle income country. Use of a relevant conceptual framework helped in drafting relevant interview questions for the three stakeholder groups. The framework informed different measures required for conducting the stakeholder analysis.

This study is very timely as India has recently announced that it is considering a national ban on the sale of loose cigarettes. Findings from this study will help in garnering support from policymakers and assist them in decision making related to policy formulation and implementation regarding the ban on the sale of loose cigarettes.

Another important strength of this study is that it uses a mixed-methods design. It helped in not only learning that loose purchasers less often noticed HWLs, but also helped in learning the specific mechanisms through which the exposure got reduced. We recommend that future studies should also analyze perceptions of pack purchasers regarding exposure to HWLs and its effectiveness and compare them with those who purchased loose.

Future studies should also focus on understanding the preferences of tobacco vendors for selling loose vs packed cigarettes and whether those preferences vary by vendor type. It should also focus on understanding the perceived impact of the ban on the sale of loose cigarettes on tobacco vendors and if that varies by vendor types and neighborhood (rural vs urban).

The strength of this study also lies in its holistic approach to understand the implementation and enforcement of the ban on the sale of loose cigarettes by including all the relevant stakeholders that will impact the policy process or will get impacted by the policy itself. We interviewed cigarette users, tobacco vendors, policymakers, implementers, and law enforcement officials to learn about their perceptions about the potential impact of the policy, and the barriers and facilitators for effective policy implementation and enforcement. Even though our study provides strong evidence about the effectiveness of the policy in reducing smoking prevalence, we still recommend that simulation studies should be conducted to further strengthen the evidence. This study provided evidence regarding switching to bidis and cheaper cigarettes, future studies should also assess whether users would switch to products other than cheaper cigarettes and bidis, such as vapes, e-cigarettes, hookahs / waterpipe tobacco, and other emerging products. We also recommend that longitudinal studies are needed to examine how the policy ban on the sale of loose cigarettes would impact smoking behaviors of individuals with a focus on product switching, quit attempts, successful quitting, and relapse.

Finally, this study involved local research partners from India. They played an important role in editing the interview guide for the three stakeholders and ensured that the interview questions were appropriate to the context of India. They were also instrumental in finalizing the recruitment and interview protocol and helped with connecting me with important study participants who were policymakers, implementers, and law enforcement officials.

Conclusions

This was the first mixed-methods study that focused on understanding in-depth the issue of loose cigarette and bidi sale in India. Study findings provide clear evidence that there is widespread prevalence of loose cigarettes in India and individuals belonging to low socio-economic status, occasional smokers, and unsuccessful quitters were more likely to buy loose cigarettes meaning loose cigarettes keeps disadvantaged groups smoking and restricts successful quitting. This study also generated solid evidence that those who purchased loose cigarettes less often noticed HWLs on cigarette packs and the reduced exposure to HWLs potentially affected the effectiveness of HWLs. These findings point to the need to strengthen laws around HWLs especially for bidis and adhering to the COTPA provisions. Since India is considering a national ban on the sale of loose cigarettes, this timely study provides important evidence regarding perceptions of various stakeholders about its perceived impact. Findings strongly demonstrate that the ban on the sale of loose cigarettes would reduce cigarette consumption, assist users in quitting cigarette smoking, and prevent potential users and the next generation from initiating smoking. Finally, this study also discussed the potential barriers that policymakers and implementers would face in expanding and implementing this ban nationally, and the specific solutions that need to be adopted to overcome those barriers. This study also pointed to the poor awareness of the ban among all three stakeholder groups signaling inadequate implementation and enforcement. For effectively implementing the ban nationally, it would be crucial to increase awareness of the policy among implementers and enforcement officials, draft

clear implementation guidelines, promote health education with strict enforcement, establish systems for monitoring and evaluation, and ensure efficient multi-sectoral coordination between different enforcement agencies.

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APPENDIX A

In-Depth Interview Guide for Smokers Subject ID:

Hello! Thank you for taking the time to speak with me today. My name is Mayank Sakhuja, a doctoral candidate at the University of South Carolina in the Department of Health Promotion, Education, and Behavior.

My PhD dissertation is looking at loose cigarette and bidi use in India. I am speaking with key stakeholders/experts like you about the loose cigarette and bidi sale ban in India. I am interested to understand from your point of view about the gaps and barriers as well as motivations and facilitators for implementation and enforcement of the loose cigarette and bidi sale ban in India. Findings from this interview will help inform implementation and enforcement of tobacco control laws and have the potential to reduce tobacco-related illnesses.

The interview will last about 30 to 45 minutes and will be recorded for professional transcription. Your participation in this interview is completely voluntary and you may refuse to answer any question you do not feel comfortable answering. This interview will remain strictly confidential, and your responses will not be linked back to you in any summaries or reporting of overall findings.

Do you have any questions before we start? If not, let us begin:

Mumbai	Delhi
- Please describe to me in detail your most recent visit to a tobacco store to purchase loose cigarettes/bidis? (Probes: When did you visit the shop? What kind of store did you visit? What did you purchase, cigarettes or bidis? What cigarette/bidi brand did you purchase? How many sticks did you purchase? How much did you pay? Were you able to view pictorial warnings on cigarette/bidi packs at the time of your purchase? What was the environment or neighborhood around the store? What other things were being sold at the store?) - How would you rather buy cigarettes or bidis – loose or in packs/bundle? Why?	- Please describe to me in detail your most recent visit to a tobacco store to purchase loose cigarettes/bidis? (Probes: When did you visit the shop? What kind of store did you visit? What did you purchase, cigarettes or bidis? What cigarette/bidi brand did you purchase? How many sticks did you purchase? How much did you pay? Were you able to view pictorial warnings on cigarette/bidi packs at the time of your purchase? What was the environment or neighborhood around the store? What other things were being sold at the store?) - How would you rather buy cigarettes or bidis – loose or in packs/bundle? Why?

- How would you compare price of an individual cigarette/bidi to price of a pack/bundle? (Follow up: Does that influence your purchase decision?) - Have you heard about the ban on sale of loose cigarettes and bidis in your state? (Follow up: Who communicated with you regarding the ban?) - Do you feel the ban on sale of loose cigarettes and bidis is necessary? Why or why not? - In your opinion, why has the government banned sale of loose cigarettes and bidis? (Probes: Could lower exposure to warning labes? Could make you habitual? Could make you less want to quit smoking?) What else do you think?	- How would you compare price of an individual cigarette/bidi to price of a pack/bundle? (Follow up: Does that influence your purchase decision?) - Has your state banned the sale of loose cigarettes and bidis? Are you aware of any other state that has banned it? (Follow up: Where do you get to learn about tobacco control laws in your state?) - Do you feel the ban on sale of loose cigarettes and bidis is necessary? Why or why not? - In your opinion, what could be the reasons that the government could ban sale of loose cigarettes and bidis in the future? (Probes: Could lower exposure to warning labels?

- How easy or difficult you think is to buy loose cigarettes/bidis after the government ban? (Follow up: What role does your neighborhood plays in that?)	Could make you habitual? Could make you less want to quit smoking?) What else do you think? - How easy or difficult it is for you to buy loose cigarettes or bidis? (Follow up: What role does your neighborhood plays in that?)
- Do you think the government made the right decision by banning the sale of loose cigarettes and bidis? Why or why not? - In your opinion, has the policy ban promoted or reduced your cigarette/bidi consumption? (Probes: Do you feel more urge to smoke? Have you started purchasing packs? Have you started consuming more? Have you attempted to quit smoking?) - How much is the policy relevant to you? How has it affected your current smoking behavior? (Probes: Why has it helped you	- Do you think the government should ban the sale of loose cigarettes and bidis? Why or why not? - In your opinion, will the policy ban promote or reduce your cigarette/bidi consumption? (Probes: Will you start purchasing whole packs? Might that lead to increased consumption? Will you attempt to quit smoking?)

quit/not quit smoking? Because of higher cost of whole pack? Because of increased exposure to warning labels? Has it made you think about switching to other tobacco products?)	- How much is the policy relevant to you? How will it affect your current smoking behavior? (Probes: Why will it help you quit/not quit smoking? Because of higher cost of whole pack? Because of increased exposure to warning labels? Will it make you think about switching to other tobacco products?)
- Do you think the policy ban has restricted you from purchasing loose cigarettes or bidis? Why or why not? Who do you think could do that and how? - How much confidence do you have in Government's efforts in implementing and enforcing the policy ban?	- Do you think the proposed policy ban will restrict you from purchasing loose cigarettes or bidis? Why or why not? Who do you think could do that and how? - How much confidence do you have in Government's efforts for implementing and enforcing the proposed policy ban?
- What is your stand on the policy ban? Why would you support or oppose it?	- What is your stand on the policy ban? Why would you support or oppose it?

- What influence do you have to adhere to the proposed policy ban? Which stakeholder groups interact with you regarding adhering to tobacco control laws? (Probes: tobacco vendor? Civil society? Enforcement agencies?) Who do you think are responsible for implementing and enforcing the policy ban? - Can you describe an experience when someone may have told you that you could not purchase loose cigarettes?	- What influence do you have to adhere to the proposed policy ban? Which stakeholder groups interact with you regarding adhering to tobacco control laws? (Probes: tobacco vendor? Civil society? Enforcement agencies?) Who do you think should be responsible for implementing and enforcing the proposed policy? - Can you describe an experience when someone may have told you that you could not purchase loose cigarettes?

APPENDIX B

SURVEY INSTRUMENT FOR SMOKERS

ID

Age

Last product purchased: Cigarette? Bidi?

Did you purchase loose or pack/bundle? (If loose, smoker can be interviewed)

Last cigarette/bidi brand purchased

No. of loose cigarettes/bidis purchased

Smoking history (No. of years since first time smoked)

On average, how often do you smoke cigarettes/bidis? (Less than once a week/Once a week/Twice a week/3-5 times a week/Every day or almost every day/More than once a day

On average, how many cigarettes/bidis did you smoke last week?

On average, how many cigarettes/bidis did you smoke last month?

Tobacco status (smoked/mixed)

Are you planning to quit smoking cigarettes (within the next month/within the next 6 months/sometime in the future, beyond 6 months/not planning to quit)

Marital Status

Occupation

Education

Sex

Living status (with family/away from family)

APPENDIX C

In-depth Interview Guide for Tobacco Vendors Subject ID:

Hello! Thank you for taking the time to speak with me today. My name is Mayank Sakhuja, a doctoral candidate at the University of South Carolina in the Department of Health Promotion, Education, and Behavior.

My PhD dissertation is looking at loose cigarette and bidi use in India. I am speaking with key stakeholders/experts like you about the loose cigarette and bidi sale ban in India. I am interested to understand from your point of view about the gaps and barriers as well as motivations and facilitators for implementation and enforcement of the loose cigarette and bidi sale ban in India. Findings from this interview will help inform implementation and enforcement of tobacco control laws and have the potential to reduce tobacco-related illnesses.

The interview will last about 30 to 45 minutes and will be recorded for professional transcription. Your participation in this interview is completely voluntary and you may refuse to answer any question you do not feel comfortable answering. This interview will remain strictly confidential, and your responses will not be linked back to you in any summaries or reporting of overall findings.

Do you have any questions before we start? If not, let us begin:

Mumbai	Delhi
- In your opinion, how common is use of loose cigarettes and loose bidis in your state (Probe: Are customers asking for more loose cigarettes and bidis or full cigarette packs and bidi bundles?) - Why do people buy loose cigarettes in your state? And who purchases loose cigarettes more often? What can you say about loose bidi purchases? Is it similar or different in any way to loose cigarette purchase? - Would you rather sell loose cigarettes and bidis than whole packages and bundles? Why or why not?	- In your opinion, how common is use of loose cigarettes and loose bidis in your state? (Probe: Are customers asking for more loose cigarettes and bidis or full cigarette packs and bidi bundles?) - Why do people buy loose cigarettes in your state? And who purchases loose cigarettes more often? What can you say about loose bidi purchases? Is it similar or different in any way to loose cigarette purchase? - Would you rather sell loose cigarettes and bidis than whole packages and bundles? Why or why not?

- Is industry providing any additional incentives or potential ways to continue sell loose cigarettes or bidis to your customers? - What do you think about the government's efforts to control tobacco use? - Have you heard about the ban on sale of loose cigarettes and bidis in your state? - Tell me what you know about how the ban is enforced? Is it similar or different in any way between loose cigarettes and loose bidis? - Who do you communicate with regarding tobacco control policies?	- Is industry providing any additional incentives or potential ways to continue sell loose cigarettes or bidis to your customers? - What do you think about the government's efforts to control tobacco use? - Has your state banned the sale of loose cigarettes and bidis? Are you aware of any other state that has banned it? - Tell me what you know about how the ban is enforced? Is it similar or different in any way between loose cigarettes and loose bidis? - Who do you communicate with regarding tobacco control policies?

- Do you feel the ban on sale of loose cigarettes and bidis is necessary? Why or why not? - Why do you think the government made the decision to ban the sale of loose cigarettes and bidis?	- Do you feel the ban on sale of loose cigarettes and bidis is necessary? Why or why not? - If there is a ban in the future, why do you think the government would make the decision to ban the sale of loose cigarettes and bidis?
- Since this policy has been in effect, what changes have you observed in the behavior of your customers? (Probes: Have users started purchasing whole packs? Have users attempted to quit smoking? Have users switched to other tobacco products?) - Do you think the policy ban has restricted buyers from purchasing loose cigarettes or bidis? Why or why not? How	- In your opinion, what changes in the behavior of your customers do you anticipate might occur once this policy is implemented and enforced? (Probes: Will users start purchasing whole packs? Will users attempt to quit smoking? Will users switch to other tobacco products?) - Do you think the proposed policy ban will restrict buyers from purchasing loose cigarettes or bidis? Why or why not? How

much confidence do you have in Govt's efforts in implementing and enforcing the policy ban? - How do you think the policy ban has affected you? What is the overall perceived impact (including costs and opportunities) for you? (Probes: financial implications, viable alternatives for sellers, quit attempts by users)	much confidence do you have in Govt's efforts in implementing and enforcing the proposed policy? - How do you think the policy ban will affect you? What could be the overall perceived impact (including costs and opportunities) for you? (Probes: financial implications, viable alternatives for sellers, quit attempts by users)
- What is your stand on the policy ban? Do you support or oppose it? - What influence do you have to adhere to the policy ban? Which stakeholder groups interact with you regarding adhering to tobacco control laws? Who do you think are responsible for implementing and enforcing the policy ban? And why?	- What is your stand on the proposed policy ban? Why would you support or oppose it? - What influence do you have to adhere to the proposed policy ban? Which stakeholder groups interact with you regarding adhering to tobacco control laws? Who do you think should be responsible for implementing and enforcing the proposed policy? And why?

APPENDIX D

SURVEY INSTRUMENT AND OBSERVATIONAL CHECKLIST FOR VENDORS

ID

Age

Vendor type (Grocery store/Permanent tobacco shop/street vendor)

Do customers buy loose cigarettes/bidis from you? (Yes/No) (If yes, vendor can be interviewed)

Do your customers buy (Only singles/Mostly singles/Singles and packs equally/Mostly packs/Only packs)?

Of 100 daily customers, how many of them visit to purchase singles?

Most preferred cigarette brand by consumer

No. of cigarettes in a box

Price of box

Price of one cigarette

For the most preferred cigarette brand, do customers buy (Only singles/Mostly singles/Singles and packs equally/Mostly packs/Only packs)?

Most preferred bidi brand by consumer

No. of bidis in a bundle

Price of a bundle

Price of one bidi

For the most preferred bidi brand, do customers buy (Only singles/Mostly singles/Singles and packs equally/Mostly packs/Only packs)?

No. of years on shop

Ask to describe neighborhood around

Items sold along with tobacco (Food items, services, stationery items, combination of all)

Display of tobacco products (Yes/No)

Are pictorial warnings on the displayed products clearly visible from the entrance of the store? (Yes/No/NA)

Availability of smoking aids (matches, lighters, ashtrays)

Check if there is a board with the warning “sale of tobacco products to a person below the age of 18 years is a punishable offence”. (Yes/No)

Is it accompanied by any pictorial depiction of ill effects of tobacco use? (Yes/No)

Is there any tobacco advertisement at the entrance of the outlet? (Yes/No)

Is that advertisement accompanied by any warning on the top edge of the advertisement board? (Yes/No)

(Take a picture of the outlet after the interview)

APPENDIX E

In-Depth Interview Guide for Policymakers, Implementers, and Law Enforcement Officials

Subject ID:

Hello! Thank you for taking the time to speak with me today. My name is Mayank Sakhuja, a doctoral candidate at the University of South Carolina in the Department of Health Promotion, Education, and Behavior.

My PhD dissertation is looking at loose cigarette and bidi use in India. I am speaking with key stakeholders/experts like you about the loose cigarette and bidi sale ban in India. I am interested to understand from your point of view about the gaps and barriers as well as motivations and facilitators for implementation and enforcement of the loose cigarette and bidi sale ban in India. Findings from this interview will help inform implementation and enforcement of tobacco control laws and have the potential to reduce tobacco-related illnesses.

The interview will last about 30 to 45 minutes and will be recorded for professional transcription. Your participation in this interview is completely voluntary and you may refuse to answer any question you do not feel comfortable answering. This interview will remain strictly confidential, and your responses will not be linked back to you in any summaries or reporting of overall findings.

Do you have any questions before we start? If not, let us begin:

Mumbai	Delhi
- How are you associated with tobacco control? - How would you describe your role in policy making and policy implementation for tobacco control? **(Is your role more in policymaking or implementation?)** - Who do you communicate with regarding tobacco control policies? - Why do people buy loose cigarettes in your state? And who purchases loose cigarettes more often? What can you say about bidi purchases? Is it similar or different in any way to loose cigarette purchase?	- How are you associated with tobacco control? - How would you describe your role in policy making and policy implementation for tobacco control? **(Is your role more in policymaking or implementation?)** - Who do you communicate with regarding tobacco control policies? - Why do people buy loose cigarettes in your state? And who purchases loose cigarettes more often? What can you say about bidi purchases? Is it similar or different in any way to loose cigarette purchase?

- Can you tell me about the policy ban on the sale of loose cigarettes and loose bidis in your state? **(If not, skip next question)** - In your opinion, how is the policy ban implemented and enforced? Is it similar or different in any way between loose cigarettes and loose bidis? - Do you think this policy ban is necessary and why? - In your opinion, what does the policy ban on loose cigarettes and bidis aims to achieve?	- What do you know about the proposed policy ban on the sale of loose cigarettes and loose bidis? **(If not, skip next question)** - In your opinion, how the proposed policy ban would be implemented and enforced? Will it be similar or different in any way between loose cigarettes and loose bidis? - Do you think this proposed policy ban is necessary and why? - In your opinion, what does the proposed policy ban on loose cigarettes and bidis aims to achieve?

- Has banning loose cigarettes and loose bidis effectively controlled tobacco use? Why or why not? How has it supported other tobacco control policies? - In your opinion, has the policy ban promoted or inhibited cigarette/bidi consumption? (Probes: Have users started purchasing whole packs leading to increased consumption? Have users attempted to quit smoking? Have users switched to other products?) - Do you feel like your agency makes tobacco control a priority? (Follow up: Can you discuss how your agency prioritizes tobacco control?) Can you describe how your agency has contributed to the implementation of loose cigarette sale ban?	- Would banning loose cigarettes and loose bidis effectively control tobacco use? Why or why not? How will it support other tobacco control policies? - In your opinion, will the policy ban promote or inhibit cigarette/bidi consumption? (Probes: Will users start purchasing whole packs leading to increased consumption? Will users attempt to quit smoking? Will users switch to other products?) - Do you feel like your agency makes tobacco control a priority? (Follow up: Can you discuss how your agency prioritizes tobacco control?) Can you describe how your agency might contribute to the implementation of loose cigarette sale ban?

- In your opinion, what are the barriers that you have faced in implementing and enforcing the policy ban? (Probes: Do you have sufficient financial resources to allocate for this policy? Are there enough personnel for enforcing this ban? Do you think there is clarity regarding who is responsible for implementing and enforcing this ban?) - In your opinion, what are the facilitators/motivations that you perceive to be important for effective policy implementation and enforcement? (Probes: Political commitment, leadership, coordination with other departments)	- In your opinion, what are the potential barriers that you will face in implementing and enforcing the policy ban? (Probes: Do you have sufficient financial resources to allocate for this policy? Are there enough personnel for enforcing this ban? Do you think there is clarity regarding who is responsible for implementing and enforcing this ban?) - In your opinion, what are the facilitators/motivations that you perceive to be important for effective policy implementation and enforcement? (Probes: Political commitment, leadership, coordination with other departments)

- What type of resources do you anticipate having to be able to effectively implement and enforce loose cigarette/bidi sale ban? (Probes: Financial resources, human resources) - How confident are you that you/your agency has been able to implement and enforce the proposed ban? What makes you feel that? - Tell me about your champion (individual responsible for implementing and enforcing tobacco control policies)? If no one, do you have any insight as to why there is not a strong advocate within your organization? - What kind of technical skills do you have, or have you received training for implementing and enforcing the proposed ban?	- What type of resources might you need to be able to effectively implement and enforce loose cigarette/bidi sale ban? (Probes: Financial resources, human resources) - How confident are you that you/your agency will be able to implement and enforce the proposed ban? What makes you feel that? - Tell me about your champion (individual responsible for implementing and enforcing tobacco control policies)? If no one, do you have any insight as to why there is not a strong advocate within your organization? - What kind of technical skills do you have, or expect to receive training for implementing and enforcing the proposed ban?

- What types of support do you have from the local, state, or national bodies for policy implementation and enforcement? (Probes: Who funds you for your tobacco control efforts? Who provides you trainings for policy implementation and enforcement?) - Have you collaborated with anyone to implement and enforce the ban? If yes, tell me about your collaborations? (Probes: Police department? Civil society? Government departments?)	- What types of support do you have from the local, state, or national bodies for policy implementation and enforcement? (Probes: Who funds you for your tobacco control efforts? Who provides you trainings for policy implementation and enforcement?) - Would you collaborate with anyone to implement and enforce the ban? If yes, tell me how? (Probes: Police department? Civil society? Government departments?)

APPENDIX F

PARTICIPANT INCENTIVE RECEIPT FORM

Participant Incentive Receipt Form

I, _____ (write subject ID), acknowledge receipt of _____ (write $ amount) in cash for my participation in a study titled "***No more loosies: A mixed-methods study on the implementation and enforcement of loose cigarette and bidi sale ban in India*** " by researchers from the University of South Carolina.

_____ _____

(Signature of Participant) (Date)