

Smoke-free legislation and active smoking, second hand smoke exposure and health outcomes in low- and middle-income countries

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Thesis submitted in accordance with the requirements for the degree of Doctor of Philosophy

University of London

AUGUST 2017

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Funding: This work was supported by a Wellcome Trust Capacity Strengthening Strategic Award to the Public Health Foundation of India and a consortium of UK universities.

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Abstract

Background:

Exposure to tobacco smoke imposes a heavy morbidity and mortality burden and exacerbates health inequalities. Whilst the health and economic benefits of smoke-free legislation (SFL) are evident in high income countries (HICs), there is a lack of evidence from low- and middle-income countries (LMICs) where implementation and monitoring mechanisms are generally weak.

Objectives:

To examine whether the health benefits of SFL identified in HICs are likely to accrue in LMICs and whether any benefits are evenly distributed between socioeconomic status (SES) groups.

Methods:

1) A systematic review was undertaken to examine the impact of SFL on socioeconomic inequalities in tobacco-related health outcomes in adults 2) Secondary analyses of the Global Adult Tobacco Survey (GATS) data from 15 LMICs was undertaken to examine inequalities in second hand smoke (SHS) exposure at work and at home 3) Quasi-experimental difference-in-differences study design was used to examine whether the National Tobacco Control Programme (NTCP) in India was associated with reductions in active smoking.

Results:

1) Evidence from LMICs examining the health impacts of SFL was sparse.

Comprehensive SFL was associated with pro-equity impacts in smoking associated health outcomes in HICs 2) In LMICs, exposure to SHS at workplaces and at homes was higher among the low SES groups. Being employed in a smoke-free workplace in LMICs was associated with reduced exposure to SHS in the home 3) There was no compelling evidence that NTCP reduced bidi and cigarette consumption over and above the general reduction that occurred in all districts in India.

Policy implications:

Poor implementation of SFL in LMICs is associated with substantial forgone health benefits, especially in the low SES groups. Strengthening tobacco control is key to improve health outcomes and reduce inequalities in LMICs and attainment of the Sustainable Development Goals for Health.

Acknowledgements

I am grateful to my supervisor, Professor Neil Pearce. I would like to thank him for his constant support and guidance throughout the study. He has always provided me encouragement and constructive advice, thanks to his expertise in the field of noncommunicable disease (NCD) prevention and control, and vast research experience. Despite the fact that I was based in Public Health Foundation of India (PHFI), New Delhi (India) for the majority of study period and had limited time to spend at London School of Hygiene & Tropical Medicine (LSHTM) due to the nature of Wellcome Trust-PHFI (WTP) UK Consortium (UKC) Programme, I always had easy access, and quick and positive feedback from Professor Neil. I am also thankful to Professor Neil for introducing me to and involving me as a member of the Centre for Global NCDs at LSHTM.

I am greatly obliged to my co-supervisor, Professor Christopher Millett from Public Health Policy Evaluation Unit, School of Public Health, Imperial College London. He has provided me with extremely valuable inputs at all stages of my study right from the very conceptualization of the study for the Ph.D. application. I thank him for patiently attending to my arguments, queries, e-mails, Skype calls, and meetings; for introducing me to a number of excellent researchers from his department, of which, some have also provided invaluable inputs in my research; for having faith in me and constantly motivating me as well as others involved in my research.

I would like to thank my Indian mentor, Dr. Monika Arora from Health Promotion Division, PHFI. I started my public health career in India, working in tobacco control and NCD prevention under her mentorship from the year 2008. I continue to learn from her. She has always been a source of inspiration and learning. She has always supported and encouraged exploring opportunities and provided direction wherever needed. Dr. Arora has also enabled me to develop invaluable contacts and collaborations with several national and international researchers as well as organisations.

I would also like to thank Professor K. Srinath Reddy (PHFI) and Dr. Melissa B. Harrell (University of Texas, Austin) for considering me a suitable candidate for this programme and recommending my candidature to the WTP UKC Programme.

I would like to thank all the co-authors on research papers (published and yet to be published) resulting from this work, apart from my supervisors, including Professor Stanton Glantz (University of California, San Francisco); Dr. John Tayu Lee (Imperial College London; National University of Singapore); Dr. Anup Karan (PHFI); Dr. Swati Srivastava (PHFI); Ms. Kiara C-M Chang (Imperial College London); Professor. Richard Watt (University College London); Dr. Georgios Tsakos (University College London) and Dr. Marhazlinda Jamaludin (University College London; University of Malaya). All the co-authors have provided invaluable guidance and inputs at various stages and on different aspects of this research ranging from guidance related to data issues and statistical analysis to critical feedback on research papers and providing final approval to papers. I am highly indebted to my co-authors for their guidance and support and for allowing me to learn from them.

Last, but not the least, I would like to thank members of the WTP UKC Programme in India and in the UK (Professor Lalit Dandona, Professor Pat Doyle, Professor Sanjay Zodpey, Dr. Sanjay Kinra, Anurag Gautam, Parul Mutreja, Niall Holohan, Maebh NiFhalluin and Najma Hussain) for providing all the support and guidance related to this capacity building programme under whose umbrella, this research has taken place. I would also like to thank all the staff members at LSHTM, particularly those from my department and faculty (especially, Jenny Fleming, Lauren Dalton, and Sue Teoh) for their support throughout the course.

Finally, I would like to thank my family members - my wife (Rupali Nazar), my daughter (Aryaa Nazar), my mother (Rekha Nazar) and my father (Prafulla Nazar) for their constant support throughout the study period.

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Abbreviations and Acronyms

- ACS Acute Coronary Syndrome
- AFTC Advocacy Forum for Tobacco Control
- AMI Acute Myocardial Infarction
- AOR Adjusted Odds Ratio
- CCT Controlled Clinical Trial
- CDC Centers for Disease Control and Prevention
- CES Consumer Expenditure Survey
- CI Confidence Interval
- CO Carbon Monoxide
- COMMIT Community Intervention Trial for Smoking Cessation (Trial)
- COPD Chronic Obstructive Pulmonary Disease
- COTPA The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply, and Distribution) Act
- CPHA Canadian Public Health Association
- CRD Centre for Reviews and Dissemination
- CSO Civil Society Organization
- CTFK Campaign for Tobacco Free Kids
- CVD Cardiovascular Disease
- DALY Disability-Adjusted Life Year
- DID Difference-in-differences
- DLCC District Level Coordination Committee
- DSR Designated Smoking Room
- DTCC District Tobacco Control Cell
- ENDS Electronic Nicotine Delivery System
- EPHPP Effective Public Health Practice Project
- EPOC Effective Practice and Organisation of Care
- FCTC Framework Convention on Tobacco Control
- GATS Global Adult Tobacco Survey
- GBD Global Burden of Disease
- GHPSS Global Health Professional Student Survey
- GSPS Global School Personnel Survey
- GTSS Global Tobacco Surveillance System

- GYTS Global Youth Tobacco Survey
- HIC High Income Country
- IEC Information, Education, Communication
- IHD Ischemic Heart Disease
- INR Indian Rupee
- ITC International Tobacco Control Policy Evaluation (Project)
- ITS Interrupted Time Series
- LMIC Low- and Middle-Income Country
- LSHTM London School of Hygiene and Tropical Medicine
- MeSH Medical Subject Headings
- MI Myocardial Infarction
- MoHFW Ministry of Health and Family Welfare
- MoSPI Ministry of Statistics and Programme Implementation
- MPCE Monthly Per Capita Expenditure
- MPI Multi-dimensional Poverty Index
- NCD Non-communicable Disease
- NGO Non-Governmental Organisation
- NHM National Health Mission
- NSSO National Sample Survey Office
- NTCC National Tobacco Control Cell
- NTCP National Tobacco Control Programme
- OBC Other Backward Classes
- PHFI Public Health Foundation of India
- PM_{2.5} Particulate Matter less than diameter of 2.5 micrometres
- ppm Parts-per-million
- PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analyses
- PSU Primary Sampling Unit
- PSU Public Sector Undertaking
- RCT Randomized Controlled Trial
- RII Relative Index of Inequality
- RR Risk Ratio/Relative Risk
- RTI Respiratory Tract Infection
- SC Scheduled Caste
- SDG Sustainable Development Goal
- SES Socioeconomic Status

- SFL Smoke-free Legislation
- SHS Secondhand Smoke
- SIDS Sudden Infant Death Syndrome
- SII Slope Index of Inequality
- SLCC State Level Coordination Committee
- SLT Smokeless Tobacco
- ST Scheduled Tribe
- STCC State Tobacco Control Cell
- TIA Transient Ischemic Attack
- TPM Two-Part Model
- TUS-CPS Tobacco Use Supplement to Current Population Survey
- UCL University College London
- UKC UK Consortium
- UN United Nations
- USU Ultimate Sampling Unit
- VIF Variance Inflation Factor
- WHA World Health Assembly
- WHO World Health Organization
- WTP Wellcome Trust-PHFI

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Relevant publications and conference presentations

Published research papers

- <u>Nazar GP</u>, Lee JT, Arora M, Millett C. Socioeconomic Inequalities in Secondhand Smoke Exposure at Home and at Work in 15 Low- and Middle-Income Countries. *Nicotine & Tobacco Research*. 2016;18:1230-9.
- Nazar GP, Lee JT, Glantz SA, Arora M, Pearce N, Millett C. Association between being employed in a smoke-free workplace and living in a smoke-free home: evidence from 15 low- and middle-income countries. *Preventive Medicine*. 2014;59:47-53.

Submitted research papers

 <u>Nazar GP</u>, Srivastava S, Chang KC, Pearce N, Karan A, Millett C. Impact of India's National Tobacco Control Programme on bidi and cigarette consumption: a difference-in-differences analysis. *The Lancet Global Health*.

Research papers not yet submitted

 Marhazlinda J, <u>Nazar GP</u>, Tsakos G, Watt RG, Millett C. Smoke-free legislation and socioeconomic inequalities in smoking-related morbidity and mortality among adults: a systematic review. *PLoS Medicine* (Target Journal).

Oral presentations

<u>Nazar GP</u>, Lee JT, Arora M, Pearce N, Millett C. Association between being employed in a smoke-free workplace and living in a smoke-free home: Evidence from 15 low- and middle-income countries. *The International Conference on Public Health Priorities in the 21st Century: The Endgame for Tobacco* (New Delhi; Sept 2013).

Poster presentations

- <u>Nazar GP</u>, Lee JT, Arora M, Millett C. Socio-economic inequalities in secondhand smoke exposure at home and at workplace in fifteen low- and middle-income countries. *London School of Hygiene & Tropical Medicine (Poster Day)* (London; Feb 2016).
- <u>Nazar GP</u>, Lee JT, Arora M, Millett C. Socio-economic inequalities in secondhand smoke exposure at home and at workplace in fifteen low- and middle-income countries (LMICs). 16th World Conference on Tobacco or Health (Abu Dhabi; March 2015).

 <u>Nazar GP</u>, Lee JT, Arora M, Pearce N, Millett C. Association of employment in smoke-free workplaces with tobacco use and related behaviours in India. *The International Conference on Public Health Priorities in the 21st Century: The Endgame for Tobacco* (New Delhi; Sept 2013).

Abstract publications

- <u>Nazar GP</u>, Lee JT, Arora M, Pearce N, Millett C. Association between being employed in a smoke-free workplace and living in a smoke-free home in LMICS. Respiratory Medicine 2013;107:S6.
- <u>Nazar GP</u>, Lee JT, Arora M, Millett C. Association of employment in smoke-free workplaces with tobacco use and related behaviours in India. *Respiratory Medicine* 2013;107:S17-S18.

Abstracts accepted for oral presentation

 <u>Nazar GP</u>, Srivastava S, Chang KC, Pearce N, Karan A, Millett C. Impact of India's National Tobacco Control Programme on Bidi and Cigarette Consumption: A Difference-in-differences Analysis. 15th World Congress on Public Health in Melbourne (April 2017).

Chapter 1: Introduction, aims, objectives, and outline of the thesis

1.1. Introduction

Tobacco smoking and exposure to secondhand smoke (SHS) or passive smoking are collectively responsible for 7.2 million annual deaths worldwide while SHS exposure by itself is responsible for 0.9 million annual deaths. Tobacco smoking and SHS exposure collectively, are also the third leading risk factor for non-communicable diseases (NCDs), which are responsible for 71% of deaths globally. Worldwide, between 1990 and 2015, morbidity and mortality attributable to tobacco smoking has increased while that attributable to SHS exposure has decreased. However, low- and middle-income countries (LMICs) are likely to continue to face heavy health and economic burden due to tobacco smoking as 80% of the world's smokers reside in these settings. Over the past decade, cigarette smoking has declined in the European Region, the Region of the Americas, the South East Asian Region, and the Western Pacific Region (except China where it has notably increased), while it has increased in the Eastern Mediterranean Region and the African Region.

In high income countries (HICs) as well as in LMICs (except among women in some countries), there is clear evidence of socioeconomic inequalities in tobacco smoking such that smoking is higher among people belonging to low socioeconomic status (SES) or the poor. 4, 5 Similar inequalities also exist in the case of SHS exposure in HICs. 6, 7 However, evidence from LMICs on inequalities in SHS exposure is lacking. Further, tobacco smoking and SHS exposure are causally associated with several diseases such as cardiovascular diseases (CVDs), respiratory diseases, and cancers among others. 6, 8 Tobacco smoking and SHS exposure are therefore likely to exacerbate health inequalities. The economic costs of tobacco use are also high in HICs as well as in LMICs, 9-15 further impoverishing millions and contributing to widening socioeconomic inequalities.

The first global treaty on tobacco control, Framework Convention on Tobacco Control (FCTC) was signed under the auspices of WHO in 2003 and was implemented in 2004. 16 Currently there are 180 Parties (member nations) to the FCTC, which provides guidance on demand and supply reduction strategies for tobacco control. 17 Reduction in tobacco use and implementation of WHO FCTC strategies have been recommended for achievement of the global target - 25% relative reduction in premature mortality from

NCDs by 2025.^{18, 19} Similarly, under Goal 3 (Ensure healthy lives and promote wellbeing for all at all ages) of the United Nations (UN) Sustainable Development Goals (SDGs), reducing tobacco use is recognized as critical for achievement of the global target of 33% reduction in premature deaths from NCDs by the year 2030.²⁰ Towards that end, Article 8 of WHO FCTC recommends protection of non-smokers from exposure to tobacco smoke through implementation of comprehensive smoke-free legislation (SFL), which implies 100% smoke-free environment in all indoor public places, indoor workplaces, public transport and as appropriate, in other public places (outdoor or quasioutdoor), without any exemptions. 16 The SFL has evolved gradually from early partial laws (1969) to initial local comprehensive law in California (1998) and the first comprehensive law in a then LMIC, Uruguay (2006), to the more recent nationwide comprehensive law in Brazil (2011).^{21, 22} Despite being the most widely adopted measure for tobacco control, only 18% of the world's population is covered by comprehensive SFL, with low income countries faring the worst.²³ Several LMICs including India have implemented various tobacco control policies at different levels however enforcement is lacking. Section 4 of the Indian national tobacco control law imposes a partial ban on smoking in public places, which includes all indoor workplaces and public places (but allows designated smoking rooms [DSRs] at airports, hotels with more than 30 rooms and restaurants with a seating capacity of more than 30), public transport as well as several other places frequented by public including stadiums, bus stops, railway stations, and open auditoriums among others.²⁴ The SFL however, remains inadequately enforced in India as in several other LMICs, 25 as often, no action is taken against violations of SFL.

Research evidence, mostly from HICs, shows that comprehensive SFL is effective in improving the air quality. Rational SFL has been shown to reduce adverse cardiovascular outcomes (Acute Coronary Syndrome (ACS)/Acute Myocardial Infarction (AMI)/stroke), asthma, improve lung function, and reduce mortality associated with smoking-related illnesses. The health benefits are significantly higher in jurisdictions implementing comprehensive SFL compared with partial SFL. Among adults, SFL has also been shown to reduce the prevalence and intensity of smoking, exposure to SHS and increase quit rate. The implementation of SFL has also been shown to significantly reduce preterm births and hospital attendance for childhood asthma, as well as exposure to SHS. Comprehensive SFL has also been shown to have a neutral or positive effect on business, economy, and employment, particularly for the hospitality sector. SFL has also been shown to be highly popular and has the potential to

positively alter social norms towards exposing non-smokers to SHS, thereby leading to the adoption of voluntary measures such as smoke-free homes and private vehicles. 32-37 However, most of this research is concentrated in HICs. A recent extensive Cochrane review showed that only about 2% the research was from LMICs. 27

The implementation and enforcement of SFL are weak in several LMICs when compared with HICs. ²³ Barriers for implementation of SFL in the LMIC settings include a lack of understanding of the political economy for tobacco control, ³⁸ tobacco industry interference and the myths propagated by them, ^{21, 31} the lack of required enforcement capacity and resources, gaps in knowledge about the harmfulness of tobacco use and SHS exposure, ³⁹ the lack of political will and a cumbersome policy formulation process. ⁴⁰ A major barrier, however, is the lack of data and research on SHS exposure and the impact of SFL. There also exist facilitators that could enable implementation and enforcement of SFL in LMICs: the huge economic gains resulting from tobacco smoke attributable morbidity and mortality averted subsequent to SFL implementation, ⁴¹ pre-existing networks of tobacco control advocates, organizations, programmes and laws in several LMICs, and the increasing support for SFL and tobacco control in general, among the public. ²¹

Overall, SFL has been shown to be associated with considerable health and economic benefits mainly in HICs. However, there is a lack of evidence whether similar benefits accrue in the LMIC settings where implementation of SFL is poor and monitoring mechanisms are weak. The resulting lack of data impedes evaluation of the impact of tobacco control policies such as SFL in these settings. As tobacco smoking and SHS exposure have the potential to exacerbate health inequalities, it is also important to evaluate the impact of such tobacco control policies on inequalities. There is an urgent need to undertake focused research in the LMIC settings to generate evidence which would facilitate implementation and enforcement of pro-equity tobacco control measures such as comprehensive SFL, as observed in the HIC settings.

This thesis uses limited data available in LMICs, including a case study in India, to examine whether the health benefits identified in HICs are likely to accrue in LMICs and if so, whether these benefits are evenly distributed between SES groups. Specifically, I start by conducting a systematic review to examine whether the identified health benefits

of SFL accrue equally among adults in low and high SES groups. I then use data from the Global Adult Tobacco Survey (GATS) to determine whether implementation of SFL in LMICs is likely to produce additional health benefits, especially among women and children, by influencing smoking behaviour in the home through a shifting of social norms. In a second study using the GATS data, I examine whether exposure to SHS in workplaces and at homes in LMICs is socially patterned, such that low SES individuals are more likely to be exposed to SHS. Finally, I evaluate whether implementation of the National Tobacco Control Programme (NTCP) in India, which sought to strengthen implementation and enforcement of tobacco control policies in the country including SFL, was associated with reductions in active smoking. This thesis is based, in part, on two published research papers, 42, 43 and two yet to be published research papers (Nazar et al. submitted; Jamaludin et al. yet to be submitted), which comprise chapters 3-5, together with additional material (chapters 1, 2 and 6). Overall, my thesis provides background information and literature as well as implications of the findings relevant for LMICs, however, each section also contains some specific reference to India as the country is included as a case study within the thesis. Although research from HICs shows beneficial effect of SFL on health and SHS exposure among children, my thesis primarily focuses on adults as my research proposal was developed under the category "occupational health", which was the theme of call for proposals under the Wellcome Trust Capacity Strengthening Strategic Award to the Public Health Foundation of India (PHFI) and a consortium of UK universities in 2012, which funded this study. Further, my co-supervisor is a co-author on a study with other researchers which focuses on the impact of SFL on perinatal and child health.

1.2. Aims

- <u>Aim 1</u>: To study the impact of SFL on socioeconomic inequalities in health outcomes related to exposure to tobacco smoke.
- <u>Aim 2</u>: To study the association between SFL and exposure to SHS in the home in the LMIC settings.
- <u>Aim 3</u>: To study socioeconomic inequalities in exposure to SHS at home and in the workplace in LMICs.
- <u>Aim 4</u>: To assess the impact of its National Tobacco Control Programme (NTCP) in India on bidi* and cigarette smoking.

* Bidi is made by rolling a dried, rectangular piece of temburni leaf (Diospyros melanoxylon) with 0.15-0.25 grams of sun-dried, flaked tobacco into a conical shape and securing the roll with a thread.²³⁶

• <u>Aim 5</u>: To generate research evidence to strengthen implementation and enforcement of strong tobacco control policies including comprehensive SFL in the LMIC settings.

1.2.1. Objectives

- Objective 1: To conduct a systematic literature review to assess quantity and quality of global research describing the impact of SFL on socioeconomic inequalities in health outcomes associated with exposure to tobacco smoke among adults.
- <u>Objective 2</u>: To conduct secondary analyses on cross-sectional GATS (2008-2011) data from 15 LMICs:
 - Objective 2a: to study the association between being employed in a smoke-free workplace and living in a smoke-free home.
 - Objective 2b: to study the extent of SHS exposure at homes and at workplaces and the socioeconomic inequalities in SHS exposure therein.
- Objective 3: To evaluate the impact of the National Tobacco Control Programme (NTCP) in India (an LMIC) using repeated cross-sectional National Sample Survey Organization (NSSO) Consumer Expenditure Survey (CES) data (1999-2000; 2004-05; 2011-12) on consumption of bidis and cigarettes at household level using the difference-in-differences (DID) analysis.
- Objective 4: To draw comparisons between the findings of this study with those available from the HIC settings and generate policy recommendations to enable better implementation and enforcement of comprehensive SFL across LMICs.
- Objective 5: To generate and compile results from this study in the form of research papers (published or yet to be published) and disseminate findings/recommendations through conference presentations, seminars, and posters.

1.3. Outline of the thesis

Chapter 1: Introduction, aims, objectives, and outline of the thesis

This chapter gives a brief introduction of the current knowledge about the burden of disease and harms due to tobacco smoking and exposure to SHS. The chapter further introduces SFL, its evolution and implementation, the benefits of SFL and the

barriers/facilitators to implementation and enforcement of SFL in LMIC settings. The importance of this research for LMIC settings is introduced followed by a description of the aims, objectives, and structure of the thesis. At the end of the chapter, information about ethics approval and funding for this study are presented.

Chapter 2: Tobacco smoking, secondhand smoke exposure, and smoke-free legislation

This chapter describes in detail the background existing literature and the current knowledge on tobacco smoking, SHS exposure and SFL from HICs as well as LMICs. Topics such as the burden and prevalence of tobacco smoking as well as SHS exposure, health and economic adverse consequences of smoking and SHS exposure, international tobacco control policies with a specific focus on SFL, history, evolution and coverage of SFL, best practices in SFL implementation from LMICs, impact of SFL on health and non-health outcomes, and challenges and facilitators to implementation of SFL in LMICs are described in detail. The background section of this chapter is followed by a rationale and justification for this study. This chapter describes literature and data from various sources such as Government and non-governmental reports/publications, as well as credible websites (e.g. WHO, UN, Centre for tobacco-free kids, tobacco.org, Action on Smoking and Health, and American Non-smokers' Rights Foundation among others) of organizations active in tobacco control, data repositories, epidemiologic studies, systematic reviews and meta-analyses.

<u>Chapter 3: Impact of smoke-free legislation on socioeconomic inequalities in health</u> outcomes associated with exposure to tobacco smoke among adults

This chapter presents the results from a systematic review (in the form of a research paper) conducted as a part of this study. The review focuses on the study of quality, quantity and findings of research from HICs as well as LMICs, which have studied the impact of SFL on health outcomes among adults and which also report health outcomes by indicators of SES e.g. income/wealth, education, occupation or some other form of SES index such as area deprivation. The findings suggest that all the included studies were from HICs indicating a need for more research in LMICs on SFL impact evaluation. Moreover, studies included in the review which evaluated the impact of comprehensive SFL, reported either a neutral or equity positive effect (low SES groups benefitted more than the high SES groups) on health outcomes. Partial SFL may not reduce inequalities.

We conclude with a recommendation for implementation and enforcement of comprehensive SFL to reduce health inequalities.

Chapter 4: Secondhand smoke exposure and the impact of smoke-free legislation on protection against exposure to tobacco smoke: Multi-country evidence from Global Adult Tobacco Survey

This chapter initially provides an overview of the Global Tobacco Surveillance System and goes on to describe the GATS methodology in detail. Subsequently, the results of secondary data analyses using the GATS data from 15 LMICs are presented in the form of two research papers, published and disseminated as part of my thesis. The first paper describes the association between being employed at smoke-free workplaces and living in smoke-free homes in these LMICs and thereby suggests that SFL positively changes social norms around exposing others/non-smokers to SHS. The second paper describes the extent of SHS exposure at workplaces and at homes in these countries and shows associations with socioeconomic indicators, indicating that SHS exposure is significantly higher among the less educated and the poor in LMICs, as observed in HICs.

<u>Chapter 5: Evaluation of the impact of National Tobacco Control Programme on bidi and cigarette consumption in India</u>

This chapter initially describes India's national tobacco control laws, followed by its National Tobacco Control Programme (NTCP) and the Consumer Expenditure Survey (CES) methodology conducted by the National Sample Survey Organization (NSSO), Government of India. This description is followed by the results of a secondary data analysis (in the form of a research paper) which was undertaken to study the impact of NTCP on household level bidi and cigarette consumption using three years of repeated cross-sectional CES data (1999-2000; 2004-05; 2011-12) and a sophisticated Difference-in-differences (DID) technique, typically used in econometrics for programme impact evaluation. There was no compelling evidence that NTCP reduced bidi and cigarette consumption over and above the general reduction that occurred in all districts in India. Strengths and weaknesses of the NTCP and policy implications are also discussed in this chapter.

Chapter 6: Discussion and policy implications

This chapter presents an overall discussion based on the results of individual components of this study. Findings of each research paper are summarised along with an overall synthesis. General strengths and limitations, and policy implications of findings relevant to implementation and enforcement of comprehensive SFL in the LMIC settings are discussed, followed by a conclusion to the thesis.

All references have been listed in Vancouver style in one separate section after the last chapter. The appendices provide additional material relevant to this work including ethics approval letters, and supplementary material included in published or yet to be published research papers.

A total of four research papers (published and yet to be published) are included in this thesis. A research paper coversheet is included before each paper which provides information about the publication (or planned publication) including copyright information, author details, journal, and description of my contribution to the research paper (in the case of multi-authored research papers).

1.4. Ethics clearance

An exemption from ethics review for using anonymous secondary data from the nationally representative surveys (GATS and NSSO CES) was provided by the Institutional Ethics Committee at Public Health Foundation of India (PHFI) and the Research Ethics Committee at the London School of Hygiene and Tropical Medicine (LSHTM) (see Appendix A).

1.5. Funding

This work was supported by a Wellcome Trust Capacity Strengthening Strategic Award to the Public Health Foundation of India and a consortium of UK universities.

Chapter 2: Tobacco smoking, secondhand smoke exposure, and smoke-free legislation

2.1. Background

2.1.1. Prevalence of smoking

Tobacco smoking and SHS exposure (collectively) is the third leading risk factor for global burden of disease (GBD).¹ Collectively, tobacco smoking and SHS exposure are responsible for 7.2 million annual deaths worldwide (17% of all deaths among men and 8% of all deaths among women) and 7% of the Disability-Adjusted Life Years (DALYs) lost (9% of all DALYs lost among men and 4% among women).¹ Tobacco smoking alone is responsible for 6.4 million annual deaths worldwide, (of which, 77% are among men and 23% are among women) and 6% of the DALYs lost.¹ Although the absolute numbers of deaths and DALYs lost attributable to smoking have increased between 1990 and 2015, there has been a relative decline in the age-standardized death rate by 32% and DALYs lost by 35%.¹

Ng et al. studied the prevalence of daily smoking and the number of cigarettes smoked per day in 187 countries between 1980 and 2012.44 They report that the agestandardized prevalence of daily smoking reduced by 25% and 42% among men and women respectively over this period, however, due to increases in the population over time, there was a 41% increase in the number of men who smoked daily and a 7% increase in the number of females who smoked daily. They observed that the decline in smoking prevalence was faster before 2006, after which, it slowed down substantially, possibly due to increases in the number of smokers in some countries (e.g. China and Indonesia) and varying levels of implementation of tobacco control policies across countries. The decline was particularly notable in some of the countries (mainly HICs) such as Canada, Ireland, Iceland, New Zealand, Mexico, and Norway. 44 Apart from this study, other sources also confirm that over the past decade, cigarette smoking has declined in the European Region, the Region of the Americas, the South East Asian Region, and the Western Pacific Region (except China where it has notably increased) while it has increased in the Eastern Mediterranean Region and the African Region.³ Concurrently, there is an upsurge in the burden of death and disease attributable to NCDs, which are responsible for 71% of all deaths globally. The highest tobaccoattributable burden of disease is due to NCDs such as CVDs, cancers and chronic

pulmonary diseases.^{1, 45} It is estimated that there are a billion smokers globally and every four out of five smokers are from LMICs.² The burden of disease and death attributable to tobacco smoking and the associated NCDs is therefore set to rise further in the resource-poor LMICs. Moreover, the WHO estimates that, if uncontrolled, tobacco use would lead to a billion deaths in the 21st century.²

Giovino et al. compared the prevalence of tobacco use in 14 LMICs with that in two HICs (US and UK) using nationally representative data from 2008 to 2010 (Table 2.1).⁴⁶ The authors reported much higher prevalence of smoking and any tobacco use among men compared with women in LMICs. The prevalence of smokeless tobacco (SLT) use was reported to be highest in Bangladesh and India. Additionally, the authors reported that the women were starting to use tobacco at increasingly younger ages so that the age of initiation in younger age groups was similar among men and women.⁴⁶

		countries (HIC	s) ⁴⁶		
		GATS Countries (LMICs)		High income countries (HICs)	
		Lowest prevalence	Highest prevalence	UK	US
Current smoking	Total	India (14%)	Russia (30.1%)	21.7%	19.9%
	Males (≥15 years)	Brazil (21.6%)	Russia (60.2%)	22.8%	24.0%
	Females (≥15 years)	Egypt (0.5%)	Poland (24.4%)	20.6%	16.2%
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Current SLT use	Total	Uruguay (0%)	Bangladesh (27.2%)	-	1.8%
	Males (≥15 years)	Uruguay (0%)	India (32.9%)	-	3.5%
	Females (≥15 years)	Uruguay, Ukraine, China (0%)	Bangladesh (27.9%)	-	0.2%
Current any tobacco use	Total	Mexico (16.0%)	Bangladesh (43.3%)	21.7%	21.1%
	Males (≥15 years)	Brazil (22%)	Russia (60.6%)	22.8%	26.2%
	Females (≥15 years)	Egypt (0.6%)	Bangladesh (28.7%)	20.6%	16.3%

Lopez et al. initially described a model for the cigarette epidemic in 1994, which described the progress of the epidemic in four stages. 47 Stage I (one or two decades) – characterised by the low prevalence of smoking, low per capita consumption, and no smoking-related death and disease. Stage II (two to three decades) – characterised by rapidly rising prevalence and frequency of consumption (higher among males vs. females), no SES differences or smoking higher among the rich, and the health effects become evident among males towards the end of this stage. Stage III (approximately three decades) - characterised by a decline in male smoking, the start of the decline in female smoking towards the end of this stage, decline in smoking more evident among those with higher education, high death, and disease among males (low among females). Stage IV - characterised by a continued slower decline in male and female smoking, declining smoking-attributable death and disease among males (rising among females) and inequalities in smoking (higher rates among the low SES groups). The countries in stage IV of the smoking epidemic are mainly HICs such as the US, UK, Australia, and Canada, among others, where socioeconomic inequalities in smoking became apparent with declining smoking rates or probably even before that, during stage III of the epidemic.⁴⁷ More recent research evidence shows that in most HICs, smoking prevalence is higher among the people belonging to low SES, while on average high SES smokers smoke more per day than low SES smokers.4 Mixed evidence of socioeconomic inequality in smoking exists in LMICs as most of these countries are in stage II or stage III of the epidemic. Hosseinpoor et al. studied the prevalence of smoking from 48 LMICs that participated in the World Health Survey and found that the smoking prevalence among males was higher among those belonging to low SES in most of the countries studied (possibly stage III of the epidemic), while the smoking prevalence among females from nine countries was higher among the richest vs. the poorest (possibly stage II of the epidemic).⁵ This indicates that in LMICs tobacco control policies need to be strengthened further and targeted as per the country-specific situation.

2.1.1.1. Country specific example - India

In India, tobacco smoking led to 0.7 million deaths (majority of these deaths were among males) and 4% of DALYs lost in the year 2015.¹ The prevalence of any tobacco use is 34.6% (among those ≥ 15 years of age) (47.9% among men and 20.3% among women); current smoking is 14% (24.3% among men and 2.9% among women); and current SLT use is 25.9% (32.9% among men and 18.4% among women).⁴8 Ng et al. suggests that between 1980 and 2012, the smoking prevalence among adult Indian men decreased

from 34% to 23%, while the adult female smoking prevalence which was 3.2% in 2012 has virtually remained unchanged since 1980.⁴⁴ Overall, the smoking prevalence decreased from 19% in 1980 to 13% in 2012. The study also suggested that India has the second highest number of female smokers in the world (12.1 million) after the US, due to high absolute numbers of female smokers in India. When comparing India with HICs such as the US and the UK, although there has been an overall decline in adult smoking prevalence in India, the decline has been much slower.⁴⁴ The prevalence among females in India has stayed constant since 1980, while there has been a steady decrease in the prevalence among females from the US and the UK. The gap in prevalence between boys and girls is narrower compared with the adult men and women suggesting that young females are increasingly taking up tobacco use in India.^{48,49}

2.1.2. Prevalence of secondhand smoke exposure

SHS, also commonly known as environmental tobacco smoke comprises of the mainstream smoke (exhaled by the smoker) and the smoke emanating from the burning end of a cigarette. Deproximately 0.9 million annual deaths (1.6% of all deaths) are attributable to SHS exposure globally, of which, 61% deaths occur among women. SHS exposure is responsible for 1% of the global burden of disease in terms of DALYs lost. Between 1990 and 2015 there has been a significant relative decline in the agestandardized death rate (by 53%) as well as DALYs lost (by 56%) due to SHS exposure.

In LMICs, the bulk of burden from SHS exposure falls on women and children. ⁴⁶ Figure 2.1 shows the prevalence of SHS exposure (in past 30 days) among adults at home, at workplace and at restaurants in 22 countries (most of them are LMICs) in which the Global Adult Tobacco Survey (GATS) was implemented from 2008 to 2013. SHS exposure at home in several LMICs is typically high, ranging from 4.4% in Panama⁵¹ to 78.4% in Indonesia. At workplaces, exposure to SHS is higher among men in these LMICs participating in GATS. SHS exposure at workplaces ranges from 5.6% in Panama to over 60% in China; while the exposure is highest in restaurants where it is over 60% in nearly half of these countries. In India, 52.3% of adults are exposed to SHS at homes and 29% are exposed at public places, while 21.9% of children are exposed to SHS at home and 36.6% are exposed to SHS outside their homes.

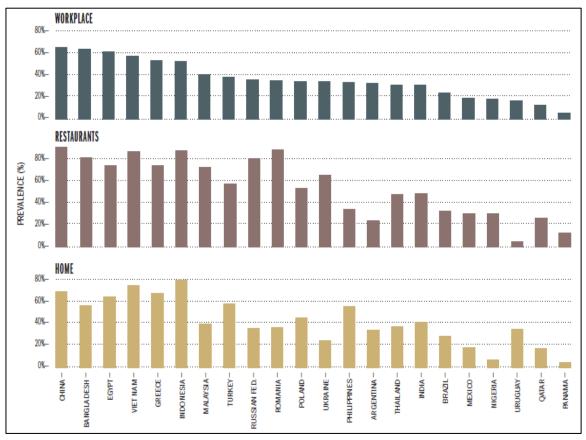


Figure 2.1: Prevalence of secondhand smoke (SHS) exposure (in past 30 days) among adults at home, at workplace and at restaurants in 22 Global Adult Tobacco Survey (GATS) countries (2008-2013)³

In the US, exposure to SHS among non-smokers has declined steadily over the years (from 88% in 1988-1991 to 25% in 2011-2012).⁷ In the European countries such as England and Scotland, there has been a significant decline in SHS exposure, both in homes and at workplaces since the introduction of smoke-free laws.^{54,55} In HICs, there exists sufficient evidence to suggest that SHS exposure is higher among the poor (e.g. people with low incomes, blacks vs. whites as well as the blue collar and the service workers).^{6,7} However, similar evidence is lacking in the context of LMICs in which the SFL is often poorly enforced and implemented. Apart from differences in the prevalence of tobacco use and trends therein across countries, a major reason for the observed differences in SHS exposure between these countries is the difference in the extent to which SFL is implemented and enforced.⁵⁶

2.1.3. Harms due to smoking and secondhand smoke exposure

As research has shown that SFL reduces smoking as well as SHS exposure among the non-smokers,²¹ it is important to have an understanding of the harms that are caused by smoking as well as by exposure to SHS. Evidence on the harmful health effects of

tobacco smoking began to accumulate after the 1962 Royal College of Physicians report observed that cigarette smoking causes lung cancer and bronchitis, and possibly other diseases, including coronary heart disease.⁵⁷ Subsequently, a 1964 US Surgeon General's report causally linked smoking with lung cancer.⁵⁸ A series of US Surgeon General's reports have been published since then. Causal associations described these reports carry additional weight as over the years, these reports have established rigorous procedures for compiling and evaluating the global scientific literature. The US Surgeon General's reports critically review the available research evidence for quality and strength of association and conservatively establish a summary causal statement for each outcome. These causal statements fall into one of the following four levels -Level 1: sufficient evidence to infer a causal relationship; Level 2: suggestive but not sufficient evidence to infer a causal relationship; Level 3: inadequate evidence to infer a causal relationship; Level 4: suggestive of no causal evidence.8 The US Surgeon General's reports published after the initial 1964 report causally linked smoking with several other types of cancers, diseases, and conditions affecting the cardiovascular system, respiratory system, and reproductive system among others (Figure 2.2). The evidence continues to be generated and the latest conditions to be causally associated with smoking in the 2014 US Surgeon General's report include: liver and colorectal cancers, age-related macular degeneration, congenital anomalies, tuberculosis, diabetes, ectopic pregnancy, erectile dysfunction, rheumatoid arthritis, diminished immunity and overall health.8

IARC Monographs use similar methodology of reviewing global evidence to assess the strength of evidence for carcinogenicity among humans and experimental animals wherein it uses four categories of classification similar to the US Surgeon General's Reports (e.g. *Group 1*: sufficient evidence of carcinogenicity among humans; *Group 2a*: limited evidence of carcinogenicity in humans but sufficient evidence of carcinogenicity among experimental animals; *Group 2b*: limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity among experimental animals; *Group 3*: inadequate evidence of carcinogenicity in humans and inadequate or limited evidence of carcinogenicity among experimental animals; *Group 4*: evidence suggesting lack of carcinogenicity among humans and experimental animals.⁵⁰ In addition to confirming the findings of the US Surgeon General's report, cancers of sinonasal cavities and the nasopharynx and mucinous ovarian tumours are suggested by the IARC Monograph to be causally associated with smoking.⁵⁰ The IARC Monograph reviewed studies of bidi

smoking separately and concluded: "bidi smoking increases the risk for cancers of the oral cavity, oropharynx, hypopharynx, larynx, lung, oesophagus and stomach." ⁵⁰

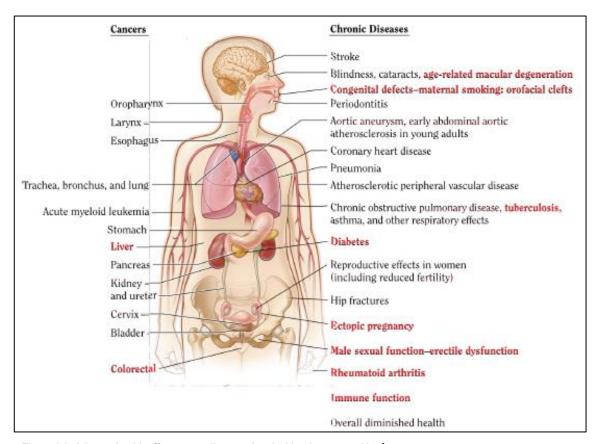


Figure 2.2: Adverse health effects causally associated with tobacco smoking⁸

SHS contains more than 7000 chemicals including 70 carcinogens and other toxins.⁸ Initial evidence on the possible adverse health effects of SHS exposure began to emerge in US Surgeon General's reports from 1972.⁸ Subsequent reports also included other possible adverse health effects of exposure to SHS such as those affecting the respiratory system, particularly among children. A causal link between SHS exposure and lung cancer among non-smokers was only established after the 1986 US Surgeon General's report, which solely focused on SHS exposure (another report solely focused on SHS exposure was published in 2006).^{6,59} The 2006 report suggested that SHS exposure is causally associated with middle ear infections, respiratory symptoms such as coughing, sneezing and shortness of breath, lower respiratory tract infections such as bronchitis and pneumonia, and sudden infant death syndrome (SIDS) among children (Figure 2.3). Among adults, exposure to SHS was shown to be causally linked with coronary heart disease, lung cancer, low birth weight babies, respiratory symptoms and stroke.^{6,8} Further, evidence is suggestive but not sufficient to infer a causal relationship

between exposure to SHS and breast cancer, pre-term delivery, chronic obstructive pulmonary disease (COPD), chronic respiratory symptoms, asthma, impaired lung function, atherosclerosis, cancer of nasal sinuses, pharynx and larynx among adults; and dental caries, neurodevelopmental disorders, asthma, tuberculosis, allergic diseases, lymphoma and leukaemia among children.^{3, 8} The IARC Monograph suggests that causal associations exist between SHS exposure and leukaemia, lymphoma and hepatoblastoma among children.⁵⁰

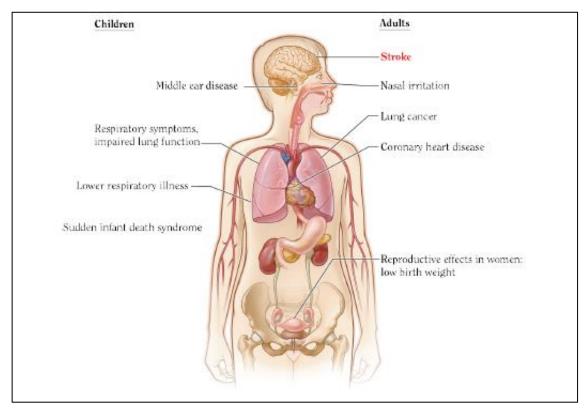


Figure 2.3: Adverse health effects causally associated with exposure to secondhand smoke (SHS)8

2.1.3.1. Economic costs of smoking

Apart from the health harms due to active smoking and SHS exposure, the cost of purchasing cigarettes and the healthcare cost of treating related diseases can be overwhelming for the smokers, the non-smokers exposed to SHS and the entire nation. In the US, lifetime cost of buying cigarettes per smoker has been estimated to be between US\$ 1.1 million to 2 million, depending on the state of residence.⁹ On the other hand, the total economic cost of tobacco smoking and SHS exposure in the US is US\$ 300 billion and US\$ 11 billion per year respectively, including direct healthcare costs and indirect costs.^{10, 11} In the UK, the annual household expenditure on cigarettes in 2014 was £19.4 billion, while the cost of buying cigarettes per year was estimated to be £3000

per year for a heavy smoker.¹² The healthcare cost of treating smoking-related diseases was estimated to be £2 billion per year to the UK National Health Services.¹² This cost was £23.3 million for the treatment of diseases related to SHS exposure.¹³ Similar high costs are also observed in LMICs. In India, the cost of purchasing cigarettes has been estimated to be INR10 million per smoker who smokes five cigarettes a day for 30 years.¹⁴ The total economic cost of tobacco use in India in 2011 was estimated to be US\$ 22.4 billion including direct health care costs and indirect costs.¹⁵ Tobacco consumption has been estimated to push 15 million people into poverty annually in India.⁶⁰ Expenditure on tobacco smoking diverts resources which could otherwise be spent on education and other household necessities. Apart from the direct and indirect costs, smoking also leads to intangible costs arising due to loss of life, pain, and suffering due to smoking-related illness. The global annual intangible cost attributable to smoking has been estimated to be US\$ 2.1 trillion, higher than most of the other risk factors for the global burden of disease.⁶¹

2.1.4. International tobacco control policies

Due to the mounting evidence on the harms of active smoking and exposure to SHS, global action to control tobacco has been strengthened in the recent years. The Framework Convention on Tobacco Control (FCTC), a treaty negotiated under the auspices of WHO at the 56th World Health Assembly (2003), came into force on February 27, 2005. As of December 2016, there are 168 signatories and 180 Parties (ratifying nations) to the WHO FCTC. The WHO FCTC provides guidance on implementation and enforcement of several evidence-based supply and demand reduction measures for tobacco control to the Parties. Each of these measures is outlined in a separate article in the WHO FCTC document. The WHO FCTC has further developed and disseminated detailed and clear guidelines separately for each article so as to enable effective implementation and enforcement by each Party. Table 2.2 lists the key demand and supply reduction measures from the WHO FCTC.

Article 8 of the WHO FCTC urges the ratifying Parties to: a) recognize that exposure to tobacco smoke can lead to "death, disease and disability" and b) "adopt and implement in areas of existing national jurisdiction as determined by national law and actively promote at other jurisdictional levels the adoption and implementation of effective legislative, executive, administrative and/or other measures, providing for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public

places and, as appropriate, other public places."¹⁶ Guidelines for implementation of Article 8 of the WHO FCTC suggest that even minor exposure to SHS can cause harm; only 100% smoke-free environments can provide complete protection from exposure to SHS while mechanical ventilation, air filtration systems or designated smoking rooms (DSRs) are not effective and should be discouraged.^{6, 62} The guidelines further require that comprehensive SFL should include all indoor workplaces, indoor public places, and public transport and as appropriate, other public places, without any exemptions and voluntary agreements. In order to ensure compliance, the public needs to be made aware by educating them about SFL, its benefits, related myths and penalties resulting from a violation of such policies. At the same time designation of an enabled agency or a group is essential to ensure effective implementation and enforcement.⁶²

Table 2.2	Table 2.2: Demand and supply reduction measures outlined in the WHO Framework Convention on Tobacco Control						
	(FCTC) 2003 ¹⁶						
	Demand reduction measures		pply reduction measures				
Article 6	Price and tax	Article 15	Illicit trade of tobacco products				
Article 7	Non-price measures	Article 16	Sale to and by minors				
Article 8	Protection from exposure to SHS	Article 17	Provision of support for economically viable alternative activities				
Article 9	Regulation of the contents of tobacco products						
Article 10	Regulation of tobacco product disclosures						
Article 11	Packaging and labelling of tobacco products						
Article 12	Education, communication, awareness and public awareness						
Article 13	Tobacco advertising, promotion, and sponsorship						
Article 14	Tobacco dependence and cessation						

2.1.4.1. Smoke-free legislation – past and present

While some activists had been warning about the dangers of smoking even before 1950 when cigarette smoking gained popularity, the researchers, the medical community, and the Governmental agencies started considering protection from tobacco smoke only after the US Surgeon General's 1964 report which causally linked smoking with lung cancer. As research evidence accumulated thereafter, SFL started to be enacted across the globe. Initial SFL tended to be 'partial' as either only certain venues/public places/workplaces were smoke-free, or there was no physical separation between the smoke-free and the smoking zones or the hospitality venues were not covered by such

policies. The first comprehensive smoke-free workplace law was introduced in the US state of California in 1998 which covered all indoor workplaces (including bars and taverns). Moreover, there have been differences between countries in terms of the level at which SFL was implemented for e.g. some of the countries introduced national SFL (e.g. Ireland, Uruguay, and India) while others implemented a state level or substate/regional level legislation and then expanded it over time (e.g. Australia, the US).²¹ Some of the countries have SFL at multiple levels e.g. national and/or state and/or city levels (as in Sydney, Melbourne, and New York City).²³ The IARC Monograph published in the year 2009 which presents comprehensive evidence on the effectiveness of SFL provides a detailed historical overview of the evolution of SFL which is briefly summarised in Table 2.3.

		Summary of key events in the evolution of smoke-free legislation (SFL) ²¹	T	
Year	Country/State/City	Detail of SFL coverage	Partial/	
			Comprehensive	
1969	Bulgaria	Ban on smoking in workplaces where non-smokers work (except if the	Partial	
		non-smokers have no objection to smoking). Exception not applicable if		
		pregnant or nursing mothers were working there.		
1970	Singapore	Ban on smoking in movie halls, theatres, public lifts and some buildings.	Partial	
1973	Norway	Restriction on smoking in public transport, meeting rooms, workplaces,	Partial	
		and institutions		
	Arizona	Smoking in libraries, theatres, concert halls and buses restricted to	Partial	
		designated areas		
	Connecticut	Smoking restricted in restaurants	Partial	
1975	Minnesota	Smoking restricted in private workplaces, restaurants, meeting rooms and	Partial	
		public places		
1988	Norway	Extension of earlier law to restrict smoking in all enclosed public places	Partial	
		and public transport (but excluded restaurants and bars)		
1989	Multiple states in the	45 states – Restriction of smoking in public places	Partial	
	US	17 states – Restriction in private sector workplaces		
1990	New Zealand	Some smoke-free public places and partial restrictions in hospitality	Partial	
		venues		
1994	California	195 municipalities implemented clean air laws at local/city level Partial		
1998	California	California smoke-free workplace law required all indoor workplaces	Comprehensive	
		in the state to be completely smoke-free (including bars and taverns)		
2002	Delaware	Smoke-free workplace law	Comprehensive	
2003	India	Cigarettes and Other Tobacco Products Act (COTPA) 2003 section 4 –	Partial	
		smoking banned in several public places (exemptions allowed in hospitality		
		venues)		
	New York	Smoke-free workplace law	Comprehensive	

2004	Uganda	Regulation of smoking in public places	Partial
	Ireland	Nationwide smoke-free workplace law	Comprehensive
	Norway	Nationwide smoke-free workplace law	Comprehensive
	New Zealand	Nationwide smoke-free workplace law	Comprehensive
	Maine, Connecticut,	Smoke-free workplace law	Comprehensive
	Massachusetts		
	Canada – 3	Smoke-free workplace law	Comprehensive
	provinces and 2		
	territories		
2005	Canada – 2	Smoke-free workplace law	Comprehensive
	provinces		
	US – 3 additional	Smoke-free workplace law	Comprehensive
	states		
	Italy	Nationwide smoke-free workplace law	Partial
2006	Uruguay	Nationwide smoke-free workplace law	Comprehensive
	Scotland	Nationwide smoke-free workplace law	Comprehensive
	Argentina – 2	Smoke-free workplace law	Comprehensive
	provinces		
	US – 4 additional	Smoke-free workplace law	Comprehensive
	states		
	Australia – 3 states	Smoke-free workplace law	Comprehensive
2007	Lithuania	Nationwide smoke-free workplace law	Comprehensive
	Iceland	Nationwide smoke-free workplace law	Comprehensive
	Australia – 3 states	Smoke-free workplace law	Comprehensive
	Northern Ireland,	Nationwide smoke-free workplace law	Comprehensive
	Wales, England		
	US – 5 additional	Smoke-free workplace law	Comprehensive
	states		
	Argentina – 1	Smoke-free workplace law	Comprehensive
	province		
2008	India	Amendment of COTPA 2003 to strengthen SFL (including all indoor public	Partial
		places, workplaces, public transport and some outdoor public places as	
		well). DSRs allowed at airports, hotels (more than 30 rooms) and	
		restaurants (more than 30 seats)	
2011	Brazil	Nationwide smoke-free workplace law (all enclosed public places	Comprehensive
		including restaurants and bars)	

Comprehensive SFL was, and continues to be the most widely implemented measure among all the tobacco control measures recommended by the WHO; yet, as per the WHO MPOWER report (2015), only 18% of the world's population was covered by comprehensive SFL in 2014.²³ The MPOWER report classifies existing SFL in a country as comprehensive SFL if all its public places (including health care facilities, educational

facilities other than universities, universities, government facilities, other indoor workplaces and offices, restaurants or facilities that serve mostly food, cafes/pubs/bars or facilities that serve mostly beverages and public transport) are completely (100%) smoke-free or at least 90% of its population is covered by complete sub-national SFL.²³ In the recent years, most of the progress in enforcement of this policy initiative has been observed in the middle income countries (particularly those from the Latin America).⁶³ With the recent additions of Chile, Jamaica, Madagascar, Russian Federation and Suriname, 49 countries in the world are now covered by comprehensive SFL at the national or sub-national level.²³ Globally, 75% of the countries still have weak or no implementation of SFL, notable among these are about 88% of the low income countries.²³ Figure 2.4 shows the status of implementation of SFL across the globe.

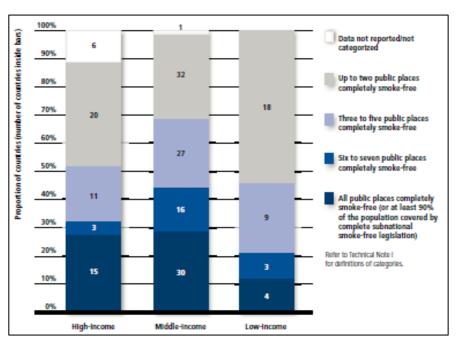


Figure 2.4: Status of implementation of smoke-free legislation (SFL) across the globe in 2014²³

A global map of smoke-free policies published in 2008 showed that across all the six WHO regions, enforcement of SFL was poor in several LMICs.²⁵ Since then, there have been several changes in the global SFL scenario. However, typically, implementation and enforcement of tobacco control policies have been observed to be poor among LMICs compared with HICs. More recently, two LMICs – Uruguay (an upper-middle income country before 2013) and Brazil have set the benchmark for all the other LMICs to follow by successfully demonstrating a significant reduction in smoking and SHS

exposure following implementation of stringent tobacco control policies including a comprehensive SFL.

2.1.4.2. Case study: Smoke-free legislation in Uruguay

Uruguay is the first country in Latin America and the first among all LMICs to have implemented a comprehensive SFL from March 1, 2006.²¹ This was possible only due to the high level of political commitment from the then President of Uruguay who was an oncologist and was well-aware of the adverse consequences of smoking and exposure to tobacco smoke. The introduction of the comprehensive legislation was a stepwise process in Uruguay – initially, only the hospitals were required to be 100% smoke-free (2004), followed by addition of all public offices (2005) and then all indoor workplaces and public places (2006).⁶⁴ An apex group, the National Commission on Tobacco Control was set up to look after and guide all the aspects of tobacco control, which consisted of members from the Government as well as the civil society, and which was very active in tobacco control in Uruguay. This group also established links with the University of Waterloo's Tobacco Control Policy evaluation project (ITC project) which provided information about the prevalence of tobacco use and also conducted an evaluation of the tobacco control policy in Uruguay. 65 The enforcement of SFL is implemented by the Government (Ministry of Health) while the citizens act as watchdogs and facilitate the implementation. Violations of the SFL are subject to heavy penalties, imprisonment, and closure of the hospitality venue in question. Therefore, there is a high level of compliance with SFL in the hospitality venues (90%) and at workplaces (70-80%) in Uruguay.66

The media was utilised effectively throughout this campaign. In order to address the issue of compliance following implementation, raise awareness about the policy and create a social norm for smoke-free air, the Government launched the 'One Million Thanks' campaign wherein over a million signatures were collected thanking the smokers for not smoking in public places.⁶⁴ The nationwide campaign was launched by the President himself. Another campaign was 'Smoke-free Uruguay' which was launched on the World No Tobacco Day in 2006 to launch a logo for smoke-free environment.⁶⁴ Various strategies such as posters, brochures, and radio/television spots were used in this campaign.

Research evidence from Uruguay has shown that the SFL has a high level of support from the general public. An opinion poll conducted nine months after implementation of the policy showed that 95% of the participants supported 100% smoke-free environments including 92% of the smokers.⁶⁴ Uruguay also implemented a number of other evidence-based tobacco control measures along with the SFL from 2005. Between 2005 and 2011, the prevalence of smoking in Uruguay reduced by 3.3% and the number of cigarettes smoked per person reduced by 4.4% per year.⁶⁶ Between 1998 and 2012, the prevalence of smoking in Uruguay reduced from almost 50% to 20%.⁶⁶ Comprehensive SFL in Uruguay has been shown to be more effective than weaker policies (e.g. in some Mexican cities) in reducing exposure to SHS.⁶⁷ Two studies conducted after implementation of the SFL in Uruguay have shown that AMI admissions in hospitals reduced by 22% and 17% after 2 years and 4 years respectively.^{68, 69}

2.1.4.3. Case study: Smoke-free legislation in Brazil

Brazil is the world's largest country to have a comprehensive SFL since December 15, 2011, when the then President of Brazil signed it into law. 70 Brazil strengthened its SFL along with other tobacco control measures progressively. DSRs were allowed at certain collective places in 1996, all aircraft and public transport went smoke-free in 2000, and all indoor workplaces and public places went 100% smoke-free in 2011.71 Three national agencies played an important role in the tobacco control policy formulation, strengthening, implementation and enforcement since 1999 in Brazil: an inter-ministerial National Commission for Tobacco Control, the National Agency for Sanitary Surveillance (ANVISA) (governs product and content regulation) and the Ministry of Finance (governs taxation).²² Evidence of the effect of tobacco control policies on smoking prevalence and their attributable fractions have been estimated through research conducted in Brazil. As a result of the periodic strengthening of its tobacco control policies including the SFL, adult smoking prevalence in Brazil has been declining steadily since 1989.^{72, 73} Between 1989 and 2008, adult smoking prevalence reduced by half from 35% to 18.5%, which prevented over 0.4 million premature deaths. 72,73 The SimSmoke (simulation) model predicted that among all the tobacco control policies implemented in Brazil, tobacco price rise was responsible for most of the reduction in smoking (46%), while the next largest measures were SFL and marketing restrictions (14% reduction through each).⁷⁴ Thus, SFL, in conjunction with other strong tobacco control measures such as price increases, restriction on tobacco advertising, promotion and sponsorship, strong and large pictorial health warnings on tobacco packs, tobacco cessation facilities and

tobacco product regulation have the potential to greatly reduce smoking in LMICs such as Brazil, when they are effectively implemented and enforced.

2.1.5. Benefits of smoke-free legislation

Evidence, mostly from HICs, demonstrates that comprehensive smoke-free laws are effective in improving air quality and population health, reducing the prevalence and intensity of smoking and exposure to SHS, and increasing the quit rates. In HICs, SFL has also been shown to be beneficial to the business and economy contrary to the tobacco industry claims of losses following implementation of SFL. As more and more LMICs implement SFL, the evidence is gradually emerging from these countries although rigorous, high-quality pre- and post-intervention evaluation studies are often lacking.

2.1.5.1. Impact on air quality and secondhand smoke exposure

Semple et al. studied the concentrations of particulate matter less than a diameter of 2.5 micrometres (PM_{2.5}) (a good marker of SHS in indoor places where there are no other sources of combustion) in bars of England, Wales and Scotland before and up to 12 months after implementation of comprehensive SFL.⁷⁵ They observed that in all of these countries, there was a significant reduction in the PM_{2.5} concentrations post-implementation of the law, in the order of 84%-93%.⁷⁵ Similar improvements in the air quality have been observed in studies undertaken in New York,⁷⁶ Ireland,⁷⁷ and Ontario.⁷⁸ Pre- and post-implementation evaluation of the SFL implemented in 2007 in Israeli bars, pubs and cafes suggested that post-implementation, there was a significant 34% reduction in the PM_{2.5} concentration, a 10% decline in the number of smoking patrons in these venues and an increase in the number of non-smoking venues.⁷⁹ A similar pre- and post- SFL evaluation conducted in 21 hospitality venues of Cyprus has shown that within 2-4 months of implementation of the smoke-free law, the particulate matter in hospitality venues reduced significantly by 98%.⁸⁰

Another study was conducted in 2011 at nine busy airports across the US (five allowed smoking in the DSRs at airports and four were completely smoke-free) which involved measurement of the PM_{2.5} concentrations at different locations in these airports.⁸¹ Results of the study showed that DSRs at airports where smoking was allowed, had 16 times higher mean concentrations of PM_{2.5} compared with the non-smoking areas of

these airports and 23 times higher compared with the airports that were completely smoke-free. Moreover, PM_{2.5} concentrations in the areas immediately adjacent to DSRs of airports that allowed smoking were four times higher than the average levels in non-smoking areas of these airports and five times higher than the average levels in non-smoking airports. These results suggest that separate DSRs and ventilation systems are not effective in removing the tobacco smoke which gets dissipated to the non-smoking areas of these venues, resulting in high concentrations of the harmful particulate matter throughout the venue. Only 100% smoke-free air would offer complete protection against SHS exposure to the non-smokers.

A study was conducted in Uruguay, which assessed changes in air nicotine concentrations at public places and workplaces, to evaluate the impact of comprehensive SFL introduced in the country in 2006.82 It was observed that a year after the introduction of comprehensive SFL, there was 91% reduction in air nicotine concentration across the sampled venues (compared with concentrations in 2002), with greatest reductions observed in schools and airports, followed by hospitals, government buildings, and restaurants/bars.82 Another study conducted in Sao Paulo, Brazil assessed changes in carbon monoxide (CO) levels (in the environmental air and in the air exhaled by hospitality venue workers) in its hospitality venues to study the effect of a state level SFL introduced in 2009.83 Significant reductions were observed in CO levels from pre- to post-ban in indoor areas (4.57 to 1.35 ppm), semi-open areas (3.79 to 1.16 ppm), smoking employees (15.78 to 11.50 ppm) as well as non-smoking employees (6.88 to 3.50 ppm). 83 There are studies from other LMICs such as Turkey, 84 India, 85 and Argentina, 86 which report changes in the air quality following SFL implementation but seem to suffer from methodological issues and lack of rigour. Hence, the results need to be interpreted with caution.

Smoke-free laws have also been shown to reduce exposure to SHS among the general public (including children) and especially among the hospitality industry workers. Studies have assessed the hospitality industry workers for self-reported or measured respiratory symptoms and cotinine levels (in saliva, urine, serum or hair) as markers of exposure to SHS.⁸⁷ In a pre-post SFL evaluation study conducted with 77 asthmatic and non-asthmatic bar workers in Scotland, it was shown that within one and two months of implementation of the smoke-free law, there were significant reductions in respiratory symptoms (coughing, wheezing, shortness of breath and phlegm) and sensory

symptoms (eye and throat irritation, sneezing, runny and itchy nose) by 26% and 32% respectively. Significantly improved lung function, reduced serum cotinine and improved quality of life (among asthmatics) were also observed following implementation of the SFL. Similar improvements in respiratory symptoms, lung function and reduction in cotinine levels have been observed among the hospitality industry workers in other studies undertaken in Ireland California after the implementation of SFL.

Two studies conducted with adult participants and primary school children after the implementation of Scotland's SFL in 2006 suggested that within one year after the law went into effect, there was a 39% reduction in SHS exposure in both groups (determined by salivary cotinine concentrations). 30, 90 Moreover, it was observed that the fall was greater in participants who lived either in homes with low or no SHS exposure. Participants also noted the greater reduction in SHS exposure at restaurants/cafes, pubs (among adults), public transport and workplaces (among adults). Similar reductions in SHS exposure following implementation of the SFL have been observed in other countries such as Spain,91 New Zealand,92 and the US.93 Among LMICs, a study was conducted with 80 bar and restaurant workers in the city of Nequen, Argentina which showed that after three months of implementation of 100% SFL, there was a significant reduction in SHS exposure among these workers.⁹⁴ It was observed that there were significant reductions in respiratory symptoms (57.5% pre-SFL to 28.8% post-SFL), and sensory irritation symptoms (86.3% pre-SFL to 37.5% post-SFL) among these workers; while there were significant improvements over the same period in forced vital capacity as observed through spirometry. 94

2.1.5.2. Impact on smoking prevalence, intensity and quitting

Smoke-free laws have also been shown to be associated with a decrease in the prevalence of smoking and an increase quit rate. 95-97 In a secondary analysis of repeated cross-sectional health survey data (2003-2008) from about 54,333 British adults, it was observed that after the introduction of SFL in 2007, there was a significant decrease in the prevalence of smoking at work from 14% to 2%, inside bars or pubs from 34% to 2%, inside canteens, restaurants, and cafes from 9% to 1% and at homes from 65% to 55%. 98 Another study conducted in the US as part of the Community Intervention Trial for Smoking Cessation (COMMIT) trial with smoker employees suggested that those working in smoke-free workplaces were 2.3 times more likely to

quit smoking and smoked on an average 3.85 lesser cigarettes compared with those who were employed in workplaces where smoking occurred.⁹⁵ In England, in response to the SFL, quit attempts among smokers did increase temporarily.⁹⁹ In the first five months following implementation of the SFL, 19% of the smokers who made a quit attempt did so in response to the SFL.⁹⁹ A study conducted in China also showed reduction in the prevalence and volume of smoking, and higher quit attempts among workers employed in a smoke-free workplace (vs. those working in the workplace where only some restrictions were in place), a major limitation being that it was conducted in a single multi-national company.¹⁰⁰

2.1.5.3. Impact on attitudes and social norms around secondhand smoke exposure and support for smoke-free legislation

Studies from HICs suggest that SFL may change attitudes and social norms about exposing others to SHS at home, 32-34 as well as in private vehicles. 36 Cheng et al. conducted secondary analysis on data from tobacco use supplement to current population survey (TUS-CPS) (1992-2007) from the US and found that among the people living with smokers, living in smoke-free homes was seven times more likely when they were living in a county with 100% smoke-free workplaces (compared with those living in counties with partial or no smoke-free workplaces).³³ Among the people not living with smokers, the odds were four times.³³ Another cohort study assessing the impact of SFL on smoking behaviour found similar reductions in smoking at home after the introduction of comprehensive SFL in Ireland (85% to 80%; p=0.002) and the UK (82% to 76%; p=0.003).35 Further, a more recent study conducted in the US has shown that 100% smoke-free indoor air laws increase the likelihood of having voluntary smokefree homes by 5% and smoke-free cars by 4%.36 Among LMICs, only one study from India has been published which used the GATS data and suggested that those employed indoors in a smoke-free workplace are twice as likely to have a smoke-free home.³⁷ There is a need for further research on this aspect in LMICs. This is important because, in certain cultures in LMICs, tobacco smoking is deeply rooted in the cultural context and is highly socially acceptable which can act as a hindrance to effective tobacco control in that society. Research from HICs indicates that SFL changes social norms around exposing others to tobacco smoke, which is why in such settings people are also adopting voluntary smoke-free policies at homes and in cars contrary to the tobacco industry claim that SFL would increase smoking in homes.

The growing support for and popularity of smoke-free laws have also been studied earlier in the developed countries. ¹⁰¹ In the study conducted by Fong et al. in Ireland, significantly more adult smokers supported smoke-free laws in bars/pubs (from 13% pre-ban to 46% post-ban), restaurants (from 45% pre-ban to 77% post-ban) and workplaces (from 43% pre-ban to 67% post-ban), one year after implementation when compared to before implementation. ³⁵ The evaluation of SFL in France suggested that support for SFL increased significantly after its implementation and has remained so even five years after. ¹⁰² Similar support in favour of the SFL has been observed in other countries such as the US, New Zealand, and Scotland. ¹⁰¹ In LMICs as well, strong support for smoke-free policies has been documented. Surveys in Brazil after implementation of SFL have shown that 85% of the people favoured smoke-free public places and 83% supported smoke-free restaurants while a poll conducted in urban Uruguay after implementation of 100% SFL has shown that 80% of its population supported this policy measure. ¹⁰³

2.1.5.4. Impact on business and economy

The tobacco industry tried to perpetuate the myth that SFL would harm the businesses particularly, the hospitality business and would cause damage to national economies. In the earlier section on harms of tobacco smoking and SHS exposure, the economic cost related to buying tobacco products (for the user), the healthcare cost of treatment of smoking related diseases and the indirect costs were discussed. These costs far outweigh the benefits due to the revenue that tobacco generates. For example, in England, the total cost of tobacco smoking to the society in 2015 was estimated to be £13.9 billion per year, including the direct and indirect costs, while the revenue generated through tobacco taxation was estimated to be £12.3 billion per year. 104 Similarly, in India, the revenue generated through tobacco amounts only to 17% of the total economic cost of tobacco use. 15 As per the evidence described earlier, SFL leads to reduced smoking and exposure to SHS and increased guit rates and would, therefore, lead to a decline in the economic cost of tobacco smoking. SFL in that sense would only be beneficial to the economy as the loss of revenue would be offset by greater savings on the economic cost of tobacco smoking. Apart from this benefit, studies conducted in HICs have shown that absenteeism is higher among smokers than non-smokers and that smoker employees take longer breaks in between their work. 105 Smoke-free workplaces are more likely to require less maintenance and repairs and have a lower likelihood of catching fires due to cigarette butts. 105 Three large reviews studied the economic impact of SFL in 2003,31 2005,106 and 2009,21 and consistently reported that

such policies do not have a negative impact on the business profits, and revenue or employment (particularly at hospitality venues). In fact, an increase in profits and business following implementation of the SFL has been well-documented in the middle-and high-income countries (e.g. Mexico City, 107 Argentina, 108 the US, 109 and New Zealand 110).

2.1.5.5. Impact on health outcomes

Initial research studying the impact of SFL on health outcomes started from the year 2004 onwards, which focused on reduction in hospital admissions for AMI among adults after implementation of the SFL in Helena (Montana), 111 Pueblo (Colorado), 112 and Piedmont (Italy).¹¹³ Khuder et al. studied the impact of SFL in Bowling Green, Ohio, on adult hospital admissions due to ischemic heart disease (IHD) (including AMI, and other heart conditions such as angina) and heart failure. 114 The results of the Helena (Montana) study which showed a 40% fall in AMI admissions due to the SFL were particularly criticised due to its small sample size (304 cases) resulting in wide confidence intervals (CIs) for the point-estimates.¹¹¹ Dinno and Glantz compiled evidence from these early studies (from the US and Italy) in a meta-analysis and concluded that the SFL led to a 27% reduction (RR 0.73 95% CI 0.56-0.89) in hospital admissions due to heart disease (including IHD and heart failure). 115 Later, three metaanalyses conducted in 2008 (19% reduction), 116 2009 (17% reduction), 117 and 2013 (23% reduction)¹¹⁸ reported significant but lower reductions in the risk of AMI following SFL implementation. Two other meta-analyses reported a 10% and 12% reduction in the risk of acute coronary events (this included in addition to AMI, ACS, coronary heart disease including angina and heart failure, and IHD) following introduction of comprehensive SFL¹¹⁹ and SFL,¹²⁰ respectively. Jones et al. further observed that the reduction was much higher in locations with comprehensive SFL (14% reduction) compared with locations which had partial SFL (8% reduction). 120

Callinan et al. conducted a systematic review to assess the impact of SFL on multiple parameters (smoking, exposure to SHS, ACS hospitalizations, respiratory and sensory symptoms among the hospitality industry workers and others) in 2010.²⁸ For the health outcomes, twelve studies describing the impact of SFL on hospital admissions or deaths due to ACS were included up to the year 2009. Ten studies showed a positive impact of the SFL on hospital admissions (reduced admissions post-SFL); one study showed reduced deaths due to ACS whereas another study showed better prognosis following

ACS among non-smokers.²⁸ The most recent systematic review, Frazer et al. was an update of Callinan et al.'s review and reported the impact of SFL on multiple health outcomes e.g. cardiovascular, respiratory and perinatal outcomes and observed a consistently positive impact of national SFL on reducing adverse cardiovascular outcomes (ACS/AMI/stroke), asthma, lung function, and mortality associated with smoking-related illnesses.²⁷ The effects of SFL on COPD and perinatal health were inconsistent; while they reported significant health benefits among the countries with comprehensive SFL compared to countries with partial SFL. Frazer et al. also report the relevant impact of SFL on health outcomes among the sub-groups (mostly age and gender) for cardiovascular outcomes.²⁷ While they present some indicators for SES, the impact of SFL on socioeconomic inequalities in health outcomes has not been discussed in detail.

A study was conducted in Uruguay using data from 37 hospitals to assess the impact of its 100% SFL introduced in 2006 on hospital admissions for AMI.⁶⁹ It was observed that two years after the introduction of SFL, there was a significant decline in hospital admissions for AMI by 22% overall (compared with hospitalizations in the two years prior to the legislation), and across all sub-groups (private/public hospitals, men/women and age groups).⁶⁹ Another study was conducted in Santa Fe (implemented 100% SFL in 2006) and Buenos Aires (implemented partial SFL) (Argentina) to assess the impact of the legislation on hospital admissions due to ACS.¹²¹ There was a significant 13% decline in ACS hospitalizations in Santa Fe immediately after the intervention, followed by a sustained decline; no immediate or sustained decline was evident in Buenos Aires, indicating that 100% SFL was more effective in reducing ACS hospitalizations compared with partial SFL.¹²¹

Apart from its impact on adult health outcomes, evidence of the impact of SFL on child and perinatal health outcomes has also been steadily accumulating. Been et al. conducted a meta-analysis of studies published between 1975 and 2013 and studied the effect of SFL on three outcomes: low birth weight, pre-term delivery and hospital attendance for asthma.²⁹ Out of the 11 studies from Europe and North America included in the meta-analysis, it was observed that SFL was associated with significantly reduced hospital admissions for pre-term births (10.4% reduction; four studies) and 10.1% reduction in hospital admissions for asthma (three studies).²⁹ Another study conducted by Been et al. in 2015 studied the impact of England's SFL on childhood admissions for

respiratory tract infections (RTIs) using the Hospital Episode Statistics database. ¹²² It was observed that immediately following the implementation of SFL, there was a 3.5% reduction in RTI admissions of which, 13.8% were attributable to lower RTI. The decline in upper RTI was more gradual and occurred at the rate of 1.9% per year after implementation of the SFL. ¹²²

The benefits of SFL probably primarily accrue due to the reduction of active smoking and reduction of SHS exposure in public places. However, the benefits may also partly arise due to a change in social norms around exposing others to SHS. Early on, there were concerns that SFL would lead to behavioural compensation and therefore, would lead to increased smoking in private places such as homes. Research mostly conducted in HICs,³²⁻³⁵ and in India,³⁷ have shown that these concerns have not materialised as those employed in smoke-free workplaces have been shown to be more likely to stay in smoke-free homes. This evidence indicates that SFL may positively alter social norms around exposing others to SHS or improves the sensitivity of smokers towards exposing non-smokers to tobacco smoke.

2.1.6. Challenges to implementation and evaluation of smoke-free legislation

2.1.6.1. Political economy

Despite the availability of evidence about the benefits associated with SFL and other evidence-based tobacco control policies, their implementation and enforcement in the majority of LMIC settings remain inadequate. Bump and Reich suggest that this is mainly due to a lack of LMIC specific research that looks into the political economy for tobacco control. According to the authors, politics, tobacco, wealth, economy, and power are highly interlinked and can act as hindrances to tobacco control (including the SFL) if not properly researched. Further, the authors suggest that providing traditional information, education, and communication to most stakeholders is not enough and requires proper analysis of the politics and economics of tobacco. The authors describe five relevant policy areas and suggest that a political economy analysis in these could open up opportunities for effective tobacco control. The five policy areas are: 1) a lack of information among the general public and relevant policymakers about the harms of tobacco use, which is further clouded by misinformation campaigns and interference by transnational tobacco companies 2) multi-national and national tobacco trade and

related disputes 3) smuggling of tobacco products 4) industry interference to raising taxes and SFL and 5) conflicting priorities of various ministries or departments within the Government.³⁸ An editorial by leading tobacco control advocates has described how the tobacco industry tries to interfere with tobacco control measures by engaging in consultations or agreements with Governmental agencies or policymakers (for example in Pakistan, India, and Laos).¹²³ Such involvement of the tobacco industry in public health matters derails and definitely delays the implementation and enforcement of strong tobacco control measures including comprehensive SFL.¹²³ In addition to tobacco industry interference,¹²⁴ specific challenges to the implementation and enforcement of SFL in LMICs are: the lack of required enforcement capacity and resources, and gaps in knowledge about the harmfulness of tobacco use and SHS exposure.³⁹ Lax enforcement of the smoke-free laws, a lack of political will and a tedious policy formulation process are the other barriers.⁴⁰

2.1.6.2. Tobacco industry generated myths

After the evidence about harms of tobacco smoke became well-established and people started supporting the SFL, the tobacco industry recruited 'ventilation experts' to propagate the myth that ventilation could be a better alternative to 100% smoke-free air. However, scientific studies have revealed that this is a myth and that ventilation systems are neither feasible nor effective in protecting non-smokers from exposure to SHS.²¹ Only comprehensive SFL can protect non-smokers from such exposure. Despite the existing evidence of the ineffectiveness of ventilation systems, several public places in HICs as well as in LMICs continue to have such ventilation systems to remove the tobacco smoke from enclosed rooms. Another well-known myth that was propagated by the tobacco industry was that SFL would lead to substantial economic losses to the concerned businesses e.g. the hospitality industry, including restaurants and bars, which was also supported by some industry-sponsored research. A systematic review was conducted by Scollo et al. to study the economic impact of SFL on the hospitality industry.31 The authors observed that 94% of the studies which reported a negative impact of SFL were industry sponsored. Such studies were several times more likely to report a subjective outcome and were several times less likely to be peer-reviewed (compared with the non-industry sponsored research). The best quality studies demonstrated either a neutral or a positive effect of the SFL on restaurant and bar sales or employment.³¹ Such myths are often used (successfully in several LMICs) to delay and dilute strong SFL, often leading to exemptions (for public places such as bars,

restaurants, hotels), resulting in the implementation of partial SFL which has been shown to be ineffective.^{21, 23}

2.1.6.3. Knowledge gaps around harms of secondhand smoke among the general public

A report combining findings from the International Tobacco Control Policy Evaluation (ITC) Project and the Global Tobacco Surveillance System (GTSS) showed that knowledge of harms associated with exposure to SHS is low in HICs as well as in LMICs. 39 The ITC study follows cohorts of smokers, ex-smokers and non-smokers in around 20 countries (both HICs and LMICs) through surveys while the GTSS surveys adults, youth, health personnel and school personnel through separate surveys in multiple LMICs. Further details about GTSS are described in chapter 4. The ITC report showed that over 50% of the smokers in Viet Nam and China are unaware of the fact that exposure to SHS leads to heart disease. 39 Further, even in HICs such as Australia, Canada, UK and the US, almost 50% of the smokers are unaware of the fact that their smoking can lead to heart disease among non-smokers exposed to SHS around them. 39 Such lack of knowledge in the general public could lead to a lack of support for SFL as they are not likely to be aware of the benefits associated with comprehensive SFL.

Some of the lack of knowledge among the politicians might be genuine whereas part of it may be construed as a result of interactions with the tobacco industry. For example, when large pictorial health warnings were proposed by the Government of India, consultation of a Parliamentary committee with the tobacco industry before implementation of large warnings led the Chair of the committee to comment that there was no Indian evidence that tobacco use was associated with cancer and that the current laws were based on studies conducted in other countries. This was despite the fact that there have been numerous case-control and cohort studies conducted in India which have conclusively documented that tobacco causes different types of cancers. It is also a widely known and a scientifically proven fact.

2.1.6.4. Newer and alternative types of tobacco products and smoke-free legislation

Globally, electronic cigarettes (e-cigarettes) are the most popular form of electronic nicotine delivery systems (ENDS) that do not burn tobacco but use a vaporised mixture

containing nicotine that is inhaled by the user. The e-cigarette liquid (that is vaporized by inhalation) comprises of nicotine, propylene glycol, with or without glycerol and flavouring agents. 125 The tobacco industry claims that it can be used safely in enclosed spaces without exposing the non-smokers to SHS; alternatively, it can also be used as a cessation product by delivering nicotine to the smoker without actual tobacco smoking. A recent review which studied the effects of e-cigarettes, its constituents and its policy implications suggests that e-cigarettes contain substances such as carbonyl compounds in concentrations which can be cardiotoxic. 126 Further, nicotine itself can cause hemodynamic and metabolic changes that can increase the risk of cardiovascular events. 126 The review concluded that e-cigarettes are not safe to be used as cessation products or as harm reduction alternatives. 126 Despite the existing evidence and the WHO recommendations to regulate the sale of e-cigarettes, these products are rapidly becoming popular. Twenty-three countries have completely banned the sale of ecigarettes including Brazil, Uruguay, Thailand, Seychelles, Singapore and the majority of countries of the Middle-East. 127 As of February 2016, 71 countries across the globe regulate e-cigarettes in one or the other way. 128 Only three countries have completely banned the use of e-cigarettes in public places (Cambodia, Jordan, and the United Arab Emirates).¹²⁷ There is, however, no global consensus yet on whether these products should be covered under the SFL.

There have also been concerns about violations of the SFL in Hookah/Shisha bars. Hookah or Shisha use typically entails passing tobacco smoke through water before it is inhaled. Flavoured varieties with or without added tobacco are also available in the market. It is believed to be a safer variety of smoked tobacco as smoke first passes through water before being inhaled; however, the smoke contains the same harmful chemicals and is not a safer product. Hookah/Shisha bars are known to flout the SFL and their employees have been known to be exposed to high SHS concentrations. Being a product of the Middle-East, which has also become popular in the developed settings, violations of the SFL by Hookah bars have been reported from both HICs as well as LMICs. Hookah/Shisha bars need to be subject to the same SFL as other indoor workplaces/public places in countries which have implemented the smoke-free laws.

2.1.6.5. Lack of data and research from LMICs

Monitoring of tobacco use and prevention policies (including the SFL) is recommended by the WHO for effective tobacco control.²³ Article 20 of the WHO FCTC requires Parties to establish tobacco surveillance systems in respective jurisdictions to monitor tobacco use and SHS exposure, its patterns, determinants, and the associated health and economic consequences. 16 GATS and Global Youth Tobacco Survey (GYTS) are the examples of national surveillance systems to regularly monitor tobacco use using validated scientific methods. 133 Other independent research studies can complement such data collection efforts. However, a majority of the countries of the world still have no data or partial and infrequent data while only 65 countries (28 of these, LMICs) of the world covering 30% of the world's population have recent, periodic and representative data available.²³ Monitoring systems are still weak in many LMICs while tobacco use in these countries is rising.¹³⁴ Out of the 77 studies included in the recent review by Frazer et al., which studied the impact of SFL on smoking, exposure to SHS and health outcomes, only two studies (2.6% of total studies) were from LMICs (Panama and Turkey).²⁷ The resulting lack of research evidence on the prevalence and other aspects related to SHS exposure including the effectiveness of SFL in LMICs acts as a barrier to more widespread adoption of SFL in these settings.

2.1.7. Facilitators to implementation of smoke-free legislation

2.1.7.1. Health and economic benefits of smoke-free legislation

Even though there are numerous barriers to implementation and evaluation of SFL in LMICs, several facilitating factors also exist which can ensure that comprehensive SFL is implemented in these settings. As outlined in the earlier sections, there are spectacular health benefits associated with implementing the SFL among children (reduced pre-term deliveries, emergency hospitalisations for asthma) as well as among adults (mortality and hospitalisations due to cardiovascular and respiratory diseases). Kalkhoran and Glantz estimate that even a 10% reduction in the emergency department visits due to asthma and hospital admissions due to the implementation of SFL and other tobacco control laws could generate savings of US\$ 7 billion annually for the US and Europe collectively. Generally, it is assumed that the return on investing in tobacco control initiatives such as the SFL would give delayed returns in the form of improved health and economic gains, making the politicians hesitant to implement such policies. Contrary to this belief, there is evidence that the returns are incredibly fast. Kalkhoran and Glantz exemplify this through California's tobacco control programme

which provided a 100 fold economic gain on the investment between 1989 and 2008 (investment-US\$ 2.4 billion; gain-US\$ 243 billion).⁴¹ The health and economic gains due to the implementation of SFL and other tobacco control policies, therefore, provide a strong justification in their favour for the LMIC settings.

2.1.7.2. Tobacco control advocates and organisations

Several LMICs have a strong presence of one or more civil society groups/organisations actively working in the field of tobacco control or even national tobacco control bodies (as a part of the public sector). For example, in India, there is a National Tobacco Control Cell (NTCC) which is involved in policy planning, mass media campaigns, product regulation, monitoring, and surveillance as well as capacity building for tobacco control initiatives. 135 Apart from this Government agency, there is a coalition called the Advocacy Forum for Tobacco Control (AFTC), which is a collective of health professionals, public health experts, researchers, as well as various Indian nongovernmental organisations (NGOs). 136 AFTC is active in the field of tobacco-related advocacy, research, capacity building and awareness generation. In Brazil, there is the National Commission for implementation of FCTC (CONICQ) as well as the National Agency for Sanitary Surveillance (ANVISA) (product regulation) which are entrusted with responsibility for effective tobacco control.²² In the US and South America, the American Non-smoker's Rights Foundation is actively working to protect the non-smokers from tobacco smoke at various levels of Government and through various action-oriented initiatives/programmes. 137 Apart from such groups/organisations, agencies such as the WHO and various UN bodies have a presence in several LMICs in the form of regional offices. They also work in close collaboration with the Health Ministries or the Health Departments of several countries which can leverage their technical expertise in relation to tobacco control, including implementation and evaluation of the SFL. Such groups and organisations actively working in the field of tobacco control in the LMIC settings represent a huge opportunity for implementation of comprehensive SFL and other tobacco control policies.

2.1.7.3. Pre-existing tobacco control policies and programmes

Several LMICs have pre-existing tobacco control policies, including the SFL. The WHO notes that in the majority of LMIC settings, SFL is not comprehensive as several exemptions (at public places such as bars, restaurants, hotels, airports, etc.) exist to 100% smoke-free policies.²³ However, based on the available research evidence, these

countries can easily strengthen their SFL by adding one or more exempted public places to their list of smoke-free public places and thereby move progressively towards implementing comprehensive SFL. For example, the Government of India is planning to remove exemptions which currently allow DSRs at hotels with more than 30 rooms and restaurants with more than 30 seats. Once this has been done, India will only be one step away from comprehensive SFL, as DSRs will still be permitted at the airports. Apart from this, some LMICs such as Brazil and India have existing national-level tobacco control programs which have already incorporated all or several of the WHO FCTC provisions including Article 8 (protection from exposure to tobacco smoke). Dedicated resources have been earmarked for implementation of activities under these national tobacco control programmes. Such pre-existing laws and programmes represent an opportunity to strengthen the existing tobacco control legislation/activities in the LMIC settings.

2.1.7.4. Increasing public support for smoke-free legislation and tobacco control

A few decades ago, tobacco control was not even the topic of debate in LMICs. This scenario in LMICs has changed over the years and people are now increasingly talking about tobacco-related issues and policies. Results from a longitudinal study (ITC Project) conducted with adult smokers from seven cities in China show that between 2007 and 2012, the support for complete smoking ban in indoor workplaces, restaurants as well as bars has grown steadily in all the seven cities. 139 The authors observed that the support for strong SFL was higher than that observed before the implementation of comprehensive SFL in Ireland, implying that China is now ready for implementation of comprehensive SFL. 139 Another study conducted with participants aged 14 years and above in Ashanti region of Ghana (in 2011) showed that awareness of the health risks of tobacco smoke exposure and support for comprehensive SFL (97%) was very high among the participants. 140 Similarly, strong support for comprehensive SFL after its implementation has been observed among the countries of Latin America such as Uruguay, Brazil, and Mexico.¹⁴¹ Such increasing support for SFL in LMICs represents increasing acceptance of SFL by the public and therefore, an opportunity to implement comprehensive SFL or to strengthen existing SFL.

2.2. Rationale and justification for this thesis

Although globally there has been a decline in the age-standardized death rates and disability rates associated with smoking and SHS exposure from 1990 to 2015 as shown by the recent GBD study, LMICs (majority of them still in stage II and III of the tobacco epidemic) are still expected to be affected by major health and economic adverse consequences attributable to tobacco smoking in the future, as 80% of the world's smokers reside in these settings. The healthcare costs of treating tobacco-related diseases and the resulting indirect costs are extremely high and several times higher than the revenues generated through the tobacco business. Such huge economic losses are unaffordable for any country, particularly the resource poor LMICs. Therefore, there is an immediate need for these countries to take appropriate tobacco control measures (consistent with the WHO FCTC) including protection of the people from exposure to tobacco smoke through the adoption of comprehensive SFL. 16

Despite the growing evidence about the adverse consequences of smoking and SHS exposure, as well as effectiveness of the SFL (in reducing smoking, SHS exposure, morbidity and mortality associated with exposure to tobacco smoke, a positive effect on the hospitality business and related employment as well as on social norms and attitudes),^{21,27} implementation and enforcement of SFL (along with other tobacco control measures) remains weak in several LMIC settings compared with the HIC settings.²³ Among several barriers to implementation of SFL in the LMIC settings, a key factor is inadequate monitoring mechanisms resulting in the lack of data, research, and evaluation. Therefore, there is a lack of evidence to ascertain whether the same health and economic benefits of SFL accrue in the context of LMICs as observed in HICs. For example, socioeconomic inequalities are clearly evident in HICs where smoking and exposure to SHS is higher among the poorer or low SES groups compared with the rich, indicating the need for targeted tobacco control strategies including comprehensive SFL.^{6, 7} There is limited evidence from LMICs on socioeconomic inequalities in exposure to SHS. Further, there is yet insufficient and unclear evidence on the impact of SFL on socioeconomic inequalities in health outcomes. As tobacco smoking and SHS exposure can increase health inequalities, it is important to evaluate if SFL only benefits the rich or is pro-equity for key health outcomes. If the reduction in morbidity and mortality associated with exposure to tobacco smoke is higher among the low SES groups (vs. the high SES groups) after implementation of SFL, such legislation may be shown to be effective in reducing health inequalities. Research, mostly from HICs shows that the SFL is effective in positively altering social norms towards exposing non-smokers to tobacco

smoke, therefore resulting in voluntary measures such as smoke-free homes and private vehicles. ²¹ This could lead to additional health benefits among the vulnerable women and children and the non-smokers through protection from SHS exposure. However, there is scant evidence from LMICs in this regard. Some LMICs such as India have implemented their tobacco control programmes (with SFL implementation and enforcement as a key activity), however, evaluation of the impact of the programme on smoking (and therefore exposure to SHS) has not been undertaken and relevant implications for the LMIC settings remain unknown.

The lack of research evidence and the resulting weak implementation and enforcement of SFL and other tobacco control policies in general, in the LMIC settings, threaten the achievement of 25x25 target for reducing premature NCD related mortality, ^{19, 142} and the UN SDG Goals which call for ensuring healthy lives and promoting well-being for all at all ages as well as reducing inequalities within and among countries. ^{20, 143} This study will contribute to the evidence base on what works to strengthen the SFL and tobacco control in general, in LMICs and what are the associated impacts of SFL on health equity.

Chapter 3: Impact of smoke-free legislation on socioeconomic inequalities in health outcomes associated with exposure to tobacco smoke among adults

In section 2.1.5.5, the health benefits associated with SFL were described. SFL is associated with significant reductions in hospitalizations and mortality due to smokingrelated health conditions particularly, the CVDs and respiratory diseases,^{27, 28} and the benefits are significantly higher with comprehensive SFL compared with partial SFL.²⁷ As smoking and SHS exposure (in HICs) are known to be higher among the low SES groups or the poor, it is likely that the adverse health effects of exposure to tobacco smoke are also socially patterned and are higher among the disadvantaged, therefore exacerbating health inequalities. According to the UN SDG 10, policies and programmes should aim at reducing inequalities. 143 Although the health benefits of SFL have been extensively studied (mainly in HICs), the equity impact of SFL on health outcomes is not yet reported. A systematic review was conducted to examine this aspect as a part of this thesis. In this chapter, the systematic review has been described in the form of a research paper, which addresses Aim 1 (to study the impact of SFL on socioeconomic inequalities in health outcomes related to exposure to tobacco smoke) and Aim 5 (to generate research evidence to strengthen implementation and enforcement of strong tobacco control policies including comprehensive SFL in the LMIC settings) and the corresponding objectives 1, 4 and 5 of this thesis.

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Student	Gaurang Prafulla Nazar
Principal Supervisor	Professor Neil Pearce
Thesis Title	Smoke-free legislation and active smoking, second hand smoke exposure and health outcomes in low- and middle-income countries.

If the Research Paper has previously been published please complete Section B, if not please move to Section C

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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)

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Date: 10/DEC/2016

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Section D - Student's role in multi-authored work

This research paper is authored by Dr. Marhazlinda Jamaludin, Dr. Gaurang P. Nazar, Dr. Georgios Tsakos, Prof. Richard G. Watt and Prof. Christopher Millett in this order. I am the second author while Dr. Marhazlinda is the first and the corresponding author for this manuscript. Two Ph.D. students (myself from LSHTM and Dr. Marhazlinda from University College London [UCL]) have contributed collectively and equally for this work. Prof. Christopher Millett from Imperial College London is co-supervising me as well as Dr. Marhazlinda; while Prof. Richard Watt and Dr. Georgios Tsakos are supervising Dr. Marhazlinda at UCL.

- The work was jointly conceptualised by myself and Dr. Marhazlinda under the guidance of Prof. Millett (and other supervisors), wherein it was pre-decided and agreed upon to undertake this work jointly and with equal contributions from both the students. The authorship order was also agreed upon a priori.
- A draft of the systematic review protocol was developed by Dr. Marhazlinda and first shared with me wherein I contributed to editing and revising the protocol, and then after an agreement between the two students, the protocol was shared with the supervisors. Based on inputs from the supervisors, the protocol was further revised, submitted and subsequently published in the PROSPERO International prospective register of systematic reviews, University of York, Centre for Reviews and Dissemination (PROSPERO 2016: CRD42016035744). The protocol is available online from:

http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD4201603574

- A search strategy was developed by the two students jointly for Medline first and agreed upon with guidance from the supervisors.
- Dr. Marhazlinda conducted the database searches. Relevant literature (by title)
 was shared with me from all the relevant databases and other sources including
 a number of previously published systematic reviews and meta-analyses on a
 closely related topic. The two students separately reviewed the titles and the
 abstracts of relevant literature and also the reference lists of previous systematic
 reviews and meta-analyses.
- The two students separately applied the inclusion/exclusion criteria and then came up with a final number of research papers to be included in the study. Any

- disagreements were resolved through discussion and with the guidance of a third reviewer, Prof. Millett.
- Using appropriate and valid data extraction and quality (risk of bias) assessment forms, the two students separately undertook data extraction and quality assessment initially. Thereafter, we mutually discussed and agreed upon final tables to be included in the study in consultation with the supervisors. Any disagreements/queries were resolved in consultation with the third reviewer.
- Due to heterogeneous nature of studies in terms of geographic locations, SFL across countries, health outcomes studied and measures of socioeconomic status included in the studies, it was decided as per the guidance of supervisors to present a narrative synthesis with a graphical representation (Harvest Plot) instead of a meta-analysis.
- The background, results and discussion section including data synthesis
 presented in this research paper were drafted by me in consultation with Dr.
 Marhazlinda and Prof. Millett. The methods section was initially drafted by Dr.
 Marhazlinda and then revised by me in consultation with Prof. Millett.
- Work on finalising the research paper for submission to journal is in progress and will be completed in the due course.
- It has been agreed upon between all the authors and the supervisors that the
 draft of this work will be included in the theses of both Ph.D. students (in
 research paper form for my thesis and in the usual book style format for Dr.
 Marhazlinda).

3.1. Smoke-free legislation and socioeconomic inequalities in smoking-related morbidity and mortality among adults: a systematic review*

3.1.1. Abstract

3.1.1.1. Objective

To investigate the impact of SFL on socioeconomic inequalities in smoking-related: a) disease-specific morbidity and mortality and b) all-cause mortality.

3.1.1.2. Data sources

We searched Medline, Embase, Web of Science, Scopus, CINAHL Plus, DARE, Global Health (CAB), Cochrane Central Register of Controlled Trials (CENTRAL), IndMed, SciELO, IMEMR, IMSEAR, AMED, LILACS, AIM and KoreaMed from inception to September 2016 using detailed search strategies. Reference lists of known credible reports, reviews, meta-analyses, and websites closely related to the topic were also screened.

3.1.1.3. Study selection

All experimental, quasi-experimental or observational studies in English language which investigated the impact of SFL (national/state/regional/local or city level; comprehensive/partial; with or without a comparison group) in public places on socioeconomic inequalities in morbidity and mortality associated with cardiac, cerebrovascular, respiratory and other smoking-related diseases among adults ≥18 years were eligible for inclusion. Cross-sectional, modelling/simulation, cost, and qualitative studies were excluded.

3.1.1.4. Data extraction methods

Relevant data extraction and quality assessment for risk of bias (using the Cochrane EPOC criteria for interrupted time series [ITS] studies and EPHPP criteria for observational studies) was undertaken using validated tools by two researchers

*Jamaludin M, <u>Nazar GP</u>, Tsakos G, Watt RG, Millett C. Smoke-free legislation and socioeconomic inequalities in smoking related morbidity and mortality among adults: a systematic review. *To be submitted in PLoS Medicine.*

separately and any disagreements were resolved by consultation with a third reviewer.

3.1.1.5. Data synthesis

A combination of graphical and narrative methods was used, including a novel matrix or 'Harvest Plot' to test competing hypotheses. The null hypothesis was no SES differences (neutral effect) in the effect of SFL; alternative hypotheses were: 1) positive effect: greater health benefits among the low SES groups 2) negative effect: greater health benefits among the high SES groups 3) mixed effect. A total of eight studies were included, all from the high income countries (HICs) (six ITS studies and two before-after studies). Five studies reported the impact of national comprehensive SFL; three studies reported the impact of partial SFL. Implementation of comprehensive SFL led to either a positive effect (3 studies) or no effect (2 studies); partial SFL led to either no effect (2 studies) or an unclear effect (1 study). The majority of studies had a suitable study design and were high-quality studies (except two before-after studies). The choice of SES indicator appeared to be important in influencing outcomes.

3.1.1.6. Conclusions

Comprehensive SFL has the potential to reduce socioeconomic inequalities in health outcomes resulting from exposure to tobacco smoke; partial SFL may not. Research from LMICs is lacking. Countries must strengthen their tobacco control policies and move towards comprehensive SFL to achieve the UN SDG goals of reducing inequalities and premature mortality from NCDs by 2030.

3.1.2. Introduction

3.1.2.1. Global burden of secondhand smoke exposure and related harms

Apart from the adverse health consequences of smoking, exposure to secondhand smoke (SHS) is also causally associated with coronary heart disease, lung cancer, nasal irritation, stroke and adverse reproductive outcomes (e.g. low birth weight) among adults; and middle ear disease, respiratory illnesses and sudden infant death syndrome among children.⁸ As per the Global Burden of Disease (GBD) 2015 study, in the year 2015, about 0.9 million deaths globally were attributable to SHS exposure, in addition to the 6.4 million deaths due to tobacco smoking.¹ Deaths due to SHS exposure accounted for 1.6% of the global deaths and 1% of disability-adjusted life years (DALYs) lost.¹ Most

of the deaths and disabilities due to SHS exposure are observed among the women and children.^{1,56} In 2015, tobacco smoking and SHS exposure collectively, was the third leading risk factor for global burden of disease, responsible for 6.9% of DALYs lost.¹

3.1.2.2. Socioeconomic differentials in SHS exposure and resulting health inequalities

Exposure to SHS has been shown to be highest among the children, and the non-smoking men and women from low- and middle-income countries (LMICs) in European and Western Pacific Region (between 50-60%), followed by high income countries (HICs) (30-40%) and LMICs of African, South East Asian, American and Eastern Mediterranean Regions (10-40%). In HICs as well as in the majority of LMICs, it has been observed that smoking and exposure to SHS are higher among those belonging to the low socioeconomic status (SES) e.g. the less educated and the poor. In Low SES groups, therefore, are also more likely to suffer from the adverse health and economic consequences of smoking and SHS exposure, thereby resulting in health inequalities.

3.1.2.3. Smoke-free legislation and review evidence of its effectiveness on health outcomes

Guidelines for Article 8 of the WHO Framework Convention on Tobacco Control (FCTC) recommend comprehensive smoke-free legislation (SFL) (100% smoke-free environments in all indoor workplaces and public places, public transport, and as appropriate, other public places), without any exceptions, for complete protection of the non-smokers from exposure to environmental tobacco smoke. Further, such policies should not be voluntary and should not allow the use of designated smoking rooms (DSRs) and mechanical ventilation to remove the tobacco smoke, as these have been shown to be ineffective. By 2014, only 18% of the world's population was covered by comprehensive SFL as per WHO MPOWER report. Most of the countries of the world still have partial or no SFL.

Initial research studying the impact of SFL on health outcomes started from year 2004 onwards, which focused on reduction in hospital admissions for acute myocardial infarction (AMI) after implementation of SFL.¹¹¹⁻¹¹³ Dinno and Glantz compiled evidence from these early studies (from the US and Italy) in a meta-analysis and concluded that

SFL led to a 27% reduction (RR 0.73 95% CI 0.56-0.89) in hospital admissions due to heart disease (including ischemic heart disease [IHD] and heart failure)¹¹⁴.¹¹⁵ Subsequently, three meta-analyses conducted in 2008 (19% reduction),¹¹⁶ 2009 (17% reduction),¹¹⁷ and 2013 (23% reduction)¹¹⁸ reported significant but attenuated reductions in the risk of AMI following SFL implementation. Two other meta-analyses reported a 10% and 12% reduction in the risk of acute coronary events (this included in addition to AMI, acute coronary syndrome (ACS), coronary heart disease including angina and heart failure, and IHD) following the introduction of comprehensive SFL¹¹⁹ and SFL,¹²⁰ respectively. Jones et al. further observed that the reduction was much higher in locations with comprehensive SFL (14% reduction) compared with locations which had partial SFL (8% reduction).¹²⁰ However, the differential effects of SFL by SES were not assessed.

Preliminary review evidence on the differential effects of SFL by SES indicated that the benefits of SFL were higher among the affluent population as they were more likely to visit restaurants and pubs than those from the disadvantaged groups; this may have continued to widen existing inequalities. ¹⁴⁸ Evidence, however, was limited as some of the studies yielded contradictory findings, thus, the conclusions were inconsistent. ^{149, 150} Other reviews had attempted to stratify, but none reported any differential effects of tobacco control interventions by SES. ^{96, 151-153} Thomas et al. found no strong evidence to associate the effects of SFL with income and educational levels. ¹⁵⁴ A review by Hill et al. reported mixed effects of SFL on socioeconomic inequalities in exposure to tobacco smoke. ¹⁵⁵ Findings of Brown et al. indicated increased socioeconomic inequality in smoking among youth as 19 out of 25 studies reviewed showed negative equity impact of partial, regional or voluntary SFL where affluent populations were more responsive to interventions. ¹⁵⁶

Despite studying the differential effects of SFL on health outcomes such as AMI, and acute coronary events, reviews conducted by Callinan et al.²⁸ and Lin et al.¹¹⁸ did not report the differential effects by SES. The most recent systematic review, Frazer et al. was an update of a 2010 review by Callinan et al.,²⁸ and reported the impact of SFL on multiple health outcomes e.g. cardiovascular, respiratory and perinatal.²⁷ They observed a consistently positive impact of national SFL on reducing adverse cardiovascular outcomes (ACS/AMI/stroke), asthma, lung function, and mortality associated with smoking-related illnesses.²⁷ The effects of SFL on chronic obstructive pulmonary

disease (COPD) and perinatal health (low birth weight/small for gestational age babies/pre-term deliveries) were inconsistent; while they reported significant health benefits among the countries with comprehensive SFL compared to countries with partial SFL.²⁷ Frazer et al. also report the relevant impact of SFL on health outcomes among sub-groups.²⁷ Apart from the age- and gender-specific results, they did report impact on some health outcomes by socioeconomic indicators (five papers that have also been included in our present study).²⁷ Despite presenting a fairly extensive evaluation of the SFL, they do not include a detailed analysis and in-depth discussion on impact of SFL on socioeconomic inequalities in health outcomes and it was not an objective of their study.

As smoking and SHS exposure are higher in low SES groups, it is highly plausible that they would benefit more from SFL and therefore, the health inequalities will reduce. On the other hand, some argue that people belonging to high SES groups: may be smoking at a higher frequency vs. those from the low SES groups, 157, 158 are more likely to frequent hospitality venues such as restaurants, bars, hotels etc. where such laws are newly implemented, 159 are more likely to make successful quit attempts with professional help following SFL implementation, 159 and are more likely to visit/work at places with comprehensive (rather than partial) SFL (vs. the low SES groups who are more likely to work at places covered by partial/no SFL). 6, 21 Therefore, it is plausible that SFL or comprehensive SFL unduly benefits the rich, thereby increasing health inequalities. On the basis of mixed results of earlier reviews, although smoking restrictions have been shown to be effective, the potential of these interventions to reduce smoking-related health inequalities is still inconclusive. The introduction of SFL in many countries now provides opportunities to strengthen the evidence. The resulting evidence would be important to address the debate whether SFL/comprehensive SFL increase or decrease health inequalities.

SFL is expected to have an impact through two causal pathways: 1) reductions in active smoking 2) reductions in SHS exposure among non-smokers. These may influence health outcomes differently in different social strata. Previous systematic reviews have combined findings on smoking behaviour and health outcomes and concluded that the weight of evidence suggests neutral equity impacts or lower benefits in poor groups. He But this may be because studies which focus on smoking behaviours only capture one part of the causal pathway which is pro-rich. An updated review of all the papers

which focus on health outcomes is therefore warranted as the number of studies has increased since these reviews have been published.

Our aim was to conduct a systematic review to investigate the impact of SFL on socio-economic differences in: a) smoking related disease-specific morbidity and mortality and b) all-cause mortality. Our specific objectives were to systematically evaluate the impact of SFL in public places on socioeconomic differences in a) smoking related disease-specific morbidity among adults; i) acute coronary events (AMI) and other cardiac diseases (ACS and coronary heart diseases) ii) cerebrovascular accident (stroke) and other cerebrovascular diseases (transient ischaemic attack (TIA)) iii) respiratory symptoms and other respiratory diseases (asthma and COPD) iv) lung cancer; b) cause-specific and all-cause mortality among adults.

3.1.3. Methods

A review protocol specifying the objectives, search strategy, inclusion/exclusion criteria, outcomes, data extraction and synthesis methods has been documented and registered with the International Prospective Register of Systematic Reviews (PROSPERO), Centre for Reviews and Dissemination, University of York (Registration no: CRD42016035744). The protocol is attached in Appendix B-1 and available online at: http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016035744

3.1.3.1. Eligibility criteria

Inclusion criteria

Primary studies which investigated the impact of SFL in public places on socioeconomic inequalities in morbidity and mortality associated with cardiac, cerebrovascular, respiratory and other smoking-related diseases among adults aged 18 years and above were eligible for inclusion. SFL referred to any comprehensive or partial ban on smoking in public places including bars or restaurants and workplaces, at community, regional, city, state or national level. A comprehensive ban referred to 100% smoke-free indoor public places and workplaces while a partial ban was when there existed exemptions to SFL e.g. smoking allowed in designated areas or in specific indoor public places such as casinos, bars, and the like. ¹⁶² Following the Cochrane Effective Practice and Organisation of Care (EPOC) guidelines, ¹⁶³ randomised controlled trials (RCTs;

including cluster RCTs), controlled clinical trials (CCTs; including cluster CCTs), quasiexperimental studies including interrupted time-series (ITS) and controlled before-after studies were the study types considered eligible for inclusion. As per the results of our scoping search, we anticipated a small number of these study types to fulfil the EPOC criteria, therefore, we decided to expand the eligibility criteria to include the following types of studies in addition: uncontrolled before-after studies, prospective and retrospective cohort, case-control, and nested case-control studies. We considered income/wealth, education, occupation, race and geographic location/area as indicators of SES. Some studies reported the use of a complex composite score for SES. Primary outcomes were socioeconomic differences in disease-specific mortality i.e., sudden cardiac death and death from; i) AMI, ii) stroke, iii) asthma and COPD, iv) lung cancer and all-cause mortality among adults. Secondary outcomes were socioeconomic differences in: i) hospital admission due to AMI, ii) hospital admission due to stroke, iii) hospital admission due to other smoking-related cardiac diseases (ACS and coronary heart diseases), iv) hospital admission due to other smoking-related cerebrovascular diseases such as TIA, v) emergency department visits due to respiratory illness (respiratory symptoms, asthma and COPD) and finally hospital admission due to lung cancer.

Exclusion criteria

Cross-sectional studies, modelling/simulation studies, cost and qualitative studies were excluded. Studies focusing on intermediate outcomes such as smoking behaviours, SHS exposure and other outcome indicators such as quitting/quit attempts, knowledge, attitudes, and air quality were also excluded.

3.1.3.2. Data sources and search strategy

Relevant Medical Subject Headings (MeSH) phrases and free text were used as keywords to retrieve eligible published studies from databases: MEDLINE, EMBASE, ISI Web of Science, SCOPUS, CINAHL Plus, Global Health (CAB), Cochrane Central Register of Controlled Trials (CENTRAL), IndMed, SciELO, IMEMR, IMSEAR, KoreaMed, AMED, LILACS and AIM from inception to September 2016. Initial searches for each database were updated to include literature up to September 2016. The search strategy used for MEDLINE and EMBASE is provided in Appendix B-2. The strategy was adapted for other databases. Only the studies published in the English language were included and the references of the retrieved relevant articles, conference abstracts

and proceedings, and citations of articles of interest were also screened for additional studies. We also screened the reference lists of known credible reports on this topic such as the WHO MPOWER Reports (2009, 2015),^{23, 162} IARC Monograph Vol 13,²¹ the US Surgeon General's report (2006),⁶ the Institute of Medicine (IOM) report (2010),¹⁶⁴ and the references cited on the CDC website.¹⁶⁵ Some details on the presence of comprehensive or partial SFL in the selected studies were obtained from other credible sources e.g. 2015 WHO MPOWER Report²³ and www.tobaccocontrollaws.org website of Campaign for Tobacco Free Kids (CTFK).¹⁶⁶ Review articles were not included but their reference lists were used as key sources for study identification.

3.1.3.3. Study selection

Out of the studies retrieved, duplicates were first removed, and eligibility criteria were then applied to the titles and abstracts. Two reviewers (MJ and GPN) independently screened the titles and the abstracts for potentially eligible studies and assessed the full text of remaining potentially relevant studies to confirm inclusion. The study selection process is described in the form of a PRISMA flow diagram in Figure 3.1. EndNote Referencing Software (Clarivate Analytics, Philadelphia, v.X7) was used to manage all the citations. In the case of duplication, only the largest study was retained to avoid duplication of information. In the event of a disagreement, a third reviewer was consulted (CM).

3.1.3.4. Data extraction and quality assessment

Relevant data were extracted using a standardised and customised form which included authors' names and the year of publication, study design, place where the study was undertaken, SES indicators used, type of intervention, health outcomes assessed, findings and impact on health inequalities (Table 3.1). Standard guidelines appropriate for community studies and clinical trials included in Cochrane Collaboration tool were adapted for assessing the suitability of the study design. The quality of included ITS studies was assessed using the seven risk of bias assessment criteria outlined in the Cochrane Handbook and available on the EPOC website (Table 3.2).

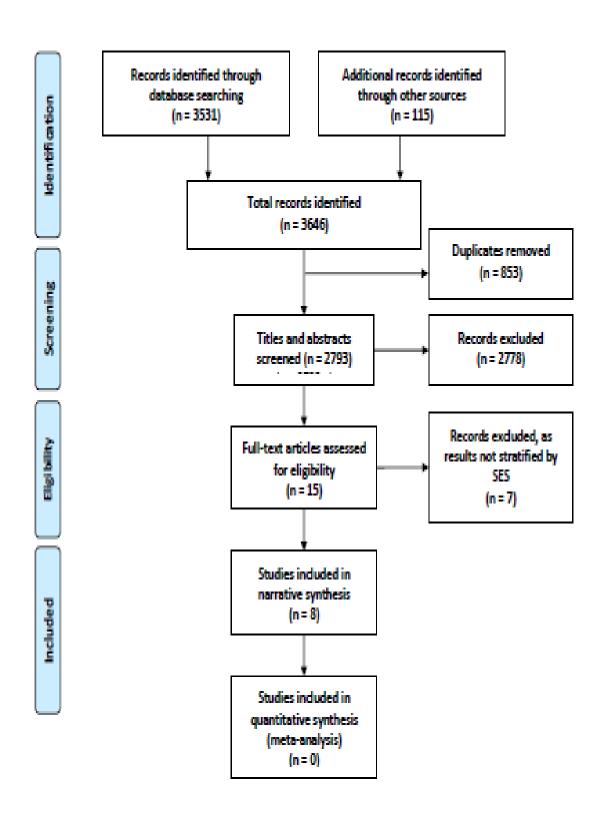


Figure 3.1: PRISMA flow diagram - study selection process

The seven quality criteria included: 1) intervention independent of other changes, 2) shape of the intervention effect pre-specified, 3) intervention unlikely to affect data collection, 4) knowledge of allocated intervention adequately prevented, 5) incomplete outcomes data adequately addressed, 6) study free from selective outcomes reporting, and 7) study free from other risks of bias. The EPOC suggested risk of bias criteria for ITS studies are attached in Appendix B-3. Accordingly, each criterion was scored as 'low risk', 'high risk' or 'unclear risk'. The quality of before-after studies was assessed using the Effective Public Health Practice Project (EPHPP) quality assessment tool for quantitative studies (Table 3.3). 169 The six quality criteria included in the EPHPP tool were: 1) participant selection (representativeness), 2) blinding and randomization, 3) comparability of the groups at baseline, 4) reliability of data collection tools, 5) attrition rates, and 6) attributability to the intervention. The EPHPP tool and the study rating criteria are attached in Appendix B-4. The studies were classified according to their quality ratings into low, moderate or high-quality studies. As we used two different quality criteria (EPOC and EPHPP) described above, for uniformity in reporting, we report the number and percentage of quality criteria fulfilled by each study. Data extraction and quality assessment of the included studies were done independently by two reviewers (MJ and GPN) and any disagreement was resolved through discussion or by referral to a third reviewer (CM).

3.1.3.5. Data synthesis and reporting

Due to the heterogeneous SES indicators and multiple health outcomes reported by the studies included in this review, a meta-analysis was deemed to be unsuitable. Thus, a novel hypothesis-testing approach was used to examine the balance of evidence about the differential equity effects of intervention employed. Following this approach, data was synthesized using a combination of graphical and narrative methods, including a novel matrix or 'Harvest Plot' (Figure 3.2) devised by Ogilvie et al.¹⁷⁰ For each dimension of socioeconomic inequality (e.g. income/wealth, education, occupation, area deprivation, or a composite index), we populated the relevant row of this matrix by placing a bar representing each study in one of the four columns representing the following competing hypotheses:

- i) The null hypothesis was defined as no evidence of differential effects in the effectiveness of SFL for any given socioeconomic indicators.
- ii) The alternative hypotheses were:

- a) There was a positive effect of SFL on socioeconomic inequalities in smoking-related morbidity and mortality, which meant that the intervention was more effective in less advantaged groups (defined for this purpose as the less affluent, those with a lower level of education, those in less skilled occupational groups, those with lower incomes or most disadvantaged racial or ethnic group in the context of a particular study) or that these groups were more responsive to the SFL.
- b) There was a negative effect of SFL on socioeconomic inequalities in smokingrelated morbidity and mortality, meaning that the intervention was more effective in more advantaged groups (defined as the more affluent, those with a higher level of education, those in higher-skilled occupational group, those with higher incomes or more advantaged racial or ethnic group in the context of a particular study) or that these groups were more responsive to the SFL.
- c) There was a mixed effect of SFL on socioeconomic inequalities in smokingrelated morbidity and mortality, which meant that both, the positive effect and the negative effect were observed (for different types of outcomes) in the same study.
- d) There was an unclear effect of SFL on socioeconomic inequalities in smokingrelated morbidity and mortality, which meant that the results were ambiguous and a clear effect of SFL could not be ascertained.

A key to the interpretation of Harvest Plot matrix is shown in Box 3.1 and therefore, is placed before Figure 3.2. In the plot, each study has been represented by a bar in each row for which that study had reported relevant results. Suitability of the study design was indicated by the height of the bar, where the tallest bars represented the most suitable study designs and the lowest bars represented the least suitable study designs. Each bar was annotated with the number (and the percentage) of other methodological criteria (seven in the case of EPOC and six in the case of EPHPP) met by that study.

3.1.4. Results

Out of a total of 2793 unique research papers screened using titles and abstracts, 15 papers were potentially eligible for inclusion. After reviewing full texts of these eligible papers, eight papers were finally included in our study. The flowchart for study selection process is shown in Figure 3.1. The majority of literature during the search was included from electronic databases and from reference lists of existing reports and meta-analyses or systematic reviews.

Table 3.1 shows data from the included studies. Out of the eight studies included in this review, all were all from HICs. One study each from Italy, 149 the UK, 171 Ireland, 172 New Zealand, 173 Scotland, 150 and Norway 174 was included; while two of the studies included were from the US. 158, 159 Six of the included studies were ITS studies with no concurrent comparison groups;149, 150, 159, 171-173 while Eagan et al. 174 and Head et al. 158 were (single measurement) before-after studies without and with a concurrent comparison group respectively. The included studies reported socioeconomic inequalities in the impact of comprehensive 149, 150, 171-173 or partial 158, 159, 174 SFL implemented at national 149, 150, 171-174 or regional^{158, 159} level on either hospital admissions/discharges, 149, 150, 158, 159, 171, 173 or out-of-hospital/pre-hospital deaths, 149, 150, 172 owing to cardiovascular (acute coronary events, 149 AMI, 158, 171, 173 IHD, 172 stroke, 150, 158, 172 and TIA 158) or respiratory (COPD, 158, 172 and asthma^{158, 159}) causes using retrospective, secondary, mortality or hospital discharge data on adult participants. Eagan et al. reported the impact of SFL on socioeconomic inequalities in changes in respiratory symptoms;¹⁷⁴ while Liu et al. reported the impact of SFL on participants aged more than or equal to 16 years. 171 The indicators of SES in the included studies were area deprivation, 149, 150, 171, 173 education, ¹⁷⁴ race, ^{158, 159} and a composite SES indicator (inclusive of structural [education, occupation, family composition, and nationality] and material [Car access, unemployment, house tenure] indicators of SES). 172 Other indicators of SES such as occupation and income/wealth were not reported in any of the included studies.

3.1.4.1. Socioeconomic inequalities in the impact of comprehensive SFL on health outcomes

Five studies published between 2008 and 2014, one each from Italy, ¹⁴⁹ the UK, ¹⁷¹ Ireland, ¹⁷² New Zealand, ¹⁷³ and Scotland ¹⁵⁰ reported the impact of a national comprehensive SFL on health outcomes (Table 3.1). Three of these five studies reported an overall positive effect of comprehensive SFL on health outcomes. ^{149, 171, 173} Three of the five studies reported a positive effect of comprehensive SFL on socioeconomic inequalities in health outcomes i.e. the SFL was found to be more effective in the lower SES groups compared with the high SES groups. ^{149, 171, 172} Cesaroni et al. reported that one year after the nationwide comprehensive SFL implementation in Italy, reduction in the age-standardized acute coronary events (including out of hospital deaths and hospital admissions) among those in 35-64 years age group was significantly higher among the residents of most deprived areas

compared with residents of least deprived areas. 149 Liu et al., reported that three years after the nationwide comprehensive SFL implementation in the UK, reduction in the agestandardized hospital admissions for AMI in Liverpool was highest in the most deprived wards (census areas), followed by the middle ranked wards and the least deprived wards. They further reported a reduction in absolute as well as the relative risk of hospitalisation due to AMI among the most deprived groups compared with the least deprived groups.¹⁷¹ Stallings-Smith et al. reported that five years after the implementation of a nationwide comprehensive SFL in Ireland, the age- and genderstandardized mortality reductions for IHD, stroke, and COPD were concentrated in the most deprived tertiles by specific structural indicators of SES as well as the composite index.¹⁷² One of the five studies under the comprehensive national SFL category reported that one year after its implementation in New Zealand, despite a significant reduction in AMI hospital admissions (in Christchurch) in the 55-74 year age group among the less deprived (vs. the more deprived groups), such reduction was not consistently observed across all the age groups, suggesting a neutral or no effect on socioeconomic inequalities. 173 Last of the five studies under the comprehensive national SFL category reported that four years after its implementation in Scotland, there was a significant decline in pre-hospitalization deaths and hospital admissions due to cerebral infarction in the least deprived quintile, however, there was a reported significant increase in the immediate next deprivation quintile. No long term significant effect was observed in the other deprivation quintiles. 150 We, therefore, reached a consensus that the SFL had a neutral effect on inequalities in stroke deaths and hospitalisations in Scotland.

Table	3.1: Data extrac	tion form for t	he impact of smok	ce-free legisla	tion (SFL) on socioeconon	nic inequalities health outcomes among	adults
Author, Year of study	Study design	Country, High/Low income	SES indicator/s	Intervention (National or Regional)	Outcomes	Effects/Impacts on Overall outcome and SES inequalities	Summary (Positive, Negative, Neutral, Unclear, Mixed)
Comprehens	ive Smoke-free Le	gislation					
Cesaroni et al, 2008 ¹⁴⁹	Interrupted time series with no concurrent comparison group	Rome, Italy High Income	Area deprivation – Composite index derived from Census 2001 data distributed into quintiles	National	Age-standardized acute coronary events (out-of-hospital deaths and hospital admissions) in city residents 35 to 84 years of age comparing the data from pre- (2000 –2004) and post-	Overall, there was a significant decline in acute coronary events post-legislation among 35-64 year (RR 0.89; 95% CI 0.85-0.93) and 65-74 year (RR 0.92; 95% CI 0.88-0.97) old groups. SES inequalities: Significant decline in acute	Positive effect on inequalities
					legislation (2005)	coronary events among the 35-64 years (youngest group) belonging to low SES categories:	
						Quintile 3 – RR 0.88; 95% CI 0.79-0.98 Quintile 4 – RR 0.90; 95% CI 0.81-0.99 Quintile 5 (lowest SES) - RR 0.85; 95% CI 0.77-0.93	
						The protective effect of the law seemed to be stronger for residents living in low socioeconomic areas than for those living in high socioeconomic areas	
Liu et al, 2013 ¹⁷¹	Interrupted time series with no concurrent comparison group	Liverpool (City), UK High income	Area deprivation – Wards divided into 3 groups of 10 wards each	National	Trend gradient and change points (by trend regressions analysis) in age-standardised MI admissions in Liverpool between 2004 and 2012 in those ≥16 years of age; by sex and by socioeconomic status.	Overall, between '2005-2006' and '2010-2011', MI admissions reduced by 42%. SES inequalities: Between '2005-2006' and '2010-2011', MI admissions reduced by 45% for the 10 most deprived wards, 42.3% for the 10 middle-ranked wards, and 38.6% for the 10 most affluent wards	Positive effect on inequalities
						The average absolute risk difference between the most and the least deprived wards over the first 2 years was 69.8 MI admissions per 100 000 person-years. The rate for the final 2 years was 32 MI admissions per 100 000	

Stallings- Smith, 2014 ¹⁷²	Interrupted time series with no concurrent comparison group	Ireland High income	7 discrete indicators:- Structural: Education, occupation, family composition, nationality Material: Car access, unemployment, house tenure A composite index:- combination of structural and material indicators	National	Monthly age and gender- standardised mortality rates for IHD, stroke, and COPD for the period of 2000–2010 among those ≥35 years of age, stratified by tertiles of each SES indicator	person-years (A rate ratio of 0.46, 95% CI of 0.044 to 4.76). The average <i>rate ratio</i> between the most and the least deprived wards over the first 2 years was 1.38. The relative difference for the final 2 years was 1.26 (A ratio of 0.91, 95% CI of 0.43 to 1.91). SES inequalities: Post-ban mortality reductions by structural SES indicators were concentrated in the most deprived tertile for all causes of death. For IHD and COPD, least deaths were seen only in the most deprived tertile by education and in local authority areas of Ireland with the greatest population of non-Irish/non-UK nationals. Strongest effects in the most deprived tertile by manual occupation and families of ≥5 persons were observed only for IHD. For Stroke, strongest effects were observed in the most deprived tertiles by manual occupation and families of ≥5 persons. Reductions in deaths by material SES indicators were more equitable across SES tertiles by male unemployment, population unemployment, and rented/free housing tenure. Greater effects observed in the intermediate and most deprived tertiles by the no car access indicator. For IHD and COPD, effects were attenuated in the composite index when compared to effects by discrete SES indicators. Overall, there was a decline in AMI	Positive effect on inequalities
Barnett et al, 2009 ¹⁷³	Interrupted time series with no concurrent comparison group	Christchurch , New Zealand High Income	Neighbourhood (Area) deprivation – Census Area Unit quintiles based on NZ Deprivation Index	National	Rate of AMI hospital admissions before (2003/04) and after (2005/06) the introduction of the SFL to assess whether there was a significant change over time among patients ≥30 years of age.	admission rates after the implementation of the smoke-free legislation (RR 0.92; 95% Cl 0.86–0.99). SES inequalities: Only among the 55 to 74 year age group AMI admissions were significantly lower in less deprived areas post SFL implementation – quintile 2 (RR 0.76; Cl 0.59–0.97)	effect on inequalities

				No. of the last of		No consistent effects of SFL on AMI admissions by deprivation were observed across three age groups (30-54; 55-74; ≥75)	
Mackay et al, 2013 ¹⁵⁰	Interrupted time series with no concurrent comparison group	Scotland High income	Area deprivation – quintiles derived from Scottish Index of Multiple Deprivation	National	Percentage step (on the day of SFL) and slope (post-SFL) change in stroke incidence (both pre-hospital deaths and hospital admissions) including all strokes, and its sub-types - cerebral infarction, intracerebral haemorrhage and unspecified stroke using morbidity and mortality data from 2000 to 2010.	Overall, there was no significant decrease in the incidence of cerebral infarction (-0.40%) or confirmed stroke (-0.23%) in the long term after SFL implementation. SES inequalities: Significant decrease in cerebral infarction in quintile 1 (most affluent) by -2.01% and a significant increase in quintile 2 by 1.30% in the long term after SFL. No significant effect on other deprivation quintiles A significant increase in confirmed stroke only in quintile 2 by 0.91% in the long term after SFL. No significant effect on other deprivation quintiles	Neutral effect on inequalities
Partial Smok	e-free Legislation						
Eagan et al., 2006 ¹⁷⁴	Before-after study (without concurrent comparison group)	Norway, High income	Educational level	National	Change in mean sum-score for five respiratory symptoms from before (May 2004) to after SFL implementation (Sept/Oct 2004) among hospitality industry workers	Overall, there was a pronounced and significant decrease in mean sum-score (for all the 5 respiratory symptoms) from baseline to follow-up (1.72 to 1.60; p<0.001). Fully adjusted results were significant but have not been presented. SES inequalities: There was no significant difference in the changes in mean sum-score of five respiratory symptoms among workers across educational levels. Fully adjusted	Neutral effect on health inequalities
Head et al., 2012 ¹⁵⁸	Before-after with a concurrent comparison group	Beaumont and Tyler, Texas, US High Income	Racial difference (non-hispanic blacks vs. whites)	Regional	Change in hospital discharge rates for 5 tobacco-related conditions (AMI, TIA, stroke, COPD, asthma) before (2004-2006) and after (2006-2008) SFL implementation in Beaumont, Tyler (comparison group- no SFL), and all Texas	results for SES have not been presented. Overall, hospital discharges for AMI and CVA declined significantly by 26% and 29% respectively after SFL implementation in Beaumont. There was a concurrent 27% decline in CVA discharge rates in Tyler. SES inequalities: Hospital discharges declined significantly for both, blacks and whites, for AMI and CVA in Beaumont after the ban.	Negative effect on Inequality (COPD and asthma) Neutral effect Inequality (acute MI, CVA and

					examined by race.	COPD discharges declined by 36% and asthma discharges declined by 31% only among whites (but not among blacks in Beaumont)	total discharges)
Marchese et al., 2015 ¹⁵⁹	Interrupted time series with no concurrent comparison group	Michigan, US High income	Racial difference (blacks vs. whites)	Regional	Monthly rate of adult asthma hospitalisations (20 to 64 year-old patients) in Michigan before (Jan 2002 to May 2010) and after (May 2010 to Dec 2012) implementation of the SFL	Overall, adjusted results showed that there was an 8% reduction in the population-wide rate of asthma hospitalisations in the 12 months after the implementation of SFL (RR, 0.92; 95% CI, 0.90–0.93). SES inequalities: In the first 12 months of the ban, black hospitalisation rates decreased 7% (RR 0.93 95% CI 0.91-0.95) and white hospitalisation rates decreased 10% (RR 0.90 95% CI 0.88-0.92).	Unclear effect on inequalities

Study/ Author	Sı	uitability	of stud	dy desig	n	Intervention independent of other changes (Criterion 1)	Shape of the intervention effect pre- specified (Criterion 2)	Intervention unlikely to affect data collection (Criterion 3)	Knowledge of allocated interventions adequately prevented (Criterion 4)	Incomplete outcomes data adequately addressed (Criterion 5)	No selective outcomes reporting (Criterion 6)	Study free from other risks of bias e.g. seasonality (Criterion 7)
	Α	В	С	D	E							
Cesaroni et al., 2008 ¹⁴⁹		Х				Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Barnett et al., 2009 ¹⁷³		Х				High risk	Low risk	Low risk	Low risk	Low risk	Low risk	High risk
Liu et al., 2013 ¹⁷¹		Х				High risk	Low risk	Low risk	Low risk	High risk	Low risk	High risk
Mackay et al., 2013 ¹⁵⁰		Х				Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Stallings Smith et al., 2014 ¹⁷²		Х				Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Marchese et al., 2015 ¹⁵⁹		Х				Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk

Suitability of study design was summarised using a five-point scale from A (most suitable) to E (least suitable).

Suitability of Study Design

- a. Category A: The study design includes concurrent comparison groups AND prospective measurement of exposure and outcome b. Category B: The study design includes at least two 'before' measurements and at least two 'after' measurements but no concurrent comparison group
- c. Category C: The study design involves single 'before' and 'after' measurements with concurrent comparison group
- d. Category D: The study design involves single 'before' and 'after' measurements with no concurrent comparison group
- e. Category E: The study design involves measurements of exposure and outcome made at a single point in time

Table 3.3: Quality of studies based on a scale of suitability of study design and six items for risk of bias assessment for quantitative studies from EPHPP

Study / Author	Suitability of study design				ign	Quality of study					
	Α	В	С	D	Е	Representativeness	Randomisation	Comparability	Reliability of data collection tools	Attrition or drop rate	Attributability to intervention
Eagan et al., 2006 ¹⁷⁴				Х		Weak	Moderate	Moderate	Moderate	Weak	Weak
Head et al., 2012 ¹⁵⁸			Х			Moderate	Moderate	Weak	Strong	Moderate	Weak

Suitability of study design was summarised using a five-point scale from A (most suitable) to E (least suitable).

Suitability of Study Design

- a. Category A: The study design includes concurrent comparison groups AND prospective measurement of exposure and outcome
- b. Category B: The study design includes at least two 'before' measurements and at least two 'after' measurements but no concurrent comparison group
- c. Category C: The study design involves single 'before' and 'after' measurements with concurrent comparison group
- d. Category D: The study design involves single 'before' and 'after' measurements with no concurrent comparison group
- e. Category E: The study design involves measurements of exposure and outcome made at a single point in time

	est Plot Matrix of evidence of socioeconomic inequalities in the effects of smoke-free egislation (SFL) on smoking-related health outcomes among adults
No effect	Defined as no evidence of differential effects in the effectiveness of the intervention for any given socioeconomic indicators
Positive effect	Defined as evidence that less advantaged groups in terms of the less affluent, those with a lower level of education, those living in more deprived area or most disadvantaged racial or ethnic group in the context of a particular study are more responsive to the intervention
Negative effect	Defined as evidence that more advantaged groups in terms of the more affluent, those with a higher level of education, those living in more affluent area or more advantaged racial or ethnic group in the context of a particular study are more responsive to the intervention
Mixed effect	Defined as evidence that there are mixed effects of the intervention on both advantaged and disadvantaged groups in responding to intervention
Unclear effect	Defined as evidence that there are unclear effects of the intervention on both advantaged and disadvantaged groups in responding to intervention
Bars in row	Each bar in each row represents one study
Colour of bars & Type of SFL	ACE / MI Stroke Respiratory/ COPD/ Asthma Comprehensive SFL (Blue bar) ACE / MI Stroke Respiratory/ COPD/ Asthma Partial SFL (Red bar)
Height of bars	Low, medium, high based solely on the suitability of design, where:
Ü	Highest = Suitability category A or B, Medium = Suitability Category C or D, Low = Suitability Category E.
	Category A: The study design includes concurrent comparison groups AND prospective measurement of exposure and outcome.
	Category B: The study design includes at least two 'before' measurements and at least two 'after' measurements but no concurrent comparison group.
	Category C: The study design involves single 'before' and 'after' measurements with concurrent comparison group
	Category D: The study design involves single 'before' and 'after' measurements with no concurrent comparison group.
	Category E: The study design involves measurements of exposure and outcome made at a single point in time.
Number above each bar	Total number (and percentage) of quality items from EPHPP passed which indicate strong and moderate quality. Maximum 6 (representative of the sample; randomization of intervention allocation; comparability of groups at baseline (where relevant); credibility of data collection tools; attrition rate (where relevant) or sample size; attributability of observed effects to intervention) (Used in case of two before-after studies)
	OR
	Total number (and percentage) of risk of bias criteria met which indicate low risk of bias in EPOC review of risk of bias criteria. Maximum 7 (intervention independent of other changes, shape of intervention pre-specified, intervention unlikely to affect data collection, knowledge of intervention adequately prevented, incomplete outcomes data adequately addressed, no selective outcomes reporting, study free from other risk of bias) (<u>Used in case of six ITS studies</u>)

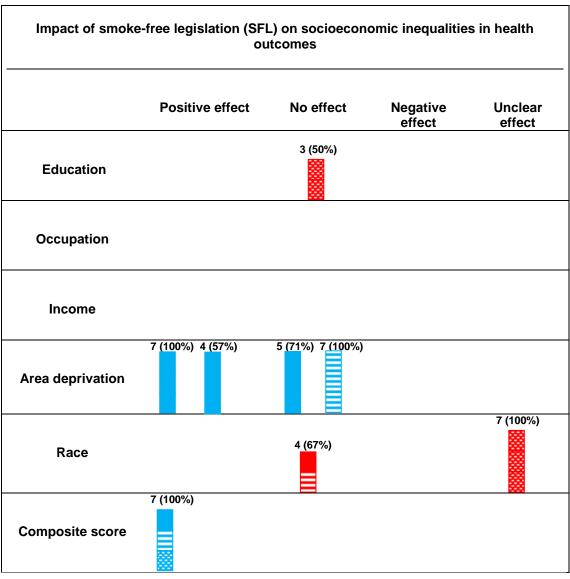


Figure 3.2: Harvest plot of evidence of socioeconomic inequalities in the effects of smoke-free legislation (SFL) on smoking related health outcomes and quality of included studies based on suitability of study design and study quality criteria

Findings of quality assessment for each of the included studies assessing the impact of comprehensive SFL are shown in Table 3.2 and represented graphically by the Harvest plot in Figure 3.2. The key for interpretation of the Harvest plot is described in Box 3.1. All the five studies 149, 150, 171-173 describing the impact of comprehensive SFL were ITS studies without a concurrent comparison group, for which the suitability of the study design was classified as the highest (represented by tallest, blue coloured bars in the harvest plot). Three of the five studies fulfilled all the seven criteria (EPOC) for assessment of risk of bias within the studies, indicating the least possibility of bias and high quality of these studies. 149, 150, 172 Liu et al. 171 met four (except intervention independent of other changes, incomplete outcomes data adequately addressed, and study free from other risk of biases) while Barnett et al. 173 met five (except intervention independent of other changes, and study free from other risk of biases) of the seven EPOC criteria for assessment of risk of bias within the studies, indicating some possibility of bias and moderate quality of these studies. Three of the five studies describing the impact of comprehensive SFL fulfilled the alternative hypothesis. Three of the studies demonstrated a positive effect of the SFL on socioeconomic inequalities (two on cardiac outcomes^{149, 171} and one on stroke, cardiac as well as respiratory outcomes¹⁷²). Two studies demonstrated a neutral effect of the SFL on socioeconomic inequalities in stroke mortality¹⁵⁰ and cardiac hospital admissions.¹⁷³

3.1.4.2. Socioeconomic inequalities in the impact of partial SFL on health outcomes

One study from Norway published in 2006 and included in this review reported the impact of a national, partial SFL on socioeconomic inequalities in changes in respiratory symptoms among hospitality industry workers.¹⁷⁴ Two studies from the US, one from Texas (2012)¹⁵⁸ and one from Michigan (2015)¹⁵⁹ reported the impact of regional, partial SFL on socioeconomic inequalities in hospital discharge rates for five tobacco-related respiratory symptoms (a morning cough, daytime cough, phlegm cough, dyspnoea and wheezing) and asthma hospitalizations respectively (Table 3.1). Overall, all the three studies showed a positive effect of partial SFL on the health outcomes. Two of these three studies reported no effect of the partial SFL on socioeconomic inequalities in health outcomes. Eagan et al. reported that five months after implementation of a national level, partial SFL in Norway, there were no significant differences in the changes in mean sum-score of five respiratory symptoms among workers across educational levels.¹⁷⁴ Head et al. reported that two years after implementation of a local partial SFL in Beaumont (Texas) hospital discharges due to AMI, and stroke and total

discharges declined significantly among the non-Hispanic blacks as well as non-Hispanic whites, compared with Tyler (Texas) where there was no SFL, showing no effect of Beaumont's partial SFL on socioeconomic inequalities. There was, however, a negative effect of the SFL on COPD and asthma discharges, where there was a significant decline in discharges only among the non-Hispanic whites but not among non-Hispanic blacks. Marchese et al. reported that 12 months after implementation of the state-wide partial SFL in Michigan, there was a significant decline in asthma hospitalisations among both, the blacks and the whites. The decline was however marginally higher among whites compared with blacks and statistically insignificant, suggesting an unclear effect of the partial SFL on socioeconomic inequality in asthma hospitalisations.

Quality assessment of the studies reporting the impact of partial SFL as observed from the Harvest plot (Figure 3.2) and the tables 3.2 and 3.3 shows that Marchese et al. was an ITS study without a concurrent comparison group, for which the suitability of the study design was classified as the highest (represented by tallest red coloured bars in the harvest plot). 159 Eagan et al. 174 was a before-after study without a concurrent comparison group while Head et al. 158 was a before-after study with a concurrent comparison group. Both, Eagan et al. and Head et al. studies were classified as medium in terms of suitability of study design (represented by medium red coloured bars in the harvest plot). Marchese et al. fulfilled all the seven criteria (EPOC) for assessment of risk of bias within the studies, indicating least possibility of bias and high quality of the study. 159 Eagan et al. met three of the six criteria (EPHPP) (except representativeness, attrition or drop rate, and attributability to the intervention) for assessment of risk of bias within the studies, 174 while Head et al. 158 met four of the six EPHPP criteria (except comparability, and attributability to the intervention) indicating the possibility of bias and weak quality of these studies as per the EPHPP criteria. One of the three studies reporting the effect of partial SFL fulfilled the alternative hypothesis. Marchese et al. reported an unclear effect of partial SFL on socioeconomic inequalities in asthma hospitalisations. 159 Eagan et al. favoured the null hypothesis of no effect of the SFL on socioeconomic inequalities in changes in respiratory symptoms. 174 Head et al. favoured null hypothesis in the case of total discharges, and discharges due to AMI and stroke; while a negative effect on socioeconomic inequalities was observed in the case of COPD and asthma. 158

3.1.5. Discussion

This systematic review closely examines existing global research on the impact of SFL on socioeconomic inequalities in health outcomes (morbidity and mortality) associated with exposure to tobacco smoke such as AMI, acute coronary events, IHD, stroke, TIA, COPD, and asthma. We found only eight studies till the time of completion of this review, which could be included. All of these eight studies were from HICs of Europe, the US, and New Zealand. This is a significant research gap, more so for LMICs, as SFL is the most widely adopted tobacco control measure globally, with 49 countries (15 HICs and 34 LMICs) covered by comprehensive SFL; while 139 countries are reported to have partial SFL.²³ Therefore, there is a clear and urgent need for LMICs to undertake studies of the impact of SFL on socioeconomic inequalities in health outcomes related to tobacco smoke exposure.

Most of the studies we reviewed were ITS studies, ^{149, 150, 159, 171-173} without a concurrent comparison group (the type of study design used when randomization is difficult; as the SFL is introduced nationwide in some countries, it is not possible for them to get a suitable comparison group in the same country) and were highly suitable in terms of the study design for evaluation of the impact of policies implemented at population level and at a clearly defined point in time. ¹⁷⁵ Only two studies ^{158, 174} were before-after studies (one with a control group and another without a control group) which were are considered to be relatively weaker in terms of suitability of the study design. ¹⁷⁶ Uncontrolled before-after studies cannot account for secular trends and sudden changes in outcomes while controlled before-after studies suffer from an inability to ensure baseline comparability of the intervention and control (which is not randomly selected) groups, making it difficult to attribute the change in the outcome to the intervention. ¹⁷⁶ Accordingly, we observed that these two before-after studies also did not meet some of the EPHPP risk of bias criteria, due to which, they were classified as weak in terms of study quality. Therefore, results of these before-after studies need to be interpreted with caution.

Overall, we found evidence that implementation of comprehensive SFL led to either a positive effect (three out of five studies) on socioeconomic inequalities in health outcomes or no effect (two out of five studies); while implementation of partial SFL led to either no effect (two out of three studies) or an unclear effect (one out of three studies). Our findings, therefore, suggest that only comprehensive, 100% smoke-free indoor public and workplace policies can lead to a reduction in socioeconomic inequalities in

health outcomes related to tobacco smoke exposure by benefitting the low SES groups more (compared with the high SES groups); while partial SFL may not reduce inequalities. Our findings are consistent with some of the earlier studies. A study was conducted in England in 2005 when the UK Government decided to exempt pubs not serving catered food and private members' clubs from SFL and thereby introduce partial SFL.¹⁷⁷ Most of the pubs not serving catered food were located in the deprived areas of England and in these areas, almost 67% of these venues would be exempt from the SFL while in the affluent areas, only 33% of these venues would be exempt. 177 This finding suggested that introduction of partial SFL would worsen socioeconomic inequalities in health and the prevalence of smoking. 177 Similar findings were reported in another study conducted in North West England in the same year. 178 After the introduction of a comprehensive SFL in England in July 2007, a study assessed its impact on hospital admissions due to childhood respiratory tract infection (RTI). 122 Post implementation of comprehensive SFL, gradual decline in childhood RTI hospitalisations was significantly higher in the most deprived children compared with the most affluent, indicating that implementation of comprehensive SFL would lead to a reduction in health inequalities. 122 Unlike our findings, however, a systematic review assessing the impact of tobacco control policies on smoking among youth showed an equity negative effect of comprehensive, national level SFL.¹⁵⁶

Our findings potentially contribute to clarify the dilemma arising from some of the earlier research which suggested that SFL led to increasing health inequalities.¹⁴⁸ Further, as people belonging to the low SES groups (whose exposure to tobacco smoke and SHS is higher compared with the high SES groups) are more likely to be working in or frequenting places with partial/no SFL,^{6, 21} it is even more important to implement and enforce comprehensive SFL at such indoor venues to protect this vulnerable group.

Area deprivation was considered as the indicator for SES in half of the studies included in our review. 149, 150, 171, 173 We found evidence from two studies that people living in more deprived areas (representative of low SES) were likely to have greater reductions in adverse cardiac outcomes (compared with those living in less deprived areas); 149, 171 while two other studies using area deprivation as an indicator of SES showed no effect on inequalities. 150, 173 This measure of SES, derived from the census data and sometimes by combining information from multiple Government data sources may not always be suitable for LMICs where such data might not always be available and where

deprivation may be a much more complex issue.^{179, 180} Two studies considered race as an indicator of SES and showed either no effect of partial SFL on health inequalities¹⁵⁸ or an unclear effect of partial SFL in reducing asthma hospitalisations among the Whites (compared with the Blacks). 159 Both of these studies were from the United States where there exists a racial wealth gap with African Americans faring worse (have lesser assets compared with the Whites) due to issues such as lower incomes, lower inheritance rates and discrimination in housing markets. 181 Race as an indicator of SES also may not be suitable for the LMIC settings. One study reported education as an indicator of SES and found no effect on inequality.¹⁷⁴ Education as an indicator of SES is fairly easy to assess and interpret (even in LMICs) but it misses out on the complexity of deprivation or SES when considered as a standalone indicator of SES. One study used a composite score (a combination of seven structural and material indices of SES) as an indicator of SES.¹⁷² Alkire and Santos mention that deprivation is multidimensional and describe the Multidimensional Poverty Index (MPI) developed specifically for LMICs, which consists of 10 indicators from three different dimensions – education, health and standard of living. 179 Such measures, although complex to interpret, would be helpful to provide the depth required to assess socioeconomic inequalities in outcomes and would also be suitable for the LMIC settings. None of the included studies reported 'occupation' or 'income/wealth' as indicators of SES. These two measures along with education and assets possessed, either as discrete indicators or in the form of a composite index are the most commonly reported SES indicators in the LMIC settings.

To some extent, our findings indicate that the choice of SES indicator may influence the outcomes (as SES is an important confounding factor in the association between implementation of SFL and the health outcomes) and hence, studies should assess the impact of interventions (SFL in our case) on differences in health outcomes across multiple indicators of SES instead of focusing on one particular indicator. For example, equity positive effect or no effect on equity was observed in case of studies which reported 'area deprivation' as an indicator of SES; an unclear effect or no effect on equity was observed in case of 'race' as an indicator of SES; while no effect on equity was observed in case of 'education' as an indicator of SES. We, however, cannot be confident about this as the number of studies reporting each type of SES indicator was very low in this review. Future studies should explore this research question.

3.1.5.1. Strengths and limitations

Previous reviews present conflicting evidence (and some of them demonstrate no effect or a negative effect) with respect to the impact of SFL on socioeconomic inequalities in health outcomes related to exposure to tobacco smoke. 148, 155 Moreover, previous reviews assessing the impact of SFL have clubbed together health outcomes and smoking behaviour. 148, 155 Causal pathways indicate that SFL has an impact through a reduction in active smoking as well as a reduction in SHS exposure, 160 which could potentially lead to differential effects by SES on health outcomes. It is possible that previous reviews only captured the causal pathway which favoured the high SES groups. Our updated review is therefore vital as it specifically focuses on and analyses in depth, SES differences in health outcomes. We have made a considerable effort to include literature from several databases, existing known reports and systematic reviews/meta-analyses related to the topic, as well as grey literature available online to ensure that all the relevant published and unpublished literature was included in our review. However, in these types of studies, there is always a possibility that some informal or unreported evaluation of SFL was missed. An important challenge in this review was to undertake comparisons across different indicators of SES reported in the studies. In order to deal with this, instead of just presenting a narrative synthesis, we adopted a validated methodology – the Harvest plot, 154, 170 to test competing hypothesis with respect to the impact of SFL on socioeconomic inequalities in health outcomes resulting from exposure to tobacco smoke. We used two different quality assessment criteria, EPOC for ITS studies (which captures more information on intervention fidelity) and EPHPP for before-after studies (which captures more information on study design features). Ideally, intervention fidelity would be important for both ITS and before-after studies. We, however, used standard guidelines and our quality assessment results should be interpreted cautiously in light of limited comparability between the two study types.

3.1.5.2. Policy implications

The United Nations Sustainable Development Goals (UN SDGs) specify the following two important targets for reducing inequalities (Goal 10) and improving health outcomes (Goal 3): 1) *Ensure equal opportunity and reduce inequalities of outcome, including by eliminating discriminatory laws, policies and practices and promoting appropriate legislation, policies and action in this regard*¹⁴³ 2) *By 2030, reduce by one-third premature mortality from non-communicable diseases through prevention and treatment* (for which reducing tobacco use has been recognized as critical).²⁰ In order to ensure

timely achievement of both these SDG targets, it is important that pro-equity, population-level tobacco control policies such as comprehensive SFL are urgently implemented and enforced across all the countries. This is particularly important in LMICs which bear the highest tobacco-related burden² and are lacking more in terms of implementation of comprehensive SFL.²³ It is equally important that countries which do not yet have any SFL or have implemented partial SFL take appropriate steps towards implementation of comprehensive SFL, as outlined in the WHO FCTC⁶² and the WHO MPOWER¹⁸³ to protect the vulnerable low SES groups.

The national/state/regional Governments (particularly in the LMIC settings) should encourage and support high-quality research to evaluate the impact of population-level policy measures such as SFL. Along with the differential impact of policies by demographic indicators, it is important for researchers to assess differences by SES as well when SES is likely to be an important confounding factor in the association between the policy intervention and the outcome/s. As measuring SES or deprivation can be complex in LMICs, research should focus on multiple appropriate SES indicators as well as on composite indicators of SES.

3.1.6. Conclusion

Comprehensive SFL has the potential to reduce socioeconomic inequalities in health outcomes resulting from exposure to tobacco smoke; partial SFL may not. Research from the LMIC settings focusing on this issue is lacking. Countries must strengthen their tobacco control policies and move towards comprehensive SFL along with other evidence-based tobacco control measures to achieve the UN SDG goals of reducing inequalities and premature mortality from NCDs by 2030.

Chapter 4: Secondhand smoke exposure and the impact of smoke-free legislation on protection against exposure to tobacco smoke: Multi-country evidence from Global Adult Tobacco Survey

4.1. Global Tobacco Surveillance System

In order to help its member nations implement effective tobacco control measures, the WHO devised the FCTC and the MPOWER strategy.¹⁸³ The MPOWER consists of guidance on implementation of six evidence-based tobacco control strategies to reduce the demand for tobacco¹⁸³:

- 1) Monitor tobacco use and prevention policies
- 2) Protect people from tobacco smoke
- 3) Offer help to guit tobacco use
- 4) Warn about the dangers of tobacco
- 5) Enforce bans on tobacco advertising, promotion, and sponsorship
- 6) Raise taxes on tobacco

Article 20.2 of the WHO FCTC urges parties to:

"Establish, as appropriate, programmes for national, regional and global surveillance of the magnitude, patterns, determinants and consequences of tobacco consumption and exposure to tobacco smoke. Towards this end, the Parties should integrate tobacco surveillance programmes into national, regional and global health surveillance programmes so that data are comparable and can be analysed at the regional and international levels, as appropriate." 16

In the late 90's some HICs collected some form of data on tobacco use behaviour, however, there was no uniform data collection system in most LMICs which would enable comparison of tobacco use and policy measures across these countries. ¹⁸⁴ To overcome this issue and towards fulfilment of 'M' of the MPOWER strategy and Article 20.2 of the FCTC, the WHO, in collaboration with the Centers for Disease Control and Prevention (CDC) and the Canadian Public Health Association (CPHA) developed the Global Tobacco Surveillance System (GTSS) in 1999. ¹³³ The aim of GTSS is to enable capacity building among the WHO member nations to monitor tobacco use and related indicators so that they can design, implement and evaluate interventions for tobacco

control and monitor progress on implementation of tobacco control policies. ¹³³ GTSS provides uniform survey methodology and protocols, common core survey questionnaire (with the freedom to incorporate country-specific questions), standardised data collection, management, analysis and reporting guidance. GTSS comprises of four types of surveys. ¹³³

Three school-based surveys:

- 1) Global Youth Tobacco Survey (GYTS) (13-15 year-old youth)
- 2) Global School Personnel Survey (GSPS) (Adult school personnel)
- 3) Global Health Professional Student Survey (GHPSS) (adults-medical, dental, pharmacy, nursing students)

One household level survey:

4) Global Adult Tobacco Survey (GATS) (non-institutionalized adults aged ≥15 years of age)

All the surveys collect data on the following 185-188:

- a) Prevalence of tobacco use
- b) Knowledge and attitudes
- c) Access and availability
- d) Exposure to SHS
- e) Economics
- f) Media and advertising
- g) Cessation
- h) School curriculum and training
- i) Demographics

Figure 4.1 shows the GTSS plan.¹⁸⁹ After the survey is conducted, data is analysed and reported as per standardised protocols. The feedback from the periodically repeated surveys not only provides information about tobacco use behaviour but it also helps develop and strengthen national tobacco control programmes/plans and monitor progress. GTSS also allows development of applied research in the field of tobacco control wherein the data from various components can be used freely by tobacco control researchers for undertaking secondary data analyses. For example, the data from GTSS components, protocols, reports, country-factsheets, questionnaires and other survey related material are freely available for download from the GTSSData website.¹⁹⁰ GTSS

also allows for enhancement of the role of civil society where they can be engaged in surveillance, monitoring, policy and programme development.¹⁸⁴

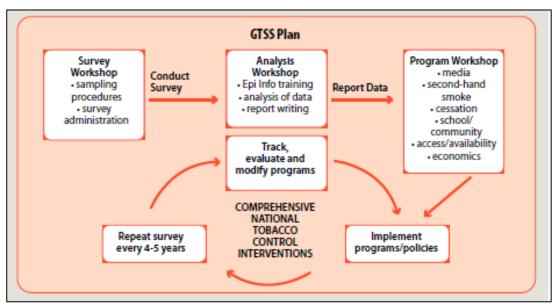


Figure 4.1: Global Tobacco Surveillance System (GTSS) Plan – The process of implementation of GTSS and relevance for national tobacco control policies/programmes¹⁸⁹

4.2. Global Adult Tobacco Survey

GATS, the newest component of GTSS launched since 2007, is a nationally representative cross-sectional household survey of non-institutionalized adults aged 15 years and over. ^{133, 191} It is considered to be the global standard for monitoring adult tobacco use and key tobacco control indicators. GATS employs standardised survey methodology with a few country-specific variations in the questionnaire. ¹⁹² The GATS core questionnaire and the optional questions are available from the GTSSdata website at: https://nccd.cdc.gov/gtssdata/Ancillary/Documentation.aspx?SUID=4&DOCT=1. ¹⁹² GATS is designed to collect household as well as individual level data. The individual questionnaire includes questions on demographics, tobacco use and cessation, exposure to SHS, economics of tobacco use, anti- or pro-tobacco media exposure, and knowledge/attitudes/perceptions regarding the harms of tobacco use. ¹⁹² Multi-stage cluster sampling design is used in GATS. The three stages of sampling in GATS involve ¹⁹³:

a) First stage of sampling – Selection of Primary Sampling Units (PSUs) which are specific geographical regions in a country (Minimum 100 PSUs and 400 smaller

segments selected through probability proportional to size technique to ensure regional representation with each selected smallest area consisting of around 250 households)

- b) Second stage of sampling After house listing exercise in each of the selected geographical area, approximately 25 households are randomly selected from the selected PSUs.
- c) Third stage of sampling Random selection of an eligible participant from the selected households (also possible to select specific gender if gender randomization is required).

The recommended minimum participant sample size for implementation of GATS in any country is 8000 per region when results are to be reported jointly by urbanicity and gender and 4000 per region when results are to be reported separately by urbanicity and gender. ¹⁹³ The minimum required sample size would be expected to move upward when considering design effect in excess of 2 and participant non-response or ineligibility. ¹⁹³

Once the required number of households are selected from each geographic region, trained interviewers visit the households for surveys. During the visit, the interviewers obtain demographic information from any adult household member about all household members and with the help of electronic hand-held devices, they then randomly select one eligible member ≥ 15 years of age (in some countries, this selection can be stratified by gender) from each household, to participate in the survey.¹⁹⁴ The selected participant from each household is then invited to participate in the GATS. The GATS questionnaire is then administered by the trained interviewers to consenting participants using electronic hand-held devices.¹⁹⁴

In order to account for the complex multi-stage design of GATS, sampling weights are employed for analysing GATS data. Sampling weights are intended to account for the probability of inclusion of each participant in the survey, non-response rates, differential demographic composition and other such factors which affect the sample composition.¹⁹⁵

Between 2008 and 2011, the first round of GATS was implemented in 17 LMICs in five WHO regions (Table 4.1). Country-specific, anonymous GATS data for 16 of the 17 LMICs (all but Indonesia) was freely available from the CDC GTSSData website, ¹⁹⁶ which was used for secondary analyses in this study. Data for Malaysia only became available on the CDC website during later stages of this study and hence in some of the analyses presented as part of this study, Malaysia was not included. Moreover, subsequently, GATS has been conducted in 10 additional countries till December, 2016. ¹⁹¹ The additional countries include Argentina, Costa Rica, Greece, Kazakhstan, Kenya, Nigeria, Pakistan, Panama, Qatar, and Senegal. Data for 23 countries is now available from the CDC GTSSData website. ¹⁹⁶

Table 4.1: Global Adult Tobacco Survey (GATS) countries in WHO Regions (2008-2011)								
South East Asian	Western Pacific	Region of the	European Region	Eastern Mediterranean				
Region (SEAR)	Region (WPR)	Americas (AMR)	(EUR)	Region (EMR)				
India	China	Brazil	Poland	Egypt				
Bangladesh	Malaysia	Mexico	Romania					
Thailand	Philippines	Uruguay	Russian Federation					
Indonesia	Viet Nam		Turkey					
			Ukraine					

This chapter, along with the two research papers which are included in it, addresses Aims 2, 3, and 5 of the thesis. The first research paper presented in this chapter addresses Aim 2 (To study the association between SFL and exposure to SHS in the home in the LMIC settings) and the corresponding objective 2a. The second research paper presented in this chapter addresses Aim 3 (To study socioeconomic inequalities in exposure to SHS at home and in the workplace in LMICs) and the corresponding objective 2b. These research papers have also been published in peer-reviewed journals and presented as oral and poster presentations at international conferences and therefore, this chapter also addresses Aim 5 (To generate research evidence to strengthen implementation and enforcement of strong tobacco control policies including comprehensive SFL in the LMIC settings) and the corresponding objective 5.

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SECTION A - Student Details

Student	Gaurang Prafulla Nazar
Principal Supervisor	Professor Neil Pearce
Thesis Title	Smoke-free legislation and active smoking, second hand smoke exposure and health outcomes in low- and middle-income countries.

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B - Paper already published

Where was the work published?	Preventive N	Preventive Medicine						
When was the work published?	2014;59(100):47-53.							
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A							
Have you retained the copyright for the work?*	Yes	Was the work subject to academic peer review?	Yes					

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SECTION D	- Multi-authored	work
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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)

Please refer to attached Section D following this coversheet

Student Signature:

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Section D – Student's role in multi-authored work

This research paper is authored by Dr. Gaurang P. Nazar, Dr. John Tayu Lee, Prof. Stanton A. Glantz, Dr. Monika Arora, Prof. Neil Pearce and Prof. Christopher Millett in this order. I am the first and the corresponding author. Prof. Neil Pearce is my supervisor from London School of Hygiene and Tropical Medicine, Prof. Christopher Millett is my co-supervisor from Imperial College London. Dr. Monika Arora is my mentor from PHFI (India) for my Wellcome Trust-PHFI funded Ph.D.

- With the guidance of my co-supervisor, I conceptualised this work as a part of my Ph.D. study, wherein it was pre-decided to undertake secondary analyses using GATS data to study various aspects related to SHS exposure.
- I acquired the GATS data for 15 countries from GTSSData website where the data is freely available for download.
- Under the guidance of Prof. Millett, Dr. Lee and Prof. Pearce, I conducted secondary analyses (ran all descriptive statistics, cross-tabulations, statistical tests including logistic regression models and the meta-analysis) on the acquired GATS data from all the 15 countries using statistical software STATA. Specific guidance on statistical issues related to multiple logistic regression, multicollinearity diagnostics, survey weights and sensitivity analysis was provided by Dr. Lee; while specific guidance on the random effects meta-analysis was provided by Prof. Glantz and Dr. Lee.
- Apart from the data analysis, I also interpreted the statistical outputs and the results.
- I further drafted the first cut of the entire research paper fully by myself and then shared the manuscript with the co-authors for their inputs.
- After receiving substantial inputs, both, in terms of paper writing and data analysis, I further worked on data analysis and revised the paper critically for intellectual content.
- I, with guidance and approval from my co-authors, finalised the paper for submission to the journal.
- I submitted the paper to the journal, handled journal communications related to the paper, responded to reviewer queries with the guidance of and consultation with the co-authors. After one round of revision, the paper was accepted for publication.

•	I, as the first and corresponding of the paper, am responsible and accountable for the accuracy and integrity of all the aspects presented in the paper.													

4.3. Association between being employed in a smoke-free workplace and living in a smoke-free home: Evidence from 15 low- and middle-income countries*

4.3.1. Abstract

4.3.1.1. Objective

To assess whether being employed in a smoke-free workplace is associated with living in a smoke-free home in 15 low- and middle-income countries (LMICs).

4.3.1.2. Methods

Country-specific individual level analyses of cross-sectional Global Adult Tobacco Survey data (2008–2011) from 15 LMICs was conducted using multiple logistic regression. The dependent variable was *living in a smoke-free home*; the independent variable was *being employed in a smoke-free workplace*. Analyses were adjusted for age, gender, residence, region, education, occupation, current smoking, current smokeless tobacco use and number of household members. Individual country results were combined in a random-effects meta-analysis.

4.3.1.3. Results

In each country, the percentage of participants employed in a smoke-free workplace who reported living in a smoke-free home was higher than those employed in a workplace not smoke-free. The adjusted odds ratios (AORs) of living in a smoke-free home among participants employed in a smoke-free workplace (vs. those employed where smoking occurred) were statistically significant in 13 of the 15 countries, ranging from 1.12 [95% CI 0.79–1.58] in Uruguay to 2.29 [1.37–3.83] in China. The pooled AOR was 1.61 [1.46–1.79].

4.3.1.4. **Conclusion**

In LMICs, employment in a smoke-free workplace is associated with living in a smoke-free home. Accelerated implementation of comprehensive smoke-free policies is likely to

^{*} Modified from original publication - <u>Nazar GP</u>, Lee JT, Glantz SA, Arora M, Pearce N, Millett C. Association between being employed in a smoke-free workplace and living in a smoke-free home: evidence from 15 low and middle income countries. *Preventive Medicine*. 2014;59:47-53.

result in substantial population health benefits in these settings.

4.3.2. Introduction

Approximately 600,000 deaths are attributable to secondhand smoke (SHS) exposure globally each year. ⁵⁶ Adverse health effects from SHS exposure include sudden infant death syndrome and respiratory disorders in children and lung, breast cancer, ^{197, 198} cardiovascular disease and poorer reproductive outcomes in adults. ^{6, 199} The bulk of the burden from SHS exposure falls on women and children living in low- and middle-income countries (LMICs), where 80% of the world's smokers reside² and where SHS exposure at home is typically high, ranging from 17% in Mexico to 73% in Viet Nam among countries participating in the Global Adult Tobacco Survey (GATS). ⁵³ Further, SHS exposure at home among non-smokers is higher among females compared with males. ⁵³

Comprehensive smoke-free policies have high levels of public support and have been associated with substantial health benefits. ^{21, 35, 200} These include reduced tobacco consumption and increased quit attempts, the virtual elimination of SHS from workplaces, lower hospital admission rates for myocardial infarction and stroke, lower admissions for acute respiratory illness in both children and adults, ^{160, 201} and lower rates of small for gestational age births. ²⁰² However, these health benefits are not equitably distributed as only 16% of the world's population are covered by comprehensive smokefree policies. ¹⁷

Research evidence suggests that smoke-free workplace policies may change social norms about exposing others to SHS in the home.³²⁻³⁵ These findings indicate that early concerns that smoke-free workplace policies would lead to behavioural compensation through an increase in smoking at home have not materialised; rather, results from richer countries³²⁻³⁴ and India³⁷ have consistently found that people employed in a smoke-free workplace are more likely to live in a smoke-free home. Replication of this finding in other LMICs would indicate that implementation of smoke-free policies in these settings will likely result in substantial reductions in tobacco-related harm globally. This study examines whether there is an association between being employed in a smoke-

free workplace and living in a smoke-free home in 15 LMICs participating in GATS between 2008 and 2011.

4.3.3. Methods

4.3.3.1. Study design, setting, and data

This study involved secondary analysis of GATS data from15 LMICs. GATS is a nationally representative cross-sectional household survey of non-institutionalized adults aged 15 years and over. ¹⁹¹ It is considered to be the global standard for monitoring adult tobacco use and key tobacco control indicators. GATS employs standardised survey methodology with a few country-specific variations in the questionnaire and is designed to collect household as well as individual level data. Multi-stage cluster sampling design is employed in GATS to select a nationally representative study sample. Between 2008 and 2011, the first round of GATS was implemented in 17 LMICs in five WHO regions. ¹⁹⁰ Country-specific, anonymous GATS data for 15 of the 17 LMICs (all but Indonesia and Malaysia) was freely available from the CDC GTSS Data website, which was used for secondary data analysis. Poland and the Russian Federation are now classified as high income countries by the World Bank; however, when the first round of GATS was conducted in these countries in 2009, they belonged to the upper middle income category. Therefore, for the purpose of our study, we treated them as middle income countries.

4.3.3.2. Study participants

We used individual level data from the first round of GATS in each of the 15 LMICs. GATS respondents in each country who reported working indoors (or both indoors and outdoors) but outside their home were included as participants for this study. Observations with missing values in the dependent or independent variables were dropped to obtain a final sample for each country. The proportion of missing cases ranged from 0.1% in Uruguay to 8.5% in China (Table 4.2). Table 4.2 describes the total number of participants included in our study from each of the 15 LMICs which ranged from 1174 in Romania to 12,912 in Brazil.

4.3.3.3. **Measures**

The GATS questionnaire includes core questions on tobacco use, SHS exposure at work and in the home, and socio-demographic information. For the present study, the dependent variable was 'living in a smoke-free home'. A participant was classified as living in a smoke-free home if he/she replied 'never' to the question: How often does anyone smoke inside your home? If the participant responded 'daily', 'weekly', 'monthly', or 'less than monthly', he/she was considered as not living in a smoke-free home. The independent variable was 'being employed in a smoke-free workplace'. The participant was classified as employed in a smoke-free workplace if he/she answered 'no' to the question: During the past 30 days, did anyone smoke in the indoor areas where you work?

The potential confounders included were: age group, gender, residence, education, occupation, current smoking, current smokeless tobacco (SLT) use and number of household members. A country-specific region variable was also included for India, Thailand, China, Brazil, Poland and Ukraine (this information was not available for other countries). Current SLT use was not included as a covariate for Uruguay, Romania, and Turkey as there were only a very small number of users or no data on SLT use was available. In China, the occupation variable consisted of five categories rather than two as the categorization for employment differed substantially from other countries. Due to a negligible number of participants educated up to the primary level in Romania, Russian Federation, and Ukraine, we merged these with the 'up to secondary level' education category. See Supplementary Table in Appendix C-1 for a detailed description of the definitions of variables used in this study.

	Table 4.2: Description of participants living in smoke-free homes among those working indoors in GATS countries (2008-2011) – Weighted %														
		SEAR	WPR			AMR			EUR					EMR	
	India N=12,561	Bangladesh N=1,663	Thailand N=4,999	Chinaª N=1,711	Philippines N=2,083	Viet Nam N=2,373	Brazil ^b N=12,912	Mexico N=2,026	Uruguay ^c N=1,805	Poland N=2,973	Romaniad N=1,174	Russian Federatione N=5,426	Turkey ^f N=2,007	Ukraine ^e N=2,741	Egypt N=4,365
Smoke-free at home	57.2	40.6	69.5	13.1	45.6	15.9	64.5	73.4	54.6	43.3	43.3	51.8	37.4	65.7	37.0
Smoke-free at work															
Yes	64.0	53.0	73.3	20.5	53.3	22.1	66.6	74.5	55.3	48.5	49.3	56.6	42.4	70.7	41.8
No	41.7	34.1	58.5	9.2	28.9	11.1	58.0	68.5	51.1	33.0	31.7	43.4	28.8	55.4	33.8
Age Group (yrs)															
15-29	53.1	40.6	63.9	11.7	43.3	12.9	62.9	75.8	43.9	42.7	39.2	51.6	31.4	60.1	30.8
30-44	58.8	39.2	70.7	14.7	47.7	17.4	66.2	71.3	60.1	46.9	45.0	52.2	40.5	67.1	40.2
45-59	59.9	46.3	75.8	11.5	47.0	19.1	64.1	72.2	56.4	38.9	42.1	51.0	40.0	66.6	40.2
≥60	62.4	30.1	63.7	11.5	38.0	17.0	64.0	76.3	63.5	46.6	58.3	55.7	56.9	80.9	48.1
Gender	•								•						•
Male	56.4	40.1	64.5	11.2	42.7	14.7	65.4	72.2	54.2	44.2	44.1	52.9	38.2	64.7	35.8
Female	61.6	44.6	74.7	16.2	48.6	17.3	63.6	75.2	55.0	42.2	42.4	50.8	34.8	66.8	41.1
Residence															
Urban	65.4	47.4	74.0	17.2	55.8	21.9	64.8	73.2	54.4	43.4	37.7	49.9	37.8	64.7	41.3
Rural	49.0	35.9	65.6	06.8	25.6	10.8	58.2	75.0	59.1	43.0	57.8	59.3	35.3	69.8	31.1
Education															
Primary	44.2	31.1	58.8	5.0	26.4	9.7	-	76.0	54.7	39.7	-	-	34.0	-	27.4
Secondary	58.8	45.8	69.6	11.5	45.6	18.3	-	73.5	53.6	39.9	43.9	50.7	34.1	62.7	34.6
Tertiary	71.8	67.2	81.1	18.5	59.4	22.3	-	71.3	58.6	52.7	41.9	52.7	49.2	71.4	48.8
Occupation															
Employed	58.7	55.8	69.8	-	46.8	21.1	65.4	72.9	54.4	43.3	41.9	51.7	37.1	65.6	38.0
Self-employed	55.1	34.5	68.1	-	40.7	11.4	62.0	75.0	55.8	43.3	59.1	53.4	38.8	67.8	32.3
Current smoking															
Yes	28.8	27.6	47.8	8.1	25.7	10.2	34.6	65.2	29.7	17.7	24.7	36.8	26.2	46.7	12.8
No	63.4	49.5	76.0	16.0	52.5	18.2	70.1	75.7	63.7	58.0	53.4	63.3	47.3	76.0	48.0
Current smokeless tob															
Yes	38.8	33.6	54.1	9.3	47.4	31.8	46.9	41.1	-	63.4	-	27.2	-	57.0	15.9
No	63.5	42.9	69.5	13.1	45.6	15.9	64.5	73.6	54.6	43.2	43.5	51.9	-	65.8	37.7
Missing cases (%)	7.1	8.2	1.6	8.5	2.2	2.8	4.0	3.6	0.1	4.2	1.5	2.7	1.5	2.6	3.3

Occupation categories in China differed from those of other LMICs. Five occupation categories were considered for China and hence have not been presented in this table for maintaining uniformity.

^b In Brazil, education categories were defined differently and were incomparable to those from other GATS countries.

oln Uruguay, there were no current smokeless tobacco users in the study population.

d In Romania, the category 'Primary' for the education variable contained only 1 case and hence, was merged with the category 'Secondary'. Moreover, the study sample in Romania contained only six cases of current smokeless tobacco users which constituted a negligible proportion and hence has not been presented in the table.

In Russian Federation and Ukraine, the category 'Primary' for the education variable contained only 10 and 8 cases respectively and hence, were merged with the category 'Secondary' In Turkey, no data was available on current smokeless tobacco use from the GATS survey.

4.3.3.4. Statistical analysis

We conducted country-specific, individual level data analysis for each LMIC. We tested for bivariate associations between the independent variable with the dependent variable using Chi-square tests. Country-specific multiple logistic regression models were run to estimate the adjusted odds ratio (AOR) and 95% confidence interval (95% CI) of living in a smoke-free home if employed in a smoke-free workplace compared with being employed in a workplace where smoking occurred. The logistic regression models were adjusted for all the covariates described above (with country-specific exclusions) to minimise confounding and ensure comparability of findings across countries. Age and number of household members were treated as continuous variables. In Brazil, the 'education' variable was not included in the model because the variable definition was not comparable with other GATS countries, 147 however, we did conduct a sensitivity analysis by including education variable in the model and found that the results were consistent with those obtained without including it in the model.

We tested for multicollinearity between the covariates adjusted for in the analysis for each country. The multicollinearity diagnostics variance inflation factor (VIF) values were all less than five, indicating reasonable independence between the predictor variables for each country-specific model.²⁰⁴ The only exception to this was Egypt where we observed evidence of multicollinearity between the variables "national region" and "residence" (urban/rural). The variable 'national region' was removed from the model in Egypt to maintain uniformity as that variable was not available for several other countries as well. Country-specific sampling weights were applied for all analyses to account for the complex study design.

To estimate the overall association of being employed in a smoke-free workplace with living in a smoke-free home across the 15 LMICs, we calculated a pooled AOR and 95% CI using a random effects meta-analysis based on the AOR's from the individual countries. All the statistical analyses were conducted using STATA v.12.0.

4.3.4. Results

4.3.4.1. Descriptive statistics

Of the participants employed indoors outside the home, the percentage reporting a smoke-free workplace was 83% in Uruguay, 81% in Mexico, 76% in Brazil, 74% in Thailand, 70% in India, 68% in Ukraine and Philippines, 66% in Romania and Poland, 64% in Russian Federation, 63% in Turkey, 44% in Viet Nam, 40% in Egypt and 35% in Bangladesh and China (data not shown). In all the 15 LMICs, the percentage of participants living in a smoke-free home was higher among those employed in a smoke-free workplace compared with those employed in a workplace where smoking occurred (Fig. 4.2, Table 4.2). Among participants employed in a smoke-free workplace, the percentage living in a smoke-free home varied from 21% in China to 75% in Mexico. Among participants employed in a workplace that was not smoke-free, the percentage living in a smoke-free home varied from 9% in China to 69% in Mexico. Table 4.2 describes the country-specific percentages of participants reporting living in smoke-free homes by their socio-demographic characteristics.

4.3.4.2. Multiple logistic regression analysis

There were significant positive associations between being employed in a smoke-free workplace and living in a smoke-free home in all LMICs except Uruguay and Mexico (Fig. 4.3, Table 4.3). The AOR estimates ranged from 1.12 [0.79–1.58] in Uruguay to 2.29 [1.37–3.83] in China. The pooled AOR for the all-country data was 1.61 [1.46–1.79]. Female participants were less likely than males to live in a smoke-free home in most LMICs but associations were only significant in India, Bangladesh, Brazil, Poland, Russian Federation, Turkey, Ukraine, and Egypt. Participants from urban settings in India, Thailand, China, Philippines, Viet Nam, Brazil, and Egypt were significantly more likely to live in a smoke-free home compared with those from the rural settings. In contrast, participants from rural settings were significantly more likely to live in a smoke-free home in Romania, Russian Federation, and Ukraine. The likelihood of living in a smoke-free home significantly increased with increasing education level in India, Bangladesh, Thailand, Philippines, Ukraine, and Egypt. Non-smokers were consistently more likely to live in a smoke-free home than smokers. No association was observed between SLT use and living in a smoke-free home.

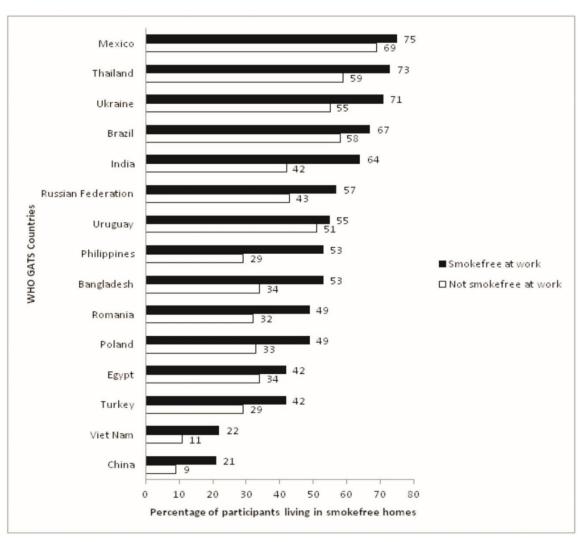


Figure 4.2: Percentage of participants living in smoke-free homes by smoke-free status of the workplace in 15 GATS countries (2008–2011)

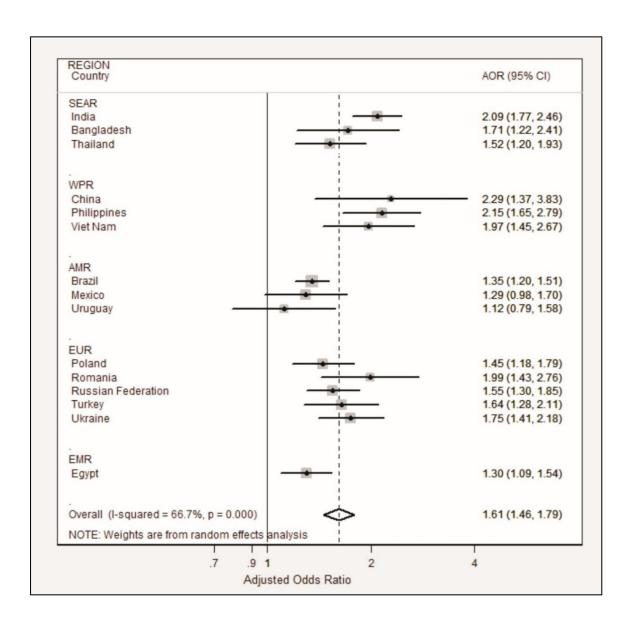


Figure 4.3: Forest plot showing country-specific and pooled adjusted odds ratios (95% CIs) of living in a smoke-free home among those employed in a smoke-free workplace compared with those employed in workplaces where smoking occurred (GATS 2008–2011)

	Tak	ole 4.3: Associat	tion of being en	ployed in a sm		ace with living i	n a smoke-free ho		working indoo	rs in GATS cou	ntries (2008-201	1) – Adjusted O	dds Ratio [95%	CI]a	
		SEAR			WPR			AMR				EUR			EMR
	India N=12,561	Bangladesh N=1,663	Thailand N=4,999	China N=1,711	Philippines N=2,083	Viet Nam N=2,373	Brazil N=12,912	Mexico N=2,026	Uruguay N=1,805	Poland N=2,973	Romania N=1,174	Russian Federation N=5,426	Turkey N=2,007	Ukraine N=2,741	Egypt ^b N=4,365
Smoke-free a	at work			•	•						•				
Yes	2.09	1.71	1.52	2.29	2.15	1.97	1.35	1.29	1.12	1.45	1.99	1.55	1.64	1.75	1.30
	[1.77, 2.46]	[1.22, 2.41]	[1.20, 1.93]	[1.37, 3.83]	[1.65, 2.79]	[1.45, 2.67]	[1.20, 1.51]	[0.98, 1.70]	[0.79, 1.58]	[1.18, 1.79]	[1.43, 2.76]	[1.30, 1.85]	[1.28, 2.11]	[1.41, 2.18]	[1.09, 1.54]
No	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)
Age (yrs)															
	1.02	1.01	1.02	1.00	1.00	1.02	1.01	0.99	1.02	0.99	1.01	0.99	1.02	1.01	1.02
	[1.01, 1.03]	[0.99, 1.02]	[1.01, 1.04]	[0.98, 1.03]	[0.99, 1.01]	[1.01, 1.03]	[1.003, 1.011]	[0.98, 1.00]	[1.01, 1.03]	[0.98, 1.00]	[0.99, 1.02]	[0.98, 1.00]	[1.01, 1.03]	[0.99, 1.02]	[1.01, 1.03]
Gender															
Male	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)
Female	0.63	0.52	0.93	0.89	0.84	0.73	0.84	1.07	0.89	0.71	0.76	0.52	0.62	0.52	0.58
	[0.53, 0.76]	[0.33, 0.83]	[0.73, 1.17]	[0.46, 1.73]	[0.66, 1.07]	[0.52,1.02]	[0.76, 0.93]	[0.82, 1.38]	[0.73, 1.09]	[0.59, 0.87]	[0.57, 1.03]	[0.43, 0.63]	[0.45, 0.85]	[0.41, 0.66]	[0.48, 0.71]
Residence															
Urban	1.57	1.28	1.31	2.05	3.06	2.01	1.28	1.03	0.81	1.09	0.48	0.75	1.06	0.77	1.31
	[1.32, 1.85]	[0.92, 1.77]	[1.04, 1.64]	[1.21, 3.48]	[2.31, 4.04]	[1.46, 2.77]	[1.01, 1.63]	[0.73, 1.44]	[0.60, 1.10]	[0.86, 1.39]	[0.33, 0.69]	[0.60, 0.93]	[0.81, 1.38]	[0.60, 0.99]	[1.08, 1.60]
Rural	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)
Education															
Primary	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	-	1 (Ref)	1 (Ref)	1 (Ref)	-	-	1 (Ref)	-	1 (Ref)
Secondary	1.58	1.54	1.86	1.43	1.70	1.60	-	0.81	0.98	0.76	1 (Ref)	1 (Ref)	0.98	1 (Ref)	1.23
	[1.34, 1.86]	[1.12, 2.13]	[1.46, 2.37]	[0.70, 2.92]	[1.13, 2.56]	[1.08, 2.36]		[0.57, 1.15]	[0.72, 1.33]	[0.47, 1.24]			[0.77, 1.26]		[0.97, 1.57]
Tertiary	2.26	2.90	2.54	1.47	2.39	0.99	-	0.73	1.06	1.05	1.13	1.04	1.61	1.30	1.60
	[1.83, 2.78]	[1.76, 4.78]	[1.92, 3.36]	[0.56, 3.87]	[1.58, 3.62]	[0.33, 3.02]		[0.49, 1.10]	[0.70, 1.60]	[0.63, 1.74]	[0.82, 1.55]	[0.88, 1.23]	[1.14, 2.28]	[1.03, 1.65]	[1.23, 2.09]
Occupation															
Employed	0.99	1.41	0.86	-	0.74	1.35	1.05	0.89	1.08	1.04	0.44	0.96	0.88	0.86	0.88
	[0.85, 1.15]	[1.02, 1.93]	[0.66, 1.14]		[0.55, 0.99]	[0.97, 1.87]	[0.94, 1.17]	[0.61,1.30]	[0.78, 1.49]	[0.81, 1.35]	[0.27, 0.72]	[0.71, 1.32]	[0.66, 1.16]	[0.59, 1.28]	[0.67, 1.15]
Self	1 (Ref)	1 (Ref)	1 (Ref)	-	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)
employed															
Current smo															
Yes	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)
No	4.49	2.50	3.07	1.67	2.84	2.04	4.53	1.62	4.18	6.07	3.78	3.58	2.47	4.25	7.64
	[3.62, 5.57]	[1.81, 3.47]	[2.34, 4.02]	[0.76, 3.65]	[2.05, 3.92]	[1.35, 3.06]	[3.98, 5.16]	[1.20, 2.19]	[3.09, 5.66]	[4.87, 7.57]	[2.74, 5.22]	[2.93, 4.37]	[1.91, 3.19]	[3.38, 5.35]	[6.04, 9.67]
	keless tobacco														
Yes	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)	-	1 (Ref)	-	1 (Ref)	-	1 (Ref)	1 (Ref)
No	1.84	1.16	1.64	0.68	1.73	0 .22	2.25	3.12	-	0.36	-	2.29	-	0.86	0.90
	[1.54, 2.20]	[0.77, 1.75]	[0.50, 5.40]	[0.09, 5.38]	[0.48, 6.31]	[0.03, 1.59]	[0.78, 6.48]	[0.83,11.68]		[0.06, 2.25]		[0.78, 6.68]		[0.10, 7.72]	[0.44, 1.86]
Number of h	ousehold memb														
	0.96	0.91	0.94	1.12	0.94	0.90	0.98	0.99	0.99	1.01	1.17	1.09	0.96	1.11	0.91
	[0.93, 0.99]	[0.84, 0.99]	[0.89, 1.00]	[0.88, 1.42]	[0.88, 0.99]	[0.81, 0.99]	[0.95, 1.02]	[0.92, 1.06]	[0.90, 1.10]	[0.93, 1.08]	[1.03, 1.32]	[1.01, 1.17]	[0.90, 1.02]	[1.01, 1.21]	[0.85, 0.96]

a Adjusted odds ratios and 95% Cls obtained from country-specific individual-level multivariate logistic regression models adjusted for age, gender, place of residence, education, occupation, current smoking, current smokeless tobacco use and number of household members. A country-specific region variable was also included in the models for India, Thailand, China, Brazil, Poland and Ukraine (not shown in the table to maintain uniformity as regions varied by country).

b Region variable was excluded from the country-specific regression model in Egypt due to collinearity (VIF>13)

4.3.5. Discussion

This study utilised data from the first round of GATS, conducted in 15 LMICs between 2008 and 2011, to examine whether being employed in a smoke-free workplace is associated with living in a smoke-free home. We found positive associations in all of the 15 LMICs studied (13 out of 15 being statistically significant) in individual level countryspecific analysis. The pooled estimate indicated that participants employed in a smokefree workplace were 60% more likely to live in a smoke-free home compared with those that worked where smoking occurred. These findings are consistent with those from previous studies conducted in high income settings. Cheng et al. in a longitudinal study conducted in the USA suggested that living in smoke-free homes was four to seven times more likely among those employed in a 100% smoke-free workplace (compared with those employed in workplaces where smoking occurred).³³ Another longitudinal study found similar reductions in self-reported smoking among smokers in their home after the introduction of comprehensive smoke-free policies in Ireland (85% to 80%; p = 0.002) and the UK (82% to 76%; p = 0.003). An evaluation of the smoke-free policy introduced in New Zealand in 2004 suggested that SHS exposure at workplaces decreased from 20% to 8% and the proportion of smoke-free homes increased from 64% to 70% between 2003 and 2006.110

Article 8 of WHO Framework Convention on Tobacco Control (FCTC) requires Parties to adopt and implement measures to reduce exposure to tobacco smoke in indoor workplaces, indoor public places, public transport and other public places. 16 However, disparities observed in the implementation and enforcement of Article 8 of FCTC in LMICs¹⁷ suggest that these benefits are not being fully realised. Our study identified substantial differences in the percentage of participants employed in a smoke-free workplace who were living in a smoke-free home. This varied from 21% in China to 75% in Mexico. These findings highlight the role of other determinants of SHS exposure in the home, including smoking prevalence, the implementation of other tobacco control strategies and cultural norms, which vary considerably in the countries studied. Knowledge and attitudes about the harms of SHS exposure are also likely to play an important role in variations in the adoption of smoke-free homes.²⁰⁵ A recent study conducted in the United States has shown that clean indoor air laws increase the likelihood of having voluntary smoke-free homes by 3-5%. ³⁶ Despite the observed country-specific variations in the strength of association, the consistency of the observed relationship across major LMIC settings is noteworthy and favours comprehensive smoke-free policies as recommended by the WHO. 199

Our study additionally implies that the benefits which arise out of smoke-free workplace policies are not only restricted to the direct health and economic benefits,²¹ but may also extend to changing societal norms around SHS exposure in the home in LMICs. Truelove et al. suggest that one pro-environmental behaviour may have unintended positive effects on another pro-environmental behaviour, a phenomenon called positive spillover effect, which may be moderated by several factors related to initial decision making, internal and external motivators, and similarity between the two behaviours.²⁰⁶ Similarly, in our case, being employed in a smoke-free workplace was observed to have a positive spillover effect on living in a smoke-free home, which may have been moderated by changing social norms and similarity between the two behaviours. Highlighting the role of social contingencies and cultural influences in SHS exposure, Hovell and Hughes suggest that acceptability of smoking demonstrates an attitude of cultural tolerance towards smoking and SHS exposure, which ultimately leads to widespread recognition of smoking and exposing others to tobacco smoke as normative behaviour.²⁰⁷ Smoke-free policies serve to disrupt such reinforcement of smoking and SHS exposure, thereby aiding effective tobacco control.²⁰⁷ Our findings suggest that smoke-free policies may consistently lead to spreading of smoke-free norms in all of the major LMICs studied, irrespective of country-specific variations in tobacco use and implementation of smoke-free policies. Further, smoke-free policies can bring about behaviour change (quitting or prevention of smoking initiation) through such normative influences.208

Our results show that women were less likely to live in a smoke-free home compared with men in most LMICs studied. This is not surprising given the generally higher prevalence of smoking among men in these settings. 46 Women and children are usually exposed to SHS due to smoking by spouses or other family members at homes in LMICs, many of which still follow patriarchal norms, 209 making it likely that women have little authority over allowance of smoking at home. 210 Other explanations of high SHS exposure among women may include having no household rules for smoking, poor knowledge about the risks of SHS exposure and misconceptions regarding tobacco use. 210 We reiterate the recommendations of Öberg et al., 56 who favour empowering and educating the women in LMICs to promote smoke-free policies to protect themselves and their families from SHS exposure.

In most of the LMICs studied, participants in urban settings were more likely to live in a smoke-free home compared with those from rural settings. This may be explained by the lower prevalence of smoking in urban settings compared to rural settings in LMICs. Moreover, this could also be explained by the typical enclosed structure of urban dwellings, which prevents smoke from dissipating to the outside environment and make smoke undesirable in this setting, compared with the rural dwellings which typically have more open space, that would allow the smoke to dissipate faster into the surrounding outer environment thereby minimizing discomfort due to the smoke.

4.3.5.1. Strengths and limitations

We used nationally representative GATS data from 15 LMICs, which include some of the most populous nations of the world. We found a consistent association between being employed in a smoke-free workplace and living in a smoke-free home across these vastly differing cultural settings, which have different smoking prevalence rates and varying implementation of tobacco control policies, including smoke-free policies. We did not conduct country-specific analyses stratified by the comprehensiveness of SFL (estimated as the percentage of participants employed in smoke-free workplaces) as we did not observe significant changes in the strength of association with increasing levels of comprehensiveness of SFL. Our data were cross-sectional and restricted our ability to determine causal direction. However, in this case, the likelihood of reverse causality i.e. a person living in a smoke-free home resulting in a workplace becoming smoke-free seems unlikely, particularly for larger workplaces. Nevertheless, previous longitudinal studies conducted in high income countries have demonstrated that persons employed in a smoke-free workplace are more likely to live in a smoke-free home prospectively. 33, 35, 36, 110 Standard definitions of SHS exposure at home and SHS exposure at workplace (in past 30 days) as reported in previously published literature were used.^{37, 53, 211, 212} However, it is possible that different definitions (e.g. daily/weekly exposure) may demonstrate different associations. Educational and occupational classifications varied and were not always comparable between GATS countries e.g. occupation in China and education in Brazil. For these, we conducted sensitivity analyses after excluding these variables from the analyses and our results remained substantially unchanged. We relied on self-reported measures of exposure to SHS at home and workplaces in the absence of biological markers such as cotinine levels. However, a good correlation has been shown between cotinine levels and self-reported measures in previous studies.²¹³

4.3.5.2. Policy implications

The United Nations High-Level Meeting on non-communicable diseases (NCDs) in September 2011 recommended establishing tobacco-free workplaces as an important component for NCD prevention and control. Our findings provide some evidence to strengthen the case for rapid implementation of smoke-free policies in LMICs involving complete elimination of smoking and SHS exposure from workplaces. However, additional evidence at the population level showing the implementation of SFL results in an increased population prevalence of smoke-free homes in LMICs would also be compelling. Leadership and action at the national level by governments is the key to strengthening the implementation of smoke-free policies. The Government of Russian Federation recently demonstrated such leadership by enacting new comprehensive tobacco control policies, which resulted in smoke-free policies being extended beyond indoor public places to outdoor public places such as playgrounds and beaches from June 2013. From 2014, all the hospitality venues, shopping areas, public transport, terminals and ports in Russian Federation are required to be 100% smoke-free.

4.3.6. Conclusion

Associations between being employed in a smoke-free workplace and living in a smoke-free home, previously demonstrated in high income countries, also exist in LMICs.

Accelerating implementation of comprehensive smoke-free public place policies is likely to result in substantial population health gain in these settings.

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Student	Gaurang Prafulla Nazar
Principal Supervisor	Professor Neil Pearce
Thesis Title	Smoke-free legislation and active smoking, second hand smoke exposure and health outcomes in low- and middle-income countries.

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B - Paper already published

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When was the work published?	2016;18(5):1	230-1239.							
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Section D – Student's role in multi-authored work

The research paper is authored by Dr. Gaurang P. Nazar, Dr. John Tayu Lee, Dr. Monika Arora and Prof. Christopher Millett in this order. I am the first and the corresponding author. Prof. Christopher Millett is my co-supervisor from Imperial College London. Dr. Monika Arora is my mentor from PHFI (India) for my Wellcome Trust-PHFI funded Ph.D.

- With the guidance of my co-supervisor, I conceptualised this work as a part of this Ph.D. study, wherein it was pre-decided to undertake secondary analyses using GATS data to study various aspects related to SHS exposure.
- I acquired the GATS data for 15 countries from GTSSData website where the data is freely available for download.
- Under the guidance of Prof. Millett and Dr. Lee, I conducted secondary analyses (ran all descriptive statistics, cross-tabulations, statistical tests including regression models and sub-group analyses) on the acquired GATS data from all 15 countries using the statistical software STATA. Specific guidance on statistical methods related to the estimation of indices such as 'Slope index of inequality' and 'Relative index of inequality' involved in this paper was provided by Dr. Lee.
- Apart from data analysis, I also interpreted the statistical outputs and results.
- I further drafted the first cut of the entire paper fully by myself and then shared the paper with the co-authors for their inputs.
- After receiving substantial inputs both in terms of paper writing and data analysis, I further worked on data analysis and revised the paper critically for intellectual content.
- I, with guidance and approval from my co-authors, finalised the paper for submission to the journal.
- I submitted the paper to the journal, handled journal communications related to
 the paper, responded to reviewer queries with the guidance of and consultation
 with the co-authors. After one round of revision, the paper was accepted for
 publication.
- I, as the first and corresponding author of the paper, am responsible and accountable for the accuracy and integrity of all aspects presented in this paper.

4.4. Socioeconomic inequalities in secondhand smoke exposure at home and at work in 15 low- and middle-income countries*

4.4.1. Abstract

4.4.1.1. Introduction

In high-income countries, secondhand smoke (SHS) exposure is higher among disadvantaged groups. We examine socioeconomic inequalities in SHS exposure at home and in the workplace in 15 low- and middle-income countries (LMICs).

4.4.1.2. Methods

Secondary analyses of cross-sectional data from 15 LMICs participating in Global Adult Tobacco Survey (participants ≥ 15 years; 2008–2011) were used. Country-specific analyses using regression-based methods were used to estimate the magnitude of socioeconomic inequalities in SHS exposure: (1) Relative Index of Inequality (2) Slope Index of Inequality.

4.4.1.3. Results

SHS exposure at home ranged from 17.4% in Mexico to 73.1% in Viet Nam; exposure at workplace ranged from 16.9% in Uruguay to 65.8% in Bangladesh. In India, Bangladesh, Thailand, Malaysia, Philippines, Viet Nam, Uruguay, Poland, Turkey, Ukraine, and Egypt, SHS exposure at home reduced with increasing wealth (Relative Index of Inequality range: 1.13 [95% confidence interval (CI) 1.04–1.22] in Turkey to 3.31 [95% CI 2.91–3.77] in Thailand; Slope Index of Inequality range: 0.06 [95% CI 0.02–0.11] in Turkey to 0.43 [95% CI 0.38–0.48] in Philippines). In these 11 countries, and in China, SHS exposure at home reduced with increasing education. In India, Bangladesh, Thailand, and Philippines, SHS exposure at workplace reduced with increasing wealth. In India, Bangladesh, Thailand, Philippines, Viet Nam, Poland, Russian Federation, Turkey, Ukraine, and Egypt, SHS exposure at workplace reduced with increasing education.

^{*} Modified from original publication - <u>Nazar GP</u>, Lee JT, Arora M, Millett C. Socioeconomic Inequalities in Secondhand Smoke Exposure at Home and at Work in 15 Low- and Middle-Income Countries. *Nicotine & Tobacco Research*. 2016;18:1230-9.

4.4.1.4. Conclusion

SHS exposure at homes is higher among the socioeconomically disadvantaged in the majority of LMICs studied; at workplaces, exposure is higher among the less educated. Pro-equity tobacco control interventions alongside targeted efforts in these groups are recommended to reduce inequalities in SHS exposure.

4.4.2. Implications

SHS exposure is higher among the socioeconomically disadvantaged groups in high-income countries. Comprehensive smoke-free policies are pro-equity for certain health outcomes that are strongly influenced by SHS exposure. Using nationally representative Global Adult Tobacco Survey (2008–2011) data from 15 LMICs, we studied socioeconomic inequalities in SHS exposure at homes and at workplaces. The study showed that in most LMICs, SHS exposure at homes is higher among the poor and the less educated. At workplaces, SHS exposure is higher among the less educated groups. Accelerating implementation of pro-equity tobacco control interventions and strengthening of efforts targeted at the socioeconomically disadvantaged groups are needed to reduce inequalities in SHS exposure in LMICs.

4.4.3. Introduction

Exposure to secondhand smoke (SHS) has led to more than 600,000 deaths globally in 2010,⁴⁵ with women and children bearing the maximum brunt of it.⁵⁶ Adverse health outcomes among adults include cardiovascular and respiratory diseases; among children, SHS exposure causes low birth weight, sudden death, and middle ear infections.⁶ Eighty percent of the world's smokers live in the low- and middle-income countries (LMICs), and SHS exposure in homes, workplaces, and other public places in many LMIC settings remains high.⁵³ The World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) recommends comprehensive smoke-free policies to protect people from SHS.¹⁶²

Socioeconomic status (SES) influences tobacco use with higher consumption among the poor and those with less education.¹⁴⁷ A recent study examined socioeconomic inequalities in smoking in LMICs and suggested a similar overall negative gradient in

smoking (smoking being most prevalent among low SES groups) to that documented in high-income countries (HICs).²¹⁷ In LMICs, as in HICs, strong tobacco control policies, including smoke-free regulations, are responsible for changing social norms by promoting smoking as an unacceptable behaviour, thereby protecting the non-smokers from SHS exposure.^{43, 218} Evidence from HICs suggests that SHS exposure is higher among the socioeconomically disadvantaged populations and occurs predominantly at homes and indoor workplaces;⁶ however, there is little nationally representative data available from LMICs on socioeconomic inequalities in SHS exposure in these settings. Understanding the degrees of socioeconomic inequalities in SHS exposure can help identify opportunities to reduce inequalities in health. We examine socioeconomic inequalities in SHS exposure at home and at the workplace in 15 LMICs using nationally representative data from the Global Adult Tobacco Survey (GATS).

4.4.4. Methods

4.4.4.1. Study design, setting, and data

We conducted secondary analysis of the GATS data, which is available freely on the Global Tobacco Surveillance System (GTSS) website¹⁹⁰ of the Centers for Disease Control and Prevention (CDC). GATS is a nationally representative cross-sectional household survey of noninstitutionalized adults aged 15 years and above. 191 It is considered to be the global standard for monitoring adult tobacco use and key tobacco control indicators. GATS employs a standardised survey methodology with a few country-specific variations in the questionnaire and is designed to collect household as well as individual-level data. Multi-stage cluster sampling design is employed in GATS to select a nationally representative study sample. Between 2008 and 2011, the first round of GATS was implemented in 17 LMICs across five WHO regions. 190 Country-specific, anonymous GATS data for 16 of the 17 LMICs (except Indonesia) was available from the CDC GTSSData website. Poland and the Russian Federation are now classified as HICs by the World Bank; however, when the first round of GATS was conducted in these countries in 2009, they belonged to the upper middle-income category. Hence, for the purpose of our study, we treated them as middle-income countries. Further, we excluded Brazil from our data analyses because a key variable of interest, that is, the "wealth index," was not comparable with that of other countries. Therefore, we included data from 15 countries in our analyses.

4.4.4.2. Study participants

We used individual-level data from the first round of GATS (2008–2011) for each of the 15 LMICs. Separate analyses were conducted to examine outcomes for "SHS exposure at home" and "SHS exposure at the workplace." In each country, analyses for the former outcome included all the GATS participants 15 years of age or older, while for the latter outcome, all GATS participants 15 years of age or older, who reported working indoors (or both indoors and outdoors) but outside their home were included as participants. Observations with missing values in the dependent or independent variables were dropped to obtain a final sample for each country.

4.4.4.3. **Measures**

Dependent Variables

SHS Exposure at Home

A participant was considered to be exposed to SHS at home if he/she responded "daily," "weekly," or "monthly" to the question: How often does anyone smoke inside your home? If the participant responded "less than monthly" or "never" to the question, he/she was considered not exposed to SHS at home.

SHS Exposure at Workplace

A participant was considered to be exposed to SHS at the workplace if he/she responded "yes" to the question: "During the past 30 days, did anyone smoke in indoor areas where you work?" If the participant responded "no" to the question, he/she was considered not exposed to SHS at the workplace.

Participants who answered "don't know" or "refused" to answer on either of the questions for the dependent variables were dropped from the study (see Supplementary Tables in Appendix C-2 and Appendix C-3 for further details).

Independent Variables

Wealth Quintile

Using a previously validated method, that is, the inverse possession weighting approach, we computed a summary score from a list of household assets that the participants possessed (e.g., electricity, flush toilet, car, and television).^{219, 220} This approach uses the inverse of the proportion of households with an asset as a weight for the indicator, that is, higher weights are given to least possessed assets.²²¹ We then divided the summary score into wealth quintiles, the lowest quintile being the poorest and the highest quintile being the richest.

Education

Education was grouped into three categories in all countries—completed education up to: primary level (no formal education, less than primary school completed, and primary school completed); secondary level (less than secondary school completed, secondary school completed, and higher secondary school completed); and tertiary level (college/university/postgraduate degree completed).

Other covariates included in the analyses were age group, gender, residence, and occupation. We also included the "geographic region" variable in the model for each country, whenever the variable was available. The countries in which "geographic region" variable was included were India, Thailand, China, Poland, and Ukraine.

4.4.4.4. Statistical methods

We used three regression-based methods to measure different dimensions of socioeconomic inequalities in SHS exposure: (1) Relative Index of Inequality (RII); (2) Slope Index of Inequality (SII); and (3) Adjusted Odds Ratio (AOR). The RII and SII are regression-based summary measures of inequalities that take into account SHS exposure across the entire socioeconomic distribution in the study population, whereas the AOR is the ratio of SHS exposure between each category of the SES variable with its reference category.^{222, 223}

To calculate RII and SII, individuals were cumulatively ranked (ranging from 0 to 1) according to their education and wealth status such that "0" represented the highest wealth/education level and "1" represented the lowest wealth/education level (RIDIT scores). The RIDIT scores for wealth and education were continuous variables unlike the use of these SES variables for calculating AOR where these were categorical variables. RII provides a prevalence rate ratio while SII gives a prevalence rate difference of SHS exposure—between participants with lower wealth/education levels and those with higher wealth/education levels. We used a "modified Poisson" approach, as suggested by Zou to compute SII and RII, which provides more robust estimates as compared to using the binary approach. All analyses for calculations of RII and SII were adjusted for age group and gender. Values of SII larger than 0 and RII values larger than 1 indicate that the poor are more likely to be exposed to SHS compared with the rich; similarly, the less educated are more likely to be exposed to SHS compared with the more educated.

Further, we included interaction terms ([RIDIT scores for wealth levels x gender] and [RIDIT scores for education levels x gender]) in the country-specific generalised linear models to assess if inequalities in SHS exposure at home and at the workplace differed significantly by gender. We found that in the majority of these 15 countries, gender was not an effect-modifier. However, considering the findings of previously published studies,⁵³ and our descriptive findings which suggest that gender differences exist in SHS exposure, we conducted disaggregated analysis by gender.

We also ran country-specific multiple logistic regression models to estimate the relationship between SES and SHS exposure (at home and at the workplace) and calculated AORs comparing the lowest (the reference group) and the higher wealth quintiles, adjusted for age group, gender, residence, education, occupation, and region (for countries in which the variable was available). We tested for multicollinearity between all the covariates adjusted for in the analysis for each country. The multicollinearity diagnostics (variance inflation factor, VIF) were all less than 5, indicating that the assumption of reasonable independence among predictor variables was met. As SII and RII are more robust measures of inequality compared with the AOR, we present only those estimates in this paper. Moreover, the country-specific AOR estimates (Supplementary Figures in Appendix C-4 and Appendix C-5) were broadly consistent with the SII and RII estimates in the majority of the countries studied.

Sampling weights (STATA svy: command) were used to account for the complex, multistage design of the GATS survey throughout the analyses. All the statistical analyses were performed using STATA version 13.1 (StataCorp LP, Texas). Exemption from ethics review for using anonymous secondary data freely available in public domain was obtained from the Research Ethics Committee at the London School of Hygiene and Tropical Medicine and Institutional Ethics Committee at Public Health Foundation of India.

4.4.5. Results

4.4.5.1. Descriptive statistics

Table 4.4 shows that the number of participants ranged from 4091 in Malaysia to 67,006 in India. The percentage of missing values was generally low (less than 5%) for all the 15 countries studied and ranged from 0.1% in Uruguay to 3.7% in Malaysia. SHS exposure at home ranged from 17.4% in Mexico to 73.1% in Viet Nam. In India, Bangladesh, Thailand, Malaysia, the Philippines, and Viet Nam, the proportion of participants exposed to SHS at home was higher among poorer participants compared with that of richer participants. In India, Bangladesh, Thailand, Malaysia, the Philippines, Viet Nam, Uruguay, and Turkey, the proportion of participants exposed to SHS at home was higher among those with lower education compared to those with higher education.

Table 4.5 shows that SHS exposure at workplace ranged from 16.9% in Uruguay to 65.8% in Bangladesh. For this outcome, the proportion of missing cases was generally low (less than 5%) for all the countries studied, except Bangladesh and Malaysia, and ranged from 0.2% in Uruguay to 11.4% in Malaysia. In 14 of the 15 countries studied (except China), the proportion of participants exposed to SHS at the workplace was higher among those with lower education compared to those with higher education. The proportion of male participants exposed to SHS was notably higher as compared with females, particularly at workplaces. Supplementary tables in Appendix C-2 and Appendix C-3 show the numbers and proportion of missing cases in the dependent and independent variables for all the 15 countries for the outcomes "SHS exposure at home" and "SHS exposure at the workplace," respectively.

			Tak	ole 4.4: SHS		t Home amon	g GATS partio			eighted %					
		SEAR				WPR		AN				EUR			EMR
	India N=67,006	Bangladesh N=9,323	Thailand N=20,437	China ^a N=13,302	Malaysia N=4,091	Philippines N=9,578	Viet Nam N=9,866	Mexico N=13,530	Uruguay N=5,576	Poland ^b N=7,640	Romania N=4,472	Russian Federation N=11,321	Turkey ^c N=8,900	Ukraine N=8,092	Egypt N=20,443
Age group (years)															
≥15 to ≤29	39.9	53.3	36.6	68.8	42.2	53.9	75.6	18.5	44.8	46.1	46.1	36.9	64.1	27.4	64.8
≥30 to ≤44	39.8	57.8	32.2	67.3	38.0	54.9	74.6	16.8	32.5	43.4	36.5	37.6	57.2	26.0	62.2
≥45 to ≤59	40.3	54.6	31.2	69.1	36.0	55.6	71.9	17.4	33.5	50.1	38.8	35.8	53.1	25.4	61.9
≥60	39.9	51.4	32.0	61.8	30.8	52.4	64.0	14.9	22.4	36.1	20.9	26.5	39.3	14.5	53.7
Gender	•					•	•	•			•				
Male	40.6	58.2	37.4	70.5	43.2	58.1	77.2	17.3	36.8	45.0	37.8	36.7	56.2	25.3	61.3
Female	39.2	51.2	29.2	63.9	33.3	50.6	69.2	17.5	31.4	43.6	33.2	32.9	56.4	22.0	63.8
Residence	•					•	•	•			•				
Urban	29.4	44.6	25.4	60.1	35.7	43.4	63.3	19.0	34.0	42.9	40.9	35.8	55.1	24.2	57.5
Rural	44.3	58.2	36.7	73.4	45.4	65.2	77.4	11.6	33.7	46.6	28.5	31.1	59.2	21.9	66.8
Education	•	•		•	•		•	•	•	•	•			1	
Up to primary level	46.9	60.7	37.6	69.0	42.4	67.5	77.5	16.0	35.3	46.3	28.7	30.1	57.3	16.3	67.0
Up to secondary level	33.8	46.3	30.9	69.7	39.6	49.4	69.5	17.9	33.1	46.6	35.5	35.6	56.9	25.0	61.9
Up to tertiary level	20.4	21.3	15.4	51.3	25.7	31.1	45.6	20.0	31.0	31.3	39.1	33.5	47.6	20.3	47.5
Wealth Quintile															
Q1 (Poorest)	48.6	67.5	45.2	66.5	52.2	69.5	77.5	11.0	37.3	47.2	35.2	37.2	60.3	23.6	62.5
Q2	42.8	58.3	41.3	73.7	43.8	64.7	77.2	15.0	33.9	45.1	31.0	33.6	55.2	26.1	67.5
Q3	40.8	53.1	33.6	69.0	41.6	59.6	77.2	16.4	33.5	46.2	29.6	33.3	56.1	24.0	64.9
Q4	32.4	51.7	25.3	67.1	35.6	48.4	70.4	20.7	33.9	46.6	40.8	31.4	57.9	24.3	56.6
Q5 (Most affluent)	22.9	38.9	13.5	60.6	28.0	34.6	58.9	19.0	32.8	37.2	36.7	37.3	53.1	20.0	53.9
Occupation															
Govt employee	27.6	34.3	19.0		29.2	44.0	56.1	16.6	33.7	40.0	36.8	33.1	FF 4	21.8	53.0
Non-govt employee	40.5	37.7	36.0	69.7	43.2	53.7	65.4	19.7	37.2	46.0	40.5	40.6	55.4	29.7	64.3
Self-employed	44.1	63.4	34.7	1	47.0	62.1	78.7	16.3	37.2	44.5	34.8	33.6	60.0	28.0	67.5
Student	33.0	42.4	31.4	64.3	31.2	45.8	67.9	18.3	39.3	40.7	44.5	29.2	64.8	21.4	59.4
Others (retd &	39.0	52.7	31.8	55.5	34.4	52.1	63.7	16.2	24.5	40.9	27.0	28.5	52.7	18.3	62.1
homemakers)	44.0	10.1	00.0	00.0	07.4	54.0	04.4	04.0	47.0	50.0	10.1	47.0	00.5	04.5	
Unemployed	44.0	46.1	32.3	63.6	37.4	51.9	64.1	21.2	47.8	58.6	49.4	47.2	69.5	31.5	64.1
% reporting SHS exposure at home	39.9	54.7	33.2	67.3	38.5	54.3	73.1	17.4	33.9	44.2	35.4	34.6	56.3	23.5	62.6
% of missing cases	3.3	3.2	0.6	0.4	3.7	1.3	0.6	0.6	0.1	2.5	1.0	0.7	1.4	0.8	2.3

AMR = Region of the Americas; EMR = Eastern Mediterranean Region; EUR = European Region; GATS = Global Adult Tobacco Survey; SEAR = South-East Asia Region; SHS = secondhand smoke; WPR = Western Pacific Region.

^a For China, it was not possible to distinguish between Government employee, non-government employee or self-employed as occupation categories have been defined differently as compared with other countries. Hence, the category 'Employee' included all those participants who were either 'Agriculture, Forestry, Fishery employee' or 'Transportation, equipment operator' or, 'Business or service industry employee' or 'Leaders of organizations' or 'Clerks' or 'Specialized Technician' or 'Medical and health personnel' or 'Teaching staff' or 'Soldier'.

^b For Poland, it was not possible to distinguish between Government employee and non-government employee categories as occupation categories have been defined differently as compared with other countries. Hence only one category 'employed' was considered to represent 'employed in company/enterprise'.

^c For Turkey, it was not possible to distinguish between Government employee and non-government employee categories as occupation categories have been defined differently as compared with other countries. Hence only one category 'employed' was considered to represent 'Paid employee'.

			ole 4.5: SHS ex	posure at Wo		g GATS participa	nts employed			home (2008-2	011) – Weighte				
		SEAR			V	VPR			MR			EUR			EMR
	India N=12,852	Bangladesh N=1,704	Thailand N=5,021	Chinaª N=1,859	Malaysia N=996	Philippines N=2,152	Viet Nam N=2,419	Mexico N=2,082	Uruguay N=1,796	Poland ^b N=3,030	Romania ^c N=1,175	Russian Federation N=5,464	Turkey ^b N=2,160	Ukraine N=2,761	Egypt N=4,490
Age group (years)															
≥15 to ≤29	31.4	64.6	20.8	63.7	40.9	26.6	49.3	18.4	18.3	31.0	38.8	38.4	37.8	32.3	59.5
≥30 to ≤44	29.5	65.5	27.1	62.9	38.9	33.1	61.3	17.8	16.7	33.5	32.9	37.2	36.9	34.1	60.7
≥45 to ≤59	29.9	68.7	29.9	72.5	41.6	37.5	58.2	22.2	16.8	35.4	34.1	35.2	38.4	30.3	59.7
≥60	30.6	67.0	38.2	64.5	34.0	45.1	69.4	19.1	12.7	39.2	24.6	25.9	34.8	33.9	56.8
Gender			•		•										•
Male	32.7	70.3	33.2	77.1	46.6	38.5	68.9	22.2	21.9	41.6	36.8	48.2	40.5	43.3	61.6
Female	17.9	29.2	18.5	47.5	30.2	25.5	41.4	13.8	11.9	24.5	31.4	26.3	27.6	21.9	54.2
Residence	l .		I.	l .	I.			l .		ı				l .	
Urban	27.9	59.7	23.4	65.2	42.2	24.9	52.8	18.9	16.8	31.4	35.2	37.2	35.6	32.5	59.1
Rural	32.7	69.9	28.3	65.9	32.5	45.9	59.1	18.0	20.3	38.3	31.9	32.9	45.1	32.5	60.9
Education													-		
Up to primary level	38.7	70.9	38.1	70.8	52.8	52.1	60.9	21.9	20.2	50.9		52.0	43.1	63.6	63.6
Up to secondary	29.5	62.2	22.6	64.6	38.9	29.9	54.5	19.2	16.7	36.8	36.1	41.7	37.8	35.7	61.0
level															
Up to tertiary level	20.4	54.4	18.9	65.5	38.8	21.2	39.5	15.9	10.8	23.1	30.0	31.5	25.4	26.2	55.2
Wealth Quintile			•		•										•
Q1 (Poorest)	35.5	68.6	35.4	61.8	47.7	45.3	58.7	16.5	20.7	37.4	36.4	36.7	39.8	34.2	62.5
Q2	37.2	68.2	29.8	66.7	31.1	41.0	56.3	20.3	14.1	31.1	35.4	34.1	31.2	36.1	58.6
Q3	31.0	65.8	25.9	69.0	44.4	30.3	59.4	19.3	20.6	34.6	30.6	35.3	34.4	34.9	62.8
Q4	28.5	68.2	25.9	68.1	40.7	31.8	53.9	17.3	18.6	32.7	36.9	36.9	39.7	27.5	60.6
Q5 (Most affluent)	23.6	60.3	17.3	60.3	38.7	26.4	53.5	19.4	13.9	33.7	32.8	38.7	41.8	33.1	54.9
Occupation					•		•			•		•			l.
Govt. employee	21.9	56.1	21.6	_	29.3	26.3	46.3	12.6	15.1		34.6	30.5		28.6	58.6
Non-govt employee	28.5	41.8	24.6	_	40.6	25.8	33.4	19.5	16.4	32.1	33.2	40.8	32.3	34.6	60.8
Self-employed	35.4	74.4	36.6	_	54.3	55.7	70.6	21.9	21.3	42.7	42.2	43.2	53.1	40.1	60.9
% exposed to SHS at workplace	30.3	65.8	26.0	65.5	40.1	32.2	56.2	18.8	16.9	33.6	34.3	36.3	37.4	32.5	59.9
% of missing cases	4.9	6.0	1.2	0.6	11.4	0.8	0.9	0.9	0.2	2.4	1.4	2.1	0.5	1.9	0.6

AMR = Region of the Americas; EMR = Eastern Mediterranean Region; EUR = European Region; GATS = Global Adult Tobacco Survey; SEAR = South-East Asia Region; SHS = secondhand smoke; WPR = Western Pacific Region.

^a Occupation categories in China differed from those of other LMICs. Five occupation categories were considered for China: Agriculture, forestry, fishery employee (78.5%); transportation equipment operator (61.7%); government, party, organization, company (73.3%); medical, health personnel (55.4%); teaching staff (54.8%). Not presented in table to maintain uniformity.

For Poland and Turkey, categorization of occupation into 'Government employee' was not possible due to the way categories were defined hence the categories were merged into one category 'Employee'.

[°] For Romania, the category educated up to primary level contained only one participant hence, this category was merged with educated up to secondary level for further analysis.

4.4.5.2. Socioeconomic inequalities in SHS exposure at home

Table 4.6 presents the RII and SII estimates and their 95% confidence intervals (CIs), respectively, for wealth and education inequality in SHS exposure at home. These comparisons are also shown graphically in the supplementary figure in Appendix C-6.

Socioeconomic inequalities by wealth

In 11 of the 15 countries studied (India, Bangladesh, Thailand, Malaysia, the Philippines, Viet Nam, Uruguay, Poland, Turkey, Ukraine, and Egypt), the RII estimates were more than 1 and the SII estimates were more than 0, indicating that the poor are more likely to be exposed to SHS at home compared with the rich. There was substantial variation between the countries in SHS exposure at home by levels of wealth. The RII estimates ranged from 1.13 (95% CI 1.04–1.22) in Turkey to 3.31 (95% CI 2.91–3.77) in Thailand, while the SII estimates ranged from 0.06 (95% CI 0.02–0.11) in Turkey to 0.43 (95% CI 0.38–0.48) in the Philippines. There was a different statistically significant association in Mexico (RII 0.57 95% CI 0.43–0.75) which suggested that the rich were more exposed to SHS at home than the poor.

Socioeconomic inequalities by education

In 12 of the 15 countries studied (India, Bangladesh, Thailand, China, Malaysia, the Philippines, Viet Nam, Uruguay, Poland, Turkey, Ukraine, and Egypt), RII estimates and their CIs were more than 1 and SII estimates and their CIs were more than 0 indicating that in these countries, those with less education are more likely to be exposed to SHS at home compared with the more educated. There was substantial variation between the countries in SHS exposure at home by levels of education. The RII estimates ranged from 1.28 (95% CI 1.16–1.43) in Turkey to 2.65 (95% CI 2.43–2.88) in India, while the SII estimates ranged from 0.07 (95% CI 0.02–0.12) in Ukraine to 0.48 (95% CI 0.43–0.53) in the Philippines.

Table 4.6 also presents findings of disaggregated analysis by gender for socioeconomic inequalities in SHS exposure at home. The results were in line with the overall observations made above; and for a majority of the countries, no significant gender differences were observed. Significant wealth inequality in SHS exposure at home was observed only among males in China, Uruguay, Turkey and Ukraine while significant education inequality in SHS exposure at home was observed only among males in Uruguay and the Russian Federation; and only among females in Ukraine.

					omic inequality	in Secondnand	Smoke (SHS)	exposure at no		ion incomplian		
Region/Country		RII [95% CI]	vveait	h inequality	SII [95% CI]			RII [95% CI]	Educat	ion inequality	SII [95% CI]	
Region/Country	Males	Females	Totala	Males	Females	Total ^b	Males	Females	Totala	Males	Females	Totalb
SEAR	waies	remaies	I Otala	wates	remaies	I Otal v	Iviales	remaies	I Otala	Maies	remaies	Total
India	1.99	2.28	2.12	0.28	0.32	0.30	2.41	3.09	2.65	0.36	0.42	0.38
(N=67,006)	[1.78, 2.22]	[2.04, 2.56]	[1.94, 2.32]	[0.24, 0.33]	[0.28, 0.36]	[0.27, 0.33]	[2.18, 2.68]	[2.70, 3.54]	[2.43, 2.88]	[0.32, 0.40]	[0.37, 0.46]	[0.35, 0.41]
Bangladesh	1.92	1.67	1.81	0.38	0.27	0.32	2.3	1.98	2.14	0.47	0.35	0.41
(N=9,323)	[1.66, 2.23]	[1.45, 1.92]	[1.62, 2.02]	[0.30, 0.47]	[0.20, 0.34]	[0.27, 0.38]	[1.93, 2.74]	[1.61, 2.42]	[1.87, 2.44]	[0.38, 0.56]	[0.26, 0.45]	[0.34, 0.47]
Thailand	3.48	3.09	3.31	0.48	0.35	0.41	2.65	2.61	2.62	0.37	0.31	0.33
(N=20,437)	[2.96, 4.10]	[2.60, 3.67]	[2.91, 3.77]	[0.42, 0.54]	[0.30, 0.40]	[0.37, 0.45]	[2.19, 3.20]	[2.06, 3.29]	[2.24, 3.07]	[0.31, 0.42]	[0.25, 0.36]	[0.29, 0.38]
WPR	[2.00,0]	[=:00, 0:0:]	[=.0., 0]	[0.12, 0.01]	[0.00, 0.10]	[0.0., 00]	[=::0, 0:=0]	[=:00, 0:=0]	[, 0.0.]	[0.0., 0]	[0:20, 0:00]	[0:20, 0:00]
China	1.19	1.09	1.15	0.13	0.06	0.10	1.38	1.32	1.35	0.24	0.19	0.22
(N=13,302)	[1.02, 1.38]	[0.93, 1.28]	[0.99, 1.32]	[0.02, 0.24]	[-0.05, 0.17]	[-0.01, 0.20]	[1.22, 1.56]	[1.15, 1.51]	[1.21, 1.51]	[0.14, 0.34]	[0.10, 0.28]	[0.13, 0.30]
Malaysia	2.26	1.78	2.08	0.38	0.19	0.29	2.24	1.71	2.05	0.40	0.19	0.30
(N=4,091)	[1.73, 2.95]	[1.32, 2.39]	[1.68, 2.56]	[0.26, 0.49]	[0.09, 0.30]	[0.20, 0.37]	[1.69, 2.96]	[1.17, 2.51]	[1.64, 2.58]	[0.26, 0.53]	[0.06, 0.32]	[0.20, 0.39]
Philippines	1.95	2.30	2.10	0.41	0.45	0.43	2.48	2.31	2.40	0.53	0.43	0.48
(N=9,578)	[1.75, 2.19]	[2.03, 2.60]	[1.92, 2.30]	[0.34, 0.47]	[0.39, 0.51]	[0.38, 0.48]	[2.17, 2.84]	[2.01, 2.66]	[2.16, 2.67]	[0.46, 0.61]	[0.36, 0.50]	[0.43, 0.53]
Viet Nam	1.35	1.24	1.29	0.24	0.15	0.20	1.35	1.36	1.35	0.23	0.22	0.22
(N=9,866)	[1.26, 1.45]	[1.15, 1.33]	[1.22, 1.37]	[0.18, 0.29]	[0.10, 0.21]	[0.15, 0.24]	[1.24, 1.47]	[1.25, 1.48]	[1.26, 1.44]	[0.17, 0.30]	[0.16, 0.29]	[0.18, 0.27]
AMR												
Mexico	0.58	0.56	0.57	-0.09	-0.11	-0.10	0.84	0.74	0.78	-0.03	-0.05	-0.04
(N=13,530)	[0.39, 0.87]	[0.43, 0.73]	[0.43, 0.75]	[-0.16, -0.02]	[-0.15, -0.06]	[-0.15, -0.05]	[0.55, 1.28]	[0.51, 1.07]	[0.57, 1.07]	[-0.10, 0.04]	[-0.12, 0.01]	[-0.09, 0.01]
Uruguay	1.37	1.22	1.30	0.12	0.03	0.07	1.57	1.25	1.41	0.16	0.05	0.10
(N=5,576)	[1.08, 1.74]	[0.90, 1.66]	[1.06, 1.60]	[0.03, 0.20]	[-0.05, 0.12]	[0.01, 0.14]	[1.14, 2.16]	[0.90, 1.72]	[1.09, 1.82]	[0.05, 0.28]	[-0.03, 0.14]	[0.03, 0.18]
EUR												
Poland	1.53	1.27	1.39	0.18	0.10	0.14	1.88	1.52	1.66	0.31	0.18	0.23
(N=7,640)	[1.26, 1.86]	[1.09, 1.47]	[1.23, 1.56]	[0.10, 0.26]	[0.03, 0.16]	[0.09, 0.19]	[1.56, 2.26]	[1.28, 1.82]	[1.45, 1.89]	[0.22, 0.39]	[0.10, 0.26]	[0.17, 0.29]
Romania	1.06	0.94	1.00	0.01	-0.03	-0.02	0.96	0.94	0.94	-0.01	-0.01	-0.01
(N=4,472)	[0.81, 1.39]	[0.70, 1.27]	[0.82, 1.23]	[-0.08, 0.10]	[-0.12, 0.05]	[-0.08, 0.05]	[0.66, 1.39]	[0.64, 1.40]	[0.71, 1.23]	[-0.14, 0.12]	[-0.11, 0.09]	[-0.09, 0.07]
Russian Federation	1.20	0.91	1.04	0.06	-0.03	0.01	1.29	1.10	1.15	0.09	0.05	0.05
(N=11,321)	[0.97, 1.47]	[0.73, 1.14]	[0.88, 1.23]	[-0.01, 0.13]	[-0.10, 0.03]	[-0.04, 0.06]	[1.01, 1.65]	[0.88, 1.37]	[0.98, 1.36]	[0.00, 0.17]	[-0.03, 0.12]	[-0.01, 0.11]
Turkey	1.20	1.06	1.13	0.10	0.03	0.06	1.20	1.40	1.28	0.11	0.19	0.14
(N=8,900)	[1.07, 1.34]	[0.95, 1.19]	[1.04, 1.22]	[0.04, 0.16]	[-0.04, 0.09]	[0.02, 0.11]	[1.05, 1.37]	[1.20, 1.64]	[1.16, 1.43]	[0.03, 0.18]	[0.11, 0.28]	[0.09, 0.20]
Ukraine	2.06	1.26	1.63	0.17	0.02	0.09	1.08	1.91	1.43	0.02	0.10	0.07
(N=8,092)	[1.61, 2.62]	[0.93, 1.72]	[1.33, 1.99]	[0.11, 0.24]	[-0.03, 0.08]	[0.04, 0.13]	[0.78, 1.50]	[1.28, 2.85]	[1.11, 1.84]	[-0.07, 0.10]	[0.03, 0.17]	[0.02, 0.12]
EMR	104	4.40	1.40	0.44	0.00	0.44	4 54	1 40	1 40	0.00	0.00	0.00
Egypt	1.24	1.12	1.18	0.14	0.08	0.11	1.51	1.48	1.49	0.26	0.26	0.26
(N=20,443) MR = Region of the Amer	[1.15, 1.34]	[1.05, 1.20]	[1.12, 1.23]	[0.09, 0.19]	[0.03, 0.12]	[0.08, 0.14]	[1.39, 1.64]	[1.36, 1.61]	[1.41, 1.58]	[0.21, 0.31]	[0.21, 0.31]	[0.22, 0.30]

AMR = Region of the Americas; CI = confidence interval; EMR = Eastern Mediterranean Region; EUR = European Region; GATS = Global Adult Tobacco Survey; SEAR = South-East Asia Region; SHS = secondhand smoke; WPR = Western Pacific Region. Bold values indicate significance level P < .05.

a RII (Relative Index of Inequality) values estimated from country-specific individual-level generalised linear models adjusted for age group and gender. A value > 1 indicates that: the poor are more likely to be exposed to SHS at home compared with the rich (in case of wealth inequality) and the less educated are more likely to be exposed to SHS at home compared with the more educated (in case of education inequality)

b SII (Slope Index of Inequality) values estimated from country-specific individual-level generalised linear models adjusted for age group and gender. A value > 0 indicates that: the poor are more likely to be exposed to SHS at home compared with the rich (in case of wealth inequality) and the less educated are more likely to be exposed to SHS at home compared with the more educated (in case of education inequality).

4.4.5.3. Socioeconomic inequalities in SHS exposure at workplace

Table 4.7 presents the RII and SII estimates and their 95% CIs, respectively for wealth and education inequality in SHS exposure at the workplace. These comparisons are also shown graphically in the supplementary figure in Appendix C-7.

Socioeconomic inequalities by wealth

In four of the 15 countries studied (India, Bangladesh, Thailand, and the Philippines), RII estimates and their CIs were more than 1 and SII estimates and their CIs were more than 0 indicating that in these countries, the poor are more likely to be exposed to SHS at workplace compared with the rich. Variation was observed between the countries in SHS exposure at the workplace by levels of wealth. The RII estimates ranged from 1.18 (95% CI 1.00–1.40) in Bangladesh to 2.30 (95% CI 1.83–2.90) in Thailand, while the SII estimates ranged from 0.12 (95% CI 0.01–0.23) in Bangladesh to 0.22 (95% CI 0.12–0.31) in the Philippines.

Socioeconomic inequalities by education

In 10 of the 15 countries studied (India, Bangladesh, Thailand, the Philippines, Viet Nam, Poland, the Russian Federation, Turkey, Ukraine, and Egypt), RII estimates and their CIs were more than 1 and SII estimates and their CIs were more than 0 indicating that in these countries, those with less education are more likely to be exposed to SHS at workplace compared with the more educated. Substantial variation was observed between the countries in SHS exposure at the workplace by levels of education. The RII estimates ranged from 1.17 (95% CI 1.02–1.33) in Egypt to 3.22 (95% CI 2.39–4.34) in the Philippines, while the SII estimates ranged from 0.10 (95% CI 0.02–0.18) in Egypt to 0.35 (95% CI 0.25–0.45) in the Philippines.

Table 4.7 also presents findings of disaggregated analysis by gender for socioeconomic inequalities in SHS exposure at the workplace. In Bangladesh, wealth inequality in SHS exposure at the workplace was not observed among males and females independently, while education inequality was observed only among males in Bangladesh, the Russian Federation, Turkey, and Ukraine but not among females; and was not observed among either males or females in Egypt. However, in almost half of the countries, the results were in conformity with the overall observations made above with no significant gender differences.

	1				c inequality in Se	conunana Sin	oke (SHS) expo	Suite at Workp		n incorrelity		
Danian/Causton		DU IOSO/ OII	wealth	inequality	011 (050/ 011			DII 10.50/ OII	Educatio	n inequality	011 5050/ 011	
Region/Country		RII [95% CI]			SII [95% CI]	T = 4 h		RII [95% CI]			SII [95% CI]	-
	Males	Females	Totala	Males	Females	Totalb	Males	Females	Total ^a	Males	Females	Total⁵
SEAR					1	1	I		1	I		
India	1.59	3.86	1.70	0.16	0.20	0.17	2.16	4.74	2.30	0.27	0.24	0.26
(N=12,852)	[1.29, 1.96]	[2.21, 6.76]	[1.40, 2.08]	[0.09, 0.24]	[0.10, 0.29]	[0.11, 0.24]	[1.76, 2.65]	[2.50, 8.99]	[1.90, 2.80]	[0.20, 0.34]	[0.13, 0.35]	[0.20, 0.32]
Bangladesh	1.18	1.53	1.18	0.12	0.13	0.12	1.37	1.32	1.36	0.22	0.08	0.20
(N=1,704)	[0.99, 1.39]	[0.65, 3.62]	[1.00, 1.40]	[-0.01, 0.24]	[-0.18, 0.43]	[0.01, 0.23]	[1.14, 1.63]	[0.53, 3.28]	[1.14, 1.63]	[0.09, 0.34]	[-0.20, 0.35]	[0.08, 0.31]
Thailand	2.51	1.88	2.30	0.30	0.14	0.21	3.00	1.94	2.65	0.38	0.13	0.23
(N=5,021)	[1.89, 3.35]	[1.30, 2.73]	[1.83, 2.90]	[0.20, 0.40]	[0.06, 0.23]	[0.15, 0.28]	[2.21, 4.07]	[1.18, 3.19]	[2.07, 3.40]	[0.27, 0.49]	[0.03, 0.22]	[0.16, 0.30]
WPR							T			T		
China	0.95	1.52	1.02	-0.05	0.22	0.03	0.97	1.23	1.00	-0.03	0.09	0.01
(N=1,859)	[0.76, 1.18]	[0.94, 2.47]	[0.82, 1.26]	[-0.22, 0.12]	[-0.04, 0.48]	[-0.12, 0.18]	[0.75, 1.25]	[0.71, 2.10]	[0.78, 1.28]	[-0.22, 0.16]	[-0.16, 0.34]	[-0.16, 0.17]
Malaysia	1.02	1.23	1.07	0.01	0.07	0.04	1.47	1.62	1.51	0.17	0.14	0.16
(N=996)	[0.64, 1.61]	[0.55, 2.73]	[0.72, 1.57]	[-0.20, 0.22]	[-0.16, 0.31]	[-0.11, 0.19]	[0.87, 2.51]	[0.60, 4.38]	[0.95, 2.40]	[-0.07, 0.42]	[-0.13, 0.40]	[-0.02, 0.33]
Philippines	1.87	2.08	1.94	0.25	0.19	0.22	3.81	2.37	3.22	0.51	0.24	0.35
(N=2,152)	[1.37, 2.56]	[1.33, 3.27]	[1.49, 2.53]	[0.12, 0.39]	[0.07, 0.31]	[0.12, 0.31]	[2.64, 5.50]	[1.52, 3.69]	[2.39, 4.34]	[0.37, 0.65]	[0.11, 0.36]	[0.25, 0.45]
Viet Nam	1.27	0.98	1.21	0.17	-0.02	0.09	1.31	1.43	1.34	0.19	0.14	0.17
(N=2,419)	[1.07, 1.50]	[0.67, 1.42]	[1.03, 1.42]	[0.04, 0.29]	[-0.16, 0.12]	[-0.01, 0.19]	[1.08, 1.58]	[1.01, 2.05]	[1.12, 1.59]	[0.05, 0.33]	[-0.03, 0.31]	[0.06, 0.29]
AMR												
Mexico	1.36	0.40	1.00	0.07	-0.10	-0.02	1.66	1.06	1.46	0.12	0.01	0.07
(N=2,082)	[0.79, 2.34]	[0.13, 1.21]	[0.58, 1.72]	[-0.06, 0.21]	[-0.21, 0.01]	[-0.12, 0.07]	[1.05, 2.60]	[0.45, 2.50]	[0.99, 2.17]	[0.01, 0.23]	[-0.11, 0.12]	[-0.01, 0.14]
Uruguay	1.43	1.39	1.42	0.08	0.04	0.06	1.41	2.38	1.69	0.07	0.12	0.10
(N=1,796)	[0.84, 2.42]	[0.64, 3.02]	[0.92, 2.21]	[-0.04, 0.21]	[-0.06, 0.15]	[-0.02, 0.14]	[0.74, 2.69]	[0.99, 5.77]	[0.96, 2.96]	[-0.07, 0.21]	[-0.01, 0.25]	[0.00, 0.20]
EUR												
Poland	1.18	0.79	1.06	0.07	-0.06	0.00	2.47	2.12	2.36	0.39	0.18	0.27
(N=3,030)	[0.93, 1.50]	[0.49, 1.29]	[0.85, 1.31]	[-0.03, 0.18]	[-0.16, 0.05]	[-0.07, 0.08]	[1.80, 3.38]	[1.28, 3.51]	[1.82, 3.07]	[0.25, 0.53]	[0.06, 0.29]	[0.18, 0.35]
Romania	0.93	1.20	1.02	-0.03	0.06	0.01	1.75	1.19	1.45	0.19	0.05	0.12
(N=1,175)	[0.56, 1.53]	[0.55, 2.63]	[0.66, 1.57]	[-0.22, 0.16]	[-0.18, 0.29]	[-0.14, 0.16]	[0.93, 3.28]	[0.60, 2.35]	[0.91, 2.31]	[0.00, 0.39]	[-0.15, 0.25]	[-0.03, 0.26]
Russian Federation	1.04	0.97	1.01	0.02	-0.01	0.00	1.97	1.32	1.73	0.32	0.07	0.17
(N=5,464)	[0.83, 1.32]	[0.68, 1.37]	[0.82, 1.25]	[-0.08, 0.13]	[-0.10, 0.08]	[-0.07, 0.07]	[1.51, 2.57]	[0.84, 2.06]	[1.36, 2.19]	[0.20, 0.44]	[-0.05, 0.18]	[0.08, 0.25]
Turkey	0.81	0.64	0.78	-0.08	-0.13	-0.09	1.79	1.57	1.74	0.24	0.14	0.21
(N=2,160)	[0.61, 1.07]	[0.33, 1.25]	[0.61, 1.00]	[-0.18, 0.02]	[-0.31, 0.05]	[-0.18, 0.00]	[1.37, 2.34]	[0.87, 2.86]	[1.36, 2.23]	[0.13, 0.36]	[-0.04, 0.32]	[0.12, 0.31]
Ukraine	1.35	1.20	1.32	0.13	0.04	0.08	2.38	1.21	1.93	0.34	0.04	0.16
(N=2,761)	[1.02, 1.78]	[0.73, 1.98]	[1.02, 1.70]	[0.01, 0.25]	[-0.07, 0.16]	[-0.01, 0.17]	[1.65, 3.42]	[0.66, 2.24]	[1.41, 2.64]	[0.21, 0.48]	[-0.09, 0.17]	[0.06, 0.25]
EMR		•					•	•		•		
Egypt	1.05	1.07	1.05	0.03	0.04	0.03	1.14	1.36	1.17	0.08	0.17	0.10
(N=4,490)	[0.92, 1.19]	[0.82, 1.39]	[0.94, 1.17]	[-0.05, 0.11]	[-0.12, 0.20]	[-0.04, 0.10]	[0.98, 1.32]	[0.99, 1.86]	[1.02, 1.33]	[-0.01, 0.18]	[-0.01, 0.34]	[0.02, 0.18]

AMR = Region of the Americas; CI = confidence interval; EMR = Eastern Mediterranean Region; EUR = European Region; GATS = Global Adult Tobacco Survey; SEAR = South-East Asia Region; SHS = secondhand smoke; WPR =

Western Pacific Region. Bold values indicate significance level P < .05.

a RII (Relative Index of Inequality) values estimated from country-specific individual-level generalised linear models adjusted for age group and gender. A value > 1 indicates that: the poor are more likely to be exposed to SHS at workplace compared with the rich (in case of wealth inequality) and the less educated are more likely to be exposed to SHS at workplace compared with the more educated (in case of education inequality).

b SII (Slope Index of Inequality) values estimated from country-specific individual-level generalised linear models adjusted for age group and gender. A value > 0 indicates that: the poor are more likely to be exposed to SHS at workplace compared with the rich (in case of wealth inequality) and the less educated are more likely to be exposed to SHS at workplace compared with the more educated (in case of education inequality).

4.4.6. Discussion

Our study of socioeconomic inequalities in SHS exposure at homes and at workplaces in LMIC settings indicates that the poor are more likely to be exposed to SHS at home than the rich in 11 out of the 15 countries studied. The association was not so consistent between being poor and exposure to SHS at the workplace and was observed only in four out of the 15 countries studied. Less educated participants were consistently more likely to be exposed to SHS at home and at the workplace. Despite the observed gender differences in SHS exposure (particularly at the workplace) in the LMIC settings studied, and as reported in earlier studies, ^{53, 147} we did not find significant gender differences in socioeconomic inequalities in SHS exposure at home in the majority of countries studied. In the case of SHS exposure at the workplace, we found some evidence that education inequality was observed only among males in some of the countries studied; however, in almost half of the countries studied, there were no significant gender differences.

Our key findings are consistent with limited available data from LMIC settings. A study assessing correlates of SHS exposure at home among non-smoking adults in Bangladesh suggested that groups with lower educational attainment and literacy were more than twice as likely to be exposed to SHS at home than groups with higher educational attainment.²²⁵ A study conducted in Viet Nam using GATS data suggested that participants who had attained tertiary, high school, and secondary education were 60%, 40%, and 30% less likely to be exposed to SHS at home, respectively, as compared with those who had attained only primary education.²²⁶ Another study conducted with adult participants in rural China showed that participants who did not complete high school education and who had low income were more likely to be exposed to SHS at home.²²⁷ Similar findings have been reported in studies from HICs.^{6,155,228}

Palipudi et al. studied the socioeconomic determinants of active tobacco use in 13 GATS countries (excluding Malaysia and Romania which have been included in our analyses) and concluded that current tobacco use (including current smoking or smokeless tobacco use, either daily or occasionally) increased with decrease in education levels in India, Bangladesh, Thailand, the Philippines, and Egypt; however there was an inverse association between tobacco use and education levels in

Turkey. 147 We found that SHS exposure at home increased with a decrease in education levels in 12 countries including the five countries mentioned above for current tobacco use, as well as Turkey. The more consistent social patterning of SHS exposure (than active tobacco use) across countries found here may be explained by differences in social norms around exposing others to SHS in different socioeconomic groups within these settings.

4.4.6.1. Strengths and limitations

Our study is based on findings from large nationally representative datasets from 15 LMICs where the majority of the world's smokers reside. We present RII and SII estimates as these are considered to be more robust measures of socioeconomic inequality compared with AORs.^{222, 223} Our study focused on socioeconomic inequalities in exposure to SHS at home and indoor workplaces as these are the two settings in which SHS exposure predominantly occurs.⁶ For the latter, we restricted our sample by excluding participants working exclusively outdoors (e.g. farmers and outdoor labourers), students, homemakers, the retired, and the unemployed. This may partly explain the absence of a socioeconomic gradient in SHS exposure in the workplace in several LMICs studied. Standard definitions of SHS exposure at home and SHS exposure at the workplace (in past 30 days) as reported in the previously published literature were used.^{37, 53, 211, 212} However, it is possible that different definitions (e.g. daily/weekly exposure) may demonstrate different associations. We were unable to examine occupation-based measures of SES as GATS provides limited information about occupational grades. Further, in the case of education variable, we merged "no formal education" with the next higher category "up to primary level" because participants in that category accounted for less than 10% of the study sample for a majority of the countries studied. For remaining countries, in which the percentage of participants in the "no formal education" category was more than 10%, we conducted sensitivity analyses by separating "no formal education" and "up to primary level" categories and found that our results remained unchanged. The authors acknowledge the heterogeneity that exists among the various LMICs studied in terms of the stage of tobacco epidemic, tobacco control policies, and diverse patterns in socioeconomic inequality; however, the fact that GATS provides uniform data from these countries allows broad comparisons to be drawn across these countries through studies such as ours and those previously published.¹⁴⁷ Data from the first round of GATS is now at least four years old and may not reflect the current state of inequalities in SHS exposure, given the fact that tobacco control efforts (particularly smoke-free policies) have been

strengthened in some settings. We relied on self-reported measures of exposure to SHS at homes and workplaces in the absence of biological markers such as cotinine levels. Although earlier studies indicate a good correlation between cotinine levels and self-reported measures, 213 more recent studies suggest that self-reported measures of SHS exposure at home and at workplace often underestimate the true prevalence of SHS exposure in the absence of biomarkers such as serum cotinine. 229 Future studies in LMICs should examine changes in SHS exposure and related socioeconomic inequalities over time and/or assess pre–post smoke-free legislation implementation changes.

4.4.6.2. Policy implications

Our results show that SHS exposure at homes and at workplaces is high in a majority of the LMIC settings studied, reflecting considerable variation between countries. The study indicates that socioeconomic inequalities exist in exposure to SHS at homes as well as at workplaces (to some extent) in these settings. Nearly 71% of middle-income and 88% of low-income countries are still not protected by comprehensive smoke-free policies.²³ Findings of the systematic review presented in Chapter 3 of my thesis and earlier studies have shown that voluntary, regional, or partial smoke-free policies are not likely to be effective and will often be equity negative. 21, 161 Reasonably good evidence suggests that comprehensive smoke-free policies have an equity positive or neutral effect on health outcomes strongly influenced by SHS exposure. For example, recent work has shown that comprehensive smoke-free legislation in England was associated with a greater reduction in admissions for respiratory tract infections in children from lower SES groups. 122 However, comprehensively enforced smoke-free policies may be less likely to be implemented in low SES settings. 155 To address socioeconomic inequalities in SHS exposure at work, there is a need for accelerated implementation of comprehensive smoke-free policies. 161 Addressing inequalities in SHS exposure at home would require addressing both inequalities in the prevalence of smoking and inequalities in social norms about exposing non-smokers to SHS. To reduce inequalities in smoking, the implementation of tobacco control policies needs to be strengthened particularly interventions that have been shown to be pro-equity, such as increasing tobacco taxation.²³⁰ Focused efforts are required to address social norms around exposing others to SHS (e.g. awareness through mass media campaigns and other educational interventions), targeting the socioeconomically disadvantaged groups. Smoke-free policies have been shown to have a positive influence on social norms concerning SHS exposure at home.⁴³

4.4.7. Conclusion

SHS exposure at home is higher among the socioeconomically disadvantaged groups (the poor and the less educated) in the majority of LMICs studied. SHS exposure at the workplace is higher among the less educated groups in the majority of LMICs studied. Accelerated implementation of pro-equity tobacco control interventions, including increased taxation, along with targeted efforts among the socioeconomically disadvantaged groups are needed to reduce both, inequalities in SHS exposure as well as tobacco smoking in LMICs.

4.5. Summary

To summarise, this chapter has provided a description of the GTSS and the GATS, followed by the results of two different analyses undertaken using GATS data from 15 LMICs. The first paper concluded that being employed at smoke-free workplaces is significantly associated with living in smoke-free homes, indicating that such policies can bring about a change in social norms around exposing others to SHS. This shows the potential of SFL to bring about additional health benefits, particularly among women and children, who are most exposed to SHS at homes. Moreover, the paper also indicates that contrary to popular belief, SFL does not lead to shifting of smoking to home. In the second paper, socioeconomic inequalities in SHS exposure at home and at work were studied in 15 LMICs. SHS exposure at home was found to higher among the less educated and the poor while SHS exposure at work was found to be higher among the less educated. Socioeconomic inequalities evident in SHS exposure in HICs also exist in the LMIC settings, indicating a higher likelihood of health and other harms associated with exposure to tobacco smoke among the vulnerable poor groups in LMICs as well. The need for stronger and pro-equity tobacco control policies in general, including comprehensive SFL and additional targeted efforts among the low SES groups was highlighted through the paper. Such measures would not only reduce inequalities in SHS exposure but also reduce overall tobacco smoking in these settings.

Chapter 5: Evaluation of the impact of National Tobacco Control Programme on bidi and cigarette consumption in India

5.1. Tobacco control policies in India

The Indian tobacco control law, 'The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act', (COTPA) 2003, came into effect on May 1, 2004.²⁴ The key provisions of COTPA 2003 include: Section 4 - prohibition on smoking in public places, Section 5 – prohibition of advertising, promotion and sponsorship of tobacco products, Section 6a – prohibition on sale of tobacco products to and by minors, Section 6b - prohibition on sale of tobacco products within a radius of 100 yards around the educational institutions and Section 7 – display of specified pictorial health warnings on tobacco products.²⁴ There are several other sections in COTPA which deal with enforcement and penalties in case of violations. In accordance with Article 8 of the WHO FCTC, Section 4 of COTPA prohibits smoking in public places. The 2004 smoke-free rules under COTPA had loopholes such as a lack of clear definition of public place resulting in poor segregation of smoking and non-smoking areas and a lack of enforcement authority. Under the new rules for Section 4 of COTPA, notified on October 2, 2008, public places were clearly defined and included all indoor workplaces, public places, public transport as well as several other places frequented by public including stadiums, bus stops, railway stations, open auditoriums etc. (even though several of them are open spaces).²³¹ As per the amended smoke-free law, it is mandatory to display a board at conspicuous spots (each entrance, each floor, each staircase, and the entrance of each lift) in public places with specifications as depicted in figure 5.1. Further, the name and the contact details of the authorised person to whom complaints can be reported in the case of violations are also to be displayed on the board. The smoke-free law in India however, is not comprehensive as DSRs are permitted in restaurants with a seating capacity of more than 30, hotels with more than 30 rooms and at airports. In case of violation of Section 4, offenders are liable for a penalty of up to INR200.232



Figure 5.1: Specifications of the 'no smoking' board to be displayed at conspicuous locations at all public places in India

The COTPA Amendment Bill (2015) proposes several changes in COTPA (2004) including increasing the penalty for smoking in public places to INR1000 and revoking the permission to have DSRs at hotels and restaurants. Other key features of the bill include increasing the minimum age for sale of tobacco products from 18 to 21 years, banning the sale of loose cigarettes, increasing penalties for violations, and setting up of a National Tobacco Control Organization for appropriate implementation and enforcement of tobacco control laws. India also has a functional National Tobacco Control Programme (NTCP) and one of the major activity under the NTCP is implementation and enforcement of COTPA provisions including the SFL. 135

5.2. National Tobacco Control Programme in India

The Government of India enacted COTPA in 2003 and also ratified the WHO FCTC in 2004 with an objective to limit tobacco use and control the resulting morbidity and mortality. In order to ensure effective implementation of the tobacco control policies at national and sub-national levels, and to fulfil its obligations under the WHO FCTC, the Government of India initiated the National Tobacco Control Programme (NTCP) in a pilot phase in the year 2007- 2008 with the following objectives¹³⁵:

- To bring about greater awareness about the harmful effects of tobacco use and tobacco control laws
- To facilitate effective implementation of the tobacco control laws

India has 29 states and seven union territories in total. In 2007-2008 (phase I), the NTCP was implemented in two districts from each of the selected nine Indian states. Subsequently, in 2008-2009 (phase II), the NTCP was expanded to include an additional 12 states (and its 24 districts). The Indian states and districts covered under the NTCP between 2007 and 2009 are shown in Appendix D-1. The NTCP is now being expanded to cover all the states and union territories of India (with 672 districts) in a phased manner between 2012 and 2017. An initial budget for the period 2007-2012 of INR1.45 billion has now been increased to INR7.0 billion for the planned expansion in 2012-2017. It is also planned to engage dedicated personnel and other resources at all levels as a part of the NTCP expansion.

The NTCP in India follows a three tier system with structures and activities in place at national, state and district levels. ¹³⁵ Figure 5.2 shows the structure of India's NTCP.

National level:

The National Tobacco Control Cell (NTCC) is led by the Ministry of Health & Family Welfare (MoHFW) and senior officers from the Directorate General of Health Services, assisted by a number of consultants in specific areas of tobacco control. The primary responsibility of NTCC is policy formulation, planning, and monitoring and evaluation of various activities under the NTCP. As tobacco is a complex and multi-dimensional issue, an inter-ministerial taskforce has been appointed, including 12 representatives from various Government departments, seven representatives of state Governments and two representatives from civil society organisations (CSOs), to garner greater multi-stakeholder engagement. Additionally, a national level steering committee has also been constituted consisting of three Government representatives, CSOs and other non-governmental bodies to handle matters relating to violations of section 5 (ban on tobacco advertising, promotion and sponsorship) of COTPA.

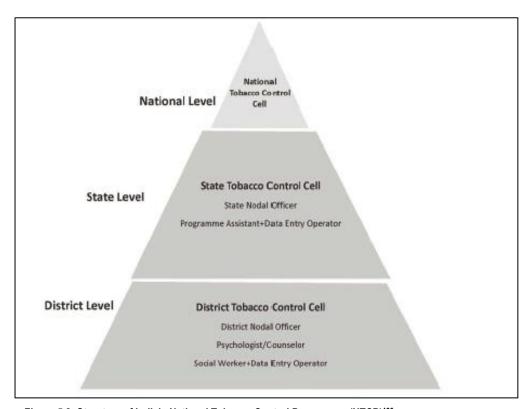


Figure 5.2: Structure of India's National Tobacco Control Programme (NTCP)¹³⁵

The major activities of NTCC are:

- National level public awareness campaigns
- Setting up of tobacco product testing laboratories
- Research on alternative crops/ livelihood of tobacco growers and workers
- Monitoring and evaluation including surveillance
- Integrating NTCP with other national programmes and as part of the National Health Mission (NHM) Framework

State level:

NTCP activities at the state level are led by a State Tobacco Control Cell (STCC) which is headed by a State Nodal Officer. The primary responsibility of STCC is overall planning, implementation and monitoring of different NTCP activities, and achievement of physical and financial targets at the state level. There also exists a State Level Coordination Committee (SLCC) consisting of multiple stakeholders including officials from various departments under the state Government. The committee is ultimately responsible for overseeing implementation of various state-level activities under the NTCP and enforcement of COTPA provisions (including the smoke-free policies). The major activities of STCC are:

- Training of various stakeholders at state level
- State level public awareness/information, education, communication (IEC) campaign
- Monitoring tobacco control laws and reporting

District level:

NTCP activities at the district level are led by the District Tobacco Control Cell (DTCC), which is headed by the District Nodal Officer, supported by the District Level Coordination Committee (DLCC) and the enforcement squad, which is responsible for ensuring enforcement of COTPA provisions and monitoring compliance with laws.

The primary objective of DTCC is overall planning, implementation and monitoring of the NTCP activities, and the achievement of physical and financial targets at District level.

The various activities of DTCC include:

- Training and capacity building of relevant stakeholders at the district level
- Implementation of school awareness programmes
- Setting up and expansion of tobacco cessation facilities
- IEC/Media campaign at the local level

Monitoring and enforcement of tobacco control laws at the local level

Apart from these, block and village level committees are encouraged under the NTCP for implementation of activities at respective levels. 135 Each DTCC reports quarterly to the respective STCC detailing its activities conducted under the programme and expenses incurred on the activities. Similarly, each STCC reports quarterly to the NTCC.

The Government of India has identified several challenges to implementation of the NTCP which are briefly listed below²³³:

- Myriad varieties of tobacco products are available in India which complicates the implementation and enforcement of tobacco control policies while newer products keep emerging in the market e.g. e-cigarettes, SLT which are not well regulated.
- Implementation, enforcement and compliance monitoring are mainly the responsibility of the state Governments, which lack capacity and resources while prioritising other issues over tobacco control.
- Shifting of tobacco growing farmers to other suitable means of livelihood has been difficult due to large numbers of farmers involved in this occupation and a lack of research on this issue.
- The lack of cooperation and coordination between non-health stakeholders in the Government to prioritise tobacco control.
- Delays in the establishment of tobacco product testing laboratories.
- Non-utilization of dedicated funds for the NTCP by the states results in a lack of implementation of programme activities or a delay in implementation.
- The lack of consistent monitoring mechanism and manpower at all levels.

5.3. National Sample Survey Office - Household Consumer Expenditure Survey

The National Sample Survey Office (NSSO), earlier known as the National Sample Survey Organization is a part of the Ministry of Statistics and Programme Implementation (MoSPI), Government of India. The NSSO has been conducting various nationwide sample surveys related to different socioeconomic aspects in India since the year 1950.²³⁴ The Household Consumer Expenditure Survey (CES) is one of the several types of surveys conducted by the NSSO. The CES is conducted every five years

across all the states and union territories of India (except some very inaccessible areas of Nagaland and Andaman & Nicobar Islands) since 1972-73. These surveys provide repeated cross-sectional data on household level consumption and expenditure on various food and non-food items.²³⁵ Apart from these five-yearly surveys, similar annual surveys are also conducted with a much smaller sample since 1986-87, which provide data between these large five yearly rounds.²³⁵ Table 5.1 lists some of the recent CES rounds.

Table 5.1	Table 5.1: Recent National Sample Survey Office (NSSO) Household Consumer Expenditure Survey Rounds in India									
Sr. No.	Round	Year	Number in CES series							
1	55 th	1999-2000	Sixth							
2	61 st	2004-2005	Seventh							
3	66 th	2009-2010	Eighth							
4	68 th	2011-2012	Ninth							

The CES provides information about the household level consumption of more than 350 food and non-food items (including goods and services) as well as the expenditure on these consumed items over a specific reference period – 'past 30 days' before the survey and 'past 365 days' before the survey for some non-food items. Specifically, the CES collects information about the household characteristics including demographic characteristics of the selected households, consumption of food, betel leaf, tobacco and intoxicants in the past 30 days, consumption of energy in the past 30 days, consumption of clothing, bedding and footwear for past 30 days as well as past 365 days, expenditure on education and medical goods and services in the past 30 days as well as past 365 days, expenditure on miscellaneous goods and services including medical (non-institutional), rents and taxes for the past 30 days and expenditure on purchase and construction of durable goods for domestic use in the past 30 days as well as past 365 days. Table 5.2 shows the types of tobacco products for which information on quantity purchased and expenditure is collected under the CES.

	Survey Rounds and	their descriptions
	Smoked tobacco forms	Smokeless tobacco forms
1)	Bidis (Bidi is made by rolling a dried, rectangular	1) Snuff (Snuff is dry powdered tobacco that is
	piece of temburni leaf (Diospyros melanoxylon)	inhaled by snorting, applied or chewed) ²³⁷
	with 0.15-0.25 grams of sun-dried, flaked tobacco	
	into a conical shape and securing the roll with a	
	thread) ²³⁶	
2)	Cigarettes	2) Zarda (a moist or dry chewing tobacco mixed with
		variety of colourings, spice essences, and perfumes) ²³⁸
3)	Hookah tobacco (hookah is an Indian water pipe	3) Leaf tobacco (natural, unprocessed tobacco leaf)
	in which the tobacco smoke passes through water	
	before inhalation) ²³⁶	
4)	Cheroot (A roll made from tobacco leaves, like a	4) Kimam (a fermented tobacco product made from
	cigar, closed at both ends) ²³⁶	tobacco, spices and essence)239
		5) Surti (a blend of dried tobacco leaves and slaked
		lime) ²³⁷
		6) Other tobacco products

Information such as the quantity of various products consumed in the household, per person (capita) consumption, total expenditure in the household and expenditure per capita (monthly per capita expenditure [MPCE]) can be derived from the CES surveys. The information in the CES is collected using a validated interviewer-administered questionnaire with either the adult head of the household or an equivalent adult member of the household ≥15 years of age through face to face surveys. Questionnaires specific to rounds 55 (http://www.ilo.org/surveydata/index.php/catalog/146/download/1510), 61 (http://mail.mospi.gov.in/index.php/catalog/145/download/1464) and 68 (http://mail.mospi.gov.in/index.php/catalog/145/download/1667) are available to download freely from the MoSPI website, Government of India.

A stratified multi-stage sampling design is used in the CES, with the primary sampling units (PSUs) being the villages in rural settings and urban frame survey blocks in the urban settings. The households represent the ultimate sampling units (USUs) in both the rural and the urban settings. In the case of a large PSU, an intermediate stage of sampling is added which involves selection of two hamlet groups (from the PSU village)

and sub-blocks (from the PSU urban blocks). The PSUs are selected using a census listing of villages (using probability proportional to size with replacement) and urban blocks (simple random sampling without replacement) after initial stratification and substratification of rural and urban sectors and allocation of PSUs to states and union territories (as per probability proportional to population size). A minimum of eight urban and eight rural PSUs are allocated to each state/union territory. Further, if the population of the PSU is larger than 1200 or 600 (in the case of a rural area), the population is further divided into a number of hamlet groups/sub-blocks and two of these smallest units are selected from each PSU (one sub-unit with the largest population and other randomly selected). From each of the smallest sampling unit selected, households are selected using simple random sampling without replacement.

The five-yearly CES have sample sizes of approximately 100,000 per round while the annual smaller CES rounds have much smaller sample sizes (~30,000 to 60,000).

This chapter presents a published case study from India, which used three rounds of NSSO CES data (1999-2000; 2004-05; 2011-12) to evaluate the impact of its National Tobacco Control Programme (of which implementation/enforcement/monitoring of tobacco control laws including the SFL are major components at the district and state level) on the prevalence and the amount of active smoking. This chapter, therefore, addresses Aim 4 and Aim 5 of the thesis and the corresponding objectives 3 and 5.

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Student	Gaurang Prafulla Nazar		
Principal Supervisor	Professor Neil Pearce		
Thesis Title	Smoke-free legislation and active smoking, second hand smoke exposure and health outcomes in low- and middle-income countries.		

If the Research Paper has previously been published please complete Section B, if not please move to Section C

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Where is the work intended to be published?	The Lancet Global Health
Please list the paper's authors in the intended authorship order:	Gaurang P. Nazar, Swati Srivastava, Kiara C-M Chang, Neil Pearce, Anup Karan, Christopher Millett
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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)

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Section D – Student's role in multi-authored work

This research paper is authored by Dr. Gaurang P. Nazar, Dr. Swati Srivastava, Dr. Kiara C-M Chang, Prof. Neil Pearce, Dr. Anup Karan and Prof. Christopher Millett in this order. I am the first and the corresponding author. Prof. Neil Pearce is my supervisor from London School of Hygiene and Tropical Medicine. Prof. Christopher Millett is my co-supervisor from Imperial College London.

- I, Prof. Millett, Dr. Anup and Dr. Swati conceptualised this work and agreed on a
 priori to include this as a part of my PhD study. It was decided to assess the
 impact of India's National Tobacco Control Programme (NTCP) on bidi and
 cigarette consumption using three waves of NSSO CES data (1999-2000; 20042005; 2011-2012) using the specialised technique difference-in-differences,
 typically used in programme evaluation in econometrics.
- Dr. Swati Srivastava, under guidance from Dr. Anup Karan acquired the NSSO
 CES datasets from Public Health Foundation of India, extracted and merged the
 datasets and then handed over the merged dataset for further management and
 analyses to me.
- Under the guidance of Dr. Karan, Prof. Millett, Dr. Chang and Prof. Pearce, I conducted secondary analyses (ran all descriptive statistics, cross-tabulations, statistical tests including the two-part regression model using the difference-in-differences approach) on the acquired CES data using statistical software STATA. Specific guidance on statistical methods related to the difference-in-differences method and the two-part models involved in this analysis was provided to me by Dr. Anup and Dr. Chang. Specific issues regarding the variables used in the analyses were discussed and resolved with inputs from Dr. Srivastava and Dr. Anup.
- Apart from data analysis, I interpreted the statistical outputs and results with appropriate guidance from Dr. Anup.
- I drafted the first cut of the entire paper fully by myself and then shared the paper with the co-authors for their inputs.
- The paper underwent several rounds of revisions as per inputs from the supervisors and the co-authors; accordingly, I further worked on data analysis and revised the paper critically for intellectual content.
- I, with guidance and approval from the co-authors, finalised the paper for submission to the journal.

- I submitted the paper to the journal, & handled journal communications related to the paper. The paper is currently under peer-review.
- I, as the first and the corresponding author of the paper, am responsible and accountable for the accuracy and integrity of all aspects presented in the paper.

5.4. Impact of India's National Tobacco Control Programme on bidi and cigarette consumption: a difference-in-differences analysis*

5.4.1. Abstract

5.4.1.1. Background

Despite the importance of decreasing tobacco use to achieve Sustainable Development Goals (SDG) mortality reduction targets in low- and middle-income countries, evaluations of tobacco control programmes in these settings are scarce. We assessed the impact of India's National Tobacco Control Programme (NTCP) on household-reported consumption of bidis and cigarettes.

5.4.1.2. Methods

Secondary analysis of cross-sectional data from nationally representative Household Consumer Expenditure Surveys (1999-2000; 2004-05 and 2011-12). Outcomes were: any bidi/cigarette consumption in the household in past 30 days and monthly consumption of bidi/cigarette sticks per person. A difference-in-differences two-part model was used to compare changes in bidi/cigarette consumption between NTCP intervention and control districts, adjusting for socio-demographic characteristics and time-based heterogeneity.

5.4.1.3. Findings

Overall, there was a decline in bidi and cigarette consumption in India between 1999-2000 and 2011-12. The NTCP was not associated with reductions in the proportion of households reporting bidi (adjusted odds ratio [AOR]: 1·04, 95% confidence interval [CI]: 0·84–1·28) or cigarette consumption (AOR: 1·01, 95% CI: 0·82–1·26). The programme was not associated with reductions in the monthly per person consumption of bidis (adjusted coefficient: 0·07, 95% CI: -0·13–0·28) or cigarettes (adjusted coefficient: -0·002, 95% CI: -0·26–0·26) in bidi/cigarette consuming households.

^{* &}lt;u>Nazar GP</u>, Srivastava S, Chang KC, Pearce N, Karan A, Millett C. Impact of India's National Tobacco Control Programme on bidi and cigarette consumption: a difference-in-differences analysis. *Submitted in The Lancet Global Health*.

5.4.1.4. Interpretation

There was a decline in bidi and cigarette consumption in India between 1999-2000 and 2011-12. There was no compelling evidence that NTCP reduced consumption over and above the general reduction that occurred in all districts. Strengthening implementation and enforcement of tobacco control policies is crucial to reduce the future burden of tobacco use in the country.

5.4.2. Research in context

5.4.2.1. Evidence before this study

We conducted a literature search in 'PubMed' and 'Scopus' to assess existing research evidence on the impact of tobacco control programmes/policies on tobacco use. We searched for all studies published before November 14, 2016, with no language restrictions, using the search terms: ("tobacco control policy" OR "tobacco control program") AND ("evaluation" OR "effect" OR "impact") AND ("smoking" OR "tobacco use" OR "prevalence" OR "frequency" OR "volume" OR "intensity"). PubMed returned 230 studies and Scopus returned 828 studies. We excluded simulation studies which predicted the impact of tobacco control policies/programme, school-based or small community-based tobacco control programmes, and studies that focused on only one specific tobacco control strategy. We reviewed abstracts of remaining studies and further excluded studies which did not specifically report impact of tobacco control policies/programmes on tobacco use behaviours. Studies were mostly from high income countries such as Spain, US (California, Massachusetts, Arizona, and West Virginia) and Australia. These suggest that comprehensive, aggressively implemented and well-resourced tobacco control programmes achieved significant reductions in tobacco consumption and prevalence. Literature from low- and middleincome countries (LMICs) was sparse. A small number of studies from Mexico, Uruguay and Bangladesh described findings of the International Tobacco Control Policy Evaluation Project (ITC Project), a multi-country cohort study (only covering few states in the country; not nationally representative), which aims to evaluate the impact of specific strategies of the WHO Framework Convention on Tobacco Control (FCTC) e.g. smoke-free policy, health warnings, tobacco advertising and promotion, education and awareness and price and taxation on tobacco use and its psychosocial correlates. As tobacco control policies have been introduced nationwide in these settings, there is limited scope to include a suitable comparison group (without existing policies) in these

studies. No previous research from LMICs has evaluated the impact of tobacco control policies on tobacco use using nationally representative data and a quasi-experimental study design.

5.4.2.2. Added value of this study

We conducted secondary analyses using a difference-in-differences method (typically used in econometrics for programme impact evaluation) on three waves (1999-2000; 2004-05; 2011-12) of nationally representative Consumer Expenditure Survey data. We found that there was a decline in bidi and cigarette consumption in India between 1999-2000 and 2011-12. There was no compelling evidence that NTCP reduced consumption over and above the general reduction that occurred in all districts.

5.4.2.3. Implications

Strengthening implementation and enforcement of tobacco control policies is crucial to achieving national and international child health and premature NCD mortality reduction targets.

5.4.3. Introduction

India is home to 275 million tobacco users, ⁴⁸ and faces a substantial associated mortality and morbidity burden. India ratified the WHO Framework Convention on Tobacco Control (FCTC) in 2004 and legislated to implement key tobacco control measures through the Cigarettes and Other Tobacco Products Act (COTPA) in 2003. In 2003. However, implementation of key tobacco control measures has been uneven and weak in many parts of the country due to resource constraints, conflicting interests of various stakeholders and tobacco industry tactics. ²³³

India launched the National Tobacco Control Programme (NTCP) in 2007-08 to ensure more effective implementation and enforcement of tobacco control measures. Initially developed as a pilot project in two districts in each of nine Indian states, ¹³⁵ the programme was expanded in 2008-09 to cover a total of 42 districts and 21 states (Supplementary Table in Appendix D-1). The objectives of the NTCP are to: a) increase awareness about the harmful effects of tobacco use and tobacco control laws; and b)

facilitate effective implementation of tobacco control laws and policies. The activities of the NTCP are distributed and implemented across three Government tiers: national, state and district levels, but much of the focus is on strengthening local tobacco control efforts at the district level. The NTCP activities include training and capacity building, public awareness campaigns, expansion of tobacco cessation facilities, monitoring and evaluation and enforcement of COTPA provisions, among others.^{135, 233} Further details about the NTCP are available elsewhere.¹³⁵

Robust assessment of tobacco control programmes in LMICs is essential given the importance of decreasing tobacco use to achieve both child and adult mortality reduction targets in the Sustainable Development Goals (SDGs).^{19, 20} However, robust evaluation is often constrained by lack of surveillance to monitor changes in tobacco use over time. The objective of our study was to evaluate the impact of the NTCP on bidi[†] and cigarette consumption at the household level.

5.4.4. Methods

5.4.4.1. Study design, setting and data

We used a quasi-experimental difference-in-differences (DID) design to evaluate the impact of NTCP on household level consumption of bidis and cigarettes. We used three waves (1999-2000, 2004-05 and 2011-12) of the nationally representative, household Consumer Expenditure Survey (CES) data conducted by the National Sample Survey Organization (NSSO) (Government of India).^{235, 241, 242} The CES used a stratified multistage sampling design covering districts from all states and union territories in India. The head of household or equivalent (adult participant aged ≥15 years) of randomly selected households were invited to participate in a face-to-face interview, and a validated interviewer-administered questionnaire was used to obtain information about the household's consumption and expenditure of over 350 food and non-food items. Full details of the CES data are available elsewhere.^{235, 241, 242}

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[†] Bidi is made by rolling a dried, rectangular piece of temburni leaf (Diospyros melanoxylon) with 0.15-0.25 grams of sun-dried, flaked tobacco into a conical shape and securing the roll with a thread.²³⁶

The sample sizes of the three survey waves varied between 100,000 to 125,000 households and spread across approximately 12,000 sub-districts (villages or urban blocks) in each wave.^{235, 241, 242} These sum up to 341,975 households included in our study after excluding 4,640 households (1.3% of 346,615 households) which had no/incomplete data recorded.

5.4.4.2. **Measures**

Dependent variables

We considered four different outcomes: a) proportion of households reporting consumption of bidis; b) proportion of households reporting consumption of cigarettes; c) number of bidi sticks consumed per person in households reporting bidi use; and d) number of cigarette sticks consumed per person in households reporting cigarette use. All of the above measures were based on reported consumption in the 30 days before the interview.

Independent variables

Main independent variables were: a) households residing in an NTCP district (Supplementary Table in Appendix D-1); b) time indicator; and c) interaction terms between households residing in an NTCP district and time.

We created a binary variable to indicate whether the household was from an NTCP district (determined by the NTCP operational guidelines). 135 We treated the survey year 1999-2000 as the reference year and created two binary variables to indicate the subsequent years of survey data: t_2 (1 if 2004-05, 0 otherwise); and t_3 (1 if 2011-12, 0 otherwise). We used two interaction terms: a) an interaction between the indicator of households residing in NTCP districts and t_2 ; and b) an interaction between the indicator of households residing in NTCP districts and t_3 . The latter captured the impact of the NTCP on bidi and cigarette consumption.

We controlled for an array of demographic and socioeconomic status (SES) indicators including the household's area of residence (rural or urban) and wealth quintile (poorest, poor, middle, rich, richest); household size (number of household members ≤ 5 or > 5); proportion of household members in each age group (0-4 years; 5-14 years; 15-29 years; 30-59 years; ≥ 60 years); proportion of male and female members of the household, proportion of household members at each educational level (illiterate, primary, middle, secondary, higher secondary, graduate and above); household religion (Hindu, Muslim, Christian, and others); caste[‡] (Scheduled Tribe [ST], Scheduled Caste [SC], Other Backward Class [OBC], and others); and employment type (self-employed, regular labourer, casual labourer, and others).²⁴³ Household characteristics of all three survey years are presented in a supplementary table in Appendix D-2.

5.4.4.3. Data analysis

Quasi-experimental difference-in-differences (DID) is a key econometric approach commonly used in policy impact evaluations. Under a basic set up of DID, the impact of an intervention (e.g. the NTCP) is estimated by comparing the average changes in outcome from before to after the intervention for the treatment group, and subtracting from it, the average changes in outcome over the same time period for the control group which is not exposed to the intervention. Thus, an important assumption of DID is that in the absence of the intervention, the outcomes for the treated and control groups are assumed to follow a parallel trend over time. 244

Since the outcomes for the treated group in the absence of the intervention are not observed, the parallel time trend assumption cannot be assessed empirically. Therefore, in addition to the data we observed for the households residing in an NTCP district or a non-NTCP district before and after the implementation of the NTCP (as defined earlier, t_2 is before and t_3 is after NTCP respectively), we included data from another preintervention time period (t_1 as defined previously) to test whether the parallel time trend assumption holds prior to the introduction of the NTCP.²⁴⁵

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[‡] a system of rigid social stratification characterized by hereditary status, endogamy, and social barriers sanctioned by custom, law, or religion

We embedded the proposed DID specification into a two-part model (TPM),^{245, 247, 248} which captures two dimensions of bidi and cigarette consumption: part I of the TPM uses a logit model to estimate the proportion of households reporting consumption of bidis/cigarettes; whereas part II uses a semi-log model to estimate the number (log) of bidis/cigarettes sticks consumed per person, conditional on the households reporting any bidi/cigarette smoking.

The full specification of DID in the TPM framework is described as the following:

$$\log it(y_{ijt}) = \alpha + d_t + \beta_1 d_G + \sum_{t=2}^{3} d_t d_G \phi_t + \beta_2 X_{ijt} + \eta_j + \varepsilon_{it}$$
 (Part I)

$$\log(V_{ijt} \mid y_{ijt} > 0) = \alpha + d_t + \gamma_1 d_G + \sum_{t=2}^{3} d_t d_G \lambda_t + \gamma_2 X_{ijt} + V_j + \mu_{it} \dots$$
 (Part II)

Where y_{ijt} is the outcome variable of interest for household i living in district j during time period t, d_G is the binary indicator for households living in an NTCP or non-NTCP district. d_t stands for time indicators for the two later time periods (2004-05 and 2011-12) with t varying from 2 to 3. The interaction terms d_t , d_G provide two DID estimators $-d_{t=2}$, d_G (DID1) represents the DID from t_1 to t_2 between households residing in an NTCP or non-NTCP district before the introduction of the NTCP; and $d_{t=3}$, d_G (DID2) represents the DID from t_1 to t_3 where households were exposed to the intervention at t_3 if they were residing in an NTCP district. DID1 is, therefore, the test of parallel time trend preintervention and it is significant if the assumption is violated. If the pre-intervention DID remains non-significant, the ratio of DID2 to DID1 (difference [DID2-DID1] in the case of part II of the model) would represent the actual effect of the NTCP on the outcome measure. We adjusted for the set of independent variables for households (X_{ij}), statelevel fixed effects (η_j and ν_j), and ε_{ii} and μ_{ii} are the usual error terms. We used robust standard errors that were clustered at the district level and sampling weights provided by the CES were applied.

To address the potential for contamination or spill-over of interventions in NTCP to neighbouring non-NTCP districts, we ran models with three different sets of control groups: a) Model 1 included controls from both NTCP and non-NTCP states; b) Model 2

included controls from NTCP states only; and c) Model 3 included controls from non-NTCP states only.

All statistical analyses were performed using STATA version 13·1 (StataCorp LP, Texas). Exemption from ethics review for using anonymous CES data for secondary analyses was obtained from the Research Ethics Committee at the London School of Hygiene and Tropical Medicine and the Institutional Ethics Committee at Public Health Foundation of India.

5.4.4.4. Role of the funding source

The funding bodies had no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

5.4.5. Results

5.4.5.1. Descriptive statistics

The proportion of households reporting consumption of bidis (31·9% to 22·1%) and the number of bidis consumed monthly per person (94·0 to 71·9 number of bidi sticks) declined over the study period (Supplementary figure in Appendix D-3). Similar reductions were observed between households in the NTCP and non-NTCP districts (Figure 5.3 & Supplementary table in Appendix D-4). The proportion of households reporting consumption of bidis was significantly higher in the non-NTCP districts at all time points. The proportion of households reporting cigarette consumption increased slightly (5·3% to 6·3%) over the study period (Supplementary figure in Appendix D-3) and was significantly higher in the NTCP districts at all time points (Figure 5.4 & Supplementary table in Appendix D-4). The number of cigarettes consumed (28·4 to 17·6 number of cigarette sticks) declined over time (Supplementary figure in Appendix D-3) but no significant differences were observed between the NTCP and non-NTCP districts at all time points (Figure 5.4 & Supplementary table in Appendix D-4).

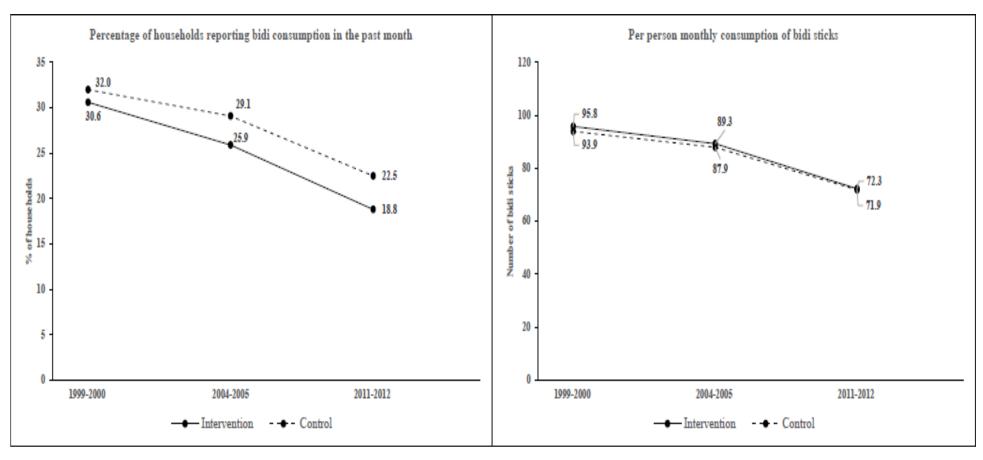


Figure 5.3: Trends in household consumption of bidis over time (Consumer Expenditure Survey rounds: 1999-2000; 2004-05; 2011-12) in NTCP districts (Intervention) vs. households in non-NTCP districts (Control)

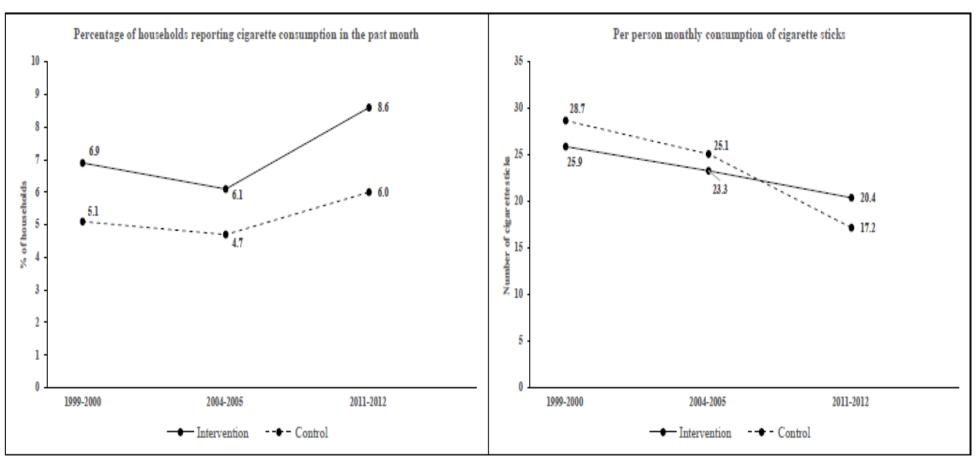


Figure 5.4: Trends in household consumption of cigarettes over time (Consumer Expenditure Survey rounds: 1999-2000; 2004-05; 2011-12) in NTCP districts (Intervention) vs. households in non-NTCP districts (Control)

5.4.5.2. Impact of the NTCP on bidi consumption

We present in Table 5.3 the adjusted odds ratio (AOR) for the proportion of households reporting bidi consumption and the adjusted coefficient for the log of monthly consumption of bidi sticks per person. We observed no significant differences in pre-intervention changes in the proportion reporting consumption or (logged) number of bidi sticks consumed between 1999-2000 and 2004-05 (DID1), suggesting the assumption of a parallel trend in outcome before the introduction of the NTCP was satisfied.

As shown in Model 1, we found that the NTCP was not associated with a reduction in the proportion of households reporting bidi consumption (AOR for the ratio of DID2 to DID1: 1·04, 95% Confidence Interval [CI]:0·84–1·28), nor was it associated with a reduction in the monthly consumption of bidi sticks per person (coefficient for the difference of DID2 subtracts DID1: 0·07, 95% CI: -0·13–0·28). Results of Model 2 and Model 3 produced consistent findings, indicating that our Model 1 findings were unlikely to be due to contamination or spill over effects of the NTCP into neighbouring districts.

5.4.5.3. Impact of the NTCP on cigarette consumption

The AOR for the proportion of households reporting cigarette consumption and the adjusted coefficient for the log of monthly consumption of cigarettes per person are shown in Table 5.4. The findings suggest that the pre-intervention changes in the proportion of consuming households or (logged) number of cigarette sticks consumed were not significant between 1999-2000 and 2004-05 (DID1) therefore, the assumption of a parallel trend in outcome before the introduction of the NTCP was satisfied.

Our Model 1 shows that the NTCP was not associated with any reduction in the proportion of households consuming cigarettes (AOR for the ratio of DID2 to DID1: 1·01, 95% CI: 0·82–1·26), nor was it associated with any reduction in the monthly consumption of cigarettes per person (coefficient for the difference of DID2 subtracts DID1: -0·002, 95% CI: -0·26–0·26). The results were consistent for Model 2. In Model 3, the NTCP was found to be associated with a borderline significantly higher proportion of households reporting cigarette consumption (AOR for the ratio of DID2 to DID1: 1·32, 95% CI: 1·00–1·73).

Table 5.3: Effect of the Indian National Tobacco Control Programme (NTCP) on bidi consumption (NSSO 1999-2000; 2004-05; 2011-12 pooled data)							
	Households reporting bidi consumption Adjusted Odds Ratio [95% CI]#			Log of per person monthly consumption of bidi sticks Adjusted Beta coefficient [95% CI] [§]			
	Model 1 (part I)§	Model 2 (part I) [†]	Model 3 (part I) [‡]	Model 1 (part II) §	Model 2 (part II) [†]	Model 3 (part II) [‡]	
	n=341,975	n=270,265	n=107,291	n=86,818	n=69,366	n=25,767	
Constant	0·490	0·397*	0·590*	4·248*	3·245*	4·178*	
	[0·155, 1·550]	[0·310, 0·508]	[0·200, 1·741]	[4·097, 4·399]	[3·107, 3·382]	[3·968, 4·388]	
NTCP (indicator for intervention districts)	0·995	1·004	0·447	0·031	0·034	-0·242*	
	[0·801, 1·235]	[0·810, 1·245]	[0·165, 1·212]	[-0·103, 0·167]	[-0·100, 0·169]	[-0·468, -0·016]	
t2 (indicator for year 2004-05)	0·702*	0·718*	0·558*	-0·119*	-0·115*	-0·150*	
	[0·659, 0·748]	[0·670, 0·769]	[0·493, 0·631]	[-0·162, -0·076]	[-0·162, -0·069]	[-0·241, -0·058]	
t3 (indicator for year 2011-12)	0·745*	0·761*	0·628*	-0·378*	-0·363*	-0·514*	
	[0·696, 0·798]	[0·706, 0·819]	[0·539, 0·731]	[-0·445, -0·311]	[-0·436, -0·291]	[-0·628, -0·400]	
NTCP x t2 interaction term (DID 1)	0·991	0·966	1·219	-0·045	-0·052	0·002	
	[0·774, 1·269]	[0·753, 1·238]	[0·938, 1·585]	[-0·231, 0·139]	[-0·239, 0·134]	[-0·194, 0·199]	
NTCP x t3 interaction term (DID 2)	1·031	1·012	1·184	0·029	0·020	0·103	
	[0·785, 1·353]	[0·768, 1·333]	[0·889, 1·577]	[-0·138, 0·197]	[-0·149, 0·190]	[-0·095, 0·303]	
Pseudo-R ² / R-squared	0.170	0.170	0.220	0.295	0.295	0.293	
Effect of NTCP (DID 2-DID 1)	1·039	1·047	0·971	0·075	0·073	0·101	
	[0·843, 1·282]	[0·847, 1·3]	[0·756, 1·246]	[-0·133, 0·283]	[-0·136, 0·282]	[-0·143, 0·345]	

[#] Estimates obtained from logistic regression model with state-level fixed effects adjusted for sector (rural/urban); household size (≤5/ >5 members); proportion of members in age groups 0-4, 5-14, 15-29, 30-59, ≥60; proportion of females/males in the household; proportion of members in education categories 'illiterate', 'primary', 'middle', 'secondary', 'figher secondary', 'graduate & above'; Religion (Hindu/Muslim/Christian/Others); Caste (ST/SC/OBC/Others); Employment type (Self-employed/Regular labour/Casual labour/Others); and Wealth quintile (poorest/poor/middle/rich/richest)

^{\$}Estimates obtained from OLS regression model with state-level fixed effects adjusted for the covariates described above for the logistic model

[§]Model 1 – Intervention districts from the intervention states and control districts from both, intervention & control states

[†]Model 2 – Intervention and control districts only from intervention states

[‡]Model 3 – Intervention districts from intervention states and control districts from non-intervention states

^{*} indicates p-value<0.05

Table 5.4: Effect of the Indian National Tobacco Control Programme (NTCP) on cigarette consumption (NSSO 1999-2000; 2004-05; 2011-12 pooled data)							
	Households reporting cigarette consumption Adjusted Odds Ratio [95% CI]#			Log of per person monthly consumption of cigarette sticks Adjusted Beta Coefficient [95% CI]\$			
	Model 1 (part I) §	Model 2 (part l) [†]	Model 3 (part I) [‡]	Model 1 (part II) §	Model 2 (part II) [†]	Model 3 (part II) [‡]	
	n=341,975	n=270,265	n=107,291	n=28,542	n=19,076	n=13,162	
Constant	0·070*	0·033*	0·105*	2·544*	1·125*	3·028*	
	[0·048, 0·103]	[0·03, 0·047]	[0·056, 0·198]	[2·144, 2·943]	[0·472, 1·778]	[2·509, 3·548]	
NTCP (indicator for intervention districts)	1·233	1·212	0·463*	-0·193	-0·212	-1·894*	
	[0·894, 1·700]	[0·877, 1·677]	[0·324, 0·662]	[-0·409, 0·021]	[-0·4, 0·002]	[-2·388, -1·399]	
t2 (indicator for year 2004-05)	1·011	0·950	1·293*	-0·147*	-0·165*	-0·060	
	[0·920, 1·110]	[0·851, 1·060]	[1·117, 1·496]	[-0·232, -0·062]	[-0·265, -0·065]	[-0·219, 0·097]	
t3 (indicator for year 2011-12)	1·182*	1·189*	1·203	-0·514*	-0·579 *	-0·300*	
	[1·064, 1·312]	[1·054, 1·343]	[0·992, 1·458]	[-0·612, -0·416]	[-0·684, -0·475]	[-0·509, -0·091]	
NTCP x t2 interaction term (DID 1)	0·852	0·896	0·735	0·192	0·197	0·090	
	[0·597, 1·215]	[0·625, 1·284]	[0·513, 1·051]	[-0·065, 0·450]	[-0·064, 0·459]	[-0·186, 0·368]	
NTCP x t3 interaction term (DID 2)	0·865	0·857	0·971	0·190	0·242	-0·082	
	[0·594, 1·260]	[0·585, 1·253]	[0·647, 1·457]	[-0·082, 0·462]	[-0·028, 0·513]	[-0·405, 0·240]	
Pseudo-R ² / R-squared	0.136	0.130	0.125	0.367	0.388	0.322	
Effect of NTCP (DID 2 – DID 1)	1·015	0·956	1·321*	-0·002	0·045	-0·173	
	[0·818, 1·260]	[0·763, 1·198]	[1·007, 1·733]	[-0·266, 0·260]	[-0·225, 0·315]	[-0·462, 0·116]	

[#]Estimates obtained from logistic regression model with state-level fixed effects adjusted for sector (rural/urban); household size (≤5/>5 members); proportion of members in age groups 0-4, 5-14, 15-29, 30-59, ≥60; proportion of females/males in the household; proportion of members in education categories 'illiterate', 'primary', 'middle', 'secondary', 'higher secondary', 'graduate & above'; Religion (Hindu/Muslim/Christian/Others); Caste (ST/SC/OBC/Others); Employment type (Self-employed/Regular labour/Casual labour/Others); and Wealth quintile (poorest/poor/middle/rich/richest)

^{\$}Estimates obtained from OLS regression model with state-level fixed effects adjusted for the covariates described above for the logistic model

[§]Model 1 – Intervention districts from the intervention states and control districts from both, intervention & control states

[†]Model 2 – Intervention and control districts only from intervention states

[‡]Model 3 – Intervention districts from intervention states and control districts from non-intervention states

^{*} indicates p-value<0.05

5.4.6. Discussion

Our findings suggest that between 1999-2000 and 2011-12, there was an overall reduction in the consumption of bidis and cigarettes in India. However, we did not find significant differences in reductions in bidi or cigarette consumption between NTCP and non-NTCP districts, four years after the programme implementation. These findings indicate that the decline observed in bidi and cigarette consumption in India may not be attributable to the NTCP. A possible explanation for our failure to detect a significant decline between NTCP and non-NTCP districts could be that COTPA was implemented in 2003 and strengthened in 2007-08, through the launch of NTCP. Hence, the control districts did not have absolutely no tobacco control intervention, just a less intense intervention, compared with the NTCP districts. Nevertheless, the findings are suggestive of inadequate implementation of tobacco control activities under the NTCP in the country, particularly at state and district levels, reflecting insufficient resource allocation and utilization and poor mechanisms for implementation and monitoring. 233, 240 This is reflected in other evidence which suggests that in 2012 only 50% of the 21 NTCP states had mechanisms in place to monitor compliance of tobacco control interventions; only 50% had collected any penalties for the violation of smoke-free law at public places; only 14% collected penalties for the violation of ban on tobacco advertising; ban on sale of tobacco products to and by minors was not enforced in many of the states; and the smoking cessation facilities were absent from districts in almost 50% of the states.²⁴⁰

Impact evaluations of tobacco control programmes in high income countries such as the US have suggested that only comprehensive, aggressively implemented and well-resourced tobacco control programmes can achieve significant reductions in tobacco consumption and prevalence. 249-252 For example, the per person consumption of cigarettes in California declined at a rate of 52% during 1989-1993 following the implementation of a state-wide comprehensive tobacco control programme, 250, 251 with similar reductions being observed in Massachusetts. 249 However when the funding for California's programme was cut in 1993, the programme suffered a slower rate of reduction (28%) during 1994-1996, which was complemented by aggressive tobacco industry tactics. 251 In a study conducted by Farrelly and colleagues, expenditures on a tobacco control programme have been shown to be independently associated with a reduction in the prevalence of smoking such that, doubling the expenditure would lead to an increased reduction in smoking prevalence by 1% to 1.7%. 253 Evaluation of tobacco control programmes in LMIC settings is sparse. However, there are a growing number of countries which have been successful in reducing tobacco use such as Brazil, which has

reduced the prevalence of smoking by 50% in the past two decades by progressively strengthening its tobacco control policies.⁷⁴

Given this context and the growing burden of tobacco smoking in India, 44 the failure of the NTCP to deliver an additional reduction in tobacco smoking (over and above the decline which would occur without NTCP) and associated magnitude of forgone health benefits is concerning. In 2009–2010, one in three employees in India reported being exposed to second hand smoke (SHS) at their workplace. 48 Simulation of tobacco interventions has shown that over one million myocardial infarctions (MI) and stroke deaths in India could be averted over the next decade if comprehensive smoke-free laws were fully implemented. 254 Recent data from England indicate substantial health benefits of smoke-free legislation for child health, including reduced infant deaths, other birth outcomes and reduced admissions for asthma and respiratory tract infections. 122, 201, 255 These findings indicate that strengthened implementation of tobacco control interventions in India and other LMICs could substantially improve child health outcomes. These findings highlight the importance of tobacco control to achieve SDG targets to improve child health and reduce premature mortality from NCDs. 19, 20

5.4.6.1. Strengths and limitations

This is the first study to assess the impact of India's NTCP on consumption of bidis and cigarettes using nationally representative, repeated cross-sectional data. Our sample sizes for each CES round were very large (100,000 to 125,000) which was a strength of the study and ensured that the study was sufficiently powered to detect any significant differences in bidi and cigarette consumption between the study groups. Impact evaluation studies all share a common challenge when there are differences in the observable and/or unobservable characteristics between the intervention and control groups. We attempted to minimise these biases by implementing the DID design while controlling for socio-demographic characteristics of households; state-level fixed effects because some activities of the NTCP may have been implemented at the state level; as well as extending the analysis to an additional pre-intervention period. We additionally ran models to test for the potential spill-over effect that may be associated with the NTCP on the neighbouring non-NTCP districts, but our findings do not support the presence of contamination or spill-over effects.

Our study has a number of limitations. First, it was not possible to separate the effect of other tobacco control activities (apart from the NTCP intervention) on bidi or cigarette consumption particularly at sub-state level (e.g. declaration of smoke-free cities, local training sessions for policy enforcers, and local NGO/civil society supported tobacco control activities), although we are not aware of other major locally implemented tobacco control interventions in our study sites which may have influenced our findings. While the focus of the NTCP was to strengthen tobacco control at the district level, some activities were undertaken at state and national levels. However, findings from our Model 3, which only included controls from non-NTCP states, suggest that a combination of district and state level activities did not have a discernible impact on bidi and cigarette consumption. Second, we did not include smokeless tobacco (SLT) in our analyses restricting the focus to bidi and cigarette consumption. Regulation of SLT products has been managed separately in India, for example through the Food Safety and Standards (Prohibition and Restriction on Sales) Regulations.²⁵⁷ Further, CES data includes a variety of SLT products (although, not all SLT products are captured) and reporting of these different products is in different units. Third, the CES provides household level data and no individual level information is available. However, previous studies have suggested that household level estimates of tobacco consumption may be more useful for policy decision making.²⁴³ Fourth, some degree of social desirability bias would be expected in CES data on questions related to household tobacco consumption as it was self-reported. Fifth, it is possible that a four-year follow-up is insufficient and that the NTCP has had more recent effects on tobacco consumption. It will be important to evaluate how tobacco consumption changes in the future, as further expansion of NTCP to other Indian states is currently underway. Finally, although most of the NTCP states were high tobacco prevalence states as observed from GATS India 2010,48 districts for NTCP implementation in each state were not selected randomly. It is possible that districts willing to implement NTCP were selected and these districts were systematically different compared to the control districts e.g. districts with some preexisting tobacco control activities were selected. It may have led to our findings which showed no significant differences in decline in bidi and cigarette consumption between NTCP and non-NTCP districts. In conclusion, although there was a decline in bidi and cigarette consumption in India between 1999-2000 and 2011-12, there was no compelling evidence that NTCP reduced consumption over and above the general reduction that occurred in all districts. Strengthening implementation and enforcement of tobacco control policies is vitally important to achieve national and international child health and premature NCD mortality reduction targets. 19, 20

Chapter 6: Discussion and policy implications

Research evidence from HICs shows that smoking and exposure to SHS are high among those belonging to the low SES groups, 4, 6, 7 resulting in socioeconomic inequalities in smoking-related health outcomes. Implementation of comprehensive SFL along with other evidence-based tobacco control measures in HICs has been shown to bring about added behavioural, health and economic benefits. 6, 21, 27, 31 While some tobacco control measures such as taxation have been shown to reduce inequalities in smoking (more beneficial to low SES groups vs. the high SES groups), there exists mixed evidence with respect to the impact of SFL. 155 LMIC settings experience heavy health and economic burden due to exposure to tobacco smoke, which is likely to escalate in the future as the majority of smokers reside in these settings.² Moreover, implementation, enforcement and monitoring of comprehensive SFL along with other WHO FCTC recommended tobacco control measures are lacking in LMICs compared with HICs.²³ Despite its urgency, research focusing on SHS exposure and the impact of SFL is sparse in the LMIC settings. The lack of research evidence, complemented with other barriers such as tobacco industry interference, a lack of political will, and poor knowledge about the health and economic adverse effects of exposure to tobacco smoke as well as the benefits of SFL, impedes effective implementation and enforcement of strong tobacco control measures in LMICs.

My thesis, using limited data available in LMICs, including a case study from India, assessed whether the health benefits of SFL identified in HICs are likely to accrue in LMICs and if so, whether these benefits are evenly distributed between SES groups. This goal was addressed through a series of research papers with the following aims:

- 1. To study the impact of SFL on socioeconomic inequalities in health outcomes related to exposure to tobacco smoke.
- 2. To study the association between SFL and exposure to SHS in the home in the LMIC settings.
- 3. To study socioeconomic inequalities in exposure to SHS at home and in the workplace in LMICs.
- 4. To assess the impact of its National Tobacco Control Programme (NTCP) in India on bidi and cigarette smoking.

The other cross-cutting objectives of my thesis were to draw comparisons between the findings of this study with those available from the HIC settings and to generate policy recommendations to enable better implementation and enforcement of comprehensive SFL along with other evidence-based tobacco control measures across LMICs.

In section 6.1 of this chapter, the key results from each research paper are summarised, followed by an overall synthesis. The strengths and limitations of this thesis are discussed in section 6.2. Each research paper presented in my thesis has its own discussion section including its strengths and limitations. Hence, I have attempted to limit repetition in this chapter. Relevant recommendations for policy and practice arising out of my research findings are discussed in section 6.3; followed by a conclusion in section 6.4.

6.1. Summary and synthesis of the research findings

In chapter 3, a systematic review was included with the objective of studying the impact of SFL on socioeconomic inequalities in health outcomes (morbidity and mortality), by assessing the quantity and quality of literature available globally. The results indicated that literature exploring this aspect of SFL is sparse. I found only eight studies that could be included in the review. All the studies included were from HICs. Further, it was observed that only comprehensive SFL (i.e. 100% smoke-free air policy without any exemptions, mechanical ventilation or filtration systems or voluntary agreements) is likely to be equity positive or more likely to benefit the low SES groups compared with the high SES groups; while partial SFL may not reduce socioeconomic inequalities. The review concluded that implementation of comprehensive SFL is important to reduce health inequalities and for countries which have implemented no or partial SFL, it is important to strengthen existing policies and move towards comprehensive SFL.

In chapter 4, secondary analyses using cross-sectional GATS data from 15 LMICs showed that SHS exposure in the LMIC settings at work and at home (most important venues where SHS exposure typically occurs) is high and it varies greatly between LMICs studied. For example, the prevalence of SHS exposure at home ranged from 17% in Mexico to 73% in Viet Nam, while at the workplace, the prevalence ranged from 17% in Uruguay to 66% in Bangladesh.⁴² These findings are consistent with those

observed in an earlier study conducted in these settings.⁵³ The variation reflects the differences in the extent and the intensity of implementation of tobacco control policies including the SFL in these settings and highlights the steady progress made by some Latin American countries in tobacco control (particularly with regard to the implementation of SFL) over the last decade.^{22, 63} In this study, it was observed that SHS exposure at home was higher among the poor and the less educated, while at the workplace, it was higher among the less educated in the majority of LMICs studied. The inequalities in exposure to SHS observed in HICs^{6, 7} were confirmed to exist in LMICs as well (as observed in this study). The need for pro-equity tobacco control interventions such as taxation and comprehensive SFL along with targeted awareness campaigns for the low SES groups in LMIC settings was highlighted. Such measures would not only reduce inequalities in SHS exposure but also reduce overall tobacco smoking, as evidenced by previous research.¹⁶¹

In another analysis conducted as part of chapter 4 using the GATS data from 15 LMICs, it was observed that those employed in smoke-free workplaces were significantly more likely to live in smoke-free homes. This finding was consistent with those from several studies conducted in HICs which showed that SFL was associated with increased likelihood of living in smoke-free homes³²⁻³⁴ and smoke-free private vehicles.³⁶ It was also observed that contrary to popular belief, SFL implementation did not lead to increased smoking at homes. To the contrary, it may have produced additional protection from exposure to tobacco smoke and associated health benefits, particularly among the vulnerable women and children.⁵⁶ The findings indicated that in LMICs, as observed in HICs,³²⁻³⁵ SFL implementation may have led to a change in social norms towards protection of non-smokers from exposure to tobacco smoke, thereby denormalizing smoking behaviour.

In chapter 5, a case-study from India (an LMIC) was presented wherein the impact of NTCP (of which, a major component at district and state level is the implementation and enforcement of tobacco control policies including the SFL) on bidi and cigarette consumption was studied using the sophisticated difference-in-differences method on data from three rounds of NSSO CES (1999-2000; 2004-05 and 2011-12). It was observed that although there was a decline in bidi and cigarette consumption in India between 1999-2000 and 2011-12, there was no compelling evidence that NTCP reduced consumption over and above the general reduction that occurred in all districts.

Strengths and weaknesses of the NTCP were discussed, which include a lack of capacity and resources, inadequate monitoring and implementation and inadequate utilisation of resources.^{233, 240} A comparison with some of the successful tobacco control programmes from the HIC settings revealed that only comprehensive, aggressively implemented and enforced, and well-resourced tobacco control programmes are likely to be effective.²⁴⁹⁻²⁵²

Findings from all the four research papers, collectively, underscore the observation that comprehensive SFL, as a part of a planned, well-resourced and aggressively implemented tobacco control programme in LMIC settings may bring about similar health benefits, through a reduction in smoking and SHS exposure, as observed in HICs. The lack of studies evaluating tobacco control policies such as the SFL from LMICs raises concerns due to the heavy health and economic burden associated with exposure to tobacco smoke and the poor implementation and enforcement of tobacco control policies (including the SFL) in these settings.²³ Extending the findings of previous reviews which demonstrated the health benefits associated with SFL^{27, 28} and greater benefits with comprehensive SFL vs. partial SFL,²⁷ it was observed in this thesis that comprehensive SFL is likely to be pro-equity, through greater reduction in smokingrelated morbidity and mortality among the disadvantaged groups (those most exposed to tobacco smoke); while partial SFL may not reduce inequalities. The benefits of SFL observed in HICs such as reductions in exposure to tobacco smoke, positive changes in social norms with regard to exposing non-smokers to tobacco smoke and the resulting likely health benefits are also evident in LMICs (as observed in my thesis). In comparison with the comprehensive tobacco control programmes from HICs (such as the California's tobacco control programme), 250, 251 those from LMICs such as India appear to suffer from drawbacks such as the lack of capacity and resources, monitoring and rigour in its implementation, which appear to be the reasons behind the lack of impact of these programmes on tobacco smoking. In order to achieve a reduction in tobacco smoking, and thereby to achieve UN SDG targets of reduction in inequalities¹⁴³ and premature deaths due to NCDs, 19, 20 it is important that tobacco control programmes in LMICs are comprehensive, aggressively implemented, well-resourced and effectively enforced.

6.2. Strengths and limitations

Each research paper presented in my thesis has its own strengths and limitations, which are discussed in respective papers. In this section, I present some of the general strengths and limitations for my thesis.

6.2.1. General strengths

In my thesis, I have used nationally representative GATS datasets from 15 LMICs for two research papers presented in chapter 4. GATS utilises uniform survey methodology, protocols and questionnaire which enabled broad comparisons to be drawn across LMICs. Further, this also ensured that I did not have to restrict myself to one specific LMIC and allowed inferences to be drawn, which would be relevant for LMICs globally. I have also used three rounds of repeated cross-sectional, nationally representative, NSSO CES for evaluation of the impact of India's NTCP in chapter 5. The case-study has been included as India (a representative of LMIC settings) is one of the leading producers and consumers of tobacco in the world,³ and has its own tobacco control programme¹³⁵ (consistent with WHO FCTC guidelines¹⁶), of which monitoring and implementation of SFL is a major component. Evaluation of the impact of NTCP in this LMIC has provided some useful insights relevant for tobacco control programmes in general, and more specifically for LMICs. I have used a variety of study designs and analytic methods in this study rather than being restricted to one specific type e.g. a systematic review using the novel 'Harvest Plot' for testing competing hypotheses (a combination of narrative and graphical method) in chapter 3, regression-based methods for cross-sectional data analyses in chapter 4 and a sophisticated difference-indifferences analysis (typically used in econometrics for programme impact evaluation) which was applied using a two-part model in chapter 5. This also shows how diverse research methods can be effectively used towards studying issues in tobacco control such as SFL in the case of my thesis. In my thesis, I have mainly focused on primary outcome indicators relevant for studying SFL such as health effects (socioeconomic inequalities therein), SHS exposure (and socioeconomic inequalities therein) and tobacco smoking (prevalence and per person sticks consumed), which are deemed to be more useful indicators in the long term compared with secondary indicators such as knowledge and attitudes, support (for policies), compliance with legislation etc. which are more relevant in the short/intermediate term.²⁵⁸

6.2.2. General limitations

In some of the analyses conducted as part of my thesis, I have used cross-sectional data (e.g. GATS in 15 LMICs). This limits the ability to assess temporality and therefore, to draw causal inferences. The GATS data used in my thesis is from the first round of survey conducted between 2008 and 2011. It is possible that there have been more recent changes in smoking, SHS exposure and implementation of SFL across GATS countries. There has been a recent addition of countries to the list of countries implementing GATS, bringing the number of countries implementing GATS to 27.191 Moreover, some countries have now implemented a second round of GATS. Nevertheless, considering the global SFL implementation scenario in LMICs,²³ the findings of this study are still very much relevant for strengthening SFL implementation along with other tobacco control measures in these settings. In both, the GATS and NSSO CES data, smoking and exposure to SHS were self-reported (and reported by the head of the household in case of NSSO CES), and therefore, likely to be subject to recall bias and respondent bias. An important limitation when assessing the impact of SFL is that participants are often concurrently exposed to SHS as well as other sources of air pollution such as biomass smoke. This seems more relevant in LMICs such as India and China, where air pollution has been linked with adverse health outcomes. However, it is often difficult to control such external influences in the absence of reliable data in studies involving multi-country comparisons and was beyond the scope of this study. Across research papers, there was an issue of heterogeneity which was due to the inclusion of a number of countries/states with different tobacco use patterns, tobacco control policies and demographic characteristics. I have tried to manage the heterogeneity in some instances through the use of specific analytic methods (e.g. difference-in-differences or adjusted regression models) and at times through the use of more generic methods to allow for the heterogeneity (e.g. Harvest Plot). I did not focus on secondary outcomes relevant for studying SFL such as air quality (PM_{2.5} and air nicotine concentrations), knowledge/attitudes/support for SFL and compliance with SFL implementation which are important short/intermediate term indicators and would be more relevant for countries that have newly implemented the SFL.²⁵⁸

6.3. Policy implications

6.3.1. Strengthen implementation, enforcement and capacity building in LMICs

Despite the benefits of SFL in both HICs and LMICs as shown by earlier research and the findings of my thesis, implementation of SFL remains weak in LMICs with considerable forgone health benefits.²³ The guidelines for implementation of Article 8 of the WHO FCTC recommend that all Parties should take appropriate measures to implement and enforce 100% smoke-free policies (without any exemptions) to offer complete protection from exposure to tobacco smoke in all indoor workplaces, indoor public places, public transport and as appropriate other public places. 62 Consistent with the WHO FCTC recommendations, the findings of my thesis also suggest that comprehensive SFL produces health benefits that may have a greater impact in low income groups; while partial SFL may not reduce health inequalities. Likewise, earlier research from HICs also demonstrates the health benefits associated with the implementation of comprehensive SFL. 160 The fact that only 18% of the world's population is covered by comprehensive SFL with a vast majority of LMICs implementing partial or no SFL,²³ calls for the strengthening of existing SFL in these settings. Over the past two decades, some of the Latin American countries (such as Brazil and Uruguay) have progressively strengthened their tobacco control policies and implemented comprehensive SFL, and have demonstrated: considerable reductions in tobacco use and associated health benefits.^{22, 64} Similarly, other LMICs can follow suit. For example, the Government of India is now seeking to amend its tobacco control law, which would remove the exemption granted to hotels and restaurants, 138 therefore, moving one step closer to the implementation of comprehensive SFL.

The WHO FCTC Article 8 guidelines also recommend imposing sufficiently large monetary penalties for violation of the SFL by individuals as well as businesses to deter smoking. 62 The penalties should be increased for offences involving repeated violation of SFL including consideration of non-monetary penalties for businesses such as cancellation of licenses. For example, in England, the penalty for smoking in a designated smoke-free public place is £50 which is reduced to £30 if paid within 15 days of being issued or a court fine not exceeding £200.259 For not displaying the appropriate no-smoking sign, the penalty is £200 (reduced to £150 if paid within 15 days of being issued) or a court fine of up to £1000.259 In case the responsible person fails to prevent smoking in a designated non-smoking area, the person is liable to be penaltized with a maximum amount of £2500 by the court.259 In some LMICs the penalties are not heavy enough to deter smoking in designated non-smoking areas. For example, in India, the maximum penalty for smoking in public place is INR200 (approximately £2.5) only.232

The COTPA amendment bill (2015) seeks to increase the amount of penalty by five times to INR1000.¹³⁸ The case study from India in chapter 5 of my thesis showed that one of the issues with NTCP was inadequate implementation including not collecting penalties for violation of smoking in public places. However, some of the countries such as Israel have in the past imposed heavy penalties on the businesses for violation of SFL to the scale of ILS160,000 (approximately £29,000).²⁶⁰

Strengthening tobacco control policies including a comprehensive SFL is not possible without an appropriate implementation and enforcement plan, with infrastructure in place, and adequate capacity building initiatives. 62 The WHO FCTC guidelines recommend establishing a national coordinating mechanism/agency for tobacco control while the existing personnel under other Government programmes can be used for monitoring and enforcement of compliance with SFL. Such monitoring of compliance can be accomplished during initial visits for licensing requirements, periodic scheduled visits, surprise visits and visits resulting from complaints of consumers. 62 It is recommended that trained and well-capacitated enforcement agents/squads carry out SFL compliance monitoring at the local level, while also educating the businesses in the initial phase of the SFL implementation.⁶² In England, local councils are responsible for implementation of the SFL while the responsibility for monitoring compliance rests with environment health officers who visit the premises.²⁵⁹ In India, the National Tobacco Control Cell (NTCC) under the Ministry of Health and Family Welfare oversees the planning and implementation the NTCP.¹³⁵ The NTCP is implemented at national, state and district levels while enforcement squads are based at the district level. These enforcement squads consist of a multi-disciplinary team of health department officials, customs and excise officials, police department officials, lawyers, and civil society members among others. 135 Despite the existence of infrastructure, the lack of capacity, resources and inadequate implementation was reflected in the failure of NTCP to demonstrate an impact on smoking in the Indian context as observed in my thesis; while planned, well-resourced, and aggressively implemented tobacco control programmes in HICs have been shown to be effective. 250 It is essential that enforcement officials are well-capacitated and trained, and capable of: immediate action, educating the businesses and also penalising the violators on the spot. Periodic training of all team members and planning is deemed to be essential for this.

6.3.2. High-level political commitment, leadership and multi-sectoral collaboration

The WHO FCTC recommends that for effective tobacco control, "strong political commitment is necessary to develop and support, at the national, regional and international levels, comprehensive multi-sectoral measures and coordinated responses." For several decades, effective tobacco control has been hampered by a lack of political commitment across the globe and in some instances, the tobacco industry was also favoured due to such a lack of commitment. Often, the conflicting priorities of different ministries or departments hamper the multi-sectoral collaboration required for effective tobacco control. For example, the department of health is driven by the adverse health consequences of tobacco use and the resulting huge economic costs, while the finance and agriculture departments and labour groups are driven by the economic gains and employment issues related to tobacco business. Over the past two decades, globally, the tobacco control advocates have managed to find allies within the Governments, the WHO and other UN bodies and have worked closely to ensure that long-term commitments and collaborations for tobacco control are garnered and sustained.

High-level political commitment has played an important role in strengthening the tobacco control policies/programmes and ensuring effective enforcement in HICs as well as in LMICs. Successful implementation of comprehensive SFL in some LMICs such as Uruguay and Brazil are examples of such high-level political commitment, where the presidents of both countries were directly involved.^{22, 64} Additionally, in Uruguay, the National Commission on Tobacco Control, which consisted of members from the Government departments and the civil society played a key leadership role and collaborated with the University of Waterloo for evaluation and with the media for the launch campaign.^{22, 64} Similarly, in Brazil, two agencies a) the National Commission for Tobacco Control and b) the National Agency for Sanitary Surveillance along with the Ministry of Finance played a key role in bringing about strong tobacco control policies that have helped reduce the smoking rates dramatically over the past two decades.²² In India, along with the NTCC there exist the state level coordination committee (SLCC) and the district level coordination committee (DLCC) which have a membership of officials from various Government departments as well as the civil society and which guide implementation of tobacco control activities under the NTCP at these levels. 135 A major issue with NTCP that was identified and presented in chapter 5 of my thesis was that implementation of NTCP rests with the states which do not prioritise tobacco control

activities, which may potentially be one of the several issues that prevented the NTCP from reducing tobacco smoking. This demonstrates a lack of commitment on part of the state Governments and sets a poor example of multi-sectoral collaboration for other LMICs. For effective tobacco control, it is important that key stakeholders in all LMICs prioritise the issue and resolve to work collaboratively.

WHO FCTC recommends international and national collaboration in terms of sharing knowledge, technology and expertise to establish effective tobacco control programmes. The Governments, policymakers, researchers and advocates from LMICs could learn and adopt the best practices in tobacco control from HICs and LMICs that have successfully implemented such policies and crossed over into the next stage of the tobacco epidemic. For example, countries like Brazil which have successfully implemented their tobacco control programme including the comprehensive SFL could lead and guide other LMICs adopt, implement and evaluate effective tobacco control measures. In some LMICs such as India, despite the existence of NTCP, high-level multi-national collaborations for tackling issues such as SFL and tobacco control, in general, are seldom observed. For encouraging such multi-national collaborations, the role of leading health organisations such as the WHO is important in developing standardised protocols for data collection and reporting. This would also enable cross-country comparisons and sharing of the best practices.

6.3.3. Strengthen monitoring and surveillance for tobacco control in LMICs

Despite the fact that WHO recommends monitoring of tobacco use and prevention policies, only 30% of the world's population (representing 65 countries – 37 from HICs, 27 from middle income countries and one low income country) have recent, representative and periodic data for both, adults and youth.²³ It was observed in my thesis that there was a lack of research from LMICs studying the impact of SFL. A key reason for the paucity of research from LMICs is the lack of periodic monitoring data. In this thesis, I used the GATS data from 15 LMICs and conducted secondary analyses presented in chapter 4 of my thesis. To some extent, surveys such as GATS in some LMICs have improved monitoring and surveillance, however, there is still insufficient data to conduct a robust evaluation of tobacco control policies. Further, in chapter 5 of my thesis, I have used three rounds of NSSO CES data which was used to evaluate the NTCP but ultimately the CES was not designed for that purpose and had its own limitations (e.g. household level data rather than individual-level data). It is therefore

important that all LMICs should become a part of multi-national monitoring and surveillance effort. This should include in addition to other tobacco use indicators, exposure to SHS at homes/workplaces/other public places, morbidity and mortality associated with exposure to tobacco smoke, assessment of air-quality including PM_{2.5} and air nicotine concentrations in all indoor public places, knowledge, attitude and support for tobacco control policies including SFL, enforcement of and compliance with policies including SFL, economic impact of policies and tobacco industry tactics. ¹⁶ Some LMICs have taken positive measures to control tobacco use (e.g. the NTCP in India) however, desired results in terms of reduction in tobacco use are not observed which in part are attributable to a lack of monitoring and surveillance. It is important that implementation and enforcement of tobacco control policies are rigorously and periodically monitored along with monitoring of capacity building initiatives so that feedback from such monitoring can be effectively utilised for incorporating corrective measures and thereby to optimise the tobacco control programme.

Currently, some LMICs do implement the GATS and GYTS every five years yet, several of these LMICs lack periodic data. Moreover, GATS and GYTS only capture certain aspects such as self-reported tobacco use and SHS exposure, expenditure on buying tobacco, exposure to pro- and anti-tobacco media, and knowledge about harms, while other key indicators are not included. Additionally, public health experts/Governments should also monitor the industry tactics (including those related to SHS exposure, and safety of newer products claimed to be smoke-free e.g. electronic cigarettes). Some of the tobacco control policy compliance data are collected through other means such as the WHO FCTC country reporting, ²⁶³ and through independent research studies. ³⁹ However, there is still scope for LMICs to expand their monitoring and surveillance in tobacco control. Results from such monitoring and surveillance may also be used to influence the public opinion and policymakers with regard to harms associated with tobacco use and the need for stronger tobacco control policies.

6.3.4. Communication and media advocacy

WHO FCTC as well as tobacco control experts recommend that all Governments should implement an ongoing, well-designed and tested public awareness raising media campaign in collaboration with the civil society – to inform about the harms of tobacco use and exposure to SHS, existing policies and regulations related to tobacco, benefits of tobacco-free (including the SFL), and education about the unreliability/harms of newer

products such as e-cigarettes which are often claimed to be smoke-free. 16, 264 Only when the public and the policymakers are aware and convinced about these issues, they will support the tobacco control movement. Particularly, when implementing a new tobacco control policy such as the SFL, it is necessary to raise awareness about the harms of exposure to tobacco smoke, provisions of the SFL with penalties and benefits of SFL to overcome the tobacco industry generated rumours about the economic harms to businesses due to the SFL, and the health rights of workers employed in hospitality venues. 62 Countries such as Brazil and Uruguay have effectively used media campaigns to raise awareness about the SFL in general masses around the period of implementation of comprehensive SFL in respective jurisdictions.^{22, 64} It was observed in my thesis that the low SES groups in LMICs are at higher risk of SHS exposure (vs. the high SES) and in need of targeted awareness campaigns. This population is also poorly covered by comprehensive SFL.²³ In LMICs such as India, it is highly likely that the disadvantaged groups are also illiterates or barely literate. TV and radio campaigns in local language are likely to appeal to these populations through their visual appeal and content and can potentially reach even the rural populations. For example, media campaigns through TV and radio for raising awareness about the harms of SLT use implemented as a part of the NTCP have been shown to have high reach and recall in India.²⁶⁵ Media campaigns have also been shown to be effective in HICs in garnering support for SFL among smokers through raising awareness about the harms of exposure to tobacco smoke and the benefits of SFL.²⁶⁶ Such media campaigns implemented around the time of introduction tobacco control policies such as the SFL in LMICs can potentially gain support from the informed masses.

The use of social media in tobacco control advocacy has been increasing and is now recognised as an inexpensive alternative for reaching large numbers of users globally and even the hard to reach targets such as politicians and celebrities to engage them in tobacco control advocacy. Hefler et al., through three case studies from Indonesia showed that the social media such as Twitter and Facebook and the online petition websites such as Change.org present important opportunities for tobacco control advocacy; moreover, Twitter and Facebook could also be vital for tracking industry activities. Such low-cost approaches would particularly be important for tobacco control in LMICs.

6.3.5. Increase funding for tobacco control including smoke-free legislation

Low prioritisation of tobacco control in LMICs including poor funding for the same is reflected in my findings from Chapter 4 which suggests that the percentage of smokefree workplaces in several LMICs is still very low. It was observed that less than 65% of the participants were employed in smoke-free workplaces in the Russian Federation, Turkey, Viet Nam, Egypt, Bangladesh and China. 42, 43 Eriksen et al. confirm these findings which have also been shown in Figure 2.1 (in Chapter 2) of my thesis.³ They additionally show that among workplaces, the percentage of restaurants that are smokefree is even lower across LMICs.3 WHO FCTC recommends that Parties should mobilise all the available resources at national, regional and local levels to fulfil the objectives of the Convention.¹⁶ Taxation of tobacco is one of the most effective tobacco control measures and also contributes to reducing inequalities in smoking.¹⁵⁵ Chaloupka et al. suggest that higher tax on tobacco is not harmful to the economy rather, this measure is even more effective when a part of the tax imposed on tobacco products is earmarked for tobacco control activities.²⁶⁸ In 2015, only 20% of the countries globally had dedicated tax revenues for tobacco control.²³ A recent WHO report suggests that funding for comprehensive tobacco control programmes is often insufficient, unsustainable and irregular; while for many LMICs, there is no dedicated funding for controlling NCDs (tobacco being one of the most important risk factors for NCDs) and earmarked tobacco tax is the only choice for driving tobacco control activities.²⁶⁹ The report describes the percentage of earmarked tobacco taxes and the processes involved for nine countries (including HICs as well as LMICs): Botswana, Egypt, Iceland, Panama, Philippines, Poland, Romania, Thailand and Viet Nam. Although the report does not describe the impact of earmarked tobacco taxes on health indicators, the experience from these countries indicates that when sufficient revenue is generated through this mechanism to be able to fund health promotion programmes, the likely impact will be a reduction in tobacco use and the resulting NCDs.²⁶⁹ In my thesis, it was observed that there was less than optimal utilisation of funds by the Indian states which may have resulted in inadequate implementation NTCP activities (including the SFL) and therefore a lack of effect on smoking. Even in states with strong tobacco control programmes such as California, a reduction in funding was shown to be associated with poor performance of the programme and therefore impact on tobacco use.²⁵¹ It is therefore important that tobacco control activities are well-funded.

Other traditional sources for funding tobacco control activities (including SFL implementation, monitoring and evaluation) are philanthropy, added national health

budget allocated to tobacco control activities/programmes, and taxes and duties imposed upon the tobacco industry. Specifically for the implementation, monitoring and evaluation of SFL, sustainable funding sources could include earmarked tobacco taxes, business licensing fees and revenues generated from the periodic renewal of licenses or earmarked business/professional taxes, and the monetary penalties that are paid to the Government for violation of tobacco control laws.⁶²

6.3.6 Tobacco control: a vital investment for achieving global NCD and inequality reduction targets

The World Health Assembly (WHA) in 2012 adopted the Global Monitoring Framework for prevention and control of NCDs which outlines nine NCD targets and related indicators. 18 One of the indicators is 25% relative reduction in premature mortality from NCDs by 2025 (25x25). Further, Goal 3 of the UN Sustainable Development Goals (SDGs) calls for ensuring healthy lives and promoting well-being for all at all ages.²⁰ A reduction in premature mortality from NCDs by one-third till 2030 by prevention and treatment and strengthening and implementation of the WHO FCTC across all countries are the targets listed for achieving Goal 3 of the UN SDG among other targets.²⁰ Further, Goal 10 of the UN SDG calls for reducing inequalities. 143 Ensuring equal opportunity and reducing inequalities of outcome, including by eliminating discriminatory laws, policies and practices and promoting appropriate legislation, policies and action is one of the targets listed for achieving Goal 10 of the UN SDG. 143 The findings of my thesis suggest that exposure to tobacco smoke is higher among the low SES groups in LMICs (as observed in HICs),⁴² where implementation of tobacco control measures including SFL is poor. This can potentially widen existing health inequalities. Reducing tobacco use through the adoption of WHO FCTC and its implementation and enforcement has been recommended by experts as critical for the achievement of NCD reduction 19, 142 and reduction of inequality. In this thesis, it was also observed that comprehensive SFL can reduce health inequalities whereas partial SFL may not. SFL (due to its demonstrated health benefits) and tobacco control in general, therefore, have the potential to be major contributors to the achievement of the WHO 25x25 target for NCDs as well as Goal 3 of the UN SDGs. 19, 20 While pro-equity tobacco control policies such as taxation and comprehensive SFL have the potential to contribute towards achievement of Goal 10 of the UN SDGs. As LMICs currently and in the future are likely to experience a heavy burden of death and disease due to tobacco smoking, it is important that tobacco control policies are strengthened across all LMICs.

6.3.7. Implications for future research

Most studies assessing the impact of SFL on health outcomes, SHS exposure, smoking behaviour and attitudes, air quality, and economic outcomes have been conducted in HICs, particularly those from Europe, Americas, or Asia-Pacific (Australia and New Zealand). Literature from LMICs assessing the impact of SFL is very limited. Such paucity of research from LMICs underscores the need for better monitoring and surveillance data, more funding to support evaluation and strengthening collaborations between researchers in HICs and LMICs. The GATS and GYTS provide information on the prevalence of smoking (in addition to other tobacco products) and SHS exposure at home, workplaces and other public places. However, in several LMICs, such data are not collected periodically. Moreover, inherent limitations of these types of surveys imply that they cannot be effectively used to assess the impact of policies or to guide the implementation and enforcement of tobacco control policies. For example, these surveys do not capture other indicators such as knowledge and support for policies, airnicotine or PM_{2.5} concentrations to assess the air quality, smoking-related mortality and morbidity or other relevant information for economic analyses. So their use in impact assessment is limited. Lessons learnt from prior tobacco control research shows that just prevalence studies are not sufficient to convince policymakers to bring about the desired policy changes.²⁶¹ Analyses of costs incurred due to tobacco use or smoking and the potential costs averted due to lives saved as a result of the implementation of tobacco control policies are more likely to receive support from the policymakers.²⁶¹

Tobacco control policy measures can have an impact on various indicators in the short or the long term. For example, SFL is likely to have an immediate impact on air quality in hospitality venues or SHS exposure, however, it is less likely to have an immediate impact on certain outcomes such as lung cancer which is likely to require several years of SFL implementation before any effect is observed. It is also likely that the impact of a tobacco control intervention observed immediately after the intervention would get diluted in the long term for example in the case of pictorial health warnings on tobacco products or tobacco control media campaigns when the messages/pictures are not rotated periodically. Therefore, it is necessary to undertake immediate as well as long-term evaluations of tobacco control policies including the SFL.²⁵⁸

As in LMICs, smoking and SHS exposure (as observed in my thesis), 42 are higher in the low SES groups and variations are also observed across population sub-groups, 5,53 it is important that future research should assess the impact of SFL among different subgroups such as age groups, gender, urban/rural, national region, and SES indicators, so that targeted control measures can be adopted to reduce disparities and inequalities in outcomes. Earlier research which has assessed SES differences in the impact of tobacco control legislation have mostly relied on the use of SES indicators such as area deprivation, income, education, occupation, and health insurance status. 155, 161 However, all SES indicators may not be relevant for LMICs. A number of surveys including GATS in LMIC settings have utilised possession of assets in the households as an indicator of SES.¹⁹² This information has been utilised to generate an 'asset index' which could be a more reliable measure of SES in the low SES settings.^{219, 220} Further, considering the multi-dimensional nature of deprivation, World Bank has recommended the use of multidimensional poverty index (MPI) for LMICs which consists of 10 indicators from three different dimensions – education, health and standard of living. ¹⁷⁹ Globardes et al. suggest that when SES confounds the relation between a tobacco control intervention and the outcomes, it is important to study the association across multiple measures of SES rather than focusing only one indicator. 182

Specifically, in the LMIC settings, more research is needed on the impact of SFL on:

- Health outcomes (morbidity and mortality due to cardiovascular, respiratory, reproductive and other causes)
- Exposure to SHS (as assessed from respiratory symptoms, or cotinine levels in saliva, urine and hair)
- Air quality (as assessed from air nicotine and PM_{2.5} concentrations in indoor public places, particularly in the hospitality venues)
- Economic activity (as assessed from the revenue generated particularly in the hospitality industry and the impact on job opportunities in the industry)
- Economic costs averted due to reduced mortality and morbidity (associated with smoking-related causes)
- Smoking behaviours (prevalence, particularly at homes and in private vehicles, frequency, cessation, and quit attempts)
- Public knowledge about and attitudes towards SFL and support for SFL

In my thesis, it was observed that there was no compelling evidence that NTCP reduced consumption over and above the general reduction that occurred in all districts in India. Several implementation issues with the NTCP were identified in Chapter 5 including a lack of monitoring, capacity and resources and inadequate utilisation of funds. As implementation and monitoring of tobacco control policies are weak in general across the LMIC settings compared with HICs, ²³ operational/implementation research in these settings could be useful to study the intervention implementation and compliance, the context, and the mechanisms of impact.²⁷⁰ A review of 500 health promotion and prevention programmes revealed that the level of implementation influences the outcomes.²⁷¹ The review highlighted that intervention implementation is affected by about 23 contextual factors including variables related to the community, the environment and the health systems or intervention implementers/providers. Hence, it is important to collect process evaluation data which can provide useful feedback to strengthen the implementation and enforcement of policies. Fong et al. describe the expected mechanisms of impact of various tobacco control policies in the conceptual model for the ITC project, wherein they describe the proximal and distal influences which mediate the relationship between tobacco control policy implementation and the outcomes.²⁷² As wide variations exist across LMICs in terms of types of tobacco used, levels of implementation and enforcement of various tobacco control policies and activities, it is important that these countries invest in studying the mediating mechanisms and processes through which tobacco control policies are expected to influence the outcomes.

Modelling studies can be especially helpful in the LMIC settings where limited data constrains robust evaluation of tobacco control policies. Levy et al. have used the SimSmoke simulation model to study the relative contributions of various tobacco control policies towards reducing smoking prevalence and associated premature mortality in several countries. In Brazil, it was observed that tobacco pricing and taxation explained almost half of the reduction in smoking prevalence while SFL explained 14% of the reduction among other tobacco control measures. A similar modelling study was conducted by Basu et al. to conclude that SFL and raised tobacco taxation would be the most effective tobacco control policies to reduce cardiovascular deaths in India. Such studies would help prioritise and strengthen relevant tobacco control policies in the LMIC settings.

6.4. Conclusions

My thesis has assessed whether similar health benefits of SFL accrue in the context of LMIC settings as observed in HICs and whether any benefits are equitably distributed. I conclude that exposure to tobacco smoke is high among the low SES groups in LMICs, which potentially worsens health inequalities. Furthermore, poor implementation of SFL in LMICs is associated with substantial forgone health benefits, especially in these low SES groups. Effective implementation and enforcement of comprehensive SFL in the LMIC settings may bring about additional health benefits for the vulnerable women and children by reducing exposure to tobacco smoke, partly through a positive change in social norms about exposing non-smokers to tobacco smoke. Strengthening implementation, monitoring mechanisms and collaborative research in tobacco control are essential to improve health outcomes and reduce inequalities in LMICs, thereby contributing towards the achievement of the UN SDG targets of reducing inequalities and premature deaths from NCDs by 2030.

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Appendices

Appendix A: Ethics Approval Letters

London School of Hygiene & Tropical Medicine

Keppel Street, London WC1E 7HT

United Kingdom

Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk



Observational / Interventions Research Ethics Committee

LSHTM

11 May 2015

Dear Dr

Study Title: An assessment of compliance with smoke-free workplace policies and associated impacts on tobacco use and secondhand smoke exposure, in low- and middle-income country (LMIC) settings.

LSHTM Ethics Ref: 9831

Thank you for your application for the above research project which has now been considered by the Observational Committee via Chair's Action.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved is as follows:

Document Type	File Name	Date	Version
Local Approval	STEPS IEC decision_2	12/10/2010	Final
Protocol / Proposal	Upgrading Report_Study Protocol	18/11/2013	Final
Protocol / Proposal	Upgrading_Revision_Final	18/11/2013	Protocol revisions
Investigator CV	cv_Gaurang	30/04/2015	LSHTM Template

After ethical review

Page 1 of 2

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee. The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form. At the end of the study, the CI or delegate must notify the committee using the End of Study form. $All\ a forementioned\ forms\ are\ available\ on\ the\ ethics\ online\ applications\ website\ and\ can\ only\ be\ submitted\ to\ the\ committee\ via\ the\ website\ at \ http://leo.lshtm.ac.uk.$ Further information is available at: www.lshtm.ac.uk/ethics. Yours sincerely, Professor John DH Porter Chair ethics@lshtm.ac.uk http://www.lshtm.ac.uk/ethics/ Improving health worldwide Page 2 of 2



Institutional Ethics Committee

Public Health Foundation of India

Delhi NCR, Plot No. 47, Sector 44, Institutional Area Gurgaon - 122002

Form VIII Communication of Decision on Request for Exemption from IEC Review

TRC-IEC No:	TRC-IEC-255/15			Date:		May 19, 2015	
TRC-IEC NO.	TRC-IEC-255/15			Date:		IVIAY 19, 2015	
Project title:	An assessment of compliance with smoke-free workplace policies and associated impacts on tobacco use and second hand smoke exposure, in low- and middle-income country (LMIC) settings						
Principal Investigator:	Dr. Gaurang Nazar						
Decision on request	Exempted from IEC review			\boxtimes			
for exemption:	Not exempted from full IEC			nmended	l '	pedited view	
	review		for:		Fu	II IEC review	
Comments:	Study meets the criteria for exemption category 3 The study is approved for the duration of 3 years and 6 months. The PI is requested to inform the secretariat of the start of study and upon completion. The PI will submit a progress report to the PHFI-IEC after study completion						

Prof. Ramanan Laxminarayan
Name and Senature of Member Secretary
CHAIRMAN / MEMBER SECRETARY
SELIC HEALTH FOUNDED ON OF INDIA

It is the investigators responsibility to notify the IEC, if any changes or modifications are made in the study's design, procedures, etc which may affect the exemption.

Page 1 of 1

FORM VIII Exemption IEC/Ver3/2012

Appendix B-1: Systematic Review Protocol





PROSPERO

International prospective register of systematic reviews

Review title and timescale

1. Review title

Give the working title of the review. This must be in English. Ideally it should state succinctly the interventions or exposures being reviewed and the associated health or social problem being addressed in the review.

Smoke free legislation and socioeconomic inequalities in smoking related morbidity and mortality among adults: a systematic review and meta-analysis

2. Original language title

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3. Anticipated or actual start date

Give the date when the systematic review commenced, or is expected to commence.

11/01/2016

4. Anticipated completion date

Give the date by which the review is expected to be completed.

30/04/2016

5. Stage of review at time of this submission

Indicate the stage of progress of the review by ticking the relevant boxes. Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. This field should be updated when any amendments are made to a published record.

The review has not yet started

Review stage Preliminary searches Piloting of the study selection process Formal screening of search results against eligibility criteria	Started Yes Yes No	Completed No No No
Data extraction	No	No
Risk of bias (quality) assessment Data analysis	No No	No No

Provide any other relevant information about the stage of the review here.

Review team details

6. Named contact

The named contact acts as the guarantor for the accuracy of the information presented in the register record.

Dr. Marhazlinda Jamaludin

7. Named contact email

Enter the electronic mail address of the named contact. rmjlja1@ucl.ac.uk

8. Named contact address

Enter the full postal address for the named contact. 18. Livingstone Road, E17 9AX, London, UK

9. Named contact phone number

Enter the telephone number for the named contact, including international dialing code. 07710483083

10. Organisational affiliation of the review

Full title of the organisational affiliations for this review, and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

1. University of Malaya, Malaysia 2. University College London. UK 3. Imperial College London, UK 4. London School Health & Tropical Medicine, UK 5. Public Health Foundation, India

Website address:

1.www.um.edu.my 2. www.ucl.ac.uk 3.www.imperial.ac.uk 4.www.lshtm.ac.uk

11. Review team members and their organisational affiliations

Give the title, first name and last name of all members of the team working directly on the review. Give the organisational affiliations of each member of the review team.

Titl	le First	Last	Affiliation
Dr	Marhazlinda	Jamaludin	Department of Community Dentistry
			Clinical Prevention, University of
			Malaysia and Department of
			and Public Health, UCL, London, UK
Dr	Gaurang	Nazar	Health Promotion Division, Public
			Foundation of India, New Delhi and
			Department of Non-communicable
			Epidemiology, Faculty of Epidemiology
			Population Health, LSHTM, UK
Dr	Georgios	Tsakos	Department of Epidemiology and Public
			Health, UCL, London, UK
Professor	Christopher	Millett	School of Public Health, Imperial
			London, London, UK
Professor	Richard	Giddie Watt	Department of Epidemiology and Public
			Health, UCL, London, UK

12. Funding sources/sponsors

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Any unique identification numbers assigned to the review by the individuals or bodies listed should be included.

Ministry of Higher Education, Malaysia and University of Malaya, Malaysia

13. Conflicts of interest

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

Are there any actual or potential conflicts of interest?

None known

14. Collaborators

Give the name, affiliation and role of any individuals or organisations who are working on the review but who are not listed as review team members.

Title First name Last name Organisation details

Review methods

15. Review question(s)

State the question(s) to be addressed / review objectives. Please complete a separate box for each question.

RQ: How does smoke-free legislation in public places affect socioeconomic inequalities in smoking related morbidity and mortality among adults?

General objective: To systematically investigate the impact of smoke-free legislation in public places on socioeconomic differences in, i) smoking related disease specific morbidity and mortality (cardiovascular, respiratory and cancer) and ii) all-cause mortality

Specific objectives: 1. To systematically evaluate the impact of smoke-free legislation in public places on socioeconomic differences in:- i) smoking related disease specific morbidity (defined as a health care attendance or hospital admission): a) acute coronary events (i.e., sudden cardiac death and acute myocardial infarction) and other smoking related cardiac diseases (i.e., acute coronary syndromes and coronary heart diseases) among adults b) cerebrovascular accident (i.e., stroke) and other smoking related cerebrovascular disease (i.e., transient ischaemic attack) among adults c) respiratory health (i.e., odor and irritation, respiratory symptoms) and other smoking related respiratory diseases (asthma and chronic obstructive pulmonary disease (COPD)) among adults d) lung cancer among adults (ii) cause specific and all-cause mortality among adults

16. Searches

Give details of the sources to be searched, and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment. Relevant Mesh phrases and free text will be used as keywords to retrieve eligible published studies. We will search the following electronic databases: MEDLINE, EMBASE, Google Scholar, ISI Web of Science, SCOPUS, CINAHL Plus, DARE, Global Health (CAB), WHO Global Health Library, Cochrane Central Register of Controlled Trials (CENTRAL), Trip, IndMed, SciELO, IMEMR, IMSEAR, and KoreaMed from inception to February 2016. We will restrict to studies in English language and will screen the references of the retrieved articles, conference abstract and proceedings, and citations of articles of interest with Google Scholar and ISI Web of Science for additional studies. Where necessary, we will contact the primary investigators or authors for details and clarifications. For in-progress and unpublished studies we also will consider the following trial registries: WHO International Clinical Trials Registry, Platform, EU Clinical Trials Register, Australia New Zealand Clinical Trial Registry, Pan African Clinical Trials Registry, Clinical Trial Registries India, Brazilian Clinical Trials Registry, Sri Lanka Clinical Trial Registry.

17. URL to search strategy

If you have one, give the link to your search strategy here. Alternatively you can e-mail this to PROSPERO and we will store and link to it. http://www.crd.york.ac.uk/PROSPEROFILES/35744_STRATEGY_20160124.pdf

I give permission for this file to be made publicly available No.

18. Condition or domain being studied

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

Smoking related cardiovascular, respiratory and cancer diseases among adults

19. Participants/population

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria. We will include primary studies with adults aged 18 and above as participants. Studies need to report socioeconomic data of the participants to be eligible.

20. Intervention(s), exposure(s)

Give full and clear descriptions of the nature of the interventions or the exposures to be reviewed

Comprehensive and partial smoke free legislation for public places (bars or restaurants and workplaces) either at national, state, city, regional or community level. Comprehensive ban referred to 100% smoke-free in any indoor areas while partial ban was when smoking was restricted to designated areas.

21. Comparator(s)/control

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group). For non-randomised studies, comparisons may include either a similar population assessed in the same time frame in an adjacent area without smoke-free legislation in place or similarly aged population or age adjusted population evaluated in the time frame preceding the introduction of the smoking ban in the same region of interest.

22. Types of study to be included initially

Give details of the study designs to be included in the review. If there are no restrictions on the types of study design eligible for inclusion, this should be stated.

We will include studies which investigated the differential effects by socioeconomic position of smoke-free legislation in public places on smoking related cardiac and cerebrovascular diseases among adults. For studies with multiple estimates of changes in different time periods, we will use the estimates from the longest follow up and also the most disaggregated level of data for estimates of diseases nested within diagnostic categories. Following the Cochrane Effective Practice and Organisation of Care (EPOC) guideline, our main analyses will be restricted to randomised controlled trials (RCTs; including cluster RCTS), controlled clinical trials (CCTs; including cluster CCTs), quasi experimental studies, interrupted time-series and controlled before and after studies. However, it is anticipated that the number of studies that will fulfil EPOC criteria will be small. Therefore, we will also consider uncontrolled before and after studies, prospective and retrospective cohort, case-control and nested case control studies. We will perform sensitivity analysis to explore the effects of including these study types on the effect estimates. Cross sectional studies, modelling, cost and qualitative studies will not be included.

23. Context

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

Studies will investigate differential effects by socioeconomic position of smoke-free legislation in public places on smoking related disease specific morbidity and mortality (cardiovascular, respiratory and cancer) and also all-cause mortality among adults. Socioeconomic indicators will include either education, income or occupation. As measures of socioeconomic indicators depend on social contexts and culture thus may differ across countries, article by Galobardes et al (2006a and 2006b) that details out the strengths and limitations of the available measures will be referred when interpreting or translating research results.

24. Primary outcome(s)

Give the most important outcomes.

Primary outcomes are socioeconomic differences either by education, income or occupation in disease specific mortality (ie, sudden cardiac death and death from; i) acute myocardial infarction ii) stroke iii) asthma and COPD iv) lung cancer) and all-cause mortality among adults.

Give information on timing and effect measures, as appropriate.

Example: Any changes in the incident of death for i) acute myocardial infarction ii) stroke iii) asthma and COPD iv) lung cancer) before and after implementation of smoke free legislation or any changes in incidence of all-cause mortality before and after legislation by socioeconomic status.

25. Secondary outcomes

List any additional outcomes that will be addressed. If there are no secondary outcomes enter None.

Secondary outcomes are socioeconomic differences in: Hospital admission from acute myocardial infarction Hospital admission from stroke Other smoking related cardiac diseases (acute coronary syndromes and coronary heart diseases) Other smoking related cerebrovascular disease (transient ischemic attack) Emergency department visits from respiratory illness (odor & irritation, respiratory symptoms, asthma and COPD) Hospital admission from lung cancer Intermediate outcomes such as smoking behaviours, second hand smoke exposures and cost effectiveness will not be included

Give information on timing and effect measures, as appropriate.

Example: Any changes in the incident of hospital admissions or emergency visits from i) acute myocardial infarction ii) stroke iii) asthma and COPD iv) lung cancer) before and after implementation of smoke free legislation by socioeconomic status.

26. Data extraction, (selection and coding)

Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted

Of those studies retrieved using the search strategies, duplicates will be removed. Two reviewers will screen the titles and abstracts for potential eligible studies and will assess the full text of selected studies to confirm inclusion.

Relevant data will be extracted using a standardized and customized form and corresponding authors will be contacted for additional information. All stages will be independently conducted by two reviewers. Any disagreement in each stage will be resolved through discussion or by referral to a third reviewer. Kappa analysis will be performed and reported in the final report. We will use EndNote 7 to manage all citations. In a case of duplication, we will retain only the largest study to avoid duplication of information. Review articles however will be excluded from quantitative statistical analysis (unless the original research cannot be obtained and a summary statistical can be reliably obtained from the review). However, they will obviously be the key sources for study identification.

27. Risk of bias (quality) assessment

State whether and how risk of bias will be assessed, how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.

Quality of studies and risk of bias will be assessed independently by two reviewers. Risk of bias will be evaluated using EPOC guideline and Cochrane risk of bias tool for randomised controlled trial, controlled clinical trial and controlled before and after studies, and only EPOC criteria for interrupted time series. Quality of observational studies will be checked using the Effective Public Health Practice Project (EPHPP) Quality Assessment Toll for Quantitative Studies. Among examples of criteria used will include patient selection, comparability at baseline, blinding and randomisation, reliability of measurement tools, appropriateness of analysis, attrition rates etc. We will grade parameters of trial quality; A. Low risk of bias B. Moderate risk of bias C. High risk of bias and will allocate studies according to their quality and risk. Any disagreement will be resolved by consensus or referral to a third reviewer. Sensitivity analysis will be conducted to test effects of removing poor quality studies.

28. Strategy for data synthesis

Give the planned general approach to be used, for example whether the data to be used will be aggregate or at the level of individual participants, and whether a quantitative or narrative (descriptive) synthesis is planned. Where appropriate a brief outline of analytic approach should be given.

If appropriate, we will provide quantitative synthesis and perform meta-analysis for primary and secondary outcomes of included studies using a random-effect method to estimate a pooled risk ratio with 95% confidence intervals and draw forest plots to display the effect estimates and confidence interval for each study and pooled estimates for each health outcome. First, we will calculate effect sizes for continuous outcomes and relative risk differences for categorical

outcomes for each study to be combined. If the outcomes reported in primary studies are continuous outcomes, weighted mean differences (WMD) will be used when all studies used the same scale to measure outcomes.

Otherwise, the standardized mean differences (SMD) will be used as summary estimates. For categorical outcomes, we will summarize individual study results as risk ratio/changes. I² statistic will be employed to investigate statistical heterogeneity. Values over 50% will be regarded as moderate heterogeneity, and values over 75% as high thus meta- analysis will be inappropriate. Reporting bias due to publication bias or due to systematic differences between small and large studies will be checked by investigating relationship between effect sizes and sample size using a funnel plot.

29. Analysis of subgroups or subsets

Give any planned exploration of subgroups or subsets within the review. 'None planned' is a valid response if no subgroup analyses are planned.

We plan to do subgroup analysis by socioeconomic position, age group and type of legislation (comprehensive and partial ban). If data permits, subgroup analysis will also be performed for high income and low to middle income countries separately. Socioeconomic indicators are either education, income or occupation.

Review general information

30. Type of review

Select the type of review from the drop down list. *Intervention, Prevention*

31. Language

Select the language(s) in which the review is being written and will be made available, from the drop down list. Use the control key to select more than one language. English

Will a summary/abstract be made available in English? Yes

32. Country

Select the country in which the review is being carried out from the drop down list. For multinational collaborations select all the countries involved. Use the control key to select more than one country. *India*

33. Other registration details

Give the name of any organisation where the systematic review title or protocol is registered together with any unique identification number assigned. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here.

The title of this review and the review protocol will only be registered at CRD York. There is no plan to register it at other places or organisation.

34. Reference and/or URL for published protocol

Give the citation for the published protocol, if there is one.

Give the link to the published protocol, if there is one. This may be to an external site or to a protocol deposited with CRD in pdf format.

I give permission for this file to be made publicly available Yes

35. Dissemination plans

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

As a PhD project, a thesis therefore will be produced when review has been completed and a report will be submitted to the sponsor of this project. In addition to that, a scientific paper will be submitted to a leading journal in this field.

Do you intend to publish the review on completion? Yes

36. Keywords

Give words or phrases that best describe the review. (One word per box, create a new box for each term) Systematic review inequality, socioeconomic difference, cardiac, cerebrovascular, respiratory, cancer, all caused mortality

Meta-analysis

Smoke-free legislation or policy Inequality Socioeconomic difference cardiac or cardiovascular cerebrovascular respiratory cancer

all-cause mortality

37. Details of any existing review of the same topic by the same authors

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

38. Current review status

Review status should be updated when the review is completed and when it is published.

Ongoing

39. Any additional information

Provide any further information the review team consider relevant to the registration of the review.

40. Details of final report/publication(s)

This field should be left empty until details of the completed review are available. Give the full citation for the final report or publication of the systematic review. Give the URL where available.

Appendix B-2: Systematic Review Search Strategy (Medline and Embase)

- 1. exp Tobacco Smoke Pollution/
- 2. exp "Tobacco Use"/
- 3. exp Smoking/
- 4. "Environmental tobacco smoke".ti,ab.
- 5. (Smok* or Tobacco or Cigar*).tw.
- 6. (Smokefree or Smoke-free or "Smoke free").tw.
- 7. (Clean air or clean indoor air).tw.
- 8. ("Passive smok*" or "Involuntary smoking").mp.
- 9. ("Secondhand smoke" or "second-hand smoke" or "second hand smoke" or SHS).mp.
- 10. or/1-9 [SMOKING CONCEPT]
- 11. exp Government Regulation/
- 12. exp Jurisprudence/
- 13. exp Law Enforcement/
- 14. exp Legislation as Topic/
- 15. exp Policy Making/
- 16. exp Health Policy/
- 17. exp Restaurants/lj [Legislation & Jurisprudence]
- 18. exp Workplace/lj [Legislation & Jurisprudence]
- 19. Tobacco Control Act.mp.
- 20. (Law\$1 or Legislat* or prohibit* or regulat* or ban\$4).tw.
- 21. (Ban* or Law* or Restrict* or Prohibit* or Regulate* or Legislat* or Polic* or Jurispruden* or Ordinan*).tw.
- 22. (Enactment or Act or Injuction or Constitution).tw.
- 23. or/11-22 [LAW CONCEPT]
- 24. 10 and 23 [SMOKING LAW CONCEPT]
- 25. exp Tobacco Smoke Pollution/lj [Legislation & Jurisprudence]
- 26. exp Smoking/lj [Legislation & Jurisprudence]
- 27. exp Smoke-Free Policy/
- 28. Smokefree Policy.mp.
- 29. Smokefree Legislation.mp.
- 30. Smoke-Free Legislation.mp.
- 31. Smoking Ban.mp.
- 32. ((smok\$ or anti smok\$ or tobacco or cigarette\$) adj3 (ban or bans or prohibit\$ or restrict\$ or discourage\$0)).ti,ab.
- 33. ((smok\$ or anti smok\$ or tobacco or cigarette\$) adj3 (workplace or workplaces or work place or work site or worksite or worksites)).ti,ab.
- 34. ((smok\$ or anti smok\$ or tobacco or cigarette\$) adj3 (ban or bans or prohibit\$ or restrict\$ or discourage\$)).ti,ab.
- 35. ((smok\$ or anti smok\$ or tobacco or cigarette\$) adj3 (public place\$ or public space\$ or public area\$ or office\$ or school\$ or institution\$)).ti,ab.
- 36. ((smok\$ or anti smok\$ or tobacco or cigarette\$) adj3 (legislat\$ or government\$ or authori\$ or law or laws or bylaw\$ or byelaw\$ or bye law\$ or regulation\$)).ti,ab.
- 37. ((tobacco free or smoke free) adj3 (hospital or inpatient or institution\$)).ti,ab.
- 38. ((tobacco free or smoke free) adj3 (facilit\$ or zone\$ or area\$ or site\$ or places\$ or environment\$ or air)).ti,ab.
- 39. (tobacco controladj3 (program\$ or initiative\$ or policy or policies or

intervention\$ or activity or activities or framework)).ti,ab.

- 40. ((smok\$ or tobacco) adj (policy or policies or program\$)).ti,ab.
- 41. (tobacco control act or clean air or clean indoor air).ti,ab.
- 42. or/25-41 [SMOKEFREE POLICY CONCEPT]
- 43. 24 or 42 [SMOKE AND LAW OR SMOKEFREE POLICY]
- 44. exp animals/ not humans.mp. [mp=title, abstract, original title, name of substanceword, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
- 45. 43 not 44 [SMOKE AND LAW OR SMOKEFREE POLICY]
- 46. exp Cardiovascular Diseases/
- 47. exp Heart Diseases/
- 48. exp Myocardial Infarction/
- 49. exp Coronary Disease/
- 50. exp Death, Sudden/ or exp Acute Coronary Syndrome/ or exp Angina, Unstable/ or exp Angina Pectoris/ or exp Myocardial Ischemia/ or exp Coronary Artery Disease/
- 51. (Cardiac or heart attack or myocardial or coronary event* or acute coronary syndrome or heart disease* or isch\$emic heart disease*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
- 52. Acute Coronary Event.mp.
- 53. or/46-52 [CARDIOVASCULAR DISEASE]
- 54. 53 not 44 [CARDIOVASCULAR DISEASE]
- 55. 45 and 54
- 56. (Socioeconomic or Socio economic or Socio-economic).ti,ab.
- 57. inequalit\$.ti,ab.
- 58. depriv\$.ti,ab.
- 59. disadvantage\$.ti,ab.
- 60. educat\$.ti,ab.
- 61. (social adj (class\$ or group\$ or grade\$ or context\$ or status)).ti,ab.
- 62. (employ\$ or unemploy\$).ti,ab.
- 63. income.ti,ab.
- 64. poverty.ti,ab.
- 65. SES.ti,ab.
- 66. demographic\$.ti,ab.
- 67. (uninsur\$ or insur\$).ti,ab.
- 68. minorit\$.ti,ab.
- 69. poor.ti,ab.
- 70. affluen\$.ti,ab.
- 71. equity.ti,ab.
- 72. (underserved or under served or under-served).ti,ab.
- 73. occupation\$.ti,ab.
- 74. (work site or worksite or work-site).ti,ab.
- 75. (work place or workplace or work-place).ti,ab.
- 76. (work force or workforce or work-force).ti,ab.
- 77. (high risk or high-risk or at risk).ti,ab.
- 78. (marginalised or marginalized).ti,ab.
- 79. (social\$ adj (disadvant\$ or exclusion or excluded ordepriv\$)).ti,ab.
- 80. exp Socioeconomic Factors/
- 81. exp Public Assistance/

- 82. exp Social Welfare/
- 83. exp Vulnerable

Populations/84. or/56-83

- 85. 84 not 44 [SES CONCEPT]
- 86. 45 and 54 and 85 [SMOKEFREE HEART SES]
- 87. cerebrovascular disorders/ or brain ischemia/ or "intracranial embolism and thrombosis"/ or intracranial hemorrhages/ or stroke/
- 88. cerebrovascular disease.mp.
- 89. Stroke/
- 90. Stroke.mp.
- 91. exp Brain Ischemia/
- 92. Brain isch\$emic.mp.
- 93. exp Cerebral Hemorrhage/
- 94. cerebral haemorrhage.mp.
- 95. exp Cerebral Infarction/
- 96. cerebrovascular accident\$.mp.
- 97. cerebral infarction\$.mp.
- 98. exp Cerebral Arterial Diseases/
- 99. cerebral artery disease\$.mp.
- 100. exp Ischemic Attack, Transient/
- 101. cerebral

isch\$emic.mp. 102.

or/87-101

- 103. 102 not 44 [STROKE CONCEPT]
- 104. 45 and 85 and 103 [SMOKEFREE STROKE SES]
- 105. exp Respiration Disorders/
- 106. exp Asthma/
- 107. Pulmonary disease\$.mp. or exp lung disease/ [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
- 108. exp Pulmonary Disease, Chronic Obstructive/ or exp RespiratoryTract Infections/ 109. (respiratory health or asthma or pulmonary disease or pneumonia or respiratory track disease or respiratory track diseases or chronic obstructive pulmonary disease or obstructive pulmonary disease or chronic obstructive airways disease or COAD or chronic obstructive lung disease).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
- 110. or/105-109
- 111. 110 not 44 [RESPIRATORY CONCEPT]
- 112. 45 and 85 and 111 [SMOKEFREE RESPIRATORY SES]
- 113. mortality.mp. or exp Hospital Mortality/ or expMortality/
- 114. morbidity.mp. or exp Morbidity/
- 115. all cause.mp.
- 116. (113 or 114) and 115
- 117. (emergency admission\$ or ED).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

- 118. (116 or 117) not 44 [OTHERS OUTCOMES]
- 119. 45 and 85 and 118 [SMOKEFREE OTHERS SES]
- 120. 45 and 54 and 85 [SMOKEFREE HEART SES]
- 121. 45 and 85 and 103 [SMOKEFREE STROKE SES]
- 122. 45 and 85 and 111 [SMOKEFREE RESPIRATORY SES]

Appendix B-3: EPOC suggested risk of bias criteria for interrupted time series (ITS) studies

Risk of bias for interrupted time series (ITS) studies

Seven standard criteria are used for all ITS studies. Further information can be obtained from the Cochrane handbook section on Risk of Bias and from the draft methods paper on risk of bias under the EPOC specific resources section of the EPOC website.

Note: If the ITS study has ignored secular (trend) changes and performed a simple t-test of the pre versus post intervention periods without further justification, the study should not be included in the review unless reanalysis is possible.

Was the intervention independent of other changes?

Score "Low risk" if there are compelling arguments that the intervention occurred independently of other changes over time and the outcome was not influenced by other confounding variables/historic events during study period. *If Events/variables identified, note what they are.* Score "High risk" if reported that intervention was not independent of other changes in time.

Was the shape of the intervention effect pre-specified?

Score "Low risk" if point of analysis is the point of intervention OR a rational explanation for the shape of intervention effect was given by the author(s). Where appropriate, this should include an explanation if the point of analysis is NOT the point of intervention. Score "High risk" if it is clear that the condition above is not met.

Was the intervention unlikely to affect data collection?

Score "Low risk" if reported that intervention itself was unlikely to affect data collection (for example, sources and methods of data collection were the same before and after the intervention); Score "High risk" if the intervention itself was likely to affect data collection (for example, any change in source or method of data collection reported).

Was knowledge of the allocated interventions adequately prevented during the study?³

Score "Low risk" if the authors state explicitly that the primary outcome variables were assessed blindly, or the outcomes are objective, e.g. length of hospital stay. Primary outcomes are those variables that correspond to the primary hypothesis or question as defined by the authors. Score "High risk" if the outcomes were not assessed blindly. Score "Unclear risk" if not specified in the paper.

Were incomplete outcome data adequately addressed?³

Score "Low risk" if missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the pre- and post-intervention periods or the proportion of missing data was less than the effect size i.e. unlikely to overturn the study result). Score "High risk" if missing outcome data was likely to bias the results. Score "Unclear risk" if not specified in the paper (Do not assume 100% follow up unless stated explicitly).

Was the study free from selective outcome reporting?

Score "Low risk" if there is no evidence that outcomes were selectively reported (e.g. all relevant outcomes in the methods section are reported in the results section). Score "High risk" if some important outcomes are subsequently omitted from the results. Score "Unclear risk" if not specified in the paper.

Was the study free from other risks of bias? Score "Low risk" if there is no evidence of other risk of biases. e.g. should consider if seasonality is an issue (i.e. if January to June comprises the preintervention period and july to December the post, could the "seasons' have caused a spurious effect).

Appendix B-4: EPHPP quality assessment tool for quantitative studies and rating criteria for the study



QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

COMPONENT RATINGS

A) SELECTION BIAS

- (Q1) Are the individuals selected to participate in the study likely to be representative of the target population?
 - 1 Very likely
 - 2 Somewhat likely
 - 3 Not likely
 - 4 Can't tell
- (Q2) What percentage of selected individuals agreed to participate?
 - 1 80 100% agreement
 - 2 60 79% agreement
 - 3 less than 60% agreement
 - 4 Not applicable
 - 5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

- 1 Randomized controlled trial
- 2 Controlled clinical trial
- 3 Cohort analytic (two group pre + post)
- 4 Case-control
- 5 Cohort (one group pre + post (before and after))
- 6 Interrupted time series
- 7 Other specify
- 8 Can't tell

Was the study described as randomized? If NO, go to Component C.

If Yes, was the method of randomization described? (See dictionary)

No Ye

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

- (Q1) Were there important differences between groups prior to the intervention?
 - 1 Yes 2 No

 - 3 Can't tell

The following are examples of confounders:

- 1 Race
- 2 Sex
- 3 Marital status/family
- Age 4
- 5 SES (income or class)
- 6 Education
- Health status
- 8 Pre-intervention score on outcome measure
- (02)If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?
 - 1 80 100% (most)
 - 2 60 79% (some)
 - 3 Less than 60% (few or none)
 - 4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) **BLINDING**

- (Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?
 - 1 Yes
 - 2 No
 - 3 Can't tell
- (02)Were the study participants aware of the research question?
 - 1 Yes
 - 2 No
 - 3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) **DATA COLLECTION METHODS**

- Were data collection tools shown to be valid?
 - 1 Yes
 - 2 No
 - 3 Can't tell
- (Q2)Were data collection tools shown to be reliable?
 - 1 Yes
 - 2 No
 - 3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

- (Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?
 - 1 Yes
 - 2 No
 - 3 Can't tell
 - 4 Not Applicable (i.e. one time surveys or interviews)
- (Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).
 - 1 80 -100%
 - 60 79%
 - 3 less than 60%
 - 4 Can't tell
 - 5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

- Q1) What percentage of participants received the allocated intervention or exposure of interest?
 - 1 80 -100%
 - 2 60 79%
 - 3 less than 60%
 - 4 Can't tell
- (Q2) Was the consistency of the intervention measured?
 - 1 Yes
 - 2 No
 - 3 Can't tell
- (Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?
 - 4 Yes
 - 5 No 6 Car
 - Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

- (Q3) Are the statistical methods appropriate for the study design?
 - 1 Yes
 - 2 No 3 Can't tell
- (Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?
 - 1 Yes
 - 2 No
 - 3 Can't tell

GLOBAL RATING

COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

Α	SELECTION BIAS	STRONG	MODERATE	WEAK	
		1	2	3	
В	STUDY DESIGN	STRONG	MODERATE	WEAK	
		1	2	3	
C	CONFOUNDERS	STRONG	MODERATE	WEAK	
		1	2	3	
D	BLINDING	STRONG	MODERATE	WEAK	
		1	2	3	
E	DATA COLLECTION METHOD	STRONG	MODERATE	WEAK	
		1	2	3	
F	WITHDRAWALS AND DROPOUTS	STRONG	MODERATE	WEAK	
		1	2	3	Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1	STRONG	(no WEAK ratings)
2	MODERATE	(one WEAK rating)
3	WEAK	(two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

- 1 Oversight
- 2 Differences in interpretation of criteria
- 3 Differences in interpretation of study

Final decision of both reviewers (circle one):

1 STRONG 2 MODERATE 3 WEAK

Component Ratings of Study:

For each of the six components A - F, use the following descriptions as a roadmap.

A) SELECTION BIAS

Strong: The selected individuals are very likely to be representative of the target population (Q1 is 1) and there is greater than 80% participation (Q2 is 1).

Moderate: The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); **and** there is 60 - 79% participation (Q2 is 2). 'Moderate' may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can't tell)

Weak: The selected individuals are not likely to be representative of the target population (Q1 is 3); or there is less than 60% participation (Q2 is 3) or selection is not described (Q1 is 4); and the level of participation is not described (Q2 is 5).

B) DESIGN

Strong: will be assigned to those articles that described RCTs and CCTs

Moderate: will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

Weak: will be assigned to those that used any other method or did not state the method used.

C) CONFOUNDERS

Strong: will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); or (Q2 is 1).

Moderate: will be given to those studies that controlled for 60 - 79% of relevant confounders (Q1 is 1) and (Q2 is 2).

Weak: will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) and (Q2 is 3) or control of confounders was not described (Q1 is 3) and (Q2 is 4).

D) BLINDING

Strong: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **and t**he study participants are not aware of the research question (Q2 is 2).

Moderate: The outcome assessor is not aware of the intervention status of participants ($\Omega 1$ is 2); **or** the study participants are not aware of the research question ($\Omega 2$ is 2); **or** blinding is not described ($\Omega 1$ is 3 and $\Omega 2$ is 3).

Weak: The outcome assessor is aware of the intervention status of participants (Q1 is 1); and the study participants are aware of the research question (Q2 is 1).

E) DATA COLLECTION METHODS

Strong: The data collection tools have been shown to be valid (Q1 is 1); and the data collection tools have been shown to be reliable (Q2 is 1).

Moderate: The data collection tools have been shown to be valid (01 is 1); **and** the data collection tools have not been shown to be reliable (02 is 2) **or** reliability is not described (02 is 3).

Weak: The data collection tools have not been shown to be valid (Q1 is 2) **or** both reliability and validity are not described (Q1 is 3 and Q2 is 3).

F) WITHDRAWALS AND DROP-OUTS - a rating of:

Strong: will be assigned when the follow-up rate is 80% or greater (Q2 is 1).

Moderate: will be assigned when the follow-up rate is 60 - 79% (Q2 is 2) OR Q2 is 5 (N/A).

Weak: will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q2 is 4).

Appendix C-1: Definition of variables used in study presented in section 4.3

	Supplementary Table									
	Definition of variables used in study presented in section 4.3									
Sr.	Variable	Definition								
No.										
Dep	endent variable									
1	Living in Smokefree home	Respondents who are living under smoke-free home are defined as those who reported "never" to the following question: How often does "anyone" smoke inside your home? Would you say daily, weekly, monthly, less than monthly, or never?								
Inde	pendent variables									
2	Employed in Smokefree workplace	Respondents who are employed in smoke-free workplace are defined as those who are not exposed to SHS at workplace. This is among respondents who work outside the home and usually work indoors or both indoors and outdoors. Respondents who are exposed to SHS at workplace are those who answered 'yes' to the following question: during the past 30 days, did anyone smoke in								
		indoor areas where you work.								
3	Age Group	Age category (in years) to which the respondent belongs i.e. ≥15 to ≤29, ≥30 to ≤44, ≥45 to ≤59, ≥60.								
4	Gender	Biological sex of the respondent i.e. Male or Female								
5	Residence	Place of residence of respondent i.e. Urban or Rural								
6	Region	National region the respondent stays in (National regions differ by country and this variable is present only in case of India, Thailand, China, Brazil, Poland, Ukraine and Egypt).								
7	Education	The level of education the respondent has completed i.e. primary level; secondary level, tertiary level.								
		Primary level includes "no formal education" and "primary education". Secondary level includes "secondary/higher secondary/ pre college/ technical/vocational school". Tertiary level includes "college/university graduate/ postgraduate, vocational/technical degrees, professional degrees". For Romania, Russian Federation and Ukraine, due to negligible proportion of participants educated up to primary level, those participants were merged in the secondary level category. Hence, these countries contained only two categories: secondary level and tertiary level.								
8	Occupation	Current occupation of the respondent i.e. Employed or Self-employed. The Government/Non-government employees categories have been merged into employed category. Other professions/owners/businesses/employers etc. categories have been merged into self-employed category. For China, respondent's occupation variable is categorised into one of the 5 categories: Agriculture employee; Machine operator, Leader of organizations, Medical/Health personnel and Teaching staff as reported by CDC.								
9	Current tobacco smoker	A respondent was classified as current tobacco smoker if he/she responded 'daily' or 'less than daily' to the following question: Do you currently smoke tobacco on a daily basis, less than daily, or not at all?								
10	Current smokeless tobacco user	A respondent was classified as current smokeless tobacco user if he/she responded 'daily' or 'less than daily' to the following question: Do you currently use smokeless tobacco on a daily basis, less than daily, or not at all?								
11	Number of people in the household	Indicates how many people live in the household of the respondent. This is the answer to the following question "In total, how many persons are living in this household?"								

Appendix C-2: Missing data for SHS exposure at Home among GATS participants (2008-2011)

	Supplementary Table: Missing data for SHS exposure at Home among GATS participants (2008-2011)														
		SEAR			V	VPR	N (%)	AN	/IR		EUR				EMR
	India N=67,006	Bangladesh N=9,323	Thailand N=20,437	China N=13,302	Malaysia N=4,091	Philippines N=9,578	Viet Nam N=9,866	Mexico N=13,530	Uruguay N=5,576	Poland N=7,640	Romania N=4,472	Russian Federation N=11,321	Turkey N=8,900	Ukraine N=8,092	Egypt N=20,443
Dependent var	riable		•	•				•	•	•	•		•	•	•
SHS	2041	229	84	33	140	121	55	27	2	151	16	69	118	37	470
exposure at home*	(2.9)	(2.4)	(0.4)	(0.2)	(3.3)	(1.2)	(0.5)	(0.2)	(0.03)	(1.9)	(0.4)	(0.6)	(1.3)	(0.4)	(2.2)
Independent v	ariables							l .		ı			ı	ı	l .
Age group	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gender	-	-	-	-	-	-	ı	-	-	-	-	-	-	-	-
Residence	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Education	137 (0.2)	64 (0.7)	40 (0.2)	5 (0.04)	17 (0.4)	1 (0.01)	4 (0.04)	26 (0.2)	-	22 (0.3)	25 (0.5)	3 (0.03)	12 (0.1)	16 (0.2)	6 (0.03)
Wealth	1	1	-	-	-	-	-	18	3	-	-	-	-	-	1
Quintile	(0.001)	(0.01)						(0.1)	(0.05)						(0.0)
Occupation	111 (0.2)	12 (0.1)	5 (0.02)	14 (0.1)	2 (0.05)	1 (0.01)	1	16 (0.1)	-	27 (0.3)	4 (0.1)	13 (0.1)	0	13 (0.2)	(0.02)
Total	2290	306	129	52	159	123	59	87	5	200	45	85	130	66	481
missing cases	(3.3)	(3.2)	(0.6)	(0.4)	(3.7)	(1.3)	(0.6)	(0.6)	(0.1)	(2.5)	(1.0)	(0.7)	(1.4)	(0.8)	(2.3)

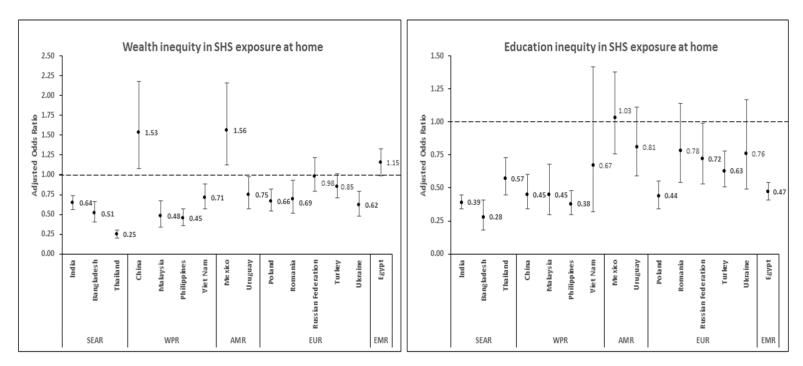
^{*}Participants who responded "Don't know" or "Refused to answer" for the question "How often does anyone smoke inside your home?" were dropped from the analysis.

Appendix C-3: Missing data for SHS exposure at Workplace among GATS participants (2008-2011)

			Suppleme	entary Table	e: Missing da	ata for SHS exp	oosure at Wo	orkplace an	nong GATS	participants	(2008-2011)				
		SEAR			\ \	VPR	11 (79)	Α	MR			EUR			EMR
	India N=12,852	Bangladesh N=1,704	Thailand N=5,021	China N=1,859	Malaysia N=996	Philippines N=2,152	Viet Nam N=2,419	Mexico N=2,082	Uruguay N=1,796	Poland N=3,030	Romania N=1,175	Russian Federation N=5,464	Turkey N=2,160	Ukraine N=2,761	Egypt N=4,490
Dependent variable															
SHS exposure at workplace*	667 (4.9)	104 (5.7)	51 (1.0)	10 (0.5)	122 (10.9)	17 (0.8)	21 (0.9)	17 (0.8)	2 (0.1)	70 (2.3)	16 (1.3)	114 (2.0)	11 (0.5)	52 (1.8)	26 (0.6)
Independent variable	es	. ,	, ,			. ,					, , , ,	, ,			
Age group	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gender	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Residence	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Education	3 (0.02)	4 (0.2)	10 (0.2)	2 (0.1)	6 (0.5)	-	1 (0.04)	2 (0.1)	-	4 (0.1)	1 (0.1)	1 (0.01)	-	1 (0.03)	-
Wealth Quintile	-	-	-	-	-	-	-	-	1 (0.05)	-	-	-	-	-	-
Occupation	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total missing cases	670 (4.9)	108 (6.0)	61 (1.2)	12 (0.6)	128 (11.4)	17 (0.8)	(0.9)	19 (0.9)	(0.2)	74 (2.4)	17 (1.4)	115 (2.1)	(0.5)	53 (1.9)	26 (0.6)

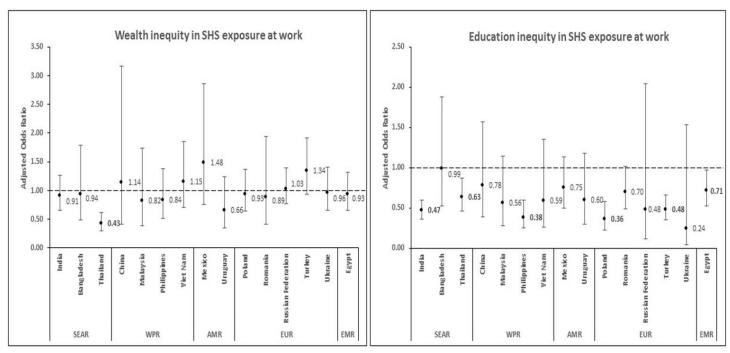
^{*}Participants who responded "Don't know" or "Refused to answer" for the question "During the past 30 days, did anyone smoke in the indoor areas where you work?" were dropped from the analysis.

Appendix C-4: Adjusted Odds Ratio estimates showing secondhand smoke (SHS) exposure at home



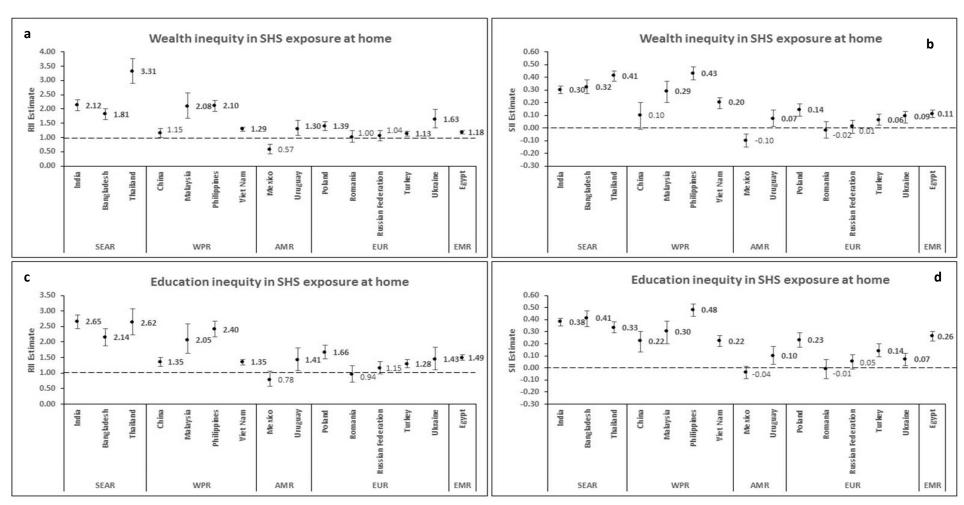
Supplementary Figure: Adjusted Odds Ratio estimates showing secondhand smoke (SHS) exposure at home [highest wealth quintile vs. lowest (ref.) and highest education level vs. lowest (ref.)]

Appendix C-5: Adjusted Odds Ratio estimates showing secondhand smoke (SHS) exposure at workplace



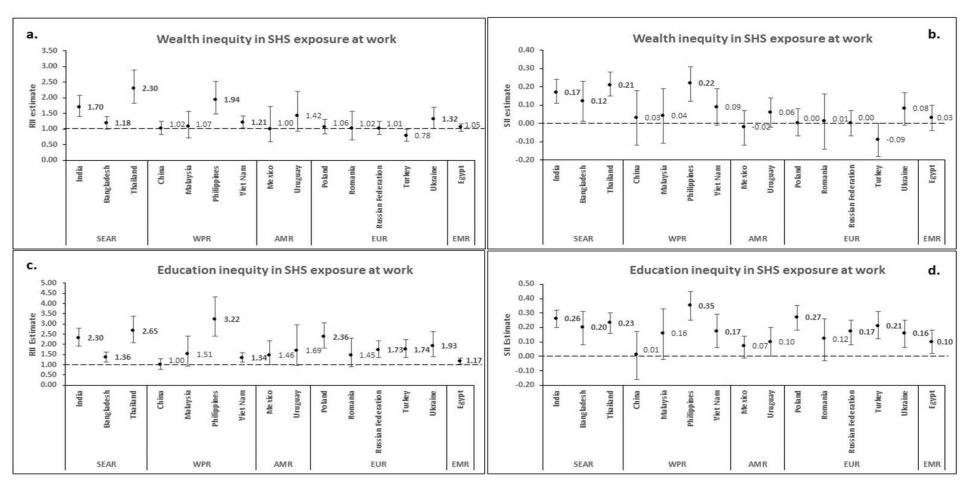
Supplementary Figure: Adjusted Odds Ratio estimates showing secondhand smoke (SHS) exposure at workplace [highest wealth quintile vs. lowest (ref.) and highest education level vs. lowest (ref.)]

Appendix C-6: Socioeconomic inequality in secondhand smoke (SHS) exposure at home



Supplementary Figure: Socioeconomic inequality in secondhand smoke (SHS) exposure at home --- a) RII estimates of wealth inequality in SHS exposure at home; b) SII estimates of wealth inequality in SHS exposure at home; c) RII estimates of education inequality in SHS exposure at home

Appendix C-7: Socioeconomic inequality in secondhand smoke (SHS) exposure at workplace



Supplementary Figure: Socioeconomic inequality in secondhand smoke (SHS) exposure at workplace --- a) RII estimates of wealth inequality in SHS exposure at work; b) SII estimates of wealth inequality in SHS exposure at work; c) RII estimates of education inequality in SHS exposure at work

Appendix D-1: States and Districts in India covered under the National Tobacco Control Programme (NTCP)

Supple	Supplementary Table: States and Districts in India covered under the National Tobacco Control Programme (NTCP)								
Sr. No.	Name of State	Name of Districts							
Phase 1 (2007-2008)								
1	Assam	Kamrup and Johrat							
2	Delhi	New Delhi and East Delhi							
3	Gujarat	Vadodara and Sabarkantha							
4	Karnataka	Bangalore and Gulbarga							
5	Madhya Pradesh	Khandwa and Gwalior							
6	Rajasthan	Jaipur and Jhunjhunu							
7	Tamil Nadu	Kancheepuram and Villupuram							
8	Uttar Pradesh	Lucknow and Kanpur							
9	West Bengal	Cooch Behar and							
		Murshidabad							
Phase 2 (2008-2009)								
10	Andhra Pradesh	Guntur and Hyderabad							
11	Arunachal Pradesh	West Kameng and East Siang							
12	Bihar	Patna and Munger							
13	Goa	North Goa and South Goa							
14	Jharkhand	Dhanbad and Jamshedpur							
15	Maharashtra	Thane and Aurangabad							
16	Mizoram	Aizawl and Lunglei							
17	Nagaland	Kohima and Dimapur							
18	Odisha	Cuttack and Khurda							
19	Sikkim	East Sikkim and South Sikkim							
20	Tripura	West Tripura and Dhalai							
		District							
21	Uttarakhand	Dehradun and Tehri Gadhwal							

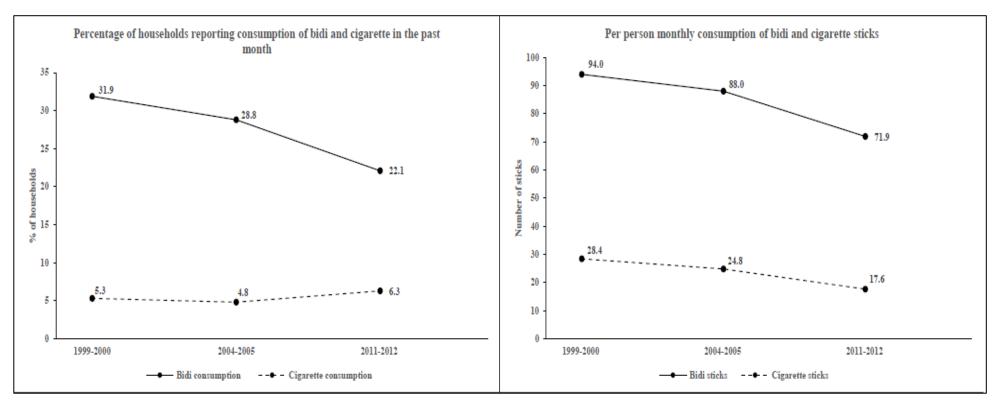
(Source: Ministry of Health and Family Welfare. Operational Guidelines: National Tobacco Control Programme. 2012. URL:

http://mohfw.nic.in/WriteReadData/I892s/2945310979Operational%20Guidelines.pdf. accessed: July 24, 2016)

Appendix D-2: Description of household characteristics in NTCP and non-NTCP districts

Supplementary	Table: Description of household characteristics in NTO Intervention* (n=35,581)			CP and non-NTCP districts (N=341,975) Control (n=306,394)		
	1999-2000	2004-05	2011-12	1999-2000	2004-05	2011-12
Sector (% [95% CI])	(n=12,281)	(n=13,001)	(n=10,299)	(n=107,259)	(n=110,742)	(n=88,393)
Rural	56·2 [54·6, 57·9]	54·0 [52·5, 55·6]	46·0 [43·9, 47·9]	74·3 [73·9, 74·6]	75·3 [74·9, 75·7]	71·2 [70·7, 71·7]
Urban	43.8	46.0	54.0	25.7	24.7	28.8
Household size (% [95% CI])	[42·1, 45·4]	[44·4, 47·5]	[52.0, 56.0]	[25.4, 26.0]	[24·3, 25·1]	[28·3, 29·3]
Number of residents ≤ 5	68.8	71.8	77·0	66-1	68.8	74·0 [73·5, 74·6]
Number of residents > 5	[67·4, 70·1] 31·2	[70·5, 73·1] 28·2	[75·3, 78·6] 23·0	[65·7, 66·5] 33·9	[68·4, 69·2] 31·2	26.0
Religion (% [95% CI])	[29.9, 32.6]	[26·9, 29·5]	[21·4, 24·7]	[33.5, 34.3]	[30·8, 31·6]	[25·4, 26·5]
Hindu	81.5	81.8	82.0	83.5	83.5	83.4
Muslim	[80·4, 82·6] 14·3	[80·6, 82·8] 14·0	[80·5, 83·4] 14·1	[83·2, 83·8] 10·6	[83·2, 83·9] 11·0	[83·0, 83·8] 11·6
Christian	[13·3, 15·3] 2·6	[13·1, 15·0] 2·8	[12·8, 15·5] 2·8	[10·3, 10·9] 2·7	[10·7, 11·2] 2·4	[11·2, 12·0] 2·4
	[2·3, 3·0]	[2·3, 3·3]	[2·3, 3·2]	[2.6, 2.9]	[2·3, 2·5]	[2·3, 2·6]
Others	1·6 [1·3, 1·8]	1·4 [1·1, 1·8]	1·1 [0·9, 1·4]	3·2 [3·0, 3·3]	3·1 [3·0, 3·2]	2·6 [2·5, 2·8]
Caste (% [95% CI]) Scheduled Tribe (ST)	7:7	7.2	8.3	9.0	9.0	8.8
. ,	[7.0, 8.3]	[6·5, 7·9]	[7.4, 9.3]	[8.8, 9.2]	[8.8, 9.3]	[8.5, 9.2]
Scheduled Caste (SC)	18·1 [17·0, 19·2]	19·0 [17·7, 20·3]	16·0 [14·6, 17·5]	19·3 [18·9, 19·6]	19·7 [19·4, 20·1]	19·5 [19·0, 20·0]
Other Backward Class (OBC)	24·7 [23·5, 25·9]	31·7 [30·3, 33·2]	39.3	36·1	41·4 [40·9, 41·8]	43·7 [43·1, 44·4]
Others	49.5	42.1	[37·4, 41·3] 36·4	[35·7, 36·5] 35·6	29.9	28.0
Employment type (of the head	[47·9, 51·2] of the household	[40·6, 43·6]	[34·4, 38·4]	[35·2, 36·0]	[29.5, 30.3]	[27·4, 28·5]
Self-employed	38-4	42.3	39.0	43.7	48.1	46.1
Regular Labour	[36·9, 39·9] 21·0	[40·8, 43·8] 21·4	[37·2, 41·0] 31·3	[43·3, 44·1] 10·4	[47·6, 48·5] 9·6	[45·4, 46·7] 17·7
Casual labour	[19·5, 22·6] 29·5	[20·2, 22·7] 24·4	[29·5, 33·2] 20·4	[10·1, 10·6] 34·1	[9·4, 9·9] 31·3	[17·3, 18·2] 28·6
_	[28·1, 30·9]	[23·1, 25·7]	[18·8, 22·0]	[33.7, 34.5]	[30.8, 31.7]	[28.0, 29.2]
Others	11·1 [10·3, 11·9]	11·9 [10·8, 13·0]	9·3 [8·0, 10·7]	11·8 [11·5, 12·1]	11·0 [10·7, 11·3]	7·6 [7·2, 8·0]
Wealth quintile (% [95% CI])	40.0	16.9	16.9		00.5	00.4
Poorest	19·2 [17·8, 20·7]	[15·8, 18·0]	[15·5, 18·4]	20·3 [20·0, 20·6]	20·5 [20·1, 20·9]	20·4 [19·9, 20·9]
Poor	20·2 [18·8, 21·6]	19·3 [18·1, 20·5]	20·7 [19·2, 22·3]	19·9 [19·5, 20·2]	20·1 [19·8, 20·5]	19·9 [19·4, 20·4]
Middle	20.1	21.4	20.2	20.0	19.8	20.0
Rich	[18·9, 21·4] 21·0	[20·2, 22·8] 20·9	[18·7, 21·8] 21·1	[19·6, 20·3] 19·8	[19·5, 20·2] 19·9	[19·5, 20·5] 19·9
Richest	[19·9, 22·1] 19·5	[19·7, 22·1] 21·5	[19·5, 22·7] 21·1	[19·5, 20·2] 20·0	[19·5, 20·2] 19·7	[19·3, 20·4] 19·8
	[18·4, 20·7]	[20.2, 22.9]	[19.4, 23.0]	[19.7, 20.4]	[19·3, 20·0]	[19·3, 20·3]
Proportion of household mem 0-4 years	bers in each age o	groups [95% CI]# 0:08	0.07	0.09	0.09	0.07
	[0·08, 0·09] 0·20	[0·07, 0·08] 0·19	[0·06, 0·07] 0·16	[0·09, 0·09] 0·22	[0·09, 0·09] 0·20	[0·07, 0·07] 0·19
5-14 years	[0.19, 0.21]	[0.18, 0.19]	[0.16, 0.17]	[0.21, 0.22]	[0.20, 0.21]	[0.18, 0.19]
15-29 years	0·28 [0·27, 0·29]	0·30 [0·29, 0·31]	0·32 [0·30, 0·33]	0·27 [0·27, 0·27]	0·27 [0·26, 0·27]	0·27 [0·27, 0·28]
30-59 year	0·35 [0·34, 0·35]	0.35	0.36	0.33	0.35	0.37
≥60 years	0.08	[0·34, 0·36] 0·08	[0·35, 0·37] 0·09	[0·33, 0·33] 0·09	[0·34, 0·35] 0·09	[0·37, 0·37] 0·10
Proportion of household mem	[0·07, 0·08] bers who are male	[0.08, 0.09] es or females [95%	[0·08, 0·09]	[0.09, 0.09]	[0.09, 0.09]	[0·10, 0·10]
Females	0.47	0.47	0.45	0.48	0.48	0.48
Males	[0·46, 0·47] 0·53	[0·46, 0·48] 0·53	[0·44, 0·46] 0·55	[0·47, 0·48] 0·52	[0·48, 0·48] 0·52	[0·47, 0·48] 0·52
Proportion of household mem	[0·53, 0·54]	[0·52, 0·53]	[0·53, 0·55]	[0.52, 0.52]	[0.52, 0.52]	[0.52, 0.52]
Illiterates	0.56	0.75	0.40	0.62	0.83	0.49
Primary	[0·55, 0·58] 0·11	[0·73, 0·76] 0·09	[0·38, 0·41] 0·12	[0·62, 0·63] 0·11	[0·83, 0·84] 0·08	[0·48, 0·49] 0·13
Middle	[0·10, 0·12] 0·11	[0·09, 0·10] 0·07	[0·11, 0·13] 0·14	[0·11, 0·12] 0·11	[0·07, 0·08] 0·04	[0·13, 0·13] 0·14
	[0·11, 0·12]	[0.06, 0.07]	[0.13, 0.15]	[0.11, 0.11]	[0.04, 0.04]	[0.14, 0.14]
Secondary	0·09 [0·08, 0·10]	0·01 [0·01, 0·01]	0·12 [0·11, 0·13]	0·07 [0·07, 0·07]	0·01 [0·01, 0·01]	0·10 [0·10, 0·11]
Higher Secondary	0.01	0.08	0.10	0.004	0.04	0.08
Graduate and above	[0·01, 0·01] 0·05	[0.07, 0.09]	[0·09, 0·11] 0·12	[0·004, 0·005] 0·03	[0.04, 0.04]	[0·08, 0·08] 0·06
	[0.05, 0.06]		[0.11, 0.13]	[0.03, 0.03]		[0.06, 0.06]

Appendix D-3: Trends in household consumption of bidis and cigarettes over time in India (Consumer Expenditure Survey rounds: 1999-2000; 2004-05; 2011-12)



Supplementary Figure: Trends in household consumption of bidis and cigarettes over time in India (Consumer Expenditure Survey rounds: 1999-2000; 2004-05; 2011-12)

Appendix D-4: Household consumption of bidis and cigarettes across intervention (NTCP) and control groups

Supplementary Table: H		bidis and cigarettes across in I groups	tervention (NTCP) and				
Percentage of		i consumption in the past mo	nth [95% CI]				
	1999-2000	2004-2005	2011-2012				
	n=119,540	n=123,743	n=98,692				
Intervention (NTCP)	30.6	25.9	18.8				
,	[29.2, 31.9]	[24.6, 27.2]	[17·3, 20·4]				
Control	[29·2, 31·9] 32·0	[24·6, 27·2] 29·1	22.5				
	[31·6, 32·4] -1·4*	[28·7, 29·5] -3·2*	[22.0, 23.1]				
Difference#	-1·4*	-3.2*	-3·7*				
	[-2.9, -0.02]	[-4·6, -1·8]	[-5·3, -2·1]				
Percentage of households reporting cigarette consumption in the past month [95% CI]							
-	1999-2000	2004-2005	2011-2012				
	n=119,540	n=123,743	n=98,692				
Intervention (NTCP)	6.9	6.1	8.6				
	[5.9, 8.1]	[5·4, 6·8]	[7·3, 9·9]				
Control	5.1	4.7	6.0				
	[4.9, 5.3]	[4·5, 4·8] 1·4*	[5·7, 6·2] 2·6*				
Difference#	1.8*		-				
	[0.7, 2.9]	[0.7, 2.1]	[1·3, 3·9]				
Monthly consumption of bidi sticks in numbers per person [95% CI]							
	1999-2000	2004-2005	2011-2012				
	n=34,196	n=33,476	n=19,146				
Intervention (NTCP)	95⋅8	89.3	72.3				
	[92·4, 99·2]	[85·8, 92·7]	[67·4, 77·2]				
Control	93.9	87.9	71.9				
	[92·7, 95·0]	[86·8, 89·0]	[70·1, 73·7]				
Difference\$	1.9	1.3	0.4				
	[-1.6, 5.5]	[-2·3, 4·9]	[-4·8, 5·6]				
Monthly consumption of cigarette sticks in numbers per person [95% CI]							
	1999-2000	2004-2005	2011-2012				
	n=9,349	n=9,310	n=9,883				
Intervention (NTCP)	25.9	23.3	20.4				
	[22.4, 29.4]	[20.4, 26.1]	[16·8, 23·9]				
Control	28.7	25.1	17:2				
	[27.6, 29.7]	[24·1, 26·1]	[16·3, 18·1]				
Difference ^{\$}	-2.8	-1.8	3.1				
	[-6·4, 0·9]	[-4·8, 1·2]	[-0.5, 6.8]				

[#] test for difference in proportions between intervention and control groups
\$ test for difference in means between intervention and control groups

^{*} indicates p<0.05