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Deemed to be University.**ADMINISTRATIVE INFORMATION****Support** - Nil.**Review Stage at time of this submission** - Preliminary searches.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2023120034**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 December 2023 and was last updated on 08 December 2023.**INTRODUCTION**

Review question / Objective This systematic review will address the following questions

- (1) What is the impact of the ban on loose cigarette sales on the initiation of smoking among the youth?
- (2) What is the impact of the ban on loose cigarette sales on current smoking prevalence in the general population?
- (3) What is the impact of the ban on loose cigarette sales on smoking intensity among daily smokers?
- (4) What is the impact of the ban on loose cigarette sales on quit attempts among current smokers?
- (5) What is the impact of the ban on loose cigarette sales on quit intention among current smokers?
- (6) What is the impact of the ban on loose cigarettes on cigarette purchase patterns among current smokers?

Rationale The prevalence of smoking and its detrimental health effects, especially premature deaths, is a significant global concern. One of the

key and cost-effective strategies to reduce the smoking burden and its health impact is the implementation of a comprehensive tobacco control policy including the ban on single-stick (loose) cigarette sales. The sale of loose cigarettes increases access and financial affordability among economically weaker sections and youths. Also, loose cigarette sales circumvent the tobacco warning messages on cigarette packets, and taxation thereby limiting their impact on smokers using loose cigarettes. Further, it promotes the illicit tobacco trade. The ban on loose cigarettes is an attempt to decrease affordability and increase the exposure to tobacco packet health warnings. Hence the ban has the potential to reduce youth smoking initiation and influence cigarette purchase and consumption patterns. Ban on the sales of single cigarettes has been implemented in 109 countries, but the effectiveness of the ban on loose cigarettes is yet to be documented. An evidence-based review of the impact of a ban on the sale of loose cigarettes on smoking is required to provide evidence to help the policymakers and stakeholders strengthen the existing singles/

loose-related strategies for tobacco control, which is the single largest cause of premature mortality in the world. The systematic review will answer the questions which will greatly help strengthen the global tobacco control policies.

Condition being studied The following conditions will be studied among the general population and current smokers

- 1) Conditions among the general population
 - a. Change in cigarette smoking initiation among youths aged 13 to 15 years
 - b. Change in current cigarette smoking prevalence among adults 15 years and above
- 2) Conditions among current smokers
 - a. Change in cigarette smoking intensity (cigarette per day) among current daily smokers
 - b. Change in quit attempts made in the last year among the current cigarette smokers
 - c. Change in future quit intention among the current cigarette smokers
 - d. Change in purchase (quantity and cost) pattern of cigarettes among current smokers.

METHODS

Search strategy This systematic review will be based on the review of original articles on the impact of the ban on loose cigarette sales on cigarette smoking. There is no restriction on the publication dates. The NLM (PubMed and PMC), EMBASE, Web of Science, and Scopus will be searched to retrieve potential original articles. In addition, the Global Tobacco Survey reports before and after the loose cigarette ban will be searched to identify potential changes in smoking patterns following the ban. Other sources such as Google Scholar, an academic search engine, will be used to identify potential research documents. The systematic review will include original articles and reports in the English language that have reported the impact of the loose cigarette ban on smoking behaviour using any research study designs (observational and analytical studies). The primary outcomes of interest will be the initiation of cigarette smoking among youths, current smoking pattern, cigarette smoking intensity, quantity and cost of cigarettes bought by current smokers, past quit attempts and future quit intention in the general population.

The search will be conducted using a combination of keywords representing population, intervention, and outcome.

The keywords for the population are "youths", "adults", "current smokers", "cigarette smokers", etc. The keywords for intervention are "ban on single-stick cigarettes," "ban on loose cigarettes," etc.

The keywords for the outcome of interest are "impact or effectiveness or change or trend" in "smoking initiation or Current smoking or cigarette per day use or intensity of cigarette use or quit attempts or quit intentions".

The Boolean operators will be used to generate a combination of words to maximize search for relevant literature.

Participant or population In the review, we have two categories of population a) General population i.e. youths and adults b) Current smokers of cigarette.

Intervention Policy intervention banning sale of loose cigarettes or single-stick cigarettes by the cigarette retailers.

Comparator To address the impact of the policy intervention we will compare populations as described above residing in countries where there is no ban on the sale of loose cigarettes. In addition, when data is available for a given country before and after the ban on sales of loose cigarettes was implemented population smoking before and after the ban will be compared.

Study designs to be included All types of studies both descriptive and analytical quantitative studies as well as qualitative studies will be included in the review. The study will also include GATS and GYTS reports and publications from tobacco surveys.

Eligibility criteria Studies included in the review must specifically investigate the consequences of prohibiting the sale of loose cigarettes. The temporal scope spans from 1980 to 2023, encompassing recent developments in tobacco control. The review will focus on English-language studies from all over the world with relevance to Bans on Single Cigarettes. Selected studies should provide data related to the impact or change in conditions under study following the ban on the sales of loose cigarettes. The review will encompass both the general population and current smokers, both males and females, and both youths (13-15 years) and adults (15 years and above). Also, studies reporting non-cigarette smoking patterns or conditions under study will be excluded. We will exclude guidelines, commentaries, editorials, or opinion pieces. Studies included in the review must specifically investigate the consequences of prohibiting the sale of loose cigarettes. The temporal scope spans from 1980 to 2023, encompassing recent developments in tobacco control. While focusing on English-language studies covering global data with relevance to Bans on Single Cigarettes:

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Information sources The NLM (PubMed and PMC), EMBASE, Web of Science, and Scopus will be searched to retrieve potential original articles. In addition, Global Tobacco Survey Reports before and after the loose cigarette ban will be searched to identify potential changes in smoking patterns following the ban. Other sources such as Google Scholar, an academic search engine, will be used to identify potential research documents. The systematic review will include original articles and reports in the English language. The review will also include reports of GATS and GYTS and other tobacco surveys to evaluate changes in conditions under study following the ban on the sale of loose cigarettes.

Main outcome(s) The outcomes under study are changes in cigarette consumption pattern before and after the ban or between countries with or without ban

- 1) Change in cigarette smoking initiation among youths aged 13 to 15 years
- 2) Change in current cigarette smoking prevalence among adults 15 years and above
- 3) Change in cigarette smoking intensity (cigarette per day) among current daily smoker
- 4) Change in quit attempts made in the last year among the current cigarette smokers
- 5) Change in future quit intention among the current cigarette smokers
- 6) Change in purchase (quantity and cost) pattern of cigarettes among current smokers.

Data management All selected publications found in various electronic databases through the above-mentioned strategies will be uploaded to the Zotero library, and duplicate records will be deleted. Titles and/or abstracts of the original publications will be screened for duplication before being assigned to two pairs of reviewers. The two pairs of reviewers will independently screen the title abstract to exclude publications that do not meet the eligibility criteria. Any disagreement that arises between pairs of reviewers will be resolved through discussion among all authors. Two independent reviewers will extract the relevant data from the included studies or reports using a

predefined form, ensuring accuracy and consistency. The data collected will be matched and in case of any difference the source will be referred. Further, if there is disagreement persists between two reviewers the issue will be resolved with mutual discussions and as well discussions with the principal investigators. The compiled data in the Excel sheet will be kept securely by the principal investigator and corresponding author. The data will be uploaded as an additional document while submitting the systematic review results for publication. The data will be also shared with the stakeholders for necessary action. The data that would be included include author or publisher, year of publication, geographical location, study design, population studied (gender, age), and smoking pattern (outcomes) before and after the ban on sales of loose cigarettes.

Quality assessment / Risk of bias analysis The independent reviewers will check each of the included studies to minimize bias and also assess the study quality independently. For randomized controlled trials, the risk of bias will be assessed as per Cochrane risk-of-bias tool for randomized trials. A series of questions that elicit information relevant to the risk of bias in various domains will be recorded. The study will have a low risk of bias if its methods allow for reliable interpretation of outcome measure data. Using methods that put doubt on the research's effectiveness is high risk of bias. The research with inadequate information or doubt about technique will be reported as ambiguous.

The evaluation of bias and study quality for non-randomized controlled trials (RCTs) will be conducted using either the 16-item quality assessment instrument (QATSDD), the Risk Of Bias In Non-Randomized Studies - of Interventions (ROBINS-I), or the Newcastle-Ottawa Scale. QATSDD is a verified quality evaluation tool specifically created for a diverse range of research studies. The measure has 16 categories, each assigned a score ranging from 0 to 3, with 3 indicating the highest performance. A score of 0 is given when writers fail to provide the necessary degree of information to assess a quality criteria. The scores of each paper will be summed and then divided by the maximum possible score to get the overall quality score of the paper. The highest attainable score for mixed papers is 48, whereas it is 42 for qualitative or quantitative studies. Subsequently, it will be transformed into a numerical value expressed as a percentage. The criteria for assessing bias include the discovery of selection bias, information bias, or confounding. ROBINS-I will be used to evaluate the health consequences of several interventions/exposures

in nonrandomized research. The NOS applies to both case-control and long-term prospective investigations. Commonly, cross-sectional studies are assessed as case-control studies. The NOS assesses three quality characteristics (selection, comparability, and outcome) distributed among eight particular questions, which vary significantly in their score for case-control and longitudinal investigations. Each item on the scale is assigned a score of one point, except for comparability, which may be adjusted to the particular subject of interest and can get a maximum value of two points. Therefore, the highest score achievable for any research is 9, and studies with a score below 5 are considered to indicate a significant risk of bias.

Strategy of data synthesis When two or more comparable studies are available with the same population, exposure, comparison, and result a meta-analysis will be performed. For heterogeneous studies, a heterogeneity (I²) model will be used, or else a random-effects model will be used. All estimates will have a 95% confidence interval (CI). We will describe the included studies using a forest plot and table. In the presence of studies exhibiting diverse features, such as varying categories of exposure, the data will be segregated into subgroups, and a comprehensive estimate of the overall data will not be given. The data analysis will adhere to the methodologies outlined in the Cochrane Handbook for Systematic Reviews of Intervention to manage the data.

The data will be analysed using the intention-to-treat principle, which involves using the initial numbers of randomized individuals assigned in the research arm as the denominator. A pooled prevalence analysis will be carried out using appropriate statistical software. Heterogeneity will be determined by using I² statistic. More than 75% will be considered as heterogeneous. If the diverse characteristics of research sites, designs, and outcome measures make it impossible to do a formal meta-analysis, studies that have comparable thematic components will be put together for narrative synthesis. The data that has been retrieved will be condensed and presented in a table, and a comprehensive written evaluation will be created. The final evaluation will give a narrative synthesis of the findings from the chosen research.

Subgroup analysis Subgroup analyses are used to explore diverse outcomes or to address specific inquiries about distinct patient cohorts, intervention modalities, or research designs. Subgroup analyses may be advantageous for comparing groups according to participant

characteristics (such as gender or age group) or for location. In this systematic review, a sub-group analysis will be carried out to make the results comparable.

Sensitivity analysis It is important to demonstrate that the conclusions drawn from a systematic review are not influenced by arbitrary or ambiguous choices. A sensitivity analysis involves reperforming the main study or meta-analysis but with other choices or ranges of values for selections that were initially arbitrary or ambiguous. In this systematic review, we will conduct a sensitivity analysis to address the issues of heterogeneity, and ambiguity in results.

Language restriction This systematic review is restricted to English Language studies only.

Country(ies) involved India.

Keywords loose cigarette, single cigarette, ban, tobacco control, smoking pattern, impact, effectiveness.

Dissemination plans The protocol as well as systematic review will be sent for publication. A policy brief will be developed for stakeholders.

Contributions of each author

Author 1 - Pratap Jena - Design, Database search, study selection, data extraction, analysis, interpretation, writing the report and policy brief.

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Author 2 - Jugal Kishore - Design, analysis, interpretation, writing the report, critical review of the report, writing the policy brief.

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Author 5 - Praveen Sinha - Design, interpretation, and critical review of the report and policy brief.