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RESEARCH PROTOCOL

Tobacco Control Policies and Sociodemographic Disparities in Cigarette Smoking Behaviors in the U.S.: A Systematic **Review Protocol**

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Since the 1998 Master Settlement Agreement in the U.S., many studies have examined the associations between tobacco control policies and smoking; however, there is a need to comprehensively examine the impact of these policies on sociodemographic disparities in cigarette smoking. This protocol outlines a systematic review that seeks to fill this gap. Quantitative observational, experimental, and quasi-experimental studies are eligible for inclusion. Policies include cigarette taxes, smoke-free air laws, anti-tobacco media campaigns, and Tobacco 21 laws implemented in the U.S. Outcomes include cigarette smoking initiation, prevalence, and cessation among youth and adults. Sources to be searched include Clarivate BIOSIS, EBSCO CINAHL Plus, Cochrane Library, Ovid MEDLINE, PsycINFO, Sociological Abstracts, Clarivate Web of Science Core Collection, and the National Bureau of Economic Research. Included studies must be written in English. Two independent reviewers will screen and analyze relevant articles and then extract data on participants, context, methods, and key findings. Studies will be assessed using the Joanna Briggs Institute critical appraisal checklists and presented in 2 reviews: 1 youth focused (aged <18 years) and 1 adult focused (aged ≥18 years). The findings are intended to inform the creation of new and potentially more targeted tobacco control policies to improve health equity.

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INTRODUCTION

Recognizing the enduring prominence of tobacco use as the leading cause of preventable death in the U.S., local, state, and federal government agencies have increasingly adopted tobacco control policies aimed at impeding youth smoking initiation and encouraging adult smoking cessation. The U.S. has observed a steady decline in adult smoking prevalence from its peak of 42.4% in 1965 to 11.2% in 2022. 1,2 Likewise, 12th-grade lifetime cigarette use has steadily declined from 65.4% in 1997 to 16.8% in 2022, with similar declines observed in 8th and 10th graders.³ Although these smoking reductions represent a major public health achievement, disparities in cigarette use persist for historically marginalized populations.

Studies have consistently documented higher cigarette use across salient sociodemographic factors, such as sex, gender identity, sexual orientation, race and ethnicity, and SES. Cigarette use is generally more prevalent in youth and adults who are male than in those who are female; in those who identify as American Indian or

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Alaska Native than in those who identify as non-Hispanic White; in those who are of low SES than in those who are of high SES; and in those who identify as lesbian, gay, bisexual, transgender, or another identity than in those who identify as heterosexual or cisgender individuals. ^{4,5} In addition, youth and adults at the intersection of multiple identities, including low-income non-Hispanic White men or non-Hispanic Black youth who identify as gay, lesbian, bisexual, or transgender, are often the most affected by cigarette smoking. ^{6–8} However, historical data show that these sociodemographic differences in smoking behaviors, which have come to be accepted as de facto today, have become increasingly disparate over recent decades.

There is a wide body of evidence that has examined the associations between cigarette taxes; smoke-free air laws; mass media campaigns; and youth access restrictions on cigarette smoking initiation, prevalence, and cessation, including several reviews. 12-20 However, few studies have considered how tobacco control policy impacts might differ across sociodemographic subgroups, particularly at the intersection of multiple identities. Reviews published in recent decades demonstrate a lack of research applying a health equity lens or considering disparities broadly. 12-15,17-20 Moreover, the majority of these reviews have focused on adult populations, 13,15,18 with few looking specifically at U.S. youth. 12,16 There is a need for reviews addressing the impacts of tobacco control policies in the U.S. on minoritized populations throughout history and across multiple identities.

The purpose of this proposed systematic review is to summarize the evidence on associations between cigarette taxes; smoke-free air laws; anti-tobacco media campaigns; and Tobacco 21 (T21) laws in the U.S. and cigarette smoking initiation, prevalence, and cessation in both youth and adults. Although the authors will examine the breadth of literature on U.S. tobacco control policies and smoking, they are particularly interested in the period after the 1998 Tobacco Master Settlement Agreement, a landmark policy that paved the way for many of the state- and local-level policies examined in this protocol.²¹ Although the associations within the general population will be assessed, the primary focus will be examining associations by age, sex (assigned at birth), gender identity, sexual orientation, race and ethnicity, educational attainment (or parental education), income, and health insurance coverage type. The study search builds upon prior reviews in 3 important ways. First, the authors include understudied sociodemographic groups with a particular focus on studies that examine policy impacts at the intersection of multiple identities. Second, the authors include more recent studies (through 2023),

which allows for additional years of policy variation. Finally, the authors focus on the U.S. policy context to examine findings through the lens of historic and current structural factors. A preliminary search of PROS-PERO (International Prospective Register of Systematic Reviews) was conducted in March 2023, and a few registered protocols on similar topics were identified. 22–27 However, because some of these protocols lack the specificity needed to assess overlap with our protocol, and others have not been completed and published as proposed, the reviews from the present protocol remain important.

Review Question

This protocol is guided by the following review question: How have cigarette taxes; smoke-free air laws; antitobacco media campaigns; and T21 laws impacted cigarette smoking initiation, prevalence, and cessation among U.S. youth and adults overall as well as across sociodemographic factors?

Inclusion Criteria

Population. Youth (aged <18 years) and adult (aged \ge 18 years) populations will be examined. The authors will exclude studies that examine pregnant or clinically defined populations.

Condition. For policies, the following tobacco control policies, as they pertain to cigarettes, will be included as exposures: cigarette taxes, smoke-free air laws, antitobacco media campaigns, and T21 laws. For taxes, the authors will include studies that examine the association between cigarette taxes, measured by tax or price, on smoking outcomes. Taxes may include state taxes, federal taxes, or a sum of both. Price may be defined as retail prices or self-reported prices. For smoke-free air laws, the authors are interested in workplace, bar, and restaurant smoke-free laws. They will also consider studies that examine comprehensive smoke-free laws, defined as a combination of smoke-free laws that include workplace laws and hospitality laws (defined as bar and restaurant). Authors will exclude studies that exclusively investigate smoke-free homes, campuses, vehicles, parks, or other locations. For media campaigns, the authors will include any measurement of anti-tobacco media campaign exposure. For T21 laws, they will require that the age restriction be 21 years (as opposed to age restrictions of 18 or 19 years).

Regarding outcomes, the authors will include cigarette smoking initiation, prevalence, and cessation in both youth and adults. All outcomes must refer to the use of combustible cigarettes. For initiation, the authors will include cigarette smoking initiation, first cigarette smoking initiation, daily cigarette smoking initiation, and

other cigarette smoking initiation. For prevalence, the authors will include current cigarette smoking, current daily cigarette smoking, current established cigarette smoking, current established daily cigarette smoking, current nondaily cigarette smoking, current established nondaily cigarette smoking, and other cigarette smoking prevalence. For cessation, the authors will include measures of n-day smoking cessation, quit attempts in past n months, not currently smoking cigarettes, and other cigarette smoking cessation. Definitions for each of these outcomes are included in Table 1. Outcomes that will be excluded from this review include smoking intensity or cigarette consumption; motivation or intention to quit; cigarette sales; and anything related to knowledge, beliefs, or perceived effectiveness of a policy. The authors will also exclude studies examining tobacco and nicotine products other than combustible cigarettes. The authors will collect all types of estimates, including probabilities, ORs, mean percentage changes, and risk ratios.

Context

This review will consider local-, state-, and federal-level tobacco control policies and the affected populations within the U.S. Although the authors will include studies that examine these populations as a whole, they are particularly interested in studies that examine populations by sociodemographic factors and at the intersection of multiple identities. Studies will not be excluded if they only examine overall effects or only examine differential effects by sociodemographic factors. The authors will emphasize studies that provide estimates by age, sex, gender identity, sexual orientation, race and ethnicity, education, income, or health insurance coverage type. Table 2 provides more information on the sociodemographic subgroups that the authors plan to examine. Should studies provide less detail or less disaggregation, the authors will adjust Table 2.

Types of Studies

The authors will include both experimental and quasiexperimental study designs, such as RCTs, non-randomized controlled trials, before and after studies, interrupted time-series studies, and ecologic studies. Other study designs the authors will consider include analytical observational studies, such as prospective and retrospective cohort studies, case-control studies, and analytical cross-sectional studies. The authors will exclude descriptive and qualitative studies.

METHODS

This systematic review will be conducted within the guidelines of the Joanna Briggs Institute (JBI)

methodology for systematic reviews of etiology and risk²⁸ and the PRISMA protocols.²⁹ This protocol is registered with PROSPERO (registration number CRD42023446886).

Search Strategy

The search strategy will be optimized to locate published studies. An example of search strategy performed in PubMed is provided below:

("Media campaign*" or "Anti-tobacco adverti*" or ((Tobacco adj3 (anti or control* or law* or tax* or regulat* or Prevent* or Polic* or messag*)) or "T21 law*")).ti. or exp *Tobacco Control/ or "Tobacco 21*". ti. or "Tobacco-21*".ti or ((Smoke or nicotine) adj3 Free).ti. or "Smoke-Free polic*".ti. or exp *Smoke-Free policy/ or "Smoking regulat*".ti. or "Smoking control polic*".ti. or "clean air law*".ti. or (anti adj3 smok*).ti. or (cigarette and (tax* or regula* or law* or price*)).ti. or (minimum.ti adj3 "sales age".ti) or MLSA.ti AND exp *Prevalence/ or exp *Smoking Cessation/ or exp *Smoking Prevention/ or((Smok* or Cigarette or Tobacco) and (Cessation or prevention or initiation or reduc* or participation or quit* or Prevalence or current or ever or Stop* or "Giving up" or behavior)).ti,ab. or (quit* adj3 behavior).ti,ab AND Adult*.ti,ab. or exp *Adult/ or exp *Adolescent/ or Adolesc*.ti,ab. or Youth.ti,ab. or young.ti,ab.

The authors will also search for working papers from the National Bureau of Economic Research (NBER). NBER provides manuscripts that, although not peer reviewed, are written by top economists who have been selected as NBER affiliates.³⁰ Searching NBER will give the researchers access to the latest econometric studies.

Authors will complete a preliminary search of Ovid MEDLINE to identify articles on the topic. They will use the titles and abstracts of relevant articles as well as index terms to develop the full search strategy. The authors will complete the search using the databases in Table 3. They will adapt their search strategy, including the keywords and index terms, specifically for each database. The authors will also examine the reference lists of all selected articles to identify any other studies of interest. Table 3 provides additional information concerning the search strategy and information sources. Studies must also be written in the English language.

Study Selection

Search results will be uploaded into EndNote 20 and deduplicated by the research team librarian using a modified Bramer deduplication method. Screening and evaluation of studies will be performed using

Table 1. Outcome Definitions

Outcome domain	Term	Definition
Prevalence	Ever smoked cigarette	Individuals who have consumed at least 100 cigarettes in their lifetime
	Current cigarette smoking	Individuals reporting any cigarette use in the past n days OR giving a non-zero answer to "During the last 30 days, on how many days did you smoke cigarettes, even 1 or 2 puffs?" OR answering 'yes' to "Have you smoked in the past 4 weeks?" OR indicating that they now smoke 'every day' OR smoke 'some days'
	Current daily cigarette smoking	Individuals reporting any cigarette use in the past n days OR giving a non-zero answer to "During the last 30 days, on how many days did you smoke cigarettes, even 1 or 2 puffs?" OR answering 'yes' to "Have you smoked in the past 4 weeks?" AND indicating that individual reported currently smoking daily
	Current established cigarette smoking	Individuals who have consumed at least 100 cigarettes in their lifetime AND report currently smoking either 'some days' or 'daily' or 'everyday' OR giving a non-zero answer to "During the last 30 days, on how many days did you smoke cigarettes, even 1 or 2 puffs?" OR answering 'yes' to "Have you smoked in the past 4 weeks?" OR report smoking in the past n days
	Current established daily cigarette smoking	Individuals who have consumed at least 100 cigarettes in their lifetime AND report currently smoking daily
	Current nondaily cigarette smoking	Individuals reporting any cigarette use in the past n days OR giving a non-zero answer to "During the last 30 days, on how many days did you smoke cigarettes, even 1 or 2 puffs?" OR answering 'yes' to "Have you smoked in the past 4 weeks?" AND reporting currently smoking 'some days' or less
	Current established nondaily cigarette smoking	Individuals who have consumed at least 100 cigarettes in their lifetime AND report currently smoking EITHER 'some days' or 'daily' or 'everyday' OR giving a non-zero answer to "During the last 30 days, on how many days did you smoke cigarettes, even 1 or 2 puffs?" OR answering 'yes' to "Have you smoked in the past 4 weeks?" OR report smoking in the past n days AND report currently smoking 'some days' or less
	Other cigarette smoking prevalence	Individuals who report daily or weekly smoking of n cigarettes OR another definition of smoking prevalence that does not fit within established categories
Cessation	Not currently smoking cigarettes	Individuals who indicate 'not at all' to the question "Do you now smoke cigarettes every day, smoke days, or not at all?" OR report any cigarette use in the past n days AND report past cigarette use
	Quit attempt past [n months]	Individuals who indicate 'yes' to the question "During the past n months, did you ever stop smoking for 1 day or longer because you were trying to quit smoking?"
	n-day cessation	Individuals who indicate maintaining abstinence from cigarettes for n days
	Other cigarette smoking cessation	Any other definition of smoking cessation that does not fit within established categories
Initiation	Cigarette smoking initiation	Individuals who identify as someone who does not smoke cigarettes at time point A AND report any cigarette use in the past n days OR give a non-zero answer to "During the last 30 days, on how many days did you smoke cigarettes, even 1 or 2 puffs?" OR answer 'yes' to "Have you smoked in the past 4 weeks?" OR indicating that they now smoke 'every day' OR smoke 'some days' at time point B
	First cigarette initiation	Individuals who identify as someone who has never smoked cigarettes at time point A AND report any cigarette use in the past n days OR give a non-zero answer to "During the last 30 days, on how many days did you smoke cigarettes, even 1 or 2 puffs?" OR answer 'yes' to "Have you smoked in the past 4 weeks?" OR indicating that they now smoke 'every day' OR smoke 'some days' at time point B
	Daily cigarette smoking initiation	Individuals who identify as someone who never smoked cigarettes OR who smokes non-daily at time point A AND report any cigarette use in the past n days OR give a non-zero answer to "During the last 30 days, on how many days did you smoke cigarettes, even 1 or 2 puffs?" OR answer 'yes' to "Have you smoked in the past 4 weeks?" OR indicating that they now smoke 'every day' OR smoke 'some days' at time point B
	Other cigarette smoking initiation	Any other definition of smoking initiation that does not fit within established categories

Table 2. Sociodemographic Subgroups of Interest

Sociodemographic factor	Subgroup
Age	Youth (aged <18 years)
	Adult (aged ≥18+ years)
Sex assigned at birth	Male
9	Female
	Intersex
Gender identity	Cisgender
	Transgender or nonbinary
	Another gender identity
Sexual orientation	Heterosexual or straight
	Lesbian or gay
	Bisexual
	Another sexual orientation
Race and ethnicity	Hispanic
	Non-Hispanic Black
	Non-Hispanic White
	Non-Hispanic Asian
	Non-Hispanic American Indian/Alaska Native
	Multiple races or ethnicities
	Another non-Hispanic race or ethnicity
Education (or parental education)	Less than high school
	High school or GED
	Some college or technical school College or more
	Another education level
Income	Low income
	Moderate income
	High income
	Another income designation (e.g., poverty)
Health insurance coverage type	Uninsured
	Medicaid
	Medicare
	Private
	Another health insurance type

Covidence.³³ Two independent reviewers will use the eligibility criteria to assess each title and abstract. The full text of potentially eligible studies will be acquired and further assessed for eligibility. The reviewers will document the reason that any full text examined is rejected. Differential estimates by sex, gender identity, sexual orientation, race and ethnicity, education, income, and/or health insurance coverage type will be sorted by

Table 3. Search Strategy

Review characteristic	Included types
Policy types	Cigarette taxes, smoke- free air laws, anti- tobacco media campaigns, Tobacco 21 laws
Outcome measures	Smoking initiation, smoking prevalence/ participation, smoking cessation
Sociodemographic indicators	Age, sex (assigned at birth), gender identity, sexual orientation, race and ethnicity, education (or parental education), income (household or parental), health insurance coverage type
Bibliographic databases	Clarivate BIOSIS, EBSCO CINAHL Plus, Cochrane Library, Ovid MEDLINE, PsycINFO, Sociological Abstracts, Clarivate Web of Science Core Collection
Unpublished studies or gray literature	National Bureau of Economic Research
Data extraction items	Policy/exposure/ intervention definition, smoking outcome, estimate, sampling characteristics, study setting, research design, sociodemographic subgroups examined

sociodemographic factor(s) during the data extraction stage. If discrepancies arise at any point, they will be resolved through discussion among all reviewers. The final systematic review will include a report of the search results, reference lists examined, and the study inclusion/exclusion process.

Assessment of Methodologic Quality

Risk of bias will be assessed using the JBI critical appraisal checklists. Study designs such as cohort studies and analytical cross-sectional studies will be evaluated using the checklists from Chapter 7 of the *JBI Manual for Evidence Synthesis* (Systematic reviews of etiology and risk).²⁸ Quasi-experimental studies will be assessed using the checklists from Chapter 3 (Systematic reviews of effectiveness).³⁴ Any RCTs, of which the authors expect a few, will also be assessed using the checklists from Chapter 3.³⁴ All of the selected studies will be independently scored by 2 reviewers. Studies will not be excluded on the basis of these assessments. Rather, the

results of these assessments will be used to inform the narrative synthesis, with studies scoring higher receiving greater attention. For example, a local or state policy before—after study without a control group will likely result in a lower quality score than the evaluation of a federal policy and, therefore, receive less emphasis in the manuscript.

The body of evidence produced by this protocol will be assessed using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. ^{35–37} GRADE considers within-study risk of bias, imprecision, inconsistency, indirectness, and publication bias. Two independent reviewers will perform this assessment initially and report findings to coauthors. Together, all coauthors will decide the final GRADE rating: high, moderate, low, or very low.

Data Extraction

The team drafted an extraction tool that collects information on the participants, context, study methods, and key findings relevant to the review question. The extraction form has 52 fields to collect data in a long format. Each row represents a new estimate of the association between the given policy and outcome. Therefore, each study may be represented by multiple rows if it examines multiple exposures, outcomes, or populations. Appendix A (available online) includes additional information on the extraction tool fields.

Data Synthesis

The final product of this protocol will be published in a peer-reviewed journal in two parts: one a review focusing on youth and another focusing on adults. Owing to the heterogeneity of both the exposure and outcome measurements accepted, the authors do not anticipate the ability to perform a meta-analysis. Instead, data in these reviews will be presented as a narrative summary with a set of summary diagrams as well as tables. One diagram will be produced for each combination of tobacco control policy (e.g., taxes) and outcome (e.g., initiation). Although these diagrams will be an oversimplification of the studies included, they will provide effective at-a-glance results for readers. In addition, tables will be included for readers who desire more study details.

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.focus.2024. 100256.

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