

PROTOCOL

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WHO Framework Convention on Tobacco Control Articles 9 and 10 implementation for sustainable tobacco control—a scoping review protocol

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Abstract

Introduction Tobacco consumption continues to pose a substantial global public health threat, resulting in more than 8 million preventable deaths annually. The WHO Framework Convention on Tobacco Control (FCTC) negotiated as the first global public health treaty under the auspices of the WHO, which serves as a critical instrument in combating the global tobacco epidemic. The WHO FCTC prioritizes a comprehensive approach that addresses both the demand for and supply side interventions for curbing tobacco epidemic globally. Strong evidence demonstrates the efficacy of these measures in safeguarding individuals, regardless of age, from tobacco initiation, and the associated harms. WHO FCTC Article 9 and 10 emphasizes upon testing and disclosure of tobacco product contents. This scoping review aims to explore the Implementation Landscape of WHO FCTC Articles 9 and 10 globally by adopting Consolidated Framework for Implementation Research (CFIR) framework.

Methods The planned scoping review will adhere to the methodology outlined by “Arksey and O’Malley and Levac et al.” Through an exhaustive search strategy, relevant literature published from 2013 onwards will be sourced from databases including PubMed, CINAHL, EMBASE, Web of Science, Scopus, government websites, and reports. A predetermined set of criteria for study inclusion and exclusion will be applied independently by four reviewers to assess study eligibility. The findings will be synthesized narratively and qualitatively analyzed, incorporating the Consolidated Framework for Implementation Research (CFIR) framework for discussion and outlining. The review will adhere to the reporting standards outlined in the “Preferred Reporting Items for Systematic Reviews and Meta-analyses Extension for Scoping Review (PRISMA-ScR)” guidelines.

Conclusions/discussion Analyzing the implementation of FCTC Articles 9 and 10 across global contexts is expected to offer valuable insights into the need for context-specific adjustments and customized interventions. Understanding regional variations in efforts to regulate tobacco products is crucial for formulating specific strategies that effectively address cultural, economic, and regulatory challenges. This comparative examination has the potential to guide policymakers, public health professionals, and researchers in optimizing tobacco control initiatives to expedite progress toward effective implementation of Articles 9 and 10 in both the WHO-SEAR region and globally.

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Ethics approval This review will identify the landscape of the implementation of WHO FCTC Article 9 and 10. This review will also identify the best practices, policies, and strategies across the globe. An ethics committee approval was not sought for this since this involve secondary data.

Keywords WHO FCTC-Article 9 and 10, Strategy, Implementation, WHO-FCTC, Tobacco product testing and disclosures

Strengths and limitations of this study

A scoping review allows for a broad exploration of the topic, considering various aspects related to the implementation of WHO FCTC Articles 9 and 10.

By examining practices, policies, and strategies worldwide, the study captures diverse experiences and insights.

This review will contain the literature which is published in English language only.

The review will encompass grey literature as well as data accessible through government websites and reports.

The review relies on the quality and availability of existing literature, which may vary.

Introduction

The World Health Organization (WHO) Framework Convention on Tobacco Control (WHO FCTC) stands as revolutionary international treaty, negotiated under the auspices of the WHO [11]. It was adopted by the World Health Assembly on 21 May 2003 and brought into effect on 27 February 2005 [11]. It has since become one of the most rapidly and widely incorporated treaties in the United Nations history [11]. This convention serves as a critical instrument in combating the global tobacco epidemic, which claims to kill half of its users every year leading to over 8 million deaths yearly, with 1.2 million attributed to second-hand smoke exposure [10]. Low- and middle-income countries account to 80% of the world's highest 1.3 billion tobacco users [10]. Since its establishment in 2005, the WHO FCTC has gained rapid global acceptance [12]. It stands out as one of the most swiftly embraced treaties in UN history [12]. Currently, 183 countries worldwide have ratified the WHO FCTC, including 50 WHO European Member States [12].

The WHO FCTC prioritizes a comprehensive approach that addresses both the demand for and supply side interventions for curbing tobacco epidemic globally (World Health Organization., [13]). Strong evidence demonstrates the efficacy of these measures in safeguarding individuals, regardless of age, from tobacco initiation and the associated harms (World Health Organization., [13]). The document comprises 38 articles grouped into

eleven distinct parts, outlining comprehensive measures for tobacco control (World Health Organization., [13]). Article 9 of the WHO FCTC addresses the regulation of the contents of tobacco products. It mandates that the Conference of the Parties, in collaboration with competent international bodies, propose guidelines for testing and measuring the contents and emissions of tobacco products, as well as for regulating these contents and emissions (World Health Organization., [13]). Each party is required to adopt and implement effective legislative, executive, administrative, or other measures for such testing, measuring, and regulation, subject to approval by competent national authorities (World Health Organization., [13]). Simultaneously, Article 10 focuses on the regulation of tobacco product disclosures, requiring each party to adopt and enforce effective measures, in accordance with its national law, that oblige manufacturers and importers to disclose information about the contents and emissions of tobacco products to governmental authorities (World Health Organization., [13]). Furthermore, each party is obligated to implement measures ensuring public disclosure of information regarding the toxic constituents of tobacco products and the emissions they may produce (World Health Organization., [13]). Recognizing the complex design of tobacco products and their influence on tobacco use, particularly among younger individuals, holds significant importance (World Health Organization, [14]). Effective tobacco product regulation is crucial for reducing demand prioritizing countries to enhance their legislative capacity building and policy development capacities (World Health Organization, [14]). Learning from nations that have made progress in product regulation provides valuable insights into the necessary investments and resource allocation (World Health Organization, [14]). Hiilamo and Glantz (Hiilamo et al. [3]) analyzed the global implementation of tobacco control measures under the WHO FCTC, highlighting the challenges in enforcing demand reduction policies. These findings underscore the need for stronger frameworks under the treaty.

Therefore, this study aims to explore the Implementation Landscape of WHO FCTC Articles 9 and 10 globally by adopting Consolidated Framework for Implementation Research (CFIR) framework. By looking at how different regions are implementing these articles, we hope

to understand the different strategies they use, what they have achieved, and what challenges they face. Our goal is to contribute to the ongoing discourse and help policymakers, public health practitioners, and stakeholders with the knowledge needed to make informed decisions.

We used the CFIR model to analyze how globally adopted strategies implement WHO FCTC Article 9 and 10, drawing from practical applications in health contexts like mHealth solutions and sexual assault prevention programs (Ardito et al. [1]). Additionally, we aim to assess the additional policies status of WHO FCTC Articles 9 and 10 across different regions. By employing this methodology, we aim to provide a concise summary of existing evidence, facilitating informed decision-making and intervention development for scaling up the WHO FCTC Article 9 and 10 strategies worldwide.

Methodology

The scoping review protocol was developed using the frameworks proposed by Arksey and O'Malley, as well as Levac et al. [2]. This review will follow the guidelines outlined in the Preferred Reporting Item for Scoping Reviews (PRISMA-ScR) ([9]). Furthermore, it will include the PRISMA-P checklist ([8]) from Annexure 1 to ensure comprehensive reporting of essential elements relevant to this scoping review protocol ([8]).

The scoping review shall be proceeded through the following steps:

Stage 1: identifying the research question

To formulate the research question, the team conducted a collaborative process of brainstorming and repeatedly refining ideas. A thorough review of the literature on WHO FCTC Article 9 and 10 implementation informed the development of a comprehensive research question, which was then further refined.

1. How do different regions at the global level vary in the implementation of WHO FCTC Articles 9 and 10?

2. What are the major achievements, best practices, and challenges faced by various regions across globe in implementing WHO FCTC Article 9 and 10?

PCC (Population, Concept, Context) format as per the JBI manual for evidence synthesis 2020 has been employed for developing the research question ([6]) (Table1).

Stage 2: identifying relevant studies

This study shall utilize the “evidence-based manual for Peer Analysis of Electronic Search Strategies (Peer Review of Electronic Search Strategies-[4])” to conduct systematic searches, as outlined by McGowan et al. (McGowan et al. [4]). The research question will be fragmented into conceptual components wherein relevant keywords within each concept shall be identified. Relevant studies will be identified using a combination of keywords such as “WHO FCTC Article 9 and 10,” “implementation,” and “Tobacco control,” across various databases. Boolean operators AND/OR will be used to combine keywords, and the search will be limited to articles published in English. A thorough search will be conducted across multiple databases, including PubMed, CINAHL, EMBASE, Web of Science, and Scopus, to retrieve relevant literature. An example of the search conducted on one of the selected databases (PubMed) is provided in Annexure 2 for reference. Moreover, additional potentially eligible articles and government website across various nations shall be identified by reviewing the reference lists of included papers. Data management will be facilitated using Rayyan software for databases and government websites shall be managed through Microsoft Excel (Ouzzani et al. [5]).

Stage 3: study selection

The identified citations shall be collected and uploaded into Rayyan, where copies of the study shall be removed after the search process. Following this, two reviewers (DW and CG) will independently screen all retrieved

Table 1 PCC framework for developing the research question

Population (P)	Policy makers, researchers, public health professionals involved in tobacco control efforts, as well as government and regulatory bodies employed with implementing WHO FCTC Article 9 and 10, across various regions or countries globally.
Concept (C)	The variations across regions, major achievements, best practices, and challenges faced in implementation of WHO FCTC Article 9 and 10. This involves assessing the employed by various regions in regulating tobacco products and promoting sustainable tobacco control measures.
Context (C)	Global: Refers to a worldwide perspective, encompassing various countries and regions.

titles and abstracts, government websites, and WHO Reports assessing for eligibility based on predefined inclusion criteria. In cases of uncertainty regarding a study's eligibility, a third reviewer or an independent opinion (SG) may be consulted. Consensus among the authors will determine potentially relevant research during the screening process, with agreement necessary to retrieve full-text articles and documents for further review. Subsequently, two reviewers will independently examine the full texts of included studies following the initial stage of document, title, and abstract screening. Any discrepancies between the evidence in the full text and the inclusion criteria will be documented with reasons for exclusion from the study. Studies included in the review will undergo data analysis, and the final scoping review will present a comprehensive report of study findings. Search findings and the procedure for included studies will be depicted using a flowchart as per the PRISMA 2020 flow diagram.

Irrespective of research quality or rigor, studies and documents meeting the inclusion criteria outlined in the prepared table shall be selected for inclusion in this scoping review. The review will encompass quantitative, qualitative, and mixed-methods studies, government websites, documents, WHO Reports, and reviews, while excluding comments, study abstracts, and conference proceedings from consideration. Furthermore, the reference lists of included papers, government websites, documents, WHO Reports, and reviews shall be scrutinized to ensure the inclusion of all relevant literature (Table 2).

Stage 4: charting the data

Data charting shall be conducted using a predefined format. Four reviewers will independently carry out data charting for each paper. Any scientific disagreements were resolved by obtaining another reviewer's opinion. Information on participants, context, concept, study methods, indicators/metrics used, facilitators, barriers, and relevant findings related to the review questions will be compiled under data charting process. Data extraction for included studies will be performed using a predefined data extraction form outlined in Table 3. Additionally, narrative data will be collected from various

sources, including methods and guidelines for WHO FCTC Article 9 and 10 implementation in different countries, as well as reasons hindering implementation. Any additional, missing information will be obtained by contacting authors of the specific studies. This procedure is designed to identify gaps in the research area.

Stage 5: collating, summarizing, and reporting the results

Findings of the study shall be presented using narrative synthesis, and analyzed within the framework of the Consolidated Framework for Implementation Research (CFIR). Characteristics and outcomes of the study will be summarized using several tables. A exhaustive list of countries and sources contributing to tobacco FCTC Article 9 and 10 research will be developed to consolidate literature published from February 2005 onwards. Data collected from developed charting tables shall be used to retrieve and cite available literature, focusing on metrics/indicators and implementation strategies for WHO FCTC Article 9 and 10. At the end, the study findings will be synthesized into comprehensive report providing intellectual insights into scientific and literature base.

CFIR framework has been found effective that is used in other studies to understand the system. The CFIR model has found application in various health systems (Ardito et al. [1]). In the current study, we applied the CFIR model to examine how globally adopted strategies facilitate the implementation of WHO FCTC Articles 9 and 10. CFIR, with its five domains, provides a comprehensive framework for analysis: (1) intervention characteristics, which explore the nature, complexity, adaptability, evidence base, and relative advantage of the intervention,(2) outer setting, which includes external factors such as the social, political, and economic context, along with the influence of external stakeholders; (3) inner setting, which considers organizational factors like culture, leadership, and resource availability; (4) individuals, which focus on the knowledge, skills, attitudes, and motivation of those involved in implementation; and (5) implementation process, which examines the specific strategies used for planning, executing, and monitoring the intervention ([7]).

Table 2 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Studies, documents, reports focused on the strategies, measures on FCTC WHO Article 9 and 10.	Investigations are focusing only on tobacco consumption prevalence/incidence/tobacco-related death/tobacco-related diseases
This study shall include all types of documents, reports, websites.	
All accessible studies, reports, and websites worldwide, published in the English language and released from 2005 onwards, shall be incorporated.	

Table 3 Inclusion and exclusion criteria

Serial No.	Items	Information/data
1	Study title	
2	Authors	Yes
3	Publication year	Yes
4	Study setting	Country name/LMIC/South Asia/America/WHO South East Asia/low and middle income country, etc.
5	Study design	Website, report, cross-sectional/qualitative/interventional/mixed method, etc.
6	Aims and objectives	
7	Findings of the study	Yes
8	WHO FCTC Article 9 and 10 implementation	Yes/no/not available
9	Any kind of strategy is being adopted?	Yes
10	What are best practices adopted by the countries?	Yes
9	Positive factors/measures or policies on FCTC Article 9 and 10 implementation	Yes
10	Negative factors/barriers or challenges on FCTC Article 9 and 10 implementation	Yes
11	Strategy/policy adopted for implementation of FCTC Article 9 and 10	Yes
12	Criteria set for implementation of FCTC Article 9 and 10	
13	Other findings/information	Yes
14	Decision	Include/exclude
15	Reason for exclusion	If excluded, the reason for the exclusion

Discussion

Analyzing the implementation of FCTC Articles 9 and 10 across global contexts is expected to offer valuable insights into the need for context-specific adjustments and customized interventions. Understanding regional variations in efforts to regulate tobacco products is crucial for formulating specific strategies that effectively address cultural, economic, and regulatory challenges. This comparative examination has the potential to guide policymakers, public health professionals, and researchers in optimizing tobacco control initiatives to expedite progress toward effective implementation of Articles 9 and 10 in both the WHO-SEAR region and globally.

Acknowledgements

The authors wish to express gratitude for the assistance provided by the Department of Community Medicine and School of Public Health at the Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, India, throughout the duration of this review, particularly for their logistical support.

Authors' contributions

SG, DW, and PR conceived and designed the study. DW drafted the protocol manuscript. DW and CG conducted the initial literature review. DW, PR, CG, and SG oversaw the development of the protocol and provided critical feedback on the manuscript. All authors reviewed the final manuscript and gave their approval.

Funding

None.

Data availability

Not applicable.

Declarations

Ethics approval and consent to participate

This scoping review does not require an ethical approval, as it synthesizes publicly available information from articles, reports, and websites. We will summarize the findings in a report submitted to journals of repute and present them at international and national conferences. Our goal is to provide a comprehensive understanding of the metrics and indicators used globally for implementing WHO FCTC Article 9 and 10 strategies.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Received: 30 May 2024 Accepted: 16 March 2025

Published online: 28 March 2025

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