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The policy environment impacting the societal harm caused by alcohol in India: Protocol for a scoping review

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Manuscript Title: The policy environment impacting the societal harm caused by alcohol in India: Protocol for a scoping review

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Abstract

INTRODUCTION: Alcohol consumption is a cause of substantial preventable societal harm globally. In India, it contributes to significant burden of disease as well as economic costs. Yet, India still lacks a consolidated national alcohol policy, but instead attempts to implement disparate and poorly coordinated policy initiatives directed towards demand and supply reduction. In this context, we will aim to comprehensively map the policy environment relating to the societal harm caused by alcohol in India.

METHODS AND ANALYSIS: We will undertake a scoping review with policy relevant adaptations in order to map the alcohol related policy environment in India. Following the six step approach put forward by Arskey & O'Malley and refined by Levac, we will first undertake an academic scoping search to identify relevant knowledge already existing in the literature about the policy environment. We will then use the knowledge that appears in this search iteratively, as is true to the scoping method, to develop a more targeted search of grey literature and government websites for policy documents. These documents will be analysed using qualitative methods to synthesise the current alcohol policy environment.

ETHICS AND DISSEMINATION: This study will only use already published information and therefore does not require an ethics review. We will circulate this protocol and the final report to policy researchers in similar settings who could make use of our adaptation of the scoping review method for a low-resource setting. We will also publish our findings in a peer-review journal.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is a novel review approach to reviewing a policy environment in a low resource setting where relevant policies can be difficult to identify through traditional search methods.
- This is the first review of its kind to attempt to consolidate the policy environment applicable to the societal harm related to alcohol in India.
- This review takes an iterative approach and therefore parts of the methods cannot be presented fully at this time.
- This protocol is informed by sources that may be seen as dated in comparison to other protocols, but this further emphasizes the necessity of investigating the research gap present.

INTRODUCTION

Alcohol consumption is a cause of substantial preventable societal harm globally. In 2012, 5.1% of the global burden of disease was attributable to alcohol use and alcohol use disorders [1]. In addition to the burden of ill health, alcohol consumption creates significant societal economic costs, equal to more than 1% of GDP in high and middle-income countries [2], through increased health costs and decreased economic productivity.

In India, alcohol use contributed 5.4% of the total burden of disease in 2009 [2], with more than half of all drinkers drinking hazardously [3]. Further, alcohol use causes harm to people other than the drinker, for instance about one-fourth of abuse against women and children in India has been connected to chronic alcohol use [4]. In addition, approximately one-third of night-time road traffic injuries and mortalities involved a driver who had consumed alcohol [4]. Further, alcohol use contributes to homelessness [5], absenteeism and unemployment [6], high risk sexual behaviour [7], and poor health outcomes for children [8]. Finally, the overall alcohol use-related economic costs to society in India, were estimated to be 244 billion Indian rupees (approximately 3.8 million current USD) in 2003-04 [6 9].

While there is growing recognition of the preventable harm that alcohol use is leading to in India, the country still lacks a consolidated national alcohol policy. This is evident in the focus on prohibition-centered supply reduction, taxation and tertiary prevention [3]; all implemented as a set of disparate and poorly coordinated and implemented policy initiatives. An additional concern is the power of the 'alcohol lobby' and especially of multinational alcohol producer and distributor corporations, that view India's population as an emerging market of new and young drinkers, who, over time, are continuing to increase their consumption and demonstrate a reducing age of initiation; all of which make a national policy even timelier [10].

Given the absence of a comprehensive national alcohol policy, we believe there is a necessity to comprehensively map the current policy environment surrounding alcohol and its use in India, something that has not been undertaken in the existing literature. A comprehensive examination of these policies would help researchers and practitioners better understand the exact policy environment with which alcohol-related societal harm is interacting in India, and also help policy makers get a clearer and more comprehensive picture of the current state of alcohol-related policies across India, in order to take steps toward reform.

METHODS

The methods for this review utilise the scoping review methodological framework put forward by Arskey & O'Malley [11] and refined by Levac [12]. A scoping review, as compared to a systematic review, uses a 6-stage process of review and allows for covering of broad topics of research areas and iterative construction of research direction. Where systematic reviews have strictly defined questions and therefore eligibility criteria at the

outset, scoping reviews are iterative in nature [12] and eligibility parameters and search strategies are therefore refined as the search identifies more relevant knowledge.

We considered the various methods available for conducting a policy review and decided that a scoping review with relevant adaptations would be the most applicable to reviewing inter-sectorial policy in an Indian context. Our strategy will start with an academic search of peer reviewed literature to iteratively define search parameters for grey literature and government website searches. In doing this, our search adapts the scoping review method by adopting a tiered approach, an 'academic search tier' followed by a 'grey literature search tier' in order to identify policy documents. The detailed steps of our search strategy are as follows:

Stage 1: Identifying the research question(s)

Based on an iterative review of the literature and the previous experience of the investigator group, our guiding research questions were developed. Our objective is to comprehensively map Indian policies that relate to alcohol related societal harm. More specifically we ask the following question:

> *What are the policies currently in place in India that regulate demand for and supply of alcohol and alcohol products, and the impact of access to, use and misuse of alcohol on a range of societal outcomes.*
> This includes alcohol use disorders (AUDs), as well as drink-driving, violence, micro- and macroeconomic outcomes, comorbid health outcomes, family member health outcomes and any other negative impacts which alcohol has on Indian society.

Stage 2: Identifying relevant studies
The first tier of our study involves identifying relevant academic literature that discuss policies which are relevant to our final search. In line with the iterative process of a scoping review, this will help set the search terms for the grey literature search for policy documents, using knowledge generated from the peer-review literature. For a description of the objectives and inclusion and exclusion criteria at each tier of the search, see Figure 1.

Electronic databases of peer-reviewed journals MEDLINE, PSYCInfo, Embase, Global Health and IndMed (database of peer reviewed medical journals published from India) will be searched. All search hits will be downloaded to a bibliographic management software. Search terms that will be used will centre around the concepts of "alcohol, "policy" and "India". The "alcohol" concept is built around synonyms and types of alcohol (e.g. spirit, liquor, beer, illicit alcohol) and terms applying to drinking (e.g. drinker, alcohol consumption, social drinking, bars) and alcohol misuse (e.g. addiction, problematic alcohol use, alcohol dependence, drink driving). The "policy" concept will

be broad and include terms covering all dimensions of policy applicable to alcohol including marketing, sales, production, importation, trade, treatment, and synonyms for these terms (e.g. de-addiction, promotion, taxes, availability, minimum drinking age, prohibition, labelling, prevention, and many others). The "India" concept includes terms for India (e.g. Indian Union) and all of its states and union territories including historical state names. The search terms under these three concepts will be used to search the databases mentioned above using a title/abstract/keyword search as well as a subject heading search where possible.

Stage 3: Study selection

Two reviewers (JS and AJ) will independently screen titles and abstracts resulting from the search process and exclude any ineligible studies. The researchers will discuss their selection of articles after this first round of screening, to arrive at preliminary consensus on the list of eligible studies. They will then complete a full text screening of all selected articles, removing any articles, which do not meet the inclusion criteria. They will again discuss their selection of articles after this second round of screening, to arrive at a final consensus list of eligible studies. Differences in opinion will be resolved through consensus between the two reviewers with a third reviewer (AN) serving as arbiter in case of disagreement. This systematic process will be reported using the PRISMA flow chart [13].

Stage 4: Charting the data

Data extraction forms will be created and used to chart relevant data from included studies. Two researchers (JS and AJ) will independently extract data. Data extraction will be compared after the first ten documents to check for consistency between the two researchers, and then again, after data extraction from all documents. Data extraction at this stage will involve collecting knowledge about policy that will be used iteratively to find policy documents in Tier 2 of the search.

Stage 5: Collating, summarizing and reporting results

Data from the academic search will be summarized into a list of policy names, a list of possible search terms and a list of potentially relevant citations to follow up. The research team will then discuss the list and make decisions for further iterative search processes of grey literature, government websites, and other strategies to find policy documents.

Further Iteration and Isolation of policies: Tier 2

The peer-review tier of our search will help generate knowledge of the parameters in which to search the grey literature and government websites. Scanning of citations,

isolating of policy names and descriptions, and knowledge gathering of relevant vocabulary will all be used to iteratively develop the strategies to isolate policies. These policy documents will be the data to be included in Tier 2. Following an iterative approach, we will use the knowledge generated from stage one in combination with researcher knowledge to help identify strategies for searching for policy documents. Possible strategies to subsequently identify and gather policy documents include the searching of grey literature through World Health Organization and World Bank websites and use of Google and/or Google Scholar. Google and English language websites of state and national Ministry websites, which are found to be relevant during our academic search, will be hand-searched for policies. As more knowledge is obtained through this process, we will continue to iteratively search through grey literature. Through these steps, we will aim to obtain the key policy documents that create the policy environment relating to alcohol related societal harm.

Tier 2 data will then be charted using a data extraction form. This form will aim to gather data relating to policy name, department responsible, goal of policy, and other details, but will developed by the team after the iterative grey literature stage has been undertaken to ensure the chart is most useful. The developed data chart will be piloted on 5-10 policy documents to ensure its usefulness once developed and changes will be made accordingly.

Data from the charting of Tier 2 will be synthesized, summarized, discussed within the team and compared with what was originally found in the academic literature. We will analyse the data with a thematic analysis approach to present the themes that emerge from the policies present and not present. This is in line with the scoping review approach, which aims to present an overview of a research area instead of appraise the quality of data [11] [12].

Stage 6: Consultation
We will consult with leading researchers and policy makers in India, on our consolidated list of policies and the thematic analysis of these policies to ensure that we have not missed anything crucial in our search.

DISSEMINATION
The study was submitted for registration on PROSPERO, but investigators were informed that scoping studies are not in scope for registration. We will be circulating the methods used for this policy review to other policy researchers, particularly those researching in low resource settings, as we believe this method is helpful in navigating intersectorial policy spaces in low resource settings. We will publish our results in a peer-reviewed journal.

CONCLUSION

This review will provide the first consolidation of the policy environment surrounding alcohol related societal harm in India, giving researchers and policy makers a clearer look towards future reforms. This review is also an important adaptation on the scoping review method for policy reviews in low resource settings that may serve as an example for other policy reviews in similar settings.

Authors' Contribution: All authors have made substantial intellectual contributions to the development of this protocol. The search question was conceptualized by AN and further developed by RV. The review approach and design was conceptualized by JS with advice from AN. JS and AJ developed and tested search terms with input and revisions from AN, RV and UB. JS initiated drafting of the manuscript followed by further iterations after substantial input and appraisal from all authors. All authors approved the final version of this manuscript.

Competing interests statement: The authors declare no competing interests.

Ethics approval: This scoping study does not require ethics approval as it only uses secondary data.

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Tier 1: Academic Search

<u>Objective</u>: Identify relevant knowledge in academic literature to create parameters and search terms for grey literature searching and website searching in Tier 2

<u>Inclusion</u>: Any academic literature identified through discussed methods that discusses Indian alcohol policy environment

INFORMS

Tier 2: Policy Search

<u>Objective</u>: Identify policy documents that describe the policy environment surrounding alcohol in India, methods developed iteratively as described in "further iteration and isolation of policies"

<u>Inclusion</u>: policy documents

Flow chart describing the tiered approach central to our scoping method

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Abstract

INTRODUCTION:
The aim of this review is to provide the first consolidation of the policy environment surrounding alcohol-related societal harm in India giving researchers and policy makers a clearer base for future reforms. This review is also an important adaptation on the scoping review method for policy reviews in low resource settings that may serve as an example for other policy reviews in similar settings.

METHODS AND ANALYSIS: We will undertake a scoping review with policy relevant adaptations in order to map the alcohol-related policy environment in India. Following the six step approach put forward by Arskey & O'Malley and refined by Levac, we will first undertake an academic scoping search to identify relevant knowledge already existing in the literature about the policy environment in India. We will then use the knowledge that appears in this search iteratively, as is true to the scoping method, to develop a more targeted search of grey literature and Indian government websites for Indian policy documents. These documents will be analysed using qualitative methods to synthesise the current alcohol policy environment in India.

ETHICS AND DISSEMINATION: This study will only use already published information and therefore does not require an ethics review. We will circulate this protocol and the final report to policy researchers in similar settings who could make use of our adaptation of the scoping review method for a low-resource setting. We will also publish our findings in a peer-review journal.

STRENGTHS AND LIMITATIONS OF THIS STUDY
- This is a novel review approach to reviewing a policy environment in a low resource setting where relevant policies can be difficult to identify through traditional search methods.
- This is the first review of its kind to attempt to consolidate the policy environment applicable to the societal harm related to alcohol in India.
- Although the sources cited are dated they are the most recent, further emphasizing the necessity of investigating the research gap.
- This review seeks to investigate a policy area that is extensive in scope, and this may limit the ability of the search to explore deeply every policy area related to societal harm related to alcohol in India.
- The search is limited to texts in English.

INTRODUCTION

Alcohol consumption is a cause of substantial preventable societal harm in Southeast Asia. In 2010, the prevalence of alcohol use disorders (AUDs) in South-East Asia was 2.2%[1]. The alcohol attributable burden of disease accounted for an average 2.7% of DALYs in 2004 in southeast Asia[2], with prevalence continuing to rise in the region[3]. In addition to the burden of ill health, alcohol consumption creates significant societal economic costs, equal to more than 1% of GDP in high and middle-income countries [2], through increased health costs and decreased economic productivity. In India, alcohol use contributed 5.4% of the total burden of disease in 2004, significantly higher than the region average[2]. By 2014, this estimate was up to 8.8%, connected to 1.4 million cases of 19 diseases[4]. In addition, consumption of alcohol has been steadily increasing in India, with recorded per capita liquor consumption increasing from 1.6 liters in 2003-2005 to 2.2 liters in 2010 to 4.3 liters in 2014[4], and more than half of all drinkers are drinking hazardously [5].

This paper will discuss societal harm caused by alcohol, defined as alcohol-related harm to the drinkers themselves and also the harmful consequences of drinking to those around the drinker – externalities of drinking – an element which receives very little policy focus[6 7] As demonstrated in India, about one-fourth of abuse against women and children has been connected to chronic alcohol use [8]. In addition, approximately one-third of night-time road traffic injuries and mortalities involved a driver who had consumed alcohol [8]. Further, alcohol use contributes to homelessness [9], absenteeism and unemployment [10], high risk sexual behaviour [11], and poor health outcomes for children [12]. Finally, the yearly overall alcohol use-related economic costs to society in India, were estimated to be 2.1 trillion Indian rupees (30.8 billion United States Dollars) in 2013-14, or roughly 2.26% of GDP [4 13].

While there is growing recognition of the preventable harm that alcohol use is leading to in India, the country still lacks a consolidated national alcohol policy. This protocol will define policy as done by the United States' Centres for Disease Control: Policy is a law, regulation, procedure, administrative action, incentive, or voluntary practice of governments and other institutions[14] This lack of consolidated policy is evident in the focus on prohibition-centered supply reduction, taxation and tertiary prevention [5] ; all implemented as a set of disparate and poorly coordinated and implemented policy initiatives. An additional concern is the power of the 'alcohol lobby' and especially of multinational alcohol producer and distributor corporations, that view India's population as an emerging market of new and young drinkers, who, over time, are continuing to increase their consumption and demonstrate a reducing age of initiation; all of which make a national policy even timelier [15]. India is a key example of WHO-Director General Dr. Margaret Chan's warning: "alcohol consumption is expanding in precisely those countries that lack the regulatory and enforcement capacities to protect their populations."[16]

Given the absence of a comprehensive national alcohol policy, we believe there is a necessity to comprehensively map the current policy environment surrounding

alcohol and its use in India, something that has not been undertaken in the existing literature, and this is the goal of the review described herein.. A comprehensive mapping would allow for the examination of these policies, helping researchers and practitioners better understand the exact policy environment, or the total composition of all the policies in place, with which alcohol-related societal harm is interacting in India. This can also help policy makers, those whom are involved in any extent in making or changing policies in place, get a clearer and more comprehensive picture of the current state of alcohol-related policies across India, in order to take steps toward reform. In performing this mapping, this protocol also puts forward an important adaptation of the scoping review method for use for policy research in low resource settings.

METHODS

The methods for this review utilise the scoping review methodological framework put forward by Arskey & O'Malley [17] and refined by Levac [18]. A scoping review, as compared to a systematic review, uses a 6-stage process of review and allows for covering of broad topics of research areas and iterative construction of research direction. Where systematic reviews have strictly defined questions and therefore eligibility criteria at the outset, scoping reviews are iterative in nature [18] and eligibility parameters and search strategies are therefore refined as the search identifies more relevant knowledge.

We considered the various methods available for conducting a policy review and decided that a scoping review with relevant adaptations would be the most applicable to reviewing inter-sectorial policy in an Indian context. Our strategy will start with an academic search of peer reviewed literature to iteratively define search parameters for grey literature and government website searches. In doing this, our search adapts the scoping review method by adopting a tiered approach, an 'academic search tier' followed by a 'grey literature search tier' in order to identify policy documents. The detailed steps of our search strategy are as follows:

Stage 1: Identifying the research question(s)

Based on an iterative review of the literature and the previous experience of the investigator group in examining the burden of alcohol use disordered (AUDs) in India and developing interventions to reduce the harm due to AUDs[19-22], our guiding research questions were developed. Our objective is to comprehensively map Indian policies that relate to alcohol-related societal harm and frame these in the context of international standards for alcohol policy. More specifically we ask the following questions:

> *What are the policies currently in place in India that regulate demand for and supply of alcohol and alcohol products?*

What are the policies currently in place in India that regulate the impact on a range of societal outcomes arising from access to, use and misuse of alcohol?.

This includes alcohol use disorders (AUDs), as well as drink-driving, violence, micro- and macroeconomic outcomes, comorbid health outcomes, family member health outcomes and any other negative impacts which alcohol has on Indian society. Our questions and scope remain broad in nature given the lack of current research and disparate policy environment expected in India where there is no national alcohol policy. We therefore leave our scope to include policies which may not be specific to alcohol but which include components that relate to alcohol use.

Stage 2: Identifying relevant studies
The first tier of our study involves identifying relevant academic literature that discuss policies which are relevant to our final search. In line with the iterative process of a scoping review, this will help set the search terms for the grey literature search for policy documents, using knowledge generated from the peer-review literature. For a description of the objectives and inclusion and exclusion criteria at each tier of the search, see Figure 1.

Electronic databases of peer-reviewed journals MEDLINE, PSYCInfo, Embase, Global Health and IndMed (database of peer reviewed medical journals published from India) were searched in August and September 2017. All search hits were downloaded to a bibliographic management software. Search terms used centred on the concepts of "alcohol, "policy" and "India". The "alcohol" concept was built around synonyms and types of alcohol (e.g. spirit, liquor, beer, illicit alcohol) and terms applying to drinking (e.g. drinker, alcohol consumption, social drinking, bars) and alcohol misuse (e.g. addiction, problematic alcohol use, alcohol dependence, drink driving). The "policy" concept was broad and included terms covering all dimensions of policy applicable to alcohol including marketing, sales, production, importation, trade, treatment, and synonyms for these terms (e.g. de-addiction, promotion, taxes, availability, minimum drinking age, prohibition, labelling, prevention, lobbying, industry and many others). The "India" concept included terms for India (e.g. Indian Union) and all of its states and union territories including historical state names. The search terms under these three concepts were used to search the databases mentioned above using a title/abstract/keyword search as well as a subject heading search where possible. The full search strategy can be found in Supplement 1.

Stage 3: Study selection
Two reviewers (JS and AJ) will independently screen titles and abstracts resulting from the search process and exclude any ineligible studies. This process is on going at the time of protocol submission. The researchers will discuss their selection of articles after

this first round of screening, to arrive at preliminary consensus on the list of eligible studies. They will then complete a full text screening of all selected articles, removing any articles that do not meet the inclusion criteria, as abstracts contain less detail than the full text. Reviewers will again discuss their selection of articles after this second round of screening, to arrive at a final consensus list of eligible studies. Differences in opinion will be resolved through consensus between the two reviewers with a third reviewer (AN) serving as arbiter in case of disagreement.

At both levels, the reviewers will use the following questions for guiding inclusion and must answer yes to all three questions to include an article: 1) Does this article discuss specific policies? 2) Does this article discuss specific policies relating to alcohol or alcohol's externalities? 3) Does this article discuss policy specific to India?

This systematic process will be reported using the PRISMA flow chart [23].

Stage 4: Charting the data
Data extraction forms will be created and used to chart relevant data from included studies. Two researchers (JS and AJ) will independently extract data. Data extraction will be compared after the first ten documents to check for consistency between the two researchers and allow for form revision, and then again, after data extraction from all documents. Data extraction at this stage will involve collecting knowledge about policy that will be used iteratively to find policy documents in Tier 2 of the search. Data to be charted may include but not be limited to title of publication, year of publication, policy name, policy description, implementing jurisdiction, and date/year of policy implementation.

Stage 5: Collating, summarizing and reporting results
Data from the academic search will be summarized into a list of policy names, a list of possible search terms and a list of potentially relevant citations to follow up. The research team will then discuss the list and make decisions for further iterative search processes of grey literature, government websites, and other strategies to find policy documents. For further analysis, the policies will be further mapped according to the World Health Organization's (WHO) Global Strategy to Reduce the Harmful Use of Alcohol, which includes 10 strategy areas across different policy sectors[24].

Further Iteration and Isolation of policies: Tier 2

The peer-review tier of our search will help generate knowledge of the parameters in which to search the grey literature and government websites. Scanning of citations, isolating of policy names and descriptions, and knowledge gathering of relevant vocabulary will all be used to iteratively develop the strategies to isolate policies.

We will then consult with leading researchers and policy makers based on the collated data from Tier 1 of the search to gain insight and scrutiny of our next steps for searching the grey literature in order to ensure that we are not missing any important documents in Tier 2.

These policy documents will be the data to be included in Tier 2 with planned coverage in August-October 2018. Following an iterative approach, we will use the knowledge generated from Tier 1 in combination with researcher knowledge to help identify strategies for searching for policy documents. Possible strategies to subsequently identify and gather policy documents include the searching of grey literature through World Health Organization and World Bank websites and use of Google and/or Google Scholar. Google and English language websites of state and national Ministry websites, which are found to be relevant during our academic search, will be hand-searched for policies. As more knowledge is obtained through this process, we will continue to iteratively search through grey literature. Through these steps, we will aim to obtain the key policy documents that create the policy environment relating to alcohol-related societal harm.

Tier 2 data will then be charted using a data extraction form. This form will aim to gather data relating to policy name, department responsible, goal of policy, and other details, but will developed by the team after the iterative grey literature stage has been undertaken to ensure the chart is most useful. The developed data chart will be piloted on 5-10 policy documents to ensure its usefulness once developed and changes will be made accordingly.

Data from the charting of Tier 2 will be synthesized, summarized, discussed within the team and compared with what was originally found in the academic literature. We will analyse the data with a thematic analysis approach to present the themes that emerge from the policies present. This is in line with the scoping review approach, which aims to present an overview of a research area instead of appraise the quality of data [17 18]. Data will be further mapped according to the WHO Global Strategy. This will allow for global comparisons and identification of gaps in policy according to the recommendations of the WHO in the Global Strategy for best practices in reducing the harm of alcohol.

Stage 6: Consultation
We will consult with leading researchers and policy makers in India, on our consolidated list of policies and the thematic analysis and mapping of these policies to ensure that we have not missed any crucial policies in our search.

Patients and Public Involvement: No patients are involved in this review.

ETHICS AND DISSEMINATION

As a review of journal articles, grey literature, and policy documents, this study will only utilize secondary material and therefore does not require ethical review.

The study was submitted for registration on PROSPERO, but investigators were informed that scoping studies are not in scope for registration. We will be circulating the methods used for this policy review to other policy researchers, particularly those researching in low resource settings, as we believe this method is helpful in navigating intersectorial policy spaces in low resource settings. We will publish our results in a peer-reviewed journal and on relevant forums such as online global health networks.

Authors' Contribution: All authors have made substantial intellectual contributions to the development of this protocol and its revisions. The search question was conceptualized by AN and further developed by RV. The review approach and design was conceptualized by JS with advice from AN. JS and AJ developed and tested search terms with input and revisions from AN, RV and UB. JS initiated drafting of the manuscript followed by further iterations after substantial input and appraisal from all authors. All authors approved the final version of this manuscript.

Competing interests statement: The authors declare no competing interests.

Ethics approval: This scoping study does not require ethics approval as it only uses secondary data.

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15&rft.date=2016&rft.jtitle=Drug+%26+Alcohol+Dependence&rft.atitle=The
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Tier 1: Academic Search

<u>Objective</u>: Identify relevant knowledge in academic literature to create parameters and search terms for grey literature searching and website searching in Tier 2
<u>Included</u>: Any academic literature identified through discussed methods that discusses Indian alcohol policy environment; no date limitation
<u>Excluded</u>: Non- English language texts

INFORMS

Tier 2: Policy Search

<u>Objective</u>: Identify policy document that describe the policy environment surrounding alcohol in India, methods developed iteratively as described in "Further Iteration and Isolation of Policies: Tier 2"
<u>Included</u>: Policy and grey literature documents as informed by academic search, policy documents which are most up to date (i.e. those which replace an older law)
<u>Excluded</u>: Non-English language texts, obsolete policy documents (those which have been replaced)

'Academic search tier' as it informs 'Policy search tier' including descriptions of the objective, inclusion and exclusion criteria of each

48x36mm (300 x 300 DPI)

A scoping review of the policy environment impacting alcohol related societal harm in India

List of authors: Jaclyn Schess, Abhijeet Jambhale, Urvita Bhatia, Richard Velleman, Abhijit Nadkarni

Table 1: Inclusion and exclusion criteria for initial search

	Included	Excluded
Year	Any	
Language	English	
Population	Any	
Setting	India and any states or UTs of India	

Databases:

1) Medline
2) EMBASE
3) PsycINFO
4) Global Health

Table 2: Search concepts

Alcohol	Policy and alcohol related policy terms	India
Alcohol	Policy	India
Substance	Scheme	Individual Indian states
Addiction	De-addiction	
Drinking	Treatment	
Alcoholism	Plan	
Alcohol use disorder	Marketing	
Drink driving	Liberalization	
Liquor	Lobbying	

Blood Alcohol Content	Demand	
Beverage	Prevention	
Bar/Pub	Promotion	
Unhealthy commodity	Point of sale	
	Supply	
	Government	
	Ministry	
	Detoxification	
	Prohibition	
	Tax	
	Management	
	Regulation	
	Act	
	Program	
	Law	
	Legal	
	Legal drinking age	
	Dry Day	
	Constitution	
	Permit	
	Excise	
	Rules	
	Amendment	
	Bill	
	License	
	Section	
	Legislation	
	Advertising	
	Enforcement	

	Restriction	
	Trade	
	Importation	
	Illicit	
	Synthetic	
	Pricing	
	Limits	
	Open Container	
	Revenue	
	Industry	
	Agreement	
	Control	
	Treaty	
	Labeling	
	Reduction	
	Packaging	
	Distribution	

Data collection and analysis

Selection of studies and guidelines

Two reviewers will independently inspect the abstracts of the studies identified through the academic search strategy described below: two lists will then be composed of potentially eligible studies. The two reviewers will then discuss their selections and in the case of any disagreement regarding inclusion, a third reviewer will be consulted for a final decision.

Data extraction

Following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, a record will be made of the number of papers retrieved, the number of papers excluded and the reasons for their exclusion. A formal data

extraction form will be designed for the papers to extract data relevant to the study aims. Two reviewers will independently perform data collection and any disagreements will be discussed and resolved.

Medline Search Strategy:

1. Alcohol*.tw
2. Addict*.tw
3. (Drink* NOT water).tw **
4. Substance use*.tw
5. Substance abuse*.tw
6. Alcohol addict*.tw
7. Alcohol abuse*.tw
8. Alcohol dependen*.tw
9. "Alcohol use disorder".tw
10. Harmful drink*.tw
11. Hazardous drink*.tw
12. Social drink*.tw
13. Dr?nk ADJ2 driv*.tw
14. Liquor*.tw
15. Liqueur*.tw
16. Spirit*.tw
17. "Blood alcohol content".tw
18. BAC.tw
19. Beverage*.tw
20. Alcohol consum*.tw
21. "Problematic alcohol use".tw
22. Whiskey*.tw
23. Rum.tw
24. Beer*.tw
25. Wine*.tw
26. Vodka*.tw

27. Unhealthy commodit*.tw

28. Bars.tw

29. Pubs.tw

30. "Illicit alcohol".tw

31. "synthetic alcohol".tw

32. OR (1-31)

33. Alcohol/

34. Addict/

35. Drinker/

36. Alcohol addict/

37. Alcohol abuse/

38. Alcohol dependence/

39. "Alcohol use disorder"/

40. Harmful drinking/

41. Hazardous drinking/

42. Drink driving/

43. Drunk driving/

44. Liquor/

45. Spirit/

46. "Blood alcohol content"/

47. Beverage/

48. Whiskey/

49. Rum/

50. Beer/

51. Wine/

52. Vodka/

53. OR (33-52)

54. 32 or 53

55. Polic*.tw

56. Scheme*.tw

57. De?addiction.tw

58. Plan*.tw

59. Government ADJ3 Polic*.tw

60. Government ADJ3 Scheme*.tw

61. Government ADJ3 Plan*.tw

62. Market*.tw

63. Liberaliz*.tw

64. Neoliberalism.tw

65. Lobby*.tw

66. Demand*.tw

67. Prevent*.tw

68. Promot*.tw

69. Suppl*.tw

70. Government*.tw

71. Ministr*.tw

72. Program*.tw

73. Tax*.tw

74. Detoxification.tw

75. Prohibit*.tw

76. Manag*.tw

77. Avail*.tw

78. Access*.tw

79. Regulat*.tw

80. Act.tw

81. Acts.tw

82. Law*.tw

83. Legal*.tw

84. Drinking age.tw

85. Legal drinking age.tw

86. Minimum drinking age.tw

87. Underage drink*.tw

88. Constitution*.tw

89. Dry day*.tw

90. Licen?*.tw

91. On-licen?e*.tw

92. Off-licen?e*.tw

93. Sale licen?*.tw

94. Resale.tw

95. Wholesale*.tw

96. Retail*.tw

97. Sale*.tw

98. Sales outlet*.tw

99. Excise.tw

100. Rule*.tw

101. Amend*.tw

102. Bill*.tw

103. Permit*.tw

104. Manufactur* permit*.tw

105. Section*.tw

106. Legislat*.tw

107. Advertis*.tw

108. Advertising restrict*.tw

109. Surrogate advertis*.tw

110. Media restrict*.tw

111. Billboard*.tw

112. Sponsorship*.tw

113. Partnership*.tw

114. Enforc*.tw

115. Public place*.tw

116. Quantity restrict*.tw

117. Restrict*.tw

118. Time restrict*.tw

119. Age restrict*.tw

120. Location restrict*.tw

121. Sale restrict*.tw

122. Point of sale.tw

123. Trade.tw

124. Trade agreement*.tw

125. Treaty.tw or treaties.tw or treatise.tw

126. Free trade.tw

127. "World Trade Organization".tw

128. "International Monetary Fund".tw

129. Import*.tw

130. Export*.tw

131. Tarrif*.tw

132. Price*.tw

133. Price setting.tw

134. Subsid*.tw

135. Limit*.tw

136. Open container*.tw

137. Revenue*.tw

138. Industr*.tw

139. Agreement*.tw

140. Control*.tw

141. Packag*.tw

142. Label*.tw

143. Reduc*.tw

144. Distribut*.tw

145. OR (55-144)

146. Policy/

147. Scheme/

148. Plan/

149. Marketing/

150. Liberalization/

151.   Lobbying/

152.   Demand/

153.   Prevention/

154.   Promotion/

155.   Supply/

156.   Government/

157.   Program/

158.   Taxes/

159.   Detoxification/

160.   Prohibition/

161.   Management/

162.   Regulation/

163.   Act/

164.   Law/

165.   Legal/

166.   Drinking age/

167.   Legal drinking age/

168.   Constitution/

169.   License/

170.   Rule/

171.   Amendment/

172.   Bill/

173.   Permit/

174.   Section/

175.   Legislation/

176.   Advertisement/

177.   Billboard/

178.   Sponsorship/

179.   Partnership/

180.   Enforcement/

181.   Restriction/

182. Age restriction/

183. Trade/

184. Trade agreement/

185. Free trade/

186. Treaty/

187. "World Trade Organization"/

188. "International Monetary Fund"/

189. Import/

190. Export/

191. Tariff/

192. Subsidy/

193. Revenue/

194. Industry/

195. Agreement/

196. Control/

197. Packaging/

198. Labeling/

199. Reduction/

200. Distribution/

201. OR (146-200)

202. 145 or 201

203. 54 AND 202

204. India* not American.tw

205. "Indian union".tw

206. OR (204-205)

207. Andaman and Nicobar Island*.tw

208. Andhra Pradesh.tw

209. Arunachal Pradesh.tw

210. Assam.tw

211. Bihar.tw

212. Dadra and Nagar Haveli.tw

213. Chhattisgarh.tw

214. Daman and Diu.tw
215. National Capital Territory of New Delhi.tw
216. Delhi.tw
217. Goa.tw
218. Gujarat.tw
219. Haryana.tw
220. Himachal Pradesh.tw
221. Jammu and Kashmir.tw
222. Janmu.tw
223. Kashmir.tw
224. Jharkhand.tw
225. Karnataka.tw
226. Mysore.tw
227. Kerala.tw
228. Travancore-Cochin.tw
229. Madhya Pradesh.tw
230. Madhya Bharat.tw
231. Maharashtra.tw
232. Manipur.tw
233. Meghalaya.tw
234. Mizoram.tw
235. Nagaland.tw
236. Odisha.tw
237. Orissa.tw
238. Punjab.tw
239. Chandigarh.tw
240. Rajasthan.tw
241. Sikkim.tw
242. Tamil Nadu.tw
243. Madras State.tw
244. Telangana.tw
245. Tripura.tw
246. Uttarakhand.tw
247. Uttaranchal.tw
248. Uttar Pradesh.tw

249.   United Provinces.tw

250.   West Bengal.tw

251.   Lakshadweep.tw

252.   P#d#cherry.tw

253.   OR (207-252)

254.   206 OR 253

255.   203 AND 254

For 'Medline' and 'Embase' databases, 'Text Word' and 'MeSH Subject Heading' were used in the indexing field.

For 'Psyc-info' and 'Global health' databases, 'Abstract' and 'Subject heading' were used correspondingly.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item		Page
ADMINISTRATIVE INFORMATION				
Title:				
Identification	1a	Identify the report as a protocol of a systematic review	X	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	X	9
Authors:				
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	X	1,2
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	X	9
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A	N/A
Support:				
Sources	5a	Indicate sources of financial or other support for the review	X	10
Sponsor	5b	Provide name for the review funder and/or sponsor	N/A	N/A
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	X	10
INTRODUCTION				
Rationale	6	Describe the rationale for the review in the context of what is already known	X	4,5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	X	6
METHODS				
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	X	Figure 1
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	X	6-9
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be	X	Supp 1

		repeated		
Study records:				
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	X	6
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	X	6
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	X	7,8
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	X	7
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	X	7
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	N/A	N/A
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	N/A	N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	N/A	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	X	8,9
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A	N/A

* It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

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The policy environment impacting the societal harm caused by alcohol in India: Protocol for a scoping review

SCHOLARONE™
Manuscripts

Manuscript Title: The policy environment impacting the societal harm caused by alcohol in India: Protocol for a scoping review

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The policy environment impacting the societal harm caused by alcohol in India: Protocol for a scoping review

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Word count: 1634

The policy environment impacting the societal harm caused by alcohol in India: Protocol for a scoping review

Abstract

INTRODUCTION:
The aim of this review is to provide the first consolidation of the policy environment surrounding alcohol-related societal harm in India giving researchers and policy makers a clearer base for future reforms. This review is also an important adaptation on the scoping review method for policy reviews in low resource settings that may serve as an example for other policy reviews in similar settings.

METHODS AND ANALYSIS: We will undertake a scoping review with policy relevant adaptations in order to map the alcohol-related policy environment in India. Following the six step approach put forward by Arskey & O'Malley and refined by Levac, we will first undertake an academic scoping search to identify relevant knowledge already existing in the literature about the policy environment in India. We will then use the knowledge that appears in this search iteratively, as is true to the scoping method, to develop a more targeted search of grey literature and Indian government websites for Indian policy documents. These documents will be analysed using qualitative methods to synthesise the current alcohol policy environment in India.

ETHICS AND DISSEMINATION: This study will only use already published information and therefore does not require an ethics review. We will circulate this protocol and the final report to policy researchers in similar settings who could make use of our adaptation of the scoping review method for a low-resource setting. We will also publish our findings in a peer-review journal.

STRENGTHS AND LIMITATIONS OF THIS STUDY
- This is a novel review approach to reviewing a policy environment in a low resource setting where relevant policies can be difficult to identify through traditional search methods.
- This is the first review of its kind to attempt to consolidate the policy environment applicable to the societal harm related to alcohol in India.
- Although the sources cited are dated they are the most recent, further emphasizing the necessity of investigating the research gap.
- This review seeks to investigate a policy area that is extensive in scope, and though this may limit the ability of the search to explore deeply every policy area related to societal harm related to alcohol in India, the review's intention is to identify and analyse, at the very minimum, existing key policies related to this topic.
- The search is limited to texts in English.

3

The policy environment impacting the societal harm caused by alcohol in India: Protocol for a scoping review

INTRODUCTION

Alcohol consumption is a cause of substantial preventable societal harm in Southeast Asia. In 2010, the prevalence of alcohol use disorders (AUDs) in South-East Asia was 2.2%[1]. The alcohol attributable burden of disease accounted for an average 2.7% of DALYs in 2004 in southeast Asia[2], with prevalence continuing to rise in the region[3]. In addition to the burden of ill health, alcohol consumption creates significant societal economic costs, equal to more than 1% of GDP in high and middle-income countries [2], through increased health costs and decreased economic productivity. In India, alcohol use contributed 5.4% of the total burden of disease in 2004, significantly higher than the region average[2]. By 2014, this estimate was up to 8.8%, connected to 1.4 million cases of 19 diseases[4]. In addition, consumption of alcohol has been steadily increasing in India, with recorded per capita liquor consumption increasing from 1.6 litres in 2003-2005 to 2.2 litres in 2010 to 4.3 litres in 2014[4], and more than half of all drinkers are drinking hazardously [5]. Total alcohol consumption is projected to reach 4.7 litres per capita by 2020[6].

This paper will discuss societal harm caused by alcohol, defined as alcohol-related harm to the drinkers themselves and also the harmful consequences of drinking to those around the drinker – externalities of drinking – an element which receives very little policy focus[7 8] As demonstrated in India, about one-fourth of abuse against women and children has been connected to chronic alcohol use [9]. In addition, approximately one-third of night-time road traffic injuries and mortalities involved a driver who had consumed alcohol [9]. Further, alcohol use contributes to homelessness [10], absenteeism and unemployment [11], high risk sexual behaviour [12], and poor health outcomes for children [13]. Finally, the yearly overall alcohol use-related economic costs to society in India, were estimated to be 2.1 trillion Indian rupees (30.8 billion United States Dollars) in 2013-14, or roughly 2.26% of GDP [4 14].

While there is growing recognition of the preventable harm that alcohol use is leading to in India, the country still lacks a consolidated national alcohol policy. This protocol will define policy as done by the United States' Centres for Disease Control: Policy is a law, regulation, procedure, administrative action, incentive, or voluntary practice of governments and other institutions[15] This lack of consolidated policy is evident in the focus on prohibition-centered supply reduction, taxation and tertiary prevention [5] ; all implemented as a set of disparate and poorly coordinated and implemented policy initiatives. An additional concern is the power of the 'alcohol lobby' and especially of multinational alcohol producer and distributor corporations, that view India's population as an emerging market of new and young drinkers, who, over time, are continuing to increase their consumption and demonstrate a reducing age of initiation; all of which make a national policy even timelier [16]. India is a key example of WHO-Director General Dr. Margaret Chan's warning: "alcohol consumption is expanding

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in precisely those countries that lack the regulatory and enforcement capacities to protect their populations."[17]

Given the absence of a comprehensive national alcohol policy, we believe there is a necessity to comprehensively map the current policy environment surrounding alcohol and its use in India, something that has not been undertaken in the existing literature, and this is the goal of the review described herein.. A comprehensive mapping would allow for the examination of these policies, helping researchers and practitioners better understand the exact policy environment, or the total composition of all the policies in place, with which alcohol-related societal harm is interacting in India. This can also help policy makers, those whom are involved in any extent in making or changing policies in place, get a clearer and more comprehensive picture of the current state of alcohol-related policies across India, in order to take steps toward reform. In performing this mapping, this protocol also puts forward an important adaptation of the scoping review method for use for policy research in low resource settings.

METHODS

The methods for this review utilise the scoping review methodological framework put forward by Arskey & O'Malley [18] and refined by Levac [19]. A scoping review, as compared to a systematic review, uses a 6-stage process of review and allows for covering of broad topics of research areas and iterative construction of research direction. Where systematic reviews have strictly defined questions and therefore eligibility criteria at the outset, scoping reviews are iterative in nature [19] and eligibility parameters and search strategies are therefore refined as the search identifies more relevant knowledge.

We considered the various methods available for conducting a policy review and decided that a scoping review with relevant adaptations would be the most applicable to reviewing inter-sectorial policy in an Indian context. Our strategy will start with an academic search of peer reviewed literature to iteratively define search parameters for grey literature and government website searches. In doing this, our search adapts the scoping review method by adopting a tiered approach, an 'academic search tier' followed by a 'grey literature search tier' in order to identify policy documents. The detailed steps of our search strategy are as follows:

Stage 1: Identifying the research question(s)

Based on an iterative review of the literature and the previous experience of the investigator group in examining the burden of alcohol use disordered (AUDs) in India and developing interventions to reduce the harm due to AUDs[20-23], our guiding research questions were developed. Our objective is to comprehensively map Indian policies that

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relate to alcohol-related societal harm and frame these in the context of international standards for alcohol policy. More specifically we ask the following questions:

What are the policies currently in place in India that regulate demand for and supply of alcohol and alcohol products?

What are the policies currently in place in India that regulate the impact on a range of societal outcomes arising from access to, use and misuse of alcohol?

This includes alcohol use disorders (AUDs), as well as drink-driving, violence, micro- and macroeconomic outcomes, comorbid health outcomes, family member health outcomes and any other negative impacts which alcohol has on Indian society. Our questions and scope remain broad in nature given the lack of current research and disparate policy environment expected in India where there is no national alcohol policy. We therefore leave our scope to include policies which may not be specific to alcohol but which include components that relate to alcohol use.

Stage 2: Identifying relevant studies
The first tier of our study involves identifying relevant academic literature that discuss policies which are relevant to our final search. In line with the iterative process of a scoping review, this will help set the search terms for the grey literature search for policy documents, using knowledge generated from the peer-review literature. For a description of the objectives and inclusion and exclusion criteria at each tier of the search, see Figure 1.

Electronic databases of peer-reviewed journals MEDLINE, PSYCInfo, Embase, Global Health and IndMed (database of peer reviewed medical journals published from India) were searched in August and September 2017. All search hits were downloaded to a bibliographic management software. Search terms used centred on the concepts of "alcohol, "policy" and "India". The "alcohol" concept was built around synonyms and types of alcohol (e.g. spirit, liquor, beer, illicit alcohol) and terms applying to drinking (e.g. drinker, alcohol consumption, social drinking, bars) and alcohol misuse (e.g. addiction, problematic alcohol use, alcohol dependence, drink driving). The "policy" concept was broad and included terms covering all dimensions of policy applicable to alcohol including marketing, sales, production, importation, trade, treatment, and synonyms for these terms (e.g. de-addiction, promotion, taxes, availability, minimum drinking age, prohibition, labelling, prevention, lobbying, industry and many others). The "India" concept included terms for India (e.g. Indian Union) and all of its states and union territories including historical state names. The search terms under these three concepts were used to search the databases mentioned above using a title/abstract/keyword search as well as a subject heading search where possible. The full search strategy can be found in Supplement 1.

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Stage 3: Study selection

Two reviewers (JS and AJ) will independently screen titles and abstracts resulting from the search process and exclude any ineligible studies. This process is on going at the time of protocol submission. The researchers will discuss their selection of articles after this first round of screening, to arrive at preliminary consensus on the list of eligible studies. They will then complete a full text screening of all selected articles, removing any articles that do not meet the inclusion criteria, as abstracts contain less detail than the full text. Reviewers will again discuss their selection of articles after this second round of screening, to arrive at a final consensus list of eligible studies. Differences in opinion will be resolved through consensus between the two reviewers with a third reviewer (AN) serving as arbiter in case of disagreement.

At both levels, the reviewers will use the following questions for guiding inclusion and must answer yes to all three questions to include an article: 1) Does this article discuss specific policies? 2) Does this article discuss specific policies relating to alcohol or alcohol's externalities? 3) Does this article discuss policy specific to India?

This systematic process will be reported using the PRISMA flow chart [24].

Stage 4: Charting the data

Data extraction forms will be created and used to chart relevant data from included studies. Two researchers (JS and AJ) will independently extract data. Data extraction will be compared after the first ten documents to check for consistency between the two researchers and allow for form revision, and then again, after data extraction from all documents. Data extraction at this stage will involve collecting knowledge about policy that will be used iteratively to find policy documents in Tier 2 of the search. Data to be charted may include but not be limited to title of publication, year of publication, policy name, policy description, implementing jurisdiction, and date/year of policy implementation.

Stage 5: Collating, summarizing and reporting results

Data from the academic search will be summarized into a list of policy names, a list of possible search terms and a list of potentially relevant citations to follow up. The research team will then discuss the list and make decisions for further iterative search processes of grey literature, government websites, and other strategies to find policy documents. For further analysis, the policies will be further mapped according to the World Health Organization's (WHO) Global Strategy to Reduce the Harmful Use of Alcohol, which includes 10 strategy areas across different policy sectors[25].

Further Iteration and Isolation of policies: Tier 2

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The peer-review tier of our search will help generate knowledge of the parameters in which to search the grey literature and government websites. Scanning of citations, isolating of policy names and descriptions, and knowledge gathering of relevant vocabulary will all be used to iteratively develop the strategies to isolate policies.

We will then consult with leading researchers and policy makers based on the collated data from Tier 1 of the search to gain insight and scrutiny of our next steps for searching the grey literature in order to ensure that we are not missing any important documents in Tier 2.

These policy documents will be the data to be included in Tier 2 with planned coverage in September-November 2018. Following an iterative approach, we will use the knowledge generated from Tier 1 in combination with researcher knowledge to help identify strategies for searching for policy documents. Possible strategies to subsequently identify and gather policy documents include the searching of grey literature through World Health Organization and World Bank websites and use of Google and/or Google Scholar. Google and English language websites of state and national Ministry websites, which are found to be relevant during our academic search, will be hand-searched for policies. As more knowledge is obtained through this process, we will continue to iteratively search through grey literature. Through these steps, we will aim to obtain the key policy documents that create the policy environment relating to alcohol-related societal harm.

Tier 2 data will then be charted using a data extraction form. This form will aim to gather data relating to policy name, department responsible, goal of policy, and other details, but will developed by the team after the iterative grey literature stage has been undertaken to ensure the chart is most useful. The developed data chart will be piloted on 5-10 policy documents to ensure its usefulness once developed and changes will be made accordingly.

Data from the charting of Tier 2 will be synthesized, summarized, discussed within the team and compared with what was originally found in the academic literature. We will analyse the data with a thematic analysis approach to present the themes that emerge from the policies present. This is in line with the scoping review approach, which aims to present an overview of a research area instead of appraise the quality of data [18 19]. Data will be further mapped according to the WHO Global Strategy. This will allow for global comparisons and identification of gaps in policy according to the recommendations of the WHO in the Global Strategy for best practices in reducing the harm of alcohol.

Stage 6: Consultation
We will consult with leading researchers and policy makers in India, on our consolidated list of policies and the thematic analysis and mapping of these policies to ensure that we have not missed any crucial policies in our search.
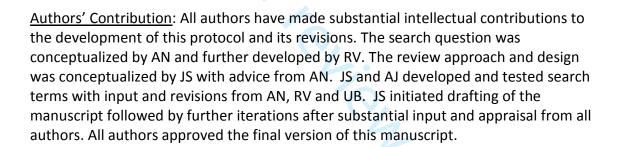
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Patients and Public Involvement: No patients are involved in this review.

ETHICS AND DISSEMINATION

As a review of journal articles, grey literature, and policy documents, this study will only utilize secondary material and therefore does not require ethical review.

The study was submitted for registration on PROSPERO, but investigators were informed that scoping studies are not in scope for registration. We will be circulating the methods used for this policy review to other policy researchers, particularly those researching in low resource settings, as we believe this method is helpful in navigating intersectorial policy spaces in low resource settings. We will publish our results in a peer-reviewed journal and on relevant forums such as online global health networks.

Authors' Contribution: All authors have made substantial intellectual contributions to the development of this protocol and its revisions. The search question was conceptualized by AN and further developed by RV. The review approach and design was conceptualized by JS with advice from AN. JS and AJ developed and tested search terms with input and revisions from AN, RV and UB. JS initiated drafting of the manuscript followed by further iterations after substantial input and appraisal from all authors. All authors approved the final version of this manuscript.

Competing interests statement: The authors declare no competing interests.

Ethics approval: This scoping study does not require ethics approval as it only uses secondary data.

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04/11/revised

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+six-year+outcome+of+alcohol+use+disorders+in+men%3A+A+population+based+study+from+India.&rft.aulast=Nadkarni (accessed May 01).

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Figure 1: 'Academic search tier' as it informs 'Policy search tier' including descriptions of the objective, inclusion and exclusion criteria of each

Tier 1: Academic Search

<u>Objective</u>: Identify relevant knowledge in academic literature to create parameters
and search terms for grey literature searching and website searching in Tier 2
<u>Included</u>: Any academic literature identified through discussed methods that
discusses Indian alcohol policy environment; no date limitation
<u>Excluded</u>: Non- English language texts

INFORMS

Tier 2: Policy Search

<u>Objective</u>: Identify policy document that describe the policy environment
surrounding alcohol in India, methods developed iteratively as described in
"Further Iteration and Isolation of Policies: Tier 2"
<u>Included</u>: Policy and grey literature documents as informed by academic search,
policy documents which are most up to date (i.e. those which replace an older law)
<u>Excluded</u>: Non-English language texts, obsolete policy documents (those which have
been replaced)

'Academic search tier' as it informs 'Policy search tier' including descriptions of the objective, inclusion and
exclusion criteria of each

215x148mm (300 x 300 DPI)

A scoping review of the policy environment impacting alcohol related societal harm in India

List of authors: Jaclyn Schess, Abhijeet Jambhale, Urvita Bhatia, Richard Velleman, Abhijit Nadkarni

Table 1: Inclusion and exclusion criteria for initial search

	Included	Excluded
Year	Any	
Language	English	
Population	Any	
Setting	India and any states or UTs of India	

Databases:

1) Medline
2) EMBASE
3) PsycINFO
4) Global Health

Table 2: Search concepts

Alcohol	Policy and alcohol related policy terms	India
Alcohol	Policy	India
Substance	Scheme	Individual Indian states
Addiction	De-addiction	
Drinking	Treatment	
Alcoholism	Plan	
Alcohol use disorder	Marketing	
Drink driving	Liberalization	
Liquor	Lobbying	

Blood Alcohol Content	Demand	
Beverage	Prevention	
Bar/Pub	Promotion	
Unhealthy commodity	Point of sale	
	Supply	
	Government	
	Ministry	
	Detoxification	
	Prohibition	
	Tax	
	Management	
	Regulation	
	Act	
	Program	
	Law	
	Legal	
	Legal drinking age	
	Dry Day	
	Constitution	
	Permit	
	Excise	
	Rules	
	Amendment	
	Bill	
	License	
	Section	
	Legislation	
	Advertising	
	Enforcement	

	Restriction	
	Trade	
	Importation	
	Illicit	
	Synthetic	
	Pricing	
	Limits	
	Open Container	
	Revenue	
	Industry	
	Agreement	
	Control	
	Treaty	
	Labeling	
	Reduction	
	Packaging	
	Distribution	

Data collection and analysis

Selection of studies and guidelines

Two reviewers will independently inspect the abstracts of the studies identified through the academic search strategy described below: two lists will then be composed of potentially eligible studies. The two reviewers will then discuss their selections and in the case of any disagreement regarding inclusion, a third reviewer will be consulted for a final decision.

Data extraction

Following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, a record will be made of the number of papers retrieved, the number of papers excluded and the reasons for their exclusion. A formal data

extraction form will be designed for the papers to extract data relevant to the study aims. Two reviewers will independently perform data collection and any disagreements will be discussed and resolved.

Medline Search Strategy:

1. Alcohol*.tw
2. Addict*.tw
3. (Drink* NOT water).tw **
4. Substance use*.tw
5. Substance abuse*.tw
6. Alcohol addict*.tw
7. Alcohol abuse*.tw
8. Alcohol dependen*.tw
9. "Alcohol use disorder".tw
10. Harmful drink*.tw
11. Hazardous drink*.tw
12. Social drink*.tw
13. Dr?nk ADJ2 driv*.tw
14. Liquor*.tw
15. Liqueur*.tw
16. Spirit*.tw
17. "Blood alcohol content".tw
18. BAC.tw
19. Beverage*.tw
20. Alcohol consum*.tw
21. "Problematic alcohol use".tw
22. Whiskey*.tw
23. Rum.tw
24. Beer*.tw
25. Wine*.tw
26. Vodka*.tw

27. Unhealthy commodit*.tw

28. Bars.tw

29. Pubs.tw

30. "Illicit alcohol".tw

31. "synthetic alcohol".tw

32. OR (1-31)

33. Alcohol/

34. Addict/

35. Drinker/

36. Alcohol addict/

37. Alcohol abuse/

38. Alcohol dependence/

39. "Alcohol use disorder"/

40. Harmful drinking/

41. Hazardous drinking/

42. Drink driving/

43. Drunk driving/

44. Liquor/

45. Spirit/

46. "Blood alcohol content"/

47. Beverage/

48. Whiskey/

49. Rum/

50. Beer/

51. Wine/

52. Vodka/

53. OR (33-52)

54. 32 or 53

55. Polic*.tw

56. Scheme*.tw

57. De?addiction.tw

58. Plan*.tw

59. Government ADJ3 Polic*.tw

60. Government ADJ3 Scheme*.tw

61. Government ADJ3 Plan*.tw

62. Market*.tw

63. Liberaliz*.tw

64. Neoliberalism.tw

65. Lobby*.tw

66. Demand*.tw

67. Prevent*.tw

68. Promot*.tw

69. Suppl*.tw

70. Government*.tw

71. Ministr*.tw

72. Program*.tw

73. Tax*.tw

74. Detoxification.tw

75. Prohibit*.tw

76. Manag*.tw

77. Avail*.tw

78. Access*.tw

79. Regulat*.tw

80. Act.tw

81. Acts.tw

82. Law*.tw

83. Legal*.tw

84. Drinking age.tw

85. Legal drinking age.tw

86. Minimum drinking age.tw

87. Underage drink*.tw

88. Constitution*.tw

89. Dry day*.tw

90. Licen?*.tw

91. On-licen?e*.tw

92. Off-licen?e*.tw

93. Sale licen?*.tw

94. Resale.tw

95. Wholesale*.tw

96. Retail*.tw

97. Sale*.tw

98. Sales outlet*.tw

99. Excise.tw

100. Rule*.tw

101. Amend*.tw

102. Bill*.tw

103. Permit*.tw

104. Manufactur* permit*.tw

105. Section*.tw

106. Legislat*.tw

107. Advertis*.tw

108. Advertising restrict*.tw

109. Surrogate advertis*.tw

110. Media restrict*.tw

111. Billboard*.tw

112. Sponsorship*.tw

113. Partnership*.tw

114. Enforc*.tw

115. Public place*.tw

116. Quantity restrict*.tw

117. Restrict*.tw

118. Time restrict*.tw

119. Age restrict*.tw

120. Location restrict*.tw

121. Sale restrict*.tw

122. Point of sale.tw

123. Trade.tw

124. Trade agreement*.tw

125. Treaty.tw or treaties.tw or treatise.tw

126. Free trade.tw

127. "World Trade Organization".tw

128. "International Monetary Fund".tw

129. Import*.tw

130. Export*.tw

131. Tarrif*.tw

132. Price*.tw

133. Price setting.tw

134. Subsid*.tw

135. Limit*.tw

136. Open container*.tw

137. Revenue*.tw

138. Industr*.tw

139. Agreement*.tw

140. Control*.tw

141. Packag*.tw

142. Label*.tw

143. Reduc*.tw

144. Distribut*.tw

145. OR (55-144)

146. Policy/

147. Scheme/

148. Plan/

149. Marketing/

150. Liberalization/

151. Lobbying/

152. Demand/

153. Prevention/

154. Promotion/

155. Supply/

156. Government/

157. Program/

158. Taxes/

159. Detoxification/

160. Prohibition/

161. Management/

162. Regulation/

163. Act/

164. Law/

165. Legal/

166. Drinking age/

167. Legal drinking age/

168. Constitution/

169. License/

170. Rule/

171. Amendment/

172. Bill/

173. Permit/

174. Section/

175. Legislation/

176. Advertisement/

177. Billboard/

178. Sponsorship/

179. Partnership/

180. Enforcement/

181. Restriction/

182. Age restriction/

183. Trade/

184. Trade agreement/

185. Free trade/

186. Treaty/

187. "World Trade Organization"/

188. "International Monetary Fund"/

189. Import/

190. Export/

191. Tariff/

192. Subsidy/

193. Revenue/

194. Industry/

195. Agreement/

196. Control/

197. Packaging/

198. Labeling/

199. Reduction/

200. Distribution/

201. OR (146-200)

202. 145 or 201

203. 54 AND 202

204. India* not American.tw

205. "Indian union".tw

206. OR (204-205)

207. Andaman and Nicobar Island*.tw

208. Andhra Pradesh.tw

209. Arunachal Pradesh.tw

210. Assam.tw

211. Bihar.tw

212. Dadra and Nagar Haveli.tw

213. Chhattisgarh.tw

214. Daman and Diu.tw

215. National Capital Territory of New Delhi.tw

216. Delhi.tw

217. Goa.tw

218. Gujarat.tw

219. Haryana.tw

220. Himachal Pradesh.tw

221. Jammu and Kashmir.tw

222. Janmu.tw

223. Kashmir.tw

224. Jharkhand.tw

225. Karnataka.tw

226. Mysore.tw

227. Kerala.tw

228. Travancore-Cochin.tw

229. Madhya Pradesh.tw

230. Madhya Bharat.tw

231. Maharashtra.tw

232. Manipur.tw

233. Meghalaya.tw

234. Mizoram.tw

235. Nagaland.tw

236. Odisha.tw

237. Orissa.tw

238. Punjab.tw

239. Chandigarh.tw

240. Rajasthan.tw

241. Sikkim.tw

242. Tamil Nadu.tw

243. Madras State.tw

244. Telangana.tw

245. Tripura.tw

246. Uttarakhand.tw

247. Uttaranchal.tw

248. Uttar Pradesh.tw

249.   United Provinces.tw

250.   West Bengal.tw

251.   Lakshadweep.tw

252.   P#d#cherry.tw

253.   OR (207-252)

254.   206 OR 253

255.   203 AND 254

For 'Medline' and 'Embase' databases, 'Text Word' and 'MeSH Subject Heading' were used in the indexing field.

For 'Psyc-info' and 'Global health' databases, 'Abstract' and 'Subject heading' were used correspondingly.

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item		Page
ADMINISTRATIVE INFORMATION				
Title:				
Identification	1a	Identify the report as a protocol of a systematic review	X	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	X	9
Authors:				
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	X	1,2
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	X	9
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A	N/A
Support:				
Sources	5a	Indicate sources of financial or other support for the review	X	10
Sponsor	5b	Provide name for the review funder and/or sponsor	N/A	N/A
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	X	10
INTRODUCTION				
Rationale	6	Describe the rationale for the review in the context of what is already known	X	4,5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	X	6
METHODS				
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	X	Figure 1
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	X	6-9
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be	X	Supp 1

Section and topic	#	Checklist item		
		repeated		
Study records:				
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	X	6
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	X	6
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	X	7,8
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	X	7
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	X	7
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	N/A	N/A
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	N/A	N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	N/A	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	X	8,9
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A	N/A

* It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.