





# BMJ Open Smoking cessation interventions and implementations in Japan: a study protocol for a scoping review and supplemental survey

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## ABSTRACT

**Introduction** Despite various tobacco control measures in Japan, smoking remains a leading cause of mortality. This manuscript outlines proposed methodology for scoping review that aims to describe the knowledge gaps for local-level smoking cessation interventions in Japan, their implementation barriers and facilitators, and the use of implementation strategies.

**Methods and analysis** A scoping review will be conducted using the updated guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses-extension for Scoping Reviews to systematically search peer-reviewed journal articles and grey literature to identify studies on smoking cessation interventions in Japan. The six-stage scoping review model will involve (1) identifying the research question; (2) identifying relevant studies; (3) selecting studies; (4) charting data; (5) collating, summarising and reporting the results; and (6) consultation exercise. Since there is little information available on the implementation context in the literature, we will use grey literature to identify organisations implementing smoking cessation interventions and conduct a cross-sectional survey among them to supplement the information gap. Based on a literature review, findings will be organised on smoking cessation interventions in local settings (ie, communities, workplaces, schools and hospitals) at the population, provider and individual levels in Japan to understand knowledge gaps. We will adopt the consolidated framework for implementation research to identify implementation barriers and facilitators, and the expert recommendations for implementing change to identify implementation strategies.

**Ethics and dissemination** This study does not require ethical committee approval. The scoping review method will be robust in searching available smoking cessation interventions in Japan. The findings of this study will be compiled as case studies of best practices on smoking cessation interventions and disseminated to relevant stakeholders at the public and private levels through publications, presentations in conferences and stakeholder meetings.

## INTRODUCTION

Smoking is the leading risk factor of mortality in Japan. The number of deaths caused by smoking annually is estimated to be 129 000,<sup>1</sup>

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study is designed to capture a comprehensive range of smoking cessation interventions in Japan. Implementation data lacking in the grey literature will be supplemented by questionnaire surveys.
- ⇒ A systematic summarisation of the study will identify the existing evidence and knowledge gaps for future studies focusing on the implementation of smoking cessation interventions in Japan.
- ⇒ This study will propose implementation strategies for effective and widely disseminated smoking cessation interventions in Japan.
- ⇒ The generalisability of the findings of this study may be limited, as it is restricted to Japan.

which is the highest among the leading risk factors of death from non-communicable diseases in Japan, while secondhand smoke accounts for 15 000 deaths per year.<sup>2</sup> Although the prevalence of smoking has been decreasing since 1995, the smoking prevalence among adult is 17% in 2019, high rate compared with those reported in other developed countries.<sup>3</sup> In particular, the prevalence among men in their 30s and 40s remains high, at approximately 30%–40%.<sup>4</sup> As smoking cessation reduces the risk of premature death and many adverse health effects, interventions to improve the health of smokers and prevent secondhand smoking should be promoted.

Evidence-based interventions (EBIs) for smoking cessation have been adopted globally over the past 50 years.<sup>5 6</sup> These include interventions at the individual level (eg, behavioural counselling, cessation medication, proactive quitline counselling and internet-based interventions), provider level (eg, clinical practice guidelines) and population level (eg, increase in cigarette price, comprehensive smoke-free policies and mass

media campaigns). Particularly, since 1990, smoking cessation interventions have expanded substantially in the USA and other tobacco control developed countries, along with population-level tobacco control measures that motivate smokers to quit.<sup>3</sup>

Japan lags behind other countries in tobacco control measures, including smoking cessation interventions. According to the MPOWER measures by WHO, Japan has improved its legislation since 2018 but has not reached the best-practice level in 2020, which is due to lack of advertising bans and limited application of smoke-free policy.<sup>3</sup> The Health Promotion Law was amended in 2018, and a smoke-free policy was applied to most private facilities, such as commercial facilities, restaurants and business offices; however, inside smoking was allowed if the facility set up a smoking room.<sup>7</sup> One of the reasons of the lag are considered due to the relationship between tobacco industry and government.<sup>8</sup> Japan Tobacco is the only tobacco manufacture in Japan, and its biggest shareholder is the Ministry of Finance<sup>9</sup> under the Tobacco Business Act, which was enacted to obtain a stable financial revenue from the tobacco industry.<sup>10</sup> While Japan has ratified the WHO Framework Convention on Tobacco Control (FCTC), there is no domestic tobacco control law, and Ministry of Finance also has jurisdiction over tobacco control, and therefore, has a contradictory structure.<sup>10</sup> Since taxation on tobacco has been one of the most important sources of the government income, and discussions of tobacco control policy tend to be controversial, leading to the delay in implementing it.<sup>8</sup> Regarding medical situation, smoking cessation treatment is provided under the universal health coverage in Japan, and people can receive the treatment by paying just 10%–30% of the treatment fee. However, less than 10% of smokers who had quit smoking used the treatment due to lack of treatment access (only 12% of medical facilities provide smoking cessation treatment), lack of media campaigns that promote smoking cessation and lack of a quitline system, including proactive quitline counselling.<sup>11</sup>

Implementation science aims to promote the uptake of EBIs into real-world practice.<sup>12</sup> Implementation science provides a systematised approach of identifying barriers and facilitators (context of implementation settings), implementation strategies (package of implementation interventions to address barriers in the context to lead the implementation success) and implementation outcomes (process outcomes of implementation, which indicates the implementation success).<sup>13</sup> There are some reviews on smoking cessation intervention focusing on implementation in hospital settings.<sup>14 15</sup> A study showed that hospital-based healthcare workers have perceived barriers in capability and motivations to provide smoking cessation interventions.<sup>16</sup> A systematic review on smoking-cessation implementation strategies at the hospital showed that staff training is the most studied object, and brief implementation approaches with a limited number of implementation strategies were less successful and

poorly sustained compared with resourceful multicomponent approaches.<sup>17</sup>

Non-hospital settings such as local communities or workplaces are also important as touchpoints for smokers.<sup>18</sup> Although there are several studies focusing on implementation at non-hospital settings,<sup>19 20</sup> few reviews have covered various settings for smoking cessation implementation. In a previous meta-analysis exploring the implementation of workplace-based policies and practices targeting behavioural risks, including tobacco use, only two out of the six included studies focused on tobacco-related interventions.<sup>21</sup> For the local community context, a systematic analysis reviewing the implementation of policies, practices and programmes in sporting organisations shows that no studies have targeted tobacco use.<sup>22</sup>

Our planned study will focus on local-level interventions because national-level interventions, such as mass media campaigns at national level, require different implementation strategies due to the scale and variety of stakeholders involved.<sup>23</sup> Similarly for policies, ‘public policy,’ that is, policies by heads of national government, parliaments and regulatory agencies (eg, reimbursed smoking cessation treatment), will be excluded as they are regarded to be national-level interventions and ‘organisational policy,’ namely, the policies of all organisations subordinate to public policy (eg, subsidies for smoking cessation treatment by municipalities), will be included as local-level interventions.<sup>24</sup>

Although Japan lags behind other countries in tobacco control measures especially in policy-making due to relationship between the tobacco industry and the government,<sup>8</sup> grassroots movements for tobacco control including smoking cessation support have been expanded, which has contributed to a drop in smoking prevalence in Japan.<sup>25 26</sup> Therefore, understanding local-level smoking cessation interventions, including communities, workplaces, schools and hospitals, is beneficial for accelerating smoking cessation in Japan, as well as in other countries where lags in national-level tobacco control exist due to strong tobacco industry interference, such as China.<sup>25</sup>

This manuscript outlines a proposed methodology for scoping review that aims to describe the knowledge gaps for local-level smoking cessation interventions in Japan, their implementation barriers and facilitators, and the use of implementation strategies. The results of this scoping review will inform a research agenda to address the knowledge gaps in Japan and applications of implementation science in smoking cessation interventions.

## METHODS AND ANALYSIS

### Methodology

The following two approaches will be used in a planned study: (1) a comprehensive scoping review of the primary and grey literature and (2) a supplemental survey of companies and organisations reported in the grey literature. In this review, using implementation science’s

definition, we define implementation as ‘the process of adopting and integrating an evidence-based practice of smoking cessation activities within specific settings’.<sup>12</sup> In our preliminary survey, we found that the ‘implementation’ of smoking cessation interventions at the local level are more likely to be reported in grey literature rather than in primary literature, but the information tends to be insufficient. Thus, we are planning to conduct a supplementary survey of the grey literature to capture more information on the implementation of smoking cessation interventions. The research period will be from April 2022 to March 2023.

### Scoping Review

The scoping review methodological framework described by Arksey and O'Malley<sup>27</sup> will be used. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) published by Tricco *et al*<sup>28</sup> as an extension of the PRISMA statement will be followed. This six-stage model includes: (1) identifying the research questions; (2) identifying relevant studies (search methods used); (3) selecting studies; (4) charting data; (5) collating, summarising and reporting the results and (6) consulting exercise.

### Identifying research questions

The research questions for the scoping review are as follows: (1) What kinds of smoking cessation interventions (eg, smoking cessation programmes, support, education and organisational policies) are provided in Japan? (2) What kind of implementation outcomes are evaluated? (3) What are the barriers and facilitators for the implementation of smoking cessation interventions? and (4) What are the implementation strategies to promote smoking cessation interventions?

### Identifying relevant studies

It is suggested that searches for scoping reviews should be as comprehensive as possible to identify all relevant studies. Therefore, grey literature, which stands for manifold document types produced at all levels of the government, academia, businesses and industries in print and electronic formats<sup>29</sup> will also be eligible. Grey literature with information on smoking cessation interventions will be eligible in this scoping review.

The search will cover studies published from April 1994, when the Japanese government approved the first medication for smoking cessation aids (nicotine gum)<sup>30</sup> until the end of September 2022. A variation of the following terms and medical subject headings will be used for each database—tobacco and smoking cessation or health promotion. A librarian will provide technical support in developing searching strategy. Searches will be performed for articles written in English and Japanese by two reviewers with scoping review knowledge. Researchers will translate the summarised results from Japanese articles into English, and conduct reverse translation to check the accuracy of meaning.

PubMed and CINAHL PsycINFO will be searched for peer-reviewed journal articles in English. Ichushi (a Japanese medical bibliographic database) will be searched for peer-reviewed journal articles in Japanese. Open Grey, which is a major grey literature database from Europe, will be searched first for grey literature in English and Japanese. Since we found only five reports on Japan in the Open Grey by preliminary search, we will use government reports from the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Economy, Trade and Industry (METI). MHLW is the ministry responsible for tobacco control measures, while METI is the ministry that promotes health and productivity management from an economic development perspective; both encourage companies to promote health at workplaces. In consultation with Japanese tobacco researchers, we searched all available government databases and selected the following reports on smoking cessation as grey literature: (1) Smoking and Health—Report of the Study Group on the Health Effects of Smoking by MHLW;<sup>31 32</sup> (2) MHLW grants system;<sup>33</sup> (3) case studies of the Smart Life Project Award by MHLW<sup>34</sup> (4) the case studies of Health & Productivity Stock Selection Programme and Certified Health & Productivity Management Outstanding Organisations Recognition Programme by METI.<sup>35</sup> The latter two reports from MHLW and METI provide short reports of the case studies of smoking cessation interventions at selected municipalities, organisations, and companies as best practices. In addition, those literatures have been reviewed by the Japanese government as a third party, and therefore, have credibility. The reference lists of all eligible studies for peer-reviewed journal articles in English will also be checked for comprehensive literature search, as suggested by PRISMA-ScR.<sup>28</sup> Details of the search methods have been provided in online supplemental appendix 1).

### Study selection

The review process will consist of two levels of screening: (1) title and abstract review and (2) full-text review. Bibliographic information will be downloaded using Reference Manager software. To ensure reliability between investigators, a training session will be conducted before screening, and the inclusion and exclusion criteria will be clarified, if necessary. In the first level of screening, two investigators will independently screen the titles and abstracts of all retrieved citations for inclusion against a set of predefined inclusion criteria. For the second level of screening, a pilot test will be conducted on a random sample of approximately 10% articles, and discrepancies will be discussed. Two investigators subsequently will screen the full texts of potentially relevant articles to determine the final inclusion articles. During both levels of screening, weekly online meetings/email-based discussions will be organised to discuss the progress and findings. An article over which the investigators have conflicts will be discussed at team meetings to reach a consensus. The systematic review approach recommended by Levac



*et al*<sup>36</sup> will be followed for selection of studies for scoping review to enhance the rigour of the review.

### Inclusion criteria

For studies to be included, they must meet the following criteria:

**Types of studies:** Any types of original studies (quantitative, qualitative or mixed methods) or reports studying smoking cessation interventions

**Population:** Studies of (1) adults aged 18 and above (including those who are pregnant or have some diseases) using any type of tobacco product or (2) health-care professionals or non-professionals who engage in cessation support for adult smokers in a community or hospital setting.

**Interventions:** Studies that describe an intervention (eg, smoking cessation treatment, programmes, support, education and organisational policies) through the following behavioural changes: (1) increase smoking cessation of target populations, (2) decrease smoking prevalence of target populations and (3) develop skill of individuals engaged in cessation support for adult smokers. Interventions for population will be included when those interventions are conducted at a local level, rather than national or prefectural level.

We will define EBIs for smoking cessation in accordance with the ‘sufficient’ interventions provided in the Surgeon General’s Report.<sup>37</sup> Furthermore, we will add ‘training and awareness programmes to health workers’ and ‘public awareness of tobacco consumption risks and benefits of tobacco cessation’ as EBIs from the WHO FCTC.<sup>38</sup> While we will not be limited to EBIs for research question 1, they will be used as inclusion criteria for research questions 2–4.

**Outcomes:** Any study that will measure influencing factors (facilitators and barriers), implementation strategies, implementation outcomes (ie, acceptability, appropriateness, adoption, cost, fidelity, penetration and sustainability<sup>39</sup>) for targeted tobacco control interventions, programmes and policies. While these outcomes will be applied to research questions 2–4, studies not including the above outcomes will be included to address research question 1.

### Exclusion criteria

Studies will be excluded if they have any of the following characteristics:

- ▶ Not primarily focused on tobacco control.
- ▶ Cover interventions that evaluate the efficacy of drugs.
- ▶ Insufficient information about the intervention (ie, the provider, target or setting of the interventions are unknown).
- ▶ Do not include original data (eg, expert opinions, editorials, commentaries, simulation studies, literature reviews).
- ▶ Focus on tobacco control policies at the national or prefecture level (eg, increasing the price of tobacco products, reimbursement policy of cessation aids,

pictorial health warnings, smoke-free policy or quit-line system at national or prefecture level).

- ▶ State interventions that cannot be classified (will be applied to research questions 2–4).

### Data charting

Standardised data collection forms will be created and used for research questions 1–4. Data will be abstracted by the first reviewer, followed by a validation of 10% review by the second reviewer. The abstracted information will include the following details: authors, publication year, country, objectives, characteristics of the study population and its size, study design, interventions (type of intervention, intervention component, provider, target populations, duration of intervention, control group, recruitment rate, retention rate and health outcomes), implementation strategies, factors influencing implementation (facilitators and barriers) and implementation outcomes. When data are available, the costs involved in smoking cessation interventions and their cost-effectiveness will also be evaluated.

### Collating, summarising and reporting the results

The results will be summarised in a tabular format, including the types of smoking cessation interventions conducted in Japan (table 1), to address research question 1. table 1 consists of intervention settings (communities, workplaces, schools and hospitals) and intervention components at two levels (public health and individual), based on the ‘sufficient’ interventions described in the Surgeon General’s Report.<sup>37</sup> Approach to populations has been defined as groups, areas, jurisdictions or institutions where changes to the social, physical, economic or legislative environment have been attempted to make them less conducive to smoking. On the other hand, approach to individuals has been defined as the voluntary involvement of individuals in interventions aiming to strengthen their capacity to quit smoking.<sup>40</sup> The trend of interventions will be summarised along with key milestones of tobacco control policies on smoking cessation support and treatment in Japan, such as over-the-counter introduction of nicotine gum in 2001, reimbursement of smoking cessation treatment combined with counselling for using nicotine patches in 2006, and reimbursement of Varenicline in 2008.<sup>30</sup> Furthermore, we will create a figure showing the number of papers or cases under each intervention categorised in table 1 by year and plotting the key milestones in the implementation of the tobacco policy. This figure is one of the outcomes of research question 1. To address research questions 2–4, the results will be summarised in a tabular format, showing the measured implementation outcomes categorised into implementation outcome framework,<sup>39</sup> relationship between smoking cessation interventions, implementation, and outcome. The consolidated framework for implementation research (CFIR) will be adopted to identify and summarise implementation barriers and facilitators,<sup>41</sup> as well as expert recommendations for implementing change (ERIC) for

**Table 1** Matrix of intervention components and settings

|   | Settings of interventions |            |         |           |
|---|---------------------------|------------|---------|-----------|
| Interventions components at two levels  | Communities               | Workplaces | Schools | Hospitals |
| 1. Public health interventions  |                           |            |         |           |
| Approach to providers:  |                           |            |         |           |
| Clinical practice guidelines  |                           |            |         |           |
| Quality and performance measures and payment reform                               |                           |            |         |           |
| Enhancing the technology of electronic health records                             |                           |            |         |           |
| Training or awareness programme to health workers                                 |                           |            |         |           |
| Approach to population:   |                           |            |         |           |
| Quitlines   |                           |            |         |           |
| Smoke-free policies   |                           |            |         |           |
| Mass media campaign   |                           |            |         |           |
| Tobacco control programmes  |                           |            |         |           |
| Public awareness about tobacco consumption risk and benefits of tobacco cessation |                           |            |         |           |
| 2. Individual interventions   |                           |            |         |           |
| Approach to individual adults:  |                           |            |         |           |
| Behavioural counselling and cessation medication                                  |                           |            |         |           |
| Proactive quitline counselling  |                           |            |         |           |
| Short text message services   |                           |            |         |           |
| Web or internet-based interventions   |                           |            |         |           |

Note: This matrix was modified using the list of evidence-based interventions in smoking cessation: A report of the Surgeon General.<sup>37</sup>

implementation strategies.<sup>42 43</sup> Summarising the evidence base, will help identify knowledge gaps in the current evidence base and also where new studies are needed.

### Consultation

The research team includes smoking cessation experts as research collaborators who will provide consultations at important milestones. The feedback from experts on the results will be integrated to indicate the available evidence and identify knowledge gaps that need to be addressed in future studies.

### Survey

As mentioned above, short reports of smoking cessation interventions at selected municipalities, organisations and companies are listed in the case studies of the Smart Life Project Award, the Health & Productivity Stock Selection Programme, and Certified Health & Productivity Management Outstanding Organisations Recognition Programme. However, we found that those reports have little information on implementation barriers, facilitators and strategies by preliminary research. Therefore, after we find the municipalities, organisations and companies conducting smoking cessation interventions by reviewing the case studies, we will conduct a cross-sectional survey among them to supplement the data. The questionnaires covering the four research questions listed above will be sent to health officers of the identified companies and organisations by mail, and respondents will answer

either online or on paper. Before finalisation, the questionnaires will be reviewed by 2–3 health officers implementing health promotion interventions in the company or organisations to confirm whether respondents could answer the questionnaires correctly. The responses will be categorised as facilitators and barriers aligned with CFIR, and implementation strategies aligned with ERIC. Following this, the survey results will be charted in the same standardised data collection forms of scoping review and summarised together with the scoping review results. We determined that a response rate of at least 30% would be appropriate based on the response rate of prior research on worksite health promotion or work style reform by the Tokyo Metropolitan Government and the Chamber of Commerce and Industry (10%–32%).<sup>44</sup>

### Patient and public involvement

No patient involved.

### ETHICS AND DISSEMINATION

All data for this project will be collected by searching online literature databases and websites, and a survey of workplaces and organisations. The approval of the Ethical Committee of the National Cancer Centre in Japan will not be required because the subject of the survey is the worksite or organisations, not an individual. The survey aims to ask the objective situation of the workplace or

organisation rather than subjective, and no personal information will be collected.

This study will identify knowledge gaps in clinical and implementation research in smoking cessation interventions in Japan and suggest areas of limited evidence for future research. The findings will be compiled as case studies of best practices on smoking cessation interventions and disseminated to relevant stakeholders at the public and private levels through publications, presentations in conferences and stakeholder meetings.

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