

C. Main Section of the proposal (not to exceed 10 pages):

1. Overall Goal & Objectives:

Background: Japan is rated very low in all parameters of assessment used in the MPOWER package of the WHO Framework Convention on Tobacco Control (FCTC-MPOWER), which indicates an obvious problem. For parameters related to FCTC Article 14, regarding smoking cessation support and smoking cessation treatment, Japan receives higher marks (3 out of 4) than for other parameters. It has been demonstrated that the use of smoking cessation treatment and smoking cessation aids increase the rate of success by 3 to 4 fold, compared to attempts to quit smoking by one's own strength without these supports. In Japan, however, these tools are less commonly used than in other countries and are used by less than 20% of those trying to quit smoking. To improve the smoking cessation rate, we need to guide smokers to medical smoking cessation programs in every environment.

In the meantime, a wide variety of new tobacco products with greater habit-forming attraction are being developed and sold in Japan, where tobacco products are not very strictly regulated. For instance, the world's first tobacco product with a menthol capsule and the world's first heat-not-burn tobacco product were launched in the Japan before any other markets. Moreover, health warning labels on tobacco products in Japan do not use a warning with an image or quit line information, both of which are the global standard. These factors may be related to the fact that only less than 30% of smokers in Japan wish to quit smoking, according to the national health and nutrition examination survey result. Smoking cessation support is provided by health care professionals, many of whom are non-smokers, representing a generation that is not aware of the attraction of tobacco products and marketing strategies of the tobacco industry.

While programs of smoking cessation outpatient clinics are gradually being developed, gaining popularity, and yielding some results in Japan, support opportunities that guide individuals wishing to quit smoking to smoking cessation outpatient clinics are limited. In addition to providing smoking cessation counseling and smoking cessation programs directly to smokers, we need to provide a targeted program to professionals engaged in health/medical care and social services (industrial health care, community medical care, and school health care among others) designed to raise their awareness of the need to guide smokers to smoking cessation programs at every possible opportunity throughout their lives, in order to increase the points of access to smoking cessation programs and to increase the number of individuals who successfully quit smoking.

Objective: to develop support programs designed for professionals in the field of health/medical care and social services to guide smokers to appropriate smoking cessation opportunities.

Target

- 1) Develop science-based support programs to be used by smoking cessation support personnel
- 2) Conduct training using the developed programs and assess the training

The support programs involve:

- Developing a science-based information booklet
- Developing and building an e-learning system
- Additionally, providing conventional-style classroom training

We will prepare trial versions of the above in the first year, and in the second year, we will implement the plan-do-check-act (PDCA) cycle to improve the content based on how the programs were run in the first year.

- 3) Increase smokers' participation in smoking cessation programs using these means and increase the number of those who successfully quit smoking.

2. Current Assessment of need in target area

According to the 2015 National Health and Nutrition Examination Survey, smoking prevalence rates in Japan are 31.4% among males and 8.3% among females, totaling 19.1% of the population. Following a decline due to a tobacco tax increase in 2010, smoking prevalence rates have leveled off for the past several years. Of those who habitually smoke, 27.9% desire to quit smoking (26.1% of male and 33.6% of female smokers). There has not been significant changes in the figure for either gender since 2007. Or rather, the ratio of those who desire to quit are declining slightly.

It has been demonstrated that the use of smoking cessation treatment and smoking cessation aids increase the rate of success by 3 to 4 fold, compared to attempts to quit smoking by one's own strength without these supports. In Japan, however, these tools are less commonly used than in other countries and are used by less than 20% of those trying to quit smoking. Many try to quit smoking only by their will, and often fail repeatedly. To improve the smoking cessation rate, we need to guide smokers in every environment to medical smoking cessation programs.

3. Target Audience:

In Japan, where smoking rates have gradually declined over a long period, few health and welfare workers are very knowledgeable about the characteristics of cigarettes and other tobacco and related products newly sold in Japan, such as electronic cigarettes and heat-not-burn tobacco products. As the tobacco industry launches new product groups after another that are more attractive and habit-forming, it is important to raise awareness of the characteristics of tobacco products and the current status of tobacco countermeasures based on international standards, and to inspire smokers to quit smoking and then, in right environments, guide smokers who desire to quit to outpatient clinics for smoking cessation.

Domestically, health centers and other organizations provide interpersonal health services within their community health activities, and, for workers, based on the Industrial Safety and Health Law, occupational health services are provided as part of industrial health services. For the former, the center that spearheads the development of human resources is our organization, the National Institute of Public Health, and for the latter, the university engaged in the development of human resources is the University of Occupational & Environmental Health, where Professor Yamato, our joint researcher, works. Both fields also have networks of academic associations.

In addition, it is important that a broad spectrum of health, medical and welfare workers, including schools nurses and pharmacists in hospitals and commercial drug stores, provide a wide range of smoking cessation support in all life stage environments. Among them, the industrial or occupational health field is a valid target for long-term health guidance, as many workers are virtually employed for their lifetime, even though a rise in employment mobility has been talked about.

Because community health, medical and welfare workers, industrial health personnel, school nurses, pharmacists and others who respond to the target population have limited opportunities to systematically learn about tobacco countermeasures, we will provide them with an opportunity to learn about the status quo and the need for tobacco countermeasures through e-learning. In addition, since it is difficult to build an instructor network with only e-learning, we will set up opportunities for collective training and train practitioners through group exercises and other activities.

Through professional networks (including mailing lists), we will share a first-year preliminary version or completed version of the teaching materials that we developed in an effort to expand its usage.

4. Project Design and Methods:

As described above in the organization description, the National Institute of Public Health provides various types of training programs. One such program is a short-term (five-day) opportunity to train professionals to develop a tobacco countermeasure plan. Based on a traditional classroom approach, this program can only train a limited number of people at a time. For a less specialized purpose of providing a support program to help guide smokers to smoking cessation programs at every possible opportunity in a health care and social service context, e-learning is a promising platform to offer greater convenience and reach a much larger number of trainees.

[1] Our implementation plan includes:

First year: development of science-based training programs

- 1) We will summarize scientific content that describes the actual status of and the need for global standard tobacco countermeasures according to the WHO Framework Convention on Tobacco Control (WHO-FCTC), learning from the experience of the above-mentioned short-term training sessions. This includes descriptions of tobacco's attractiveness, habit-forming characteristics and health impact, as well as features of some new tobacco products.
- 2) We will develop concise information materials to present this content.

Second year: implementation and improvement of the training programs

- 1) We will implement the training programs that we develop in the first year. We will also offer a more specialized training session in the conventional classroom structure to those who have completed the e-learning session.
- 2) We will obtain feedback of these activities and improve and update the contents.
- 3) We will offer improved training sessions and continue improving them based on the plan-do-check-act (PDCA) cycle.

As an example of training materials, in cooperation with Japan's leading experts in tobacco countermeasures and research (including all researchers of this project), we have published a feature article on tobacco countermeasures based on FCTC in a journal published by the National Institute of Public Health. (See next page for a specific content.) Much of this content is also shared in the above-mentioned short-term (five-day) training.

In distance learning or independent study, information in the form of an academic paper may be difficult to understand and deal with. Therefore, we will visualize basic teaching materials on

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tobacco countermeasures, including what was presented in the feature article, into a Power Point presentation and add brief explanatory notes in a handout to create teaching materials that are appropriate for independent study and can be conveniently reused by trained professionals to explain to people around them.

The page after next shows examples of these slides. With slides like these, synopses from the manuals provided in seminars will be added as notes. These slides, presented as one slide per page on both sides of the page, will be compiled as reference material and doubly serve as teaching material.

Naoki Kunugita (Ed), Topics: Effective implementation of the WHO Framework Convention on Tobacco Control in Japan. J. Natl. Inst. Public Health, 64(5): 2015.

<https://www.niph.go.jp/journal/data/64-5/j64-5.html>

- 1) T. TERAHARA: The Japanese Ministry of Health, Labour and Welfare's measures on tobacco control, Page 407-418
- 2) Y. MOCHIZUKI: Challenges of protecting public health policy from tobacco industry interference: implication of FCTC 5.3. Page 419-425
- 3) A. IGARASHI, T. FUKUDA, R. GOTO: Framework Convention on Tobacco Control Chapter 6 Health economic evaluation of tobacco-tax raising and economic burden of tobacco: Issues around tobacco tax raising and economic evaluation of anti-smoking policy. Page 426-432
- 4) H. YAMATO: Framework Convention on Tobacco Control, Article 8. Protection from exposure to tobacco. Page 433-447
- 5) Y. INABA, S. UCHIYAMA, K. BEKKI, N. KUNUGITA: Implementation of Articles 9 and 10 of the Framework Convention on Tobacco Control: Tobacco product regulation in Japan. Page 448-459
- 6) K. BEKKI, Y. INABA, S. UCHIYAMA, N. KUNUGITA: Framework Convention for Tobacco Control Article 11: International movement to use warning labels on the packaging and labeling of tobacco products. Page 460-468
- 7) T. SONE: Article 13 of the World Health Organization Framework Convention on Tobacco Control: Tobacco advertising, promotion, and sponsorship. Page 469-474
- 8) M. NAKAMURA: Article 14 of the World Health Organization Framework Convention on Tobacco Control: Demanding reduction measures concerning tobacco dependence and cessation. Page 475-483
- 9) K. SUZUKI: Effects of smoking among young women, including pregnant and child-rearing women. Page 484-494
- 10) T. HANIOKA, M. OJIMA: Tobacco control for oral health and oral diseases. Page 495-500
- 11) N. KUNUGITA, S. UCHIYAMA: K. BEKKI, Y. INABA: Public health concerns regarding novel tobacco products including smokeless tobacco and e-cigarettes. Page 501-510
- 12)

Current topics of novel tobacco products in Japan

Health Promotion Act
2003; chewing tobacco
"FireBreak"



2010: Health Director Notice; Passive smoking measures Tax rise
2010; smokeless tobacco
"Zero Style" Mint



2011; smokeless tobacco
"Zero Style" Bitter



2012; smokeless tobacco
"Zero Style"



Menthol cigarettes



E-Cigarette



2013; smokeless tobacco "SNUS"



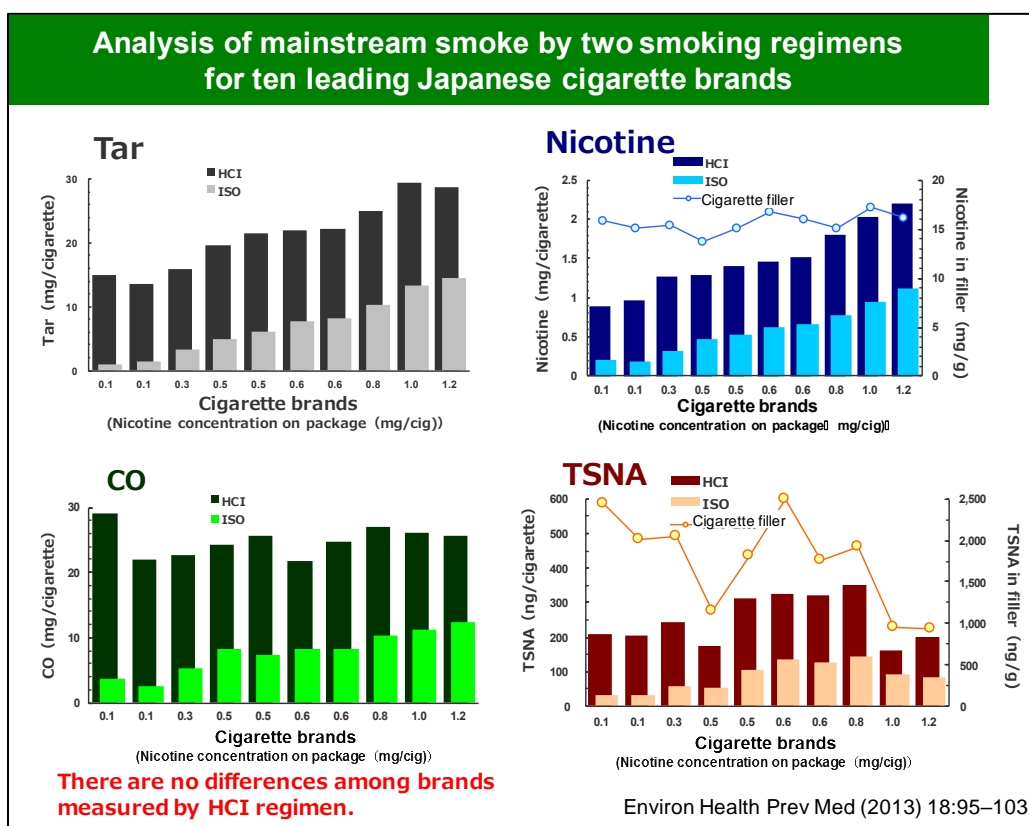
New type "heat not burn" electronic cigarettes

2014; IQOS (PMI)



2015; Ploom (JTI)





[2] These materials will also be published on our website as an e-learning resource.

The materials published on our website will be freely accessible for learning purposes following user registration, which includes both affiliation and contact information.

[3] Creation of video materials

As a complement to independent study of the aforementioned reference/teaching materials, video lectures based on the materials will be recorded and made available on our e-learning system.

The video contents provided will be for the study of the status quo and issues with tobacco countermeasures, based on the items discussed in the feature article of our journal mentioned in the page before the preceding page.

Because it is difficult for people to maintain concentration through a long video, a series of 15-to-20-minute movies with various contents will be created.

Public announcements to promote these videos will be sent through a tobacco countermeasures information mailing list of local government employees (registrants: 121 local governments, 2220+ individuals). The mailing list is maintained by Yamato, who will be responsible for the task.

For the industrial health service field, similar announcements will be made through academic associations and mailing lists of related individuals in private companies, physical examinations organizations, health insurance associations and so forth.

[4] Exercises, group activities, and networking through conventional classroom training

As e-learning alone may not be sufficient to develop backbone leaders who can guide people around them, we will create a group training program to offer to those interested, to complement the e-learning.

In this training program, priority is placed on practical exercises and group activities over knowledge provision. Another goal is to foster a network of trainees through the program.

We will implement the program based on our experience in running short-term training.

[5] Conducting a Web-based survey

In providing smoking cessation support to smokers, it is important to understand the actual status of the use of novel tobacco products sold in various ways and user opinions of them.

For example, electronic tobacco products containing nicotine is regulated by law in Japan and hence the growth of its usage is relatively limited. More specifically, based on our 2015 Web-based survey, 6.6 percent of adult respondents had used electronic tobacco products and 1.3 percent had used within 30 days prior to the survey.

On the other hand, the sales of heat-not-burn tobacco products that are electrically heated is quickly expanding, including the iQOS, marketed by Philip Morris International, which was rolled out in Japan successfully before the rest of the world. Other such products include PloomTECH, marketed by Japan Tobacco Inc., and Glo, marketed by British American Tobacco plc. A majority of those products sold in the world is consumed in Japan. Consequently, smoking patterns are rapidly changing in Japan: heat-not-burn tobacco product users account for more than 10% of all smokers. In light of these changes, we will conduct a web-based survey on the actual state of usage and users' opinions of those products to gain foundational information in providing smoking cessation support and other tobacco countermeasures. Because similar questions were asked when we conducted the aforementioned survey on electronic tobacco products, we will be able to track changes over the years. Some of the users of heat-not-burn tobacco products mistakenly believe that they have quit smoking as they have transitioned from cigarettes, and that is an important piece of information in providing smoking cessation support.

5. Evaluation Design

The following measures will be used to evaluate the outcome of the training:

- Number of people who complete our e-learning program
- Number of times that people access our web-based training material
- Number of classroom-type training sessions and number of people who complete the training (a total of three sessions are planned)

The class size of a five-day tobacco countermeasure training session offered by the National Institute of Public Health is about 20 people. E-learning is expected to train a far greater number of people at once.

(Ultimately, we hope to increase the traffic to smoking cessation outpatient clinics, but this is not used as an endpoint for the assessment of this project.)

The following is examined to assess its educational sustainability:

- Sharing about this activity at related academic societies
- Publicizing training materials that we develop on our website on a continual basis
- Building a supporters network

We will assess these parameters at the end of the first year, and implement the plan-do-check-act (PDCA) cycle to improve our course.

6. Detailed Workplan and Deliverables Schedule:

- 1) We will gather information and create a preliminary version of the textbook during the first half of the first year.
- 2) We will provide the preliminary version as e-learning material to a closed group to identify any issues.
- 3) Based on the result, we will develop a revised textbook and explanatory teaching video, and make them available on our website in the second half of the first year.
- 4) We will have the e-learning course assessed via survey, explore possible improvements and improve the material.
- 5) For these tasks, we will hold a study session for project participants every half year at the National Institute of Public Health.
- 6) In the second year, we will make available a training course using the textbook and e-learning material and hold three conventional classroom training sessions.
- 7) Based on the assessments of the above, we will publicize the final version of the material and print resource booklets.