Global Bridges Japan Full Proposal English Translation
Request ID: 3558023 (LOI#2)
Organization: Research Group of Building Capacity for Tobacco Dependence Treatment in Hokkaido
Project Title: Developing a smoking cessation training program for parents and obstetricians in Hokkaido

A. カバーページ

1. 題目

英文題目：

Developing a Smoking Cessation Training Program for Parents and Obstetricians in Hokkaido

和文題目：

北海道における産科医と連携した両親に対する禁煙プログラムの開発

Project ID:

35528023

研究グループ：

Research Group of Building Capacity for Tobacco Dependence Treatment in Hokkaido

C. Main Section of the Proposal

1. Overall Objectives and Goals

The first objective is to cultivate obstetricians and obstetrics medical staff (e.g., birthing assistants and registered nurses) in Hokkaido capable of providing cessation counseling and cessation treatment to expectant mothers and their partners when either party smokes. The second objective is to cooperate with obstetricians and medical staff (referred to below as the obstetrics team) in research. Obstetricians will assess the effectiveness of providing cessation counseling and cessation treatment to pregnant women or their partners who smoke.

2. Assessment of Current Rationale for this Target Area

The hosting of the 2020 Olympics and Paralympics in Tokyo has brought the world's attention to Japan's moves to prohibit exposing others to second hand smoke [1,2]. In 2015 the smoking rate in Hokkaido was higher than the national average at 32.6% among men and 15.6% among women [3], and

was especially high among women. A high prevalence of tobacco use is accompanied by a high prevalence of tobacco use among pregnant women, and also increases the prevalence of secondhand smoke at home and in the workplace. As a result, tobacco related diseases have a high morbidity and is a grave health concern; the need to implement tobacco control measures is certainly a high-priority public health issue [5]. In particular, smoking or passive smoking while pregnant affects more than just the mother's health; numerous studies report that these activities are a health risk to the fetus and the young child. Therefore, smoking or passive smoking while pregnant is one issue that should be dealt with as quickly as possible. The Japan Eco and Child Study from the Ministry of the Environment estimated that 5% of pregnant women smoked. The aforementioned study reported that women stopped smoking during the pregnancy [11], with other studies reporting that although women used pregnancy as an opportunity to quit smoking, many began smoking again a few years after having their babies [12]. These preceding reports show that continuing to be smoke free tends to be difficult if based solely on the individual's desire to quit.

The IKUMEN Campaign run by the Ministry of Health, Labor and Welfare is also having an effect; presently, municipalities are seeing more and more partners participating in parenting classes and maternity hospital visits [13]. Conceivably, many of these partners are thinking of their children. In other words, taking this opportunity to suggest a way to quit may be enough to prompt action toward quitting smoking. This may also be a great opportunity to create a potential mass of highly motivated quitters who are able to remain smoke free. Early-stage medical intervention is possible for partners by providing drug treatment. However, for mothers a medical intervention requires careful monitoring by her doctor especially since many drugs are banned for use during pregnancy or while nursing.

Currently, outpatient treatment through a nationally insured treatment clinic requires candidates to satisfy fixed criteria of having no less than five points assessed for nicotine dependence, and at thirty-five years or older having a Brinkman Index of no less than 200 [15]. Six hundred and fifty facilities currently provide nationally insured outpatient smoking cessation treatment [16]. However, treatment for tobacco dependence in Hokkaido is undeniably concentrated in Sapporo city, which is home to roughly one third, or 250 of the facilities [16]. Moreover, smoking cessation outpatient facilities are primarily located at large general hospitals and internist clinics, with only a few available in maternity and gynecology clinics [16]. Despite the ongoing reporting requirement, it is relatively easy to establish a smoking cessation outpatient clinic; therefore, the hope is that these services will be available at numerous general and specialist clinics in Hokkaido.

Given the forgoing, protecting the health of the smoker and the children is an urgent concern. Tackling smoking in the home would therefore be a highly effective means of addressing this

concern. During a woman's pregnancy the obstetrician and the obstetrics medical staff (i.e., the registered nurses and birthing assistants) build a trust relationship. A team can be created of the obstetrician and the cooperating medical staff and this team may provide cessation counseling and cessation treatment.

Note that the assessment of the current rationale for this project was based on data from the National Health and Nutrition Survey [17], a special investigative report on the management fees claims for nicotine dependence [18], FCTC Article 14 [19], the WHO Report [20], and e-Healthnet [21].

4. Target Audience

Five obstetricians and about twenty cooperating medical staff (birthing assistants and registered nurses). The target audience also includes pregnant women or their partners who smoke which would be about 50 people; this target audience would receive cessation counseling and cessation treatment. The possible target audience is calculated under the assumption that the smoking rate among pregnant women is 5% 11) and among men is 33% 3). Ten obstetricians were invited to the project; only around 50% of invitees are expected to participate. The obstetricians invited will select one or more medical staff (birthing assistants or registered nurses), and will form the team that will provide cessation treatment.

Pregnant women or their partners currently visiting an obstetrics department and who smoke will be the targets for cessation counseling and cessation treatment. Each of the obstetrics teams will be assigned about 10 study participants. It is predicted that roughly 70% to 80% of pregnant women or their partners who smoke would agree to participate in research since the patient and doctor should already have already built a relationship of trust. The project is anticipated to be successful and there should be no issues in recruiting obstetricians since the project leader, Professor Mori of the Sapporo Medical University Department of Public Health in the School of Medicine has a long experience cooperating with obstetricians for research.

The project will take part over two stages with obstetrician and medical staff (birthing assistants or registered nurses) also participating in the research to evaluate the effects of cessation counseling and cessation treatment on the pregnant women and their families. The obstetrics team will be offering its own research as a part of the project, and the project will include means of sharing results which should increase the motivation for these teams to implement a smoking cessation program.

Outpatient cessation therapy in Hokkaido Prefecture is primarily offered by internal medicine clinics and large general hospitals; only a few obstetricians are involved in this kind of care [16]. Providing evidence of the efficacy of smoking cessation treatment by obstetricians is likely to lead

to obstetricians opening outpatient cessation clinics. The obstetrics teams participating in the project will see the effects of the program first hand, and it is expected that these teams will lead the charge for creating outpatient cessation clinics.

Families expecting babies can also be offered outpatient cessation services for free. Creating a smoke free home would be of incredible benefit since not only the mother or father who smokes, but the children being born into the family can avoid exposure to secondhand smoke.

**Research Stage A:**

**Effects of cessation counseling and cessation treatment training program on obstetricians and medical staff (birthing assistants or nurses)**

Audience: Obstetricians and medical staff (birthing assistants or nurses) who undertake cessation counseling and cessation treatment

Research Participants: Project Team

Research Objectives; [sic] Provide a training program that serves to give obstetricians and medical staff (birthing assistants or nurses) the knowledge required to provide cessation counseling and cessation treatment.

The rate of use e.g., for the latest drug therapies, use efficiency, changes in number of outpatients, and the number of outpatient clinics being opened will be measured to demonstrate the effects of the training program.

**Research Stage B:**

**Effects of obstetrician and medical staff (birthing assistants or registered nurses) providing cessation counseling and cessation treatment to expectant mothers or their partners who are smokers.**

Audience: Pregnant women or their partners who are smokers

Research Participants: Obstetricians and medical staff who participated in Research A as a project team

Research Objective: Measure the effect on cessation by having the already trusted obstetrician and medical staff provide cessation counseling and cessation treatment to the pregnant women or their partners who smoke.

Fig. 1 Two-stage Research Concept

4. Project Plan and Methods

The project is designed as two stages of research (Fig. 1). Research Stage A is to determine the effects of a cessation counseling and cessation treatment training program on obstetricians and medical staff (birthing assistants or nurses); and Research Stage B is to determine the effects of obstetrician and medical staff (birthing assistants or registered nurses) providing cessation counseling and cessation treatment to expectant mothers or their partners who are smokers.

**A-1. Mr. Mitsuteru MORI, the principal investigator will recruit obstetricians in Hokkaido for Research Stage A and Research Stage B.**

**A-2. The obstetricians recruited, along with their cooperating medical staff (birthing assistants or registered nurses) will be required to form a team (obstetrics team) that will provide cessation counseling and cessation treatment. Obstetricians will be asked to select at least one medical staff.**

**A-3. Obstetrics teams will be asked to fill out a questionnaire survey prior to receiving cessation counseling and cessation treatment training. Obstetrics teams that join partway through the project will be asked to fill out a customized questionnaire.**

**A-4. Obstetrics teams will be asked to take a training program created by the research group; the training program includes the latest information on cessation counseling and cessation treatment. While the plan is to provide seminar-style training, those unable to attend will be able to subscribe to on-demand training by renting a DVD.**

**B-1. The obstetrics teams participating in Research Stage A will participate as research members**

in this stage. Each member will be given research funds; a portion of the research will be formalized; i.e., team cooperation, methods of assessing successful cessation treatment, and the minimum number of people under care. Beyond this, each obstetrics team will set its own research parameters. The teams may recruit current patients — pregnant women or their partners who smoke, however, the method of recruitment is entirely up to the obstetrics team.

B–2. The research group will conduct the training on cessation counseling and cessation treatment. The treatment methods will be entirely up to the obstetrics team with no involvement from the research group.

B–3. The principal investigator (Mr. Mori) has presented on the Smokefree Pass; the Smokefree Pass serves as one protocol for obstetricians and medical staff to share information, and obstetricians and medical staff are free to use or not use this protocol.

B–4. The target audience being treated by obstetricians for cessation in outpatient clinics will be surveyed. The protocol for this project will be to visit the clinic for twelve weeks; after this time patients are given a follow–up survey once a month between monthly checkups. The principal investigator (Mr. Mori)'s team will develop a questionnaire which will be the basis for the surveys conducted the obstetrician. Researchers are free to use additional questions. The treatment protocol will also be left up to the obstetrician.

B–5. Obstetrics team will individually calculate [sic] effectiveness and present findings at research meetings. The principal investigator (Mr. Mori) will take the opportunity to evaluate and review obstetrics teams on each of the areas stipulated in the research protocol: team cooperation, advantages, and points for improvement. The principal investigator will also share knowledge with the obstetrics teams.

A–5. Once Research Stage B ends, the obstetricians and medical staff will be surveyed and the survey used to assess the program. The survey will be used to assess the perceptions towards cessation counseling and cessation treatment, the likelihood of continuing the program, and increase or decrease in the number of medical staff involved in the program. Furthermore, the survey will assess transmission of information to other medical staff as well as the effectiveness of the spread of this information.

A–6. The project will end once the points for improving the program are determined and a new program is initiated.

Various ways will be devised for completing the research. The basis of this research requires that participants are presented with the latest training in opening an outpatient cessation clinic and in cessation counseling when providing the cessation counseling and cessation treatment training

program. Therefore, a workshop will be organized for obstetricians and medical staff on treatment methods and on opening an outpatient cessation clinic. Those not able to attend may receive training via DVD or other methods. The on-demand training materials developed from past research into outpatient cessation clinics [22-31] will be used as supplementary materials with the research group occasionally updating the materials with the latest findings. For instance, while drug therapies in particular have been shown as effective, there is are indications that obstetricians and medical staff are not aware of these therapies; therefore, the plan is to increase awareness of drug therapy at the workshop. It would be unreasonable expect that participants involved in research would also be able to open an outpatient cessation clinic. It is therefore anticipated that treatment will not be covered by the national health insurance.

Thus, the obstetrics teams will take part as researchers in Research Stage B to increase the teams' motivation to take on the project. Researchers will be given a share of the funding and be required to follow a uniform protocol regarding methods of investigation, minimum number of exams, and reporting; however, each of the obstetrics team are assigned investigation topics that the team can design. Therefore, participating in the project provides high degree of freedom. If the research is on track but has insufficient funds before it is complete, the principal investigator will take charge by providing additional funds or other ways of maintaining a high motivation for participating in the project.

This consideration will also be made when selecting the obstetricians that will participate in research. One central focus of this research is to also select obstetricians that are likely to open an outpatient clinic and continue with cessation counseling and treatment after the project ends. The program is also designed to ensure that participants can experience first hand the effects of cessation counseling without demanding the opening of clinics, etc. during the research phase. This will to cultivate obstetrics teams likely to open outpatient cessation clinics or continue cessation counseling and cessation treatment after the projects ends.

The research involved in this project was designed specifically for this application; and thus the research is original. Prior research in this topic has been conducted in Kanazawa, i.e., ″Helping Pregnant Women Quit Smoking″ (government policy) [32].

There are several free tools available: Pfizer's sugi-kinen.jp [22]; the anti-smoking standard (6th edition, published by the Smoke Free Policy Promotion Committee [26]; What We Can Do for Newborns published on the web by the Japan Society for Tobacco Control (cessation counseling materials) [28]; oral nicotine replacement supplements [22], nicotine replacement patches [23], smoking cessation pocketbook [24], smoking cessation guideline [25], [Providing] Guidance on Cessation during Health Consultations [27], Kumamoto No Smoke[sic] Forum [30], j-stop [sic: J-STOP] [31].

The basis for determining the probability of success of this research includes, for instance, domestic Smoke Free initiatives [1, 2, 32], public health initiatives for preventing exposure of mothers and children to secondhand smoke [4, 10, 12, 32], and moves of the National Diet toward deciding on a law banning exposing people to secondhand smoke.

5. Evaluation Design

To assess the effects of the project, Research Stage A will determine the effects of a cessation counseling and cessation treatment training program on obstetricians and medical staff (birthing assistants or nurses); and Research Stage B will determine the effects of obstetrician and medical staff (birthing assistants or registered nurses) providing cessation counseling and cessation treatment to expectant mothers or their partners who are smokers. Research Stage A will be used to measure and assess whether the extent to which the program led to the creation of outpatient cessation clinics. Research Stage B will be used to measure and assess the proportion of patients that continued to be smoke free.

The research may shift from expected outcomes depending on the level of motivation of the obstetrician involved in the project; therefore, the core of this research is to determine how to ensure a certain level of motivation among participating obstetricians. Obstetricians recruited for the project may not have a high level of motivation; this may be a barrier to the success of the project and in that case, obstetricians outside of Hokkaido will be recruited.

Given that the research period is two years, the project is scheduled to span from during pregnancy until the one-month old's first checkup. However, previous research reported that women start smoking again after the birth even on successfully quitting smoking during pregnancy; this suggests that follow up assessments will be essential in the future. Therefore, the follow-up investigation will not be conducted via mailed in personal statements; instead it will be necessary for follow-up or consultations to be conducted at child vaccinations, the 18-month checkup, the 3-year checkup, and pre-school enrollment checkup. Consequently, it will be necessary to cooperate with pediatricians, local municipalities, and public health centers, which will allow the project to spread.

6. Detailed Work Plan and Project Completion Scheduled

(1) Request participation from obstetricians in Hokkaido

January 2018 through June 2018

(2) Participating obstetricians and medical staff take the cessation counseling and cessation treatment training program

July through August 2018

(3) Participating medical staff (birthing assistants or registered nurses) takes the cessation counseling and cessation treatment training program

July through August 2018

(4) Obstetrics teams that have taken the training program will recruit pregnant women and their partners who smoke as study participants

September 2018 through June 2019

(5) Preparation period for obstetricians desiring to open an outpatient cessation clinic

January through August 2018

(6) Pregnant women or their partners who smoke visit the outpatient cessation clinic for a medical examination or checkup

September 2018 through September 2019

(7) Assessment and Reporting on Research Stages A and B

October 2019 through March 2020