Request ID: 35672599 (LOI#8)

Organization: The Research Institute of Tuberculosis, Japan Anti-Tuberculosis Association

Project Title: Expanding and Evaluating the Effectiveness of Smoking Cessation Support for

**Tuberculosis Patients** 

### A. Cover page

#### 1. Title

# 結核患者に対する禁煙支援計画の普及および効果測定

Expanding and Evaluating the Effectiveness of Smoking Cessation Support for Tuberculosis Patients

Project ID: 35672599

Main collaborator: The Research Institute of Tuberculosis, Japan Anti-tuberculosis

Association

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C. Main Section of the proposal

1. Overall Goal & Objectives

The objective of this project is to establish and fulfill the needs for smoking cessation support among tuberculosis patients in Japan. Despite warnings of the negative effects of smoking on infection, onset, treatment and prognosis of tuberculosis, and on the people nearby, tuberculosis control in Japan does not include a systematic approach to cessation support. Health care providers are often hesitant to give any advice regarding smoking despite carefully building a relationship with a patient one or more times per month to ensure compliance for anti-tuberculosis drugs. Therefore, this project aims to:

- motivate public health nurses responsible for advising tuberculosis patients to recognize the need for smoking cessation support;
- provide support for municipalities and public health nurses who include cessation support when their advising their tuberculosis patients (including persons with latent tuberculosis infection, LTBI) and thereby evaluate the rate at which cessation support is provided, and the cessation success rate after support was provided; and
- create a basis for proposing a new program of cessation support for tuberculosis patients.

To achieve the above-mentioned goals requires i) lectures on how to provide smoking cessation support to tuberculosis patients, and ii) practical support for the municipalities desiring to implement a cessation support program. This project will improve the skills of public health nurses and registered nurses involved in supporting tuberculosis patients in Japan, and will ensure that cessation support is adopted as a component in Japan's version of DOTS. Establishing cessation counseling as a part of advising tuberculosis patients should further perfect the support given to tuberculosis patients and reduce the incidence rate of and improve the prognosis for tuberculosis in Japan.

#### 2. Current Assessment of need in target area

[Dr. Toru] Mori reports<sup>1)-3)</sup> the results of investigating the pre- and post-treatment smoking habits of 1,366 smokers in 2010 and 2011; these smokers were newly registered tuberculosis patients at 28 public health centers in 11 prefectures in Japan. It became clear on comparing a sample of survey results from the general population that in 2010 there were more male and female smokers among tuberculosis patients in any age group. The age-adjusted smoking rate among men was 1.29 (95%CI 1.44 – 1.11), and among women was 1.57 (95%CI 1.89 – 1.14). Between the start and end of tuberculosis treatment 37% of the smokers quit, 14% cutback, and 49% exhibited no change in their smoking habits. It was found

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that forty-year-old heavy-smoking men with negative bacterium[TN: I am not quite sure this is right] who were poor (welfare recipients, contract or day laborers) were less likely to quit.

It is well known that smoking affects not only the onset but also the infections, and treatment and prognosis of tuberculosis; smoking also spreads the ills of tuberculosis to people nearby<sup>4-8)</sup>; however, smoking cessation support is not systematically applied to tuberculosis patients in Japan. In 1993 the World Health Organization (WHO) proposed a DOTS strategy that even today is included as an important part of patient compliance when advising tuberculosis patients. Japan also adopted the strategy; public health nurses from the public health center ensure a patient's compliance on the basis of Japan's version DOTS for the 6 to 9 months that the tuberculous patient is on anti-tuberculosis medication. Japan DOTS requires that the public health nurse confirms at least once a month that a patient is taking their medication, and so a patient must contact their public health nurse In 2010 the International Union Against Tuberculosis and Long Disease (IUATLD) created the Smoking cessation and Smokefree Environments for Tuberculosis Patients9),10) [sic]; this document proposed a structured and systematic DOTS program for effectively increasing cessation among tuberculosis patients. That is, the IUATLD program involves: (1) periodic meetings between the tuberculosis patient and the medical staff; (2) impressing on a patient with an onset of tuberculosis the need for behavioral change; and (3) garnering the family's support to help the patient quit under the assumption that tuberculosis control also includes support and cooperation of the patient's family.

A Japan Tuberculosis Patient Smoking Cessation Support Manual was proposed in 2014 based on the IUATLD program; public health centers in four municipalities in Japan<sup>11),12)</sup> then conducted trials based on the manual. Two hundred and fifty-one new tuberculosis patients were registered between July 2015 and March 2016, and forty-three of these patients were smokers. At the end of treatment two smokers quit smoking; however the smoking status of many of the other patients is unknown. While on the one hand, public health nurses providing support during the trial commented that "the smokefree manual made it easier to provide intervention", others commented that "it was overwhelming trying to explain treatment and DOTS, there wasn't even enough time to start discussing smoking cessation", and "it is a bit difficult get them to quit smoking on top of drug compliance". It is apparent that hesitancy on the part of the nurses made cessation intervention difficult. Although the Japan Tuberculosis Patient Smoking Cessation Support Manual<sup>13)</sup> was finally published based on the trials, it will be necessary to increase awareness and provide practical support for the public health nurse for practical use of the

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manual to progress. Moreover, Japan requires hospitalization of sputum smear positive tuberculosis patients; while the patients hospitalized for an average of two months tended to quit, many started smoking again after being discharged. Thus, after being discharged, the patient should continue to receive support from the nurse in charge during the patient's hospitalization.

## 3. Target Audience

i) Lectures on smoking cessation support for tuberculosis patients

The target audience is public health nurses (working at municipal public health centers) participating in training at the Research Institute of Tuberculosis, and registered nurses (working at hospitals). Trainings at the Research Institute of Tuberculosis gather roughly 500 municipal public health nurses and registered nurses working at medical facilities from all across Japan. The training comprises basic knowledge about tuberculosis through to specifics on how to support tuberculosis patients. However, in this case the training will include lectures on smoking cessation support as well as increasing recognition of the need to provide smoking cessation support for tuberculosis patients. The aim of the Japan Tuberculosis Patient Smoking Cessation Support Manual (2017) is for primarily public health nurses to support the patient; however, since sputum smear positive patients must also be hospitalized in Japan, follow up will be necessary after these patients are discharged. Therefore, it will be best to share the importance of smoking cessation support at trainings attended by both public health nurses and registered nurses.

ii) Practical support for municipalities desiring to implement a cessation support program

Interested municipalities will be recruited via snowball sampling. Training will be conducted for municipalities wishing to implement smoking cessation support for tuberculosis patients; currently about 20 of the 147 municipalities nationwide that have a public health center appear interested in training. After one year these municipalities should be able to provide cessation support for their tuberculosis patients. Smoking cessation support will be made available for all tuberculosis patients (and LTBI patients) registered in the municipality. The public health nurse responsible for tuberculosis support in the municipality will provide the support.

The Research Institute of Tuberculosis often receives requests from municipalities and the public health centers monitoring tuberculosis for advice and technical support. Consequently, using snowball sampling to find municipalities interested in the project should not be difficult.

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In 2016 there were 17,625 new tuberculosis patients beginning treatment. Assuming that 20 municipalities are willing to cooperate on the project means that on average roughly 2,400 tuberculosis patients will be registered in one year. Assuming that 400 of the 2,400 patients are smokers in need of cessation support, then a statistically sufficient sample of patients will be acquired.

The success of this project will lead to further expansion of smoking cessation support, and the results will be reported at trainings conducted by the Research Institute of Tuberculosis. This will allow for reporting and exchange among public health nurses actually involved in providing cessation support and lead to increasing the number of municipalities introducing cessation support.

### 4. Project Design and Methods

Prior to this project, a Japan Tuberculosis Patient Smoking Cessation Support Manual (Proposal) was created on the basis of the Smoking cessation and Smokefree Environments for Tuberculosis Patients9), 10) [sic](IUATLD, 2010); trials were conducted at 11 public health centers in four municipalities. The official Japan Tuberculosis Patient Smoking Cessation Support Manual<sup>13)</sup> was created based on these trials and published on the Research Institute of Tuberculosis Control Support Website (July 2017). The following i) and ii) will be implemented in this project using the Japan Tuberculosis Patient Smoking Cessation Support Manual<sup>13)</sup>.

i) Lectures on smoking cessation support for tuberculosis patients

The Research Institute of Tuberculosis will conduct training through a total of nine (9) courses for public health nurses and registered nurses for one year. These hour-long courses will train participating public health nurses and registered nurses on specific techniques for providing cessation support for tuberculosis patients on the basis of the Japan Tuberculosis Patient Smoking Cessation Support Manual<sup>13)</sup>. Trainees will be surveyed and the results of the survey assessed. The survey will ask for trainees' perceptions regarding the necessity of cessation support.

ii) Practical support for municipalities desiring to implement a cessation support program

Public health nurses in participating municipalities will continue to provide cessation support during the period they provide drug compliance support (DOTS). Each of these participating municipalities will be visited, and all public health nurses in the municipality responsible for tuberculosis control will be given training on providing smoking cessation support. Training will not only include specific methods for providing support but also share

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knowledge on reporting techniques. The departments responsible for coordinating tuberculosis control measures in the municipalities will be requested to collect data and provide reporting regarding the status of smoking cessation support in each of the public health centers, the cessation rates, and the like. The status of implementation in each of the municipalities will be confirmed, and a meeting of all the participating municipalities held twice per year at the Research Institute of Tuberculosis so that the participating municipalities may share information.

### 5. Evaluation Design

- Lectures on smoking cessation support for tuberculosis patients
  [Goals of Assessment]
  - For at least half the public health nurses supporting tuberculosis patients to recognize the need for smoking cessation support.

To make specific inquiries via a survey of trainees regarding why providing smoking cessation support is necessary.

ii) Practical support for municipalities desiring to implement a cessation support program

To evaluate the program via the number of occurrences of cessation counseling, the number of occurrences of continued support, and the results of cessation counseling.

• To evaluate the implementation rate for cessation support and the cessation success rates after implementation.

To create a "Smokefree card" for all tuberculosis patients registered in the participating municipality based on the Japan Tuberculosis Patient Smoking Cessation Support Manual. To describe the specifics of cessation support on the "Smokefree card" which can be referred to when dealing with the patient; i.e, based on the Smokefree ABCs, asking questions about smoking; giving brief advice about not smoking; and counseling on specific methods for cessation. The Japan Tuberculosis Patient Smoking Cessation Support Manual requires providing support for smoking cessation when tuberculosis treatment starts, in the second and fifth months of treatment, and at minimum four times after the patient's treatment ends. This project will assess whether cessation counseling takes place at these times. The cessation success rate will also be calculated from the patients' smoking status at the end of treatment. The smoking status and cessation rate will be calculated for tuberculosis patients registered in the previous year in the participating municipality, and compared to data collected after completion of this project.

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# 6. Detailed Workplan and Deliverable Schedule

Year	20	)18	}										2019											
Month	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
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