Request ID: 35681459 (LOI#40)

Organization: Researchers' Society of Certified Educators for Hypertension and CVD

Prevention and Control

Project Title: Development of Pragmatical Approach for Smoking Cessation on Admission -

for Every Inpatient, at Every Hospital-

C. Main Content of Proposal

1. Overall Goals and Objectives

This proposed project has the objective of developing and disseminating a smoking cessation support program tool, for all hospitalized patients before or at the time of hospitalization (hereinafter called "In-hospital Smoking Cessation Treatment Tool"), that has potential to be used in all domestic hospitals by being a versatile and continuous medium while also being systematic. The characteristic of this "In-hospital Smoking Cessation Treatment Tool" is that it will be incorporated into the hospitalization in-processing interview and orientation that is conducted on all patients at the time of booking or starting hospitalization.

Smoking is the biggest cause of non-communicable diseases in our country. Providing all smokers with smoking cessation support or the opportunity to do so is a central issue with the certified educators for hypertension and cerebro-cardiovascular disease prevention and control, some whom also have the qualification as a smoking cessation instructor. Improving individualized instruction by smoking cessation specialists is an important issue within promoting smoking cessation. In the past, many research topics or activities were geared towards training specialists or developing and fine-tuning individualized instruction programs. However, even with such efforts, it does not mean that there are smoking cessation specialists in all domestic medical institutions. Also, target smoking cessation support patients that specialists can interact with are limited to those who have referrals from their primary physician or patients who have the interest to receive support. Furthermore, if wanting to newly provide smoking cessation support, it is necessary to secure the human resources which is the biggest wall that is preventing smoking cessation treatment and provision of opportunity in general medical institutions. The "In-hospital Smoking Cessation Treatment Tool" to be developed by this application is to collaborate with the inprocessing orientation that is part of the daily tasks (including instructions on the hospital wing during hospitalization and the need for smoking cessation within the facility) as well as interviews (including evaluation of the smoking behavior of the patients) while advising smoking cessation clinics according to the needs and effects of smoking cessation matching the hospitalization purpose of the patients. With the development and dissemination of this "In-hospital Smoking Cessation Treatment Tool", it will be possible to provide smoking cessation support to all hospitalized patients in medical institutions lacking specialists, leading to the anticipation of contributing to quantitative dispersion and continuation of smoking cessation. The final objective of this proposal is to 1) expand the smoking cessation target population at the time of hospitalization, and 2) nationwide deployment of routine smoking cessation treatment.

2. Current Necessity Evaluation in the Target Areas

a Smoking is the biggest cause of non-communicable diseases in our nation, (1), (-3)

Request ID: 35681459 (LOI#40)

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Prevention and Control

Project Title: Development of Pragmatical Approach for Smoking Cessation on Admission -

for Every Inpatient, at Every Hospital-

and there is the need for smoking cessation support to be provided to all smokers. However, current smoking cessation clinic patients stem from strong suggestions of primary physicians or only self-determined patients seeking help, ^{4), 5)} while other smokers only are advised to stop smoking via posters and other visuals. They do not advocate the opportunity for smoking cessation to "each and every patient who is a smoker."

As hospitalized patients tend to feel uncertainty and fragility regarding their health, suggesting a revision of their smoking behavior at the time of hospitalization is thought to have more results than other times with less concern for their own health. 6, 7) Even with that, smoking cessation treatment rates towards patients are low. Smoking status evaluations are always done by nurses at the time of hospitalization, however, even only 20% of cancer specialist institutions discuss the importance of smoking cessation to currently smoking patients⁸⁾, leading to assume even lower numbers in general hospitals. Furthermore, int he past, there are cases that have been reported of smoking cessation specialists testing smoking cessation treatment to all hospitalized patients who are smokers⁹, however not all medical staff affiliated with domestic medical institutions have the specialized knowledge required for smoking cessation treatment and support. Not only is a large part of such undertakings due to the quality, will and power of the individual, but also it is not something that is easily deployable throughout the country due to the need of placing specialized and dedicated staff. Although training of staff who will be responsible for specialized smoking cessation treatment is important, 10), 11) in order to proved smoking cessation treatment and opportunities to do so 'whenever,' 'anywhere,' to 'whomever,' and 'forever,' it is imperative to have something that can be done within daily tasks or that can be incorporated into such tasks.

3. Target Audience

The following 3 points will be the main activities of the proposal with each having separate target audiences.

- ① Develop the "In-hospital Smoking Cessation Treatment Tool" and verify with cooperating medical institutions.
 - Definition of Target Audience and their Scale
 6-month intervention and evaluations will be conducted at medical
 institutions cooperating with the research that had more than 200 thousand
 extended hospitalization patience, and 13 thousand new hospitalizations.
 When excluding psychiatric patients, under aged patients, and people
 applicable to the excluded criteria, the target population during the
 intervention period is estimated to be around 4,000. If 10% of that
 population is to be current smokers, the number of hospitalized smokers

Request ID: 35681459 (LOI#40)

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Prevention and Control

Project Title: Development of Pragmatical Approach for Smoking Cessation on Admission -

for Every Inpatient, at Every Hospital-

during the research period is estimated to be 400-500. As smoking cessation support is always conducted during the in-processing orientation and interview, these 400-500 people are definitely going to receive the opportunity for smoking cessation.

Possibilities that can be Anticipated from the Target Audience

As hospitalization is an extraordinary event, it is easier to feel uncertainty and vulnerable about ones health. Thus, by suggesting revising smoking behavior at the time of hospitalization, it is expected to be more effective than when interest in ones health is low. ^{6), 7)}

• Benefits of and benefits from project outcomes, potential targets

After evaluating the effects of this tool, we will aim to disseminate it to all medical institutions nationwide as an information tool as part of our undertakings presented in this proposal. That is why all patients who are inhospital are thought to be the potential target that will directly benefit from our proposal.

The daily estimated hospitalized adults (20 years or older) is estimated to be 1.28 million. Although it spans all age ranges, the average length of stays is 33.3 days. ¹²⁾ From that, it is estimated that 2 million hospitalized patients participate in hospitalization orientations and interviews annually in Japan. From the research conducted by the representative of this application, it is clear that 14% of the patients are smokers at the time of hospitalization. In simple terms, it equates to approximately 280 thousand people being smokers, making them an extremely large potential target. Furthermore, if the "In-hospital Smoking Cessation Treatment Tool" that is synchronized with the orientation and interviewing can be applied to outpatient appointments as an "In-hospital Smoking Cessation Treatment Tool," even more smokers will be given an opportunity for smoking cessation.

- ② Conduct research on the number of people who wish to use the "In-hospital Smoking Cessation Treatment Tool" targeting all domestic medical institutions
 - Definition of Target Audience and their Scale

Based on the research done in 20015 on medical institutions, 7,416 general hospitals within the 8,480 hospitals nationwide (excluding 1,064 psychiatric hospitals) will be targets for our investigation. From the experience of past nation-wide hospital research regarding strokes, the response rate is expected to be 60-70% meaning that 4,500 - 5,000 hospitals should provide responses.

• Possibilities that can be Anticipated from the Target Audience

In addition to whether or not there is desire to use the "In-hospital Smoking Cessation Treatment Tool," research items plan to include the

Request ID: 35681459 (LOI#40)

Organization: Researchers' Society of Certified Educators for Hypertension and CVD

Prevention and Control

Project Title: Development of Pragmatical Approach for Smoking Cessation on Admission -

for Every Inpatient, at Every Hospital-

status of on-site smoking cessation acts and if or not there are smoking cessation clinics. Conducting the research itself is also anticipated to be a motivation accelerator for smoking cessation within medical institutions.

Benefits of and benefits from project outcomes, potential targets
 Based on the results form this investigation, medical institutions that show interest in using the "In-hospital Smoking Cessation Treatment Tool" will individually be instructed on download sites and usage, how to customize between each institution and thus provide information. These medical institutions will be able to directly reap the benefits of the results of our current research.

- 3 Dissemination activities for the "In-hospital Smoking Cessation Treatment Tool" by hosting workshops and symposiums through academic associations or related organizations.
 - Definition of Target Audience and their Scale
 - i. Hold a "Smoking Cessation Support Symposium of Certified Educators for Hypertension and Cerebro-cardiovascular Disease Prevention and Control (tentative)" regarding this proposal at the Japanese Society of Hypertension or the The Japanese Society of Cardiovascular Disease Prevention, targeting Certified Educators for Hypertension and Cerebro-cardiovascular Disease Prevention and Control nationwide (certification beginning in 2015, 169 people in 2017, expected to be 500-600 people by the time of the 2019 symposium.) Advocate for the implementation of the "In-hospital Smoking Cessation Treatment Tool" at associated medical institutions.
 - ii. Set up booths at the academic conferences of related institutions such as the Japan Society for Healthcare Administration (700 participants in 2016) and The Japan Academy of Nursing Administration and Policies (4,755 participants in 2017) to introduce the tool, explain how to use it and hold demonstrations. Such academic general meetings will have many managerial people such as head physicians, nursing directors and clerical supervisors who make decisions that will be participating. Thus, it will be possible to effectively provide information in order for the "In-hospital Smoking Cessation Treatment Tool" to disseminate.
 - iii. Hold workshops in major cities through nursing associations or university hospital nursing department managers liaison committees to introduce the tool and explain how to use it, make demonstrations, and advocate for implementation.

Request ID: 35681459 (LOI#40)

Organization: Researchers' Society of Certified Educators for Hypertension and CVD

Prevention and Control

Project Title: Development of Pragmatical Approach for Smoking Cessation on Admission -

for Every Inpatient, at Every Hospital-

• Possibilities that can be Anticipated from the Target Audience

Certified Educators for Hypertension and Cerebro-cardiovascular Disease Prevention and Control tend to conduct most of their work at medical institutions. As mid-sized medical institutions are also included, not just large-scale hospitals, it is possible to introduce the "In-hospital Smoking Cessation Treatment Tool" to a broader range of people. Also, participants of hospital or nursing management conferences tend to be in positions involved in undertakings of smoking behavior during hospitalization, not only from the health aspect of patients but also from the aspect of safety management, such as by being the person in charge such as hospital directors and hospitalization managers. Furthermore, by hosting workshops that go through nursing department manager liaison conferences and nursing associations, by appealing to such people, we can anticipate faster implementation of the "In-hospital Smoking Cessation Treatment Tool".

• Benefits of and benefits from project outcomes, potential targets

Approximately 70% of Certified Educators for Hypertension and Cerebro-cardiovascular Disease Prevention and Control are affiliated to medical institutions. Through these certified educators, advocating for implementation of the tool can mean that all patients who are smokers in each medical institution can benefit from smoking cessation treatment if smoking cessation support is incorporated into daily operations. Also, the "In-hospital Smoking Cessation Treatment Tool" that will be developed as the application item is possible to be used for instruction and support to improve lifestyle choices that include smoking, while also reducing the time of nurses by gathering information from patients that normally nurses had to gather from hospitalization orientations and interviews, now as electronic information. This can also be considered a benefit from the results of this proposed matter.

4. Project Design and Methodology

This application plans to 1) develop the "In-hospital Smoking Cessation Treatment Tool" and verify it at cooperating medical institutions, 2) investigate usage interest at medical institutions nationwide, and 3) dissemination through workshops and symposiums at conferences of instructors for preventive medicine for hypertension / cardiovascular disease. Also, as the "In-hospital Smoking Cessation Treatment Tool" will be continue to be provided for free to medical institutions, 4) the plan is to register the "In-hospital Smoking Cessation Treatment Tool" as an iOS App and publish the download site for it on related association and university homepages.

1 -1 Develop the "In-hospital smoking cessation treatment tool"

The "In-hospital Smoking Cessation Treatment Tool" that will be used as smoking cessation support including information on smoking cessation clinics and motivation

Request ID: 35681459 (LOI#40)

Organization: Researchers' Society of Certified Educators for Hypertension and CVD

Prevention and Control

Project Title: Development of Pragmatical Approach for Smoking Cessation on Admission -

for Every Inpatient, at Every Hospital-

of smoking cessation for all hospitalized patients, development is to happen utilizing the following background.

- i. Depending on the concern items inquired upon scheduling hospitalization or when in-processing, the smoking behavior of all hospitalized patients will be easily ascertainable.
- ii. During hospitalization orientation, patients will receive instructions on smoking cessation in the facility during their stay not only from the standpoint of health issues for the patients but also from the point of medical safety.
- Purposes for and departments where patients will be seen during hospitalization when making the appointment or when in-processing at the hospital.

As such, the "In-hospital Smoking Cessation Treatment Tool" that is connected to the hospitalization orientation and interviews, 1) evaluation of smoking behavior of all hospitalized patients and their identification, 2) motivation corresponding to their purpose of hospitalization, 3) emphasis on the need of smoking cessation will be done, and insured medical examinations to introduce smoking cessation clinics, smoking cessation instructors and nurses, and consultation will be provided in succession in order to introduce the smoking cessation program. In order to evaluate this tool, the following verification of effects of the "In-hospital Smoking Cessation Treatment Tool" at participating medical institutions will be done.

Also, the "In-hospital Smoking Cessation Treatment Tool" that was developed as part of this application will be provided to desiring medical institutions indicating their interest during the national hospital survey, and of course institutions that showed interest during various workshops and symposiums, free of cost even after operations are completed by being published on the websites of related academic associations as an iOS App.

本システムの要件

入院予約患者様に対して入院案内・オリエンテーションおよび問診聴取を行う際に、喫煙者への禁煙支援として、本禁煙支援ツールを用います。

タブレットを使い、入院目的に応じた禁煙の重要性・必要性、禁煙の効果、禁煙 外来の流れ等について情報提供を行い、禁煙支援の充足を目指します。

また、禁煙支援を必要としている患者様(ニーズ)を把握し、禁煙外来の受診へと 結びつけるための契機とすることを目的としています。

- 1. アンケートをiPadで入力して、プリンターで出力する
- 2. アンケートで取得したデータをパソコンに保存する
- 3. 設問(喫煙)に応じて表示内容を変えて禁煙支援の表示をする
- 4. 入院案内を表示する(敷地内禁煙等)

Diagram 1: Criteria for developing the iOS application for the "In-hospital Smoking Cessation Treatment Tool" (Provided by 3ACE, partially modified)

Request ID: 35681459 (LOI#40)

Organization: Researchers' Society of Certified Educators for Hypertension and CVD

Prevention and Control

Project Title: Development of Pragmatical Approach for Smoking Cessation on Admission -

for Every Inpatient, at Every Hospital-



Diagram 2: Overall Systems Operation Diagram

① -2 Effect validation of "In-hospital Smoking Cessation Treatment Tool" by cooperating medical institutions.

After developing the above "In-hospital Smoking Cessation Treatment Tool" and using it for 6 months at participating medical institutions, evaluations of indexes of smoking cessation clinics outpatients and people interested in smoking cessation treatment will be made, where upon any operational issues will be revisited.

During the interviews conducted until now, even if smoking behavior evaluations are conducted and current smokers are identified, they are only given instructions on on-site smoking cessation and it does not lead to smoking cessation treatment or support. By implementing and operating the "In-hospital Smoking Cessation Treatment Tool," patients who have been identified as "current smokers" will be given motivational assessments and information on smoking cessation treatment based on their reasoning for hospitalization. Those who wish to do so are able to make smoking cessation treatment appointments on the spot (or opt for smoking cessation nursing consultations).

Request ID: 35681459 (LOI#40)

Organization: Researchers' Society of Certified Educators for Hypertension and CVD

Prevention and Control

Project Title: Development of Pragmatical Approach for Smoking Cessation on Admission -

for Every Inpatient, at Every Hospital-

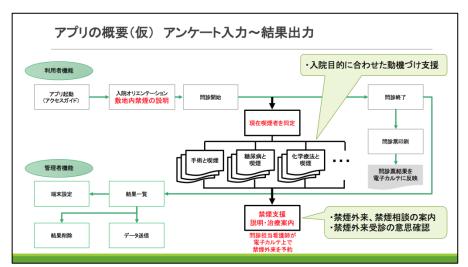


Diagram 3: Overview of "Smoking Cessation Treatment Tool" (Idea) (Provided by 3ACE, partially modified)

As such, if considering only the aspect of smoking cessation treatment, it can be considered to be a more systematic and effective undertaking than the traditional stand-alone interview process. However, as it is an interview input using the iPad application, the ease of use evaluation of the App itself, and the input support that elderly and those with poor vision and paralysis will require some further investigation. This aspect is considered very important in terms of deploying to other medical institutions.

2 Investigate the interest in using the "Smoking Cessation Treatment Tool" at all medical institutions nationwide.

Of the 8, 480 hospitals nationwide, 7,416 general hospitals (2015 Medical Institution Survey) excluding the 1,064 psychiatric hospitals will be used as the target for investigating interest in implementing the "In-hospital Smoking Cessation Treatment Tool".

From the past research done by the applicants, the response rate from all domestic hospitals is estimated to be 60-70% meaning that responses should be received from 4,500-5,000 hospitals. When conducting the investigation, the instruction document of the "In-hospital Smoking Cessation Treatment Tool" will be included, and replies will be requested regarding the following: As it is a large-scale investigation, entering the survey results will be outsourced in order to conduct speedy analysis.

- If or not there is on-site smoking cessation
- If or not there are smoking cessation clinics
- If or not there are smoking cessation treatment specialists at own facilities
- If or not there is interest in using the "In-hospital Smoking Cessation Treatment Tool" etc.

Request ID: 35681459 (LOI#40)

Organization: Researchers' Society of Certified Educators for Hypertension and CVD

Prevention and Control

Project Title: Development of Pragmatical Approach for Smoking Cessation on Admission -

for Every Inpatient, at Every Hospital-

3 Prepare for the web publication of the "In-hospital Smoking Cessation Treatment Tool" iOS App, promotion activities at workshops, etc. through academic associations and related institutions, especially surrounding the Certified Educators for Hypertension and Cerebro-cardiovascular Disease Prevention and Control.

i. Publish as an academic achievement

Academic associations (Japan Society for Healthcare Administration, The Japan Academy of Nursing Administration and Policies, Japanese Nursing Association are expected) and such places where head physicians, nursing directors who are those that make decisions on examinations within the hospitals tend to attend, and associations that focus on prevention and management of smoking related diseases will be at the center of out published results, indicating the importance of the "In-hospital Smoking Cessation Treatment Tool" as a form of evidence-based smoking cessation treatment.

ii. Certified Educators for Hypertension and Cerebro-cardiovascular Disease Prevention and Control Symposium

As part of the dissemination effort of the "In-hospital Smoking Cessation Treatment Tool" using the network of Certified Educators for Hypertension and Cerebro-cardiovascular Disease Prevention and Control who are affiliated to multiple medical institutions including small to mid-scale hospitals nationwide, the certifying association of the Certified Educators for Hypertension and Cerebro-cardiovascular Disease Prevention and Control, the Japanese Society of Hypertension, and The Japanese Society of Cardiovascular Disease Prevention, will develop, operate, and host a symposium about the effects that can be anticipated form the tool in order to advocate for the implementation of the tool at institutions in order to promote smoking cessation treatment.

iii. Set up a demonstration booth of the "In-hospital Smoking Cessation Treatment Tool" at related academic society conferences.

Booths will be applied for during academic association conferences listed in i and ii, explanation on the "In-hospital Smoking Cessation Treatment Tool" will be given, implementation will be advocated by conducting demonstrations on how to customize the tool per institution, and also on how to share information with electronic medical records and how to set them up.

iv. Hold a nationwide workshop

Selecting major cities throughout the nation (Tokyo, Osaka, Nagoya, Fukuoka) as locations, participants from neighboring prefectures will be gathered via nursing associations and university hospital nursing department managers liaison committees. Explanation on how to use the "In-hospital Smoking Cessation Treatment Tool" will be given,

Request ID: 35681459 (LOI#40)

Organization: Researchers' Society of Certified Educators for Hypertension and CVD

Prevention and Control

Project Title: Development of Pragmatical Approach for Smoking Cessation on Admission -

for Every Inpatient, at Every Hospital-

demonstrations, how to customize by each medical institutions, and how to link information with electronic medical records will also be provided.

4) Publish the iOS App for "In-hospital Smoking Cessation Treatment Tool" on the web.

In order for permanent and continuous publication and provision of the tool after the operations are complete, the "In-hospital Smoking Cessation Treatment Tool" will be registered as an iOS App and be added to the accrediting association for Certified Educators for Hypertension and Cerebro-cardiovascular Disease Prevention and Control and Shiga University of Medical Science and related organization webpages along with information and downloading options.

Evaluation Design

1) Develop the "In-hospital Smoking Cessation Treatment Tool" and verify the effects with participating medical institutions.

Main Evaluation Index: Ratio of smoking cessation clinic outpatients and those who desire smoking cessation treatment

Analysis Method: Calculate the current smokers who are hospitalized during the research period as the denominator, and evaluate the difference between the above-mentioned main evaluation index of the nonoperational period (12 months prior to commencing operation of the tool). At the current stage, it is estimated that 20% of the 500-600 target population desire smoking cessation treatment, potentially increasing by 7-8 times compare to last year's newly established smoking cessation clinic outpatients. Furthermore, differences in ratio based on hospitalization purposes will be considered as part of a subordinate analysis.

- 2 Investigate the interest in using the "In-hospital Smoking Cessation Treatment Tool" at all medical institutions nationwide.
- 3 Main Evaluation Index: Count of people wishing to use the "In-hospital Smoking Cessation Treatment Tool"

Secondary Evaluation Index: Number of medical institutions that have smoking cessation clinics, numbers of medical institutions that have smoking cessation treatment specialists

Analysis Method: Consider the difference between the main and secondary evaluation indexes based on the information provided by the medical institutions about the scale of their facility and neighborhood.

4 Promotion activities at workshops, etc. through academic associations and related institutions, especially surrounding the Certified Educators for Hypertension and

Request ID: 35681459 (LOI#40)

Organization: Researchers' Society of Certified Educators for Hypertension and CVD

Prevention and Control

Project Title: Development of Pragmatical Approach for Smoking Cessation on Admission – for Every Inpatient, at Every Hospital–

Cerebro-cardiovascular Disease Prevention and Control.

Main Evaluation Index Participant count at symposiums and workshops

During the last month of the operation year, comprehensive evaluations of activities 1)-3) will be made according to each index.

- 6. Detailed Task Plan and Completion Schedule for Deliverables
 - ① -1 Development of the "In-hospital Smoking Cessation Treatment Tool"(Outsource)

January - March 2018: Consider and decide the content and specifications

- Consider contents and algorithms according to nurses, public health notices, smoking cessation instructors, smoking cessation specialists, as well as pharmacists and dietitians involved in smoking cessation support.
- In order to operate it outside of medical institutions cooperating in the research, advice will be sought from joint researchers who are medical information specialists for processing such information so that the tool will correspond to the implementation standards and types of medical health records used in medical institutions.
- Multiple parties will receive the outline at the same time so that suggestions regarding the application can be made.

April-May 2018: Bidding, deciding on contractor

June-July 2018: Design and develop the program (Outsource)

August 2018: Dry-run within medical institutions cooperating in the research

September 2018: Final adjustments (Outsource)

April-May 2019: Brush-up after 6 months of usage

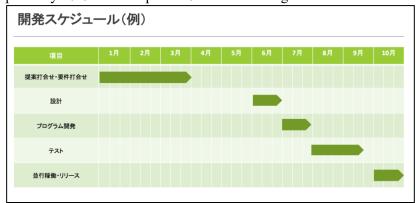


Diagram 4: Development schedule (idea) of the "In-hospital Smoking Cessation Treatment Tool" (Provided by 3ACE, partially modified)

① -2 Effect validation of "In-hospital Smoking Cessation Treatment Tool" by cooperating medical institutions.

July-September 2018: Apply for ethics review in order to have the "in-hospital smoking cessation treatment commencement tool" evaluated

Request ID: 35681459 (LOI#40)

Organization: Researchers' Society of Certified Educators for Hypertension and CVD

Prevention and Control

Project Title: Development of Pragmatical Approach for Smoking Cessation on Admission – for Every Inpatient, at Every Hospital–

scientifically

September 2018 (After the Ethics Evaluation): collect information regarding the pre and post adjustments regarding operation of the "in-hospital smoking cessation treatment commencement tool" as well as the rate of smoking cessation outpatients when not in operation.

October 2018-March 2019: Operation of the "In-hospital Smoking Cessation Treatment Tool" at cooperating medical institutions as well as followup research.

April-May 2019: Analysis and brush-up of tools.

② Investigate the interest in using the "In-hospital Smoking Cessation Treatment Tool" at all medical institutions nationwide.

March 2019: Create a list of target medical institutions as well as decide on the investigation items.

April-May 2019: Print the surveys and prepare to mail them.

June-August 2019: Investigate the desire for all domestic medical institutions (approximately 2,400 hospitals and clinics) to provide the program.

September 2019: Input data and analyze

October 2019-: Distribute to medical institutions interested in using the"In-hospital Smoking Cessation Treatment Tool"

- 3 Promotion activities at workshops, etc. through academic associations and related institutions, especially surrounding the Certified Educators for Hypertension and Cerebro-cardiovascular Disease Prevention and Control.
- April-July 2019: Invite lecturers and decide on operations workshops for the "Inhospital Smoking Cessation Treatment Tool"
- July-November 2019: Hold workshops on operating the "In-hospital Smoking Cessation Treatment Tool"
- June-December 2019: Promotion activities and exchange of information by the booth setup team; publish results at academic associations, and hold a symposium
- 4 Publish the "In-hospital Smoking Cessation Treatment Tool" iOS App in the web August-December 2019: Prepare to publish to the website November-December 2019: Publish to the website, create report.