The First HGPI Dementia Policy Project Roundtable Discussion on "Establishing a Multi-Stakeholder Public-Private Partnership in the Field of Dementia – Driving Parallel Progress on an Inclusive Society and in R&D" (August 31, 2022)
Event report

■Date and time: Wednesday, August 31, 2022; from 10:00-12:00

■Format: Zoom webinar

■Roundtable discussion members (titles omitted; in Japanese syllabary order)

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■Observers (titles omitted; in Japanese syllabary order)

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Minutes

Discussion point 1: Policy trends in and the future of dementia R&D

Expectations and future discussion points for innovation in the field of dementia

Expectations for the development of Disease Modifying Therapies (DMTs)

- While early detection and treatment are important, they are meaningless if they do not create happiness for the public. This is why it is important to develop and disseminate precision medicine. If no cures are available, it means patients, their families, and other affected parties must face hopeless situations, even when diseases are detected early. While developing early detection methods, it is important to also develop new pharmaceuticals and medical devices and to utilize Information and Communication Technology (ICT).
- There are merits and demerits to pharmacotherapy, so it is urgent that research for identifying the "right dose, right timing, and right patient" is conducted.

Expectations toward innovations that will help address challenges in communities

- A major issue outside of major metropolitan areas is the question of how to handle driver's licenses for people with dementia. There is little public transportation in such regions, so we are working with the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) to find ways to address this issue.
- While focusing on issues like a declining birthrate and aging population, or the concentration of people in major metropolitan areas, collaborative initiatives uniting industry, Government, academia, and community members must be operated efficiently as systems. There are various issues faced by rural areas which are not present in cities. We must recognize those issues and create a society that is friendly to people with dementia and their families, even if they do not live in cities.

Challenges and required actions for implementing the use of DMTs and biomarkers in society

Creating systems that can make adequate use of innovation

- Health policies and institutional initiatives for helping DMTs function within the diagnostic process in real-world healthcare settings and within the Integrated Community Care System are also urgent issues. Comprehensive, innovative discussions must be held to accelerate biomarker utilization in clinical settings with our sights set on expanding support to the preclinical phase. Expectations are high for the establishment of diagnostic and care delivery systems that take the patient journey into account and that, through administrative measures, provide networks delivering unified services from brain health checks to medical and preventive examinations.
- One municipality has introduced a collaborative effort in the field involving industry, Government, academia, and the community which is helping to accelerate R&D by serving as a model for connecting community networks for encouraging early detection and intervention to R&D. This model also has the potential to also serve as a model for the healthcare provision system after therapeutics reach the

market.

- In the current system, it is difficult to provide psychological support when informing people with no clear subjective symptoms that they are suspected of having dementia and should undergo biomarker testing. A system for following-up with patients after early diagnosis must be established to provide the support needed for easing anxiety toward progression and for encouraging positive-minded action.
- When formulating Japan's next national strategy for dementia, methods of promoting DMTs among community members must be kept in mind. Challenges to consider include drug prices and other economic issues; ensuring equitable access to adequate diagnostic facilities in all communities; and determining how to enable community collaboration needed for providing seamless responses from prevention to treatment.

Reducing costs and conducting health economic assessments for society-wide implementation

- It will be important to reduce the costs of DMTs and the biomarker tests that support the appropriate use of DMTs.
- After incorporating a health economic perspective to validate research, steps should be taken to visualize value. This is not only an issue that involves researchers; it affects everyone in Japan who will experience the super-aging society. It will also be crucial to grasp and visualize Patient and Public Involvement (PPI) in research, Patient Reported Outcomes (PROs) as a form of direct assessment, and Health Technology Assessment (HTA).

Utilizing established biomarkers, such as for preventive health services

- To make it possible to effectively utilize the DMTs and biomarkers that are developed and to facilitate efforts for early detection and prevention, a number of issues will require ample consideration. These include linking these tools to initial contact and healthcare and long-term care systems at support centers for integrated community care, to Initial-Phase Intensive Support Teams, and to each local government.
- Biomarkers in the preclinical phase and the phase of Mild Cognitive Impairment (MCI) have been identified in a cohort study conducted by the Japan Agency for Medical Research and Development (AMED). Expectations are high that these biomarkers will facilitate the development of effective prevention methods, including commercial health foods, through their application in individual studies on prevention.
- In the area of healthcare services, a randomized controlled trial called the Japan-Multimodal Intervention Trial for Prevention of Dementia (J-MINT) is currently underway. It aims to verify the effectiveness of a multi-domain intervention program that includes nutrition, exercise, cognitive training, and social participation for preventing cognitive decline.
- In long-term care settings, current topics of consideration are the introduction of Humanitude care and methods for predicting Behavioral and Psychological Symptoms of Dementia (BPSD) during early stages.

Current circumstances and issues in R&D for DMTs and biomarkers

Current circumstances and issues for R&D in DMTs

- Expectations are high for the acceleration of R&D for therapeutics targeting earlier and more advanced stages of dementia, starting with establishing pharmacotherapy for early-stage Alzheimer's disease, efforts for which are currently progressing alongside studies in molecular pathology.
- Research targeting the early and very early stages have found that differences in personal backgrounds (education, employment, past living environments, etc.) result in some people developing dementia while others do not. It is desirable that suitable methods of assessing the course of the disease on the individual level are established.

Issues for biomarker R&D

- It is growing more important to examine the background pathology of dementia to deliver personalized care. Cerebrospinal fluid has seen conventional use as a biomarker in clinical practice, but ahead of the launch of DMTs, granting insurance coverage to amyloid-related biomarkers and achieving nationwide equity in testing have emerged as challenges.
- As preparations to acquire regulatory approval for blood-based in vitro diagnostics continue to advance, discussions must be held on how to best popularize them. While referring to the "Clinical Guidelines on the Proper Use of Cerebrospinal Fluid and Blood Biomarkers for Dementia" (published March 2021), it will be crucial to promote both innovative technology and its appropriate use in parallel.
- Diagnostic imaging technology has improved and, thanks to leadership from academic societies, certain standards and criteria for accuracy have been established. However, there are still high hurdles to disseminating the use of such technology in clinics, so active involvement and support from imaging-related companies is highly anticipated.
- The development of image analysis technology is currently advancing through the manual efforts of researchers, who are building said technology by hand. There are limits as to what can be accomplished through individual effort when positioning that technology in clinics, so resources must be invested in a concentrated manner when advancing.

Systems needed to promote R&D

Supporting research that is difficult to evaluate scientifically

- Methods of verifying how the results of each R&D effort lead to real outcomes (i.e., the achievement of an inclusive society) are necessary.
- Steady research of the variety that does not attract funding and is difficult to publish, such as follow-up studies on the real-world incidence of dementia among people who develop MCI, must also be conducted. The groundwork for efficiently gathering information on people with MCI before medical examinations or during regular visits to healthcare facilities must be publicly established. It will also be important to create a system that reaches those people with information regarding clinical trials and clinical research.

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Systems for stakeholder collaboration

- Japan currently does not have a system in place to supply diagnostics for conducting the diagnostic PET scans used in research. If research using new diagnostics is forced to rely on in-house production at hospitals, research will be more difficult to conduct due to lack of funding and human resources. Building a sustainable system will require collaboration among related parties.
- Steps should be taken to promote the sharing of valuable data or blood samples and other samples among industry, Government, and academia, and eventually on the international level. Doing so will increase the value of data.
- There are too few horizontal links among studies. For example, efforts to expand findings from biomarker studies into large-scale cohort studies are insufficient.

Promoting Patient and Public Involvement (PPI) and participant recruitment for clinical trials

- Public-private-partnerships (PPPs) that include patients must be maximized so large-scale, challenging clinical trials for very early-stage Alzheimer's disease can advance smoothly. To recruit volunteers, particularly for Trial Ready Cohorts (TRCs) like the Japanese Trial Ready Cohort for Preclinical and Prodromal AD (J-TRC), it will be necessary to broadly promote feedback on research findings.
- PPI must be promoted and a system must be created so people living with dementia, their family members and others close to them, and their caregivers can participate in research freely and from the planning stages.
- AMED's 2019 "PPI Guidebook" was designed to be useful for a broad variety of stakeholders who are involved in PPI. These stakeholders include researchers, people living with dementia and their families, and other community members.
- It will be important to heighten awareness among citizens. There are high expectations for private insurance companies to play active roles while taking into account steps to effectively enhance recognition toward diseases and other conditions.

Developing the pharmaceutical market and industry

- Policy changes in the past few years have had negative effects on investments in Japan's biopharmaceutical sector. Establishing an ecosystem for drug discovery can kick off a virtuous cycle of innovation and contribute to people with dementia, their families, and society.

The need for and expectations toward national Government initiatives

Necessary steps for R&D including preclinical R&D and implementation throughout society

- Regarding future initiatives, considering the fact that clinical trials which have been expanded to include early preclinical stages have already begun, the next national strategy must introduce expanded measures that cover the preclinical stage. In the future, it will be essential for the national Government to continue building and expanding the J-TRC and to engage in initiatives for PPI and other frameworks.

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Offering support to promote R&D for early-onset Alzheimer's disease, which has low incidence

- While some believe people with early-onset Alzheimer's disease should be given priority when administering DMTs, having a sufficient number of participants in clinical trials will be difficult due to the low incidence of the disease. It will be important to create a PPP-based recruiting system for early-onset dementia and MCI for use in clinical trials and public cohort studies.

Enacting the Basic Act on Dementia and formulating the next National Framework for Promotion of Dementia Policies

- Expectations are high for the enactment of the Basic Act on Dementia to accelerate progress on various measures. It is desirable that literacy toward dementia is heightened among people with dementia, their family members, and all other people, and that we can create a society in which people can voluntarily and independently engage in activities aimed at dementia prevention and inclusion.
- Over the next year, deliberations on the Basic Act for Dementia will continue and Japan will host the G7 Summit in Hiroshima, so discussions on dementia policy are likely to deepen. We believe three important items on which to make policy progress are (1) promoting the development of new pharmaceuticals for Alzheimer's disease; (2) building a drug discovery ecosystem; and (3) building a PPP model. Focusing on early-stage research and building awareness as a nation is likely to help early diagnosis and treatment become established parts of clinical practice.
- In addition to supporting people with early-onset dementia and their social participation as outlined in the current version of the National Framework, steps should be taken to promote participation in R&D among people with early-onset dementia.

Expanding dementia R&D budgets and efficiently distributing funds

- Compared to the U.S. and the U.K., in Japan, items related to dementia are given much smaller budgets and far less funding is devoted to R&D. Financial support from the Government must be expanded.
- Another issue is efficiently allocating the limited financial resources that are available. Achieving steady progress in research initiatives means first developing human resources, so a system that contributes to human resource development must be created. Research centers that promote multiple independent research groups should be established to operate like the National Alzheimer Research Center in the U.S. and the Dementia Research Centre at University College London (UCL) in the U.K.

Necessary steps for conducting dementia research outside of early stages and for achieving a dementia-friendly society

Expectations for expanded dementia research outside of early stages

- Although the current focus of R&D is finding a cure for dementia, in conversations with affected parties, some have said, "I would like tools that will help people coexist with dementia to be developed." In recent discussions regarding new pharmaceuticals, as well, there were many people who said, "It should still be possible for people to lead happy lives after developing dementia. I want development to focus

on that."

- If clinical trials focus on the very early and early stages, people who have already developed dementia will end up being excluded from those trials. To achieve balance in R&D, it is desirable that efforts are advanced in a parallel along two fronts: foundational treatments for early stages, and treatments that enable people living with dementia and their families struggling with sleep disorders or BPSD to maintain familiar lifestyles.

The importance of basic research for developing DMTs outside of early stages

- Models that capture what occurs during advanced neurodegeneration have yet to be built, so effective therapeutics have yet to be developed. I think supporting basic research on such items will lead to the development of new therapeutics or DMTs.
- In addition to cognitive function, people experiencing BPSD or various other symptoms must also be included in clinical trials. Establishing a clinical trial system that aims for a broader sense of participation and includes families and caregivers in addition to people with dementia will enable greater variety in basic research.

Discussion point 2: Regarding a PPP in Dementia Research

Current circumstances for PPI in Japan and abroad

Legislation and PPI promotion overseas

- Including the phrase “patients and citizen involvement in dementia” in legal documents encourages the promotion of PPI. There have been many reports regarding PPI accumulated from the U.K., Europe, and Canada, and recently, the number of examples of PPI throughout the R&D cycle has been increasing. In the backdrop to that is the establishment of a legal framework for dementia in the U.K., where a foundation for steadily advancing PPI has been established.

A support system to promote PPI

- To encourage patients and citizens without any previous knowledge to learn about and participate in clinical trials, it is important for them to be involved in a continuous manner and with peace of mind. To this end, we will require a support system for PPI that conforms to existing systems and incorporates suitable consideration toward the public. Even if slight problems are encountered, people will stop participating if they encounter those problems repeatedly, and PPI in domestic dementia R&D will go unrealized. By establishing a political framework and incorporating data from the results of trial and error in other countries, it is likely that Japan has the potential to construct a good system for PPI.

The PPI framework in the field of cancer

- Rather than only holding conversations within the field of dementia, we must borrow knowledge from other disease fields where progress has been made in advanced initiatives.
- The third-term Basic Plan to Promote Cancer Control Programs (2018-2022) states, “To build a research system like those found other in countries that will enable people living with or have experienced cancer to participate in research design or assessment in Japan, from 2018, AMED will initiate a program for promoting cancer research through participation of cancer patients other people who have experienced cancer. The Government will also begin formulating a program to educate patients who can participate in research design and assessment.” A project was started this year under the Health and Labour Sciences Research Grants and steps to examine a patient education program are now being taken.
- For various academic societies starting with the Japanese Cancer Association, PPI has already become the norm, and special programs are also being provided that target people with cancer, their families, and the general public. It is safe to say that right now in the cancer field, the parties most affected are involved from basic research to treatment. Already, those most affected are participating in various opportunities for discussion and making their opinions heard on topics including research priorities, clinical study design, consent documents, and post-market surveys. While domestic progress in this area still lags far behind Western countries, expectations are high for such developments to spread to other disease fields.
- The importance of the voices of the parties most affected and peer support have come to be well-recognized in the field of cancer, where educational programs and similar initiatives have begun. The criteria used to designate hospitals have also been updated to include peer support implementation status.

It is important to gather many opinions and create a roadmap for each step, then to build up a nationwide system.

Key characteristics of R&D in the field of dementia and the need for PPI

The need for PPI in the field of dementia

- I think building a PPI framework for rapidly including many members of the general public as subjects in the J-TRC will be important for developing DMTs.
- Based on past experiences with factors that prevented progress on PPIs in the past, it will be important to have a strategy and governance to enable involvement from each stakeholder in a manner that surpasses their respective interests.

Issues in R&D and PPI that are unique to the field of dementia

- When someone participates in a clinical trial, they go in thinking they may benefit from using a new treatment, but clinical trials also require a placebo group. We must understand the feelings of participants who will obtain no direct benefits and communicate the significance of their participation, such as by telling them about their role in giving hope to people who will develop dementia in the future.
- Some are concerned that conducting trials in the preclinical stage or other early stages makes it more difficult to obtain the expected results from clinical trials, because the background of each individual differs (in terms of predispositions, personalities, developmental disabilities, etc.).
- Tools to measure cognitive function are an important topic. Current scales are insufficient for certain items like memory capacity. Without establishing appropriate scales and a framework for clinical trials, we will not be able to achieve the results we expect.
- If the target of research is shifted to earlier stages of dementia and that research is conducted over long periods, then certain participants will have to take placebo for long periods. Considering that certain study designs may cause participants to feel that their Quality of Life (QOL) or Activities of Daily Living (ADL) are not improving, it will be necessary to hold discussions within the framework of PPI to listen to the opinions of the parties most affected and discover what outcomes we should aim for.

Required actions for advancing PPI in the field of dementia

Achieving PPI that is truly patient-centered from the early stages of R&D

- One important discussion point is the stage of R&D at which parties most affected should start participating. For us to grasp the needs of those most affected and their family members from early stages, it is important for them to be involved early. If their participation is limited, it may make it impossible to conduct R&D in a manner that is truly centered on the patient.

Having communication that goes both ways during clinical trials

- To encourage people to act on the idea of participating in clinical trials, they must feel that they will benefit in some way. If their voices are not delivered and they are not able to obtain feedback on results, we will

be unable to make progress in PPI.

- Dementia is diverse, and the people living with dementia are also diverse. To make full use of each person's knowledge in individual R&D initiatives, rather than thinking "I just want them to bring me the results," researchers must be willing to reflect each individual's opinions or perspectives in the R&D process and to get involved with that process themselves.
- Researchers in academia must also be considerate toward the feelings of people living with dementia and their family members who are assigned to placebo groups in double-blind studies. The opinions of people living with dementia who participate in clinical trials and their close family members must be organized and shared with academia.

Establishing a framework for incorporating the voices of many people living with dementia

- One challenge facing PPI in dementia research is that people living with dementia, their family members, and healthcare and long-term care professionals all have different goals. Furthermore, certain voices may be more influential than others, despite not necessarily being from major parties. The field of cancer faces an issue in which only the voices of those speaking the loudest or that reflect the expectations of health professionals are gathered, so only the tip of the iceberg can be seen. This means action must be taken to make it possible to see the larger portion that is hidden under the surface.
- For dementia, there are some people who are suffering because they cannot speak up openly that they are among the parties most affected. They also may have the strong preconception that they have disabilities related to cognitive or intellectual function. These factors may mean there are some affected parties whose voices are not being reflected, just like for other diseases.

Building a framework and engaging in multi-stakeholder collaboration for promoting PPI

- In October 2021, AMED launched an organization-wide initiative to establish a division for equitable research and social co-creation with a staff member appointed to lead PPI. In addition to ongoing efforts to create a PPI guidebook, efforts for PPI in R&D projects were recently kicked off.
- It will be difficult to make progress in PPI through the efforts of researchers alone, so to lighten their burden, it will be necessary to attract personnel to fill various supporting roles by creating educational materials and programs or establishing stable frameworks for smooth recruiting and other processes. It will be important for the law to include a statement that will make it possible to allocate budgets with an eye toward building continuous relationships.
- There are perspectives that researchers at pharmaceutical companies tend to overlook, which means it is important to advance private R&D initiatives for dementia with involvement from people living with dementia, their family members, and other affected parties. Multi-stakeholders must cooperate in a unified manner.
- In addition to being a pathology of the brain, dementia also involves aspects of the environment, and is an area where there are many people with depression or who tend toward social isolation. This means that personalized responses are required to match the social environments surrounding each person. After

treatments are established, in addition to multi-disciplinary collaboration, it will also be necessary for parties like integrated support centers, community support personnel, and Dementia Supporters to collaborate. Then, while expanding the results of research across multiple disciplines, an integrated system that can be linked to a PPP must be established and policy responses must be taken.

- I think we need efforts that use PPI as a starting point for global collaboration. We should accumulate knowledge within Japan to utilize Japan's strengths, but I feel that we lack human resources. I think we should make the most of Japan's strengths to drive progress in global dementia research. Those strengths include the fact that Japan has an equitable healthcare provision system and has established a public long-term care insurance system. We require research with PPI that encompasses the perspectives of making efficient use of limited resources and building systems and frameworks that only Japan can build.

Establishing benefits for clinical trial participation, such as by providing opportunities for social participation and interaction

- Interest in Alzheimer's Association Japan among family members tends to be lower the earlier the stage of progression. It would be ideal if people living with dementia could get to know each other through involvement in clinical trials, talk about their troubles and issues, and communicate that to researchers. The benefits of participating in clinical trials should not only be based on the effects of therapeutics; they should also include peer support and interaction among families.
- Within the development of dementia-friendly products and services, progress is now being made on a project that aims to mutually benefit people living with dementia and industry. In that project, the life experiences of affected parties are utilized by industry while industry provides opportunities for social participation by involving affected parties in the development process. Moving forward, it will enter the phase in which this process is disseminated among project operators. Efforts are advancing to create a PPP that includes the knowledge possessed by the public, innovation, and PPI formed through discussions with the parties most affected.

Reinforcing information collecting and communications

- One challenge in the field of cancer is that it takes time to recruit participants for clinical trials. In the U.K., progress in PPI helped increase participation rates in clinical studies. When moving forward with research, it is important to implement designs and documents that are easy for patients and other affected parties to understand, and to hold regular conversations to provide the feedback and other information they want to know.
- Information regarding clinical studies in cancer is scattered among registries like the University hospital Medical Information Network Clinical Trials Registry (UMIN-CTR) and the Japan Registry of Clinical Trials (jRCT). Major issues in this area include the fact that each registry adds or updates information at different times, and that users are unable to search for information related to clinical studies. Another significant issue is that it is impossible to access information on clinical trials from industry. We should reexamine how to best structure communications for this type of research-related information. In the field of cancer, a

patient advocacy organization plans to issue a written request to the jRTC. Having cooperation in this effort from those in the field of dementia will be effective for addressing how information should be communicated.

- In Japan, progress is not being made in efforts to build understanding regarding the current circumstances at the forefront of R&D among people living with dementia, their family members, and other affected parties. I think there are many factors that affected this, including individual efforts, a lack of systems, and COVID-19. It will also be necessary for academic societies and similar organizations to engage in survey and research activities that gather the voices of those most affected.

Discussion point 3: Discussion points surrounding R&D programs

Necessary steps for promoting multi-stakeholder collaboration

Systematizing collaboration and making collaboration mandatory

- It may be a good idea for the MHLW to establish an internal department or team for promoting R&D collaboration. Building a system that enables total collaboration among researchers and industry or researchers and affected parties is likely to result in progress in collaboration.

Regarding data sharing

- As numerous research initiatives are advancing in parallel, data-sharing is important. While there has been progress in efforts to share diagnostic imaging data and blood biomarkers in academia, data sharing among industry and academia is insufficient. Copyrights on neuropsychological tests have become a particularly large hurdle and efforts to share data are at a standstill.
- The problem of copyright is rooted in the need for funding. Business competition surrounding the use of specimens and data is intense, which means difficult decisions must be made as to whether to proceed while maintaining exclusive rights to such items or while sharing them.

Obtaining informed consent when collecting information

- It is difficult to obtain informed consent when gathering data from elderly people. Setting the direction of studies in fields like BPSD requires large-scale data analysis, and methods of obtaining informed consent have become an issue.

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