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HEALTH AND GLOBAL POLICY INSTITUTE (HGPI)
POLICY RECOMMENDATIONS

EXPECTATIONS FOR A SYSTEM THAT SPANS DISEASES, MINISTRIES, AND AGENCIES FOR THE EFFECTIVE PROMOTION OF PATIENT AND PUBLIC INVOLVEMENT (PPI) IN RESEARCH AND DEVELOPMENT

1. Introduction

At a question-and-answer session on Patient and Public Involvement (PPI) in R&D held on April 10, 2026 and hosted by the House of Representatives Committee on Health, Labour and Welfare, the Minister of Health, Labour and Welfare stated that efforts will be advanced to include the evaluation of PPI-related initiatives when reviewing research proposals in drug discovery for substances intended for human use. Health and Global Policy Institute (HGPI) considers the inclusion of PPI among evaluation criteria as an important step in improving the quality of research as well as encouraging the reflection of patient needs, and we have high expectations for such initiatives.

Research and development in the field of drug discovery is not the only area that needs PPI. In countries leading in PPI such as the UK, Canada, and Australia, involvement of patients, other people with lived experience of health concerns, and citizens is a part of every stage of R&D, from basic research to the widespread adoption of research results in society. In addition to promoting PPI in drug discovery, which is under the jurisdiction of the Japan Agency for Medical Research and Development (AMED), we see the Minister's positive response on this topic as a good opportunity for efforts to advance PPI through all-of-Government action to be initiated.

The Cabinet Office has positioned science, technology, and innovation as "driving forces for transforming social issues into engines of growth and realizing sustainable economic growth." As patients and the public are the parties most affected by social issues, using their questions, ideas, and empirical knowledge in R&D is a perfect match for this policy concept. HGPI has been working to advance PPI for many years. In the Meaningful Involvement Promotion Project, HGPI has worked to encourage involvement in the policy-making process across diseases, and has been hosting discussions focusing on PPI in research in recent years. HGPI also offered recommendations on PPI in research through its Dementia Project during the formulation process of the Basic Act on Dementia for an Inclusive Society, and PPI was ultimately included in the Basic Act on Dementia and among evaluation criteria for the priority goals of the Basic Plan for the Promotion of Policies on Dementia formulated in accordance with that Act. From this perspective, we offer the following recommendations for the effective promotion of PPI.

2. Current Issues and Global Trends

When promoting PPI, we must address structural challenges that are unique to Japan. In leading countries in PPI, governments and other public agencies are presenting comprehensive guidance on the best forms of PPI and are comprehensively incorporating PPI concepts into systems designed in accordance with laws, strategies, guidelines, and standards. In addition to updating PPI guidance on an ongoing basis, those governments are also providing abundant practical educational resources for PPI that include guidelines, FAQs, and training programs for researchers as well as for patients and people with lived experience. Those governments have also established foundations for supporting administrative capacity, ongoing funding, and human resource development at patient groups, making it possible for PPI to be advanced without relying on uncompensated labor from patient groups or similar parties. With such efforts as a foundation, each country has established mechanisms for evaluation and funding.

Several issues have been identified for the promotion of PPI in Japan.

First, the Government of Japan has not established an official definition for “PPI.” While the Ministry of Health, Labour and Welfare (MHLW) uses the term “patient and public involvement” in policy documents and notifications, the intended definition is unclear. AMED gives a definition for PPI in its 2019 guidelines, “Patient and Public Involvement (PPI): A guide for collaboration between patients and researchers,” but it is only a definition provided by AMED as a single agency that provides research funding. Given these circumstances, there is a need for the Government to consider how it defines “patient and public involvement” in R&D. Including PPI among evaluation criteria with the definition still vague may result in more cases where PPI is only mentioned in formal descriptions without substantive collaboration, reducing PPI to a mere formality. As for the definition of PPI in research, the National Institute for Health and Care Research (NIHR) in the UK defines it as research that is “being carried out ‘with’ or ‘by’ members of the public*1 rather than ‘to’, ‘about’ or ‘for’ them.” The NIHR also provides criteria and measures for meaningful involvement, from its initiation to payment for participants and the impact and evaluation of involvement. It will also be important for Japan to avoid introducing inappropriate evaluation criteria. In addition to emphasizing the significance of involvement, other countries have also set precedents by making accommodations to ensure R&D is not assessed unfavorably when PPI is not or cannot be implemented due to the characteristics of the research or target disease.

Second, the feasibility of implementing PPI varies by disease area. While a wide range of involvement opportunities are available in disease areas with active R&D and many patients, for areas where R&D is at a standstill or where patients are few, insufficient human and financial resources or knowledge about PPI make it difficult to establish systems for PPI, even if patients want to get involved. Despite these challenges, the current system relies on the presence of patient advocacy organizations for PPI to occur, and people who do not belong to such organizations are not always able to engage in PPI. Furthermore, for conditions like dementia or psychiatric disorders, the symptoms themselves can affect a person's ability to engage in PPI, so it is sometimes difficult for participants to maintain PPI activities with the same methods or degree of involvement over the course of a study. Because there is such diversity among diseases, various forms of involvement must be introduced at various stages.

Essentially, we must adopt flexible designs and evaluation methods that account for the depth and nature of involvement at each stage of the research process with an approach that is based on the premise that involvement is a spectrum.

Third, very few people are both interested in R&D and capable of devoting time to PPI-related activities. This causes responsibilities to concentrate on certain individuals, leading to significant burdens and disparities in levels of experience. In turn, this can lead to viewpoints becoming fixed or greater difficulty when attempting to include the perspectives of people who have less experience in PPI but whose opinions are closer to those of the general public. Instead of relying on patients, others with lived experience, and citizens who participate in R&D to represent all people, promoting effective PPI will require positioning those parties as collaborators with specific experiences or perspectives, involving more people, and utilizing designs which synthesize multiple perspectives from a diversity of participants. For example, the Patient-Centered Outcomes Research Institute (PCORI) in the U.S. has developed a Compensation Framework based on the stance that compensating patient partners for their involvement is a formal obligation, not something done out of goodwill. Further efforts are also underway to provide patients, others with lived experience, and citizens with opportunities to acquire the skills and knowledge for involvement in R&D. These include the provision of free, on-demand training programs to support involvement from newcomers, such as "Research Fundamentals" from PCORI and "Open Classroom" from the European Patients' Academy on Therapeutic Innovation (EUPATI), which is operated with leadership from the EU. Another urgent issue in advancing PPI in Japan is building interest in R&D among more patients, others with lived experience, and citizens. Rather than relying on individual research groups or organizations to build interest, we must advance efforts for establishing an infrastructure for doing so in a unified manner. The same situation has emerged for researchers, who have extremely limited opportunities to deepen their understanding of PPI over the course of routine research activities. Therefore, we also look forward to the expansion of programs to educate and train researchers and research support staff on PPI.

The fourth issue is that in Japan's current system, research budgets are divided among various ministries and agencies. In addition to the MHLW, the budget for R&D is also shared with the Ministry of Education, Culture, Sports, Science and Technology (MEXT), the Ministry of Economy, Trade and Industry (METI), AMED, and many other parties. If basic research is included, that budget also extends to areas that lie outside of the health and medical strategy framework. Perspectives that span ministries and agencies will be essential if PPI is to take root throughout R&D in Japan.

*1 In addition to patients, people who may develop health concerns in the future, caregivers, and health and social service users, the term "members of the public" here also includes people from specific communities and organizations representing service users. It also includes people with lived experience of one or more health conditions or diseases, regardless of whether they are currently patients.

3. Recommendations

Based on the issues described in the previous section, we offer the following three recommendations.

Recommendation 1

FORMULATE A GOVERNMENT POLICY ON THE DEFINITION, CONCEPTS, AND EVALUATION OF PPI

The Government of Japan should clearly indicate the definition of PPI's ideal form in R&D that aligns with the Japanese context, along with the principles to emphasize, presented in the form of strategies, guidelines, and standards. As the need for PPI in measures from AMED and the Pharmaceuticals and Medical Devices Agency (PMDA) is expected to grow in the future, we hope to see the Government indicate a clear and cross-cutting approach that encompasses such measures. Rather than formulating those approaches once and considering them to be complete, they should be updated in an ongoing manner and based on changes in the times, progress in discussions on PPI, accumulated knowledge, and discussions with patients, others with lived experience, and citizens.

Furthermore, because involvement must be based on the characteristics of and circumstances in each area, in addition to creating a flexible and step-by-step*2 design that is premised on multi-tiered involvement, it will also be necessary to establish an evaluation framework that takes into full account researchers as well as patients, others with lived experience, and citizens.

To ensure that researchers, patients, people with lived experience of health concerns, and citizens can understand the specifics of the Government's PPI policy and implement it, practical guidelines should also be developed and updated regularly. It will also be vital that the practical guidelines provide clear details on appropriate compensation for patient partners for the time, experience, and knowledge they provide and to cover their expenses, and that the guidelines emphasize the need for reasonable accommodations for enabling diverse forms of involvement.

Recommendation 2

CONSTRUCT A PPI PROMOTION FRAMEWORK THAT SPANS DISEASES AND SUPPORTS INVOLVEMENT FROM A DIVERSITY OF INDIVIDUALS

When promoting PPI, a system should be established that reflects the implementation status and characteristics of each disease area without overly emphasizing specific diseases, individuals, or organizations. Before such a system can be established, we must first build a framework that can be used to accumulate and share best practices and that tracks PPI implementation status in each disease area, starting with the track record of PPI promotion efforts led by AMED. We have high expectations for such a framework to elevate standards for PPI in R&D throughout Japan by highlighting areas in need of further support, visualizing experience and knowledge, and broadly disseminating knowledge.

It will also be important to expand opportunities to match researchers and patients or others with lived experience by research objective, and to develop training and mutual learning opportunities for both sides. In addition to establishing a framework that ensures a broad range of people can participate as individuals without having to rely on groups or organizations, it will also be necessary to provide opportunities for patients, others with lived experience, and citizens to acquire skills and knowledge for involvement in R&D to prevent burdening specific individuals through over-reliance and to broaden the base of involvement. When advancing such initiatives, steps should be taken to actively utilize the knowledge and infrastructure of patient advocacy organizations, non-profit organizations, and other neutral parties that support PPI.

In addition to advocating for the need for these mechanisms through these recommendations, moving forward, HGPI plans to transmit information about opportunities for involvement in R&D, training, and mutual learning through our patient and lived-experience involvement platform, Japan's Patient Expert Platform (J-PEP).

Recommendation 3

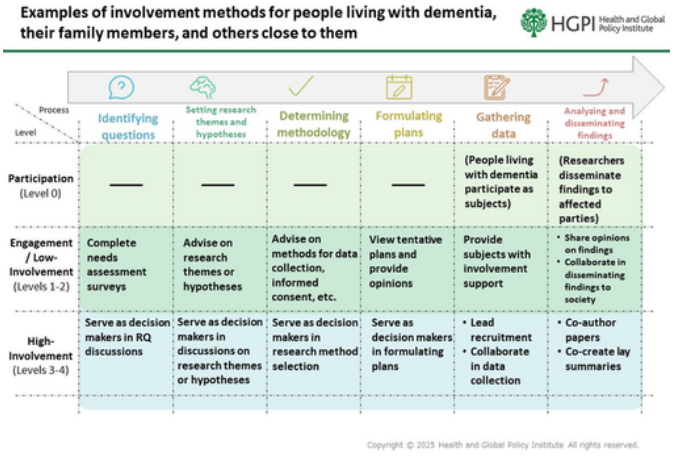
ESTABLISH A PROMOTION SYSTEM THAT SPANS MINISTRIES AND AGENCIES WITH THE CABINET OFFICE IN MIND

While the promotion of PPI is expected to proceed steadily for the time being, centered on areas under the jurisdiction of the MHLW and AMED, in the medium- to long-term, we hope to see these efforts expanded to include R&D and widespread adoption in drug discovery fields targeting a wider range of people, as well as to broader areas of science, technology, and innovation policy. To accomplish this, efforts to examine definitions, concepts, and evaluation frameworks (as described in Recommendation 1) and to gather and share best practices (as described in Recommendation 2) should not only involve specific ministries or governing bodies, but should be undertaken in a manner that spans ministries and agencies.

Therefore, for Recommendation 3, we propose establishing a system designed with the framework of the Science, Technology and Innovation initiative from the Cabinet Office foremost in mind. For example, a permanent working group could be established at the Cabinet Office to serve as a liaison conference, comprising researchers, representatives of patients and others with lived experience, and supporting organizations that advance PPI. In addition to sharing information on PPI implementation status for research projects in areas overseen by each ministry and agency as well as among non-governmental organizations, that group should be responsible for examining definitions and evaluation criteria and for compiling and disseminating best practices. The working group should also serve as a forum for government and civil society to collaborate and share about the direction of PPI promotion in Japan as a whole and drive concrete progress in PPI for each stage. Their activities for concrete progress should include determining how to best support PPI for researchers and academic societies in addition to patients and others with lived experience. As is the case with PPI, care must be taken when drafting the establishment guidelines for such deliberation bodies to prevent their membership from becoming fixed and their discussions from becoming closed. In addition to emphasizing the need for such a framework, through these recommendations, HGPI would also like to take tentative steps toward establishing such discussion forums in the future.

We have high expectations for these efforts to not only advance PPI in medical research in Japan, but to also encourage citizen involvement in science and technology and help strengthen Japan's industrial competitiveness by promoting R&D that society truly needs.

*2 For example, in the process of examining and implementing PPI in dementia research in Japan, HGPI held internal discussions on how to best define and evaluate the implementation of PPI. As a hypothetical suggestion, we outlined how involvement could be best implemented as part of a simplified research process. The outline is provided below.



Source: Moriguchi, N. (2025). *The Future of Dementia Research Co-created with affected parties, Vol.3: A Stage Theory of Patient and Public Involvement (PPI) in Medical Research on Dementia and Commentary and Recommendations on PPI Evaluation.* HGPI Policy Column 65. Health and Global Policy Institute. https://hgpi.org/en/lecture/column-65.html

4. Conclusion

The Minister's comments on the inclusion of PPI in evaluation have created a vital opportunity for advancing PPI in research in Japan. By allowing PPI to go beyond being a mere objective and expanding it appropriately to all domestic R&D, we are confident that it will contribute to greater innovation by resolving issues for society. Laying the groundwork for that expansion by providing clear definitions, advancing measures across disease areas, and establishing a framework that spans ministries and agencies will enable PPI to evolve from a formality into true collaboration, wherein researchers, patients, people with lived experience of health concerns, and citizens are able to leverage each other's expertise. In our capacity as a non-profit and independent organization, HGPI will continue deepening this discussion with various stakeholders.

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Regarding the Independent Nature of These Recommendations

These policy recommendations have been compiled in HGPI's capacity as an independent health policy think-tank. It does not, in any capacity, represent the opinions of any participating expert, speaker, related party, or organization to which those parties are affiliated.

About Health and Global Policy Institute

Health and Global Policy Institute (HGPI) is a non-profit, independent and non-partisan think tank established in 2004, dedicated to advancing citizen-centered health policy. Independent of any particular political party or organization, we bring together a broad range of stakeholders and present society with effective policy options to realize citizen-centered healthcare. Looking ahead to the future, we continue to propose innovative new ideas and values from a wide range of perspectives to build a fair and healthy society. Since its establishment, HGPI has remained at the forefront of identifying themes that were not yet receiving sufficient attention and ensuring their adoption as policy issues in areas such as women's health, cancer control, dementia, antimicrobial resistance (AMR), regenerative medicine, and global health. By ensuring such themes are reflected in the formulation of legal systems and national strategies as well as in global policy discussions, HGPI contributes to concrete policy progress. These sustained efforts have earned recognition from domestic and international policy stakeholders and organizations. We will continue participating in global dialogues in our capacity as a health policy think-tank from Japan.

We continue to present effective health policy options and advance efforts to address health and medical challenges, not only in Japan, but on a global scale.

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