



Guidance on Patient and Public Involvement (PPI) in Health Policymaking: Necessary Initiatives and Good Examples from the Public and Government

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Foreword: Expectations for PPI in the Policymaking Process

In recent years, people have started to recognize that patients' and citizens' voices are important for providing better healthcare. In the past, discussions on the healthcare system have mainly taken place among those on the provider side of care. We now recognize that patients and citizens—who are the beneficiaries of healthcare and can be seen as its purchasers and consumers—have the right to speak up for better healthcare. The rise of chronic diseases also means that rather than passively receiving healthcare, individuals are now expected to proactively manage their own health together with healthcare providers. Given this context, patients and citizens have become vital partners when considering the healthcare system.

I think this is an extremely important development for achieving a democratic healthcare system. Traditionally, discussions in the Diet held by those elected to represent the people were used to reflect the views of the public in various systems. However, society has become much more diverse, and there are limits to the degree to which opinions can be aggregated through the Diet. This means we require methods of controlling the government through democracy. In other words, moving forward, we must devise policies through cooperation among the government, patients, and citizens.

Against this backdrop, a number of processes have been established to gather the voices of patients and citizens when the government considers policy options. One example is the inclusion of patient and citizen committee members on deliberation bodies and committees for healthcare policy. However, before that involvement can take place, there are still many points that will require further consideration. For example, when a patient and citizen committee member works to represent the voices of the public, it is unclear whose voices they should represent.

We must also consider issues related to the government policy formulation process itself. For example, in recent years, to make the policymaking process more transparent, many meetings are now streamed online and are viewable to the public, but this has also made it more difficult to have free and vigorous discussions. It is now harder to adequately address conflicts of interest, which is a key function of meetings, leading to situations where no conclusions are reached.

Given these circumstances, I think a more democratic healthcare system can be created if we examine methods for reflecting the voices of a diversity of patients and citizens in policymaking. This report was compiled based on discussions and meetings held with a broad range of experts and aims to provide an accessible summary of necessary knowledge for patients, citizens, and government officials – namely, the parties responsible for PPI. It is my sincere hope that this report will contribute to advancing PPI and the creation of better health policies.

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Definitions of terminology used in this guidance

Parties engaging in involvement

Involvement from the parties affected by policies is often discussed using terms like “citizen participation” or “patient engagement.” In the fields of health, medicine, and welfare, the use of various terms such as “people with lived experience,” “the parties most affected,” “patients,” or “the public” can vary according to the context or the characteristics of the people being discussed. For the purpose of this guidance, the term “patients and citizens” is used in an inclusive manner that refers to a wide range of citizens and community members who are affected by policy in addition to patients, people living with health conditions, family members, and those close to them.

Opportunities for involvement

The term “Patient and Public Involvement” (PPI) is used in the field of medical research to describe the collaboration of patients and citizens with researchers. At the same time, initiatives from patients and citizens to collaborate with the professionals who provide healthcare are expanding within health institutions and into the policymaking process. For the purposes of this guidance, “Patient and Public Involvement” is not limited to medical research and refers to patient and citizen collaboration with all parties on the provider side of healthcare, including healthcare providers, the private sector, public officials, and researchers.



1

The significance of PPI in the policymaking process

In recent years, changes in the environment surrounding healthcare have resulted in increasing momentum in Japan and overseas for healthcare providers and related parties to collaborate with patients and citizens in various ways. In this chapter, we will examine the background, past trends, and significance of this growing movement.

1-1. The spread of and trends in PPI

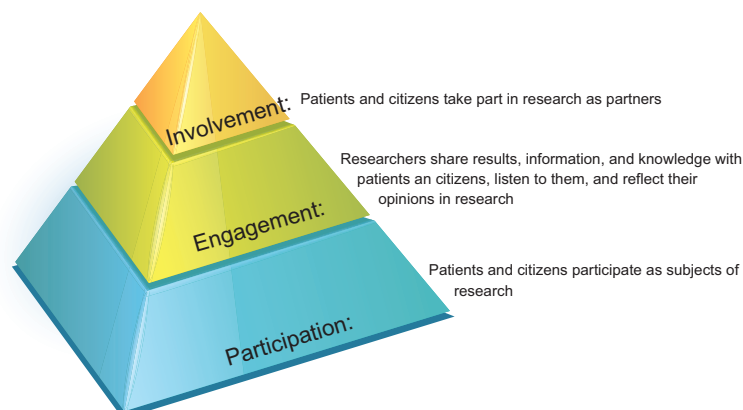


The healthcare environment has changed drastically in recent years. While infectious diseases were once a common cause of death, the disease profile has shifted to lifestyle diseases and other chronic conditions. This shift has normalized life with diseases and disabilities, and patients and citizens are no longer merely healthcare recipients. Instead, they are now expected to take an active stance and face their own diseases, disabilities, and health. A number of developments have also resulted in various initiatives with proactive patient and citizen involvement in healthcare. These include advances in science and technology, the occurrence of medical accidents, drug lag, and growing recognition of ethical concerns in health research.

Shared decision making (SDM)¹ is one example of such involvement that is being practiced in real-world healthcare settings that will be familiar to many. In SDM, healthcare providers share information related to treatment with patients, then both parties decide on a direction for treatment together. Patients and citizens are not only participating as healthcare recipients; they are also getting involved on the provider side, as well. Examples of this include the activities of peer supporters, who are people that provide counseling and support based on lived experience as patients, or the external audit committees of advanced treatment hospitals that have special functions, where patients and citizens participate to improve safety.² Their involvement is also growing more important in individual medical studies,³ the formulation of clinical and health guidelines, the development of pharmaceuticals, medical devices, and other products in the private sector, and in health policy.

Within the context of these diverse forms of involvement from patients and citizens, their participation in the field of medical research is known as Patient and Public Involvement (PPI).⁴ In addition to the Japan Agency for Medical Research and Development (AMED) guidebook on PPI that provides a summary of basic ideas for its promotion,⁵ guidelines on PPI within processes for creating guidelines for treatment and health-related services have also been compiled by the Japan Council for Quality Health Care's evidence based medicine (EMB) dissemination project, the Medical Information Network Distribution Service (Minds).⁶ Efforts to further PPI have advanced in other countries, as well. In the United Kingdom, involvement is classified into three stages: participation, engagement, and involvement. "Participation" refers to when patients and citizens simply take part as research subjects. "Involvement" refers to cooperation from patients and citizens as partners to researchers (Figure 1).⁷

Figure 1: Stages of PPI in Medical Research⁷



In addition to the narrow definition of PPI that refers to involvement in medical research, the term has recently taken on a broader meaning to refer to involvement in various settings including in policy and real-world healthcare settings. A number of actions have been taken to further PPI in the broader area surrounding healthcare. For example, in peer support, guidelines have been issued by the Japan Peer Support Association⁸ and the Ministry of Health, Labour and Welfare (MHLW),⁹ while the Pharmaceuticals and Medical Devices Agency (PMDA)¹⁰ has presented guidelines on promoting PPI in development and approval review for pharmaceuticals and medical devices.

Figure 2: Various opportunities for PPI as well as and their objectives and outcomes¹¹

Healthcare professionals



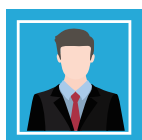
- Peer support is useful for assisting in daily life management, as a source of social and emotional support, as a way to link people to clinical treatment, and for providing continuous support.
- Representatives of the public must be included on Ethics Review Committees to ensure reviews of advanced treatment hospital operations are fair and neutral.

Researchers



- The empirical knowledge of patients and citizens can help us discover new research possibilities.
- In developing clinical practice guidelines to support collaborative decision making among healthcare users and providers, we must fully reflect the values and wishes of the users (i.e., patients and citizens), who are the parties that are directly affected.

Policymakers



- Using public comments to gather opinions from the general public helps to ensure fairness and improve transparency in government administration, as well as to protect citizens' rights and interests.
- To establish Regional Medical Care Visions that reflect the realities of their respective communities, it is important that a wide range of stakeholders, including patients and citizens, review and reach consensus on them.

Development staff



- Understanding patients' needs helps the development of pharmaceuticals and other medical products with an eye toward how they will be used, and to make progress on post-marketing safety measures.
- Involving those most affected in product development can help produce higher quality solutions that reflect their needs.

1-2. Citizen involvement in the policymaking process and democracy



PPI is also becoming more common in the field of policy. Efforts to involve those affected by policies in the policymaking process have preceded those in health policy in a number of areas, including infrastructure policy, the environment, and policies for people with disabilities. Expectations are high for this involvement to make the policy formulation process more transparent and promote better policies that meet the needs of citizens. In the field of health, too, there are high expectations for the creation of policies that meet the public's needs by involving patients and citizens who are in positions to receive healthcare alongside those who are involved in providing it.

In the past, methods of PPI in the health policymaking process were limited to expressing opinions through demonstrations or petitioning Diet members and government agencies. However, in recent years and as previously mentioned, the importance of listening to the voices of patients and citizens has come to be emphasized throughout the entire health policy consideration process. A number of methods of collecting a wide range of opinions from patients and citizens have been established, such as public hearings, public comments, and workshops. In addition, the Cancer Control Act enacted in 2007 obligated the national Government and prefectural governments to include members with lived experience such as cancer patients, their families, or the bereaved on Cancer Control Promotion Councils. Since then, other disease areas have followed suit and have introduced PPI in government committees. As we can see, we are now transitioning away from a time when the main policymakers were the government and healthcare providers to a new stage in the policy formulation process, in which the voices of individual patients and citizens are delivered to policy and in which those parties are active participants.

Column

The evolution of democracy and the roles of the legislative and executive branches

Democracy is a form of governance in which citizens, as members of society, make decisions that directly or indirectly affect society as a whole. "Representative democracy" is a form of democracy in which the responsibility for making policy decisions on behalf of citizens rests with representatives chosen through elections or a legislature. This arrangement reduces the burden placed on each citizen to be involved in every decision that concerns them while allowing for their opinions to be reflected in policy through the legislature.

In addition to the legislature, in recent years, initiatives have been introduced by municipal and prefectural governments and the executive branch of the national Government in which opinions are solicited from a variety of citizens so a broader range of opinions can be reflected. Examples of such efforts include public hearings and public comments hosted by the government, and citizen involvement in councils and conferences. These methods enable citizens to exercise their right to have their voices heard in policymaking and contribute to more democratic policymaking in the government.

In the field of political science, particularly in political thought, it has been suggested that past research has focused on the legislative branch and that there has not been sufficient research on citizen involvement through government.^{12,13}

PPI in the government's policy formulation process is one effort to fortify representative democracy and generate health policies that are based on the voices of patients and citizens through both the legislative and executive branches. Expectations are high for the further promotion of PPI in the future.

The stages of citizen participation

The stages of citizen participation have long been arranged in an eight-step ladder, shown in Figure 3¹⁴. Ideally, participation would gradually move up the ladder with more proactive involvement from citizens, with them ultimately taking direct charge of policy formulation with the government supporting them. This framework is even referenced in the field of healthcare. For example, using this ladder as reference, the National Health Service (NHS) in the United Kingdom has arranged stages of PPI in medical research into five levels (Table 1)¹⁵ and is working to encourage patients and citizens to participate more proactively. These also apply to the field of health policy, where it will be ideal to promote PPI through holding workshops where patients and citizens can have their opinions heard, encouraging their involvement in meetings, and ultimately, gaining more proactive involvement from patients and citizens so they can take the lead in policymaking, with the government acting as support.

Figure 3: The Ladder of Citizen Participation



Table 1: Public involvement arranged in stages by NHS

| | |
|--|--|
| 1. One-way information provision | Giving information and reference materials |
| 2. Opportunities for hearing opinions and consultation | Getting information through interviews and citizen panels |
| 3. Discussion opportunities | Establishing forums for debate with patients and citizens and administrators |
| 4. Temporary collaboration | Working with committee members at decision-making bodies |
| 5. Collaborating as partners | Working in partnership for projects as a whole or in part |

As we can see, there is progress in PPI, but new challenges are emerging. For example, some local governments do not receive any responses from interested patients and citizens when they collect applications to participate in health policy meetings, so there is a shortage of people who want to serve as patient and citizen committee members. There have also been cases in which people affiliated with certain organizations or specific individuals serve on committees for several years, which have led to concerns about fairness in opportunities for involvement. On top of this, discussions tend to use lots of jargon, which can make it difficult for patient and citizen participants to keep up with discussions and make statements on the spot (Figure 4). We hope that by identifying existing issues such as these and investigating solutions, we can further promote fair and effective PPI and strengthen democratic policymaking.

Figure 4: Challenges facing PPI in the health policy formulation process



This trend of promoting PPI in the policymaking process can be seen around the world. The World Health Organization (WHO) is advocating for the promotion of PPI among Member States and has compiled a handbook¹⁶ on society-wide decision making for patients, citizens, and other stakeholders. The WHO has also created a framework¹⁷ for developing and reviewing policies and services related to non-communicable diseases (NCDs), mental illnesses, and neurological disorders together with the parties most affected. Based on the current situation and these trends in Japan and around the world, this guidance aims to serve as a foundation for advancing PPI in the health policymaking process in Japan and compiles concrete methods of advancing PPI, establishing the necessary environment for PPI, and other actions that must be taken for this purpose.

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2

The need for the government to consolidate the diverse voices of patients and citizens

Gathering the voices of a broad range of patients and citizens and reflecting them in policies is an important step in generating policies that suit the needs of those parties. As mentioned in Chapter 1, a broad range of patient and citizen views is gathered as part of the policymaking process at both the legislative and executive branches of the government. Focusing on PPI in the government's policymaking process, this guidance will introduce necessary perspectives for the fair and effective implementation of PPI.

2-1. Establishing conference bodies and selecting patient and citizen committee members



Taking into account representativeness and fairness in opportunities for involvement, establish a quota of two or more patient and citizen committee members with set terms of appointment

Patients and citizens have diverse needs. Even in cases where people have the same disease or disability, they often face different challenges. Meetings involve only small groups of people that look to patient and citizen committee members to represent the voices of patients and citizens so these diverse needs can be consolidated. However, the opinions of all committee members carry some degree of bias, so there are limits to the representativeness that can be expected of any single patient and citizen committee member. We hope that multiple patient and citizen committee members will be appointed with pre-determined terms of office to ensure fair participation and to effectively gather patient and citizen voices.

Adopt highly-transparent methods of committee member selection to ensure impartiality

Administrative meetings take various forms, from those held by central ministries to those held by local governments, and they can have very different agendas. Since these meetings have different objectives and place different demands on patient and citizen committee members, we should adopt impartial selection methods that are tailored to the purpose of each meeting. Specific examples of selection methods include appointing members from patient groups and related organizations, conducting open recruitment, accepting introductions from other committee members, and selecting community members at random.

Regardless of the selection method that is adopted, it is important to ensure that it is fair. This requires clearly communicating both the selection method and selection criteria to patients and citizens. When using open recruitment, for example, it is best to present participant requirements and selection criteria in a manner that reflects the placement and purpose of each meeting to ensure both the people who are selected and those who are not can accept the outcome of the selection process. Some foreign countries and local governments have developed highly-transparent selection processes in which applications or interviews are evaluated using predefined and openly presented selection criteria. We have high expectations for best practices like these to be widely adopted.

Overseas examples of setting requirements for patient and citizen committee members according to committee objectives

The requirements for patient and citizen committee members vary depending on the meeting's placement and objectives. For many years, both the Food and Drug Administration (FDA) in the U.S. and the National Institute for Health and Clinical Excellence (NICE) in the U.K have been actively promoting PPI. Here, we will compare their requirements.

Both the FDA and NICE require committee members to be of legal age, to be patients or primary caregivers, and to be able to engage in constructive discussions. The points where their criteria differ relate to the knowledge and qualifications required of committee members. The FDA's Patient Representative Program (PRP) also requires patient representatives to have the "ability to be objective while representing the concerns of others in their communities" and "knowledge about most treatment options and research for their areas of experience they are representing."¹ It is in this sense that the name of the program includes "Representative," as participants are expected to be able to represent many patients and citizens and be able to communicate with other stakeholders on issues. On the other hand, NICE often treats patients and citizens as lay members (or, ordinary patients and citizens) and only requires that they are affected parties (such as patients, their family members, or their caregivers) and have experience using health services.^{2,3}

As we can see, the requirements for patient and citizen committee members vary among governing bodies, with no uniform criteria for PPI. It will be important to establish and disclose appropriate criteria in advance and in line with the objectives of the PPI.

Securing human resources among patients and citizens who want to be involved

Depending on the agenda of the meeting and the region in which it is held, only a few people may want to serve as patient and citizen committee members. There have been cases where open recruitment has failed to attract any applicants at all. Achieving fair PPI requires involvement from multiple people who want to represent patients and citizens, so it will be important to create an environment that fosters interest in involvement among citizens and to strengthen links between interested citizens and the government in advance. Some municipalities have established citizen networks to appoint a diversity of people who are interested in involvement. To address this, one municipality has created a list of relevant patient organizations in surrounding regions, while another has created a registration system for randomly selecting committee members. In that system, invitations are sent to randomly-selected citizens and only those who wish to participate are added to the pool of committee member candidates (Figures 5 and 6).⁴

Figure 5: Committee member selection process using open recruitment and a registration system to randomly select candidates



Figure 6: Challenges before the introduction of the randomized candidate selection system and its results^{4,5}



Before introduction

- Not enough people were applying to be committee members through open recruitment, so the seats for participants selected through open recruitment were filled by the same people each time.
- There was a lack of age and gender diversity among those selected through open recruitment. This limited our ability to reflect the opinions of a wide range of citizens.

After introduction

- Selecting who to ask to participate randomly using a list with no age or gender bias led to diversity in committee members without disproportionate representation.
- It has resulted in fairer and more transparent committee member selection.
- Because the system provides guidance to citizens who may not be interested in getting involved, it has helped raise awareness toward the system.

2-2. The support patient and citizen committee members need for effective PPI



Taking information asymmetry into account, provide patient and citizen committee members with adequate explanations and training

Most health policy meeting participants are people involved in providing healthcare, but patient and citizen committee members are healthcare recipients. In general, people are aware that there is information asymmetry between those who provide healthcare and the patients and citizens who receive it. In addition, many committee members represent specific organizations that provide them with support, but patient and citizen committee members are usually not representatives of organizations. This means the environments surrounding patient and citizen committee members differ greatly from other committee members, and meetings themselves are structured in a manner that can make it difficult for patient and citizen committee members to offer comments.

Allowing diverse stakeholders including patient and citizen committee members to engage in effective discussions will require establishing a common language and understanding to base discussions on and to reduce information asymmetry. In particular, many committee members have specialized medical training, but patient and citizen committee members lack such training and require careful explanations and training in advance. This includes explanations of terminology.

Support before and during meetings

The knowledge that patient and citizen committee members need to participate in meetings includes items specific to each meeting (e.g. terminology for certain diseases) as well as knowledge that applies to many meetings, such as basic knowledge related to the healthcare system or government meeting decorum. It is important that this information is uniformly provided to patient and citizen committee members who are not used to taking part in meetings.

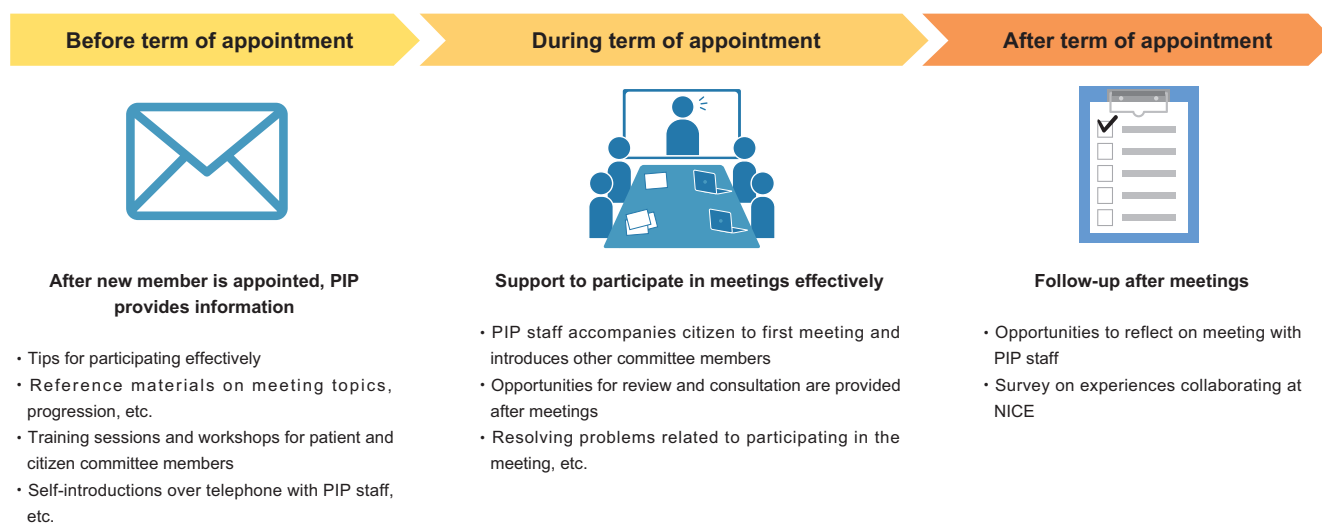
Support after meetings

In addition to providing support before meetings, it is also important to provide follow-up after meetings. Explaining meeting outcomes and providing participants with feedback allows them to reflect on their involvement and be more effective in the future. In domestic PPI in medical research ethics committees in Japan, or in PPI overseas, initiatives have emerged in which patient and citizen representatives reflect on their involvement together with meeting administration after they are done serving as committee members.

Training provision methods and precautions

Rather than letting such training and explanations consist of only one-sided communication, care must be taken to ensure patient and citizen committee members have obtained a full understanding without developing unnecessary biases. Creating an environment that ensures psychological safety and lets them feel comfortable asking questions can make it possible to provide training and explanations tailored to each committee members' needs. It also helps patient and citizen representatives learn. Overseas, initiatives are being implemented to prevent patient and citizen committee members from developing unnecessary biases through explanations held in advance by providing third-party support through independent departments or organizations that are not the meeting organizers.

Figure 7: Comprehensive support provided to patient and citizen committee members through the NICE's Public Involvement Programme (PIP)³



Creating an environment for effective PPI

The unique burdens of attending meetings shouldered by patients and citizens

Since many patient and citizen committee members live with a disease or disability, it is necessary to be considerate toward the burdens they shoulder to attend meetings. For example, in addition to reasonable accommodations, it is also necessary to consider individual needs, such as the need to manage their working hours or attend hospital visits. In particular, special considerations must be made when meetings are urgent or must be held frequently so committee members who have to make regular hospital visits and who are employed can still participate. As attending meetings may result in equal or greater burdens for patients and citizen committee members compared to other committee members, they should receive financial compensation that is in line with other committee members. In addition to compensating them for the burden of attending meetings, this should also be done out of recognition for their expertise as patient and citizen representatives.

Promoting PPI through cooperation from other committee members and meeting administrators

While providing support to patient and citizen committee members, the government and other committee members must learn about PPI methods and understand the need for PPI. In particular, learning to see the lived experiences of patient and citizen representatives as a form of expertise and recognizing the value of those perspectives will encourage other participants to listen more carefully and help create an environment in which patients and citizens feel comfortable offering comments. As government officials and meeting chairs who preside over each meeting have significant influence over how meetings progress, it is important that they fully understand the need for PPI and PPI methods.

Policy-making processes with the people with lived experience right at the centre: The practice in dementia policy in Scotland

Scotland is known worldwide for its human-rights based dementia policy, influenced by the voices of people with lived experience. It has in recent years developed and implemented a policy-making process in which people with lived experience of dementia (including those living with dementia, families and carers) are at the centre of decisions taken about the policies that matter to them.

This effort to upscale the involvement of dementia communities took place through the creation of a National Dementia Lived Experience Panel made up of over 20 people. Selected by an independent group containing members from a third-party organisation, the public sector, academia and lived experience, the group has worked with Scottish Government from the outset of the process to develop its new Dementia Strategy. This includes:

- Participating in an initial National Conversation, including setting the questions of that Conversation
- Contributions at in-person and hybrid meetings, as well as in writing to the Strategy as it formed
- Their words used to directly inform and shape priorities set out for Scottish Government for the next 10 years

As we moved into delivery:

- Individual members were supported to co-chair delivery subgroups on what we should prioritise in delivery
- Participation and contributions from members of the panel have helped shape a national anti-stigma campaign, which we will launch later this year
- Their role in holding us to account for delivery has been enhanced, with a new governance approach going forward placing equal weighting to our Lived Experience Panel and delivery partners, in a combined Strategy Delivery Group.

The panel is continuing to evolve, with a sub-group now forming made up only of people with a diagnosis of dementia to ensure their perspective is fully understood and inputted to our work.

This practice may influence the power dynamics in the policy making process unfavourably for the administration and other stakeholders. Therefore, implementing it must be done with the full agreement of the parties involved. In fact, in Scotland, the practice would not be sustained without other commissioners and frontline administrative officials recognising that the interests of those with lived experience should be at the centre of discussions and the need to share discretionary powers. This has been achieved through a long-standing campaign by third sector organisations and other groups on civil society involvement, as well as political leadership that has driven change towards an even more democratic policy-making process. The benefits this process has brought has rebalanced the delivery priorities to reflect the needs of dementia communities, and enhanced the credibility of those priorities being the right ones.



2-3. Creating various opportunities to deliver the voices of patients and citizens to policy



Considering the fact that meetings have limitations, develop a system for utilizing a broad range of opportunities for involvement that are aligned with meeting objectives

Patients and citizens have diverse needs and a wide range of their voices are impossible to fully cover with the small numbers of patient and citizen representatives that can attend meetings. This means it will be important to use various other opportunities for involvement to gather a wide range of voices. Public hearings, workshops, individual opinion hearings, and public comments can also be seen as forms of PPI, so it will be important to pick the best method for the purpose and stage of policy formulation after considering the strengths and weaknesses of procedures for each one.

For example, using written formats to gather opinions such as surveys or public comments can be efficient for gathering many patient and citizen opinions. However, even when survey results are presented or responses to opinions gathered through public comments are provided, there are limits to the degree of two-way communication that these methods provide. Methods of gathering opinions that allow for two-way communication include those that involve face-to-face communication such as public hearings, workshops, and opinion hearings with individuals. These face-to-face opportunities for involvement also require less expertise than committee meetings, councils, or other meetings, making them more accessible to many patients and citizens. There are also aspects that allow patients and citizens to learn how to participate.⁶ Given their characteristics, these procedures must be implemented where appropriate for the intended purpose.

Establish PPI guidelines to promote various procedures for gathering the voices of patients and citizens

Developing guidelines on policy formulation processes that consolidate the voices of a diversity of patients and citizens will be effective for ensuring that a variety of procedures are widely implemented in line with the purpose of each meeting. Efforts to implement measures for citizen engagement are currently being made under the Administrative Procedure Act, the Local Autonomy Act, and under laws in various other fields, such as Article 16 of the City Planning Act (Table 2). Local governments are also developing ordinances and informal guidelines for citizen engagement.⁷ With sufficient flexibility to ensure methods adopted for PPI are appropriate for each intended purpose, and while referencing efforts in other areas, we hope to see guidelines established for PPI in health policy.

Table 2: Examples of laws in other areas that outline involvement of citizens and community members⁶

| Legal foundation | Details of regulations on citizen participation |
|------------------------------|---|
| Local Autonomy Act | Indirect participation through elections; direct participation through direct claims to local governments and other requests |
| City Planning Act | Necessary measures to reflect residents' opinions are to be implemented when formulating city plans |
| Administrative Procedure Act | When a national Government institution provides instructions, etc., steps must be taken in advance to broadly solicit opinions from the public and opinions gathered must be taken into consideration |

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3

Helping patients and citizens build the capacity to be involved as experts

As we can see in the look back provided above, even if we say “patient and public involvement,” there are various ways that involvement actually takes place. In Chapter 3, we will discuss the skills patients and citizens need to get involved and how those skills can be developed. Specifically, we will identify necessary skills for participating in government meetings as patient and citizen committee members, which can be considered a hurdle for involvement. We will also introduce various processes by which people become patient and citizen committee members and share lessons learned from people who have actually taken part in PPI.

3-1. The various opportunities and competencies patients and citizens need to play active roles

The invaluable expertise of patients and citizens

The lived experiences of patients and citizens are an invaluable form of expertise that can provide perspectives different from those of medical or policy specialists. According to the WHO, lived experience should be considered a form of expertise that stands alongside evidence.¹ As we can see, there is a trend in Japan and around the world for the voices of patients and citizens to be viewed as a form of expertise that is equal to that of other experts.

The expertise of affected parties is necessary in various healthcare settings. For example, when peer support is provided at health institutions and in communities, it allows people to come together because the people providing it have firsthand experience with the same disease or disorder. In medical research, instead of only treating affected parties as research subjects, attempts are being made to utilize their expertise so they can collaborate with researchers at various stages of the research process, including planning, design, and evaluation. People with lived experience of diseases and disorders can contribute to research by providing a firsthand perspective on the needs of patients and citizens, which are often difficult for researchers to grasp. In health policy, conveying the opinions and needs of patients and citizens through opportunities like meetings at the municipal, prefectural, and national governments, public hearings, and public comments contributes to the creation of policies that encompass the perspectives of patients and citizens.

The adaptability needed to make the most of expertise

Many fields need patient and citizen expertise, so they must have the abilities to match

Patients and citizens must adapt to each field of activity to make full use of their expertise. For example, when providing peer support, it is important for them to first know items like points of note to keep in mind when communicating with patients and citizens, and to understand other forms of support that are available to patients and citizens. Also, when participating in medical research or health policy, they can convey the voices of patients and citizens more effectively if they understand research or policy to a certain degree. In the same manner, they must also acquire the knowledge and skills they need for each setting in which they are involved in order to more effectively utilize their expertise as patients and citizens.

While there is specific expertise patient and citizen committee members must possess for each setting in which they participate, there are also common skills that are shared among many involvement settings. Skills that are necessary and used in every setting include, for example, understanding the significance of PPI and the ability to convey experiences and opinions to others in a manner that is easy to understand.

PPI has various stages and each one requires patients and citizens to possess certain capabilities

The fact that there are several stages of PPI is well-known. For example, responding to surveys and continuously participating in and sharing opinions at meetings are both considered involvement in health policy, but the degree of involvement is very different. In general, the more proactive the form of participation, the higher the standards for participants' skills.

In Section 3-2, we will examine the skills patients and citizens need to proactively participate as representatives and consider policy together with other stakeholders and the government when taking part in the health policy formulation process.

3-2. Competencies required of patient and citizen committee members who attend meetings

Mental preparations for serving as a patient and citizen committee member

Being aware of representativeness

Attendees at government meetings include people from groups that represent the interests of healthcare providers and the private sector. In order to represent the interests of patients and citizens, patient and citizen committee members sometimes have to confront these stakeholders. It is in this sense that they are recognized as patient and citizen representatives, so they must understand they are participating to convey the interests of those parties. Instead of simply sharing personal experiences and feelings, they must recognize the importance of speaking for others. This means saying “We” and not “I” and being ready to represent the voices of as many patients and citizens as possible.

Having a broad viewpoint without limiting one’s focus to certain information

When we say “patients and citizens,” who exactly are we referring to, and who are their representatives? Other committee members may fully represent their respective organizations due to internal processes such as elections or discussions. However, it is often difficult for patient and citizen committee members to provide the same level of representation as other committee members because it is unclear who the term “patients and citizens” refers to. This makes it practically impossible for a single patient and citizen committee member to represent a wide variety of patient and citizen voices. Recognizing the limits of representativeness, in an objective and inclusive manner, they must generalize and communicate the voices of the widest range of patients and citizens possible, especially those whose voices are going unheard.

Column

Striking a balance between the narratives of individuals and evidence

As stakeholders, patient and citizen committee members represent healthcare service beneficiaries and taxpayers, and they are invaluable players in creating health policies that are based on the needs of patients and citizens. But whose interests are we referring to when we say that they “represent the interests of patients and citizens”? Furthermore, how many patients and citizens must have their voices heard before we can say their interests are being represented? The answers to these questions are not always clear, so it will be important for those serving in the capacity of patient and citizen committee members to understand the diverse voices of patients and citizens using a variety of methods.

It is also important to note that there are various methods for gathering the voices of patients and citizens and that the opinions obtained will vary depending on the method. For example, there are often differences between the narratives of individuals obtained through interviews with patients and their families and evidence generated through the opinions of groups of patients and citizens using surveys. As such, it is important to recognize that there are patient and citizen narratives that are not captured by the evidence, and to strike a balance between evidence and narrative.

Gathering feedback from patients and citizens and understanding their needs

Obtaining an objective and inclusive perspective requires listening to the voices of many patients and citizens. Before attending meetings, participants must listen to the voices of multiple patients and citizens who will be impacted by the policy in question to understand their needs in advance. People involved in patient groups who hear from many patients and citizens about their troubles on a daily basis have a foundation for consolidating the voices of those parties, so it is safe to say they possess the qualities needed by patient and citizen committee members. It is not absolutely necessary for them to belong to patient groups, however, but it is important that they have opportunities to hear a wide range of patient and citizen voices through their daily activities and in their communities.

Necessary actions for gathering a diversity of voices from patients and citizens

In the past, when I attended meetings with people in various roles such in the government, medicine, or research in my capacity as a patient, I was often asked, “From a patient’s point of view, what do you think?” Even though I did not think of myself as a representative of patients, others expected me to share opinions as such, and they took my statements to represent the opinions of patients. Depending on the situation, my statements could result in gains or losses for many other people. I am now somewhat afraid to attend meetings

unless I can first gather the voices of other patients as much as possible through conversations, questionnaires, and other opportunities.

For kidney disease, which I am affected by, I operate a website and conduct frequent surveys on various themes. I am also working to continuously hear the voices of various people through peer support activities and consultations. In addition to continuing such efforts even after hearing the voices of a number of people, I think it is also important to be mentally prepared to make statements from the position of “our voices” rather than “my voice.”

Takeshi Shukunobe (President and CEO, PPeCC)



Necessary knowledge for patient and citizen committee members

Government meetings are forums for discussion among committee members who are experts in various areas. While serving as experts with a patient and citizen perspective that other committee members do not have, patient and citizen committee members must learn common terminology and understandings possessed by other members. Over this learning process, they may have many questions. While it is important for them to be proactive about asking questions when encountering something they do not understand, for these parties to participate in discussions among specialists, it is also important for them make full use of briefings and training seminars in advance as well as various forms of support provided by administrators on the days of the meetings to learn the items described below.

Deepening knowledge regarding diseases and healthcare

Patient and citizen committee members must have advanced knowledge of themes related to healthcare and the health system relevant to the meeting topics. Many of the terms used in meetings are not often used in everyday conversations. If participants are not familiar with these terms, they are unable to follow discussions or speak effectively. It is important for them to have a certain degree of understanding regarding topics like disease areas related to the meeting or the frameworks used to provide healthcare services. Depending on the meeting, it is also sometimes good for them to have a detailed knowledge of topics like the pharmaceutical development process or the rules surrounding the pharmaceutical industry.

Learning about policy and government meetings

It is also important for patient and citizen committee members to understand the objectives of the meetings they attend and the placement of those meetings in the policymaking process. Government meetings have various functions and a significant impact on policymaking. Not knowing how policies are formed and implemented or the objectives and placement of meetings within the policymaking process makes it difficult for participants to offer accurate statements or proposals during meetings. Having some knowledge of the policy process including the objectives of meetings and their placement makes it possible for patient and citizen committee members to prevent policies from advancing in directions that are undesirable for patients and citizens, to identify the specific needs of patients and citizens, and introduce the needs of patients and citizens to the policy agenda.

Skills for participating in government meetings

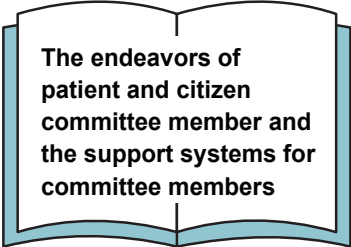
The purpose of government meetings is arriving at single policies through discussions held with various affected stakeholders. Developing better policies requires careful discussions, but such discussions face time constraints and other limitations. Patient and citizen committee members must understand how meetings are conducted, including items like operational constraints, the amount of time provided for speaking, how to make statements, as well as how to communicate before and after meetings. These will be important in helping them communicate their arguments in an appropriate manner. Below, we will introduce some of the particularly important points for contributing to achieving the objectives of meetings.

Working with various stakeholders and holding constructive discussions

Government meetings are places where committee members with different positions, opinions, and interests must reach consensus on single policies. This is difficult to achieve if members are unwilling to budge on their own positions and are critical of each other. Serving as a member of such committees requires participants to be willing to contribute and cooperate toward achieving the meeting's objectives. Even when other committee members represent different positions or opinions, participants must have a mutual understanding and engage in constructive discussions. There are also important aspects to representing the positions of patients and citizens; namely, those who do so must not be afraid of confrontation and be willing to assert themselves in a calm and courageous manner. They must learn to be cooperative while being assertive and consistent regarding their important points.

Speaking effectively when time is limited

All committee members must be able to communicate their points clearly and concisely in a limited amount of time. Patient and citizen committee members must learn to prepare in advance by arranging the main points of their statements to provide explanations that stakeholders in different positions will find easy to understand. They must also be prepared to speak persuasively to ensure that patients' and citizens' voices are communicated clearly at meetings. To assert the needs of patients and citizens, they should utilize impactful information such as objective data or narratives that convey the real voices of these parties.

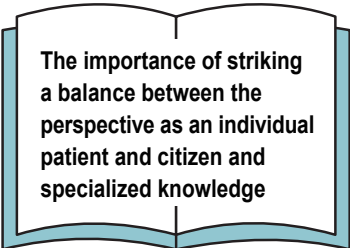


The endeavors of patient and citizen committee member and the support systems for committee members

I have been a member of the MHLW Health Sciences Council Subcommittee on Pharmaceuticals and Medical Devices as a patient and citizen representative since 2021. Even though I have professional experience at a medical device manufacturer as well as personal experiences as a mother of a child with dysphagia and as a patient group administrator, when I first started attending meetings at the Subcommittee, I did not understand its themes and could barely keep up with discussions.

To effectively communicate my opinions during these highly technical discussions, first, I began by researching the history of the Council and by looking up content from related fields to get an overall picture of the Subcommittee I was participating in. It also took support from people with the MHLW Secretariat and other more experienced committee members as well as completing a private sector training program before I was able to understand the content of the meetings and could speak up. Participation in meetings definitely requires a certain level of knowledge and self-improvement in order to acquire that knowledge, but I find it rewarding to be able to share my views from the perspective of a patient and a citizen in such an important decision-making forum.

Kyoko Yamuchi (Representative, Swallow Association)



The importance of striking a balance between the perspective as an individual patient and citizen and specialized knowledge

In the past, I have participated in meetings of the MHLW and the PMDA as well as on ethics review committees at advanced treatment hospitals. It has only been a few years since I began attending such meetings, but each time I do so, I feel that members of the public need to study before attending. Because of this, I attend advance briefings from parties like the Government as well as look up information on my own. At the same time, participating in meetings provides me with opportunities to hear the opinions of health professionals, and there are many lessons I can learn from them.

Personally, I think I should take care not to forget my position as a patient and citizen committee member and the fact that I am not an expert. For example, when examining explanations written for patients that are handled by bodies such as ethics review committees, I think it is the role of a patient and citizen committee member to provide a layperson's perspective on whether the explanations are easy to understand for patients or their family members who may be reading them for the first time. However, as I gradually build experience attending such meetings, I may begin to lose my sense of what it feels like to read such documents for the first time. This has reaffirmed for me the importance of always going back to the starting line and not forgetting the perspective of the individual patient and citizen while working to acquire the necessary knowledge.

Junko Sakamoto

Advance preparations for effectively participating in government meetings

Compared to other methods of involvement, people must possess certain skills in order to participate in government meetings as patient and citizen committee members. While making the most of support from parties around them such as the government or other related parties, patient and citizen committee members should confirm the following items in advance (Figure 8).

Figure 8: Checklist before attending a government meeting

Preparedness

- Keep in mind that you are speaking from a broad perspective that represents the voices of multiple patients and citizens

Knowledge

- Identify terminology for diseases and other healthcare topics that are related to the agenda of the meeting you are attending
- Confirm that you know the purpose and placement of the meeting you are attending

Decorum

- Keep in mind that you must cooperate with participants from various positions and hold discussions that are constructive
- Time is limited, so be prepared to share your opinion in a clear and concise manner



3-3. Cultivating the ability to take part in PPI

Utilize training accordingly based on the objective

There are a variety of training programs available that people can use to acquire the knowledge and skills they need to make the most of their expertise as patients and citizens. These programs range from those provided by the government to those offered by academic societies, civil society groups, and the private sector. Many focus on specific diseases or disorders or the areas each organization is involved in, such as peer support, medical research, or health policy. The themes of these programs sometimes temporarily include recent trending topics, as well. There are also some that provide learning opportunities about PPI in general.

These training programs vary widely in terms of content and purpose, so participants will need to choose those that best suit their own interests and goals. Their first step should be considering how to utilize their knowledge and experiences in their activities moving forward, which will lead them to the next step. By closely reviewing their expertise as an affected party, they will be able to clearly see the skills they have and the ones they should build for their activities in the future. It is important they choose fields that interest them while paying attention to the method of involvement, and after completing the program, to organize their experiences with involvement and what they learned.

Column

Providing systematic learning opportunities and sorting what one has learned: Best practices from the area of cancer research

Recently, a large number of training programs and seminars for patients and citizens have become available. While this increase has made it possible for many people to attend such programs, it has resulted in a number of issues from the perspectives of patients and citizens. For example, they may find it difficult to understand which program or seminar they should attend, or they may have trouble organizing their training history and end up joining seminars covering content that they already know. A framework must be created that enables patients and citizens to systematically organize their learning and use it to build up careers.

In the area of peer support, there are joint efforts from the public and private sectors to identify the qualities that peer supporters need for each objective of peer support and to establish a curriculum to help people develop those qualities. However, the qualities patients and citizens must possess to participate in research and policy have not been completely identified. In the future, we hope that a shared curriculum will be established and that systematic training will be provided.

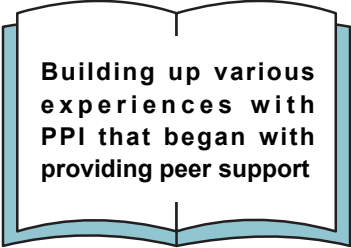
Given these circumstances, a new endeavor in medical research on cancer is currently underway at a website called the "Learning Plaza for PPI in Cancer Research."² The site has compiled information on the desirable skills and qualities for PPI in medical research on cancer and provides a systematic curriculum on those traits. A curriculum code has also been established that clearly positions each training program or seminar in the overall curriculum. It is currently being used to develop educational content.

This system has made it easier for patients and citizens to select training programs and seminars to attend in accordance with the curriculum as well as to keep track of the lessons they have learned. It also provides a number of benefits for the people providing training programs by allowing them to provide brief descriptions of training program objectives and content as well as by making it easier for users to find information on training programs. This system is currently being used to connect training providers and attendees by the Japanese Society for Palliative Medicine and the Japan Society of Clinical Oncology. While using this innovative effort as a point of reference, we look forward to seeing further progress in efforts to identify the necessary qualities for each opportunity for involvement and to establish systematic training systems.

Gaining experience participating through opportunities in one's immediate surroundings

While each involvement opportunity has some unique necessary skills, some skills are common to all PPI opportunities. For example, providing peer support inside and outside of healthcare facilities can be a source of useful experience for participating in medical research or health policy. There are also various stages of involvement in each field. Having experience being involved in each of those stages can elevate one's expertise as a patient and citizen. For example, the experience of attending workshops hosted by the local government in one's own community can be useful when attending government meetings.

There are various hurdles patients and citizens must clear to serve as committee members for the national government, especially if they are working alone or if such opportunities emerge unexpectedly. However, efforts to diversify methods of delivering the voices of patients and citizens to healthcare are advancing, and there are many opportunities for them to participate in a more carefree manner. These may include cooperating with other parties close to them such as patients and citizens, healthcare providers, and local governments. Starting out with PPI in more familiar settings allows people to contribute to the daily lives of patients and citizens who need help while building the skills they need to actively serve as patients and citizens.



Building up various experiences with PPI that began with providing peer support

About 20 years ago, I was diagnosed with schizophrenia and was hospitalized a number of times. Among my memories of that period, the feelings of warmth and encouragement I received from communicating with people who shared my hospital rooms are particularly strong. It was the first time I experienced how valuable it can be to connect with other affected parties who share your position. I later experienced many twists and turns that led to my involvement in a number of groups including patient groups for people living with mental disorders, liaison groups that represented various disabilities, and community self-support councils.

I am currently engaged in social action that involves cooperating with other people in similar positions to compile surveys and research among affected parties, to generate recommendations to convey our opinions as a patient advocacy organization, and to identify problems with existing systems and frameworks. Through my relationships with people involved in research, I am focusing on a research method that places affected parties in a central role called "user-led research." Working together with the National Center of Neurology and Psychiatry, I am currently researching how to advance user-led research through a project on disaster prevention-related investigative activities.

I feel that my past activities at a patient advocacy organization and experiences being involved in the field of research have been very useful when participating in MHLW and Cabinet Office study groups. I feel that my awareness toward delivering the voices of various affected parties (a key role as a patient advocacy organization representative) and my ability to express those voices to shape policy have been fostered through each process and are always useful for whatever initiative I am involved in next.

Although it may seem like there are high hurdles to participating in research and policymaking, viewing it in broad terms, I think these are ways to be connected to society through the perspectives of affected parties. My first connections were encounters with affected parties I shared hospital rooms with and who lived in my community. My involvement in a patient advocacy organization gradually expanded to involvement in policy and research. However, in the area of mental diseases, there are a number of lingering issues for PPI resulting from stigma and circumstances that make it difficult to clarify the position of mental disorders. I think that first, it will be important to create opportunities for affected parties to connect with each other over their lived experiences and positions, such as through peer support activities, in areas that are close to them.

Yuhei Yamada (Representative Director, Porque, the Organization of Persons with Psychosocial Disabilities)

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Afterword: The roles of patients and citizens in achieving better healthcare

When a “citizen” becomes a “patient,” the change is sudden. In 1990, I was diagnosed with ovarian cancer just before turning 25. This was before the concept of informed consent was generally well-known, and no matter how much I wanted to have an accurate understanding of my condition, I was not even told its name. My experience as a patient then led me to develop a strong awareness of the need for communication in healthcare settings, so I joined COML after my treatment had finished.

My first involvement in COML activities was providing telephone consultations. I provided many patients with telephone consultations during which I listened to their problems and worked with them to think about how they could proactively address them. To date, COML has handled almost 70,000 telephone consultations. Of those, I have personally handled 25,000.

I am currently involved in a wide range of activities that include lecturing at places like hospitals, organizations related to healthcare, conferences, and universities. I also work to raise public awareness toward healthcare. The foundation of these activities is my lived experience as a patient and the many voices of patients and their families that I heard while providing telephone consultations. On top of that, taking part in many discussions on healthcare in general at the MHLW and other councils and study groups has led to my involvement in highly-specialized activities, such as the formulation of policy recommendations.

We are moving from the era in which patients and citizens were passive recipients of healthcare into one in which they participate and collaborate in it. Patients’ and citizens’ voices are now needed more than ever before, and there are more opportunities for them to be involved in policy. That is why we, as citizens and patients, must understand and calmly face the challenges, limitations, and uncertainties of healthcare. It is my sincere hope that many people will take a greater interest in healthcare, cultivate healthcare literacy, and step forward to participate so that we can achieve better healthcare in the future.

Ikuko Yamaguchi (Chief Director, Consumer Organization for Medicine and Law (COML))



Acknowledgements

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Disease Control Division, Healthcare Department, Saitama Prefecture
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Dementia Policy Unit, Scottish Government

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Health and Global Policy Institute: Guidelines on Grants and Contributions

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