ECONOMIST IMPACT

Empowering the patient voice in healthcare decisions

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About this report

Empowering the patient voice in healthcare decisions is an Economist Impact report, sponsored by Janssen. This report aims to examine patient empowerment in the Asia-Pacific region and compare it with best practices globally, as well as examine how the patient voice can be empowered when decisions are being made about individuals' health.

The report is informed by both desk research and in-depth interviews with experts from patient groups, non-governmental organisations, regulatory bodies and academic institutions. We would like to thank the following individuals (listed alphabetically) who have generously contributed their views and insights for this report:

- Axel Mühlbacher, Professor of Health Economics and Healthcare Management, Hochschule Neubrandenburg, Germany
- Amy Jackson, Japan Representative, Pharmaceutical Research and Manufacturers of America (PhRMA), Japan
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- Jin-Young Paik, Representative, Korea Kidney Cancer Association, Korea

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- Shi Li Zheng, Director, Health Systems Analytics Research Center, Tulane University, US
- Wang Yiou, Secretary-General, Illness Challenge Foundation, China
- Wendy Benson, Administration Manager, Australian Patients Association, Australia

The views of interviewees are their own, and not necessarily those of their affiliated institutions.

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Executive summary

In the Asia-Pacific region, the cost and future sustainability of healthcare systems is a major concern for governments, driven in no small part by rapidly ageing populations. As governments continue to grapple with the economic impact of covid-19 and seek to arrest any declines in population health from missed or forgone medical care, their interest in measures that could enhance the efficiency and sustainability of healthcare systems will be heightened. In this context, we explore the role of patient empowerment and the significant opportunities that it offers to drive more sustainable and equitable healthcare systems in the region.

Patient empowerment is multifaceted, and there are different opinions as to what patient empowerment involves. Some view it as a process, while others consider it both a process and an outcome. Patient empowerment can be viewed as part of a patient journey, where, partly through increased health literacy, patients become both more aware of decisions regarding their health and better equipped to make them.

While patient empowerment entails having the capacity and opportunity to engage in shared decision-making, it extends beyond the clinical setting, into the patient's community and across the wider healthcare system. Patient empowerment facilitates the acquisition of self-management skills that patients require to better care for themselves within their own community, while also enabling them to understand, participate and contribute towards decisions about their health.

Patients who actively engage with and participate in decisions about their health are more likely to stick to and be satisfied with their chosen treatment path. When patients are empowered to be part of the decision-making process, they are also more likely to build better and more trusting relationships with their healthcare providers, which enables them to work as partners in achieving better health outcomes. This shared decision-making, based on a foundation of mutual trust and shared goals, drives more appropriate and effective use of healthcare resources and better health outcomes, potentially eliminating wastage or unnecessary costs in the health system.[1,2]

Interest in increasing the level of patient involvement in healthcare decisions has been rising among patients, the public and

policymakers in recent times. In particular, the US and Europe have formalised measures to improve the level of patient engagement in their medicine regulation and reimbursement systems.[3-6] Despite these positive steps, the systematic, meaningful involvement of patients in decision-making across health systems remains more of an aspiration than a reality around the world, and particularly in the Asia-Pacific region.

Through our analysis, we have identified the following key takeaways:

A concerted multi-stakeholder effort is required to empower patients

Empowered patients are more likely to be satisfied with their healthcare, enjoy a better quality of life and have better health outcomes. For patients to be empowered, however, all stakeholders in the health system need to recognise the importance of shared decision-making and work together to build capacity and opportunity, using a combination of strategies. Governments must lead national efforts to enhance patient empowerment through policies and legislation. Healthcare professionals must be both willing and able to support shared decision-making. Patients must have access to knowledge and skills, as well as an environment that enables them to be truly empowered to make decisions about their health. As not all health systems in the region are starting from the same baseline, each requires varying interventions and improvements that are based upon their current health system needs and development.

Culturally relevant approaches to shared decision-making—developed in partnership with healthcare professionals and patients—are needed

The experts we interviewed spoke of the paternalistic nature of the healthcare professional-patient relationship across many countries in Asia, and how it impedes shared decision-making. The concept of shared decision-making has been developed and refined largely in Western populations, and some stakeholders have questioned its suitability in an Asian context. Research on the development, testing and implementation of shared decision-making tools for patients in Asia-Pacific countries such as China is lacking.[7] Despite this, surveys show that most young clinicians in China want to participate in shared decision-making with their patients.[8]

There needs to be a shift from paternalistic to patient-centred care models founded on the fundamental right of patients to participate in decisions about their healthcare. Cultural sensitivities and personal preferences must be taken into account when designing health-communication models and tools, such as patient decision aids for shared decision-making. Healthcare professionals need training on how to properly assess their patients' health literacy and support them to make health decisions by discussing options, potential benefits and harms, as well as their personal values and preferences.

Culturally relevant approaches to shared decision-making are needed. While global resources exist, it is not possible to simply adopt them as they are—they need to be adapted, through collaboration with all relevant stakeholders, to ensure that they are culturally appropriate.

Health and media literacy should be prioritised in national healthcare policies across the region

The proportion of people with limited and inadequate health literacy across the Asia-Pacific region is worryingly high. These estimations range from almost half in Australia to over 85% in Japan.[9,10] This shortcoming has prompted governments in the region to make health literacy a priority. Australia's National Statement on Health Literacy is designed to drive national and community initiatives on health literacy; China has government-driven National Health Literacy Promotion initiatives; and researchers in Japan have piloted educational programmes to increase health literacy in clinical and community settings—although it is not known if such programmes have been adopted in practice.

Patient groups, medical societies and non-governmental organisations play key roles in helping to improve health literacy. The experts that we interviewed for this research said that more efforts are needed to address low health literacy and combat misinformation, especially among disadvantaged groups such as migrants, the elderly, minorities faced with language barriers, and those of lower socioeconomic and educational status.

The internet is a catalyst for patient empowerment, but its capacity as a source of misinformation makes it a double-edged sword, as has become abundantly clear during the pandemic. On the one hand, the internet has reduced the traditional asymmetry in access to information between doctors and patients and given rise to "peer-to-peer healthcare", where patients exchange information and experiences with others. This can prompt discussions between patients and doctors about alternative approaches to their healthcare. On the other hand, misinformation can mislead and even disempower patients, turning them away from positive health-seeking behaviour and encouraging them to disengage from discussions about their healthcare. Therefore, approaches to improve the health and media literacy of the public are essential. Significant insights into how to achieve this are starting to be realised because of the covid-19 pandemic.

Systematic processes must be implemented to involve patients in drug approval and reimbursement decisions in a meaningful way

Patients are seldom involved in decisions related to drug approval or reimbursement in Asia. Australia has processes in place to gather consumer comments, and to involve patient or consumer representatives in committee meetings for health technology assessments (HTAs). However, the burden of input lies on the patient group or patient. In Korea, patient groups do participate in HTAs, but only in the final stage of approval and not at the initial stage of discussion. The opportunities for patients to be involved or engaged in drug development design or approval are very limited in China and Japan, and there is no clear process.

There is a lack of clear, transparent methodologies on how to engage with patients in a meaningful way, specifically how to solicit and process their knowledge and input to inform drug approval and reimbursement processes. Patients, policymakers and industry alike need clear guidance on how to ensure that patients are part of the decision-making process, and more needs to be done to formalise the structure of engagement to move from ad hoc to regular

interaction and the co-creation of solutions. It is also important to build the capacity of patients to contribute to the regulatory and reimbursement decision-making process in a meaningful and informed way.

Patient preference studies, which provide quantitative data from a large sample of patients, have the potential to be utilised in decisions regarding the approval and reimbursement of medicines. Such studies have increased in recent years and have demonstrated that patient preference data can be used to guide drug development and inform regulatory approval and reimbursement decision-making. Patient preference data can inform multiple aspects of the health system and have great potential in pushing health systems further in their quest to provide more patient-centred care. Systematic use of patient preference data across industry, regulatory and HTA processes will truly empower the patient voice in healthcare decision making.

With governments potentially making difficult decisions about the prioritisation of health spending, the systematic and meaningful involvement of patients in decisions impacting their health has never been more important.

Chapter 1.
Exploring patient empowerment

Why empower patients?

It is widely acknowledged that patient empowerment benefits healthcare systems by improving health outcomes.[1] When patients are empowered to take responsibility for their own health through partnerships with health professionals, they take steps in health maintenance and disease prevention, seek earlier diagnosis and adhere to treatment, all of which can reduce healthcare costs in the long term.[2]

The World Health Organization (WHO) defines patient empowerment as "a process through which people gain greater control over decisions and actions affecting their health, and as such individuals and communities need to develop skills, have access to information and resources, and the opportunity to participate in and influence the factors that affect their health and well-being."[13] The EU Joint Action on Patient Safety and Quality of Care defines empowerment at the individual level as "a multi-dimensional process that helps people gain control over their own lives and increases their capacity to act on issues that they themselves define as important," while collective empowerment is "a process through which individuals and communities are able to express their needs, present their concerns, devise strategies for involvement in decision-making, and take political, social and cultural action to meet those needs."[1]

What is patient empowerment?

Patient empowerment is a multifaceted concept with no universally accepted definition.[11,12] Different stakeholders have different interpretations of what patient empowerment is, running the gamut from theory, process, intervention, outcome, feeling to paradigm. The majority of definitions regard patient empowerment as being both a process, whereby a patient acquires greater knowledge and capacity, and an outcome, whereby a patient has more autonomy to make informed decisions regarding their health.

Notably, the EU's Health Program uses the term "people empowerment", on the basis that gaining control over decisions and actions affecting health is important for healthy people as well.[14] While we acknowledge this, the term "patient empowerment" is useful to distinguish it from other economic or social inequalities.

When used broadly in the healthcare context, the term "patient" does not just refer to people who are unwell; it also includes anyone who receives medical intervention or advice, such as a healthy person getting vaccinations, or a pregnant woman having antenatal check-ups.

We view patient empowerment as part of a patient journey, where health literacy empowers patients so that they are more aware of their health, and better equipped to make decisions about it. Patient empowerment entails having the capacity and opportunity to engage in shared decision-making and extends beyond the clinical setting into the patient's community and across the wider healthcare system. Patient empowerment facilitates the acquisition of self-care skills for patients to manage their health within their community, while also enabling them to understand, participate and contribute towards healthcare system design and delivery. Importantly, there must be a facilitating environment to achieve patient empowerment. The structure and design of the health system must be able to support the processes of patient empowerment and provide avenues for meaningful patient participation. Notably, health equity and equitable access to healthcare are foundational to patient empowerment (see Box 1). Following this view, we explore patient empowerment at the individual level, including crucial factors such as health literacy,

Box 1. Urgent need to improve health equity and access, the foundation of patient empowerment

According to the World Bank and the WHO, half of the world lacks access to essential health services.[15] The table below shows the WHO's universal health coverage (UHC) index of essential service coverage in selected countries:

Country	UHC index of essential service coverage (%)
Australia	87
China	79
Denmark	81
Japan	83
South Korea	86
US	84
UK	87

Source: The Global Health Observatory, World Health Organization, 2017

shared decision-making and patient-reported outcome measures (PROMs). We also look at patient empowerment at the healthcare system level, including how the patient's voice can be incorporated into regulatory processes and health technology assessments.

1.1 At the individual and community levels

At the individual level, patient empowerment involves gaining personal skills and knowledge, whereas at the community level, it involves connecting with other patients for mutual support or information sharing, or to form patient advocacy groups.[16]

Health literacy

Health literacy is a key aspect of patient empowerment at an individual level. Commonly defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions", health literacy is recognised as an important factor in health behaviours, healthcare and overall health status.[17] While the impacts of health literacy and patient empowerment are deeply intertwined, high literacy may not necessarily entail empowerment and vice versa.[18]

At its core, health literacy refers to patients' capability of making good, informed decisions related to their health, whereas patient empowerment grants patients the responsibility to make these decisions. According to the health-empowerment model developed by Peter J Schulz and Kent Nakamoto, two experts in health communications, mismatches can have damaging consequences—high health literacy with low levels of patient empowerment causes patients to be unnecessarily dependent on healthcare professionals, resulting in a waste of resources, whereas a high level of patient empowerment with low health literacy presents a risk of dangerous or suboptimal health choices (Figure 1).[18]

The role of the internet

The internet has democratised health by reducing the traditional information asymmetry between doctor and patient. More than 80% of Internet users search for health-related information online.[19] By becoming better informed, patients can actively participate in consultations and decision-making, altering the doctor-patient relationship. The internet and social

Figure 1. Relationship between health literacy, patient empowerment and patient behaviour

		Patient Empowerment	
		Low	High
Health literacy	High	Needlessly dependent patient	Effective self-manager
	Low	High needs patient	Dangerous self-manager

Reproduced from *Patient Educ Couns.* 2013;90(1):4-11.

media have also given rise to "peer-to-peer healthcare", where patients exchange information and experiences online.[20,21] Some may even form organised patient groups (see chapter 1.3). Multiple studies have shown that social media makes patients feel empowered.[20] However, the internet is a double-edged sword (Figure 2) on which a large amount of misinformation and disinformation circulates, as has been apparent throughout the covid-19 pandemic. Disturbingly, a review found that patients may disregard high-quality information if low-quality (biased or inaccurate) information is easier to understand or more engaging.[22,23]

Cultural differences may impact preferences in online health information. A survey found that Koreans and Hongkongers showed more trust in experience-based health information sources, such as blogs, online support groups and social networking sites than Americans, whereas Americans showed a stronger preference for using expertise-based sources than Koreans and Hongkongers.[24]

In a situation of widely and easily available health information, misinformation and low health literacy are legitimate threats to public health, and this has never been more apparent than during the covid-19 pandemic. For example, an analysis undertaken in April 2021 into how communities on Facebook promoted covid-19 vaccine misinformation in the Netherlands found that anti-vaccination communities on social media downplayed the severity of covid-19, undermining nationwide efforts to tackle its spread and promoting anxieties about the vaccine. Over a six-month period, membership of groups on Facebook promoting anti-vaccination messages almost doubled, from about 480,000 followers in October 2020 to more than 780,000 followers in April 2021. Concerningly, not only was covid-19 vaccine misinformation shared internationally, further compounding vaccine hesitancy at critical stages in the pandemic, it was also not fact-checked by most of the relevant social media platforms.[25]

Figure 2. Positive and negative effects of the internet on patient empowerment

Positive/empowering effects	Negative/disempowering effects
Patients gain easy access to medical information.	Patients may encounter inaccurate or conflicting information or face information overload.
Patients are able to connect with others and provide mutual support.	Patients may experience cyberbullying or negative comments online.
Patients can share and exchange experiences, to gain tips on managing their condition or review medical services received, for example.	Experiences are subjective. Patients may be unduly influenced by others' experiences (for example, they may reject treatment because someone else experienced a side effect).
The internet provides a platform for healthcare professionals, scientists, health authorities and other reputable sources to disseminate information to patients.	Misinformed groups (antivaxxers being one example) also use the internet to lobby for their agendas, which may confuse and mislead patients.

The consequences of health misinformation disproportionately affect disadvantaged communities. Barriers to accessibility, language constraints and (lack of) content relevance can all exacerbate the negative effects of the proliferation of health misinformation.[19] Health misinformation needs to be addressed from multiple perspectives, and health literacy is a key component. Media organisations have a role to play in addressing the issue, as do health and patient organisations. An example of positive action being undertaken to enhance health literacy by international health organisations in the context of covid-19 is Share Verified, a UN collaboration with Purpose, a communications agency that focuses on social impact, to cut through the noise to deliver lifesaving, evidence-based information.[26]

Shared decision-making

Shared decision-making (SDM) is one way to empower patients in clinical care settings.[27] It is the process whereby a clinician and a patient jointly make a health decision after discussing options, potential benefits and harms, and considering the patient's values and preferences.[28] This approach recognises that clinicians and patients contribute different yet equally essential forms of expertise to the decision-making process.[29] The clinician's expertise is based on biomedical knowledge and practical experience in treating diseases, whereas patients are experts on the experience of the disease in their lives, and their attitude to risk, values and preferences.[30]

Patients' views may differ from doctors, but SDM recognises patients' rights to make decisions about their care while ensuring that they are adequately informed about the pros and cons of each option. For example, a patient preference study in South Korea highlighted significant differences in treatment choice, with healthcare professionals assigning higher relative importance to efficacy, while the patient group tended to value safety and tolerability more. There is compelling evidence that patients who actively participate in managing their health have better outcomes than patients who are passive recipients of care.[30]

Notably, the SDM paradigm has been developed and refined largely in Western populations, and some have questioned whether SDM may be transposed to the Asian context.[31] The traditional relationship between patients and healthcare professionals in most Asian countries is often characterised as paternalistic.[32] Some Asian cultures do not have a tradition of individuals making autonomous decisions in this context. The experts that we spoke to observed that some patients actually prefer doctors to make decisions for them, and may even feel lost when presented with several options. In addition, the process of SDM is time-consuming, and not every doctor is able or willing to spend time on it. Other barriers to SDM include poor patient-doctor communication, which may also stem from the lack of time to explain medical terms properly, lack of information and low health literacy levels.

Whilst SDM may not have the same level of uptake in Asia to date, experts believe that it should not be discounted. Engagement with doctors and patients is needed to better understand the barriers and potential pathways to enable SDM in ways that are culturally appropriate.[33] A wealth of global resources is available to support shared decision-making; however, these would need to be adapted, through collaboration with all relevant stakeholders, to ensure that they are culturally appropriate.[34]

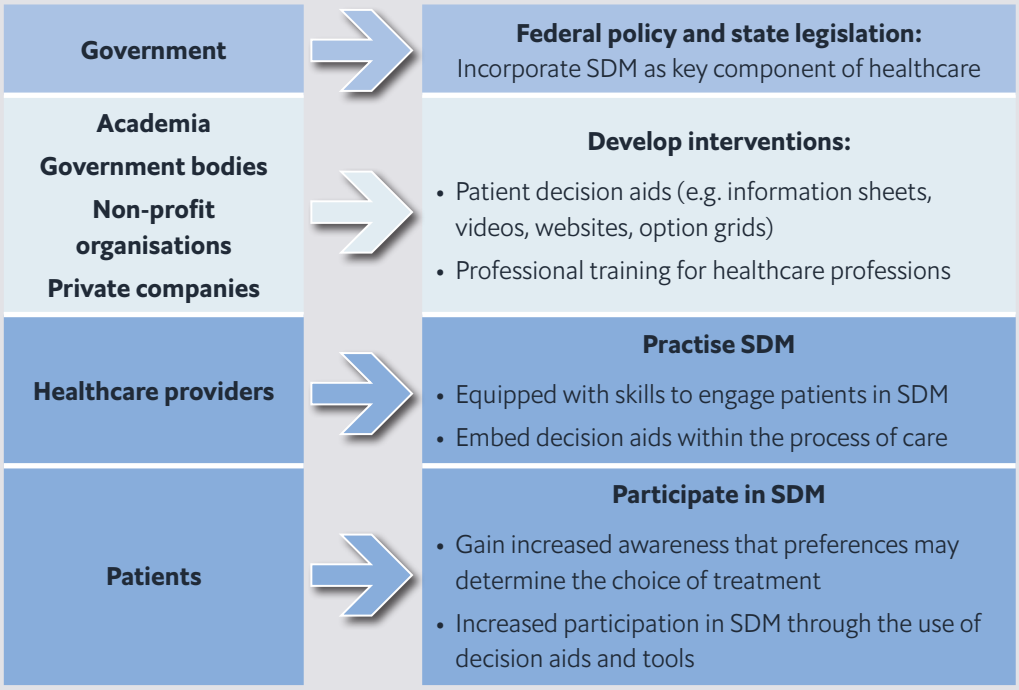
In all cultures, there will be some patients who would prefer their doctor, or another person who they trust, to make healthcare decisions for them. Regardless, the basic premise of SDM—that patients fundamentally have the right to make decisions about their care—remains relevant across cultures, regardless of whether patients choose to exercise that right or not.

With short consultation times recognised as a barrier to SDM implementation in Asia, it is noted that decision aids are one useful resource that can facilitate SDM without substantially increasing consultation times.[37] Best practice is to provide doctors, and other members of healthcare teams, with the skills to engage patients in SDM, in conjunction with the provision of decision aids for patients. This training should be provided by organisations with suitable expertise and should include techniques that encourage the involvement of the patient and their loved ones in the decision-making process.[37]

Best practices for implementation of SDM

Some countries, including the United States and Canada, used multifaceted interventions targeted at systems or practices to implement SDM (**Figure 3**).[35,36]

Figure 3. Multi-pronged approach to implement SDM



1.2 At the healthcare-system and policymaking level

Patients perceptions of their health and experiences

Measuring patients' perceptions of their health and experiences is key to providing high-quality patient-centred care, and PROMs, along with patient-reported experience measures (PREMs), are often used to standardise this feedback from patients.

A review on the development of 193 PROMs found that a quarter of PROM development studies did not involve any patients. [40]

PROMs measure patients' views of their health status, while PREMs measure their views of their experience while receiving care. This approach gives voice to the patients' evaluations of the healthcare that they have received and links those evaluations to healthcare funding, thereby empowering patients.[38]

These data are collected and used in research, quality-improvement projects, clinician performance evaluation, audits and economic evaluation. In 2005-17 45.1% of the trials registered in the Australia and New Zealand Clinical Trials Registry included PROMs, and the proportion increased over this period. PROMs have also been used as a measure of patient empowerment.[38] Countries that collect PROMs data routinely at the national or jurisdictional levels include England, Canada, the Netherlands and the US.[39]

Although use of PROMs is relatively established, patient involvement is lacking in their development. A review on the development of 193 PROMs found that a quarter of PROM-development studies did not involve any patients.[40] Patients were most commonly involved in item development (58.5%) and testing for comprehensibility (50.8%), but few were involved in determining which outcome to measure (10.9%).[40] To truly capture patients' perspectives, patient involvement is essential, as only patients can determine which outcomes are relevant to them.

The development of a definitive and robust patient-empowerment-driven PROM is full of challenges. Reviews have found that PROMs measure different constructs of patient empowerment, and even tools designed to measure the same construct in the same type of patients were found to ask very different questions.[41] Measures can be generic or disease-specific (as patient empowerment often leads to different outcomes) and have different mechanisms depending on the type of disease (Figure 5).[20]

PREMs, which assess patients' needs and experiences during care, are growing in popularity. They have been used across health services in many countries, including the UK, Canada, Australia and South Korea.[42-45] Usually administered in the form of surveys, questions cover a range of aspects including patients' perception of the accessibility and quality of services, as well as interactions with healthcare professionals and whether they show empathy, compassion and respect, and involve patients in care decisions.

Importantly, studies have shown that patient experience is consistently positively associated with patient safety and clinical effectiveness across a wide range of disease areas, population groups and outcome measures.[46,47] Patient

Figure 5. Patient empowerment has different mechanisms depending on the type of disease

Type of disease	Mechanisms of empowerment
Common chronic diseases such as type 2 diabetes and psoriasis	Successfully managing the condition in daily life, with lifestyle changes
Poorly understood diseases such as ADHD, Fibromyalgia and chronic fatigue syndrome	Being diagnosed and accepted as someone who has the disease in order to get access to medicines without prejudice
Rare diseases such as amyotrophic lateral sclerosis (ALS) and fibrodysplasia ossificans progressiva	Getting information about the condition, obtaining the right diagnosis, access to an expert with experience, access to new or experimental medicines

Adapted from *BMC Med Inform Decis Mak.* 2015;15(1):1-9.

experience is a pillar of quality with clinical importance; it has been positively associated with self-rated and objectively measured health outcomes, adherence to recommended treatments, preventative care such as the use of screening services and immunisations, healthcare resource use such as hospitalisation and primary-care visits, technical quality-of-care delivery, and adverse events.[46]

Therefore, PREMs may be used to identify strengths and weaknesses of healthcare delivery, drive quality improvement, monitor healthcare delivery over time, benchmark experience across various institutions, and promote patient choice, serving as an avenue for patients to be heard.

Regulatory processes

In the US and Europe, a range of initiatives have been established to facilitate patient involvement in regulatory processes. In the US, the Prescription Drug User Fee Act (PDUFA) aims to enhance patient involvement in drug development and expedite the drug-approval process. Part of the PDUFA is a patient-focused drug-development programme to obtain patients' input on their conditions, the impact on daily life and available therapies. This establishes the context in which regulatory decisions are made.

In Europe, the European Medicines Agency (EMA) and European Patients' Academy on Therapeutic Innovation have published guidance for patient involvement in regulatory processes (Figure 6).[49-51] Transparency in the regulatory process is enhanced, and patients gain more trust in regulatory processes. Patient preference studies are highly relevant, as they enable regulators to understand whether there are subgroups of patients with different preferences concerning the benefit-risk trade-off for new drugs.[52]

In benefit-risk discussions, patients bring "a unique and critical input based on their real-life experience of being affected by a disease and its current therapeutic environment," says the EMA. "This element fills a gap that other scientific experts cannot fill, and which has proven necessary to achieve the best possible results within the regulatory process."[51]

Case study: A discrete choice experiment study to uncover preferences for a covid-19 vaccine in China

Researchers in China assessed preferences for a covid-19 vaccine using a discrete choice experiment (DCE) among the general population, via an online survey.[48] The DCE examined vaccine preferences across six attributes: effectiveness, duration of protection, side effects, frequency of injections, price and origin of the product. Each participant completed ten choice scenarios that asked participants to choose between two slight variations of the attributes in each set.

Over 1,200 people participated in the research, demonstrating the utility of DCE methodologies in garnering patient or public preference information from a large sample. The attribute identified as highest preference was "effectiveness of the vaccine" to the public in China, followed by "long protective duration", "very few adverse events" and "being manufactured overseas". Interestingly, the least important attribute affecting public preference in selecting the covid-19 vaccine was cost.

Attribute	Treatment A	Treatment B
Effectiveness (%)	 90	 70
Protective duration (months)	 12	 18
Adverse event	 No reaction	 Fever 1-2 days
Frequency of injection	 3	 1
Price (CNY)	 200	 800
Place of origin	 Domestic	 Imported
Select vaccine option		

Figure 6. Opportunities for patients and patient organisations to participate in EMA regulatory processes

Where[50]	For what	When[51]
• Governance of the EMA via the Management Board • Members in scientific committees • Consulted by Scientific Advice Working Party and scientific advisory groups • Consulted by the EMA scientific committees	• Consultation on guidelines and policies • For benefit-risk discussions • Reviewing documents destined for the public • Disseminating information, participating in workshops, networks and research projects	• Regulators are undecided on a marketing authorisation application for an unmet medical need • Regulators want to assess impact of recommendations to maintain, suspend, revoke a marketing authorisation or restrict the indication of a medicine • Regulators are seeking feedback on a risk-management plan • Regulators need a review of information on the package leaflets • A company decides to withdraw a medicine from the market • There is a potential shortage in supply of a medicine

Health technology assessment (HTA)

Involving patients in health technology assessment (HTA) and reimbursement decision-making is a key step towards empowering patients, and leads to more informed, transparent, accountable and legitimate decisions about health technologies.[53] HTA is defined as a "multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making to promote an equitable, efficient and high-quality health system."[54]

HTAs may be applied to a broad range of activities, including introducing a new medicine into a reimbursement scheme, rolling-out broad public health programmes (such as immunisation or screening), setting priorities in healthcare, identifying health interventions that are cost-effective, and setting prices for medicines and other technologies.

Patient involvement in HTAs can lead to more informed, transparent, accountable and patient-centric decisions about health technologies. Despite these benefits, patients are not always involved in the HTA process. If they are, their involvement is often viewed

'tokenistic', though how and when patients are involved varies substantially between HTA bodies.

A study examined patient involvement in HTA agencies in single-payer countries in Europe, and North America (England, France and Canada) with those in Asia (Taiwan, Japan, South Korea, Thailand). The authors concluded that the degree, methodology, and significance of formal patient involvement differs across countries. England (1999), Thailand (2009), and Canada (2010) were the first to formally involve patients in assessment frameworks, followed by South Korea (2012), Taiwan (2015), and France (2016), while there is no patient involvement within Japan's HTA framework. The greatest level of patient involvement was observed in England and Canada, where patients are involved throughout the HTA process (scoping, evidence gathering, consultation, appeal/ resolution, dissemination, review). Some best practice examples from Canada are detailed in the box below.

Involvement from the outset

The Canadian Agency for Drugs and Technologies in Health (CADTH) seeks patient input from the outset of the HTA process. For each assessment of a new pharmaceutical product, patient groups are invited to submit their views with regard to the impact of the disease on patients and their families, experiences with current therapies, and expectations or experiences regarding the product under assessment. The view of patients is integrated within the assessment protocol and the assessment reports.[56]

Patient-centredness in considering patient-related factors

In CADTH's guidelines, patient heterogeneity in relation to treatment effects is mentioned. An analyst, by means of a modelling study, should uncover heterogeneity in data relating to aspects such as costs, outcomes and patient preferences in stratified analysis.[56]

Using multiple channels to seek the patients' voice

CADTH developed a formal approach for incorporating patients' perspectives on health outcomes and issues in both the assessment and appraisal phases. Calls for patient input and the respective deadline are sought via CADTH's website, e-alerts and Twitter account. Patient views are collected using a Patient Input Template provided online. If no patient input is submitted, CADTH may search for grey literature and/or seek advice from patient groups outside of Canada.[56]

Patients are included in stakeholder consultation

CADTH formally asks for feedback from different stakeholder groups (including healthcare professionals, patients, industry, associations and others) on projects and draft reports. In addition, processes are in place for patient groups to provide input on

pharmaceutical products that are reviewed through the Common Drug Review and the pan-Canadian Oncology Drug Review.[56]

Capacity building via the provision of feedback

CADTH was the first HTA agency to provide patient groups with feedback on the difference that their submission made to the deliberations of the appraisal committee and the resulting recommendations.[57] This mechanism was introduced in 2014, and has since been adopted elsewhere. Patient groups have reported appreciating the personalised feedback, as well as using it to amend subsequent submissions in areas including data-collection methods, direct patient quotations and provision of more detailed explanations.

1.3 Patient groups

Patient groups play an important role in representing the interests of people with a specific health condition, often a chronic or terminal disease. They consist of groups of patients or caregivers in manifold indication areas who often act and organise themselves on a voluntary basis. The often multi-faceted role of patient groups in patient empowerment is highlighted in Figure 7.

In Asia, patient groups are generally not as advanced and sophisticated as in Europe, although the number of patient groups and their roles have been increasing. For example, the Korean Alliance of Patients' Organizations, formed in 2010, was instrumental in instigating the country's Patient Safety Act.

In China, patient organisations focused on rare diseases have been involved in drug development, regulatory approvals, marketisation and the reimbursement process. However, this level of involvement is not uniform across the region.

Most patient groups in Asia offer some form of peer support, either online or in person. Participation in online and peer support groups has been shown to endorse patient empowerment by increasing knowledge and enhancing social wellbeing.[58] Peer support also increases empowerment in terms of self-efficacy (a person's confidence in their ability to act positively towards a health objective), perceived social support and understanding of self-care.

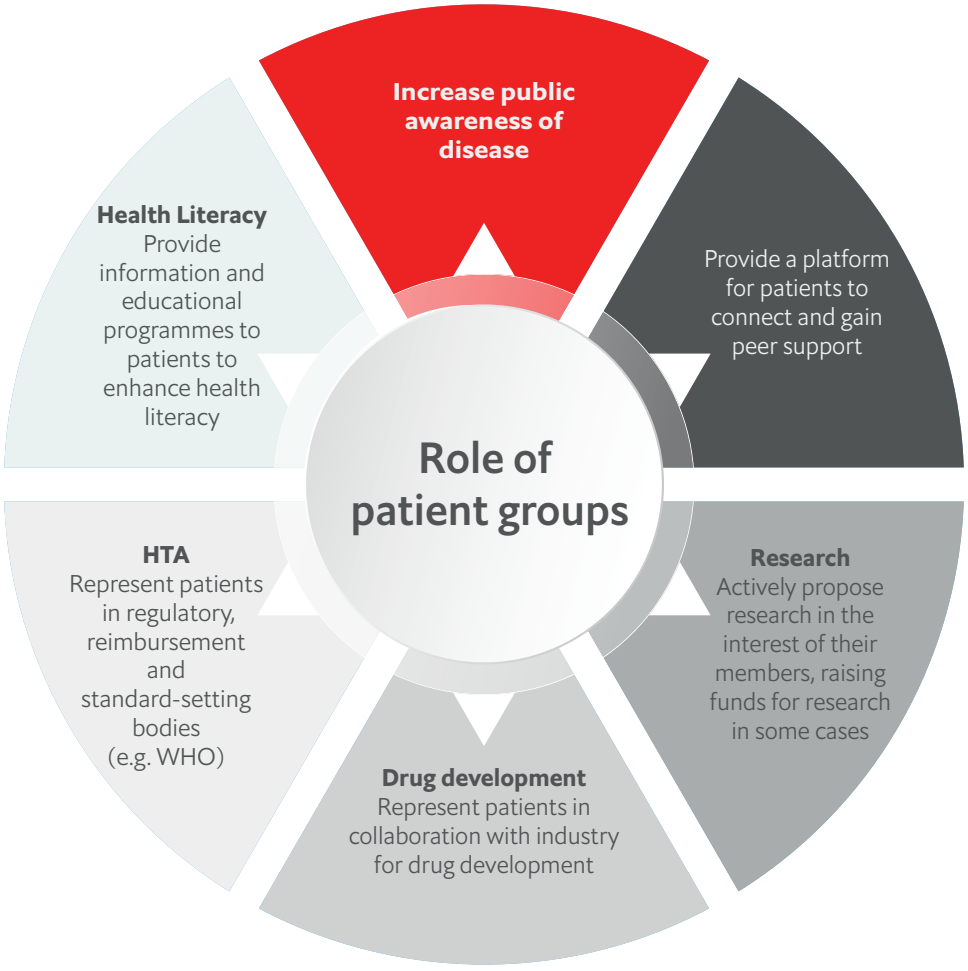
Patient- and community-led groups are now omnipresent in drug-regulatory agencies and global standard-setting bodies, including the WHO and the EMA.[59] In recent years, they have played a pivotal role in elevating the voice of patients and energising the research agenda for many rare diseases and infectious diseases, and some non-communicable diseases. They have been praised by many medical experts as representing an advance in the field of global health.[59]

One example of a group that successfully directed research priorities is the Cystic Fibrosis Foundation. In 2000, there was only one available therapy, however, 12 therapies had been approved by the US Food and Drug Administration (FDA) by 2020. In 2019

this patient-led, donor-funded organisation committed US$500m for research through 2025, in the hope of advancing a cure for cystic fibrosis.[59]

Many patient groups receive financing from industry partners and may struggle to get funding from other sources. This may create conflicts of interests, as patient groups may find it harder to publicly raise concerns about the safety or pricing of a product, in case it may affect future funding. Consumer health organisations often work on educating patients, yet accepting industry funding may result in "perception problems", according to Ann Single, a member of the steering committee of the Patient Voice Initiative, an Australian patient-empowerment organisation. Open and transparent processes, such as disclosing payments received by source and the purpose of support, can help to improve perceptions while retaining much-needed support.

Figure 7. The role of patient groups in patient empowerment



Source: Economist Impact.

1.4 Summary of best practices in patient empowerment

Health literacy:

Governments, patient groups, medical societies and other relevant organisations should work together to implement educational programmes to increase the health and media literacy of patients. Health systems could also be redesigned in a way that makes processes to access health services and information more intuitive for patients and so reduce the burden of navigating the system.

Shared decision-making:

Patient decision aids should be developed and incorporated into the process of care and healthcare professionals should be trained and equipped with skills to engage patients in SDM. Patients should be made aware that their preferences may have an impact on their treatment decisions and given adequate information to participate in SDM.

Research and development:

Patients should be given the opportunity to be involved in drug development programmes by giving input on their unmet needs and the impact of the condition on their daily lives. Where applicable, PROMs and patient preference studies should be included.

Regulatory processes:

Ideally, drug approval processes should involve patients in benefit-risk discussions. Patients should be consulted on guidelines and policies that affect them and be asked to review documents intended for public viewing.

Health technology assessment:

Patients should be involved from the outset of the HTA process, and multiple channels utilised to seek patient input. Patients should be included in stakeholder consultation, and feedback should be provided to patients regarding their input.

Patient groups:

Patient groups should be well-organised and represent the views of their patient population. Patient groups should seek a breadth of funding sources, and declare all funding sources (in particular from commercial entities) and the purpose of the support provided, to ensure transparency and credibility.

Chapter 2.
Patient empowerment in selected countries

2.1 Europe and North America

Countries in Europe and North America have been spearheading the patient empowerment movement. The UK government has embraced the patient empowerment concept politically since the early 2000s, moving to make the Expert Patient Programme (a six-week course for anyone living with one or more long-term conditions) a centrepiece of the approach by the National Health Service (NHS) to manage chronic disease, ultimately seeking to establish a true partnership between the public and health professionals.[60,61]

Ngawai Moss, patient and public involvement leader for Elly Charity, and an honorary research fellow at the Institute of Population Health Sciences, Queen Mary University of London, acknowledges that patient empowerment in the UK is good compared to other countries, but also highlights shortcomings. "Patients are able to plug into many parts of the healthcare landscape [see Figure 8]. However, there is a lack of equality in the representation of certain groups—for example, children, older frail adults or those who are socio-economically disadvantaged. And the financial and administrative aspects of managing patient involvement may also be a challenge," she says.

"From the perspective of establishing themselves as independent entities, patient organisations are extremely sophisticated in Europe," says Camilla Krogh Lauritzen, a scientific advisory board member at the International Alliance of Patients' Organizations and European lead on patient advocacy at Orphazyme, a Danish pharmaceutical firm. "In addition to being well-orchestrated, they work not only in the local community, at the country level, but also with peer organisations in other countries. In matters of policymaking, EU patient organisations have a specific focus on preserving their integrity via financial independence from industry. This aligns with and reflects principles and guidance led by patient super-structures in the EU [such as] the European Patients' Forum and Rare Diseases Europe. Unlike in Canada and the US, you are unlikely to find a patient organisation in the EU that is fully pharma-funded".

Figure 8. Patient involvement in the UK

Health system	All NHS bodies have a legal duty to involve and consult the public about the running of local health services.
Hospitals	Non-executive directors represent the needs of patient communities
Research	Patients are involved in ethics committees, advise priorities to focus on and can be co-applicants or investigators in funding applications
Regulatory	The Medicines and Healthcare products Regulatory Agency (the UK's drugs regulator) has a Patient Group Consultative Forum
Medical societies	The Academy of Royal Colleges, which represents 23 medical royal colleges in the UK and Ireland, involves patients in different capacities.
Healthcare charities, advocacy groups and NGOs	Groups such as the King's Fund and the British Heart Foundation help to educate patients, increase health literacy and promote the patient voice

A number of the experts that we spoke to highlighted the positive results and improved outcomes that are derived from partnerships between pharmaceutical firms and patient organisations. However, Ms Lauritzen mentioned the potential risks that can arise from an actual or perceived loss of independence and integrity: "If a patient organisation is seen as being in the pocket of pharma, the consequences may be fatal for the organisation; it may lose its advocacy role, power and mandate, and in essence go out of business."

This is where codes of practice between patient organisations and the healthcare industry are vital to ensuring that such partnerships can continue to co-create solutions that improve patients' lives. "It is critically important that essential pharma/patient organisation partnerships, such as R&D partnerships, are documented, transparent and do not lead the patient organisation to become financially dependent on any one company," says Ms Lauritzen.

Health literacy

"Health literacy in the UK is mixed, both improving in some populations but still immobile for others—for example, in migrant communities," says Ms Moss. "The UK is multicultural, with different health beliefs and languages. Silent animations with accompanying text can help with language barriers. Access to information, such as research papers, may be limited. Higher levels of health literacy are required to interpret complex data, statistics or prediction models that can be used to make decisions."

The European Patients' Academy on Therapeutic Innovation, an independent non-profit foundation based in the Netherlands, aims to promote patient engagement through education.[62] "Patients can educate themselves on how and where to play a role in medicines R&D through this, and it's free," says Ms Lauritzen, although she acknowledges that this attracts patients with high self-efficacy. She explains that, in the Nordics, many patients demonstrate a high interest

in new medicines development and in their own disease management. For patients who are more passive, their family or community would usually step in. Patient organisations and patient digital networks also play a role in reaching out to those with lower health literacy.

SDM

SDM is implemented throughout Europe. "Denmark and the Nordics, in general, have a very consumer-friendly treatment system," says Ms Lauritzen. "For example, in cancer, treatment options and investigational drug options are presented to patients, and doctors will discuss the efficacy and safety profiles of the options and patients can be part of the implied decision-making."

However, Ms Moss points out that the degree of implementation varies. "Patients are encouraged to make decisions, but sometimes the patient does not have access to all necessary information to make informed decisions, so it is not true SDM," she says.

"When we talk about the patient voice, it's about having a more democratic health system."

Axel Mühlbacher, professor of health economics and healthcare management, Hochschule Neubrandenburg, Germany.

Presence of patient voice in drug development and approval

The FDA and the EMA have formal documents and various programmes for patient engagement. Some of the FDA's patient engagement initiatives include Patient-Focused Drug Development meetings, Pilot Listening Sessions for rare diseases, a Patient Engagement Collaborative forum, the Patient Engagement Advisory Committee and the Patient Representative Program. In the EMA, patients are involved in various phases of the medicine regulatory lifecycle, including early dialogue on medicine development, evaluation for authorisation and safety of medicines. Patients are voting members of some committees or are consulted for advice.

However, within individual countries in Europe, there are differences in how much say patients have. For example, the reimbursement councils of different countries differ in the level of (and transparency around) patient involvement. In Germany, when it comes to approval of health technologies, only the statutory health insurance providers and care providers are allowed to vote. Patient organisations at the table can voice opinions but cannot vote. In contrast, the reimbursement council in Denmark includes a patient key opinion leader with decision-making powers.

Patient involvement in HTAs

In England, the National Institute for Health and Care Excellence (NICE), which publishes guidance covering all aspects of healthcare delivery, has a dedicated team, the Public Involvement Programme (PIP), to support and advise on patient and public involvement across all of its work programmes. PIP identifies relevant patient organisations to participate in HTAs. There is opportunity for patients or patient organisations to be involved in all stages of the HTA (scoping, evidence gathering, committee consideration, consultation, appeal or resolution, publication, and review).[63]

In Denmark, patient involvement in HTA was developed at the national and regional levels

Summary of patient empowerment in Western countries

Health literacy	SDM	Drug development and approval	HTA	PROMs and PREMs
Many resources are available for patients, but certain vulnerable groups face barriers.	Implemented in most countries but the degree of implementation varies.	Formalised programmes for patient engagement have been implemented. Differing levels of transparency and voting rights are given to patients in regulatory bodies.	Patient involvement has been embedded within most HTA processes. However, incorporation of patient preference data may be lacking.	These are incorporated in most healthcare institutions and the pharmaceutical industry, but there may be gaps in how data are applied.

as early as the 1980s.[63] Patients participate as stakeholders in HTA processes through representation in stakeholder groups. In addition, the strategy for patient involvement includes research on patient-related aspects—to produce patient-based evidence—as an integral part of HTA.[63]

Since 2004, patient participation has been legislated for in Germany's Federal Joint Committee (G-BA, by its German name) and the Institute for Quality and Efficiency in Healthcare (IQWiQ).[63] The G-BA is the highest decision-making body for pharmaceuticals, therapeutic methods and medical devices, while IQWiG drafts HTA reports commissioned by G-BA.[63] In 2017 around 250 patient representatives were active in G-BA committees. Patient representatives may participate in discussions and are entitled to submit petitions, but they are not allowed to vote.[63]

Despite inclusivity in the process, German HTAs are lacking when it comes to the incorporation of patient preference data. "We need HTA frameworks that have a structured, transparent approach to incorporate patient preference data into the decision-making process," says Axel Mühlbacher, professor of health economics and healthcare management at Hochschule Neubrandenburg, a university of applied sciences.

Use of patient-reported outcome measures and patient-reported experience measures

Though PROMs and PREMs are incorporated in most healthcare institutions and by the pharma industry in Europe, there may be gaps in how these are systematically used. According to Ms Lauritzen, even though data may be consistently collected, it may not be used proactively across all of pharma.

2.2 Australia

"Whilst we have a national health system that is one of the best in the world, there is still a long way to go in terms of patient empowerment," says Wendy Benson, administration manager of the Australian Patients Association. Ms Benson cites limitations with access and choice of medical care in regional areas, and the challenges of interacting with healthcare professionals who may not know how to communicate clearly with empathy and compassion.

"The environment has changed in Australia in many ways to support patient empowerment groups, such as the establishment of the Consumer Evidence and Engagement Unit in the Department of Health's Office of Health Technology Assessment," says Ms Single of the Patient Voice Initiative.

In Australia, consumer submissions to the Pharmaceutical Benefits Advisory Committee (PBAC), the agency responsible for HTA, almost doubled from 2013 to 2016, reflecting increasing interest from patients and patient advocacy groups in how healthcare decisions were made.[64] However, there is a lack of transparency in processes, and patients may not know how to get involved.

"A barrier to SDM is the contention over expertise—who knows best and what is best for the patient, including what matters most and what should be part of the discussion. It is dangerous to assume what patients want without properly discussing [it] with them."

Ann Single
Steering committee member, Patient Voice Initiative, Australia

Health literacy

Health literacy in Australia is in need of improvement—one study estimated that almost half of Australians have limited functional health literacy, impairing their ability to manage their own conditions and participate in SDM.[9]

Using simple language and offering language translations and interpretations are essential in a multicultural society like Australia, says Richard Vines, chair of Rare Cancers Australia. Qualified information may contain complicated terms that patients do not understand. "It might be safe, but it doesn't actually inform anybody," he says. Patients should be allowed to drive communication in their communities. A good example is the culturally specific YouTube videos produced by indigenous communities to explain social distancing in the covid-19 pandemic.

Consumer health organisations are well placed to promote health literacy, as they have a good understanding of what chronic patients want. However, health literacy efforts should go beyond preparing information and sending it out to an assumed patient. "If you develop products and services with patients then you may start to talk about them in a similar way to patients, in a way that connects with their interests and makes sense to them. This might reduce some of the burden for large education or literacy programs," says Ms Single.

SDM

In Australia, SDM is embedded within the national clinical standards for accrediting hospitals, day procedure services, public dental services, medical education, general practice, aged care and disability services.[65] At the individual level, there has been a shift

from provision of information to patients in selected areas, to engagement in all aspects of healthcare that they wish to participate in.[65] At the health service level, there is increased scope for consumers to be partners and co-creators of healthcare service design, delivery and quality improvement.[65] Since 2019, all health services have been assessed against these standards for accreditation.[65]

However, some patients may not want to participate in SDM. "Our surveys show that about 50% of patients are not comfortable with asking doctors questions during their rounds. Older patients tend to leave decisions to their doctors without questioning," says Ms Benson. Language diversity and time constraints in busy institutions are other barriers to SDM.

Patient involvement in HTAs

At a national level, two main committees make recommendations for public funding of health interventions in Australia.[63] These are the PBAC for medications and vaccines, and the Medical Services Advisory Committee (MSAC) for medical services, diagnostics and devices. Both include at least one patient representative on their expert committees and provide opportunities for patient and public input.[63] The PBAC seeks input during the appraisal stage, whereas MSAC seeks input at the protocol development stage.[63]

"The burden of patient input lies on the patient or patient group"

Ann Single
Steering committee member, Patient Voice Initiative, Australia

The PBAC has a process of taking consumer comments by publishing its agenda on its website eight weeks in advance of the committee meeting. The patient representative reviews and presents these comments at the meeting. However, consumers are not informed of the details submitted, nor do they receive feedback regarding their comments.[63] The public summary documents acknowledge the patient input received but lack detail on the content and impact.[63] The MSAC has consumer members who raise issues on behalf of patients and communities. These consumer members, who sit on the overarching committees and subcommittees, go directly to key patient groups to ask them specific questions as part of developing papers for the MSAC committee. However, it is unclear how patients can get involved in this process.

Notably, the burden of input lies on the patient group or patient. This is subject to barriers such as poor communication, lack of transparency, and inadequate representation and time for input.[66]

Use of PROMs and PREMs

PROMs and PREMS are used in clinical practice in Australia, says Ms Benson—public hospitals in Victoria are one example of this. "It's important to be sure that PROMs and PREMs are actually what matters most to patients rather than clinicians," says Ms Single. "But regulators, HTA bodies and patient groups are increasingly aware that patients need to get involved so that the research measures outcomes are relevant to their communities."

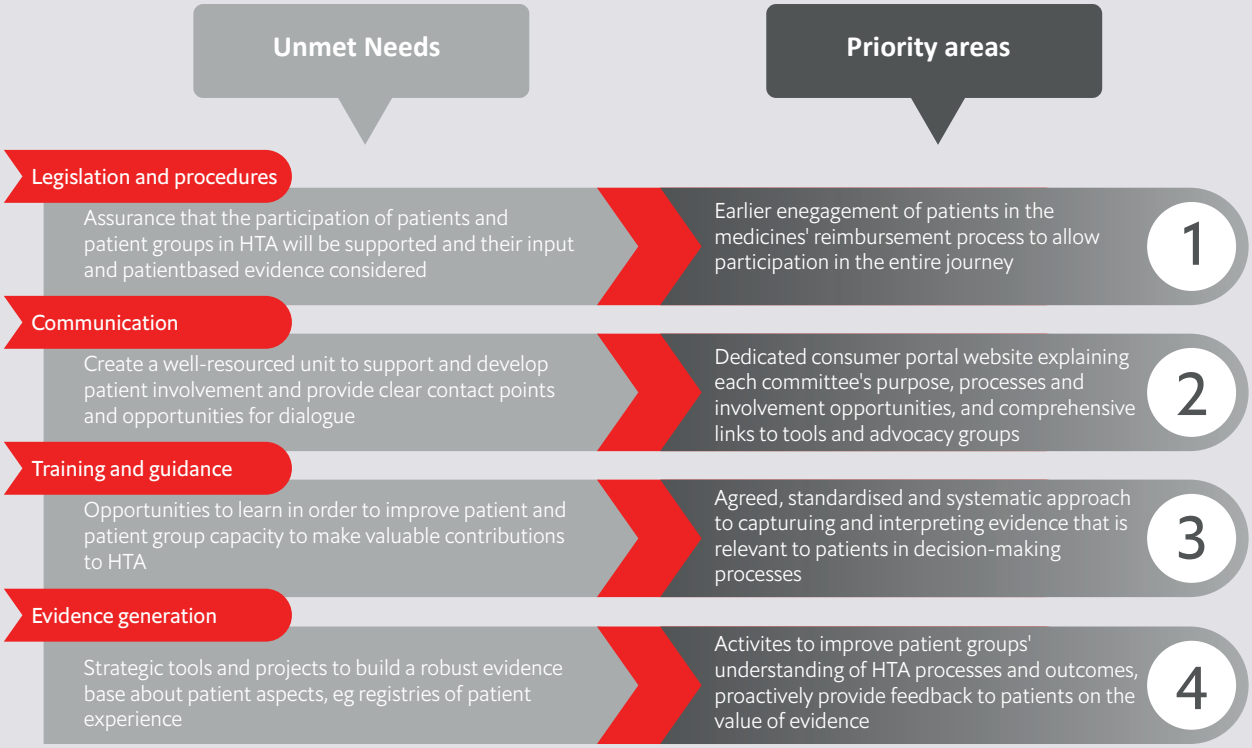
Case study: Patient Voice Initiative

Patient Voice Initiative (PVI) is a collaboration between patients, researchers and industry that works towards strengthening the patient voice in the Australian health system. PVI advocates for the inclusion of the patient perspective in all aspects of Australia's health system, as well as the development, approval and funding of medical technologies.

PVI was founded in 2015 with the purpose of growing the presence of the patient voice in HTAs. Through meetings in Sydney, Melbourne, Brisbane and Canberra, the organisation achieved consensus over unmet needs and identified four priority areas for improvement (Figure 9).[64] PVI's work aims to address these unmet needs and focus on the four priority areas.

Besides this, PVI functions as a forum for collaboration and dialogue among stakeholders, proposes initiatives to support patient involvement, and provides tools and resources for consumers, patients and health professionals to enhance the delivery of patient input, as well as patient-based evidence. PVI relies on funding from multiple pharmaceutical companies and in-kind contributions to conduct its activities and programmes, which are free for patients and patient groups.

Figure9. Unmet needs and priority areas for the patient voice in the Australian health system



Source: Economist Impact.

Summary of patient empowerment in Australia

Health literacy	SDM	Drug development and approval	HTA	PROMs and PREMs
Almost half of Australians have limited functional health literacy.	SDM is implemented within national clinical standards and medical services. However, some patients may not want to participate in SDM.	There is little patient involvement in drug development.	Patient representatives are involved, and there are opportunities for public and patient input.	PROMs and PREMs are being used in research and in certain clinical settings. However, data collected is not always accepted as evidence for decision-making.

2.3 China

The concept of patient empowerment is relatively novel in China.[67] Due to the country's culture of collectivism, patient empowerment may take a different form compared with the individualistic culture of the West. One survey shows that patient empowerment in China is associated with frequent health-related Internet use and strong relationships with social networks.[67] These networks may influence empowerment by providing emotional support, improving self-efficacy, and offering information and different perspectives.[67] Crucially, having positive patient-centred interactions with healthcare providers predicted patient empowerment—so much so that it lessened the effects of internet use and relationships on patient empowerment.

"Patient empowerment is not just the patients' responsibility—it is something that the whole system needs to work on."

Dong Dong
Research assistant professor, Chinese University of Hong Kong

Social media in China has enabled the formation of patient groups, with individuals becoming ambassadors for particular diseases. Some form professional grassroots groups, dedicating full-time resources and hiring employees, says Shi Li Zheng, director of the Health Systems Analytics Research Center at Tulane University in the US.

"Self-medication and self-care are forms of patient empowerment," says Dong Dong, a research assistant professor at the Chinese University of Hong Kong whose research focuses on patients with rare diseases. "There is a huge discrepancy among patients based on socioeconomic status, education level, ethnicity, access to healthcare services, past experience with medical systems and type of symptoms or diseases. These factors interfere with patients' empowerment and confidence in controlling their own diseases."

Health literacy

In China, surveys are conducted routinely to monitor health literacy levels. The first two nationwide surveys on health literacy were conducted in 2008 and 2012 respectively.[68] Results of the latter showed that only 8.8% of the population had adequate health literacy.[69] In 2014 the National Health Commission of China issued a new strategic plan to increase this level to 20% by 2020.[69] People in rural areas tend to have a lower level of health literacy compared with those in urban cities. Within Beijing, the estimated level of adequate health literacy was 24.7% in 2012 and 28% in 2015.[69] Female gender, age (25 to 34 years), a higher level of education and higher household income were predictors of health literacy.[69]

Funded by the government, national initiatives to promote health literacy include public advertisements on essential health knowledge and skills; health education and promotion activities in various settings, including communities, health facilities and workplaces; and population-based surveillance.[70] Conventional health literacy initiatives focus on educating patients through campaigns, activities and materials. But Dr Dong as per interviewee suggests that, instead of trying to "raise the bar" of patients' knowledge, initiatives could "lower the bar" by simplifying the expert knowledge and making the system better tailored to patient needs.

More efforts are also needed to combat misinformation in the media, which people with low health literacy are susceptible to. Sponsored advertorials in the form of news or documentaries may make it difficult for the public to differentiate between factual science and advertising, says Dr Dong as per interviewee.

SDM

A 2015 review found almost no reports or research on the development, testing or implementation of SDM tools for patients in China.[7] However, interest in SDM in China has been growing in the past few years, with more research conducted in the theoretical aspects of SDM, as well as greater use of translations of SDM questionnaires and SDM tools in clinical practice.[31] One study suggests that most young Chinese clinicians want to participate in SDM, but lack experience and time.[8]

There are also regional differences. "In Guizhou, patients and doctors are not used to the idea of SDM; patients want the doctors to decide for them. Whereas in Shanghai, more patients make active decisions," says Dr Dong as per interviewee, who has conducted ethnographic studies in Guizhou and Shanghai.

Wang Yiou, secretary-general of the Illness Challenge Foundation, a Chinese organisation focused on rare diseases, points out that patients may want to participate in SDM but may be limited by their situation and resources. The education level of patients, their knowledge about their disease, their ability to express their needs and the length of consultation time impact patients' ability to be involved in SDM. Affordability also impacts the decision. Patients with limited resources may only be able to afford one treatment, which may not necessarily turn out to be the best option.

While SDM is hardly practised, informed consent has been implemented in China.[71] "There are regulations on informed decision-making, patient consent and ethics," says Dr Dong as per interviewee. "Legal forms can help to resolve doctor-patient conflicts, but there

is no patient involvement in designing the forms, and some patients sign them without understanding. The forms usually benefit the doctors, like a responsibility waiver."

Patient voice in drug approval and reimbursement processes

To our knowledge, there is no systematic process for patient engagement or involvement in drug approval in China. Nevertheless, professional patient organisations are sometimes consulted, especially in rare diseases. There are a few channels for patient organisations to participate in research development and regulations, although they do not sit on boards associated with these processes.

"In rare diseases, patient organisations are usually involved in drug development, regulatory approvals, marketisation and the reimbursement process," says Dr Dong as per interviewee. "For more common conditions, the government usually relies on medical experts for forming policies. Patient organisations can exert their influence through these experts. However, there are also political and economic power-plays—doctors, pharmaceutical companies and patients may share some goals, but they also have their own interests and agenda. Patient organisations are not as rich as pharmaceutical companies, and not as powerful as the experts, so they are less influential."

"Insights from PROM data can be used can be used in the discussion between patients and providers to facilitate SDM."

Shi Li Zheng, director, Health Systems Analytics Research Center, Tulane University, US

Use of HTAs

HTA is a relatively new discipline in China. With the support and leadership of the Ministry of Health, several HTA research institutions were established in the 1990s, and in 2007 the China National Health Development Research Center set up a department called the Health Policy Evaluation and Research Branch, which conducts HTA projects.[72]

"There is no process for patient involvement in HTA in China yet," says Mr Shi, who has co-authored a paper on the challenges and opportunities of HTA in China. "The concept of patient involvement in reimbursement decision-making has been introduced, though it will take time for patient-centred HTA to be officially implemented."

HTA has been adopted by some policymakers, but it has not been routinely integrated into the decision-making process.[72] There is no clear role of HTA in the regulatory, pricing or reimbursement systems, as institutional segmentation means that more than 12 ministries govern the health sector in China.[72] China needs to address capacity and administrative barriers with actions targeting both research and policymaking to foster a better use of HTAs in the decision-making process.[72]

Use of PROMs and PREMs

Notably, several PROMs have been developed specifically for the Chinese population, owing to the fact that such questionnaires are strongly dependent on cultural background and translation is not straightforward.[73] PROMs developed overseas should be adapted and validated in the Chinese population.

In mainland China, there is no standard practice for collecting or using PROMs; individual hospitals decide whether to collect the data. Doctors usually collect PROMs for research purposes, rather than in clinical practice. However, some of the data are collected without standardised scales or validated questions, says Dr Dong as per interviewee, meaning the responses are not valid or reliable.

In terms of PREMs, the China Healthcare Improvement Evaluation Survey (CHIES) was the first national standard for collecting and publicly reporting on patients' perspectives of care. The CHIES, which was conducted in 2016 and 2018, included the Chinese Patient Experience Questionnaire Survey.[74] This identified several areas for improvements in tertiary hospitals, such as environmental and humanistic aspects of care, as well as non-medical services.[74] It is not clear whether this survey will be conducted regularly or how its findings will be applied.

Summary of patient empowerment in China

Health literacy	SDM	Drug development and approval	HTA	PROMs and PREMs
Health literacy levels are low, especially in rural areas. National health literacy promotion initiatives have been set up to raise literacy levels.	SDM is hardly practiced, although informed consent has been implemented. Significant barriers include low health literacy, short consultation time and unaffordability of treatment options.	There is no systematic process for patient involvement in drug development or approval. However, professional patient organisations are sometimes consulted.	There is no process for patient involvement in HTA in China. HTA has not been routinely integrated into the decision-making process.	There is no standard practice for collecting PROMs, and most are used for research purposes. In terms of PREMs, the China Healthcare Improvement Evaluation Survey collects and reports patient perspectives.

2.4 Japan

"The Cancer Control Act was a landmark event in the history of patient engagement in Japan," says Junko Sato, the office director of the Office of International Programmes of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan's medicines regulator. "It was one of the key drivers of the patient empowerment movement here. In 2006, some cancer patients and cancer survivors were invited to give their views on developing and implementing the Act. This experience encouraged patient engagement in Japan, and many groups started to engage patients in conferences for discussion."

Traditionally, the healthcare system in Japan has been paternalistic, with a marked difference of status between healthcare professionals and patients. Doctors tended to be held in high regard and patients did not question their decisions. In recent years, circumstances have been changing to raise patients to a more equal level.

"In Japan, patient groups are not as well-organised or well-funded as they are in the US and EU; patient groups do not really have a seat in Japan's healthcare policymaking process," says Amy Jackson, Japan representative of Pharmaceutical Research and Manufacturers of America, a trade group.

However, change is on the horizon. "The chief executive of PMDA issued a directive to enhance patient and public involvement," says Dr Sato. "To this end, the Working Group on Patient Centricity within PMDA was established in April 2019. [Dr Sato is a member] The group aims to publish guidance to improve patient engagement in Japan by 2021."

Health literacy

Although Japan has an excellent and accessible healthcare system, the healthcare literacy of its population is lower than that of other countries.[10] One study suggests that the inefficiency of the Japanese primary healthcare system, and the lack of comprehensive, reliable national online platforms for medical information, are partially to blame for the country's low level of health literacy.[10]

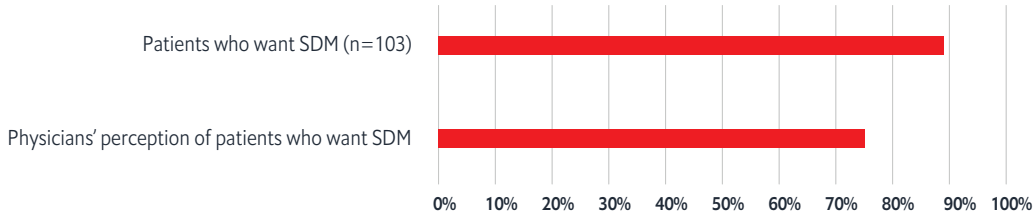
"Some medical societies and scientific consortiums provide information and education to patients via various platforms, such as websites or seminars, to enhance their health literacy," says Dr Sato. Besides this, there are few opportunities for the public to acquire basic information concerning the healthcare system, available healthcare resources or skills to enable them to effectively interact with healthcare professionals.[75]

SDM

"Shared decision-making in healthcare policy is not given much attention in Japan," says Ms Jackson. "Most patient organisations are not big or well-organised enough to have an advocacy platform to interact with policymakers and other stakeholders to push for a greater voice in healthcare decision-making."

A survey conducted in 2015 in Japan showed that many patients are interested in SDM, whereas physicians underestimate patients' desire to be involved in SDM (Figure 11).[76] Patients with a poorer health-related quality of life were more likely to prefer to be involved in the treatment decision.[76]

Figure 11. Comparison of patients' desire for SDM versus physicians' perceptions of patient preference for SDM[76]



There is a growing need for high-quality SDM tools for physician-patient interactions in the ageing society of Japan. As the number of older patients and patients with comorbidities increases, the number of complex medical decisions also increases. Japanese guidelines clearly stipulate the need for close dialogue between physician and patient for decision-making processes regarding medical care and treatment during patients' later stages of life.[77]

Patient voice in drug development and approval

Despite increasing interest and focus on patient-centric research, there has not been much involvement of Japanese patients in this respect.

"There is a committee for drug approval process, which gathers opinions from the public, consumer and those that sufferer from disease," says Dr Sato. However, these processes are not transparent, and there is no clear documentation on how patients or the public can be involved.

Use of HTAs

A new HTA programme was provisionally implemented in Japan in 2016 and formally launched in April 2019, in an attempt to address rising costs of healthcare expenditure.[78] Unlike other countries where HTA is used in coverage or reimbursement decisions, HTA in Japan is used in determining or adjusting price.[78] The process uses cost-effectiveness evidence (incremental cost-effectiveness ratios), with quality-adjusted life years as the basis for deciding pricing of the drug or medical device.[78] Patient preference data is not considered in this process.

Use of PROMs and PREMs

The importance of PROMs is recognised in Japan, but they are mostly used in the research setting, and not in routine medical care.[79] Unlike the FDA and the EMA, Japan's PMDA does not regulate the use of PROMs in label claims. However, a study found that PROMs are used in clinical trials and label claims, with PROMs assessing symptoms, quality of life and functioning being the most commonly used.[80]

Measures of patient satisfaction have been largely replaced by patient experience measures as a quality indicator of patient-centeredness.[81] In Japan, the Patient Experience Survey has been conducted at the national level in three-year intervals since 1996 as part of a survey by the Ministry of Health, Labour and Welfare.[82] This survey systematically measures patient experience and allows patients to give feedback on the quality of care received.

Summary of patient empowerment in Japan

Health literacy	SDM	Drug development and approval	HTA	PROMs and PREMs
An online survey of more than 1,000 Japanese adults found 85% had either inadequate or problematic health literacy.	SDM is not part of the healthcare policy. Most patient groups are not well-organised enough to have an advocacy platform with policymakers.	There is not much involvement of patients in drug development or approval. Processes are not transparent.	HTA is only used to determine or adjust price, and there is no scope for patients to be involved.	PROMs are used in research settings. The Patient Experience Survey is conducted nationally every three years.

2.5 South Korea

Korea's medical system is easily accessible, and patients have freedom of choice in selecting care providers. This autonomy can be seen as empowering, although it is open to misuse, says Jin-Young Paik, a representative of the Korea Kidney Cancer Association: "Some patients with mild diseases may go to tertiary care institutions, instead of primary care centres, and overburden resources."

Instances of patient empowerment are seen through the formation of patient groups and grassroots advocacy. The Korean Alliance of Patients' Organizations (KAPO), comprised of seven patient groups, was established in 2010.[83] The KAPO launched an initiative, the Shouting Café, gatherings at venues around the capital, Seoul, for the public to share experiences and grievances about the medical system. One such event, where a mother recounted how her child died from a medication error, sparked national interest and resulted in the Patient Safety Act, legislation enacted in 2016.

Health literacy

Information about health and medical services is communicated through the media and discussed in forums and online. Though rates of internet access are high in South Korea, disparities in internet use persist, especially among the elderly. The rate of internet use among a representative sample of South Korean diabetes patients aged 65 years and older was found to be only 16%.[84]

A nationwide survey conducted in 2016 estimated that 61% of participants had inadequate health literacy (Figure 12).[85] Being aged older than 40 years, having lower education, living in the capital city and the presence of barriers in getting information

Figure 12. Nationwide survey in South Korea:

Approximately six out of ten people have inadequate health literacy

predicted inadequate health literacy.[85] Another study found that the level of health literacy among disabled elderly adults was lower than among those who were not disabled.[86] Hence, more efforts are needed to promote health literacy in South Korea, especially for disadvantaged groups. Literacy education, combined with community-based health literacy programmes as well as digital competency training, could be useful for older adults.

SDM

"Relationships between HCPs and patients have improved; the current atmosphere has changed to respect the opinions of patients in hospital," says Ms Paik. "However, there is still a strong dependence on healthcare professionals to make decisions, due to limited time for medical treatment, and the complex, technical medical fields that may be difficult or confusing for patients. In the health and medical delivery system, we are preparing a system to establish an environment where patient-centred sharing decisions can be made," she says.

The average consultation time per person at a general hospital in Korea is 6.2-7.4 minutes.[87] In 2015 Seoul National University Hospital implemented a 15-minute, in-depth consultation system for first-time patients in outpatient clinics who had been referred by a primary care physician.[87] The in-depth consultations utilised SDM to choose further treatment actions. When compared with a control group who received regular consultations, the in-depth consultation group reported better patient-centred care, including higher perceptions of medical professionals, wait and consultation times, treatment, patient advocacy, and patient satisfaction.[87]

Patient voice in drug development and approval

Patient group representatives are invited to participate in health and medical policy-related committees. For example, the head of the KAPO is currently on the Health Insurance Policy Deliberation Committee (HIPDC) and the director of KAPO is on the Drug Reimbursement Evaluation Committee (DREC). However, most of the discussions are conducted at the final stages of approval, making it difficult to directly reflect patients' voices in the drug approval process.

Individual patients with unmet needs may conduct single-person demonstrations or visits in front of the National Assembly, the Ministry of Health and Welfare, the Health Insurance Review and Assessment Service (HIRA), and the National Health Insurance Service. Patients are also interviewed by the media in TV broadcasts and newspapers.

Use of HTAs

South Korea's HTA system was implemented in 2007, based on the organisational and methodological experience of established HTA systems such as those in Australia, Canada and the UK. South Korea was the first Asian country to introduce economic evaluations for reimbursement decisions.[88]

The DREC, which consists of representatives from medical associations and consumer interest groups, determines whether to fund the drug.[88] The DREC reviews all reimbursement applications submitted to HIRA. The ultimate decision is made by the HIPDC. Though patient groups may be involved, there is still room for improvement (Figure 13).

Figure 13. Gaps in patient involvement

- Certain therapeutic areas are not represented in the DREC (for example, no oncologists or cancer patients are involved)[88]
- Patient groups participating in the DREC and HIPDC do so only in the final stage of approval, not during the initial stage of discussion
- Assessment for drugs usually covers only "clinical efficacy" and not quality of life or PROMs

Summary of patient empowerment in South Korea

Health literacy	SDM	Drug development and approval	HTA	PROMs and PREMs
A nationwide survey estimates that 61% of people have inadequate health literacy.	SDM is starting to be practised. There is still a strong dependence on healthcare professionals to make decisions, although patients' opinions are respected.	Patient group representatives are invited to participate in policy discussions. However, most discussions are only conducted at the final stages of approval, making it difficult to reflect patients' voices through the process.	Patient groups are involved in HTAs for drug reimbursement decisions. However, there are still gaps in patient involvement.	PROMs are mainly used in the research setting. National surveys of patient evaluations are conducted.

"Even if a drug is found to be clinically beneficial, it may not be approved if it exceeds the price originally determined by the DREC," says Ms Paik. "In the future, collecting patient voices in all processes, or opinions from patient groups of the disease, [should enable the creation of] a clearer and more transparent system."

Use of PROMs and PREMs

PROMs are mainly used in the research setting. There have been efforts to use PROMs in local studies, but there is greater scope to apply the use of PROMs for practical purposes.[89]

As for PREMs, the Ministry of Health and Welfare and the National Medical Centre conduct surveys of patient experience in Korea. "Since a year or two ago, the Health Insurance Review and Assessment service has collaborated with several university research teams to conduct research on patient experience evaluations, and reported overall findings from the interviews and surveys," says Ms Paik. "For example, they conducted research on patient safety and experience for patients who have been admitted to a tertiary hospital."

Chapter 3.
Future steps

Empowering patients to be part of decisions that impact their health can create more sustainable and equitable healthcare systems. Opportunities exist in the Asia-Pacific region to draw on best practices to accelerate and amplify efforts to empower patients and, thus, improve population health and health system sustainability. Drawing on the evidence and expert opinions captured in this report, we have identified the following calls to action:

1. Increase public health and media literacy

Surveys have demonstrated that general populations in the Asia-Pacific region have lower levels of health literacy compared with other populations, and several governments have already undertaken actions to improve this. However, more efforts are needed to address low health literacy, particularly among disadvantaged groups such as migrants, the elderly, and those of lower socioeconomic and educational status.

Many patients get information from the internet and social media, where misinformation abounds. Media literacy is required to equip patients against misinformation so that they can verify if information comes from a legitimate or reliable source and ultimately make decisions that are evidence-based.

Context-specific health communication and tools should be developed, as significant sociocultural differences contribute to differences in communication and interaction, which in turn influences patients' ability to participate in health decision-making.[90] In addition, the provision of reputable sources of health information can help patients and their families to gain knowledge of health conditions, treatment plans and

healthcare access. Such knowledge builds the foundation for informed, shared decision-making, and, ultimately, the ability to control chronic conditions and maintain one's health.

2. Develop culturally relevant approaches to shared decision-making in partnership with healthcare professionals and patients

Shared decision-making requires health professionals and patients to contribute different yet equally essential forms of expertise to health decision-making.

Patients, patient organisations, families and loved ones must have access to the knowledge and skills needed to make informed decisions, as well as a facilitating environment that means people are truly empowered to make decisions about their healthcare.

Healthcare professionals must create this facilitating environment by actively communicating their commitment and support for shared decision-making, while also ensuring that they have the skills to adequately assess patient health literacy and facilitate open discussions about treatment options.

Cultural sensitivities and personal preferences must be considered as part of the shared decision-making process. While global resources exist to support shared decision-making, it is not enough to simply adopt them—they need to be adapted (through collaboration with all relevant stakeholders) to ensure that they are culturally appropriate.

3. Commit to national policies that recognise the fundamental right of patients to have a voice in healthcare decisions

It is both an expectation and an aspiration for patients in the Asia-Pacific region to have a meaningful voice in decisions that impact their health. To truly empower patients in health decision-making at a system level, governments must take a leadership role by setting national standards and community expectations regarding the rights and roles of patients in relation to decisions that impact their health. This includes ensuring that national health policies and legislation recognise the fundamental right of patients to be part of decisions that impact their health, and that formal processes exist to involve patients in the decision-making process in systematic and meaningful ways.

4. Implement systematic processes to involve patients in drug approval and reimbursement decisions

There is a lack of clear, transparent processes to gather consumer comments and involve patient and consumer representatives during drug approval and reimbursement decisions. Criteria that cover all decision stages and explicit discussion of these criteria and procedures are essential for accountability to patients and the wider public.

A feedback loop with patients and patient groups should be a standard part of the process, with proactive feedback provided on the value and impact of patient contribution to the decision-making process.

Patients and their representatives need technical skills to understand some aspects of healthcare delivery, clinical research, regulation and HTA. Training in these technical aspects would help patients to feel more confident when engaging health authorities, and more able contribute to decision-making.

References

1. European Patients' Forum. EPF Campaign on Patient Empowerment: Roadmap for Action. Brussels. European Patients' Forum, 2017. Available from: https://www.eu-patient.eu/globalassets/campaign-patient-empowerment/roadmap/roadmap_patient-empowerment_-epf_2017.pdf.
2. Bailo L, Guiddi P, Vergani L, et al. The patient perspective: investigating patient empowerment enablers and barriers within the oncological care process. Ecancermedicalscience. 2019;13:912.
3. US FDA. CDER Patient-Focused Drug Development. Maryland. Food and Drug Administration; [updated 27 July 2021]. Available from: https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development.
4. FDA patient-focused drug development guidance series for enhancing the incorporation of the patient's voice in medical product development and regulatory decision making. Available from: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm610279.htm.
5. European Medicines Agency (2014) Annex II: EMA activities where patients and consumers are involved. Available from: Maryland. Food and Drug Administration; [updated 18 June 2020]. Available from: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm610279.htm.
6. European Medicines Agency. Incorporating patients' views during evaluation of benefit-risk by the EMA Scientific Committees. London. European Medicines Agency; [updated 16 Oct 2014]. Available from: https://www.ema.europa.eu/en/documents/other/revised-framework-interaction-between-european-medicines-agency-patients-consumers-their_en-1.pdf.
7. Huang R, Gionfriddo MR, Zhang L, et al. Shared decision-making in the People's Republic of China: current status and future directions. Patient preference and adherence. 2015;9:1129-41.
8. Huang R-C, Song X-T, Zhang D-F, et al. Preferences and attitudes of young Chinese clinicians about using a shared decision making tools for communicating cardiovascular risk. Chronic diseases and translational medicine. 2019;5(2):105-12.
9. Adams RJ, Appleton SL, Hill CL, et al. Risks associated with low functional health literacy in an Australian population. Med J Aust. 2009;191(10):530-4.
10. Nakayama K, Osaka W, Togari T, et al. Comprehensive health literacy in Japan is lower than in Europe: a validated Japanese-language assessment of health literacy. BMC Public Health. 2015;15(1):505.

11. Bravo P, Edwards A, Barr PJ, et al. Conceptualising patient empowerment: a mixed methods study. BMC Health Services Research. 2015;15(1):252.

12. Cerezo PG, Juvé-Udina ME, Delgado-Hito P. Concepts and measures of patient empowerment: a comprehensive review. Rev Esc Enferm USP. 2016;50(4):667-74.

13. World Health Organization. Regional Office for Europe. Regional Committee for Europe Sixty-second session Health 2020 policy framework and strategy. World Heal Organ. 2012;(September 2012):10-13.

14. Tohver P, Taal H, Peters E, de Bruin K. eHAction Joint Action supporting the eHealth Network D4.1-Draft Policy Framework on People Empowerment. Brussels. eHAction, 2019. Available from: https://ec.europa.eu/health/sites/default/files/ehealth/docs/ev_20190611_co312_en.pdf.

15. The World Bank and WHO: Half the world lacks access to essential health services , 100 million still pushed into extreme poverty because of health expenses. Geneva. The World Bank; [updated 13 Dec 2017]. Available from: https://www.worldbank.org/en/news/press-release/2017/12/13/world-bank-who-half-world-lacks-access-to-essential-health-services-100-million-still-pushed-into-extreme-poverty-because-of-health-expenses.

16. De Santis M, Hervas C, Weinman A, et al. Patient empowerment of people living with rare diseases. Its contribution to sustainable and resilient healthcare systems. Ann Ist Super Sanita. 2019;55(3):283-291.

17. Selden C, Zorn M, Ratzan S, Parker R. National Library of Medicine Current Bibliographies in Medicine: Health Literacy. Bethesda, MD: National Institutes of Health; 2000.

18. Schulz PJ, Nakamoto K. Health literacy and patient empowerment in health communication: the importance of separating conjoined twins. Patient Educ Couns. 2013;90(1):4-11.

19. National Academies of Sciences Engineering and Medicine, Health and Medicine Division, Practice, et al. Addressing Health Misinformation with Health Literacy Strategies. Washington (DC): National Academies Press (US); 2020.

20. van Berkel JJ, Lambooij MS, Hegger I. Empowerment of patients in online discussions about medicine use. BMC Medical Informatics and Decision Making. 2015;15(1):24.

21. Pew Research Centre. Peer-to-peer Healthcare. Pew Research Centre. https://www.pewresearch.org/internet/Reports/2011/ P2PHealthcare.aspx. Washington DC. Pew Research Centre; [updated 12 May 2011]. Available from: https://www.pewresearch.org/internet/2011/05/12/peer-to-peer-healthcare-2/.

22. Loeb S, Sengupta S, Butaney M, et al. Dissemination of Misinformative and Biased Information about Prostate Cancer on YouTube. Eur Urol. 2019;75(4):564-7.

23. Swire-Thompson B, Lazer D. Public Health and Online Misinformation: Challenges and Recommendations. Annu Rev Public Health. 2020;41:433-51.

24. Song H, Omori K, Kim J, et al. Trusting Social Media as a Source of Health Information: Online Surveys Comparing the United States, Korea, and Hong Kong. J Med Internet Res. 2016;18(3):e25.

25. Institute for Strategic Dialogue. Covid-19 Vaccine Misinformation Monitor: The Netherlands. London. Institute for Strategic Dialogue; [updated 18 May 2021]. Available from: https://www.isdglobal.org/digital_dispatches/covid-19-vaccine-misinformation-monitor-the-netherlands/.

26. UN Verified initiative. New MIT study says united nations pause campaign slows spread of life-threatening misinformation. New York. Verified; [updated 1 July 2021]. Available from: https://shareverified.com/wp-content/uploads/2021/07/press_release_pause_campaign_final_1_july-1.pdf.

27. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). Soc Sci Med. 1997;44(5):681-92.

28. Kambhampati S, Ashvetiya T, Stone NJ, et al. Shared Decision-Making and Patient Empowerment in Preventive Cardiology. Curr Cardiol Rep. 2016;18(5):49.

29. Patient Empowerment Network. Shared Decision Making: Putting the Patient At The Center of Medical Care Patient Empowerment Network; [updated 27 March 2016]. Available from: https://powerfulpatients.org/2016/03/27/shared-decision-making-putting-the-patient-at-the-center-of-medical-care/.

30. Coulter A, Collins A. Making shared decision-making a reality: no decision about me, without me. London: King's Fund; 2011.

31. Yao M, Finnikin S, Cheng KK. Call for shared decision making in China: Challenges and opportunities. Z Evid Fortbild Qual Gesundhwes. 2017;123-124:32-5.

32. Kuga S, Kachi Y, Inoue M, et al. Characteristics of General Physicians who Practice Shared Decision Making: A Mail Survey of All Clinics in 12 Municipalities in Tokyo subtitle_in_Japanese. An Official Journal of the Japan Primary Care Association. 2016;39(4):209-13.

33. Hawley ST, Morris AM. Cultural challenges to engaging patients in shared decision making. Patient education and counseling. 2017;100(1):18-24.

34. NHS. Guidance and resources. London. National Health Service. Available from: https://www.england.nhs.uk/shared-decisionmaking/guidance-and-resources/.

35. Frosch DL, Moulton BW, Wexler RM, et al. Shared decision making in the United States: policy and implementation activity on multiple fronts. Z Evid Fortbild Qual Gesundhwes. 2011;105(4):305-12.

36. Légaré F, Stacey D, Forest PG, et al. Moving SDM forward in Canada: milestones, public involvement, and barriers that remain. Z Evid Fortbild Qual Gesundhwes. 2011;105(4):245-53.

37. Stiggelbout AM, Van der Weijden T, De Wit MP, et al. Shared decision making: really putting patients at the centre of healthcare. BMJ. 2012;344:e256.

38. McAllister M, Dunn G, Payne K, et al. Patient empowerment: the need to consider it as a measurable patient-reported outcome for chronic conditions. BMC Health Serv Res. 2012;12:157.

39. Williams K, Sansoni J, Morris D, Grootemaat P, Thompson C. Patient-Reported Outcome Measures: Literature Review. Sydney: Australian Commission on Safety and Quality in Health Care; 2016.

40. Wiering B, de Boer D, Delnoij D. Patient involvement in the development of patient-reported outcome measures: a scoping review. Health Expect. 2017;20(1):11-23.

41. Eskildsen NB, Joergensen CR, Thomsen TG, et al. Patient empowerment: a systematic review of questionnaires measuring empowerment in cancer patients. Acta Oncol. 2017;56(2):156-65.

42. Australian Institute of Health and Welfare. Australia's Health 2018: 7.17 Patient-reported experience and outcome measures. Canberra. Australian Institute of Health and Welfare, 2018. Available from: https://www.aihw.gov.au/getmedia/31d2844d-323e-400a-875e-e9183fafdfad/aihw-aus-221-chapter-7-17.pdf.aspx.

43. Canadian Institute for Health Information. About the Canadian Patient Experiences Survey on Inpatient Care. Ottawa. Canadian Institute for Health Information. Available from: https://www.cihi.ca/en/patient-experience/about-the-canadian-patient-experiences-survey-on-inpatient-care.

44. NHS Quality Care Commission. London. National Health Service. Available from: https://nhssurveys.org/.

45. OECD & WHO. Evaluating Quality Strategies in Asia-Pacific Countries. Geneva. Organisation for Economic Co-operation and Development & World Health Organization, 2015. Available from: https://www.oecd-ilibrary.org/social-issues-migration-health/evaluating-quality-strategies-in-asia-pacific-countries_9789264243590-en.

46. Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. BMJ Open. 2013;3(1).

47. Manary MP, Boulding W, Staelin R, et al. The patient experience and health outcomes. N Engl J Med. 2013;368(3):201-3.

48. Dong D, Xu RH, Wong EL, et al. Public preference for COVID-19 vaccines in China: A discrete choice experiment. Health Expect. 2020;23(6):1543-78.

49. European Medicines Agency (2014) Annex II: EMA activities where patients and consumers are involved. London. European Medicines Agency; [updated 16 Oct 2014]. Available from: https://www.ema.europa.eu/en/documents/other/revised-framework-interaction-between-european-medicines-agency-patients-consumers-their_en-1.pdf.

50. Haerry D, Landgraf C, Warner K, et al. EUPATI and Patients in Medicines Research and Development: Guidance for Patient Involvement in Regulatory Processes. Frontiers in medicine. 2018;5:230-.

51. European Medicines Agency. Incorporating patients' views during evaluation of benefit-risk by the EMA Scientific Committees. London. European Medicines Agency; [updated 23 Oct 2014]. Available from: https://www.ema.europa.eu/en/documents/other/incorporating-patients-views-during-evaluation-benefit-risk-european-medicines-agency-scientific_en.pdf.

52. Holtorf A, Cook N. The Role of Patients in Market Access. In: G K, Wertheimer A, eds. Pharmaceutical Market Access in Developed Markets. ; 2018:267-288.

53. Abelson J, Wagner F, DeJean D, et al. Patient involvement in health technology assessment: a framework for action. Int J Technol Assess Health Care. 2016;32(4):256-64.

54. O'Rourke B, Oortwijn W, Schuller T. The new definition of health technology assessment: A milestone in international collaboration. Int J Technol Assess Health Care. 2020;36(3):187-90.

55. Mesana L, Syed IA, Constantin J, et al. Patient Involvement in Health Technology Assessments: An International Comparison. Value in Health. 2018;21:S54.

56. Oortwijn W, Determann D, Schiffers K, et al. Towards Integrated Health Technology Assessment for Improving Decision Making in Selected Countries. Value Health. 2017;20(8):1121-30.

57. Facey KM, Bedlington N, Berglas S, et al. Putting Patients at the Centre of Healthcare: Progress and Challenges for Health Technology Assessments. Patient. 2018;11(6):581-9.

58. van Uden-Kraan CF, Drossaert CH, Taal E, et al. Participation in online patient support groups endorses patients' empowerment. Patient Educ Couns. 2009;74(1):61-9.

59. Zarocostas J. Patient groups and biomedicine: for better and for worse. Nat Med. 2020;26(10):1500-3.

60. Garattini L, Padula A. Patient empowerment in Europe: is no further research needed? Eur J Health Econ. 2018;19(5):637-40.

61. Donaldson L. Expert patients usher in a new era of opportunity for the NHS. BMJ (Clinical research ed). 2003;326(7402):1279-80.

62. EUPATI: Patient engagement through education. https://eupati.eu/.

63. Facey KM, Hansen HP, Single ANV, editors. Patient Involvement in HTA. Singapore: Springer; 2017. doi:10.1007/978-981-10-4068-9.

64. Patient Voice Initiative. Recommendations to improve the patient voice in health technology assessment in Australia. Sydney. Patient Voice Initiative; [updated 07 Aug 2018]. Available from https://www.patientvoiceinitiative.org/pvi-reports/recommendations-to-improve-the-patient-voice-in-health-technology-assessment-in-australia-august-2018/.

65. Trevena L, Shepherd HL, Bonner C, et al. Shared decision making in Australia in 2017. Z Evid Fortbild Qual Gesundhwes. 2017;123-124:17-20.

66. Lopes E, Street J, Carter D, et al. Involving patients in health technology funding decisions: stakeholder perspectives on processes used in Australia. Health Expect. 2016;19(2):331-44.

67. Jiang S, Street RL. The effects of patient-centered communication, social capital, and internet use on patient empowerment: a cross-sectional study in China. Global Health Promotion. 2018;26(4):33-43.

68. Shen M, Hu M, Liu S, et al. Assessment of the Chinese Resident Health Literacy Scale in a population-based sample in South China. BMC Public Health. 2015;15(1):637.

69. Shi J, Qi L, Li Y, et al. Investigation of Health Literacy Status in Beijing, China. Health literacy research and practice. 2020;4(3):e174-e84.

70. WHO. The mandate for health literacy. Geneva. World Health Organization. Available from: https://www.who.int/teams/health-promotion/enhanced-wellbeing/ninth-global-conference/health-literacy.

71. Gong N, Zhou Y, Cheng Y, et al. Practice of informed consent in Guangdong, China: a qualitative study from the perspective of in-hospital patients. BMJ Open. 2018;8(10):e020658.

72. Shi L, Mao Y, Tang M, et al. Health technology assessment in China: challenges and opportunities. Global Health Journal. 2017;1(1):11-20.

73. Hu X, Zhao Z, Zhang S-K, et al. CA-PROM: Validation of a general patient-reported outcomes measure for Chinese patients with cancer. Cancer Epidemiology. 2020;67:101774.

74. Hu G, Chen Y, Liu Q, et al. Patient experience of hospital care in China: major findings from the Chinese Patient Experience Questionnaire Survey (2016–2018). BMJ Open. 2019;9(9):e031615.

75. Ishikawa H, Yamaguchi I, Nutbeam D, et al. Improving health literacy in a Japanese community population-A pilot study to develop an educational programme. Health expectations : an international journal of public participation in health care and health policy. 2018;21(4):814-21.

76. Schaede U, Mahlich J, Nakayama M, et al. Shared Decision-Making in Patients With Prostate Cancer in Japan: Patient Preferences Versus Physician Perceptions. Journal of Global Oncology. 2017(4):1-9.

77. Ministry of Health, Labour, and Welfare. The practice guidelines for process of decision-making regarding treatment in the end-of-life care at a glance. Tokyo. Ministry of Health, Labour, and Welfare, 2018. Available from: https://www.mhlw.go.jp/file/04-Houdouhappyou-10802000-Iseikyoku-Shidouka/0000197701.pdf.

78. Kamae I, Thwaites R, Hamada A, et al. Health technology assessment in Japan: a work in progress. J Med Econ. 2020;23(4):317-22.

79. Tang AC, Kim H, Crawford B, et al. The Use of patient Reported Outcome Measures for Rheumatoid Arthritis in Japan: A Systematic Literature Review. The open rheumatology journal. 2017;11:43-52.

80. Ledesma DA, Tanaka E, Adachi K, et al. The Use of Patient Reported Outcomes (Pros) By the Pharmaceutical Industry in Japan - A Brief Review of Pmda Data in Comparison With Fda and Ema-Approved Label Claims. Value Health. 2014;17(7):A517.

81. Aoki T, Yamamoto Y, Fukuhara S. Comparison of Primary Care Experience in Hospital-Based Practices and Community-Based Office Practices in Japan. Annals of family medicine. 2020;18(1):24-9.

82. Kawashima TK, Etsuji EO, Hiroko Miura O. What makes Patients Satisfied with their Healthcare? Nationwide Patient Experience Surveys in Japan. J Nurs Care. 2015;04(05). doi:10.4172/2167-1168.1000294.

83. An G. Korean Patients' Voices: From Shouting to Acting. 7th Global Patients Congress of the International Alliance of Patients' Organizations, 2016. Available from: https://www.iapo.org.uk/sites/default/files/files/GPC2016%20speaker%20presentations/GPC2016_Gi-Jong_An.pdf.

84. Park S, Kim B. Predictors of Internet Use Among Older Adults With Diabetes in South Korea: Survey Study. JMIR Med Inform. 2020;8(12):e19061.

85. Jeong SH, Kim HK. Health literacy and barriers to health information seeking: A nationwide survey in South Korea. Patient Educ Couns. 2016;99(11):1880-7.

86. Kim Y, Lee H, Park B, et al. Predicting health literacy among disabled elderly in Korea: implications for health justice. Innovation in Aging. 2017;1(Suppl 1):392-.

87. Sohn KH, Nam S, Joo J, et al. Patient-Centeredness during In-Depth Consultation in the Outpatient Clinic of a Tertiary Hospital in Korea: Paradigm Shift from Disease to Patient. Journal of Korean medical science. 2019;34(15):e119-e.

88. Cho E, Park EC, Kang MS. Pitfalls in reimbursement decisions for oncology drugs in South Korea: need for addressing the ethical dimensions in technology assessment. Asian Pac J Cancer Prev. 2013;14(6):3785-92.

89. Rhee Y, Jun S, Choi S-E, editors. Concepts and Applications of Patient-Reported Outcomes & Quality of Life Measure: Practical Recommendations for Korea2015.

90. Pun JKH, Chan EA, Wang S, et al. Health professional-patient communication practices in East Asia: An integrative review of an emerging field of research and practice in Hong Kong, South Korea, Japan, Taiwan, and Mainland China. Patient Educ Couns. 2018;101(7):1193-206.

ECONOMIST IMPACT

LONDON

20 Cabot Square
London, E14 4QW
United Kingdom
Tel: (44.20) 7576 8000
Fax: (44.20) 7576 8500
Email: london@economist.com

GENEVA

Rue de l'Athénée 32
1206 Geneva
Switzerland
Tel: (41) 22 566 2470
Fax: (41) 22 346 93 47
Email: geneva@economist.com

NEW YORK

750 Third Avenue
5th Floor
New York, NY 10017
United States
Tel: (1.212) 554 0600
Fax: (1.212) 586 1181/2
Email: americas@economist.com

DUBAI

Office 1301a
Aurora Tower
Dubai Media City
Dubai
Tel: (971) 4 433 4202
Fax: (971) 4 438 0224
Email: dubai@economist.com

HONG KONG

1301
12 Taikoo Wan Road
Taikoo Shing
Hong Kong
Tel: (852) 2585 3888
Fax: (852) 2802 7638
Email: asia@economist.com

SINGAPORE

8 Cross Street
#23-01 Manulife Tower
Singapore
048424
Tel: (65) 6534 5177
Fax: (65) 6534 5077
Email: asia@economist.com