



Alliance &
Partnerships for
Patient
Innovation &
Solutions

APPIS 2022
Asia Pacific, Middle East, and Africa

SHAPING HEALTH POLICY WITH COLLABORATIVE PATIENT ENGAGEMENT

Handout for Patient Organizations

This handout is part of the Alliance and Partnerships for Patient Innovation and Solutions (APPIS) 2022 initiative. Organized and funded by Novartis, APPIS aims to enable the convergence of perspectives between patient communities and key stakeholders in the healthcare ecosystem, such as policymakers, payers, physicians, members of academia, and digital innovators, to improve health outcomes in the Asia Pacific, Middle East, and Africa.

The collective wisdom of key partners from patient communities, policy experts, and organizations identified health policy shaping as one of the themes. The theme was identified given the real-world needs for patient-centric health policy-shaping interventions and the gaps in involving patients and organizations in the decision-making processes who want to make a difference in the healthcare experience of patients and caregivers at all levels. Involving patient organizations is the key to improving patient engagement in health policy development. Unifying patient voices can build effective health policies and more robust healthcare systems and overall improve the healthcare experience for patients and their caregivers.

This handout is an accompaniment to the Guidance Document and is designed for easy use and for reference during meetings, workshops, and consultative discussions for patient organizations to take forward practical ways to implement the proposed action items.

Visit www.appisinitiative.com to learn more about APPIS and download the full version of the Guidance Report on Health Policy Shaping



01 Identify Mobilizers

Identify key influencers who are aligned with the same cause. Look for non-traditional stakeholders who will help in sharing resources, experience, and guidance.

03 Brainstorm

Think about your stakeholders' perspectives on your stakeholders on factors that can influence the health policy-shaping process.

06 Engage Stakeholders

- Maintain a unified voice and priorities with all
- Develop a strong case in front of policymakers
- Involve identified stakeholders and representatives from the health policy-shaping process and patient organizations
- Use networking platforms to share the need for engaging patients in the health policy decision-making process; share patient experience and policy needs with data
- Organize roundtable discussions with government, regulatory bodies, payers, health policy institutions, and experts on health policy
- Co-host theme-based educational sessions with key stakeholders
- Publish and disseminate a white paper on the roles and responsibilities of patient organizations in the health-policy shaping process.

02 Shortlist and Prioritize Mobilizers

Plot your stakeholders to help identify who is most influential and interested in listening and engaging with the organizations. Seek input from sources such as research, media documents, conferences, white papers, healthcare organizations, and online platforms. Engage with global organizations in a specific disease area or global alliances.

04 Understand Local Health Policy Processes

Document and study the health policy processes and the key enablers and their role in the decision-making process. e.g., Are there HTAs used in the country? If so, what steps are followed? Who is engaged in the process and at what stage? In what ways are stakeholders engaged in the process? How is the feedback used in the decision-making process? How is the decision communicated back to the participating stakeholders?

05 Define Roles and Channels

- Define the role and responsibilities of each of the stakeholders identified
- Understand what channels can draw their attention to share their views
- Establish channels and create a process to engage them.



POTENTIAL STAKEHOLDERS



Healthcare Organizations



Research and Academic Institutions



Policymakers and Regulators



Government representatives



Industry Experts



Not-for-Profit and NGOs



Unions, associations, and representatives from groups such as:

- Doctors and nurses
- Patients and advocates



Specialists and Supportive Stakeholders such as:

- Journalists from print and digital media
- Communication experts
- Experts in specific disease areas
- Public health experts



- How much will the stakeholder contribute to Health Policy Decision-Making Process?
- How much influence will the stakeholder have in the process of engaging with Patients and Patient Organizations?
- Who are some of the organizations and stakeholders (including healthcare providers) supporting patient-led health policy shaping?
- What are the stakeholder's important priorities?
- How could the stakeholder contribute to the process of engaging patient organizations in the health policy-shaping process?
- What are the values and factors important to the stakeholder?
- How can the stakeholder hinder the process of engaging patient organizations in the health policy-shaping process?
- What is the strategy to engage the stakeholder?

Stakeholder Mapping & Engagement

Sample Template

Stakeholder Name	Contact Person <i>Phone, Email, Website, Address</i>	How much will the stakeholder impact in contributing to the Health Policy Decision-Making Process? (Low, Medium, High)	How much influence will the stakeholder have in the process of engaging with Patients and Patient Organizations? (Low, Medium, High)	What is important to the stakeholder?	How could the stakeholder contribute to the process of engaging patient organizations in the health policy-shaping process?	How can the stakeholder hinder the process of engaging patient organizations in the health policy-shaping process?	Strategy to engage the stakeholder
(Examples) Regulator		High	High	Compliance with the norms, usage, and patient experience	Agree for policymakers to support and implement the new reforms, legal mandates, etc. Engage patients and patient representatives in the HTA process.	Reluctant to engage	Roundtable discussions, Workshops, Special Interest Groups
Patient Group X							
Specialist Doctor and Medical Associations X							
Payer							
Academic and Research Institute							
Times Newspaper							



PARTICIPATE IN NETWORKING PLATFORMS AND FORUMS:

Three steps to engage, collaborate, and advocate



1) Gather Information

- Identify and list the networking forums and platforms for a specific disease area. These are usually organized by patient groups, healthcare organizations, non-profits, and academia.
- Find patient engagement platforms through the existing regional and global knowledge hubs. Here are some examples: WHO, the International Alliance of Patient Organizations, and country-specific events.
- Stay informed about events organized by the health policy experts, payers, regulatory bodies, and industry on engaging patients in health policy shaping.
- Identify the champions in the health policy ecosystem.
- Find out the specific disease areas or healthcare areas that they are working on.
- Identify patient groups that have become successful in advocating for their group. It can be for legislative or administrative reasons, and they should be learned from.
- Learn about the objectives and goals of listed networking forums, cross-learning platforms, and experts working on specific disease areas.

Questions to help patient organizations:

- ? What are the active patient groups and healthcare organizations in your geography?
- ? What are some of the relevant and upcoming events and initiatives on their website or social media?
- ? What are these stakeholders trying to achieve?
- ? And would you benefit or be able to help?



PARTICIPATE IN NETWORKING PLATFORMS AND FORUMS



2) Identify Resources

- Explore the required resources to use networking forums and platforms.
- These resources can include but are not limited to:
 - Patient champions
 - Subject matter experts
 - Content writers
 - Funding
- Knowledge products such as tools, guidelines, manuals, publications, newsletters, discussion forums, and networking platforms for a cross-country and in-country learning exchange for peer-to-peer learning and advocacy process.
- Unify smaller, fragmented organizations to help create one voice in pushing for positive change.
- Collaborate to provide strength in numbers, making up for lacking experience or maturity for early-stage patient organizations.
- This synergy will help convince policymakers through perspectives that bring evidence; incorporate the clinical and scientific voices beyond the patient anecdotes.

Questions to help patient organizations:

- ? Who are the champions and interested members in your networks who would like to use these platforms to learn more?
- ? Can these members help others learn and use these platforms themselves?
- ? Which of the above-mentioned resources does your network or organization already possess?
- ? Which members possess the expertise to consolidate the resources if unavailable?



PARTICIPATE IN NETWORKING PLATFORMS AND FORUMS



3) Train, Build Capacity, and Advocate

- Understand the training needs and identify areas of interest for different stakeholders to encourage participation in the health policy dialogue and decision-making process.
- Look for training, capacity-building, and advocacy events organized by networks and forums in the shortlisted areas.
- Co-host capacity-building workshops and virtual webinars at networking forums and knowledge hubs with key stakeholders.
- Propose thematic multi-stakeholder discussion forums to engage patients in the health policy-shaping process.
- Customize local or regional knowledge hubs for specific thematic areas, such as Health Technology Assessments for non-communicable diseases, cancers, etc.
- Patient organizations should upskill on available channels of communication, information on training and networking activities, e.g. the EUPATI platform.
- Conduct a training needs assessment and scope training and capacity-building program(s) through existing platforms or devise in-country program(s).
- Identify successful resource persons from other patient organizations, CSOs, alliances, etc., for their experience and expertise.
- Plan to customize a regional knowledge hub by planning and raising questions such as:
 - Training and capacity building on technical themes and processes such as:





PARTICIPATE IN NETWORKING PLATFORMS AND FORUMS



- How are patient organizations in some countries able to engage with stakeholders and decision-makers better than others?
- How did patient organizations in some countries advocate for patient engagement to be mandated in the health policy decision-making process?
- Publish a white paper from a network forum discussion with the problem statement, challenges, and recommendations outlined
- Review, refer and use regional and global knowledge hubs such as Lion Bridge and HTAasialink for patient engagement.
- Advocate for a process to engage patients in:
 - Policy-shaping process
 - Laws and rights around data protection and privacy
 - Inclusion of patients in health policy decision-making processes

Questions to help patient organizations:

- ? What are the available entry points for your organization or patient group to engage based on this landscape? What do the literature, evidence, and data show?
- ? Are there organizations you can partner with whose advocacy is centered around co-morbidities of the disease concerned?
- ? Does your organization have enough resources or expertise to gather further resources? Where and who can you look up for resources and expertise?
- ? How would you define the roles and responsibilities of the involved and potential stakeholders?
- ? To carry out data-based advocacy, are there partnerships you can develop with data experts such as key opinion leaders, digital health experts, and living lab field experts?
- ? What are the required resources and partnerships you need?

Gather Information

Checklist

Notes

Leadership support

Use the stakeholder mapping template to identify patient organizations in the same disease area and other relevant stakeholders whom you need to look to secure leadership support.

Identify subject matter experts (or third-party consultants) who can assist/facilitate in gap analysis or planning and also identify sponsors who can support funding strategies that are sustainable throughout the process.

Identify specific disease area and locate vulnerable patient population and develop clear definitions for policy-level needs of the populations.

- Patients and caregivers with communication barriers
- Patients and caregivers who need training on understanding the health policy decision-making process
- Patients and caregivers who do not have contact with other peer patient organizations in the same disease area.

Identify government departments, regulators, payers, and social services already involved with vulnerable patient populations and industry partners who will be engaged in the networking and discussion forums.

Identify local groups, organizations, and institutions (community-based organizations, healthcare organizations, research and academic institutions, experts on health policy, and specialist doctors) to invite to the planning forum to address gaps and barriers with engaging in the health policy-shaping process.

Assess gaps with patient groups defined above on health policy shaping for a targeted approach to communicate with policymakers and other key stakeholders.

Identify existing networks and key contacts, such as WHO, International Alliance of Patient Organizations, Patient Engagement Forums, and country-specific events.

Create a master list of community-based organizations, government agencies, industry, providers, specialists, healthcare support staff, and shortlist champions.

Identify resources: key partners and funding to host events, webinars, training workshops, publishing articles, research papers, writing blogs, participating in international forums, and seeking expert guidance on content design, respectively.

Build Leadership Team

Checklist

Notes

Plan the first meeting with identified stakeholders.

(The purpose of this meeting will be to share the gaps by engaging patients in the health policy decision-making process. The meeting will also serve to brainstorm an approach to engage in shortlisted networking forums and cross-learning platforms and discuss channels to communicate the message with identified stakeholders on a regular basis.)

Create Communication Channels		
Checklist		Notes
<p>Determine how to share information about the needs and purpose of engaging patients in the health policy decision-making process</p> <ul style="list-style-type: none"> Discussion forums Webinars Podcasts Focused Group Discussions and Workshops (where there is no access to virtual engagement) Advocacy 		
<p>Establish communication roles and responsibilities among leadership team</p> <ul style="list-style-type: none"> Planning of in-person and virtual events Content development Training needs assessment Publications, blogs, and newsletters 		
<p>Assess communication resources and assets with the partners in the leadership team. Identify the types of communication resources the leadership team already have prior to an event and what value add the patient organizations can bring to the forums and platforms.</p>		
Sustain Engagement		
Checklist		Notes
<p>Update the master list of network members and update them at regular intervals</p>		
<p>Identify gaps in patient population represented in or reach out and engage new partners on a yearly bases</p>		
<p>Form agreements</p>		
<p>Equip network members to perform their roles</p>		
<p>Evaluate training and capacity-building activities</p> <p>Consider new policies to engage patients in the decision-making process and reframe existing ones through advocacy activities</p>		
<p>Establish common terminology</p>		
<p>Use performance measures and tracking with the networking forums and cross-learning platforms</p>		
<p>Conduct an after-action review and debriefing soon after an event within the leadership team</p> <p>Develop an after-action report to capture lessons learned and actions that worked</p> <ul style="list-style-type: none"> Use a facilitator in the debriefing who can: <ul style="list-style-type: none"> Ensure all issues are addressed fully and thoughtfully. Focus on both positive and negative actions and outcomes, as well as suggested corrections. Participate in public fora where new patient groups can improve their confidence level. <p>Ensure that participants do not feel intimidated or pressured to say something or to silence themselves about events that happened.</p>		



PARTICIPATE IN BUILDING PATIENT REGISTRIES AND STANDARDIZE DATA

01

Scope



- Identify institutions and departments engaged or responsible for building patient registries.
- Identify the key stakeholders involved in the design and conceptualization of building patient registries. Identify possible partners in creating the patient

registry such as medical societies, health alliances, government agencies, etc.

- Scope out and identify the existing patient registries in specific disease areas.
- Identify datasets that will be instrumental in influencing health policy.
- Identify linkages between the health policy priorities and the patient registries if there are any.
- Look for opportunities to integrate with existing registries if not done already.

Questions to help patient organizations:

- ? Does the existing registry gather the right patient data that aligns with the requirement of policymakers?
- ? Does the data help to evaluate patient experience with respect to patient treatment, outcome, and patient journey?

02

Planning



- Determine if a registry is an appropriate means to achieve the purpose.
- Analyze and articulate the purpose of the registry. Find data from existing registries that may support

the relevant focus and objective of the patient registries.

- Determine the permissions required to allow for patients, caregivers, and clinicians to enter data on the registry.
- Determine the data requirements for policymakers and regulators on patient health and patient experience.
- Use existing or co-create a structured manual on patient data gaps and processes.
- Identify the stakeholders and define the user access management provisions for different stakeholders.
- Gather sources of data and determine the guidelines to use the data for analysis.
- Provide user access to the data as per requirement and agreement between patient organizations and stakeholders.

Questions to help patient organizations:

- ? Why do you want to develop a patient registry?
- ? What problem in your organization does the patient registry solve?
- ? What are the different kinds of data access that the stakeholders (health policy officials, regulators, clinicians, and patients) have requested?
- ? Do the stakeholders in your networks or through networking forums and platforms possess an existing manual on common data gaps in patient data and processes to fill them?
- ? What are the broad buckets in which the data access requested by different stakeholders are segregated? (e.g., only data view; data entry and view; data entry, view, and edit; data organizing and analysis, etc.)
- ? What are the dos and don'ts of using these registries for all the stakeholders?



03

Resourcing & Organizing



- ➔ Build a team
 - Project management
 - Patient representatives
 - Database management
 - Registry manager
 - Registry experts
 - Legal personnel
 - Quality assurance
 - Study lead
 - Marketing Communications
- ➔ Establish governance and oversight
 - Advisory board
 - Internal Governance
 - Executive or Steering Committee
 - Scientific Committee
 - Liaison Committee/Individual
 - Data Access, Use, and Publications Committee
 - Institutional Review Board for ethical study conduct
- ➔ Define the dataset, sources, patient outcomes, and target population.
 - Assess the infrastructural and training needs required to process and synchronize data relevant to policymakers
 - Data element domains: Personal, exposure, and outcomes
 - Data sources:
 - Patient identifier
 - Patient selection criteria
 - Treatments and tests
 - Confounders Cost/resource utilization
 - Disease or condition data
 - Treatment or therapy data
 - Laboratory data
 - Healthcare provider data
 - Insurance data
- ➔ Capacity Building
 - Conduct capacity-building training session/s for the stakeholders to fully understand their tasks and responsibilities.

04

Launching



- ➔ Checklist of plans
 - Timeline and Schedule Management Plan
 - Cost Management Plan
 - Risk Management Plan
 - Scope Management Plan
 - Quality Management Plan
 - Communication Plan
 - Procurement Plan



BUILD A PATIENT REGISTRY

Reference Guide

Areas	Purpose/Principle	Examples/Context	Notes
Identify registry's aim and objectives	This information will guide the selection of data elements you will seek to collect.	<p>Improve diagnosis (Examine effectiveness of screening)</p> <p>Treatment and prevention (identifying patients for clinical trials, real-world evidence of treatment)</p> <p>Patient safety (monitoring safety of vaccines, devices).</p> <p>Data required to build a case for investment in the specific disease area.</p>	
Define registry dataset	The selection of registry data should be confined to routinely recorded, reproducible, objective data. Select defined health outcomes that are systematically measured which are standardized at predefined intervals. Registry data should adequately describe the patient's condition & major co-morbidities using clinical outcome measures captured by healthcare professionals.	Patients with certain chronic conditions may require annual assessment, which provides an opportunity to capture variables at yearly intervals.	
Establish registry data collection	Data collection needs to be both reliable and sustainable. The depth of the data is crucial for future research purposes; however, the credibility of the registry's population-level statistics is linked to its coverage of the population.	A useful way to establish the distribution of your patient population is a survey or census of all hospitals and/or other relevant institutions.	
Sustain registry data collection	Aim for sustainable long-term data collection from data sources that are ongoing. Having clear guidelines on consent and data storage is important for sustaining long-term data collection from data sources and safeguards the use of registry data in years to come. Simplify the data collection process wherever possible. When collecting data, have a clear protocol to ensure consistency across data collection sites and data entry personnel.	Providing regular refresher training on the protocol for those doing the collection is important. Avoid duplication of data wherever possible.	



BUILD A PATIENT REGISTRY

Reference Guide (cont.)

Areas	Purpose/Principle	Examples/Context	Notes
Select registry software	The software should have the capacity to collect longitudinal data. User-friendly interface for multiple users with different backgrounds and allow differing levels of access rights. Have appropriate data security/protection measures. Reporting interface or engine should also be carefully considered when selecting registry software.	Use of open-source technology is a very valuable approach as it facilitates interoperability with other data collections and ensures that you can gain access to the software source code.	
Governance	The ownership of the registry is not by any one individual but rather by collective membership of the organization and the governing board.	Registry governance requires expertise in issues not solely related to medical care of your patient group but also research ethics, legislation, business, finance, and others.	
Data protection	Ensuring best practice is adhered to. If possible, have legal services involved in the development of data protection practices. Data governance protocols are needed to structure a process for external researchers and organizations to request the registry data.	Data access agreement will ensure all parties abide by the terms of the data sharing arrangement Best practices include: - Laying out data ownership guidelines - Use of data and scope of data responsibility - Protection Act of personal medical information - Report creation using patient data - Application of blockchain technology.	
Resource and funding	Budgeting and resourcing of patient registries should take into account whether the registry is in a planning (design), implementation, operation, or growth phase.	Acquiring funding requires building strategic alliances and building a stakeholder base external to the registry organization. Participate in research studies, budget for registry participation in the study can be factored into research grant.	
Sustain the registry	Build a skilled management and operations team. Ensure the ongoing need for the registry data. Data extraction generally involves accessing, reading, and interpreting written notes in paper hospital records. A registry research nurse, clinical research nurse, or registry coordinator is needed. Participation in patient conferences and dissemination of reports is a way of showing how patient data is used.	The skillset and competencies required to set up the registry may not be the same for the long-term management of the registry Become part of an international community providing real-world evidence for new therapies, outcomes based on new policies, and health technology assessments (HTAs).	



01

Plan and research

Questions to help patient organizations:

- ? What are you trying to achieve?
- ? Who can do it?
- ? What needs to be communicated to them?
- ? Who should persuade them to speak?



02

Define goals

- Clear, measurable, doable, and unambiguous goal setting
- Identify which action item needs to be of priority as part of the campaign and in what order
- Aim to bring about a law that mandates engaging patients in the health policy decision-making process



03

Marshall your allies & engage stakeholders

Questions to help patient organizations:

- ? List stakeholders who are best placed to be engaged in the campaign.
- ? Design the roles for stakeholders to bring clarity to the engagements and discussions to be held with each stakeholder.
- ? Questions to help patient organizations map the target audience:
 - ⇒ Who are they? ⇒ What is their thinking?
 - ⇒ What are the key values that drive them to seek healthcare?

- Stakeholders to be identified
- Legislators who are already in favor of your position
- Beneficiaries of the policy
- People who work in organizations offering services aimed at the issue
- Recognized “experts” in the field
- Supportive community and business leaders
- Credible celebrities who are sympathetic to the issue
- Organizations concerned with the issue or with the population affected
- Engage with experts for advice and collaboration from organizations that support public interest.





6 steps to plan an advocacy campaign (cont.)

04

Articulate messages

→ Messages for the campaign are:

- Simple, outcome-oriented and goal-specific
- Resonate with the stakeholders and garner support
- Builds a compelling case with the target audience



05

Develop a coordination and communication structure

→ Communication channels can be:

- Lobbying, formal meetings, informal corridors, networking during events, campaigns, street action, media interviews, press conference

- Monitor media actions and developments to update the advocacy team.
- Reach out to professionals, patient groups, and industry partners for resources on communications.



06

Approach the legislators

- Implementation is key and needs to be broken down into various levels
- Adapt communication approaches customized to individual stakeholders and for each action item identified
- Reach out to legislators through letters and publications to support the need for a legal mandate and communicate the message through in-person meetings





LEGISLATIVE ADVOCACY CAMPAIGN PLAN TEMPLATE

What do we want? (Goals and objectives)	
Who can help us achieve these? (Examples: President (executive orders), ministry or government agency (administrative orders) or judiciary (Republic Act))	
What do they need to hear? (Messages)	
Who do they need to hear it from? (Influencers, coalitions, alliances)	
How do we get them to hear it? (Delivery and communication channels)	
What have we got? (Resources; strengths)	
What do we need to develop? (Challenges; gaps)	
How do we begin? (First steps: Listen and gather feedback from those advocating for change.)	
How will we know if it's working or not working? (evaluate, strategize, and plan again)	