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PATIENT PATHWAY TOOLKIT

From Challenges to Change: Advocacy Planning Guide

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From Challenges to Change: Advocacy Planning Guide

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1. Introduction

1.1. What is the aim of this document?

This guide is a supporting document for the Patient Pathway Mapping Toolkit. It aims to give patient organisations an overview of available tools for implementing various advocacy projects. We cannot all be experts in everything; there are so many toolkits out there already that come from experienced patient advocates or other stakeholders. This guide is a catalogue of available and free-of-charge tools that can support your organisation throughout projects. Many organisations or institutions have websites or provide additional resources if you would like to dive deeper into specific topics.

1.2. Who is it for?

This toolkit is for patient organisations that want to address challenges identified along the patient pathway for their patient community. This document will help you choose the right action for the selected issue you want to target, and support the planning and implementation of the advocacy project. Although advocacy can look different based on region and disease area, common themes can be observed in advocating for engagement and understanding of patients. This tool is based on these common themes.

1.3. How to create change?

Patient organisations are often powered by volunteers, and sometimes it can be difficult to clearly determine which actions are most beneficial for addressing the challenges of that particular patient community. Patient organisations often don't know where to start or how to grow advocacy projects to reach their goal. These actions or projects to address challenges can occur at and target different levels, at various stages of the patient pathway and diverse decision makers. In Table 1 (below), we attempt to illustrate how the three aspects align. Further down, Figure 2 illustrates each stage of the patient pathway in isolation.

Table 1. Creating change on different levels. Who to reach out to at what step of the patient pathway.

Health system level	Stage of the patient pathway	Policy makers
Local department/clinic/hospital	Design of the end-to-end services for: • Diagnosis • Referral • Treatment/management • Long term monitoring • Screening	• Department head • Hospital manager • Local GP groups • Formulary/procurement committee
Local region healthcare system	• Provision of local support services such as home care • (Sometimes) the budget available to hospitals in the region • (Sometimes) The health priorities that local hospitals and GPs should be targeting	• Local Representative • (Health) Governor/Senator • Mayor • Local Parties
National healthcare system	The overall strategy, budget and priorities of the public healthcare system • National cancer plans • National rare disease plans • Setting targets such as reducing time to diagnosis • Providing resources (money and staff) to deliver healthcare • Setting the remit for how new medicines will be assessed for reimbursed access	• Health Minister • Parliamentarians • HTA Agencies • Civil servants/government employees • National parties • National Specialist Medical Societies • National medicines or devices regulatory committees

2. Overview of available toolkits

Share4Rare (https://www.share4rare.org/) is a European Project that had the vision to improve patients' lives by bringing together expertise from multiple rare diseases and share best practices and capacity building. As part of this community, a platform for patients and care was created to exchange knowledge and improve science. Alongside the network, the Share4Rare community created a toolkit for patient advocacy and organisational capacity building. This comprehensive toolkit draws from the knowledge of well-recognised organisations and institutions and also is not limited to rare disease patient organisations, but can be equally useful for more common diseases, such as cardiovascular diseases or diabetes.

EUPATI (European Patients' Academy on Therapeutic Innovation) is a program that offers training and education to patients and patient advocates to increase their knowledge for meaningful engagement in medicines research and development (R&D), and to improve the availability of medical information. The program is the result of a public and private partnership IMI-project. EUPATI offers a large variety of online and in-person training opportunities, and in some instances in local languages. It is a very comprehensive training that requires substantial commitment of the participants; however, fellows who complete the course are internationally recognised as competent advocates who can function at high level in scientific and medical committees or projects.

WECAN Academy provides free-of-charge online and in-person educational material relevant to cancer patient advocates in WECAN's member organisations. It covers all areas of patient advocacy from the knowledge and skills required for advocacy to local, national, and European policy and research. WECAN has close connections to European Policy and Regulatory Bodies, and this source is particularly helpful, for example, to understand the EU General Data Protection Regulation, in addition to all cancer-specific EU policies.

PMFD (Patient Focused Medicines for Development) is a collaborative initiative designing a patient-centred healthcare system that engages patients as partners. They offer a variety of training, tools, and information on their website.

Notably, PMFD has created the PEM SUITE which is a global hub with practical tools to plan, assess, and execute any patient engagement initiatives.

3. Finding the right tools

Patient organisations need to continuously stay informed and provide relevant insights and feedback to the appropriate institutions to evolve a strong patient advocacy position. The following sections provide tools and toolkits on relevant areas.

Please be aware that the following tools and toolkits are derived from various sources and are partially directed at specific disease areas, or specific geographical regions or countries. All sources will provide valuable information to overcome existing challenges and support your advocacy projects. Therefore, do not be dissuaded if the information is not directly relevant to the disease or condition you represent or the regional circumstances, as you still may be able to gleam useful transferable insights and information that you can apply to your own area. Think about how you can adapt the tools to meet your needs.

4. Patient pathway

The patient pathway is a process with distinct stages patients go through. While the stages can look different depending on the condition, common issues along the path can be identified for most patients that need to be addressed. Below is an example of a patient pathway (Figure 2) and tools that can support your organisation in addressing identified problems for your community.

Figure 2. Stages of the patient pathway

The Innovative Partnership for Action Against Cancer (iPAAC) was an EU-funded project that aimed to improve cancer control, building upon previous EU projects. One deliverable has been the Patient pathways for Comprehensive Cancer Care Networks, which provides information and tools on patient pathways. While the project focused on cancer, relevant insights can be applied to other conditions. **The International Alliance of Patients' Organizations (IAPO)**, which represents patients across the world and disease areas, developed The Patient Safety Toolkit addressing Global Patient Safety Issues publication in 2008. While this document is older, most information contained within it is still relevant today and covers the distinct safety issues throughout the patient pathway, while simultaneously laying out concrete advocacy action(s) that can be taken. Furthermore, the document has been created with insights from patient group members, and is therefore a good example of patient engagement in tool development.

5. Project management

To ensure that projects are successful and implemented effectively, project managers need to consider many aspects of a project at the same time. Below you can find tools that can help you to create a project plan, create SMART goals, and work with relevant stakeholders to achieve the best results for your community.

An example of the tools **Share4Rare** offers to the community is the Strategy Plan. The plan consists of a one-page document in which you can fill out the most relevant information for any project independent of region or disease indication. This can help an organisation to identify the key features of any project, providing a succinct guidance and reference document for the organisation.

The concept of SMART Goals (Specific, Measurable, Attainable, Relevant, and Time-Bound) has been around since 1981 and still to this day provides the backbone of many project plans around the world. While there are a variety of templates to plan SMART goals, this website provides an introduction to the concept, explanations for each category, and a free downloadable template.

Another **Share4Rare** resource that is worth mentioning is the Target Audience tool which can help you to identify your target audience and their needs, wants, and expectations. This can be a key tool to help understand the important stakeholders related to your project.

One of the most essential parts of projects is to identify project partners. Depending on your network and the type of project you are building, you are going to need different partners. Patient organisations cooperate with stakeholders that have their own agenda. Working with others while maintaining independence can be difficult. The **International Alliance of Patients' Organizations (IAPO)** provides valuable insights that can support you through this operation, through this published toolkit "Working with partners and stakeholders, Patients' organisation toolkit".

Digital engagement has emerged as a pivotal tool in amplifying patient voices and driving impactful advocacy projects. Accordingly, the community at the European Patient Innovation Summit 2020 (EPIS 2020) united to deliberate on a pressing question: "How can we ensure that patients continue to benefit from digital engagement opportunities?"

This collaborative inquiry sparked the creation of the "Digital Engagement Toolkit". This comprehensive toolkit is designed to guide patient advocacy groups in harnessing digital tools effectively. It covers a wide range of digital engagement strategies and offers practical templates to help users draft detailed plans tailored to their specific goals.

6. Health care system

Every country has its own healthcare system that may be hard to navigate. Patients need to consider many things while manoeuvring through the system.

For example, Health Consumers Queensland published a toolkit called "Getting the Healthcare you need: An advocacy toolkit for people using the healthcare system in Queensland." As the name indicates, it is focused on a specific region. However, the toolkit provides many useful insights that are generalisable, for instance, how to prepare for a clinic visit and what to bring.

7. Research/clinical trials

Clinical research is a relevant aspect for many patients especially for those with rare diseases or under-researched diseases. Patient engagement in research is receiving more attention in recent years. To be able to provide input into research, patients need to understand the processes and phases of research and development (R&D). Below you can find information that can support patients to fully engage in research processes in a meaningful way.

The first toolkit is from **Global Genes** and while it focuses primarily on rare diseases, it provides a general overview of many aspects of research and development as well as the publication and understanding of scientific papers from which all communities can benefit. The document is called "From Molecules to Medicine: How Patients can Share their Voices throughout the Drug Development Process".

A great visual tool that displays how patients can have an impact on research and development is provided by **EUPATI.** They have created the "Patient involvement in medicines R&D: a practical roadmap". This roadmap is also a part of the broader EUPATI toolkit that is recommended in the overview section.

8. Health Technology Assessment

Health Technology Assessment -usually referred to as HTA- is a multidisciplinary process in which stakeholders evaluate medical, social, economic, and ethical information on a specific technology with the aim to inform policy. Technology in this context can mean any health intervention, such as medicines, vaccines, screening tools, etc. An HTA decision summarises the added value of a given technology along with specific recommendations, e.g., whether costs for use should be reimbursed, who it should it be available to, or whether it should be accessible over the counter, etc. Many countries have started or are planning to involve patients in this process, acknowledging the value of lived experience as a form of data. It is critical that patients fully understand the HTA process and the implications of decisions, despite it being a somewhat complicated process. The tools provided below offer a wealth of information regarding the HTA process for patients.

First is the HTA 101 tool from the **National Institutes of Health (USA Gov)**. An important caveat to this tool is that it is, at times, very US-specific, meaning some of the information contained within it may not apply to your local context. However, it provides a clear overview of relevant aspects of HTA decision-making.

Another useful source of information is the "Health Technology Assessment process: Fundamentals" toolkit provided by **EUPATI.** The toolkit offers insights into processes and relevant information for patients in patient-friendly language and with a European perspective.

The **EUNetHTA** is a network for HTA across Europe. It consists of multiple national HTA bodies and aims to develop reliable, timely, transparent, and transferable information to support all parties in navigating the HTA process. On their website, they publish, amongst other tools, tools on the methodology, Planned and Ongoing Projects (POP) database or Declaration of Interest (DOI).

9. Young patients

Young patients have been under-represented within the patient advocacy field, yet they often face unique and different challenges and experiences compared with adults. Even if the disease you represent does not directly affect young people, it is worth identifying tools that can support young patient advocates in your context, if it is relevant. Remember that young people can not only be patients but also caregivers to loved ones and their lives can be impacted by virtually any disease, albeit indirectly.

The European Patient Forum (EPF) created an online advocacy course for young patients.

10. Working with the media

Getting your voice heard and raising awareness is challenging for many organisations. Engaging the media either through traditional outlets or new media can be a powerful tool to reach a larger audience and get your message to the right people. Below you can find tools that can support you in this process.

The European Network of Gynaecological Cancer Advocacy Groups and the European Society of Gynaecological Oncology released a "Media toolkit training guide" that provides information on how to effectively engage the media. While the target audience of the toolkit may be rather specific, questions regarding media engagement are answered that are applicable for all patient advocates. Among the many issues included are for example, message development and writing press releases or letters to editors.

A similar toolkit was published by Rare Cancers Europe. Their tool is called "Speaking up for Rare Cancers" and covers all relevant steps towards engagement with the media and other stakeholders to get the most out of your project.

11. Evidence-based advocacy

Evidence-based advocacy (EBA) might not always be known under this exact name. Patients often do not have the same experience or needs that others might think they do. Consequently, patient sometimes need to find the data that underpins their advocacy claims. The data can be gathered through different means. For example, surveys can be carried out with members of patient organisations to generate quantitative and qualitative data around people's experiences with the disease, including diagnosis (and misdiagnosis), experiences with different treatment, impact of the disease on quality of life, and more. One example of how evidence might be generated would be through a survey that identifies the fact that patients in their disease area are misdiagnosed three times before getting the right diagnosis; the collected data can be presented to medical societies making them aware on common misdiagnosis, and the impact that has on the patients' experience.

You can find educational materials on EBA on at the **WECAN Academy**. WECAN (Workgroup of European Cancer Patient Advocacy Network) consists of 20 cancer umbrella cancer patient advocacy organizations active in Europe which have the aim to strengthen cancer patient advocacy and improve outcomes for all cancer patients through collaboration. While the materials are focused on cancer, there is relevant information within them that may be transferable to other disease areas.

Other relevant data that can be gathered and generated is Patient ExperienceData. This may be gathered through interviews or qualitative surveys with members in patient organisations. While this data does not need to be collected by patients themselves, the resulting data can have great implication for patient advocacy activities. PFMD **(Patient Focused Medicines for Development)** have created the tool The Global Patient Experience Data (PED) Navigator in cooperation with stakeholders. The Global PED Navigator provides an extremely useful tool to navigate through the different impacts the patient experience data has across different stakeholders.

They provide four levels of a PED matrix:

1. Tool to identify select approaches that could be used to determine what outcomes matter most to patients & families
2. Tool to select appropriate measurement methods of outcomes that matter to patients & families
3. Tool to identify PED use per stakeholder throughout the product development cycle
4. Tool to identify PED use per stakeholder throughout the healthcare process

12. Fundraising

Fundraising is really a separate topic worthy of extensive review, perhaps beyond the scope of this current document. It serves several critical functions that extend beyond simple financial sustenance. Firstly, it provides the essential financial backing required for the development, launch, and ongoing support of advocacy initiatives. This encompasses costs associated with technological development, hosting services, content creation, and the execution of comprehensive promotional strategies aimed at engaging the community. Furthermore, the acquisition of funds facilitates innovation by allowing for investments in cutting-edge digital tools and technologies. These advancements significantly enhance the connectivity and support between advocacy groups and their communities, enabling the creation of tailored digital platforms, mobile applications, and the use of sophisticated data analytics.

Moreover, successful fundraising efforts enable these projects to broaden their outreach, ensuring messages and advocacy efforts reach a more extensive and varied audience. This is particularly vital in digital engagement, where the aim is often to interact with a diverse set of individuals across different locations. The financial resources garnered through fundraising activities also ensure the sustainability of advocacy efforts, providing a stable foundation for maintaining advocacy platforms, regularly updating content, and keeping the community actively engaged over time.

Additionally, fundraising plays a pivotal role in empowering patients and stakeholders. It supports the production of educational materials and projects in advocacy. Lastly, success in fundraising can pave the way for collaborations and partnerships with technology companies, other non-profits, and stakeholders in the patient advocacy realm. These alliances bring in additional resources, expertise, and the visibility needed to magnify the impact of advocacy projects. Thus, fundraising is not merely about securing financial resources; it's about empowering patient advocacy projects to innovate, expand, and sustain their impact, ultimately enriching the lives of patients.
Examples of toolkits to get started on planning your fundraising campaign is the "Finding your Fundraising Strategy" by Global Genes, a non-profit organization dedicated to eliminating the burdens and challenges of rare diseases for patients and families globally or the Advocacy Toolkit developed by Union for International Cancer Control (UICC), both can be very useful for you and your organisation when establishing the fundraising strategy and campaign.

Yet, when engaging and asking for financial support, the organisation needs to set some ground rules on what the dynamics with the funding body need to be. We have provided a template for a suggested Code of Conduct (Annex I), establishing the ground rules when working with pharmaceutical companies.

13. Reporting and Communication to Stakeholders

A final -but critically important- step to every advocacy project is to maximise and leverage the impact of that particular project through effective reporting and communication. Typically, there will have been some reporting step included in the project plan, however, a classic pitfall for patient organisations is to hurry through that step as an unwanted necessity. However, the timely and effective reporting of an advocacy project has many advantages. Firstly, it is an opportunity for communication with your stakeholders, to strengthen and consolidate your community. Let them know what you have done with their input, and thank the appropriate parties (e.g., funders, participants in a survey, volunteers and staff that spent time on the project, etc). Use a strategy for communication to amplify the impact, for example, send an message that the project will be finishing soon and that they should keep an eye out for the report, then send the report, with accompanying infographic or visual abstract (this can also be a PowerPoint slide, be sure to include a "advertisement" for an upcoming event or awareness month), consider a slogan that reminds stakeholders of your organisation's mission (e.g., Together We Are Stronger), and use your organisation's colour palette and logo throughout. This is important for branding purposes and recognition of your organisation. Reporting on each project will also make your annual activity report much easier to compile.

1. Write a short summary of the unmet need your project addressed, or why that advocacy project was necessary.
2. Write a paragraph about how you went about performing the project.

3. Write about the project's results, and use graphics as much as possible. You can also record a short video explaining the project, and put a QR code of the video in the report. Mention anything unexpected that may have occurred, or any obstacles encountered in the project.
4. Write about any potential or measurable impact, and whether there will be any follow up of that project, what the next steps might be.
5. Generate a plan for digital and social media about the project. You can use any graphics or videos generated in the reporting to amplify key messages. If appropriate, prepare a press release, and contact media, or the professional medical society that primarily treats the condition you represent. Large language models such as ChatGPT can automatically generate social media messages from your report.
6. Place the report on your organisation's website and link to any other relevant projects. Make a QR code of that report and use in newsletters or social media. Consider writing an abstract to submit to a medical congress about that project. Ask any medical or scientific advisors for your organisation if they think that it might be publishable as an article. Publication of your activities is a deliverable most funders will value, and it will benefit any medical professionals you work with, thereby consolidating their involvement in your organisation.
7. Take the time to celebrate the completion of any project! Your organisation will be incrementally stronger as each project is finished, and celebrating appropriately (even just a zoom meeting toasting all individual involved is enough) is important to acknowledge effort made by the team and provide closure.

Annex I

Code of Conduct template:

A. Purpose of Policy

To ensure [the organisation] has a consistent and transparent approach to working with commercial companies.

To ensure [the organisation] maintains its independence from commercial influences. [the organisation] reserves the right to terminate any project or partnership where agreements have been transgressed or where the relationship contravenes [the organisation]'s Code of Conduct.

To clarify [the organisation]'s position to patients, its affiliate organisations, commercial companies and the wider public.

To provide clear direction for the [the organisation] Board of Directors/Members, enabling them to initiate relations with commercial companies with the full backing and endorsement from the affiliated organisations who comprise [the organisation].

[the organisation]'s board of Directors/Members is expected to adhere to this policy that is reviewed annually but may be revised as circumstances demand.

B. Funding: Categories

There are different funding categories, including:

Project funding is where the [the organisation] will establish a collaborative partnership with a commercial company to undertake a project relating to an issue of mutual interest. The following features will apply to this relationship:

- [the organisation] maintains editorial control over all materials produced in connection with the project
- The company will have representation on the project steering committee
- The sponsor's logo can be used – in negotiations with the company
- [the organisation] will not endorse or promote the company or its individual products or services
- The wording and/or position of the credit will be agreed upon in negotiations with the company
- [the organisation] and the commercial partners will both benefit from the relationship

Sponsorship is where a company funds a single activity such as a meeting or newsletter. In this case the following will apply:

- The company has no involvement in the activity for which the sponsorship is granted
- [the organisation] maintains editorial control over all materials or meeting programmes
- [the organisation] will not endorse or promote the sponsor or its individual products or services
- The sponsor's logo can be used – in negotiations with the company

- The wording and/or position of the credit are part of the sponsorship negotiations with the company
- [the organisation] and the commercial partners will both benefit from the relationship

Unrestricted grants are defined where all of the following apply:

- The company has no involvement in the project for which the grant is used
- The grant will be acknowledged
- The company's logo is not used
- [the organisation] controls the wording and placement of the credit
- [the organisation] will not endorse or promote the company or its individual products or services

Core funding: Funds for core activities will always be received on an unconditional basis. To avoid undue reliance on any particular company, such funds will be balanced and diversified as much as possible to avoid conflicts of interest and to guarantee independence.

Companies may offer financial donations and in-kind support to the [the organisation]; However, there is no obligation on the part of the [the organisation] to acknowledge the support, although [the organisation] may decide to do so.

C. Sustaining Partnership

[the organisation] sustaining Partners are commercial companies that want to establish a long-term relationship with [the organisation] and wish to demonstrate their commitment to [disease area] patients by helping [the organisation] promote global understanding of the burden of [disease area] and the right of patients to effective early diagnosis detection, better treatment and supportive care.

A Sustaining Partner that donates a minimum of X USD/€ per year receives in that year:

- Recognition as a Sustaining Partner on the [the organisation] website and other communication materials of the [the organisation].
- Direct link from and to the Websites. (This is only possible in negotiations with the company and in accordance to the legal regulations.)
- Opportunity to meet the [the organisation] board of Directors/Members at an annual meeting to discuss issues of concern to both commercial organisations and patients.
- Opportunity to propose collaborative projects which will have priority status over those proposed by Non-Sustaining Partners.
- Regular e-mail updates on [the organisation]'s activities.

D. Funding: Guiding Principles

[the organisation] will foster dialogue and establish collaborative partnerships with companies/ trusts/funds/charitable organisations whose commercial decisions affect the survival and quality of life of [disease area] patients.

Partnerships between Patient organisation and pharmaceutical companies are sometimes viewed with scepticism by decision-makers, the media and the general public. Some people believe pharmaceutical companies may coerce patient organisations into conforming to their marketing agenda. In order to protect the [the organisation]'s reputation and demonstrate that [the organisation] does not conform to commercial agendas, [the organisation] will adhere to the following principles when accepting project funding, core funding, sponsorship, grants or donations from commercial companies/trusts/ funds/charitable organisations:

- [the organisation] will maintain an open and transparent relationship with all commercial and non-commercial partners.
- Where possible, [the organisation] will solicit funding from consortia composed of two or more companies from the same industry (known as multi-sponsoring).
- Before accepting funding, the [the organisation] board of Directors/members must be satisfied that there are strong grounds for believing the donation, grant or sponsorship will result in benefit to the organisation and its members.
- [the organisation] will closely review all potential commercial partners' corporate governance policies, their reputation in working with patient organisations and their environmental policies and practices. If there is any cause for concern, [the organisation] will reject the funds.
- [the organisation] will not endorse or promote a company or its individual products or services. The purpose of the [the organisation] is to inform affiliate organisations independently and not to promote or recommend special therapies, services, clinical trials or off-label use of therapies.
- A company's support will be acknowledged in an appropriate way following discussions with the company concerned.

[the organisation] commercial partners must agree to abide with the guidelines outlined in "Section E" below.

If a company makes any attempt to coerce the [the organisation] to conform to its marketing agenda, either explicitly or implicitly, or does not conform to the agreement, [the organisation] will reject the funds or terminate an ongoing project.

E. Guidelines for Commercial Companies

[the organisation] will not embark upon or continue with any sponsorship, grant making or collaborative venture that might damage its reputation or result in the dissemination of biased and inaccurate information to the general public and/or cancer patients. Therefore, when working with [the organisation], commercial companies should adhere to the following guidelines:

1. [the organisation] must be consulted whenever and wherever its name is used, particularly in external communications. Approval must be sought for any text or copy produced which refers to a [the organisation] initiative supported by a commercial organisation.
2. At no time can [the organisation] logo be used without expressed written permission from the Board of Directors/Members.
3. At no time can Press Releases be issued which refer to [the organisation] without prior approval of the Board of Directors/Members. Likewise suggested quotes can be prepared but must always be agreed by the Board of Directors/Members.
4. [the organisation] retains a veto over all materials produced in connection with an initiative. Adequate approval time needs to be allowed for this as it may require approval from one or more members of the Board of Directors/Members.
5. All materials produced as part of an initiative of [the organisation] will be in full compliance with the applicable legislation on information and advertising of medicinal products and will be impartial as to products discussed.
6. For all projects where [the organisation] may be working in collaboration with a company and/or agency, clear lines of communication need to be established with agreement on respective responsibilities and assignments to ensure smooth progress

with the project. [the organisation] will have one point of contact identified within the company.

7. All correspondence to [the organisation] should be directed to the Administrative Team or to the elected Board of Directors/Members not to individual members. The Board of Directors/Members will delegate special responsibilities to individual Board members such as the relationship management to commercial companies.