EURORDIS
RARE DISEASES EUROPE

GUIDE FOR PATIENT INVOLVEMENT IN THE DEVELOPMENT OF CLINICAL PRACTICE GUIDELINES & CLINICAL DECISION SUPPORT TOOLS

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Background

Patient[1] involvement in clinical guideline development and appraisal is recognised as a fundamental requirement for the development of high-quality Clinical Practice Guidelines (CPGs) and Clinical Decision Support Tools (CDSTs) (AGREE II and GRADE). Patients ensure that the CPG meets their needs and ultimately improve the implementation of CPG recommendations across healthcare systems.

It is important to note that patient involvement in the development of CPGs and CDSTs is even more important in the field of rare diseases due to the scarcity of evidence and the low prevalence of conditions. However, there exist two main barriers to effective patient involvement:

1. **Perception barriers –** it has been reported that clinicians perceive patient involvement as stifling scientific discussions. However, this perception may change over time [1].
2. **Capacity barriers –** patients believe that they have insufficient information, for example on terminology or content, and are unwilling to contribute if they do not feel adequately educated [2].

Despite existing barriers, patient involvement in CPG development has evolved from patients being presented the final CPG prior to publication, to patients now being involved from the outset [1]. High quality capacity building for patient involvement in CPGs and other CDSTs now exists, for example via the **European Patient Ambassador Programme** of the **European Lung Foundation**.

EURORDIS, in collaboration with the patient community, has developed this practical guide to address the above-mentioned barriers and support the involvement of patients in the development of CPGs and Consensus Statements. This guide draws on the European Reference Networks (ERNs) methodological handbooks to develop, adapt and adopt **Clinical Practice Guidelines** and **Consensus Statements**, as well as on existing best practice for patient involvement in CPG development [3–6]. Additionally, in this document you will find:

- **A planning and tracking** tool which will assist you in keeping a record of where and how you involve patients in your project **(Annex 1, pages 13 - 14)**.
- **A glossary of terms** to help you to better understand and navigate CPGs and Consensus Statements methodology and jargon **(Annex 2, page 15)**.

1. In this document, the term "patient" is used to refer to individual patients, carers or relatives and representatives of patient organisations.

What are Clinical Practice Guidelines and Consensus Statements?

CPGs are statements that support decision making in a specific clinical circumstance typically related to screening, diagnosis, surveillance, treatment or long-term follow up [7,8]. They are based on a systematic evaluation of the most up-to-date medical/scientific evidence. On the other hand, Clinical Decision Support Tools (CDSTs) are usually based on the consensus of experts' opinion and clinical experience, in areas where there is limited published scientific evidence available, due, for example, to the small population sizes such as in rare diseases [9].

Why are CPGs and Consensus Statements important and how can they be used?

CPGs and Consensus Statements are useful and powerful tools for both patients and healthcare professionals that [7,8]:

- allow clinicians, experts and non-experts, as well as the patient community, to make recommendations and/or outline best practices on diagnosis, care and/or treatment based on the best available evidence derived from reliable clinical research and practice.
- reinforce patients' trust in healthcare services and ensure that they have access to the best existing care possible.
- encourage a common and standardised approach to diagnosis and clinical management.
- leave room for variations, based on clinical judgment, as long as these are justified [10]. CPGs are guidelines and not legally binding standards for care; therefore, clinicians are not obliged to follow the recommendations if they don't think they are suitable for certain patients. Care should be informed by CPGs but tailored to the specific needs of each patient and their presentation.

Why should patients be involved in the development of CPGs?

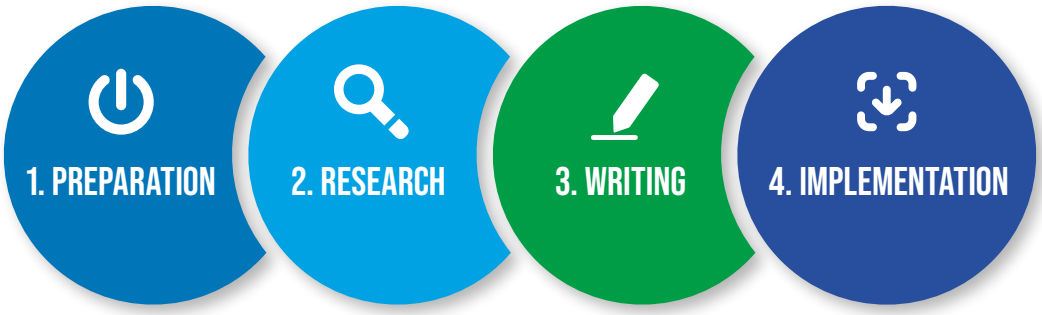
Involving patients helps to identify issues from the holistic perspective of a lived-experience expert, which may be overlooked by clinicians. Highlighting areas where the patients' perspective differs from that of healthcare professionals will ensure that CPGs address key issues of concern to patients.

Patients can contribute to the CPG development process and discussions internally by being active members of the **Guideline Development Group** supported by a **Patient Advisory Board.** External engagement with the community can be organised via focus groups, priority setting surveys, expert panels and other consultation methods.

How are CPGs developed and how can patients be involved in their development?

CPGs are developed following a stepwise process, structured under the following 4 main stages: **1) Preparation, 2) Research, 3) Writing** and **4) Implementation.** Patients can be involved in CPG development throughout these 4 major stages.

4 STAGE PROCESS



The main added value of patients' involvement resides in shaping the CPG scope to best meet their needs, as well as weighing the benefits and harms of clinical decisions, and expressing their preferences based on the balance between desirable and undesirable effects [11].

This guide walks you through the role of patients in the different stages of CPG development and suggests different methods to support patient involvement as a valued partner in the process. The **Summary Table** (page 12) provides a snapshot of *why, where* and *how* patients can be involved in each of the **4 stages** of the CPG process. Additionally, **Annex 1** (pages 13-14) provides a checklist that can help you to plan and keep track of how you involve patients in your project.

STAGE 1: PREPARATION

The **Preparation Stage** is the time to plan and make important decisions, i.e., define your priorities and goals. Patient involvement should be considered and defined in this stage before the development of the CPG has started [11]. Early patient involvement and consultation will allow the Chair of the **Core Team,** who leads the development of the **Guideline Development Group,** to set expectations for why and where patients will be involved at the different stages of the development process and how their input will be integrated [5].

The **Preparation stage** can be broken down into 3 activities:

1.1 Topic prioritisation

The general topic of the CPG must be first selected, prioritised and approved, including the disease area and the specific clinical circumstance, for example: *Is it a guideline for diagnosis, surveillance, or overall disease management? Which clinical circumstances and presentations should be included?*

Patient input is critical at this stage to ensure topic prioritisation is in line with the expectations, needs and experiences of the patient community [3,5,6,12].

1.2 Team assembly

The development of CPGs is typically led by a small **Core Team** integrated by a multidisciplinary team of healthcare professionals who are experts in the clinical circumstances addressed by the guideline. The Core Team will identify the extended members of the **Guideline Development Group.** Patients should be part of this extended group, alongside healthcare professionals [12].

To articulate patient involvement in the **Guideline Development Group,** it is recommended to set up a **Patient Advisory Group** formed by 8-10 patients, when possible [3–6]. The **Chair of the Patient Advisory Group** (Patient Lead) would then join the **Core Team** and **Guideline Development Group** as a member to relay feedback and represent the patients' views [12].

To manage expectations, there should be clear communication from the outset about the role of patients including *why, when* and *how* patient involvement will occur throughout the development process [2].

1.3 CPG scoping

Once the overall topic is determined and the group has been established, the scope of the CPG is defined by specifying the **P**opulation, **I**ntervention, **C**omparison and **O**utcome **(PICO)** that the guideline will address. Patients have a critical role at this point as they can [3,5,6,12]:

- **advise on the guideline scope,** including the target population, intervention, comparative treatment and also clinical questions, suggesting or highlighting factors and parameters that should be used to search the published literature.
- **select meaningful outcome measures** and also review the outcome measures that will be included in the scope in terms of their relevance and importance to patients.
- **identify clinical experts and patients** who can contribute or be consulted in defining the CPG scope.

During the **Preparation stage,** it is **recommended** to collect patients' needs, views and preferences on priorities [5,6,12] through joint discussions with healthcare professionals involved in the ERNs, for example during the **Guideline Development Group meetings** (internally), and/or through online surveys, focus groups and other consultation mechanisms (externally).

TOP TIPS

- **Determine with the Chair of the Core Team and the Patient Lead on *where*, *when* and *how* patients and their voices can be integrated into the discussions and development of the CPG, setting expectations and parameters for patient involvement.**
- **The Chair of the Guideline Development Group can support patients with the ranking of outcomes by summarising the initial outcomes used to scope the CPG and by developing a glossary of terms to explain terminology around clinical outcomes.**
- **Patients are encouraged to engage with the Chair of the Guideline Development Group if they need additional information to rank and prioritise outcomes.**

STAGE 2: RESEARCH

In the **Research Stage a literature search and analysis of the literature** is performed to **answer the questions** defined in the **Preparation stage.** The systematic review process is normally led by an individual researcher or a small team and it takes time. The average time to conduct a systematic review is 3-6 months. The involvement of patients and clinical leads at this stage is limited compared to the **Preparation stage.** The **Research stage** can be simply subdivided into 4 activities:

2.1 Literature Search

The size and quality of the published literature retrieved in the initial search of the literature will determine whether a systematic review of the evidence or a consensus process is pursued.

2.2 Systematic Review

When there is a substantial body of evidence, a systematic review is conducted. In parallel, where there are gaps in the evidence, a **patient-centred literature search** can complement the systematic review of the medical literature. For example, searching for articles directly reporting the **patient experience** (e.g. interviews or focus groups), can be an effective strategy to capture and integrate patient views that might be missing in the scientific publications [5,12].

2.3 Consensus Process

The low prevalence and small affected populations of the majority of rare diseases directly impacts volume of research and published evidence. Following the completion of the systematic review, the **Guideline Development Group** and **Patient Advisory Group** can identify 'gaps' in the evidence where the Guideline Development Group can draw on the body of clinical expertise and experience to develop consensus-based recommendations. It is important that, despite having gaps in the evidence, the CPGs should not be translated into gaps in treatment. Patient representatives can play an active role in **Delphi consensus building processes.** The formation of consensus recommendations should be developed through a robust methodology such as a **Delphi approach.**

2.4 Grading

The **synthesis** and **appraisal of the evidence** using the **GRADE** (Grading of Recommendations Assessment, Development and Evaluation) method is a highly technical methodology that requires differentiated and unbiased expertise. Typically, the **Guideline Development Group,** including the patients involved in this group, will receive updates and further questions throughout this step [5,12]. Patient consultation at this stage may allow for the generation of opinions on patient values and preferences, equity, acceptability (e.g. *the benefits and harms of the recommendation)*, and feasibility [12].

It is **recommended** that during the **Research stage,** patient views can be externally elicited to provide comments, e.g. *whether the questions addressed are relevant to them and will make a positive impact on patient care, or whether important aspects of the experience of illness are considered, via focus groups, surveys or by conducting social media listening* (i.e., collecting data from online discussion forums or social media) [5,6,12].

TOP TIPS

Patients can gather information about patient experiences of the topic to help supplement the scientific literature while the systematic review is underway. This could be through:

- **Patient-centred literature review of published research (e.g. interviews, focus groups)**
- **Review of patient experiences in blogs, online discussion groups and social media**
- **Consultation with their patient community (e.g. survey, discussion groups**

STAGE 3: WRITING STAGE

The **Writing Stage** can be described as the point where the **Guideline Development Group** "goes from evidence to recommendations" [5,12].

Patient input here can help create a good balance between what clinicians need to guide their decision-making, and **what is important to patients,** informed by their **preferences based on weighing the benefits and harms** for a specific intervention.

Individuals will have different views, so it will be important to consider perspectives beyond those of patients sitting on the **Guideline Development Group,** including the results of the patient literature review, survey data or the views of the wider **Patient Advisory Group.**

3.1 Pre-meeting with Patient Advisory Group to discuss evidence

The research lead can present the evidence and findings from the systematic review to the **Patient Advisory Group.** The **Patient Advisory Group** can discuss the different aspects of the evidence as a group and formulate feedback that can be shared with the **Core Team** and the **Guideline Development Group.**

3.2. Evidence to decision meeting

Patient representatives from the **Patient Advisory Group** should be involved and supported to contribute to the 'Evidence to Decision Meeting' in order to provide transparency of the discussions and rational for formulating the initial recommendations.

3.3 Developing recommendations

Emerging recommendations can be shared with the **Patient Advisory Group** as part of their development. Patient input here can help find a good balance between what **clinicians need** to guide their decision-making, and what is **important to patients,** informed by their **preferences based on weighing up the benefits and harms** for a specific intervention.

Patients can be involved in the following **3** activities [5]:

1. provide valuable insights into how the recommendations can work in practice and make sure the final CPGs are useful in the real world by contributing to the development of the recommendations.
2. review the draft CPGs and verify that patient views have been incorporated and addressed, e.g. highlight evidence gaps in areas that they consider important, such as discomfort.
3. be included as co-authors or noted in the acknowledgements.

At this stage, patients' involvement can focus on [5,12]:

1. explaining to what extent they value an intervention *(e.g., position themselves in terms of how they perceive the benefits and harms of a given medication).*
2. helping to reflect on the varied preferences of patients and the factors they consider when making choices about their treatment *(e.g., would patients adhere to a certain medication scheme?).*
3. expressing whether they feel an intervention promotes equity *(e.g., is this intervention accessible to those living in rural areas?).*
4. reviewing the wording of the recommendation.

During the **Writing stage** it is **recommended** to systematically involve patients in internal meetings (e.g. the *'evidence to decision meetings' of the Guideline Development Groups and Patient Advisory Group meetings*), by participating in expert panels and through participation in consensus procedures (e.g. Delphi process) [13,14].

TOP TIPS

- **Patients in the Patient Advisory Group can together review the emerging evidence and recommendations, weighing the harms and benefits. Preferences can be reported back to the Guideline Development Group by the Patient Lead.**
- **The Guideline Development Group can present the draft and final recommendations to the Patient Advisory Group and check their understandability, soundness and usefulness for the guideline target population.**
- **The initial recommendation and evidence should be presented to the patients by the lead researcher or the lead of the Core Team to enable a reflection on the important elements, whether these are medical or quality of life factors, to facilitate the formulation of a consensus to refine the working of the recommendation.**
- **Patients can put the spotlight on where gaps in clinical evidence can be found, and their needs at specific points of treatment pathways to drive future research.**

STAGE 4: IMPLEMENTATION STAGE

The **implementation stage** is where a CPG will be **published, disseminated** and **communicated.** This is a crucial stage as implementing the CPG ensures that healthcare professionals, patients and healthcare systems will benefit from the pooled knowledge and recommendations [15]. Hence, although dissemination and communication in clinical settings are key to ensure proper implementation, outreach and communication around the CPG should also target other stakeholders.

The **implementation stage** can be divided into the following **3** activities:

4.1 Publish

Before publication, the **Guideline Development Group** usually sends the final CPG for peer review, involving peers in a professional society, publication in a leading journal, etc.. Publication in a peer-reviewed journal enhances the scientific credentials of the CPG and acts as a **"stamp of approval"**.

Patients can also show their support for the CPG recommendations by endorsing them as well as co-developing – alongside professionals – **'patient-professional perspective articles'** and developing plain language summary of the CPG.

4.2 Disseminate & Communicate

Effective dissemination and communication of a CPG is the rate limiting factor for access to the evidence-based care captured in the CPG. Careful consideration and investment in active dissemination and communication by all stakeholders is therefore key to enable patients to benefit from evidence-based care.

Promoting CPG dissemination can be done by creating awareness through lay versions. Ideally, patients involved in the development of the CPG should also contribute to developing the lay versions [16].

4.3 Implement

Given the importance of the **Implementation Stage,** a working group should be established to carefully plan the activities, i.e., planning the implementation, analysing the context and drafting an **implementation roadmap,** including the development of actions to measure implementation and allow for continuous improvement [15]. Patients can assist with this last stage by participating in the **implementation working group** [3,5,15,16]. By offering a comprehensive and unique perspective, patients are essential participants, thereby facilitating a better context analysis (e.g. *identifying any resistance with particular recommendations*) and ensuring that relevant and meaningful aims and outcomes are established.

During the **Implementation Stage,** it is recommended to involve patients internally in meetings (e.g. *implementation and CPG lay language working groups)* as well as externally via surveys to test the **implementation roadmap** [3,15].

TOP TIPS

- **Patients can be involved in the implementation working group to contribute to the definition of the implementation plan.**
- **Patients may assist with CPG dissemination and access to treatment information. These foster shared patient-clinician decision-making and development of patient summaries.**
- **Patients can be involved in implementation activities to both patient and professional audiences, e.g. as patient speakers in training webinars, advocacy activities to support implementation at a national and European level.**
- **Patient organisations can help drive health system change through advocacy activities to promote evidence-based care.**

SUMMARY

Patients play an important role throughout all the stages of CPG development and implementation. As a minimum, based on best practice, the following key activities to involve patients are recommended:

a. **Preparation stage:** Patient representatives help to define the **CPG scope,** specifically the **PICO** questions and outcomes.
a. **Research stage:** Patients are involved in the **discussions of the emerging evidence,** identifying gaps for future research and investigation.
a. **Writing stage:** Patients share their preferences, **weighing the benefits and harms** and supporting the wording of the **draft and final recommendations.**
b. **Implementation stage:** Patients support the **CPG dissemination** and ensure patients have access to treatment information, which fosters shared patient-clinician decision-making and the development of patient summaries [1].

ADDITIONAL RESOURCES

- ePAG Good Practices: Clinical Practice Guideline development, PowerPoint presentation and factsheet
- Webinar patient involvement in clinical practice guideline development
- Webinar "*How-To-Guide On Implementation of an ERN Guideline"*
- ePAG good practice webinar: Patient involvement in identifying unmet needs on clinical patient guidelines and resulting paper

If good CPGs already exist, how can patients be involved in their adaptation and adoption?

When there is already a CPG available, it might not be necessary to develop a new one. In those cases, a multidisciplinary **CPG Adoption & Adaptation Working Group** can be set up to adopt or adapt an existing CPG. It is recommended that patients should be part of this working group.

The first step to decide whether a CPG should be **adopted** or **adapted** is to assess its independence and quality. Patients can be part of this review process [17].

The working group should assess if each recommendation included in the CPG is **acceptable** and **applicable** [17], determining if it considers both health benefits and risks and whether its implementation is useful for patients, promotes appropriate care and reduces inappropriate or harmful care.

The evaluation of an existing CPG for **adoption** is a simple process, using the **Appraisal of Guidelines for Research & Evaluation Instrument 'AGREE II'** instrument to inform a recommendation for **adoption** [17].

The working group should also review if any new evidence has been published since the CPG was published. If there is new evidence, then the CPG can be **adapted using the 'Adapt' methodology.** Adapting an existing CPG includes the following stages (1) definition of specific questions that need to be answered by the CPG; (2) assessment of CPG quality and independence; (3) systematic review; and (4) writing the recommendations. At the end of the adaptation process, an external review should be performed, and patients and/or carers should be consulted [17].

When adapting existing CPGs, experts should also consider issues related to complexity or ease of use [17]. Another important criterion to consider is the **compatibility of the recommendations** with patient preferences and values in the setting where they are going to be used, e.g. *Is it compatible with the culture and values of the healthcare system where it is to be implemented or does the benefit to be gained from implementing the recommendation make it worthwhile?*

SUMMARY

Patients should be involved in the process to **adapt** or **adopt** existing CPGs by:

a. being part of the **CPG Adoption & Adaptation Working Group**;
b. being consulted, through different approaches, on their perspective around the **acceptability** and **applicability** of each recommendation according to their preferences, experiences, and values.

Specifically, the views of patients can be elicited to [17]:

- **assess the independence and quality** of existing CPGs as part of the review process to decide whether a CPG should be adopted or adapted.
- **assess acceptability and applicability,** i.e. consider if each recommendation within an existing CPG is **compatible with patient preferences and values** in the setting where it is to be used.
- **appraise existing guidelines** using the **AGREE II** Tool (for adoption of existing CPGs).
- **conduct an external review** at the end of the CPG adaptation process, as part of the external review committee, alongside healthcare professionals and managers and policy makers (for adaptation of existing CPGs).
- **conduct supplementary literature** searches to review certain clinical questions focusing on **patients' values and preferences,** economic analysis, etc.

How are Clinical Decision Support Tools (CDSTs) developed and how can patients be involved in their development?

Clinical decision support tools (CDSTs) provide timely and targeted clinical knowledge, patient information, and other health data to help inform and guide decisions about patient care. They encompass a variety of tools to enhance decision-making in the clinical workflow, including, among others, **consensus statements** [18].

The stages involved in the development of **consensus statements** greatly overlap with those of CPG production. Indeed, the main difference is the **level of research/clinical evidence** available. While CPGs are based on high-quality evidence to make recommendations, **consensus statements** are often the best alternative when there is limited published evidence [13].

The development of both instruments should follow systematic methodologies and protocols to ensure their robustness, such as **GRADE** when there is a volume of published evidence, or a **Delphi consensus building approach** where there is limited evidence or where there are gaps in the evidence [13].

Similarly, to CPG development, the involvement of patients in **consensus statements** should happen early on in the process and be sustained throughout to ensure that the final statement reflects the perspectives, needs and interests of both the patients and the clinicians. For the development of **consensus statements,** the **4 stages** identified for CPGs are broadly applicable. However, some adjustments are needed, especially at the research stage where specific **consensus-building procedures** must be applied **(Summary Table, page 12).**

Patients are key stakeholders in consensus processes and should be part of the **Multidisciplinary Consensus Panel** to contribute to **formal consensus-building procedures** i.e., asking a group of people to discuss the topic and come to an agreement to consider gaps in evidence [13].

SUMMARY

Patients can be involved in the process to develop, adapt or adopt **consensus statements** by:

a. integrating the **consensus panel**;
b. taking part in the consensus building process using a **Delphi methodology**;
c. external **review in the appraisal** of existing CDSTs.

Patients' views can be elicited through consensus-building procedures, including [13]:

- **Delphi method.** This method consists of rounds of **questionnaires,** which different groups of experts (including patients) complete to 1) first understand their **individual views**, and then to 2) understand the **wider views of other stakeholder groups,** with the aim of reaching agreement or consensus amongst the whole panel.
- **Nominal Group Technique (NGT).** The **NGT** is a structured interaction based on individually generated ideas discussed and ranked in a group session where the consensus panel (incl. patients) voice their opinions.
- **Consensus Development Conference (CDC).** The **CDC** consists of a panel of 10 experts defining questions, e.g. the appropriateness of the use of a certain treatment, with experts and patients presenting the evidence to the participants of the CDC [19].

ADDITIONAL RESOURCES

- ePAG Good practice webinar: Patient Involvement in the development of Surgical Consensus Statements for Esophageal Atresia (EA) disease, PowerPoint presentation and Factsheet

Summary table of patient involvement in the different stages of the CPG development process

	1. PREPARATION	2. RESEARCH	3. WRITING	4. IMPLEMENTATION
Main steps in each stage	• Support & training for patients and clinicians involved in the process • Topic prioritisation/ selection • Team assembly • External Consultation on topic • Determining CPG Scope • Formulate PICO Questions	• Literature Search (search, screening and selecting relevant papers) • Evidence extraction and revision: (i) when there is robust evidence, data extraction for systematic review using GRADE; ii) when evidence is less abundant summarise Key Evidence using modified GRADE; iii) if evidence is very limited or lacking proceed to develop a **Consensus Statement*** • Consensus-Building	• Translating evidence into recommendations • Formulate Recommendations • Writing CPG • Peer review • Co-author CPG	• Set up the implementation working group • Develop lay versions • Raise awareness of and disseminate the CPGs
Potential role of patient representatives	Early patient **input is critical** to ensure an agreement on when and how to collect and integrate patient input. Patients can help **identify areas** where a CPG is needed in their disease area, e.g. a clinical trial has shown a new treatment to be effective and an update to the treatment CPG is needed. Patients should integrate the **Guideline Development Group.** Additionally, a **Patient Advisory group** can be set up to ensure patient early and continued CPG input. Patients suggest **aspects important to them,** e.g. **PICO** questions (**P**opulation, **I**ntervention, **C**omparison, **O**utcome). Patients **identify outcomes which matter** and rank them for importance, e.g. *number of flare ups, hospitalisations, quality of life, etc.*	Patient **role is limited** in scientific literature review, particularly in grading evidence. Patient perspectives may be sought via **review of patient experiences via published qualitative literature,** e.g. ***focus groups, interviews** about experience of diagnosis.* Patients may be consulted when using GRADE by **weighing the benefits and harms,** burdens, and cost of a treatment, raise questions about the **practicality of a particular treatment approach and help to ensure that patients will support outcomes** of the CPG. Patients may identify **evidence gaps** in areas they consider important, e.g. *discomfort.*	Patients play a **vital role** in developing the recommendations by providing their **input during 'evidence to decision' meetings.** Patients **review draft publication,** ensure patient views are included and acknowledged.	Patients should integrate in the multidisciplinary **implementation working group** (responsible for creating and enforcing the implementation plan) Patients play an important role in developing **lay language** CPG versions and other products. Patients may help **raise awareness of and disseminate** CPGs, namely through patient organisations and ERN communication channels, e.g. newsletters, social media channels. Patients can co-develop **'patient-professional perspective' articles.**

* Note: For the development of **consensus statements,** the **4** stages identified for CPGs as well as the role of patients in each stage are broadly applicable. However, some adjustments are needed, especially at the research stage where specific **consensus-building procedures** must be applied. Formal consensus-building procedures for Consensus Statement development, either used alone or in combination include: 1) Delphi method; 2) Nominal Group Technique, and 3) Consensus Development Conference [13].

Annex 1: How to involve patients in the development of Clinical Practice Guidelines and Clinical Decision Support Tools

YOUR PATIENT INVOLVEMENT ACTION PLANNER AND TRACKER

The involvement of patients in **Clinical Practice Guidelines (CPGs)** and **Clinical Decision Support Tools (CDSTs)** should be organised early in the process and be sustained.

This checklist can help you plan and keep track of the actions taken to ensure the patient voice is successfully included in the development of **CPGs** and **Consensus Statement development projects.**

This tool is organised into the different Stages (and associated phases) of CPG and CDSTs development and implementation. For each Stage and associated phase, you will find information about how patient involvement can be organised along with questions designed to help your decision-making process and/or record your decisions and actions. It can also serve you and your team to brainstorm, plan and make decisions regarding patient involvement in your CPGs and/or CDSTs.

PREPARATION STAGE

Action planner & tracker:
How are you planning to or how have you already listened to the patient voice during the topic prioritisation? (Select ALL the options that apply) ☐ Survey ☐ Focus group ☐ Dedicated meeting/workshop ☐ Not planning to / not included the patient voice at this stage ☐ Other (please specify):
Action planner & tracker
How are you planning to or how have you already included patient representatives in your team? (Select ALL the options that apply) ☐ Members of the Guideline Development Group ☐ Set up a Patient Advisory Group ☐ Not planning to / not included patient representatives in the team ☐ Other (please specify):
Action planner & tracker
How are you planning to or how have you already included patient input in PICO definition? (Select ALL the options that apply) ☐ Advise on the CPG scope, including the target population, clinical questions, suggesting or highlighting questions that should be used to search the published literature ☐ Select meaningful patient-reported outcome measures (PROMs), review and rank the clinical outcomes for the inclusion in the PICO in terms of their relevance and importance ☐ Not planning to / not included patient representatives in PICO definition ☐ Other (please specify):

RESEARCH STAGE

Action planner & tracker:

How are you planning to or how have you already included patient insights in the research stage?
(Select ALL the options that apply)

- ☐ Conducted a patient-centred literature search
- ☐ Conducted a survey
- ☐ Set up focus groups
- ☐ Delphi voting
- ☐ Conducted social media listening
- ☐ Not planning to / not included patient representatives in the research stage
- ☐ Other (please specify):

WRITING STAGE

Action planner & tracker:

How are you planning to or how have you already included patient preferences at this stage?
(Select ALL the options that apply)

- ☐ Consulted patients to inquire about their preference, acceptability and/or feasibility of the interventions included in the recommendations.
- ☐ Included patients as reviewers of the draft and final recommendations to ensure understandability, soundness and usefulness to them
- ☐ Co-authors of the publication
- ☐ Included patients in the evidence to decision meetings
- ☐ Not planning to / not included patient representatives in the Writing stage
- ☐ Other (please specify):

IMPLEMENTATION STAGE

Action planner & tracker:

How are you planning to or how have you already included patient preferences at this stage?
(Select ALL the options that apply)

- ☐ Involved patients in the Implementation Working Group amongst others to co-define the implementation plan
- ☐ Involved patients to test the implementation roadmap
- ☐ Not planning to / not included patient representatives in the Implementation stage.
- ☐ Other (please specify):

Annex 2: Glossary of terms

AGREE II	The Appraisal of Guidelines for Research & Evaluation Instrument is a tool developed to evaluate the methodological quality CPGs [20].
CDSTs	Clinical Decision Support Tools are a variety of different tools that provide timely and targeted clinical knowledge, patient information, and other health information to help inform and guide decisions about patient care.
CDC	Consensus Development Conference is a panel of healthcare professionals and patients who define the questions to be answered in a consensus statement [13].
Consensus Statements	CDSTs based on consensus of expert opinion and clinical experience. Consensus Statements are very important and commonly created in areas where limited published evidence is available, such as in the field of rare diseases.
CPGs	Clinical Practice Guidelines are evidence-based recommendations that establish high-quality patient diagnosis, care, monitoring, treatment and/or follow-up standards.
GRADE	Grading of Recommendations Assessment, Development and Evaluation is a method for rating the quality of evidence for systematic reviews and Clinical Practice Guidelines [21].
Delphi method	A consensus-building technique based on a series of questionnaire rounds. The responses are aggregated and shared with the group after each round [13,14].
Guideline Development Group	A group of experts, which should include patient representatives, who lead the planning and development of CPGs.
ERNs	European Reference Networks are 24 virtual networks launched in 2017 with the aim of improving the health care of people living with rare diseases in Europe.
Focus groups	Group discussions to explore participants' expertise and experiences. Discussions are led by moderators and ideally observers can be involved to take notes.
NGT	Nominal Group Technique is a structured interaction method in which individually generated ideas are discussed and ranked in a group session.
Patient Advisory Group	A committee formed by 8-10 (when possible) patient representatives to provide advice on CPG development. The PAG chair should integrate the CDG.
PICO	Population, Intervention, Comparison and Outcome is a framework to help clearly determine, define and structure the different aspects of what will be investigated. PICO helps target the right evidence to use in practice.
PROMs	Patient-reported Outcome Measures are questionnaire-based tools that capture a person's perception of their own health and disease. PROMs enable patients to report on their quality of life, daily functioning, symptoms, and other aspects of their health and well-being.
Survey	Quantitative research method that uses structured and relevant questions to get information on a specific topic from a defined target audience.

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