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Methodological Handbooks & Toolkit for Clinical Practice Guidelines and Clinical Decision Support Tools for Rare or Low prevalence and Complex Diseases

Handbook #11: Methodology for the Elaboration of Patient Information Booklets for Rare or Low prevalence and Complex diseases

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This handbook includes a detailed explanation of the process for developing Patient Information Booklets for rare diseases, including:

- ✓ Composition of the working group
- ✓ Decision on document design
- ✓ Define the scope and purpose
- ✓ Development of the content
- ✓ External review

Purpose:

To provide guidance for the development of Patient Information Booklets for rare diseases.

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ABBREVIATIONS

CDSTs	Clinical Decision Support Tools
CPGs	Clinical Practice Guidelines
ERN	European Reference Network
EU	European Union
IACS	Aragon Health Sciences Institute

01.

BACKGROUND

There are a number of challenges surrounding the development of CPG and CDST for rare diseases. One of the most relevant barriers is the lack of high-quality evidence, in which the foremost methodological frameworks like GRADE [1] rely on.

Therefore, there is a need for specific methodological approaches that can provide reliable and useful Clinical Practice Guidelines (CPGs) and Clinical Decision Support Tools (CDST) for rare diseases to be used. The project also aims to provide a common methodology, in order to harmonise the elaboration process of CDST and CPGs.

It is worth noting that within the scope of this handbook, "rare diseases" is the term used to refer to rare diseases as well as low prevalence complex diseases.

1.1 | Context for the Patient Information Booklets development in rare diseases

Patient information booklets (also called patients versions) are documents that provides condition-specific information in lay language, to inform patients on best medical practice in an informative and accessible way [2, 3]. They translate information originally produced for health professionals about care processes into a form that is easier for patients and the public to understand and use [4]. Information materials in the field of rare diseases is primarily intended for people who are affected by a rare disease or a rare disability, their families and relatives, and also for a broader audience among health professionals and the general public [5].

Patient versions are short, useful, practical and understandable, aimed at patients, their families and caregivers, to assist in the management of their health condition and to promote their autonomy [5]. Patient information booklets can be based on a CPG, a CDST or be a stand-alone product that provides general information for the patient.

Patient versions for patients and their families have several purposes [4, 6]:

- ✓ Provide high quality (evidence-based) information in order to facilitate patients' knowledge on and, management of the health condition
- ✓ Allow priorities to become clear to patients and highlight the benefits and harms of interventions to support decision-making
- ✓ Promote and improve communication between health professionals and patients
- ✓ Contribute to make patients feel reassured and confident in their care

- ✓ Facilitate dialogue between the patient and family or caregivers and the society, in relation to the illness or health condition.
- ✓ Identify lifestyle interventions and ways in which the patient can take steps to manage their condition

Patient information booklets must be based on high quality evidence. It is crucial to select information to express the strength of a recommendation and uncertainty in the evidence, and how to present the options available to a patient. Besides, a fundamental requirement for elaborating a helpful information material for patients is that language and format are adapted to the final target audience.

It is worth noting that in the framework of ERNs, patient information booklets must be available in all languages in Europe.

This section of the Development Handbook describes the elaboration method to develop Patient Information Booklets, and it is mainly based on handbooks for developing patient versions of CPGs [4, 6].

1.2 | The development process of Patient Information Booklets: Main Steps

TASK	DEFINITION
Composition of the working group	• Constitution of the team that will develop the patient information booklet •Consultants, especially patients and carers, can be contacted at any time during the process
Decision on document design	•A style guide to be considered during the development •Patient information booklets should be easy to find and use
Define the scope and purpose	• The scope comprises what it is the target audience, condition or specific topic addressed, as well as the intended users
Development of the content	•The structure and content of a patient information booklet should be flexible •It is determined by the characteristics of the condidtion being addressed and the target population
External review	• The draft should be reviewed by patients and carers, as well as other professionals who have not participated in the development process

02.

COMPOSITION OF THE WORKING GROUP

As a general rule, a patient information booklet must be elaborated by a multidisciplinary working group of healthcare professionals with expertise in the topic, and patients and/or carers that will define its content on the basis of a literature review and patients and carers consultations.

Regarding the development of the patient version of a CPG or CDST, the working group usually consists of patients and/or carers and health professionals who have participated in the elaboration of the CPG or the CDST on which it is based.

Additional experts, as well as a wider group of patients, can participate as reviewers of the patient information booklet draft.

When the term 'patients' and 'carers' is used in this handbook, it is intended to include people with specific rare disease conditions and disabilities and their family members and carers. It also includes members of organisations representing the interests of patients and carers.

2.1 | Consultation throughout the development of the patient information booklet

Ideally patients or carers who have been involved in the development of the CPG or the CDST will participate in the development of the patient version of the document, since they are aware of the different aspects included in the CPG or CDST.

Although their participation during the selection of the content is crucial, it may be more feasible to have their collaboration at specific stages of the development of the patient information booklet as consultants.

Thus, they can be involved in different ways and stages:

- ✓ during the elaboration of the content
- ✓ improvement of readability and comprehensibility
- ✓ choice of the most suitable format, according to the target population
- ✓ identification of other useful resources for patients
- ✓ external reviewers
- ✓ updating: patient information booklets should be reviewed and updated regularly.

03.

DESIGN OF THE PATIENT INFORMATION BOOKLET

The design of the document is a relevant aspect in the development process of patient information booklets. There is no single approach to developing a patient information booklet, due to the fact that they should be tailored to the needs of patients, the peculiarities of the rare disease addressed and the system of provision of care. Readability and style of presentation must be considered, as well as the most appropriate format adapted to the target population to which the document is addressed.

3.1 | Readability and format

Patients and carers play an important role in achieving adequate readability and understandability of the patient information booklet. It can be directly improved with the patients and/or their families themselves, since they know the terminology used in everyday life by those affected by the condition. They are aware of what is relevant, in a language that is appropriate and suitable for the final audience. They can also participate as occasional consultants or reviewers of the final draft.

The following aspects support **readability** [6]:

- ✓ Avoid the use of medical terms, acronyms, technical words and abstract terms. When used, medical terms are defined.
- ✓ Common, everyday language is used.
- ✓ Use short words and do not abuse words with three syllables or more.
- ✓ Sentences should also be short, with no more than 15 or 20 words per sentence.
- ✓ Avoid words and phrases that are capitalized, italicized, or underlined (exceptions to this rule are proper names and the first letter of a sentence).
- ✓ Phrases should not contain more than two ideas and should not mix concepts.
- ✓ Verb tenses must be in the present tense and in the active voice.
- ✓ The wording should be neutral, without bias, especially when the information relates to risks, benefits and side effects.
- ✓ Do not use ambiguous sentences.

- ✓ Limit the number of pages (15-20 pages). Do not exceed the number of pages.
- ✓ The question and answer format for writing the contents is useful to divide and make the text more agile.
- ✓ Use informative headers.
- ✓ Prioritise the information, structuring it to facilitate its reading (from general to particular).
- ✓ An adequate spacing helps reading.
- ✓ A summary is provided.

The following aspects help improve the **style and format** of patient information booklets:

- ✓ Visual cues (e.g., arrows, boxes, bullets, etc.) help to draw attention to key points. The use of bullets or numbers to divide up complicated information.
- ✓ Reproduce exactly the sentence, quotation or other text sequence of a patient, especially when qualitative research techniques have been used with patients. It may be a useful way to personalise the information.
- ✓ Visual aids (e.g., illustrations, tables, photographs, etc.) reinforce the information and make it patient-friendly, but they should not distract from the content.
- ✓ Leave blank spaces to make information easier to read.
- ✓ Write the numbers one to nine with letters, as they are easier to read; from 10 onwards they can be represented with numbers.
- ✓ Choose a font size of no less than 12 points.
- ✓ Use, whenever possible, diagrams, pictures, photos, drawings or audios.
- ✓ Use fonts, typefaces and letter sizes that suit the potential users of the patient information booklets.
- ✓ Distribute in special sections as a way of highlighting information or key messages.
- ✓ Good use of colour can make things easier to read.
    - The use of colour must be consistent, so as not to be confusing to the reader.
    - Light text on light backgrounds and dark text on dark backgrounds should be avoided.
    - Colour blindness should be considered too. Using red/green combination and blue/yellow combination of colours together should be avoided.
    - The use of pale pastel colours is not helpful for people with visual impairment.

3.2 | Patient information booklets should be easy to find and use

It is important to define the media in which the information will be displayed, which will be determined by the target population to which it is addressed. For example, if the patient information booklet is aimed at visually impaired patients and their families, audio versions may be provided tool[6].

More and more patients and their families search for information on the internet. Electronic formats are preferred by some people, but other patients often like information they can read on paper. A suggestion is to develop short paper documents together with longer, interactive electronic versions

or resources linked to them (though they can also be printable) [4]. If a printable version on paper is going to be available, the dimensions, size, colours and texture will be agreed by the working group.

The patient version of a CPG or a CDST could be incorporated within the original document itself so that health professionals can more easily access it when having conversations with their patients[4].

3.3 | Languages

In the ERN framework, patient information booklets must be available in all European languages.

04.

DEVELOPING A PATIENT INFORMATION BOOKLET

4.1 | Defining scope and purpose

In the first place, it is essential to define the objective and the scope of the patient information booklet. The scope comprises what it is the target audience, condition or specific topic addressed, as well as the intended users.

- ✓ Objective: the purpose of the patient information booklet must be completely evident [6]. It will cover the key ideas to be conveyed to the patients and their families.
- ✓ The material must not include information that distracts from its purpose.
- ✓ Target audience must be defined.
- ✓ Patient versions should be clear about to whom the information is addressed [4]. Although written for patients, the booklet acknowledges that family members and caregivers may also read it.
- ✓ Condition: background information about the condition must be provided.
- ✓ It may cover a specific topic (e.g., diagnosis) or patients and their families may need wider information (e.g., knowledge of progress and natural history of a condition).
- ✓ The need for presenting information on cost effectiveness may vary depending on the health system, with interest being greater in health systems with larger out-of-pocket health costs for patients. It should be discussed by the working group.

4.2 | Development of the content

The content of patient information booklets should be flexible and determined by the characteristics of the condition being addressed and the target population/patient group.

Specific indications for the development of patient versions of CPG and Pathways, which have a significant interest for patients, are given in the following sections.

4.2.1 | Content and structure of a patient version of a CPG

4.2.1.1 | Structure of the document

Common points that patient versions of CPGs should contain are the following [6]:

- ✓ Title: should be brief, contain key words and provide patients with clear guidance on the topic being reported
- ✓ Data on the people who have produced the version for patients: name and occupation. Specify whether they are professionals or patients, consultants or external reviewers
- ✓ Declaration of interest of all members who have participated in the elaboration must be included
- ✓ Date of publication must be indicated
- ✓ Data on the information sources
- ✓ Funding for the document
- ✓ Target audience
- ✓ Condition or topic addressed (diagnostic, treatment, monitoring, disease course, prognosis, etc.)
- ✓ Pictographs, tables, algorithms, etc., if appropriate
- ✓ Additional information where patients and their families could find more help (e.g., patient associations, Internet websites, books, and other resources of interest to improve knowledge and management of the disease)
- ✓ Update should be planned. Ideally the information should be reviewed and updated regularly
- ✓ Bibliography

4.2.1.2 | Content of the patient version of a CPG

The patient version of a CPG should select the most relevant information to be convey to patients and their families. Since these documents include recommendations about what should or should not be provided or done, the original content of a CPG should not be compromised when producing patient versions [4]. Another key aspect is the contextualisation of the information (e.g., it is essential to define whether the information will be given before or after a diagnosis of a rare disease).

Patient versions should prioritise what patients can influence or discuss with their clinician. The aim is to include useful information for patient and carers. Additional information might be included if it helps to encourage an understanding of the recommendations of the CPG or support self-management [4]. The working group will need to consider each CPG individually to determine the purpose of the patient version of the CPG and then agree on the content [4]. Therefore, patient involvement is crucial in this stage.

Information may be divided into the following sections:

- ✓ Condition, diagnosis, treatment and progression
    - Information about the health condition or disorder. Epidemiological information; impact on quality of life. The health problem should be described clearly, objectively and concisely and the natural course of the rare disease explained.
    - Diagnostic methods

- Evolution and prognosis
- Treatment and follow-up of the rare disease

✓ Managing and dealing with a rare disease

- Impact of the rare disease in patient's and family's life
- Information on the benefits and risks of each intervention and how they affect the quality of life of the patient (how the patient may feel, how they may affect their daily life, how to deal with the rare disease, etc.), including information on possible risks if no intervention is performed.
- The relationship between patients and their families with health professionals
- Advice and issues to consider when consulting a health professional

✓ Additional information (other useful resources)

The patient version of a CPG should also provide more information about where patients and their families could find more help (e.g., patient associations, Internet websites, books, and other resources of interest to improve knowledge and management of the disease). These resources need to be updated and their quality checked.

✓ Provide precise, detailed and understandable information on the methodology used.

This should also be reflected in the methodology section of the patient version of the CPG aimed at professionals.

4.2.1.3 | Sources of information

The relevant information to be included may come from the following sources:

✓ The CPG itself

✓ Information for patients produced by other guides

✓ Other information for patients (patient associations, scientific societies, virtual communities and other institutions)

✓ Available evidence and related research on the topic

✓ Conducting qualitative health researches with patients

✓ Sending to other patients the patient information booklet in order to review the content

4.2.1.4 | How to select information to be included in the patient information booklet and put it into context

As mentioned before, patient information booklets should prioritise information or recommendations that patients can influence or discuss with their clinician [4].

It is important not only to define the patient of interest, but also be clear about when patients and/or their families will receive the information, as this will influence what is included and how it is presented (e.g., will the patient and/or their family have the opportunity to discuss it with a healthcare professional?; will the patient and/or their family receive it at the time of diagnosis?; will the patient and/or their family receive it at a later stage of the condition?; is the aim of the booklet facilitate managing their own care?; etc.) [4].

The best way to do this is to involve patients, carers and/or patient representatives. Ideally, patients who have been involved in the development of CPG also participate in the choice of content of the patient information booklet. To do this, the working group can use qualitative techniques approaches.

To help patients and health professionals decide which information is helpful, the following should be considered [4]:

- ✓ Can it help patients to understand their own condition?
- ✓ Does it offer information about the steps to confirm the diagnosis?
- ✓ Do they recommend lifestyle interventions and ways in which the patient can take steps to manage their condition?
- ✓ Do they assess harms and benefits of the intervention in question and empower patients to make informed decisions?
- ✓ Do they indicate options for treatment or care?
- ✓ Do they highlight treatments that have no evidence of benefit?

Once the working group has decided what information should be included in the patient information booklet, it should be translated into lay terms in order to be easily understood. If additional data is needed to understand the recommendations or general information (e.g., anatomy, physiology, other treatments options or other), it should be provided either along with the document or in specific chapters or paragraphs [4], and properly linked to the bibliography (either be evidence-based or derived from consensus statements).

When communicating recommendations from a CPG, there are different ways to convey their strength. Qualitative language can be used to represent the strength of the statements. For example, a strong one can be presented as a "recommendation", while a weak recommendation could be introduced as a "suggestion". Sometimes, this can lead to misunderstandings, so including symbols, other labels and/or reasons is advisable. The use of symbols to represent a recommendation labelled as "strong", "weak" or "conditional" may be helpful to patients, as they can easily understand how the recommendations were different to each other. Regardless of the system being used, it is necessary to include a legend [4].

Patients participate also in the logical sequence in which the information is presented.

4.2.1.5 | Graphical approaches of the patient version of a CPG

In addition to the selection of the content of the patient information booklet and the logical sequence in which the information is presented, the use of explanatory charts must also be decided. Pictographs and tables tend to be efficient tools, and they can facilitate the understanding to patients. Patients should also participate in this decision [4, 6].

The following should be noted:

- ✓ If tables are used, they should include short and clear row and column headings
- ✓ Too many logos can be confusing and distracting for patients
- ✓ Complex and technical diagrams should be avoided
- ✓ Relevant graphics, tables, illustrations to explain the condition or the topic addressed should be selected and not to be upsetting for the patient

4.2.2 | *Content and structure of a Patient information booklets based on a diagnostic, Monitoring and Therapy Pathway*

Regarding diagnostic, monitoring and therapy pathways, patient versions consists of a graphic representation of what patients may expect as they move along their care journey (triage to department, monitoring, possible referral to other specialists (e.g., surgical specialists), hospital admissions, follow-up care, etc.), i.e., a patient's roadmap (see Handbook #7: Methodology for the elaboration of Diagnostic, Monitoring and Therapy Pathways for rare diseases).

The patient's roadmap should enable patients and their families to know all phases of the care process. The graphic representation of diagnostic, monitoring and therapy pathways should include:

- ✓ Care setting where the services are delivered
- ✓ Professionals involved and the activities that each one performs
- ✓ Good practices
- ✓ Key safety points
- ✓ Information and communication points

The graphic representation must be clear and precise, and complex and technical diagrams should be avoided. In addition, it should not include information that is irrelevant to patients.

Too many logos can be confusing and distracting for patients.

05.

EXTERNAL REVIEW

After the development of the document, the draft of the patient information booklet should be reviewed by a wider group of patients and/or carers, to ensure that the patient information booklet[4]:

- ✓ provides useful information that helps patients make decisions
- ✓ is accessible to patients
- ✓ is relevant to patients
- ✓ uses appropriate language, fonts and graphics
- ✓ has a sensible layout that patients can use effectively

Different methods can be used to obtain feedback depending on the intended audience [4]:

- ✓ Circulation of the document to ERN patients and families for written comment. A structured questionnaire/survey could be used to collect information
- ✓ Use of discussion groups to provide feedback from ERN patients, for example a discussion group with children and young people may be more effective than written consultation
- ✓ Consulting patient organisations with a broader experience with patient counselling

Feedback from other healthcare profesionals, general practitioners or paediatricians from other care contexts, as well as other professionals, who have not participated in the elaboration process is also needed, as they might assess to what extent the patient information booklet could be useful for their patients.

After the review, the draft will be returned to the development working group. If necessary, a meeting will be held in order to discuss the comments and address potential changes in the document.

The method used and the process should be well documented and transparent.

Key issues

- Patient Information Booklets must be elaborated by a multidisciplinary working group of patients and carers, and healthcare professionals with expertise in the topic
- Patients and carers must be actively involved in different stages of the development of the patient version (selection of the content, improvement of the readability and comprehensibility, choice of style and format, external review, etc.)
- The design of the patient information booklet is very relevant, since they must be practical, useful and understandable for the patients
    - Readability aspects, style and format must be considered during the elaboration
    - It is important to select the media in which patient information booklets will be displayed in order to be easy to find and use
    - In the ERN framework, patient information booklets must be available in all European languages
- It is essential to define the scope and purpose of the patient version, in order to select the most appropriate content
- Regarding patient versions of CPGs, priority should be given to information (recommendations and additional information) that can be discussed with health professionals. A key aspect is the contextualisation of the content
- Patient information booklets based on diagnostic, monitoring and therapy pathways consist of graphic representations of what patients may expect as they move through their care journey
- The draft of the patient information booklet should be reviewed by patients and/or carers, as well as other professionals (e.g., other ERN members, general practitioners or paediatricians, etc.)

09.

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