Implementation of Clinical Practice Guidelines recommendations in Shared Decision-Making.

Methodological Manual

CLINICAL PRACTICE GUIDELINES OF THE SPANISH NATIONAL HEALTH SYSTEM
MINISTRY OF HEALTH

MINISTERIO DE SANIDAD

RED ESPAÑOLA DE AGENCIAS DE EVALUACIÓN DE TECNOLOGÍAS Y PRESTACIONES DEL SISTEMA NACIONAL DE SALUD

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Presentation

Patient-centered care requires healthcare professionals to take into account patients' expectations and previous experiences, up-to-date scientific knowledge, joint approach to the uncertainty associated with each procedure, and to develop a care plan that takes into account their preferences.

Clinical Practice Guidelines (CPGs) have a significant role in this healthcare model. They encourage safe and effective decision-making, through recommendations that take into account the risks and benefits inherent in each procedure, the related costs, and patient expectations and experiences.

The CPGs developed within the framework of the Clinical Practice Guidelines Program in the Spanish National Health System (SNHS), coordinated by GuíaSalud, have been developed thanks to the participation of patients and patient representatives throughout the various stages of its development.

This methodological manual, Implementation of Clinical Practice Guidelines recommendations in Shared Decision-Making, is another step towards patient participation in the management of their own health, since Shared Decision-Making is included in the CPG development process. The aim is to offer the tools needed to develop CPGs and Patient Decision Aids (DAs) which encourage the participation of patients in any decisions taken clinical encounters.

This manual provides instructions on how to write recommendations and communicate research results to patients. It also offers tools to include DAs in the development process of CPGs, as well as instructions for searching, selecting, assessing, adapting or developing DAs.

This document is the result of the joint efforts of a team made up of experts in methodology, healthcare professionals, and patients with experience in Shared Decision-Making and in developing Clinical Practice Guidelines.

From the Directorate-General for Public Health, we would like to express our gratitude to all these people for the work done and we hope that this will help to encourage SDM through CPGs, thus improving patient healthcare.

PILAR APARICIO AZCÁRRAGA
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Abbreviation

CPGs	Clinical Practice Guidelines
DAs	Patient Decision Aids
EtD	Evidence to Decision framework
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GRADEpro	Grading of Recommendations Assessment, Development and Evaluation profiler
IFLA	International Federation of Library Associations and Institutions
IHP	Integrated Healthcare Procedures
IPDAS	International Patient Decision Aids Standards
IPDASi	International Patient Decision Aids Standards instrument
MAGICapp	Making GRADE the Irresistible Choice
NICE	National Institute for Health and Care Excellence
PLAIN	Plain Language Association International
PSA	Prostate-specific Antigen
PyDeSalud	Participate and Decide on your Health
RedETS	Spanish Network of Assessment Agencies for Health Technologies and National Health System Performance
RMI	Resident Medical Intern
SDM	Shared Decision-Making
SNHS	Spanish National Health System
SWELANG	CLARIN Knowledge Centre for the Languages of Sweden

1. Introduction

Lucía Prieto, Patricia Gavín

The values and preferences of patients should always be considered for decision-making in clinical practice, as they are key determining factors in situations where: the balance between patient risk and patient benefit is uncertain; when there is no scientific evidence that is reliable enough; or there are several suitable or comparable options that could be assessed differently on an individual basis[1].

These situations require active participation of the patient, meaning that they may choose from any diagnostic or therapeutic options which are suggested to them. For that purpose, it would be ideal if healthcare professionals were qualified and duly informed, as well as having tools and abilities to assist patients during deliberation.

Shared Decision-Making (SDM) is the process through which healthcare professionals accompany patients through a deliberative process in order to choose between the therapeutic and diagnostic options suggested. During this process, healthcare professionals should clearly explain all therapeutic options and patients should make their values and preferences known. The aim is for patients to make informed decisions according to their values and preferences[2].

Patient Decision Aids (DAs) arise as a conductive element and as an intermediary between healthcare professionals and patients during said deliberative process. These tools have been created based on scientific evidence, they help to include any relevant aspects about patient context, and they adopt an individual approach through which they support patients so that they can make informed decisions in accordance with their values and preferences.

DAs are varied regarding their form and content (fact sheets, presentations, interactive audiovisual material, etc.), and they may be used in contexts of greater or lower intensity and scope of patient participation, but always included as part of a SDM process.

1.1. Shared Decision-Making when using Clinical Practice Guidelines

Clinical Practice Guidelines (CPGs) are a basic reference point in decision-making, both for professionals and for patients, meaning they can facilitate and promote SDM[3]. On the other hand, the inclusion of CPG recommendations in SDM —used as a base for creating the DAs— can encourage their implementation and dissemination among healthcare professionals and patients.

Nevertheless, CPGs, developed with the best scientific evidence available, are generally based on population estimates. Although this approach is relevant and valid for certain decisions within clinical practice, it does not consider the values and preferences of the patient.

For all these reasons, the use of CPGs must be facilitated in SDM processes, and they should be complemented with DAs whenever the inclusion of a patient's values and preferences are considered especially relevant.

For that purpose, a systematic review of relevant literature and a qualitative study (in-depth interviews) were carried out in 2017 to gather and analyze the perceptions of experts with regard to the development of DAs from CPGs recommendations[4].

Professionals of GuíaSalud and of the Spanish Network of Assessment Agencies for Health Technologies and National Health System Performance (RedETS), experts in CPGs, experts in DAs and SDM, healthcare professionals, expert patients, managers and healthcare planners took part in its development. The main conclusions were as follows:

- The need to prepare a joint protocol to include patient values and preferences in a decision-making process based on CPGs, establishing a collaborative CPG and DAs development process might be more efficient since it would share the same scientific evidence. It might also boost the implementation of CPGs and DAs in clinical practice.
- The development of DAs directly derived from the CPG recommendations through GRADE system could improve the decision-making process in clinical meetings between healthcare professionals and patients.
- The semiautomatic production of interactive summaries of scientific evidence in different layouts and obtaining recommendations from that evidence could allow us to identify conditional recommendations liable to become DAs which boost the decision-making process.
- The automated production of DAs from CPGs in digital format where CPGs can be shown, as well as scientific evidence summaries and DAs, on a wide range of electronic devices might facilitate its implementation in clinical practice.

From this research, this manual has been developed to apply the recommendations of CPGs to SDM.

1.2. Aim and scope

The aim of this manual is to boost SDM and the use of DAs through their inclusion in CPGs. For that purpose, it intends to provide methodology experts, healthcare professionals and patients with an agreed and standardized methodology to include SDM, and consequently DAs, in the implementation of CPGs recommendations.

As a result, this manual includes the following aspects regarding CPG implementation in SDM:

1) Standards and instructions to make it easier for those writing guidelines to include SDM in CPGs.
2) Tools to identify and prioritize recommendations requiring active involvement of patients in the decision-making process and which, therefore, can benefit from using a DA.

3) Advice for sourcing, selection, assessment, adaptation or *de novo* implementation of DAs for the recommendations that have been identified and prioritized.

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2. Shared decision-making derived from recommendations of Clinical Practice Guidelines

2.1. Writing Recommendations and some international initiatives

Montserrat Moharra, Lilisbeth Perestelo-Pérez

This chapter sets forth recommendations and instructions for the authors of Clinical Practice Guidelines (CPGs) on how to facilitate the translation of a CPG recommendation into a tailored plan for a specific patient, especially focusing on language and layout. This chapter also proposes strategies on how to promote dialogue in a consultation between patients and healthcare professionals in order to carry out a Shared Decision-Making[1] (SDM).

2.1.1. Introduction

The way in which a recommendation is written and presented may facilitate dialogue between patients and healthcare professionals in clinical practice. The language and layout used can determine the way in which both professionals and patients may understand and interpret the recommendations. Strategies for writing recommendations which facilitate SDM process are proposed below.

2.1.2. Recommendations regarding the writing of CPGs to facilitate SDM

When writing recommendations, it is very important to use simple, clear language and a presentation format that helps both patients and professionals to understand the message intended to be transmitted. To that end, texts should meet some minimum standards.

In this sense, it is essential to analyze the concept of «easy reading». According to the «Guidelines for easy-to-read materials» of the International Federation of Library Associations and Institutions (IFLA)[2], published in 1997 and reviewed in 2010, there are two definitions of the term «easy-to-read»: a linguistic adaptation of a text that makes it easier to read than the average text but which does not make it easier to comprehend; the other definition means an adaptation that makes both reading and comprehension easier.

Although there is not a fixed standard to refer to «easy reading», and is it impossible to adapt a text to all the abilities of people who struggle with reading, writing and comprehension, these guidelines establish three different levels: *Level 1. Short texts,*

with simple vocabulary and many illustrations; Level 2. Easy-to-follow stories with everyday vocabulary and expressions (with illustrations); Level 3. Longer texts with some unusual words and sometimes figurative language (with stories that can jump in time and space, with few illustrations)[*]. This last level is the most used in CPGs.

The general features of «easy reading» include aspects related to form, content, publication, layout and edition. Particularly, the following recommendations are given: simple and straightforward language; short sentences (only one idea per sentence); large font sizes (for example, Arial 14pts); avoid abbreviations; use only one font; punctuation should be simple, with the full stop (.) and the comma (,) being especially recommended; avoid special characters (i.e., #, $, &); do not use difficult words, but explain them if they are used; do not write the whole text in uppercase letters; only the most important information to understand the topic should be added; do not divide any word in two lines; highlight any important information in bold and use images next to the text to make it easier to understand.

«Easy reading» also comprises the graphical representation of information which includes, illustrations, symbols or tables, among others. In this sense, although sometimes we try to be clear when writing recommendations for CPGs, these may be misunderstood and, thus, we suggest the authors of CPGs consider the use of both words and graphical representations, since sometimes these may be less confusing than numbers or letters in order to express the strength of recommendation. In this way, whatever the terminology used by the group writing CPGs[3] to express the recommendation —with symbols, letters or any other coding— it is important to inform potential users about the implications of the terms used.

«Easy reading» is a language format which is being gradually implemented to make content accessible to the entire population[4]. In the United States, the initiative *Plain Language Association International* (PLAIN)[5] has been promoting clear language both in the public and private sectors for more than 20 years, encouraging clear and simple writing, which makes it possible for the reader to understand a document the first time that they read it. In some countries, like Sweden, «easy reading» has been developed to a high degree. The *CLARIN Knowledge Centre for the Languages of Sweden* (SWELANG[6]) has the objective of identifying, preserving, and disseminating scientific knowledge and material concerning the Swedish language, minority languages, Swedish sign language and Swedish dialects. In Spain, «easy reading» has started to be promoted through experiences which have had a significant impact. Among them, it is worth mentioning the United Nations International Convention on the Rights of Persons with Disabilities[7].

Population, intervention and context

So that the recommendations may benefit a tailored plan (i.e., a plan that is as individualized to the patient's health conditions, circumstances, needs, and preferences as possible) and the SDM process, it is required that the recommendations specify several factors in detail: the population to which it is addressed (i.e., disease, level of severity, or other relevant

*. https://www.cjex.org/wp-content/uploads/2017/08/documento-lectura-facil.pdf

factors); the recommended intervention; as well as the context in which it could be applied (i.e., primary healthcare, hospital), although this will depend on the scope of CPGs and the available evidence, among other factors.

Presenting information

Taking into account that recommendations in the passive voice may be confusing, it is suggested to present them in the active voice to facilitate understanding. For strong recommendations, you may use sentences such as «it is recommended…» or «healthcare professionals should…», whereas for conditional or weak recommendations, it is suggested to use «it is suggested…», «healthcare professionals might…», which encourage the addition of patients' values and preferences in SDM process.

An appropriate example would be CPGs for patients who require palliative care, which establishes the following recommendations about recognizing the signs of last days of life*:

«It is recommended to investigate and rule out, in a proportionate manner and taking into account the values and preferences of the patient/relatives, any possible reversible causes of deterioration: dehydration, infections, opioid toxicity, steroid withdrawal, acute renal failure, metabolic alterations and, if necessary, initiate the corresponding treatment.»

Also in the recommendations for Shared Decision-Making and for developing the care plan:

«During the decision-making process it is recommended to explore the expectations, wishes and preferences of patient with regard to the assistance and care that they wish to receive in accordance with their values. If the patient is in a situation which does not allow them to take any decision, then it is recommended to verify:

- *The existence of any advance directive or living will.*
- *Any notes in the medical history referring to any process of advance and shared care planning.*
- *Any preferences stated by the patient's relatives and/or next of kin regarding the care that they would like to receive.*
- *If the patient appointed any representative. If there is not any appointed representative or any relatives and/or next of kin, the therapeutic team will be responsible for making decisions, seeking the highest consensus and always acting in the best interest or benefit for the patient.»*

Other examples can be found in the CPGs for pediatric patients requiring palliative care; regarding the recommendations about the treatment of mild or severe pain in pediatric palliative care, it is advisable:

«To inform both the patient and their family of any benefits or potential adverse effects of pain treatment. To devise a therapeutic plan taking into account the personal preferences and the individual needs of each patient and their family.»

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*. https://portal.guiasalud.es/wp-content/uploads/2021/09/gpc_612_atencion_paliativa_avaliat_pacientes_cast.pdf

Also in the recommendations concerning palliative chemotherapy and radiotherapy:

«Healthcare professionals should explain to the patient, according to their level of development, and to the family, any benefits, risks, and the potential suffering associated with the treatment options (palliative radiotherapy, palliative chemotherapy, or support measures) in an honest, simple, polite, accessible and coherent manner, expressing all the pertinent information so that they may participate in decision-making. In addition, active listening and appropriate silences should be implemented to know their needs in each moment.»

Or in the recommendations about the place preferred for care during the last days of life:

«It is suggested that the healthcare professional talk with the child or adolescent and their family about their preferences regarding the place for care and death, taking into account their cultural, religious and spiritual values.»

Likewise, in order to link the development of a DA[8] to the CPG recommendations, it is important to write the text in such a way that the healthcare professional feels inclined to take into account the opinion and preferences of patients instead of following a strict or rigid speech (for example, «telling» or «presenting» the patient the option of prescribing antibiotics instead of just «prescribing antibiotics)».

Incorporation of values and preferences

It is advisable to include the concerns of patients or any issues relevant to them, as well as taking their preferences into account. For that purpose, the patients' own experiences can be used with examples or exact words that facilitate the explanation of the recommendation, and they may be accompanied by a presentation of the values and preferences that underpin the recommendation. For example, in CPGs concerning the prevention and treatment of thrombosis in pregnancy, it is stated that: *«recommendations reflect the belief that most women would place a low value on avoiding pain, on the costs associated with the procedure, and on the inappropriateness of heparin therapy to avoid the small risk of a minor abnormality in their children associated with warfarin prophylaxis.[8]».*

The group writing CPGs may also use examples to express aspects whenever the recommendation does not match the values and preferences expressed by patients. This is an adapted example which tries to use a simple language to facilitate its reading: «*Minimally invasive myotomy is indicated for surgery in most healthy people with achalasia. For patients who prefer to avoid such surgery and its common aftereffect (gastroesophageal reflux), pneumatic dilation, which has a lower initial efficacy and more long-term recurrences, may be reasonably offered.[9]».*

2.1.3. Some international initiatives on the development of DAs derived from CPG recommendations

Some international experiences, like the MAGIC project (*Making GRADE the Irresistible Choice*; https://magicevidence.org/)[10,11,12], organize information from CPGs so that it is easily transformed into DAs for use by both professionals and patients. The different formats of DAs are published on a web platform and are presented in an interactive way, adapted to tablets, web portals or to the electronic medical history of the patient.

Other international initiatives, like the DAs in short format[13,14] (i.e., Option Grid™, decision boxes, Statin Choice, etc.) are used during consultations and provide answers for frequently asked questions from patients about topics related to health results and practical topics of daily life which may have arisen during CPG development.

The GRADE working group has developed the frameworks «from evidence to decision»[15,16] (EtD) for the various types of recommendations or decisions. The objective of EtD frameworks is to help panelists and methodologists who contribute to CPG development to rely on evidence in a structured and transparent way, so they can be better informed of decisions regarding clinical recommendations, medical coverage decisions, and recommendations or decisions about the health system or public health. EtD frameworks inform users about decisions that have been made and about the evidence that they are based on in order to facilitate the decision-making process. EtD frameworks are currently used within the scope of the Clinical Practice Guidelines Program in the Spanish National Health System, coordinated by GuíaSalud. The GRADEPro Guideline Development Tool (GRADEpro GDT; www.gradepro.org), the interactive EtD framework (iEtD; http://ietd.epistemonikos.org/) and the interactive summary of findings (iSoF; http://isof.epistemonikos.org/) are free-of-charge network software solutions. iEtD frameworks and iSoF tables are also integrated into alternative tools for authorship and publication, like the tools developed within the framework of MAGIC project (Making GRADE the Irresistible Choice; www.magicapp.org).

The result of these initiatives are products based on scientific evidence and easy-to-use DAs, since they graphically show information about different options in terms of any benefits and disadvantages, according to the most concerning criteria to patients (see chapter 2.2 with examples of graphical representation of risks/benefits). This type of products based on scientific evidence and DAs promote and focus on discussion between patients and healthcare professionals, with the information that they provide in the exact moment of consultation and with materials adjusted to their needs at all times. These DAs both favor dialogue and increase deliberative speech, even with changes in «body language», since it implies that patients and healthcare professionals think together about the information, adopting different stances when these DAs are used (i.e., reading or sitting together while looking in the same direction towards a screen or an explanatory document)[17].

2.1.4. Use cases

The format of DAs in CPGs should be written and presented in a way that helps patients during SDM.

The text should include explanations and questions focused on the patient that allow us to learn about their preferences. The use of clear and specific questions helps to offer information in a clearer and more comprehensible format. For example, the use of verbatims or direct quotes, which directly show the experience of the patient, is a good way of giving first-hand examples that aid understanding of information.

It is important to include formats which allow for comparison of information relating to any available therapeutic options to help to boost SDM. For example, comparative tables of different drugs may be included in order to help patients in SDM make a decision about the prescription of drugs or on the option of undergoing certain tests or not for early detection, diagnosis and/or follow-up.

Some examples of these resources and tools may be reviewed in the links below:

— DA of the Mayo Clinic[18] on the use of statins (Statin Choice Decision Aid) in order to reduce the risk of a heart attack:

  This tool helps healthcare professionals to discuss with patients during consultation how the risk of a heart attack can be reduced. It helps to make decisions about the use of statins through some risk calculator models.

  - https://statindecisionaid.mayoclinic.org/

— DA of the National Institute for Health and Care Excellence[19] (NICE – decision aid Option Grid™) for melanoma:

  - Risks and benefits of sentinel lymph node biopsy (https://www.nice.org.uk/guidance/ng14/resources/sentinel-lymph-node-biopsy-yes-or-no-pdf-250598414)
  - Procedure for lymphadenectomy after a positive sentinel lymph node biopsy (https://www.nice.org.uk/guidance/ng14/resources/completion-lymphadenectomy-yes-or-no-pdf-250598415)
  - Follow-up and imaging tests (https://www.nice.org.uk/guidance/ng14/resources/followup-with-regular-ct-scans-yes-or-no-pdf-250598416)

— Interactive summary of findings of GRADEPro (iSof table) about antibiotics for middle ear infection (acute otitis media) in children:

  - https://isof.epistemonikos.org/#/finding/55ddb808352a506111abe4ea

Summary of key aspects

- The language and layout used can determine the way in which both professionals and patients understand and interpret the recommendations derived from CPGs.
- It is important to use a simple, accessible language presented in an appropriate way that helps patients understand information about CPG recommendations from specific criteria which meet minimum readability standards.
- Some international experiences may be used as a reference to organize information from CPGs so that it is easily transformed (with the appropriate language and layout) into DAs that can be used by professionals and patients.

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2.2. Communicating Numerical Results for Shared Decision-Making

Laura Diego, Ricard Meneu, Lucía Prieto, Pedro Rey-Biel

The objective of this chapter is to provide healthcare professionals and developers of Clinical Practice Guidelines with useful information about effective strategies for communicating numerical data so that, by facilitating comprehension and the ability to compare, they may help in Shared Decision-Making. For this purpose, this chapter covers problems related to numeracy, comprehension problems, and the potential to alter how information is interpreted, both among healthcare professionals and among any other parties involved in the communication, receipt and interpretation of numerical results in the area of health, as well as its implications for Shared Decision-Making. Also, this chapter gives advice on properly communicating these numerical results and describes the different tools which are available to do so, indicating how to use them and their potential limitations.

2.2.1. Introduction: Health Numeracy

Health literacy has been defined by the National Library of Medicine (NLM) as «the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions»[1]. For the Institute of Medicine (IOM), health literacy includes a broad range of skills aside from reading and writing, including numeracy, listening comprehension, and speaking, based on cultural and conceptual knowledge[2].

The users of health-related information, such as healthcare professionals, patients, relatives, managers, decision-makers or even journalists, often find it difficult to understand the meaning of health statistics and their graphical representation, which may give rise to wrong conclusions and non-ideal decisions. Scientific evidence shows that numeracy problems are widespread among all agents, that they arise due to a non-transparent framework of information, both unintentionally (attributable to comprehension problems), as well as, occasionally, as a consequence of intended efforts to manipulate or persuade, and this can have serious consequences for health[3].

2.2.1.1. Is available evidence properly interpreted?

In order to properly communicate and process the results that have been obtained, they must be correctly understood. However, understanding is not a problem limited to those receiving the information: even healthcare professionals often find it difficult to properly interpret simple statistical results[4].

The aforementioned study[4], described in more detail later, may serve as an example, in which 160 German gynecologists were given the value of the prevalence, sensitivity and false positive rate of a cancer screening test, asking them to indicate the probability that a woman subject to it was a true positive. Answer options were 1%, 10%, 81% and 90%. Only 21% of participants chose the correct answer (10%) while 60% chose the options that grossly overestimated. The variability observed was especially worrying, with 1%

estimates coexisting with 90% estimates. The example is especially alarming due to the fact that those who incorrectly interpreted relatively simple statistical information were the very specialists accustomed to working with it, who, in turn, were responsible for transmitting it and for guiding decisions regarding performing screening tests or regarding the patient treatment plan if the test were positive.

A more complex experiment[5] assessed medical residents' understanding of evidence presented to them regarding cancer screening and its recommendation to patients, as well as their prior beliefs, their numeracy, their level of scientific literacy, their knowledge of statistics on screening and their training in statistics and demography. The study showed that understanding statistics on cancer detection and the ability to infer potential benefits for patients are essential for experience-based recommendations. However, the authors of the study point out that strong belief in favor of screening, favored by promotional campaigns, may influence the way in which doctors process the evidence of specific evaluations, showing a greater proclivity towards screening than what is supported by evidence.

The most common cognitive biases, described in this section, may influence on the accuracy of diagnosis or mislead professionals in clinical management. In a systematic review of studies carried out on physicians using case vignettes or real-life scenarios, nineteen cognitive biases were identified. The overconfidence effect, the anchoring effect, information and availability bias, as well as risk tolerance, are the biases most commonly associated with diagnostic inaccuracies or with suboptimal case management[5].

2.2.1.2. Is there any evidence that better numeracy improves the decision-making process?

As shown below, low numeracy may distort the perception of the risks and benefits of screening, reduce medication adherence, hamper access to treatment, worsen the communication of risks and even negatively affect results, based on the limited amount of research carried out on them. It is also associated with greater susceptibility to factors unrelated to rational decision-making, such as the effects of mood, the way that information is presented, and biases in judgment and in the decision-making framework, e.g., framing and relationship bias effects[6].

Generally, low health literacy is associated with an increase in hospital admissions, greater use of emergency services, lower use of mammographies and influenza vaccination, problems adhering to treatments or a lower ability to interpret patient information leaflets and health messages. The most important factors observed among individuals with a lower ability to interpret numerical information are age, worse health conditions or belonging to groups with higher mortality rates[7].

Below are some examples, mainly from experimental design studies, of the relationship between numeracy and results in health. Likewise, some solutions are presented to both facilitate numerical understanding and also present graphical information in a way that is easier to understand, less prone to interpretations caused by cognitive biases, and has less capacity for manipulating a shared decision. However, even today, these types of studies are relatively scarce[8] and the results found are inconsistent to some degree. For this reason, although more research is still needed, we believe that the following examples are substantiated enough to offer some initial guidelines on how the different formats in which

information is presented can affect risk perception, persuading patients to make decisions that may be not necessarily ideal.

2.2.2. Use of Visual Aids to Improve the Communication of Numerical Data

Visual aids are graphical representations that can be used to help to understand the likelihood of an event[8,9,10]. For this reason, they facilitate informed decision-making for health professionals, patients or users[11,12,13,14].

2.2.2.1. Key Aspects When Using Visual Aids

When using visual aids to communicate numerical data, some aspects regarding the information recipient should be considered, such as their ability to understand graphical information, aspects concerning the objective of communication and the design of the tool itself.

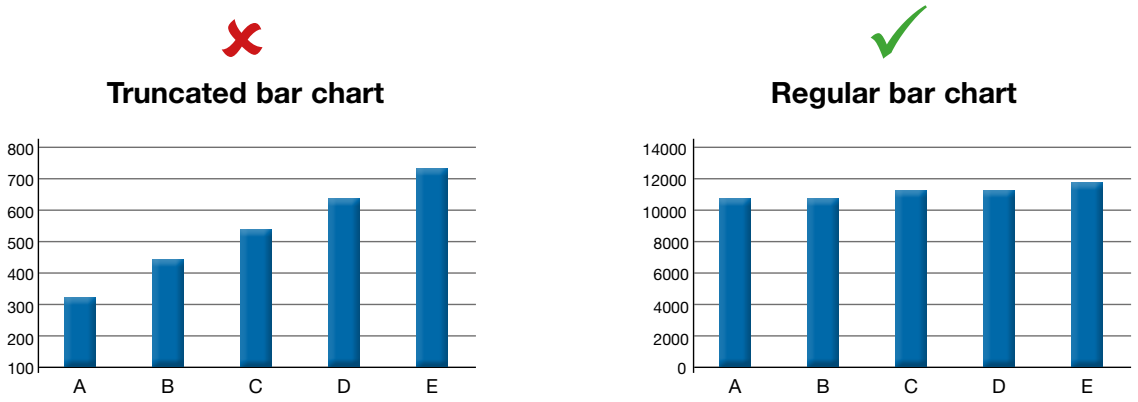
The ability of individuals to understand graphical information, and to make inferences and draw conclusions from it is summarized in the level of graph literacy. Individuals with a low level of graph literacy are more likely to ignore the most relevant elements of a visual aid[15] and, therefore, wrongly interpret visual representations[16], in comparison with individuals who have a higher level of graph literacy. However, although they may be compensated for through use of appropriately designed visual aids, the determining factors of graph literacy level remain unclear[18]. For this purpose, certain general design considerations must be taken into account, as well as the type of graph chosen[19].

2.2.2.2. General considerations for visual aid design

When designing visual aids, it is advisable to avoid any ambiguous or misleading messages or representations, since the arrangement of information within a graph may lead to misinterpretation. For this reason, it is advisable to follow some basic rules:

- Use clear titles and descriptions.
- Use simple language that is understandable and familiar to the recipient.
- Include key messages in the descriptions of visual aids.
- Provide a measurement scale and use the same one when showing comparisons.
- Avoid truncated graphs. These are graphs in which one of their axes, or both, do not start from zero. Truncated graphs are those in which data axes are visualized in such a way that only the possible data range on which there is information is shown. An example of a truncated graph is shown in figure 2.2.1.

Figure 2.2.1. Example of misleading graph



On the other hand, it is advisable to avoid unnecessary information or superfluous elements and focus the represented content on the message that is intended to be communicated, taking into account the following issues:

- Present only one message with each visual aid.
- Use the visual aid to represent the most important information.
- Choose two or three key aspects that you want to communicate and represent them by means of different visual aids.

Finally, color must be used properly. The color choice will depend on the data and the type of image. But three other elements must be considered[20]:

- Take into account the existence of conventionalisms associated with some of the colors chosen, as well as any potential positive or negative connotations and, if they interfere with the information that is intended to be transmitted, avoid them.
- Make sure that any potential user of visual aids can understand the message with the colors used. For example, color blind people find it difficult to distinguish some colors. The most common confusion is between red and green. If green and red are used to show a difference between two different areas, color blind people will be incapable of distinguishing them properly.
- If there are relatively few kinds of data for the values of a continuous scale, the use of different shades of the same color may be considered, instead of using different colors. If the data to be represented are modest or with positive and negative values, different colors may be used.

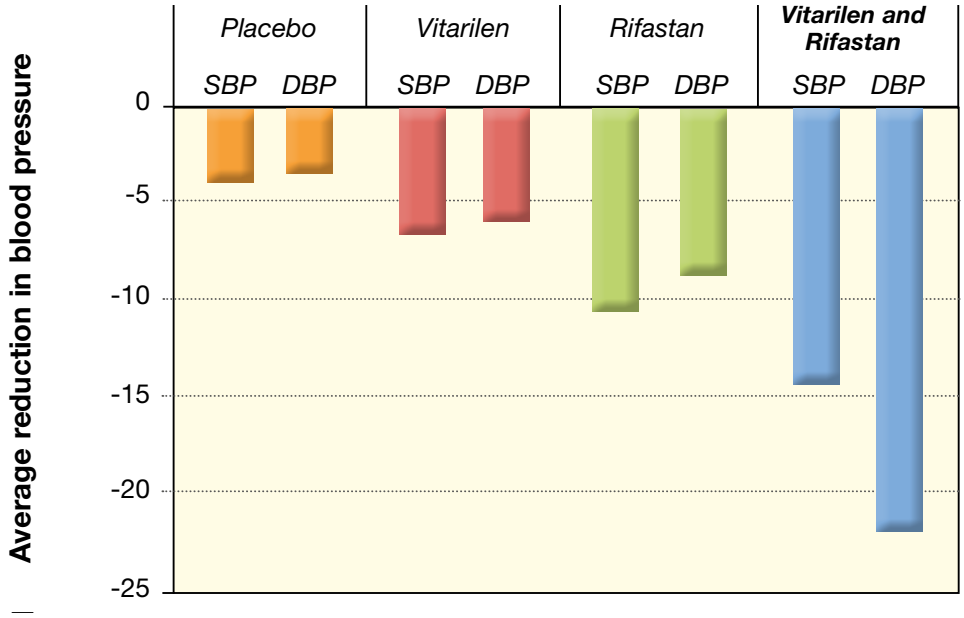
2.2.2.3 Considerations on the type of graph to be used

To choose the right type of graph, it is essential to know the objective of what is being communicated. For example, we would not use the same graph if we wanted to communicate data about survival or to show the comparison between the risks associated with two treatments. The most suitable types of graphs are detailed below according to the aim of communication:

a) Comparing different data: Bar chart

Classic bar charts use horizontal or vertical stacked bars (column chart) to show discrete numerical comparisons among categories (qualitative variables). One axis of the chart shows the specific categories being compared (for example, types of procedures, or procedure and comparing element) and the other axis represents a measured value (for example, blood pressure levels). The data of bar charts are categorical and, therefore, they answer the question «How much/many?» for each category. An example of a bar chart used to compare the effects of different drugs and placebo on blood pressure in two population groups can be seen in Figure 2.2.2.

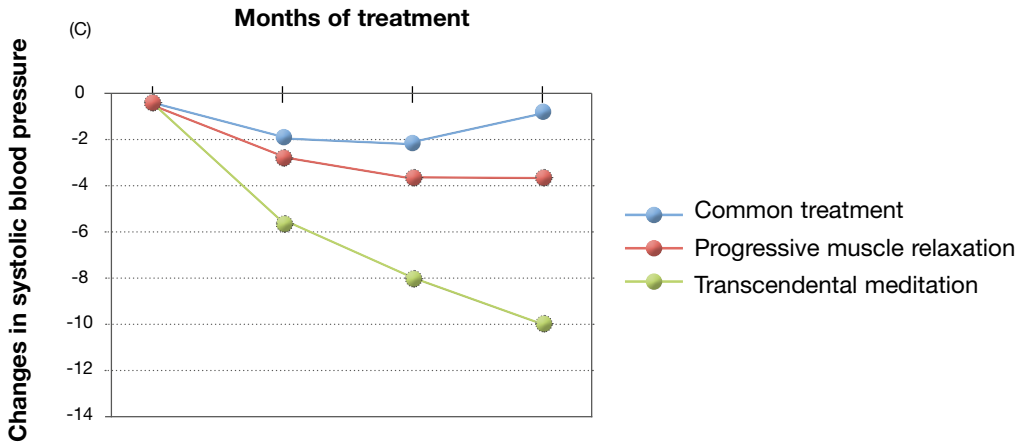
Figure 2.2.2. Comparison of the effect of different drugs and placebo on blood pressure.



b) Representing trends over a period of time: Line graph

Line graphs are used to show quantitative values in a continuous interval. Normally, the Y axis (vertical) will show a quantitative value (for example, the variation in systolic blood pressure) and the X axis (horizontal) will show categories or sequences (for example, months of treatment). An example of a line graph used to show changes in systolic blood pressure for three different treatment options over three months can be seen in Figure 2.2.3.

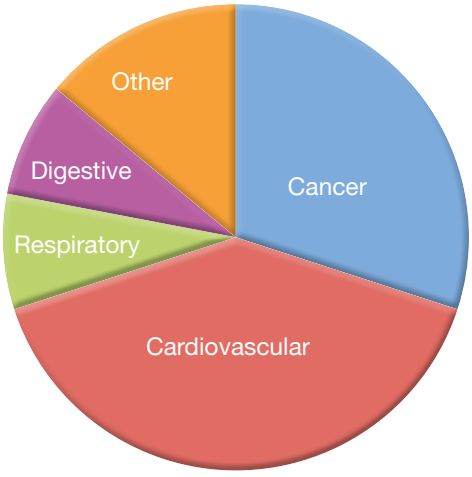
Figure 2.2.3. Changes in systolic blood pressure over three months of treatment with usual care and two different surgical procedures



c) Communicating information about proportions: Pie chart

Pie charts help to illustrate proportions and percentages among categories. The arc length of each slice is proportional to the quantity it represents, whereas the whole circle represents the total sum of data, equal to 100%. Figure 2.2.4 shows an example of a pie chart used to represent the frequency at which different types of comorbidities associated with a condition occur.

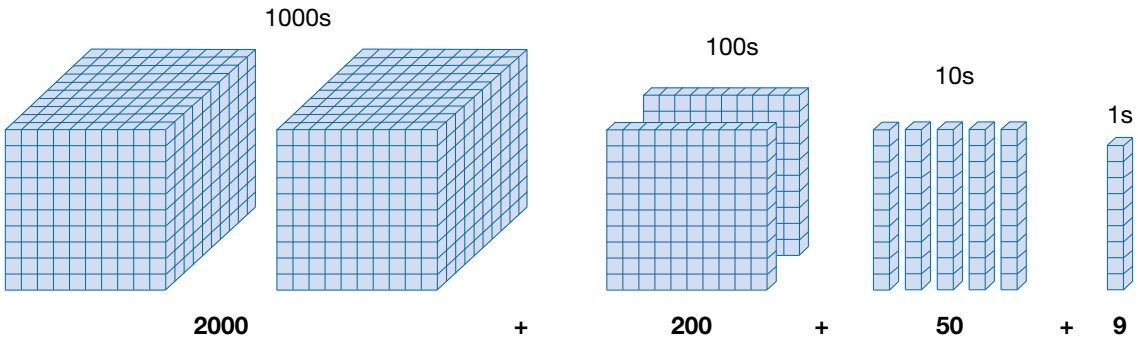
Figure 2.2.4. Representation of the different types of comorbidities associated with a condition



d) Representing very large numbers: Square pie chart

This type of chart uses grids to divide the display of numbers. Thus, units, tens, hundreds, thousand units, etc. are represented in the same way that it is formed. The number 2,259 is represented by means of grids in figure 2.2.5.

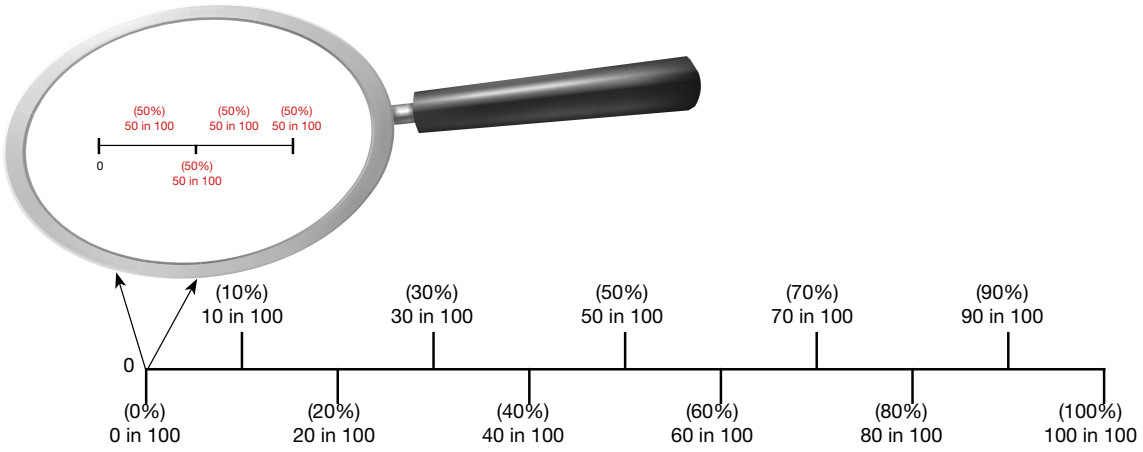
Figure 2.2.5. Representation of number 2,259



e) Representing really small numbers: Expanded scales

Expanding a scale provides details on a small range of data within a larger scale. Figure 2.2.6 shows an example of the visual expansion of a scale.

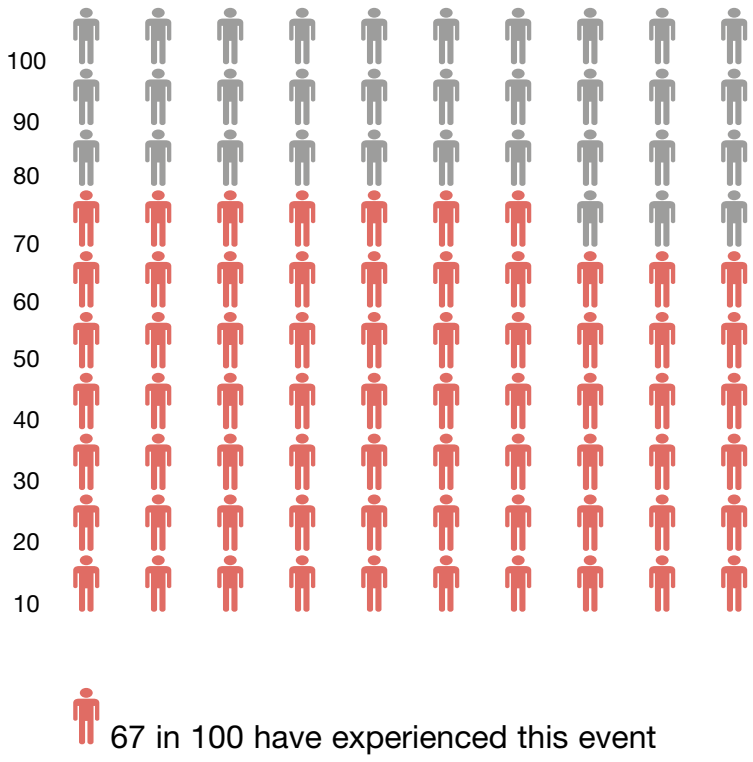
Figure 2.2.6. Expansion of a data interval



f) **Communicating risk reduction due to treatment or the risk of side effects:** Icon set

Icon sets display discrete data in units (icons), each of them colored or differentiated by a color or signal, used to represent a particular category, and grouped in a matrix. The risk of suffering a side effect is represented in figure 2.2.7. In a population group of 100 people, this graph shows those who would suffer side effects in red. This way, the risk of suffering such an effect is visually displayed.

Figure 2.2.7. Representation of risk of suffering a side effect

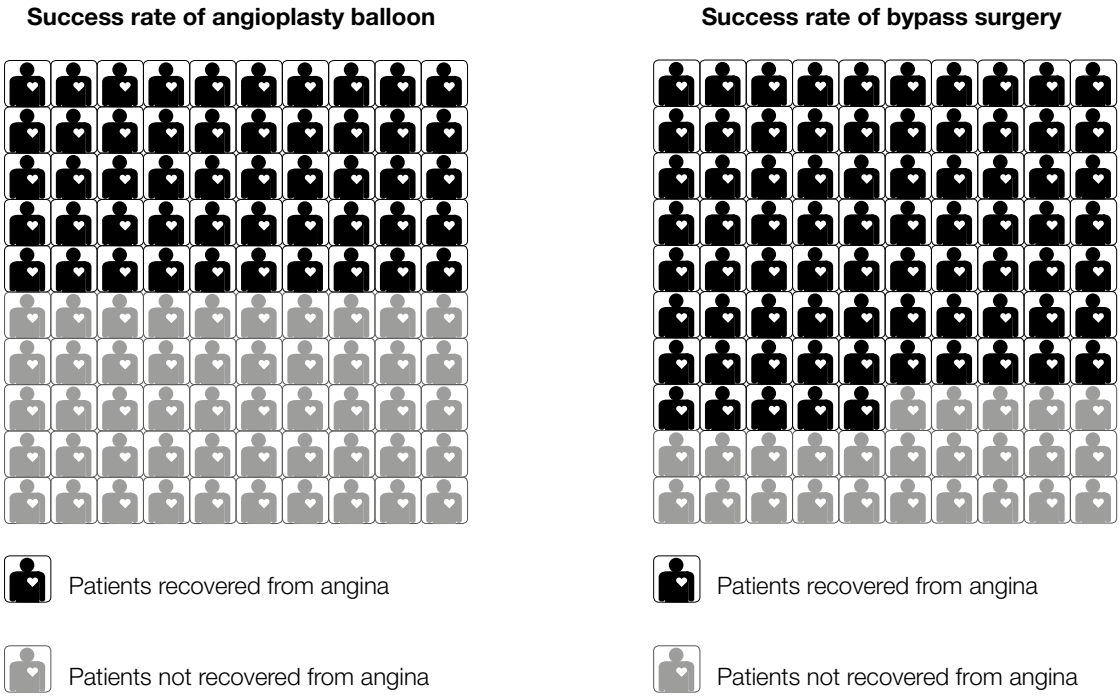


Recommendations for facilitating communication of risk through icons

When using icons to represent population at risk, it is advisable to take into account the following recommendations:

1. Use different sets of icons to represent baseline risk (over the sample of individuals without treatment) and the increased risk due to treatment (over the sample of treated individuals).
2. Represent affected individuals (numerator) and population at risk (denominators).
3. When comparing risks or success rates, use the same magnitude of denominator (population at risk) for both intervention groups and comparison groups. In Figure 2.2.8, you can see a graphical representation with denominators of the same magnitude.

Figure 2.2.8. Representation of success rates of two surgical procedures



4. Place the icons that represent the individuals that you want to differentiate (for example, the affected individuals) grouped in a block, not randomly distributed.
5. Bear in mind that random distribution of icons can make it difficult to understand what you are trying to convey, since it requires a more careful analysis of the image.
6. Use icons that resemble a person, whenever it is possible.
7. If a risk is clearly higher for a gender, it is recommended to represent it with that gender. Otherwise, one or the other may be used without distinction, but not always the same one.

2.2.3. Strategies to Improve the Communication of Numerical Data to Professionals and Patients

Communicating uncertain events, such as the foreseeable progress of a disease or the chances of success of a medical treatment, is far from trivial, especially given the important repercussions it can have on the patient's life. The correct communication of risks is not only a problem for the recipient but also for the issuer of the information, which can cause difficulties. This potential problem has three aspects: 1) the correct understanding of the information, 2) the patient's interpretation of the information, even when it is properly understood, and 3) the existence of the possibility of persuasion with regard to subsequent actions by the patient and healthcare professional. Below are some of the most common problems in medical risk communication and some clarified examples, as well as the existing evidence on possible solutions.

2.2.3.1. Framing when presenting results

The framing effect is a cognitive bias whereby a person's preferences vary when faced with a decision problem depending on how the information is presented, that is, the frame[21]. This is one of the classic ways of influencing the perception of data. Studies on the effects of framing on decisions have focused on negative versus positive framing and gain versus loss framing. A simple example of positive or negative framing would be an outcome with a 97% probability of survival or 3% mortality.

Both ways of presenting information are objectively equivalent, but informing a person of a probability as a possible benefit to their health or as detrimental to it affects emotions differently and has an impact on decision-making[22]. The existence of the framing effect paves the way for potential manipulation of patients – presenting information in one way or another to persuade them and so that, in the end, they make the decision that the physician considers appropriate.

Evidence shows that positive framing is more effective than negative framing when trying to persuade people to choose riskier treatment options. In addition, gain versus loss framing has proved to have a great influence upon diagnostic tests decisions. In contrast, negative framing focuses on the potential losses of not undergoing a diagnostic test, such as loss of health or longevity. Loss framing has been shown to increase the number of people who undergo screening tests such as mammography compared to gain framing such as for maintaining a good health[23]. These outcomes can be explained by the psychological concept of loss aversion, which is when losing something is more impactful than gaining something of equivalent value. Nevertheless, the systematic review of literature about the framing effect concludes that its effects can be different in each circumstance[24].

A classic example is a study that was carried out several decades ago in which patients were offered two treatments for cancer: one in which benefits such as 1-year and 5-year survival were presented, and another one in which the same odds were presented as mortality in the same period of time. The framing successfully inverted patient preferences between the two treatments based on whether they were presented in one way or another and, what is even more interesting, the result was independent of whether those who expressed their preferences between the two treatments were patients or doctors.[25].

Given that the best strategy to avoid framing is currently unclear, and until more decisive evidence is available, this issue may be resolved in a practical way by making a double presentation including the information using both a positive and a negative framing. That is, both the effectiveness of the procedure and therapeutic failure, since it seems that when complete information is presented, the effect tends to disappear[26].

2.2.3.2. Communication using verbal and numerical descriptors

Words have different meanings for different people and therefore their interpretation can be ambiguous. When communicating risks, the use of vague terms such as «sometimes» or «frequently» are misleading because recipients interpret the frequency that these words convey differently[27].

When the patient information leaflet of any drug informs that a side effect is «frequent», it refers to, and thus makes explicitly clear, a frequency of 1-10%. However, a study has shown that when a person is informed that an adverse effect is «frequent», they estimate that it occurs 50% of the time, and 25% if it is a healthcare professional[28,29].

It is recommended to prioritize the use of numerical descriptors over verbal ones, since the possible ambiguity in their interpretation could lead to overestimating risk and subsequently affect decision-making. Along the same lines, and with the aim of communicating results to professionals and patients in a clearer way, a recent GRADE publication proposes a template to help generate recommendations based on the results of systematic reviews in line with to the size of the effect and the degree of certainty of the evidence[30].

2.2.3.3 Communicating event probability

In order to present the probability of an event, simple frequencies (20 in 100) or percentages (20%) are generally used, but people tend to attribute different risks to equivalent probabilities presented in these two formats.

Below are the different biases when presenting the information in frequencies or percentages[27]:

- When risk is presented as simple frequencies, it tends to be magnified with respect to when its equivalent percentage is presented, especially in patients with low arithmetic skills.
- It is common to interpret 20% as 1 in 20.
- Presenting different results in frequencies using different denominators makes understanding difficult and increases the perception of risk.
- Avoid presenting results in 1 in X formats as it makes it difficult to compare the different risks presented.
- Frequencies expressed with small denominators (100) are easier to interpret than those with larger numbers (10,000) since larger numbers are more complicated to memorize.
- Presenting information in decimals, without rounding to integer, makes interpretation difficult.
- When the risks are very low, there is an intuitive tendency to interpret that the probability is very small, close to zero.

To avoid these biases, it is generally recommended to present the probabilities in integers, without decimals, using small denominators and being consistent in the way the information is presented throughout the text. Some authors suggest using percentages and frequencies simultaneously[27,31] however there is no evidence that this use improves the interpretation of results.

In addition to the biases identified in the presentation of probabilities, for an optimal presentation of the information it is necessary to take into account whether there are single or multiple event probabilities or conditional probabilities, as explained below.

a) Communicating single event probabilities

«Tomorrow there is a 30% chance of rain» is a single event probability.

«If you take this antidepressant, you have a 30%-50% chance of suffering an adverse sexual effect» is a single event probability, however, it can be ambiguously interpreted.

Probability, in this case, refers to a single and specific event, but people generally think in terms of classes of events. If the class to which it refers is not made explicit to us, it is likely that each person will construct their own reference, generating confusion

and different interpretations[32]. In this sense, a study has observed that physicians associate data with patients, whereas patients associate data with their own experience. Therefore, some interpreted that 30-50% of patients would have sexual problems, others that they would have problems in 30-50% of their sexual relationships and some even that they would have sexual relationships that would turn out to be a 30-50% less satisfactory[32].

This problem can be avoided using simple frequencies instead of percentages. Thus, transforming a message like «if you take this medication, you have a 30-50% chance of having a sexual problem» to «of the 10 patients who were prescribed this antidepressant, 3-5 of them have a sexual problem» facilitates the interpretation of risk[32].

In order to present single event probabilities, it is important to define the denominator and make clear which class of event is being referenced in order to avoid misinterpretations.

b) Communicating multiple event probabilities

Presenting the efficacy of drugs A, B and placebo in a clinical trial is a multiple event probability. Presenting this information where a patient has to choose between drugs A or B may lead to information overload, and it is important to simplify its reception.

In these cases, it is deemed more appropriate to express probability as follows: «the probability of resolution with treatment A is 15%, with treatment B it is 30% and with a placebo it is 5%» instead of saying that the drugs are effective in 1.5 out of every 10 cases (A), 3 out of 10 (B), and 0.5 out of 10 (placebo)[32].

To compare multiple event probability results, it is recommended to express them as percentages, since they facilitate comparison with the presentation of information as natural frequencies.

c) Communicating conditional probabilities

The chance of having breast cancer depending on the result of a mammography, and also taking into account the sensitivity and specificity of the test, is a conditional probability. This type of probability requires applying Bayes' theorem, which requires at least three calculations, and, regardless of whether it is for healthcare professionals or patients, makes it difficult to obtain a positive predictive value[33].

At a medical congress, the following data were presented to the 160 attending gynecologists after several studies in which the joint probabilities were investigated[33]:

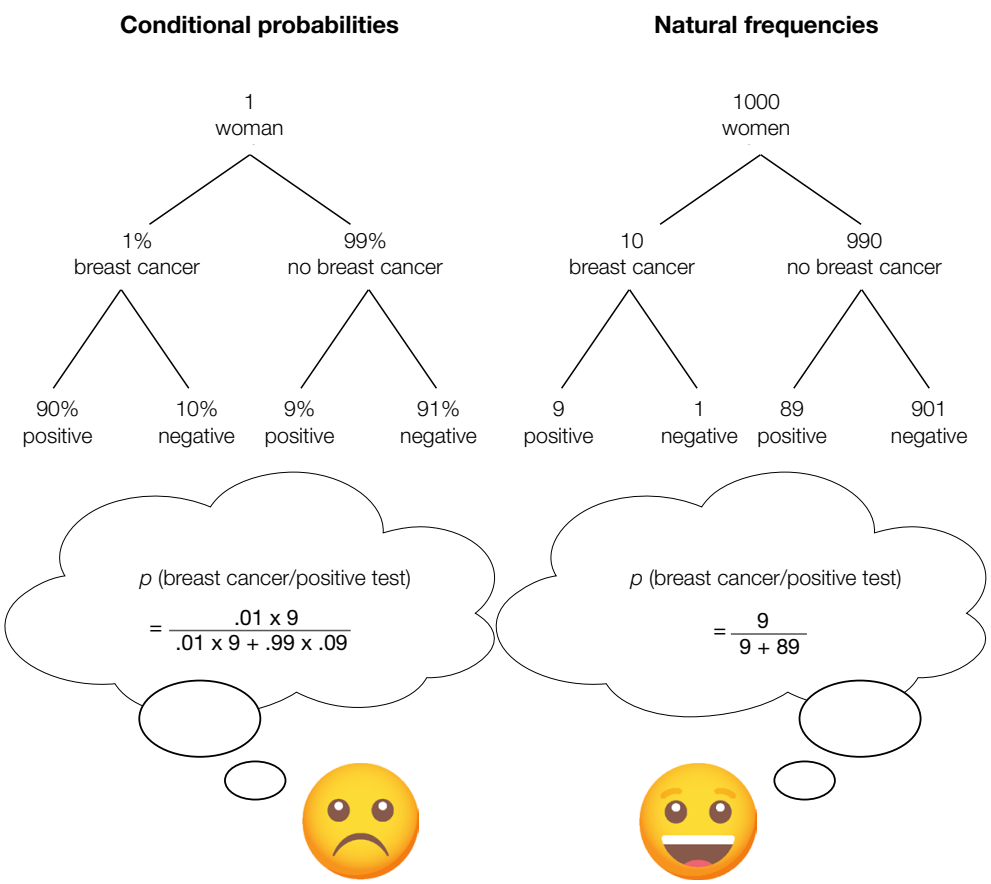
- The probability that a woman will develop breast cancer is 1%.
- In women with breast cancer, the probability of a positive result of a mammography is 90%.
- In women who do not have breast cancer, mammographies can test positive in 9% of cases.

Afterwards, they were asked about the probability that a patient who tests positive in a mammography actually has breast cancer, presenting four possible answers. Most of the gynecologists did not know how to calculate the correct answer and there was a great diversity among answers. On the contrary, when the same information is presented but expressed as natural frequencies, it is much easier to know the answer:

1. Prevalence: 10 in 100 women develop breast cancer.

2. Sensitivity: 9 of these 10 women with breast cancer were diagnosed by a mammography.
3. Specificity (false positives): 89 in 990 women without breast cancer were diagnosed with breast cancer.

Figure 2.2.9. Conditional probabilities and natural frequencies



Showing the information in this way, using natural frequencies and not probabilities, we almost immediately realize that of the 98 women whose mammographies indicate that they have developed breast cancer, only 9 of them have actually developed it, which means that 90% of women who are diagnosed with breast cancer by a mammography actually have not developed it. Therefore, the correct answer in view of these objective data is that the probability of having developed breast cancer after having given a positive result in a mammography is only 10%.

A systematic review has shown that natural frequencies facilitate understanding with respect to conditional probabilities in the context of presenting screening results or diagnostic tests without differences having been found depending on whether they are professionals or patients[34].

It is recommended to report on joint probabilities using natural frequencies and not percentages, since they are more intuitive and make calculations easier.

2.2.3.4. Communicating changes in numerical results

In general, the communication of changes caused by medical intervention, such as the effects of a treatment or changes in long-term health, are expressed as changes in probability. In order to present this information, risk measures such as absolute risk (AR) and relative risk (RR) are used, or when differences between the two interventions are presented, they are expressed as risk reductions. Another way of presenting this information is through the NNT (number needed to treat) (see glossary). The NNT is a risk measure that was introduced in the 1980s with great acceptance among professionals since its clinical interpretation was more intuitive.

It is known that presenting risks as RR overestimates the results compared with presenting them as AR, especially if the baseline risk is small. This has been traditionally used to persuade, presenting data with an apparently greater impact, which has sometimes had a significant social repercussion[34]. For example, in 1996, an official government communication from the United Kingdom warned that the second-generation contraceptive pill doubled the risk of suffering from venous thromboembolism. This information caused great concern among women, causing a decrease in the use of contraceptives and having an impact on the number of pregnancies and abortions, where an excess of between 12,000 and 14,000 cases was estimated. The information given to women used RR, warning that risk doubled. Considering that the baseline risk was very low (1 in 7,000) and that with the new pill the risk increased to 2 in 7,000[35], should this information had been provided, many women would not have made the same decision.

A systematic review has shown that presenting the information as RR makes both patients and health professionals perceive the interventions as more effective or more persuasive in order to prescribe or accept an intervention than when the results are presented as AR or NNT[34]. In this sense, using RR tends to misinform with regard to decision-making, especially when the baseline risk is low, and not reporting it tends to exaggerate the perception of difference. On the other hand, studies show that professionals and patients perceive the interventions as more effective and that the results are understood better when they are presented as AR than when they are presented as NNT. However, no differences were found in relation to the ability to persuade regarding the prescription or acceptance of a medication.

It is recommended to present changes in results through AR since the use of RR and NNT is more persuasive and difficult to understand respectively. An alternative would be to present the increased risk, which implies presenting the absolute risks accompanied by the baseline risk. The increased risk works better when it is accompanied by visual aids. Should it be necessary to present the RR, it is recommended to accompany it with baseline risk.

2.2.3.5. Communicating personalized risk estimates

Studies suggest that when information about risk is personalized, there is an increase in the perception of risk and it improves knowledge, unlike when the information is presented in a generic way. In any case, evidence is limited and presents various results that raise

reasonable doubts as to whether presenting personalized or «tailor-made» information truly has an impact on health decisions.

Most of the research done on personalized risk estimates has focused on cancer screening, showing an increase in the number of active participants with regard to, for example, breast and cervical cancer screening[36]. A meta-analysis has shown that personalized risk estimates are effective for behavioral changes, but the size of their effect is very small[37].

At the moment, it is not possible to make recommendations on personalized risk information since it is not yet known exactly how it affects comprehension or its impact on decision-making[27].

2.2.3.6 Communicating long-term results

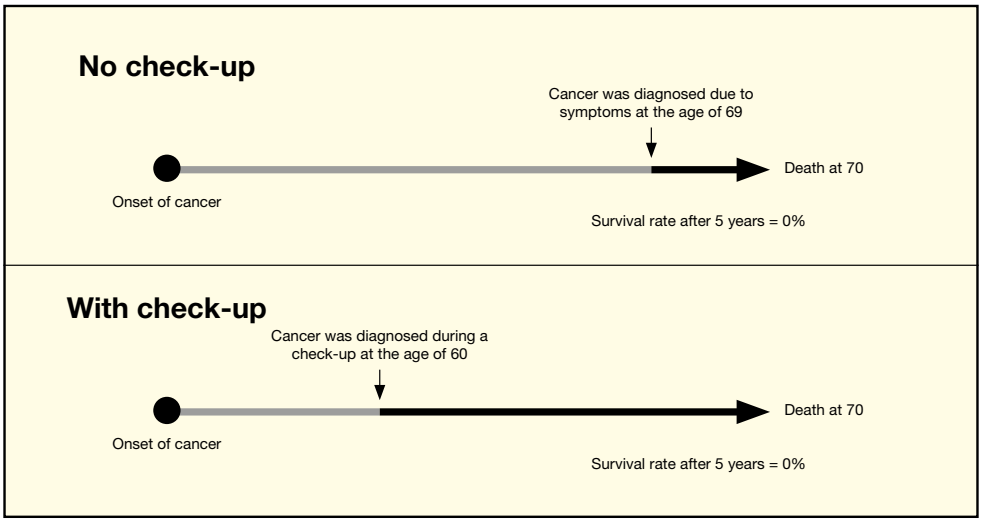
Patients are interested in getting long-term information about the results of procedures that they undergo. In addition to the difficulties associated with having these kinds of data available —clinical trials often involve a follow-up period of only 1-2 years— there are also difficulties presenting long-term data in an easy to understand way.

There are different ways to present these types of results[27]:

- Probability of an event in a specific moment in time. It is used, for example, to present the 10-year cardiovascular benefits of drugs such as antiplatelet drugs and statins.
- Probability of an event in several moments over time. For example, the probability of having to repeat a bypass 5 or 10 years after the first surgery.
- Mortality or survival curves commonly used when presenting the benefits of cancer screening programs.
- Cumulative probability of an event over time as those commonly used for the presentation of breast cancer risk in patients with BRCA gene mutations.
- The incidence of an event that is constant over time is used to represent the annual risk of pregnancy in patients treated with a specific contraceptive method.

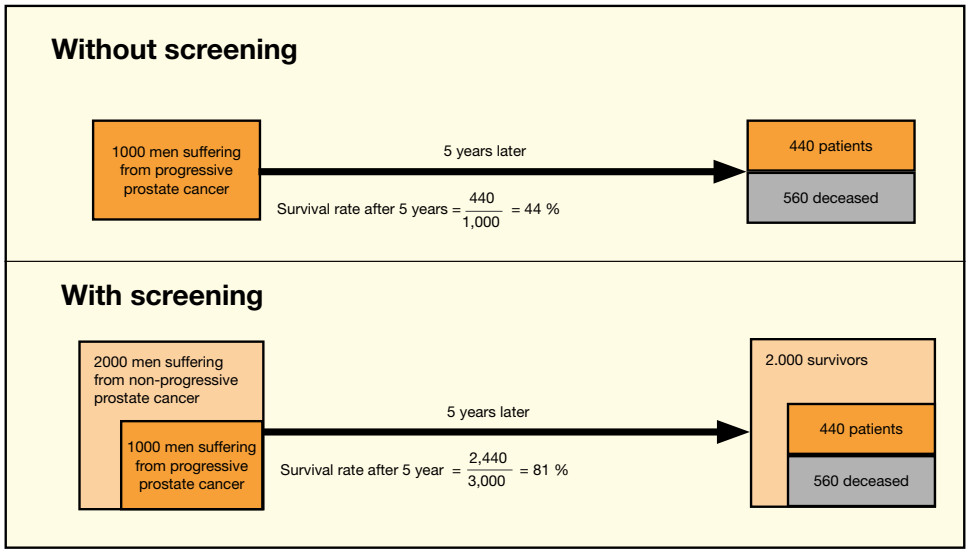
Regarding screening tests, one way of presenting long-term results is the survival rate after 5 years. However, this can be misleading and cause misinterpretations that an increase of the survival rate entails saving lives. Although, intuitively, it seems impossible that a procedure that increases survival does not reduce mortality, it is a frequent confusion generated by two cognitive biases: temporal bias and overdiagnosis. Temporal bias in screening implies that, although we are able to detect tumors early with this procedure, a reduction of mortality is not necessarily achieved since it may mean living longer with a positive diagnosis of the disease, but not living for more years (see figure 2.2.10).

Figure 2.2.10. Temporal bias



The second difficulty lies in overdiagnosis: screening tests allow for the detection of tumors that fit with the pathological definition of cancer, but that grow very slowly or do not grow at all, and therefore they would not have caused death[38]. As shown in Figure 2.2.11, it is also observed that, the greater the overdiagnosis, the higher the survival rate, but there is no implied reduction in mortality.

Figure 2.2.11. Overdiagnosis bias



Research into presenting screening results regarding survival rates has shown that it not only misleads patients, but also physicians and even medical journal editors[38]. In one study, 3 in 4 physicians surveyed mistakenly believed that 5-year survival rates could show reductions of mortality through screening, when the reality is that a procedure can only prove to save lives through reduced mortality[39].

There are no clinical trials available that have studied the effect of the different forms of presentation of long-term risks and, therefore, it is impossible at the moment to make recommendations in this area. Until more conclusive results are available, it seems that the most practical option is to choose the representation that best suits the type of information that has to be presented.

Regarding the presentation of results of long-term benefits of screening, it is recommended to use mortality rates, since 5-year survival rates can be misleading, creating the illusion of a reduction of mortality when this is not the case. In the specific case of cancer screening campaigns, we must not overlook the fact that the main objective is to provide patients with the best information for decision-making, rather than increasing the number of participants in the campaign itself.

2.2.3.7 Communicating uncertainty

There is a high degree of uncertainty in medicine. Numerical estimates of risk are mathematical expressions, but no probability can predict what will happen to a particular patient. We can only show the information gathered with regard to what happened in similar patients in the past. Uncertainty can be divided in two types: a) random, reflecting the vagueness of future facts; or b) epistemic, reflecting the limitations on confidence, credibility or suitability of information about risks. Understanding this type of uncertainty is essential in decision-making[27].

Communicating random uncertainty has been assessed in short studies, which have proven that it does not have a significant effect on the perception of risk. Communicating epistemic uncertainty, studied through the use of confidence intervals, has also shown that it has a very limited effect on the perception of risk, although this could increase concern among patients[27].

As of today, no clear evidence is available and more studies are needed to determine the role of the communication of uncertainty in patient perceptions, understanding and decision-making. We must be to be honest and communicate the uncertainty associated with the different procedures that a patient may face as clearly and as precisely as possible. Intuitively, it seems that communicating uncertainty could generate distrust and aversion, but the preliminary results of some studies suggest that the doctor-patient relationship and trust may not be affected to a great extent[27].

2.2.3.8 Narrative presentation of the probability of an event

Sometimes the information presented to patients includes the stories of other patients as a data support[27]. The experience of any patient contains a great number of first-hand details about what it feels like to suffer from an illness or undergo a treatment, and they have proven to be useful in initiatives such as *patients like me* or in expert patient programs[40].

The use of stories affects the perception of risk and influences decision-making, like, for example, the intention to get vaccinated. In drug studies, while supplementing information with patient stories has proven to reduce the incidence of adverse effects, this does, however, also increase the severity of those that occur[27]. Stories have also been observed to affect decisions about elective surgery: for example, the group of patients who learned about the experiences of other patients undergoing bypass surgery were more likely to opt for surgery than the group who did not hear the stories[27].

Although the use of stories has been proven to affect the perception of risk and influence decision-making, it is recommended to use them with caution until the exact extent of their impact is known, especially in those situations where the aim is to persuade patients into a change of habits. If they are used to present information about benefits and risks, they must be accompanied by information in the form of pictograms.[26].

2.2.3.9. Context of numerical estimates and evaluative labels

Traditionally, communicating risks has been based on numerical estimates of probabilities. However, as discussed throughout this chapter, patients find it difficult to interpret this information. Evidence shows that providing contextualized data, that is, accompanied by comparative data, evaluative labels or symbols, helps to interpret them better. [41]

In studies where the result has been interpreted as either bad, good or excellent, for example, it has been shown that patients have made use of this information for decision-making. It has also been observed that the use of symbols such as stars, colored dots or check marks (ticks) can help to interpret information. Comparisons have been used to facilitate weighting, evaluation and interpretation of the numerical value of a risk, for example, also showing the result of the average patient. [41]

Given that studies in this field have shown inconsistent results in relation to how they affect decision-making, even though it has been confirmed that they can be used to persuade, it is recommended to select the context in which the information will be presented with great caution. [41]

Conclusions

The key factor in presenting the probabilities of risks and benefits of different interventions for patient decision aids involves the presentation of numerical information with consistent risk formats that allow for comparison of the different options and their results. At times it will be necessary to find a balance between the pros and cons of using a certain format, however, the decision must be made to present the information in a consistent and unbiased way.[41]

It is recommended to test the formats used with the end user, especially when contextual information and evaluative labels are used, or when the skills of patients are limited.[41]

Although there are still certain areas where more research is needed to provide clear guidelines, it is necessary to understand how different formats may affect the perception of risk in order to avoid inadvertently persuading patients into a certain option.

Summary of key aspects

- The available evidence shows that numeracy problems are common among healthcare professionals, so it is advisable to provide them with practical information and communication aid tools that improve the correct understanding of the data in order to facilitate Shared Decision-Making.
- Different levels of graph literacy can be compensated for by using properly designed visual aids.
- When designing visual aids, it is advisable to use clear and simple language, avoiding excessive information and misleading representations, such as truncated graphs, which may confuse the recipient.
- The ideal graph type will be determined by the communicative aim.
- The inability to understand numerical information is primarily due to deficiencies in information presentation rather than the cognitive abilities of the recipient.
- Framing is a classic way to influence decisions. To avoid persuading, it is recommended to present information in both ways, in a positive and in a negative way or as gains and losses.
- When presenting probabilities, it is recommended to:
    - Use numerical descriptors instead of verbal descriptors, since the latter are not specific and lead to a different interpretation of the associated risk.
    - Be consistent in the way that data are presented.
    - If you are using frequencies, always use the same denominator.
    - Use integers instead of decimals.
    - Avoid using very small numbers since they can be interpreted as almost zero-risk.
    - Regarding single event probabilities: use frequencies and indicate the denominator.
    - Regarding multiple event probabilities: use percentages since it simplifies the comparison.
    - Regarding conditional probabilities: use frequencies because it simplifies the associated calculations, facilitating their interpretation.
- When presenting numerical changes in events, it is recommended:
    - To use absolute risks and avoid relative risks, since they tend to exaggerate results. Should it be necessary to use relative risk, it is recommended to accompany it with baseline risk as a reference.
    - Regarding low absolute risks, it is necessary to contextualize them, indicating the baseline risk.
    - To avoid using NNT if an adequate explanation is not given, since it may confuse patients. It is better to use absolute risks.
- The impact of personalized risk estimates on decision-making must be assessed.
- Regarding the presentation of probabilities over time, there are no studies which have assessed the effect of different formats. It is recommended to present the benefits of screening as 5-year mortality, since using 5-year survival is misleading because it incorporates temporal bias and overdiagnosis.
- The impact of communicating the uncertainty inherent to medical processes is unclear.
- Presenting stories or declarations of patients must be done cautiously since it has been proven to influence the perception of risk, but for the time being, its impact upon decision-making is still unknown.

Resources

- Harding Center for Risk Literacy; https://www.hardingcenter.de/en
- Université Laval Decision Box; https://www.boitedecision.ulaval.ca/en/
- Mayo Clinic Shared Decision Making National Resource Center; https://carethatfits.org/
- DynaMed Shared Decisions. Option Grid; https://www.ebsco.com/clinical-decisions/dynamed-solutions/dynamed-decisions
- Cate's Plot; https://www.nntonline.net/visualrx/cates_plot/
- The Ottawa Hospital. Patient Decision Aids. https://decisionaid.ohri.ca/
- Dr Chris Cates' EBM Website – Evidence Based Medicine, NNT, Visual Rx & The Cates Plot at Dr Chris Cates EBM Website [Internet]. [cited on 10 May 2021]; Available at: http://www.nntonline.net/

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2.3. Shared Decision-Making based on Recommendations

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This chapter explains the process that Clinical Practice Guidelines (CPGs) development groups should follow to identify and prioritize the recommendations likely to require the development of some type of Patient Decision Aids (DAs). Regarding the identification of these recommendations, this chapter discusses the most common factors and scenarios that lead to a conditional (or weak) recommendation according to *Grading of Recommendations Assessment, Development and Evaluation* (GRADE) system, taking the *Evidence to Decision frameworks* (EtD frameworks) as a point of reference. In this chapter, we propose a set of criteria to prioritize the *de novo* adoption, adaption or development of DAs, and ultimately, a process is presented for the identification and prioritization of recommendations for DA development, in the various phases of CPG development.

2.3.1. Introduction

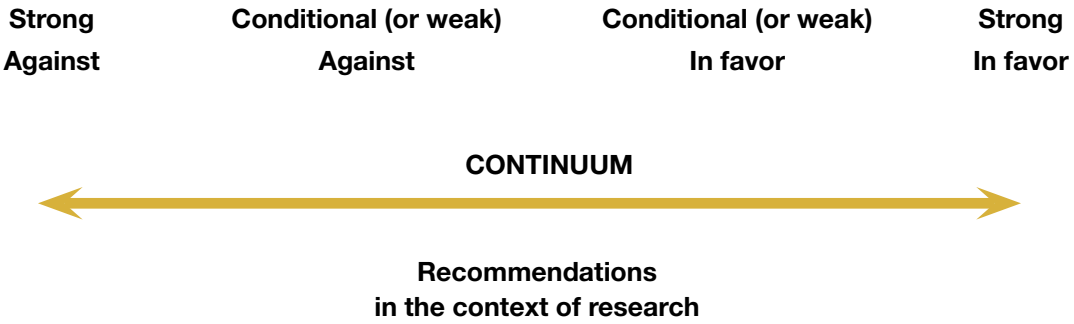
Achieving a real link from both Shared Decision-Making (STD) and DAs to recommendations requires integrating the adoption, adaptation or development of these types of tools into the CPGs development process. It is necessary to plan this work properly to invest available resources efficiently. The first step is to identify the recommendations that are most sensitive to the patient preferences, and then prioritize the recommendations for which DAs will be sought, adopted, adapted, or developed *de novo*.

2.3.2. Identifying Recommendations requiring SDM: Relevant Factors with regard to the Criteria Considered by EtD Frameworks (GRADE)

According to GRADE**,** recommendations can be classified depending on their strength and direction (see figure 2.3.1). The strength of a recommendation (strong or weak) reflects the extent to which a guideline panel is confident that desirable effects of an intervention outweigh undesirable effects, or vice versa, across the range of patients for whom the recommendation is intended. On the other hand, the direction of a recommendation may be in favor of or against the implementation of an intervention depending on the balance between desirable and undesirable effects, among other factors [1].

Recommendation strength understood as a continuous spectrum, which GRADE classifies in 4 categories

Figure 2.3.1. Classification of recommendations according to GRADE



All recommendations can be used in a SDM process. Nevertheless, weak recommendations are the main candidates for shared and informed decision-making among healthcare professionals and patients[2]. According to GRADE, a weak recommendation refers to a recommendation in which desirable consequences are likely to outweigh undesirable consequences (a weak recommendation in favor of a procedure) or the undesirable effects are likely to outweigh the desirable consequences (a weak recommendation against a procedure), but with noticeable uncertainty. There is a third scenario in which the difference between the desirable and undesirable consequences does not favor any of the procedures in particular. This can generate a weak recommendation that presents different alternatives that the patient may choose from, without opting for one in particular (a recommendation which is neither for nor against a procedure). The greater the uncertainty regarding the consequences determining the strength and direction of a recommendation, the more likely it is that a recommendation is weak, and that the decision is subject to a SDM process.

A weak recommendation implies that not all patients will benefit from the recommended action. From the patients' point of view, a weak recommendation implies that a higher percentage of people in that situation would agree on the suggested course of action, although many others would disagree. Therefore, DAs could be especially useful in this context for patients to make a decision consistent with their values and preferences. Table 1 describes the implications of each type of recommendation for patients, healthcare professionals and for decision makers/managers.

Table 2.3.1. Implications of each type of recommendation depending on the interest group

	STRONG RECOMMENDATION	WEAK RECOMMENDATION
For patients	Most individuals in this situation would want the recommended course of action and only a small proportion would not. DAs will probably not be necessary to help people to make decisions consistent with their values and preferences.	The majority of individuals in this situation would want the suggested course of action, but many would not. DAs can be useful in helping to make decisions consistent with the values and preferences of each person.
For healthcare professionals	Most individuals should receive the recommended course of action.	Recognize that different choices will be appropriate for different patients, and that you must help each patient arrive at a health-management decision consistent with her or his values and preferences. DAs can be useful in helping to make decisions consistent with the values and preferences of each person.
For decision makers/ managers	The recommendation can be adapted to health policy in most situations. The implementation of this recommendation included in the guidelines could be helpful as a quality criterion or as a performance indicator.	Health policy making will require substantial debate and involvement of many stakeholders. Adequate documentation of the decision-making process for a weak recommendation could be helpful as a quality measure, particularly if the weak recommendation in based on high-quality evidence.

Source: Manual de Elaboración de Guías de Práctica Clínica en el Sistema Nacional de Salud[9].

Detailed below are all the factors determining the strength and direction of recommendations which are related to SDM[3,4]:

- **Quality of scientific evidence**: if evidence is not high-quality, confidence in results will not be high either. Therefore, the strength with which a recommendation is formulated will decrease as well, being more likely to be a weak recommendation.
- **Assessment of outcomes by patients:** In certain scenarios, uncertainty about how patients or those affected by the recommendation assess the main outcomes could be a reason for not making a strong recommendation. The same thing could happen if there is a significant variability about how patients assess outcomes.
- **Balance between benefits and risks**: the balance between benefits and risks of an intervention can be positive or negative. The greater the difference between benefits and risks, the more likely that a strong recommendation is made in favor or against said intervention. Conversely, the smaller the difference, the more likely that a weak recommendation is made.

- **Patient costs**: the higher the costs of an intervention, the more likely that a weak recommendation is made.
- **Acceptability, equity and feasibility**: the uncertainty or variability regarding the acceptability of an intervention by stakeholders (for example, caregivers), will be other factors to be considered. Likewise, feasibility (for example, the fact that a person cannot travel to have rehabilitation) and the probability of unequal situations occurring (disadvantaged groups) regarding access to interventions are factors that must also be considered.

2.3.2.1. Use cases: identifying recommendations requiring a DA

Two cases are presented below to highlight the factors that were taken into account by the Guidelines Development Group (GDG) when formulating weak recommendations for each case. The first example illustrates the balance between risks and benefits of the intervention as a factor which is responsible for the formulation of a weak recommendation. The second one shows how variability in patient-assessment of outcomes led to the formulation of a weak recommendation.

1) European Guidelines for Breast Cancer Screening and Diagnosis[5]

Question: Should women over the age of 69 who are not at high risk for breast cancer undergo breast cancer screening?

Recommendation: For asymptomatic women aged 70 to 74 with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) suggests mammography screening over no mammography screening, in the context of an structured screening program (conditional recommendation, moderate confidence in evidence).

Explanation: The conditional recommendation (rather than strong) in favor of mammography screening is due to the fact that, despite there being moderate-quality evidence on the benefits of screening for women's health, there is a degree of uncertainty or variability about the way in which these women consider the main outcomes.

2) American Society of Hematology Guidelines for Management of Venous Thromboembolism: Prophylaxis for Hospitalized and Nonhospitalized Medical Patients[6]

Question: Should graduated compression stockings, LMWH (low molecular weight heparin) or acetylsalicylic acid be used over no venous thromboembolism (VTE) prophylaxis in long-distance travelers (more than four hours)?

Recommendation: In long-distance travelers (more than four hours) without risk factors for VTE, the GDG of the guidelines suggests not using graduated compression stockings, LMWH, or aspirin for VTE prophylaxis (conditional recommendation, very low confidence in the evidence regarding the effects).

Note: People with no known risk factors that value VTE prevention may decide to wear graduated compression stockings (which also reduce edema).

Explanation: The GDG decided that, in general, for all interventions, undesirable consequences were greater than the desirable ones, and therefore made recommendations against their use, with the exception of patients with risk factors for VTE. People with no known VTE risk factors who place a high value on VTE

prevention may decide to wear graduated compression stockings. Regarding LMWH and aspirin, for people at a substantially increased risk of VTE (for example, after a recent surgery, prior history of VTE, hormone replacement therapy, pregnant or postpartum women, active malignancy, or two or more VTE risk factors) may present more benefits than risks to health.

2.3.3. Prioritizing Recommendations requiring SDM

Since, generally, it will not be possible to adopt, adapt or develop a DA for each of the recommendations in which the need for a SDM process is recognized, its development would benefit from an organized and explicit prioritization process, taking into account the resources and time available.

2.3.3.1. Criteria for prioritizing recommendations

In order to prioritize the recommendations in which a DA should be developed, it is necessary to determine what the added value of a DA will be when implementing each recommendation, taking into account the potential benefit for patients, as well as the priorities for the Spanish National Health System (SNHS). The factors to be considered for prioritization are described below, in no particular order[7,8]:

- If there are similar risks and benefits between the options and the patient's preferences, this being the main determining factor for prioritization.
- The urgency of the medical care required. The more urgent the intervention, the less sensitive to preferences a recommendation will be.
- The degree of variability in the assessment made by patients about the outcome measures which are important for them (morbidity, quality of life, etc.). The greater the difference in the assessment of the outcome measures, the more sensitive to preferences a recommendation will be.
- The potential complexity of the SDM process derived from the number of options from which to choose. The more options there are to choose from, the more sensitive to preferences a recommendation will be.
- If it is a high-risk decision (i.e., when it is quite likely to lead to life-threatening or dramatic consequences for the patient), the recommendation will be more sensitive to preferences.
- Degree of generalization of evidence (i.e., the results obtained in the studied sample may be extrapolated to different populations). The less generalizable the evidence, the more sensitive a recommendation is to preferences.
- The degree of impact on the patient's quality of life due to side effects. The greater the number and the severity of side effects, the more sensitive to preferences a recommendation will be.
- The degree of discrepancy between what caregivers think is the best option for patients and what adequately informed patients would decide by themselves. The greater the evidence, the more sensitive a recommendation is to preferences.

- The existence of an unjustified variation in access to the different options due to the existence of cultural, sociodemographic, functional and economic diversity, etc.
- The usefulness of a graphical representation of the options with their respective risks and benefits to patients.
- The level of priority for the SNHS (for example, the frequency with which patients or service users may have to face a decision).

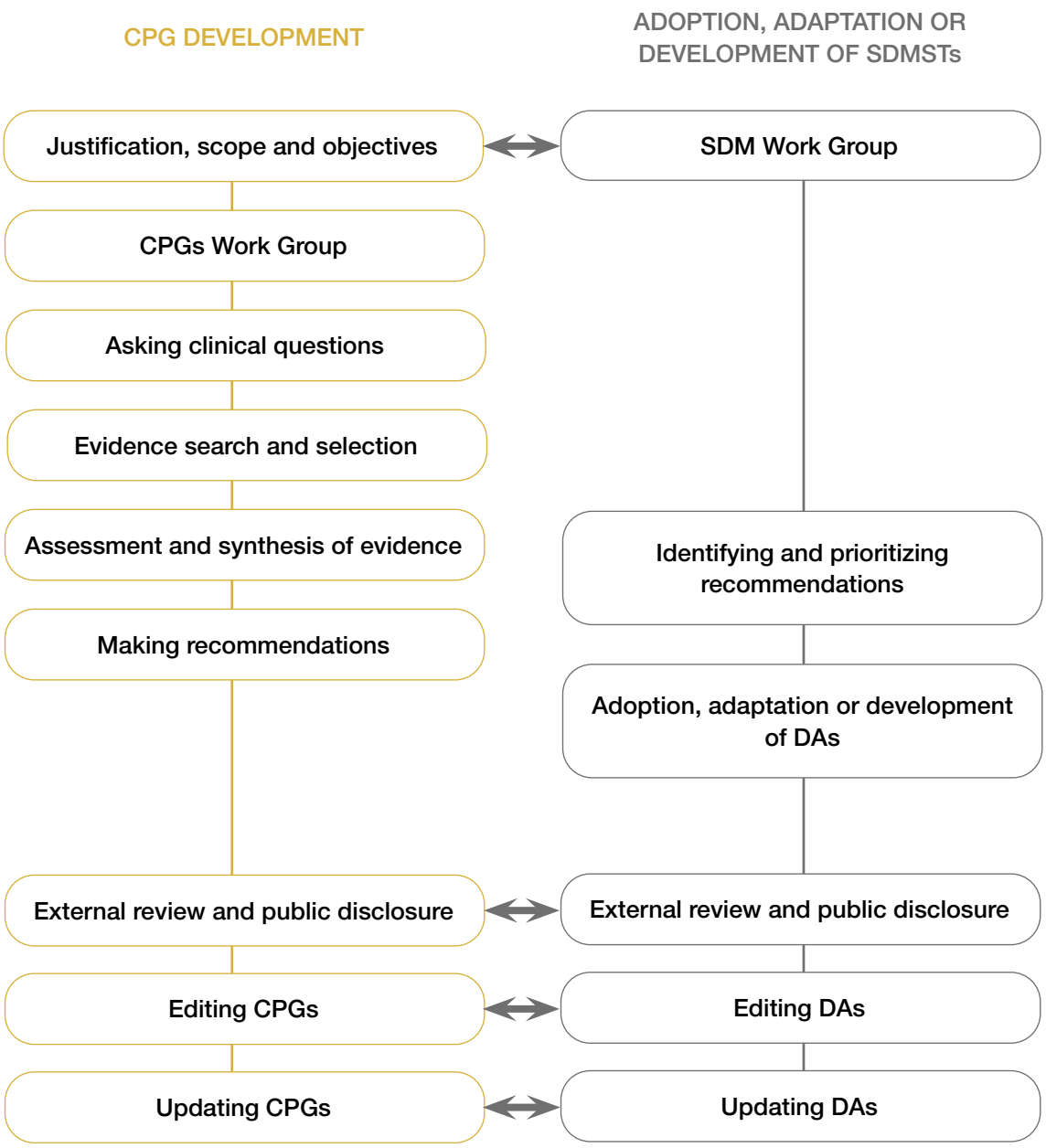
Based on these criteria, each potential DA can be assigned low, medium or high priority. A template to assess these criteria can be found in Annex 1.

2.3.3.2. Prioritization process of recommendations during CPG development or updates

It is important to integrate the process of identifying and prioritizing the recommendations that are most sensitive to SDM from the initial phases of CPG development. This strategy will make it easier to decide when to develop DAs linked to specific recommendations. It also favors the SDM process by benefiting from the collaboration of the healthcare professionals and patients who participate in the preparation of CPGs, and who are potential target users of DAs. Finally, it makes possible to publish DA at the same time that CPGs[7,8].

Figure 2.3.2 shows a diagram that incorporates the prioritization process of recommendations and the adoption, adaptation or development of DAs to the different phases of CPG development, which are described in detail in the «Manual de Elaboración de Guías de Práctica Clínica en el Sistema Nacional de Salud»[9].

Figure 2.3.2. Inclusion of the adoption, adaptation or development of DAs in CPG development



1. Forming the SDM work group

The GDG, in charge of evaluating evidence and making recommendations, will carry out the task of identifying and prioritizing recommendations which are most in need of being complemented by a DA. For that purpose, it will be necessary to create a work group within the GDG.

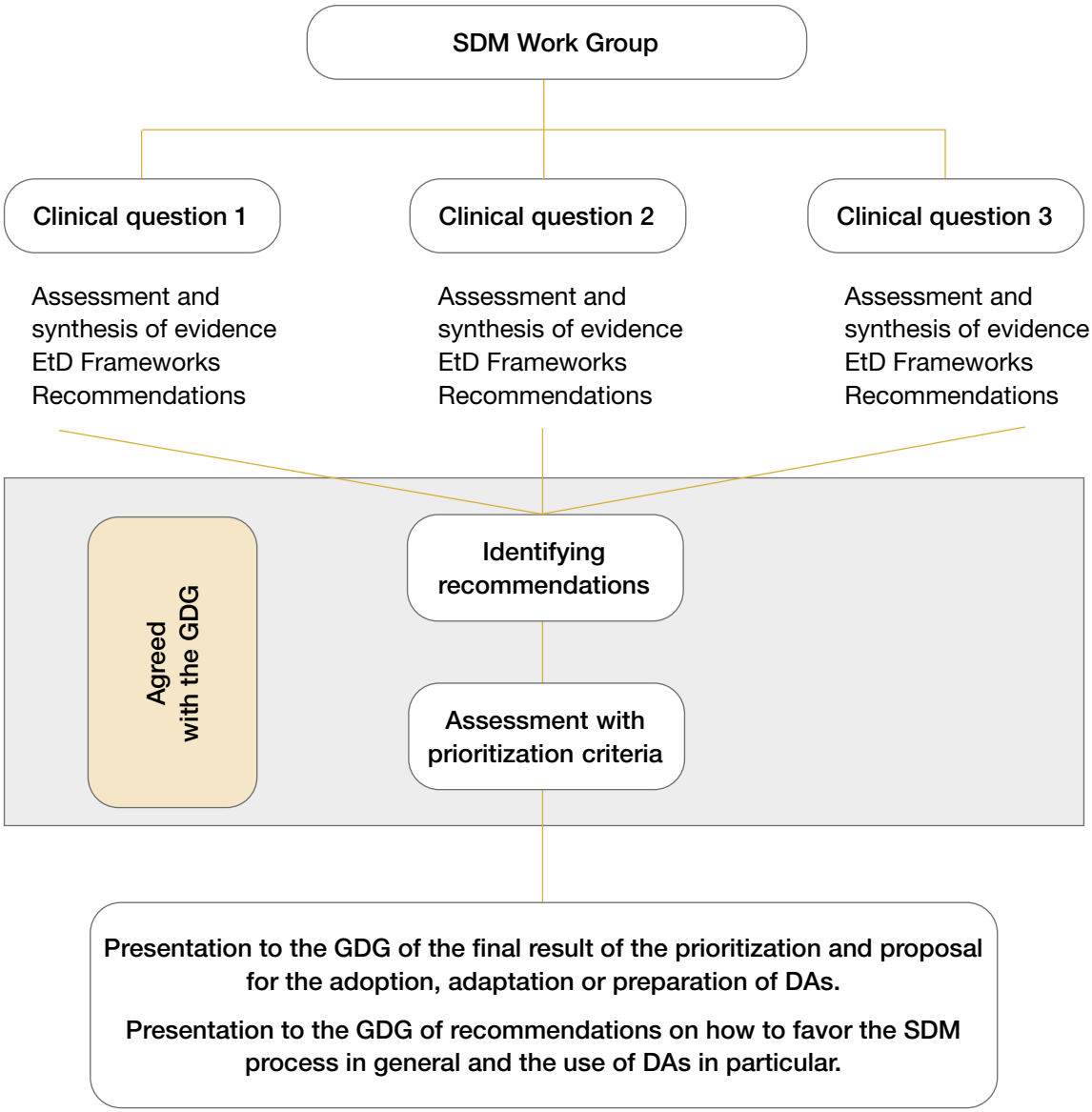
- Forming the SDM work group:
  It should be formed, at least, by one patient or one patient representative, two healthcare professionals with different relevant profiles (for example, medicine, nursing or psychology professionals) and one expert in both methodology and the healthcare model focused on the person, SDM and/or DA development. Based on the thematic areas examined by CPGs, the number of group members can be increased to add more professional profiles (i.e., social workers, experts in ethical/legal aspects, etc.) or more patients.
- Tasks of the SDM work group:
  The main task of the SDM work group is to identify and prioritize recommendations based on their sensitivity to SDM. In addition, this group will collaborate with the CPG methodological team on the adoption, adaptation and development of DAs, as well as to refine their content and formats (for more information, see the chapters on adoption, adaptation and preparation of DAs in this manual).

2. Workflow during CPG development

As discussed in section 1, the SDM work group is formed by some of the members of the GDG and should ideally be put together during the first meeting of the GDG[9]. The methodology expert should provide the necessary training and information to the rest of the SDM work group (identification of recommendations and prioritization criteria, sections 2.3.2 and 2.3.3.1) to regularly examine potential recommendations and to identify and prioritize recommendations which are more sensitive to SDM. This monitoring should ongoing, occurring at the same time as evidence is assessed, as each Evidence to Decision Framework (EtD) is developed and, finally, as recommendations are made. The SDM work group makes an initial assessment and preselection of identified recommendations in each clinical question by means of the prioritization criteria (section 2.3.3.1), which is presented to and agreed with the GDG. Once the monitoring and preselection process of all questions is finished, the SDM work group presents a definitive, reasoned proposal to the GDG, about the need to adopt, adapt or develop DAs linked to specific recommendations, considering the available time and resources. Figure 2.3.3 shows the suggested workflow.

On the other hand, if there is the possibility of linking a DA to a recommendation in the initial phases of CPG development, the GDG may take the decision to start the adoption, adaptation or development of the DA before having finished making all recommendations. When it is not possible to carry out an adoption, adaptation or development process of a DA (for example, limited resources), we suggest adding a section to CPGs about specific aspects which favor the SDM process. The objective would be to provide professionals with guidelines for facilitating the discussion process in consultations.

Figure 2.3.3. Identifying and prioritizing recommendations during the writing of CPGs



Summary of key aspects

- Once the recommendations needing a DA have been identified, they must be prioritized so that they can be adopted, adapted or developed.
- The suggested process of identifying and prioritizing the recommendations that require SDM must be integrated from the initial phases of CPG development.
- A work group within the GDG (SDM work group) can identify and prioritize recommendations needing to be complemented with a DA. This group should be formed by at least two healthcare professionals, one patient or one patient representative, and one expert in both methodology and the healthcare model focused on the person, SDM and/or DA development.

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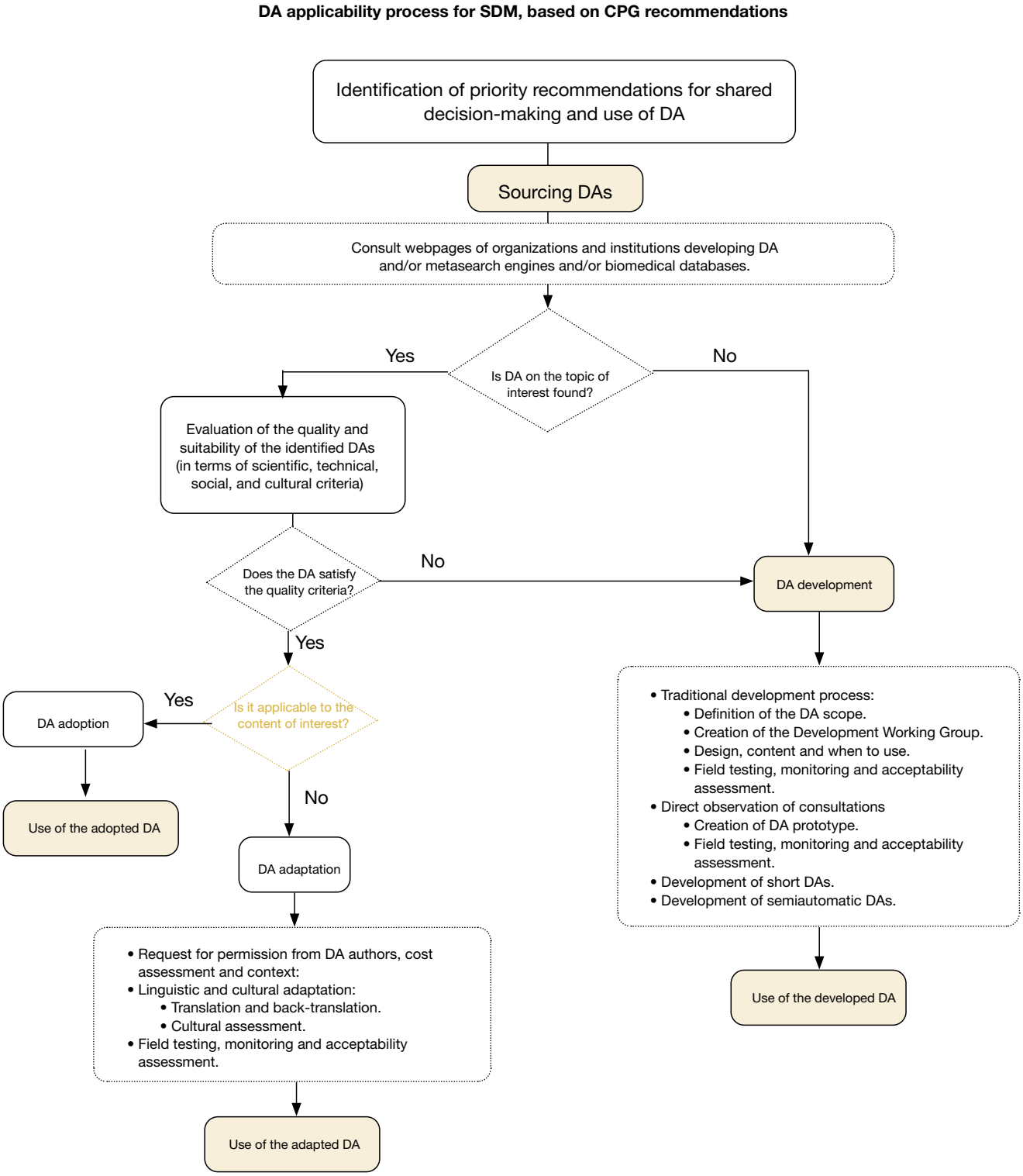
3. Applicability of patient decision aids based on CPG recommendations

The DA applicability process for SDM based on CPG recommendations begins after identifying and prioritizing the CPG recommendations that are likely to require the development of some type of DA. Subsequently, a search process of available DAs is carried out on the subject of interest, and an evaluation of the quality and suitability of the identified DAs is done in terms of scientific, technical, social, and cultural criteria. Depending on the results of this evaluation, the identified DA may be used/adopted, adapted to said context, or it will be concluded that said DA is not applicable to the context of interest in question. In the latter case, as well as if DAs that address the topic of interest are not identified in the initial search, a process of *de novo* development of a DA would be considered.

Figure 3.1 presents an algorithm that illustrates the DA applicability process for SDM, based on CPG recommendations, and the steps of which will be addressed in this chapter.

Figure 3.1. Algorithm that illustrates the DA applicability process for SDM, based on CPG recommendations



3.1. Sourcing DAs

María P. Blas, Yolanda Triñanes, María José Vicente

This chapter discusses the DA search process and provides information about web-accessible resources that include DAs at a national and international level. It also addresses the most important aspects of a DA-related literature review in bibliographic databases.

3.1.2. Searching in institutions and organizations

The most direct and efficient way to find DAs is by consulting webpages, directories and repositories of entities. In recent years, there has been a considerable increase in the number of these websites where DAs can be found. Generally, it is governmental entities and associations that prepare them or file them in repositories.

This section presents a list of some resources published on the web pages of entities, both national and international, public and free-access, related to DAs. However, before using any DA in clinical practice, both its quality and suitability should be assessed.

3.1.2.1 On an international level:

The Ottawa Hospital – Patient Decision Aids:

The information that appears on this web page is presented in two sections: decision-making tools (includes the option to search by specific condition or through a search engine, as well as a decision support guide to help identifying decision-making needs, planning next steps, tracking your progress, and sharing your insights about the decision) and resources for developing, implementing, and evaluating interventions in Shared Decision-Making.

Access: https://decisionaid.ohri.ca/index.html

NICE - Shared decision-making:

The National Institute for Health and Care Excellence (NICE) has developed a repository of patient decision aids. NICE has also written a guide describing the DA development process, from the identification of the topic to be covered, to its selection, prioritization and, finally, its development.

Access: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making

Dartmouth-Hitchcock Health:

This is an institution in the United States dedicated to promoting shared decision-making. On their webpage, you can find a range of products including guidelines and tools to facilitate the implementation of DAs (both for primary healthcare centers and hospitals),

workshops, presentations and DA-related training courses. The website also includes a list of resources related to DAs.

Access: https://www.dartmouth-hitchcock.org/decision-making-help/patient-resources

Mayo Clinic Shared Decision-Making National Resource Center:

On this website, you can find DAs, resources to facilitate their implementation (including first-person accounts, scientific publications, material for clinical sessions with case studies and presentations), a list of other international associations, and publications in scientific journals in the field of DAs.

Access: https://shareddecisions.mayoclinic.org/

Colorado Program for Patient Centered Decisions:

This program is included in the «Adult and Child Center for Health Outcomes Research and Delivery Science (ACCORDS)» at the University of Colorado School of Medicine. It mostly contains tools for use in cardiology, but also for colorectal cancer and others. It includes videos and, in some cases, even pamphlets in Spanish. It also contains documents explaining the methodology followed to develop the tools.

Access: https://patientdecisionaid.org/

Australian Commission on Safety and Quality in Health Care:

This Commission was created in 2006 by the Australian Government to manage and coordinate improvements in the safety and quality of healthcare in Australia. Their webpage includes a section dedicated to «Shared Decision-Making» with different resources, including, but not limited to, DAs for osteoarthritis or the use of antibiotics.

Access: https://www.safetyandquality.gov.au/our-work/shared-decision-making/patient-decision-aids/

James M. Anderson Center for Health Systems Excellence:

This center belongs to the Cincinnati Children's Hospital in Ohio (USA). On their webpage, there is a «Shared Decision-Making» section featuring several resources, DAs among them. Each DA includes the evidence on which it is based and whether it has been presented or published in scientific journals. These DAs are directed at children, adolescents, young people and their families.

Access: https://www.cincinnatichildrens.org/research/divisions/c/chronic-disease/decision-making-lab

Cochrane Musculoskeletal:

In collaboration with «The Patient Decision Aids Research Group (The Ottawa Hospital)», the «Cochrane Musculoskeletal» Review Group has published all the DAs that they have developed on their website. The tools included cover topics related to osteoarthritis, osteoporosis and rheumatoid arthritis.

Access: https://musculoskeletal.cochrane.org/decision-aids

3.1.2.2. On a national level

GuíaSalud:

GuíaSalud is working on the creation of a DAs catalog. In the near future, any entities that develop DAs will be able to request the inclusion of such tools on the GuíaSalud website. For now, however, we can find Clinical Practice Guidelines and patient information documents which may be helpful in SDM processes.

Access: https://portal.guiasalud.es/

The tools developed by the agencies of the Spanish Network of Assessment Agencies for Health Technologies and National Health System Performance (RedETS) will also be available on their webpage.

Access: https://redets.sanidad.gob.es/productos/buscarProductos.do

PyDeSalud:

This web platform has been developed by the Regional Government of the Canary Islands and includes resources to promote knowledge, autonomy and active participation of people with regard to their own healthcare. Broadly speaking, it is based on: 1) Patient stories; 2) Tools to promote Shared Decision-Making among healthcare professionals and patients, and 3) Research Needs and Priorities from a patient perspective. It currently includes eight patient decision aids.

Access: https://www.pydesalud.com/

Shared decisions:

This web platform from the Regional Government of Catalonia contains resources to help support the information exchange process and aid Shared Decision-Making in the clinical environment. It currently includes information about several diseases and conditions (multiple sclerosis, diabetes mellitus, knee osteoarthritis, breast reconstruction, care during the last days of life, among others) and they have been designed to show the risks and benefits of the different options.

Access: http://decisionscompartides.gencat.cat/es/decidir-sobre/

Patient decision aids:

This webpage from the Regional Government of Andalusia includes documents for citizens about Integrated Healthcare Procedures (IHP), which include two tools: one for the treatment of breast cancer and another for the treatment of prostate cancer.

Access: https://www.juntadeandalucia.es/organismos/saludyconsumo/areas/calidad/pai/paginas/pai-cancer-prostata.html

https://www.juntadeandalucia.es/organismos/saludyconsumo/areas/calidad/pai/paginas/pai-cancer-mama.html

3.1.3. Searching in Databases

Finding DAs has been become easier thanks to the creation of specific repositories and websites which enable users to quickly retrieve relevant documents, as described in the previous section. They are very interesting sources to start searching for information.

Sourcing DAs may be complemented using the main bibliographic databases. Pubmed/Medline www.pubmed.org and EMBASE www.embase.com are two examples of the most consulted databases. We may also consult other databases such as: The Cochrane Library (which contains systematic reviews), CINAHL (which includes studies about nursing and care) and PsycINFO (about psychology), among others.

Currently, there are several manuals and resources on literature review methodology that can make this task easier[1,2,3].

DAs can be found in these databases, since portions of these tools are usually published as articles in scientific journals. We can also find information about the DAs development process, acceptability tests, and about the effectiveness of these tools.

They differ in terms of the information that they provide, since some of them only contain bibliographic information (references and summaries). In these cases, it is necessary to use other web resources to obtain the complete text of the study of interest. It is important to take into account that we may have to create an account to be able to consult most of these databases.

The most satisfactory way to carry out this search is by combining the terms corresponding to the population and/or condition with the terms corresponding to the specific treatment or intervention, and then also with the terms that define the DAs[4]. For this latter purpose, the terms in the literature that make reference to DAs have been identified, and we recommend including them in the search: «decision aids»; «informed choice»; «informed decision»; «shared decision-making»; «patient decision-making»; «patient decision aids»; «decision tool»; «decision support»; «decision instrument»; «visual aids».

Other information sources that can be used to find DAs are metasearch engines, which simultaneously search for references across multiple sources and information resources, such as Google Scholar (scholar.google.es). The metasearch engine Tripdatabase (www.tripdatabase.com) includes DAs as a document typology («patient decision aids»), making it easier to find them.

Summary of key aspects

- In view of the need to have a DA, it is advisable to carry out a search of already existing and available DAs in order to consider whether they will be adopted or adapted to our context.
- The most direct and efficient way to find DAs is by consulting webpages, directories and repositories of entities and associations.
- Should you wish to expand or complement this search, you may perform a search in the main bibliographic databases and using metasearch engines, which are useful sources of information to find links to DAs.

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3.2. DA Quality Assessment

Yolanda Triñanes, María José Vicente

This chapter covers the quality assessment process of DAs. Its aims are to describe the process and phases of this assessment, as well as explain the different tools to assess the quality of DAs in detail and describe the relevant elements to be considered when assessing DAs.

3.2.1. Introduction

In recent years, there has been a considerable increase in published DAs. Therefore, considering the potential impact that these tools can have on decision-making[1], it is important to assess its quality, and determine whether they can be deemed useful and reliable sources of information[2,3,4].

Deciding if a tool is to be adopted, adapted or developed *de novo* will depend greatly on the evaluation of its quality, as well as other factors such as format, language or the population to which it is addressed, among others.

3.2.2. DA Quality Assessment Process

Phase 1. Definition and conceptualization of a DA

The first phase of the process when determining the quality of any tool is to check that the resource under assessment can be defined as a DA. GuíaSalud[5] has adopted the IPDAS definition[4], considering DAs as «tools that facilitate choosing between two or more options regarding any health problem, for both patients and caregivers, allowing them to:

- Understand the outcomes that could occur when applying different options.
- Take into account any implicit and/or explicit personal values attributed to the potential risks and benefits.
- Participate in decision-making with their healthcare professionals.

In this phase, we can also use the IPDAS instrument qualification criteria, which are described in the section below, since this instrument covers the criteria that a tool must meet to be considered a DA.

Phase 2. Quality assessment

Currently, the reference instruments to assess the quality in the context of the Spanish National Health System (SNHS) and, within the framework of GuíaSalud, have been developed thanks to the collaboration with IPDAS[4] (see 3.1.3). These instruments are considered to be a national and international point of reference because they have been designed taking into account the best scientific evidence available and with the agreement of experts on an international level[4].

The quality assessment must be considered alongside additional evidence assessment procedures, since the criteria do not permit as assessment of the accuracy of clinical content (of the quality of the scientific evidence considered).

3.2.3. IPDAS tools for the assessment of the quality of DAs

The IPDAS collaboration is made up of professional researchers, patients and other stakeholders. Their main objective is to improve the quality and effectiveness of DAs by establishing an evidence-based shared framework with a set of quality criteria to improve content, development, implementation and evaluation of DAs.

The IPDAS criteria are interesting for people and organizations that use and/or develop DAs[4], including:

- Patients who need to make a health decision.
- Professionals guiding patients through the decision-making process.
- People who develop, research or assess DAs.
- People responsible for formulating health policies or health system management policies.

Presently there are three different versions of this tool[6,7]. The only one of the three options which has been translated into Spanish so far is the original checklist.

Original IPDAS checklist (74 items)

This version of the IPDAS checklist provides a set of criteria to assess the quality of the content, the development, the process and the effectiveness of a DA:

- **DA content**: These criteria help us to assess the quality of the information provided about various options, whether the results are understandable, and the availability of methods to clarify and express patient values. In addition, specific criteria for diagnostic/screening tests are included here, like, for example, test risks, consequences of a positive/negative result, or the accuracy of diagnosis, among others. These criteria are therapeutic or diagnostic/screening options included in a particular tool and are specific to the disease.
- **DA development and process**: These criteria analyze aspects related to the way that information is presented (the balance between risks and benefits), to the qualification of the developers of the tool, to the scientific evidence sources used, to the declaration of interests or to the type of language used. All these aspects are generic, since they refer to design and development criteria which are relevant to any DA, regardless of the disease or the options considered.
- **DA effectiveness**: It is assessed whether the decision-making process has been based on all available information and on the patient's values. These criteria are also generic, since they refer to the general principles for promoting a high-quality choice and decision process.

These criteria consist of 74 items, grouped as per the different assessment dimensions:

(1) systematic development process
(2) information about the options
(3) information about probabilities
(4) clarification and expression of values
(5) use of patients' experiences
(6) support with assessment or deliberation and communication
(7) disclosure of conflicts of interest of authors
(8) DAs on the Internet
(9) presentation of the options
(10) plain language
(11) information based on up to date scientific evidence
(12) establishing effectiveness

To assess the quality of the DA, we must check whether it meets the requirements described in each item or not. We will not get a quantitative score on items, dimensions or global scores, but a qualitative assessment.

This version allows the DA user to assess the content, the development process and the effectiveness of tools. These quality criteria may also be useful for the development of new tools, since they offer information about the different elements and processes needed to develop them.

This checklist has been written in English[8] and translated into Spanish. It is available in a document detailing the theoretical justification for each of the dimensions of quality, the available scientific evidence and the uncertainty in relation to each of these dimensions[3]. The Spanish version of IPDAS is available in Annex 2 of the Spanish version of this manual, with the original English source available in this version.

IPDASi instrument (47 items)

The IPDASi instrument (IPDASi), also called IPDASi v3.0, was published in 2009, and it allows each of its items to be scored. There is an extended 47-item version representing 10 quality dimensions, and a short 19-item version assessing 8 of the dimensions of the original 2006 checklist. Each item consists of a 4-point Likert-type scale (strongly agree, agree, disagree, strongly disagree). Although it offers a score, it does not provide a quality classification system relating to the score obtained, and therefore, there are no guidelines about when a tool can be deemed suitable and good-quality.

This version, both in its extended and short form, offers the advantage of obtaining a quantitative score, and both of these forms have less items than the original version, which makes it easier to implement them. It could also be useful to compare the scores of different tools[9].

IPDAS Minimal criteria (44 items)

This instrument includes 44 items to assess different aspects of a DA (6 of them related to qualification, 10 of them related to certification and 28 of them related to quality). The criteria that all DAs should fulfill are related to qualification and certification:

- Qualification criteria (6 items): These criteria are required so that a resource can be considered a DA. They may be answered with a yes or no answer, and the tool must fulfill them all.
- Certification criteria (10 items): These criteria are aimed at avoiding the risk of bias, and they are suggested for use in DA certification. They are scored according to a 4-point Likert-type scale (from strongly agree to strongly disagree), and the tool should get a score of 3 or more in each item in order to be certified.

The desirable criteria (28 items) are criteria which help to assess quality: however, they are not deemed essential to reduce the risk of bias. Therefore, they could improve experiences when using DAs, but it is not expected that their absence will negatively influence the decision. For example, providing note sheets can help patients to create a list of questions which they may want to ask their healthcare professionals, but the lack of note sheets would not generate any harmful bias nor any negative influence on their decision[10].

Summary of key aspects:

- The number of Patient Decision Aids is becoming more and more important, so it is necessary to have frameworks and instruments in place to assess them before considering their application or adaptation in clinical practice.
- Assessment must be carried out in two phases. The first phase is to check that the tool fits the definition of a DA. If it does, the second phase will be quality assessment.
- In order to assess quality, there are checklists and instruments that have been developed and agreed on by experts on a national level through the IPDAS collaboration, some of them being available in Spanish. The instrument selected for use will depend on the aim of the required assessment.

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3.3. Adaptation and adoption of DAs

Ana María Carlos, Ana Toledo Chávarri

This chapter is aimed at identifying and developing the phases which allow the adaptation or adoption of Patient Decision Aids (DAs) from other authors and/or contexts. This chapter covers the following phases of the adaptation or adoption process of a DA: planning the adaptation or adoption, characteristics of adaptation and adoption processes, and considerations on their publication and implementation. Adoption consists of using an existing, reliable DA without modifications (definition modified from GRADE-ADOLOPMENT)[7]. On the other hand, adaptation means modifying a DA to adapt it to the application context.

As a starting point, we have considered the steps developed in the manual prepared by Perestelo et al. (2017)[1] regarding the development of Patient Decision Aids derived from the recommendations of Clinical Practice Guidelines, the «Manual Metodológico para la Elaboración de GPC en el Sistema Nacional de Salud» (updated in 2016)[2], and the model suggested by the GRADE[3] system and by ADAPTE[4], a tool designed to adapt CPGs.

3.3.1. Planning the adaptation or adoption

When planning the adaptation of a DA, three fundamental aspects must be considered: the members of the work group, the sourcing and quality assessment of DAs, and the request for adaptation permits.

Forming the work group

In order to form the work group, it is very important to have a secondary group of experts from the GDG, as explained in Chapter 2.3 (Shared Decision-Making based on Recommendations). One of its main characteristics is its multidisciplinary nature, with the participation of professionals providing healthcare for the target population, as well as methodologists, and patient representatives and/or caregivers.

For the external review of the DA, it is advisable to have the participation of Scientific Associations, patients and/or caregivers who participate either individually or by representing patients' associations. All the participants will have to make a statement with regard to any potential conflicts of interest[5,6].

Sourcing and quality assessment

A bibliographic search of DAs will be made, and their quality assessed as per the indications for the search and assessment process detailed in Chapters 3.1 and 3.2.

The contents of any DAs found will be analyzed and assessed in order to determine their quality, the validity of their contents and whether they have to be modified to be used in our context.

The most suitable option will be considered (adaptation or adoption of a DA), as well as the need for linguistic and cultural adaptation, depending on whether it is necessary to make modifications, and their feasibility. For this assessment, the indications in section 3.2.2 will be followed.

Request for adaptation permits

Before the adaptation process, a permit must be requested together with a short explanation of the project, preferably in writing. In the case of a DA being developed by an organization which has procedures for using their products, this channel will be used (i.e. https://www.nice.org.uk/re-using-our-content).

3.3.2. Characteristics of DA adaptation/adoption

The DAs will be adapted or adopted (also linguistically and culturally) according to the following instructions:

3.3.2.1. DA adoption and adaptation

The work group in charge of the adaptation will have to assess whether the pending DA includes all the critical components (or if any relevant absence is noticed), as well as considering the need to make modifications and verifying the viability of making these modifications. Once the assessment has been carried out, the work group will decide whether to opt for an adoption or an adaptation:

A. **DA adoption**. This situation will occur if the work group in charge of the adaptation accepts a DA as it is, without modifying its content or layout, so it will only be appropriate when an adequate and updated DA with evidence-based content is identified.

B. **Adaptation**. Adaptation may consist of:

   1. Accepting **specific parts of the DA**. The work group in charge of the adaptation decides to include some content and reject others, like those which would need to be substantially modified or which would not make sense in the context of application: for example, there might be specific evidence for a certain center or area and using it in the adapted DA would require replacing any data from studies carried out in a different field. Therefore, it will be necessary to consider the following factors: the suitability of information regarding the options and probabilities of events, whether the DA includes methods which help to clarify and express the values of patients, whether it includes organized guidelines for discussion and communication, and the simplicity of language[6,8].
   2. Accepting all the content of the DA with **modifications**. The work group in charge of the adaptation can identify the need to **modify some aspects or domains** to show the balance more clearly, to improve the expression of the values and needs of patients, and to facilitate the discussion or to change expressions which facilitate understanding and simplify language (based on the criteria suggested for IPDAS, available at http://ipdas.ohri.ca/IPDAS_

checklist.pdf). In addition, any aspects related to the resources and the costs arising from the inclusion of a DA in clinical practice and Shared Decision-Making may be considered or included.

In the event that the group decides to adapt a DA, they will have to consider the following aspects:

- If the work group identifies the need to **modify** the DA, they will have to be especially cautious to avoid any changes which might significantly modify contents[7]. It is also advisable that modifications are discussed in a meeting and that coordinating said meeting guarantees the opportunity to present the opinions of all group members.
- We must choose the most adequate **format** so that the information is shown as clearly and as balanced as possible, neutral and without biases, showing the available options and the information related to them, as well as following the indications of the chapter about presenting results (section 2.2). To deem information as complete and neutral, equal emphasis should be placed on positive and negative aspects, and all available options should be presented, including the possibility of keeping an expectant attitude[6].

3.3.2.2 Linguistic and cultural adaptation of a DA

For the **linguistic and cultural adaptation** of a DA, it is necessary to check that its content and format are both accurate, relevant and adequate. Linguistic adaptation is aimed at ensuring the equivalence between the words and expressions used in the original and the translated DAs, and it will be ideally made through the translation and back-translation process, which is explained in the next section. Cultural adaptation is aimed at ensuring that DAs are suitable for their context of use. DAs should be adapted to health literacy and to the values of the local population, to the health system, and to the needs of the specific organizations where they are going to be used, whether these include hospitals, primary healthcare centers or other services. Linguistic and cultural adaptation must be made through the following phases, which may be repeated if deemed necessary[9]:

1. **Review of the original DA and the cultural context to which it is going to be adapted**. The content and the structure of the original DA will be assessed to inform which sections should be adapted to the new cultural context. The different elements of the DA will be assessed, from written information to graphical information and images. In addition, we will have to assess the concepts and the theoretical framework on which the DA is based through the literature related to the original DA. Assessing the cultural context to which the DA is going to be adapted can be done by reviewing the literature, with the participation of stakeholders or by qualitative research with the public to whom the DA is addressed. Cultural assessment will take into account issues such as the health system, the context of the health service-providing organization where the DA is going to be used, cultural and/or religious values, the degree of literacy of the target population or the potential use that is intended to be made of the tool (for example, Shared Decision-Making versus individual reading and consideration). Sometimes there may be several original DAs for the topic at hand to be adapted.

This prior assessment of said original DAs and of the new cultural context can facilitate the selection of the DA that requires less adaptation or can lead to the development of a new one based on some sections of the DAs that have been found.

2. **Adapting the original DA to a new cultural context.** Linguistic and cultural adaptation requires making changes to the structure and content of the DA, according to the previous paragraph. This process, based on the discussion among the experts in the work group in charge of the adaptation, usually takes place at the same time as the translation and back-translation of the DA, taking into account the readability and the communication of risks (see also sections 2.1 and 3.3).
3. **Field testing and monitoring**. Once the DA has been adapted and translated, the prototype should be tested and monitored according to the guidelines of section 3.3.

3.3.2.3. Translation and back-translation

Should it be necessary to translate the DA, ideally a translation and back-translation will be carried out, just like those done for the linguistic adaptation of questionnaires and materials for patients. The process to be followed is summarized below[10,11].

1. **Translation into the target language.** The first step is to translate the DA from the original language into the target language. The translator should preferably be a native speaker of the target language and have health knowledge.
2. **Back-translation.** The second step is back-translation, which is the translation of the translated DA from the target language back into the source language of the original text. The translator who does the back-translation will not have any reference to the original DA. In addition, they should be a native speaker of the language of the original DA and should have health knowledge.
3. **Assessing the difficulty of the translation**. The parties who do the translation and back-translation will assess the difficulty of finding equivalent concepts in the different parts of the DA using an analogous visual 0-to-10 scale, with 0 being the least difficulty.
4. **Assessment by the work group in charge of the adaptation and a third translator**. The discrepancies between the original DA and the back-translated DA will be analyzed in terms of layout, wording or grammatical structure in order to assess whether the concepts classified as being high-difficulty need a further translation and back-translation process with the participation of a different source-to-target-language translator or if, conversely, the objective has been achieved.

3.3.3. Publication and implementation of the adapted DA

3.3.3.1. Publication and implementation

Before being published, the final document will be reviewed and approved by the whole work group, as well as any professionals appointed by clinical and methodology experts of the group. The patients will also do this review, either individually or as an association, which will allow for the assessment of acceptability, understandability and the potential barriers and limitations with regard to its implementation. In addition, an update plan according to the source document will be suggested.

In order to develop the implementation plan, the support documents created by GuíaSalud will be used[12,13]. These documents identify three proposals to facilitate implementation, which can be adapted to the implementation of DAs. These proposals are: to facilitate their inclusion in the workflow, to provide support whenever and wherever decisions are made, and to offer recommendations. In addition, these documents include specific strategies and interventions aimed at being disseminated and spread among professionals, including:

- Dissemination in electronic format on webpages of the health services and the companies and associations involved (professionals and patients).
- Presentation at scientific events (conferences, congresses and meetings).
- Publication of the DA with the aim of disseminating it as widely as possible –always pointing out that it is an adaptation and identifying the original document.
- Establishing the DAs as support systems for computer software used in the associated health services.

Summary of key aspects

- The phases of DA adaptation are: planning the adaptation, identifying the characteristics of adaptation and adoption processes, and considerations for their publication and implementation.
- During planning, the work group will be formed, a bibliographic search will be performed, and the quality of the DA found will be assessed.
- We should consider context during adaptation to ensure feasibility, taking into account linguistic and cultural adaptation in particular.
- Before publication, it is necessary to obtain the final approval of the work group (including the patients) and propose an update plan. Whenever possible, it would be advisable to consider the possibility of drawing up an implementation plan.

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3.4. *De novo* preparation of DAs from CPGs recommendations

Yolanda Álvarez-Pérez, Idoia Gaminde

After exploring the identification and prioritization process of recommendations requiring SDM in chapter 2.3 of this manual, this chapter covers the preparation of DAs from CPGs recommendations. It describes some of the available resources to prepare DAs and, finally, discusses the need to carry out the certification process on the DAs developed as a quality criterion.

3.4.1. Introduction

Shared Decision-Making is based on discussion between healthcare professionals and patients. Currently, some authors distinguish two types of DAs: those designed so that patients can use them when not in consultation and make decisions independently (known as *Decision aids* (DA), which correspond to the IPDAS proposal included in the «Manual con criterios de evaluación y validación de las HATDC») and those developed based on consultations known as *Conversation Decision Aids*–cDA)[1,2,3]. This distinction has a clear impact upon the way that a DA is developed.

In both cases, we must describe current knowledge about a certain type of problem, as well as the different options to face it. The aim is to give patients relevant information so that they may acquire better knowledge about their health problems and any possible options. Another aim is to encourage them to get involved in decision-making, since this will help them to make their own decisions or to be prepared to participate in Shared Decision-Making with healthcare professionals.

3.4.2. Developing DAs

To develop a DA based on a recommendation, some key elements have been described: scope, design and development of a prototype through an iterative process with patients and healthcare professionals.

I. Scope

Based on the specifications of the CPGs, in the DA we should comment briefly on its scope:

- Describing the condition or health problem.
- Defining the decision which should be considered.
- Specific recipients.
- Defining what information needs should be considered.
- Explicitly identifying the theoretical framework on which the information is based, if applicable.

II. Creating the Development Working Group

A Development Working Group in charge of assessing the evidence to be included in each DA will be created. Its members and functions are explained in section 2.3 of this manual.

III. Design and content

III.1. Clinical and patient perspective

Clinical perspective: As a general rule, to prepare the content of the DA, it is recommended to carry out a systematic review (SR) of the literature. Good-quality CPG recommendations are a feasible alternative because they are based on a systematic review of the available evidence regarding the risks and benefits of the different alternatives. Information based on scientific evidence will provide content about the DA disease, test or treatment.

It is advisable to prepare guide notes with the questions to be answered, and answer them with the information on the risks and benefits of the different options included in the CPG recommendation. The information needs that are expressed by patients in qualitative publications should also be considered when asking questions, so it is recommended to consider this type of evidence in the literature search.

Once a draft of the DA content is available, the development group must adapt it to patients in terms of readability and risk communication (see also sections 2.1 and 3.3).

Perspective of readability: Readability is the ease with which a reader can read and understand a written text, and it is basic element when preparing content addressed to patients[4,5,6]. In a broader sense, it is the suitability of a text to be read easily and comfortably, in relation to both typographic elements, as well as how text is presented on the page, style, clarity of expression, and the language used[7]. Some elements for consideration in terms of readability when preparing content for patients can be seen in table 3.4.1.

Table 3.4.1. Readability aspects of a DA

Words
• Words should be common, simple and easy to understand. • Avoid using acronyms, technical words and abstract vocabulary. • Reduce synonyms to avoid confusing the reader. • Add a glossary of technical vocabulary. • Use personal pronouns to refer to the reader or the person who is writing.
Sentences
• Sentences should be short, with no more than 15 or 20 words per sentence. • Sentences should not contain more than 2 ideas and they should not mix concepts. • It is advisable to use verbs in the present tense and in active voice. • Use a question-and-answer style diagram to write the content. • The wording of the sentences must be neutral, without any bias towards any positive or negative aspects, especially when the information refers to risks, benefits, and side effects. If the wording cannot be neutral, we must give the information from both the positive and the negative points of view.

Source: Hermosilla-Gago T. Manual: Elaboración de una herramienta de ayuda en la toma de decisiones relacionadas con la salud para los pacientes (HATD-P). Fundación Enebro; 2010.

Communicating risks: This is an essential element in the decision-making process shared with patients, and it is closely related to the concepts of readability and numeracy. The communication of risks is explained in chapter 2.2.

Clarifying values: There is scientific evidence suggesting that people facing new and complex decisions often do not have stable or clear preferences. One of the objectives of DAs is to help patients to clearly establish their personal values and expectations for results in collaboration with healthcare professionals. This allows an action plan to be established in accordance with the patient's wishes, taking into account what is important to them, depending on the type of decision to be made, and the circumstance and psychological state they are in. In this sense, it would be ideal for DAs to include value clarification exercises: these may be implicit and non-interactive (for example, thinking about what is important for your decision) or explicit and interactive (for example, establishing a rating scale for each option in order to determine the importance of each one in relation to your decision)[8,9].

III.2. Layout and use:

Describing layout: The choice of presentation layout for DA content should be justified by making reference to the availability of detailed documentation about the development of the written layout of the DA (messages, graphical guide notes) and of the audiovisual format (video, brochure, program). For more information about layout, see chapter 2.

Explicit description of the situation when it should be used: We must define how and when the DA will be distributed to patients and/or healthcare professionals, considering the format (printed, audiovisual, web, computer apps, debates, educational groups and/or any combination thereof), the distribution methods (in health centers, mass mailing via post or online, telephone service, etc.) and the area of use (primary, specialized, or community healthcare).

Describing the development of the DA prototype: The DA draft should include graphical guide notes, text guide notes, web designs and resources with a sufficient degree of detail about the development process.

IV. Field testing and monitoring with patients and healthcare professionals in an iterative process

Developing the field testing and monitoring of the DA with the people directly involved in the development process (patients/relatives, healthcare professionals and experts) to receive feedback on understandability (adequate content, design and structure) of the DA, its usability (ease of use) and feasibility. Feedback should follow several phases, in an iterative process, through focus groups, interviews, and direct observation of patients and healthcare professionals. After this phase evaluating the design and acceptability of the developed DA, the appropriate corrections will be made to the aforementioned iterative evaluation process and a proposal for a review and update plan of the DA will be developed in accordance with the source document, as mentioned in section 3.3.3.

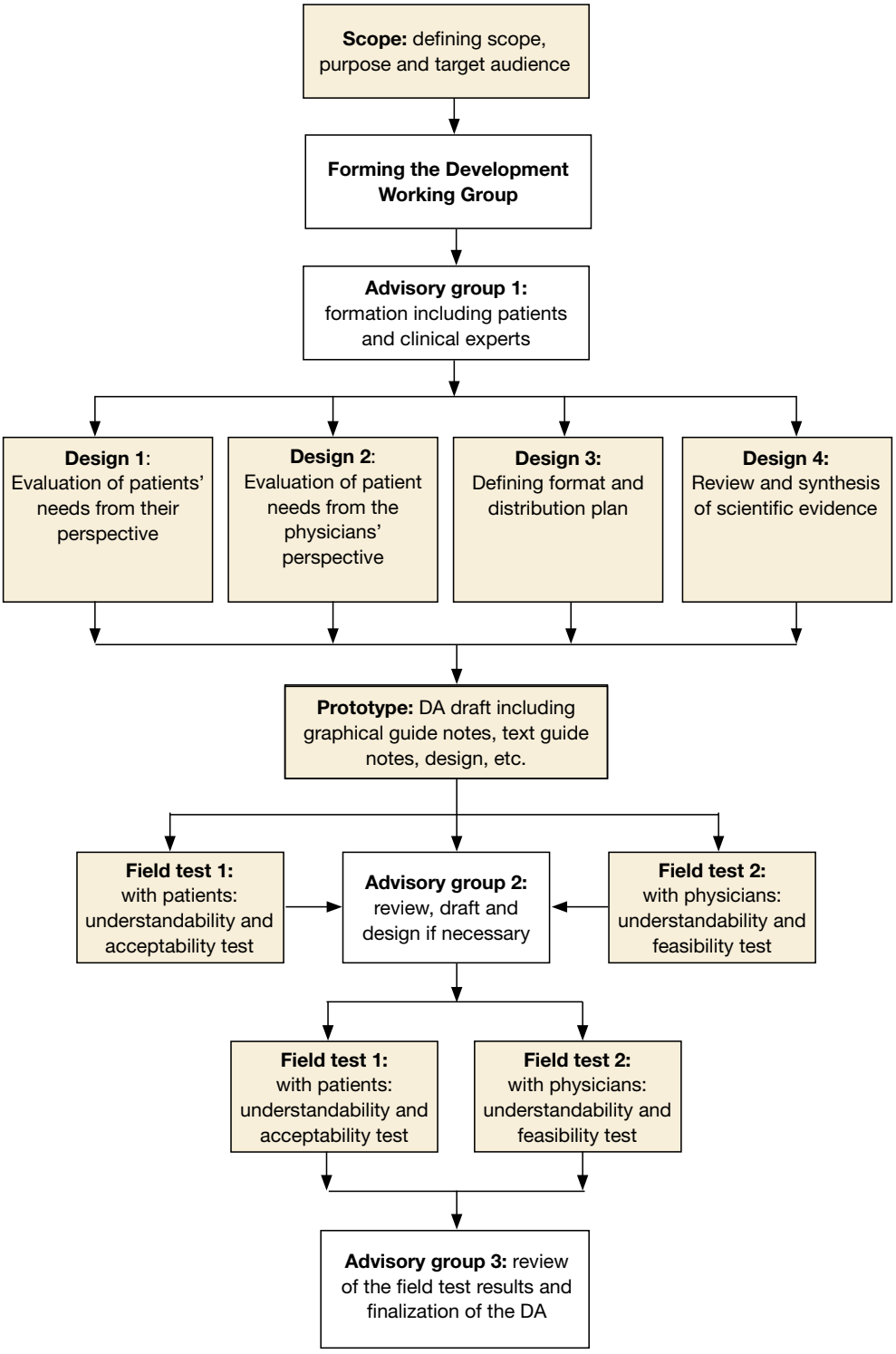
V. Field testing and monitoring with patients and healthcare professionals in real conditions

Finally, to assess its feasibility, it would desirable to do field tests with patients, healthcare professionals and experts who have not participated in the DA development process under «real» conditions.

Whenever possible, and when the necessary time and resources are available, DA effectiveness assessments should ideally be carried out in the context of a clinical trial.

A graphical summary of this DA development process is shown in Figure 3.4.1.

Figure 3.4.1. Development process model of a DA



Original source: Coulter, A., Stilwell, D., Kryworuchko, J., Mullen, P. D., Ng, C. J., & van der Weijden, T. (2013). A systematic development process for patient decision aids. BMC medical informatics and decision making. 2013;13(Suppl 2). doi:10.1186/1472-6947-13-S2-S2.

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3.4.2.1. Preparation of DAs based on the observation of consultations

The DAs developed through direct observation of consultations aim to facilitate the process of deliberation and interaction between healthcare professionals and patients in a collaborative manner[10,11,12]. This methodology is similar to the methodology already described, however, since they are both focused on the consultation, the volume of information necessary to work on decision-making with the patient is usually lower.

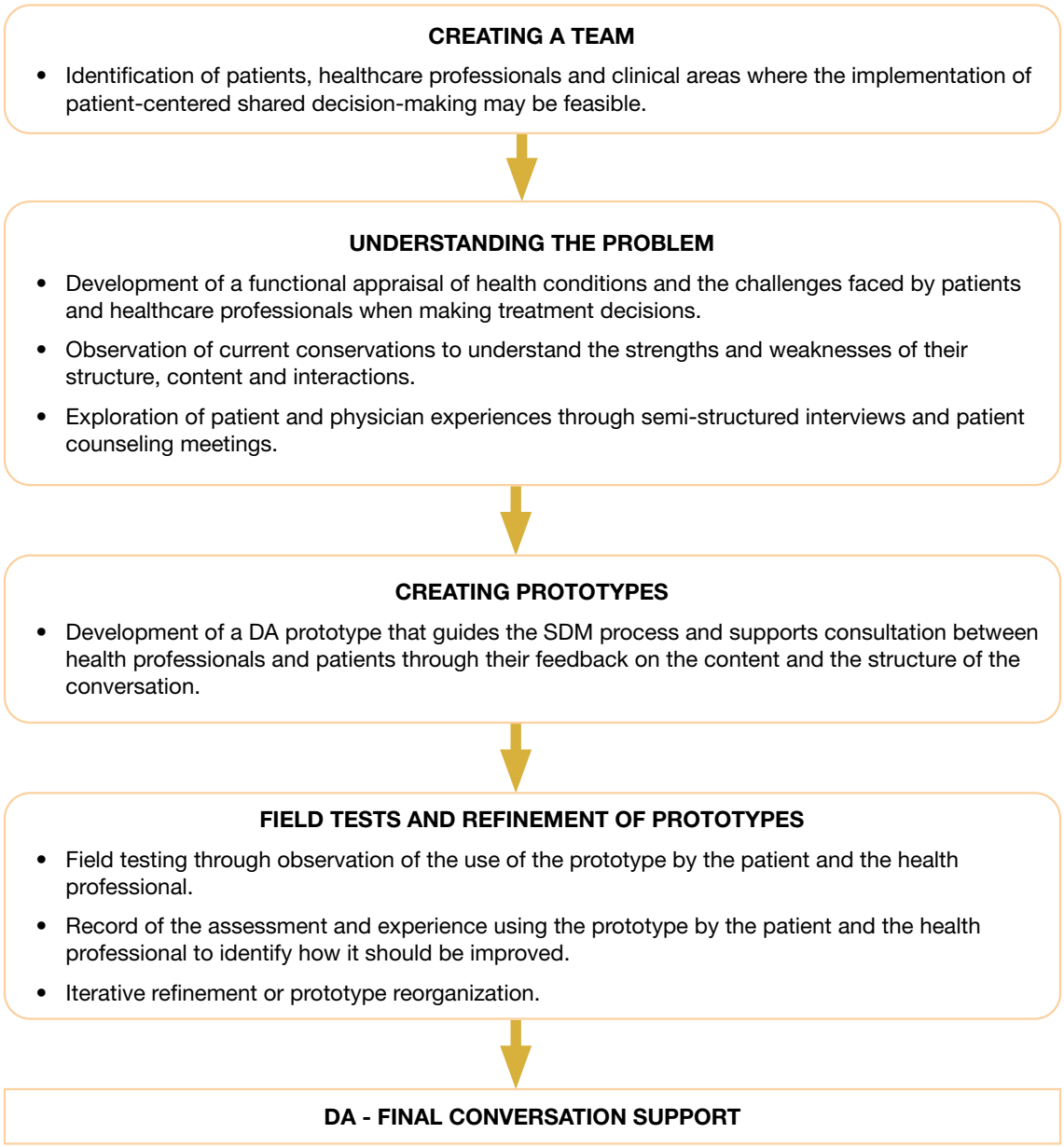
These DAs are generally more focused on supporting deliberation between healthcare professionals and patients, since professionals can include information as necessary throughout the process. These types of tools require little to no preparation on the patient's part before going to the consultation.

It is a type of DA elaboration that requires healthcare professionals and patients to engage in a calm, empathetic and productive conversation, in which they can clarify what the problem is and find the best way to deal with it. The DAs created following this process also include relevant alternatives and it is necessary to understand them together with the results of clinical research in order to respond to the patient's situation. This process results in tools with graphical presentations of the risks and benefits of different proposals with regard to the issues that are relevant to patients.

The methodology proposed by the Mayo Clinic team[12] is the use of direct observation (it can also be a video recording of a consultation) of consultations in primary or specialized healthcare where treatment decisions are made. In addition, they use information on the resources and the questions that both patients and clinicians referred to in the interaction, the concerns that they showed during deliberation, if any decision was made and how it was made consistently, as well as any changes in the quality of healthcare or in the personal interaction between patients and physicians working together.

Based on the observations of interactions and reflections of the team, a list of all the data needed to support the conversation about the problem and typify issues, such as the patient's risk and alternatives to mitigate it, will be created. Once all the relevant information is available, we will create the so-called prototypes, which will be validated in consultations and with groups of patients. Prototypes allow for the assessment of different ways of presenting information (Figure 3.4.2).

Figure 3.4.2. **Development process model of a DA based on the observation of consultations. Adapted from Zeballos-Palacios et al. (2019)[11]**



For example, with regard to Type 2 Diabetes (T2D)[10], the first prototype was focused on index cards about each drug, and it seemingly did not generate the desired level of interaction. Subsequently, index cards of a more narrative nature were developed and tested again, thus creating a prototype that, when tested with patients suffering from T2D, was observed to generate the desired level of deliberation in the consultation in order to guarantee informed decision-making. Regarding the T2D tool, and after testing different prototypes, it was concluded that, instead of having an index card for each drug, it is better to have index cards focused on relevant issues, such as weight loss, and how each drug affected patients. Furthermore, it is advisable to carry out a field test and monitoring with the final prototype of the DA in order to assess its acceptability.

These index cards satisfy the following IPDAS criteria: a systematic development process, presentation of the conflict of interest, use of plain language (including visual elements), presentation of the information in a balanced way which allows for the comparison of the different options, and allowing for an informed decision-making process based on the patient's values.

3.4.4. Technological resources to prepare DAs

3.4.4.1. Option grids

Option grids are a resource originally designed for use on paper, although some web versions have also been proposed[2] to help patients to compare different treatment options using the most frequently asked patient questions with concise, evidence-based answers. This evidence is gathered from systematic reviews with the aim of obtaining the best evidence available to answer patient questions. The table format provides a brief option comparison (one page), which is easy to read and easy to use (it only takes a few minutes). They are intended to be short enough to be used in consultations and to facilitate a better-quality dialogue between patients and physicians. Patients use it by reading the questions and the included answers, and then they compare the risks and benefits presented for each therapeutic option. Patients are requested to identify and highlight the questions or the problems that they are most interested in, and to discuss these questions in more detail with their healthcare professional[13,14]. Option Grids belong to the company EBSCO: this company has developed a more interactive web version with subscription-based access and payment to use some functions.

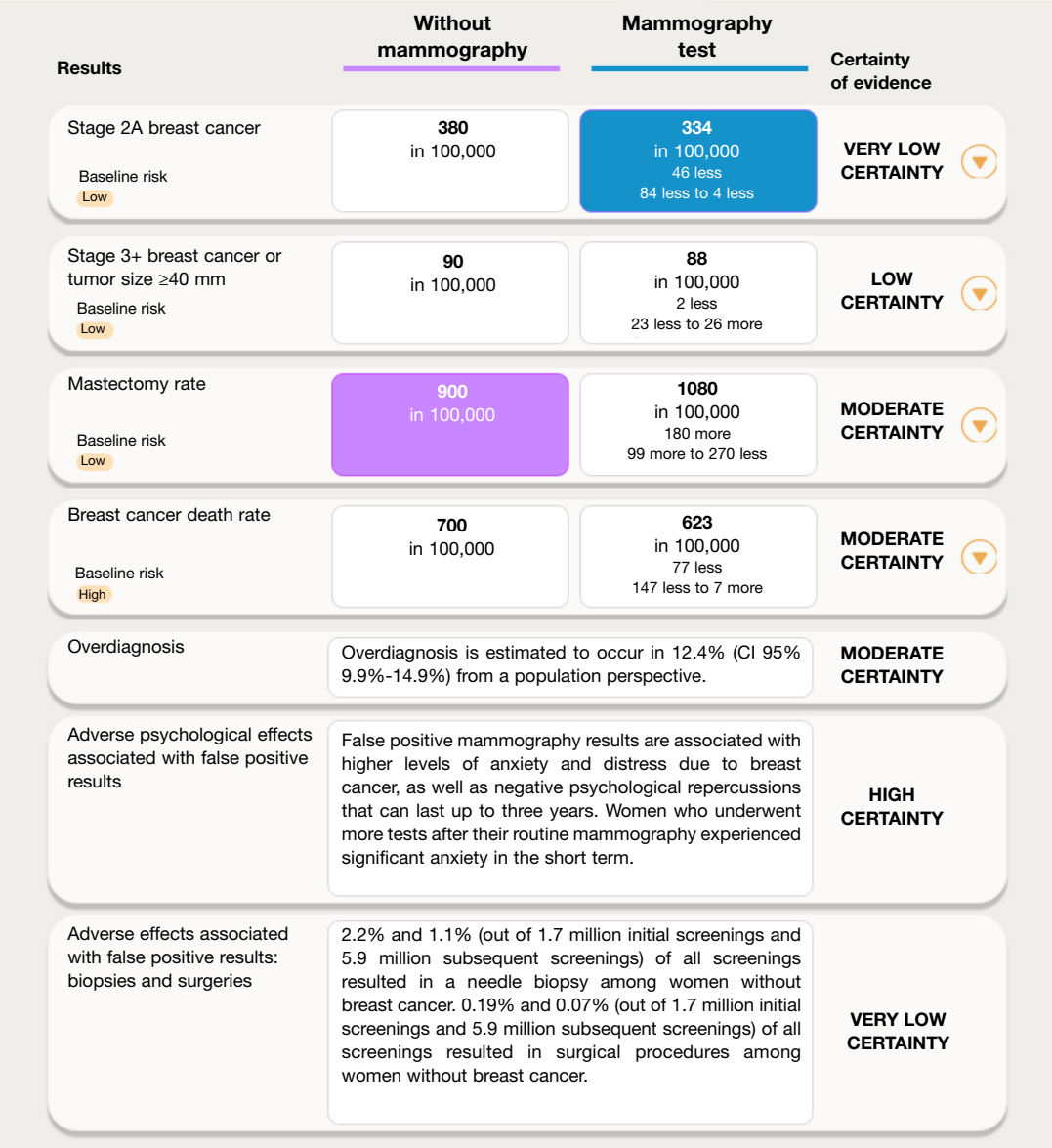
3.4.4.2. Technological applications to develop DAs

There are technological applications that facilitate the preparation of DAs through a platform that displays the sections that still have to be completed: from the target population, the clinical options considered, and their effects upon different health outcomes, to the discussion and reference points to include in DAs, going over key information, adaptation and support for decision-making. Some examples of these applications are GRADEpro and MAGICapp.

3.4.4.2.1. GRADEpro

The software GRADEpro (GRADE profiler) allows for the creation of DAs based on recommendations. This is currently a paid feature. Figure 3.4.3 shows an example for breast cancer screening.

Figure 3.4.3. Example for breast cancer screening



Results	Without mammography	Mammography test	Certainty of evidence
Stage 2A breast cancer Baseline risk Low	**380** in 100,000	**334** in 100,000 46 less 84 less to 4 less	**VERY LOW CERTAINTY**
Stage 3+ breast cancer or tumor size ≥40 mm Baseline risk Low	**90** in 100,000	**88** in 100,000 2 less 23 less to 26 more	**LOW CERTAINTY**
Mastectomy rate Baseline risk Low	**900** in 100,000	**1080** in 100,000 180 more 99 more to 270 less	**MODERATE CERTAINTY**
Breast cancer death rate Baseline risk High	**700** in 100,000	**623** in 100,000 77 less 147 less to 7 more	**MODERATE CERTAINTY**
Overdiagnosis	Overdiagnosis is estimated to occur in 12.4% (CI 95% 9.9%-14.9%) from a population perspective.		**MODERATE CERTAINTY**
Adverse psychological effects associated with false positive results	False positive mammography results are associated with higher levels of anxiety and distress due to breast cancer, as well as negative psychological repercussions that can last up to three years. Women who underwent more tests after their routine mammography experienced significant anxiety in the short term.		**HIGH CERTAINTY**
Adverse effects associated with false positive results: biopsies and surgeries	2.2% and 1.1% (out of 1.7 million initial screenings and 5.9 million subsequent screenings) of all screenings resulted in a needle biopsy among women without breast cancer. 0.19% and 0.07% (out of 1.7 million initial screenings and 5.9 million subsequent screenings) of all screenings resulted in surgical procedures among women without breast cancer.		**VERY LOW CERTAINTY**

(https://gdt.gradepro.org/decision-aids/#/p_l_helena_czerwinska_evidenceprime_com_0_16f7dd8b-566a-43c8-a77e-f076d93caf22/decision_aid_a163095b-8946-409a-aae3-0f97148ba30c/1566897331581)

3.4.4.2.2. MAGICapp

- **MAGICapp (Making GRADE the Irresistible Choice)** (www.magicapp.org This software allows for the development of DAs directly using CPG recommendations and a support system of decisions with organized data. An example of this software in stroke management is shown in figures 3.4.4 to 3.4.6, obtained after having accessed the website of MAGICapp (https://app.magicapp.org/#/guideline/4887), and then selecting «*Home assessment*» followed by «*Decision Aids*»[1].

Figure 3.4.4.

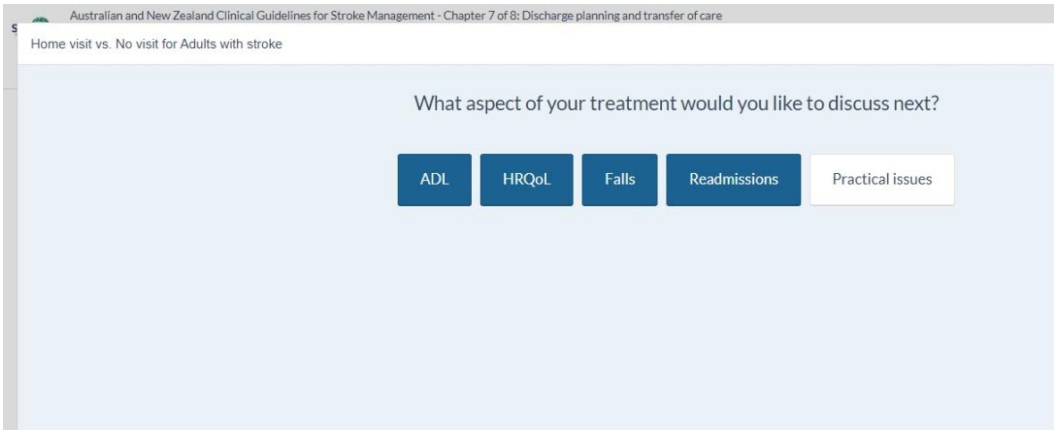
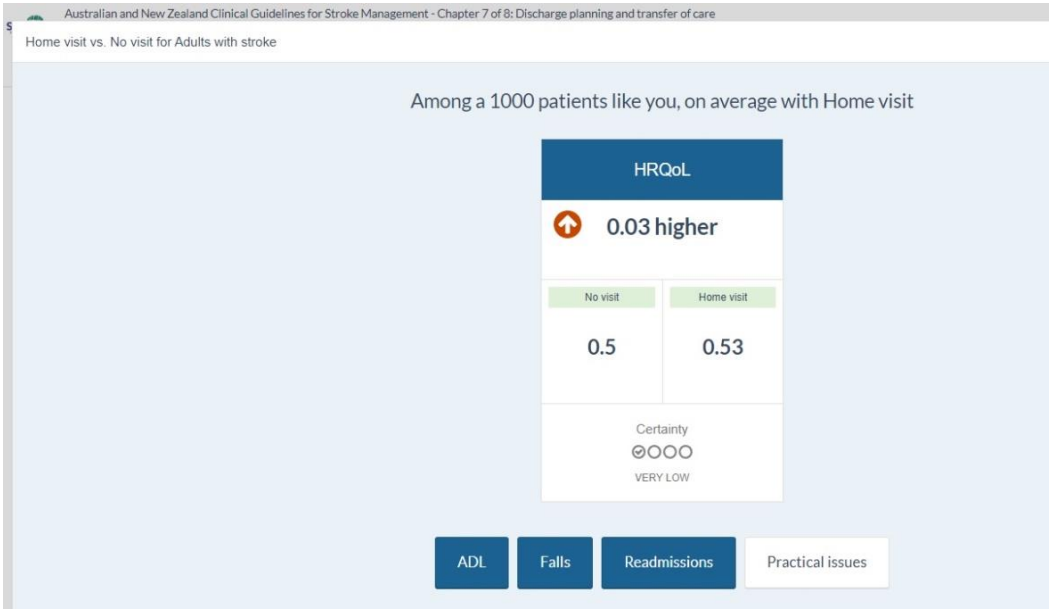
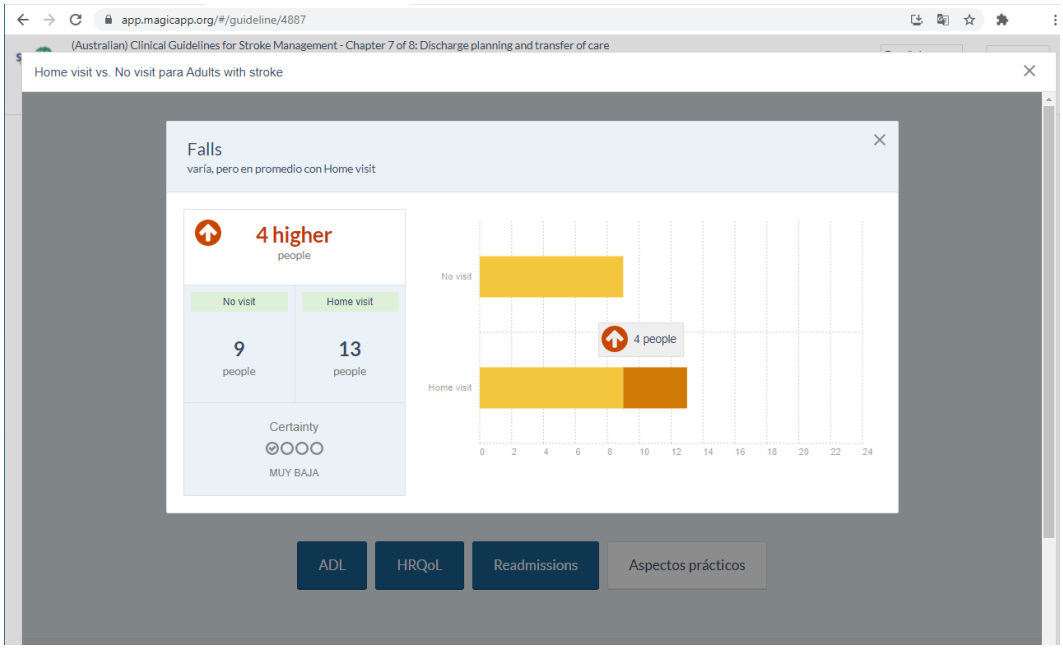


Figure 3.4.5.



1. It is recommended to consult the browsing guide on the website in case of updates after the publication of this manual.

Figure 3.4.6.



3.4.5. Certification of DAs

Due to the impact that DAs have on patient decisions, we must be especially careful with the quality of content. Therefore, it is increasingly common that DAs undergo a certification process as a quality criterion.

One of the first proposals was outlined by the IPDAS group (see chapter 3.1 to read more detailed information about the IPDAS tool), suggesting version 4.0 as a certification tool[15]. These proposals are very recent, but there are three certification modalities: **a)** the certification of each DA with a standardized procedure (using the IPDAS); **b)** the certification of developers of clinical guidelines (such as NICE); and **c)** a combination of the two as appears to be the case with the SNHS certification proposal. In the US, there has been certification experience in the State of Washington since 2016 with the certification of tools through a standardized process, thus suggesting a certification proposal[16].

Summary of key aspects

- The development process of DAs must consider their scope, as well as the iterative process of assessment with the healthcare professionals, and the patients using these DA regarding the understandability, usability and feasibility of the developed DA.
- There are resources to develop short and semiautomatic DAs, like option grids and certain applications that allow for the semiautomatic construction of tools based on recommendations.
- There are activities associated with the development of DAs that are recommended for consideration if the necessary resources are available, such as evaluating the effectiveness of the DAs developed in the context of a clinical trial, as well as submitting them to a certification process to minimize the risk that the content is inaccurate, biased, inappropriate or open to conflicts of interest.

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Annexes

Annex 1. Support guide for the prioritization of recommendations potentially subsidiary to Shared Decision-Making

Prioritization criteria, as well as their evaluation, which is presented below, are intended to guide users in prioritizing the recommendations that are most sensitive to SDM during CPG development. Each criterion is given a score depending on its priority (high priority = 3 points, medium priority = 2 points, low priority = 1 point). The final result for each recommendation will be the sum of all points across all criteria.

This guide to support the prioritization of recommendations is a proposal that is pending approval for use in future editions of this manual.

Recommendation:				
CRITERION	**ASSESSMENT**			**REMARKS**
The degree of urgency of the medical care required.	LOW	MEDIUM	HIGH	
The degree to which the evidence that the recommendation is based on is generalizable.	LOW	MEDIUM	HIGH	
The probability of vital or dramatic consequences for the patient.	LOW	MEDIUM	HIGH	
The potential complexity of the SDM process derived from the number of options from which to choose.	LOW	MEDIUM	HIGH	
The degree of similarity of risks and benefits among the options.	LOW	MEDIUM	HIGH	
The degree of variability in the appraisal of the result measures made by the patients.	LOW	MEDIUM	HIGH	
The degree to which expected side effects may affect the patient's quality of life.	LOW	MEDIUM	HIGH	
The degree of discrepancy between what caregivers think is the best option for patients, and what adequately informed patients would decide by themselves.	LOW	MEDIUM	HIGH	
The existence of an unjustified variation in accessing different options due to the existence of cultural, sociodemographic and economic diversity, etc.	LOW	MEDIUM	HIGH	
The usefulness of a visual representation of the options with their respective risks and benefits to patients.	LOW	MEDIUM	HIGH	
The frequency with which patients or service users may have to make a decision.	LOW	MEDIUM	HIGH	
No. of answers:				

Annex 2. 3.2.3 IPDAS checklist for DA quality assessment

I. Content: Does the patient decision aid...

Provide information about options in sufficient detail for decision-making?

- describe the health condition
- list the options
- list the option of doing nothing
- describe the natural course without options
- describe procedures
- describe positive features of options (benefits)
- describe negative features of options (harms, side effects, disadvantages)
- include chances of positive / negative outcomes

Additional items for tests

- describe what test is designed to measure
- include chances of true positive, true negative, false positive, false negative test results
- describe possible next steps based on test result
- include chances the disease is found with / without screening
- describe detection / treatment that would never have caused problems if one was not screened.

Present probabilities of outcomes in an unbiased and understandable way?

- use event rates specifying the population and time period
- compare outcome probabilities using the same denominator, time period, scale
- describe uncertainty around probabilities
- use visual diagrams
- use multiple methods to view probabilities (words, numbers, diagrams)
- allow the patient to select a way of viewing probabilities (words, numbers, diagrams)
- allow patient to view probabilities based on their own situation (e.g., age)
- place probabilities in context of other events
- use both positive and negative frames (e.g., showing both survival and death rates)

Include methods for clarifying and expressing patients' values?

- describe the procedures and outcomes to help patients imagine what it is like to experience their physical, emotional, social effects

- ask patients to consider which positive and negative features matter most
- suggest ways for patients to share what matters most with others

Include structured guidance in deliberation and communication?

- provide steps to make a decision
- suggest ways to talk about the decision with a health professional
- include tools (worksheet, question list) to discuss options with others

II. Development process: Does the patient decision aid...

Present information in a balanced manner?

- able to compare positive / negative features of options
- shows positive / negative features with equal detail (fonts, order, display of statistics)

Have a systematic development process?

- includes developers' credentials / qualification
- finds out what users (patients / practitioners) need to discuss options
- has peer review by patients / professional experts not involved in development and field testing
- is field tested with users (patients facing the decision; practitioners presenting options)

The field tests with users (patients / practitioners) show that the patient decision aid is:

- acceptable
- balanced for undecided patients
- understood by those with limited reading skills

Use up to date scientific evidence that is cited in a reference section or technical document?

- provides references to evidence used
- report steps to find, appraise, summarize evidence
- report date of last update
- report how often the patient decision aid is updated
- describe quality of scientific evidence (including lack of evidence)
- uses evidence from studies of patients similar to those of target audience

Disclose conflicts of interest?

- report source of funding to develop and distribute the patient decision aid

- reports whether authors or their affiliations stand to gain or lose by choices patient make after using the patient decision aid

Use plain language?

- is written at a level that can be understood by the majority of patients in the target group
- is written at a grade 8 equivalent level or less according to readability score (SMOG or FRY)
- provides ways to help patients understand information other than reading (audio, video, in-person discussion)

Meet additional criteria if the patient decision aid is Internet based

- provide a step-by-step way to move through the web pages
- allow patients to search for keywords
- provide feedback on personal health information that is entered into the patient decision aid
- provides security for personal health information entered into the patient decision aid
- make it easy for patients to return to the patient decision aid after linking to other web pages
- permit printing as a single document

Meet additional criteria if stories are used in the patient decision aid

- use stories that represent a range of positive and negative experiences
- reports if there was a financial or other reason why patients decided to share their story
- state in an accessible document that the patient gave informed consent to use their stories

III. Effectiveness: Does the patient decision aid ensure decision-making is informed and values based?

Decision processes leading to decision quality. The patient decision aid helps patients to...

- recognise a decision needs to be made.
- know options and their features.
- understand that values affect decision.
- be clear about option features that matter most.
- discuss values with their practitioner.
- become involved in preferred ways.

Decision quality. The patient decision aid...

- improves the match between the chosen option and the features that matter most to the informed patient.

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