

Standards framework for shared-decision-making support tools, including patient decision aids

Corporate document

Published: 17 June 2021

www.nice.org.uk/corporate/ecd8

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Overview

This framework sets out a series of standards to support people using patient decision aids (PDAs) in assessing the usefulness and quality of a PDA. The framework will also be useful to those developing PDAs in enabling them to undertake a self-assessment of the quality of their tools and processes.

It will help people who use healthcare services and healthcare professionals to identify and understand the elements of a good quality PDA. It will also help people developing or reviewing PDAs to understand how to produce high-quality decision support and what elements they need to include.

Background and context

Shared decision making

The [NHS Constitution for England](#) notes that 'Patients, with their families and carers, where appropriate, will be involved in and consulted on all decisions about their care and treatment.'

Shared decision making is a collaborative process that supports a person and their healthcare professional to work together to reach a joint decision. It could be about care someone needs straightaway, or care they might have in the future, for example through advance care planning. It involves choosing tests or treatments, based on evidence and the person's individual preferences, beliefs, circumstances and values.

It means making sure the person understands the benefits, harms and possible consequences of different options through discussion and information sharing. This joint process empowers people to make decisions about the care that is right for them at that time. The option of choosing not to have treatment is always included.

Terminology used

Traditionally, tools to support shared decision making have been thought of as being either:

- primarily aimed at people receiving care to help them make choices about their own care, with the support of their healthcare professionals (tools known as patient decision aids), or
- primarily aimed at healthcare professionals to support them in their decision making, involving the person receiving care in the decision as appropriate (tools known as decision support tools).

Our ambition is to bring these 2 approaches together to ensure that decisions about investigation, treatment and care are shared between people and healthcare professionals wherever possible. We aim to transform the terminology in shared decision making to reflect this integration under the heading of 'decision support tools' but for the purposes of this framework, the term 'patient decision aid' or 'PDA' is used throughout, as this is the term most commonly used in the NHS.

The process for information, options and decisions is suggested as follows:

Step 1. Information and context

Information is collected about the condition, such as prognosis, possible diagnoses, likely impact on the person and supporting organisations.

Step 2. Options

The appropriate treatment, investigation and goals are identified in line with the person's needs and what matters to them. The person and their healthcare professional work together to consider all the options and alternatives, and the risks, benefits and consequences of these choices.

Step 3. Decision making and consent

A preference-based choice is made from the available options, then there is a formal agreement about the treatment, procedure, investigation or test. There is also an agreement about how medicines are administered. The decision is recorded and shared with the person.

Steps 2 and 3 are repeated, as necessary.

Patient decision aids

Patient decision aids (PDAs) are designed to:

- Help people decide on healthcare options by providing evidence-based information on the available options, likely outcomes, benefits, harms and uncertainties.
- Support and prepare people to make informed decisions with their healthcare professional. PDAs do not advise people to choose one option over another and are not meant to replace a conversation with a healthcare professional.
- Support health professionals to adopt a shared decision-making approach in a consultation, to ensure that patients, and their family members or carers where appropriate, can make informed choices consistent with the person's values and preferences.

This framework is designed to help people to identify good quality PDAs to aid that process, and to support the development of these.

Definition of patient decision aids

For the purposes of this framework we have used the [definition of decision aids in a 2017 Cochrane Review](#). It states that people can use PDAs when there is more than one option and neither is clearly better, or when options have benefits and harms that people value differently. They state the decision, describe the options, and help people think about the options from a personal view (for example, how important are possible benefits and harms).

Patient decision aids may vary in length and detail, and may be used before, during, or after a person has spoken to a healthcare professional. They may be intended for the person to read for themselves, to support healthcare professionals during a consultation conversation using standardised, evidence-based information, or for the person and healthcare professional to work through together.

This definition includes any PDAs that:

- have a clear decision that needs to be considered
- provide evidence-based information about a health condition, the options, associated benefits, harms, probabilities, and uncertainties
- help people to recognise the value of the decision and to help support the value they place on the benefits and harms.

Information for decision making and consent

Every person should have basic information about their condition, treatment and care so that they can engage in and manage their health. Some information is only designed to inform the person rather than to aid decision making.

The information people need for shared decision making (of which PDAs are a part) is the same as needed for informed consent. This framework doesn't cover the consent process, although PDAs are sometimes helpful in supporting this process. For further information about obtaining informed consent, see [advice from the General Medical Council \(GMC\)](#) or another relevant professional body.

About this framework

Who is the framework for?

The framework is for people who use healthcare services and healthcare professionals. It helps them identify and understand the elements of a good quality patient decision aid (PDA), providing a clear guide to the content they should expect and how content should be presented.

The framework also supports those commissioning, developing, assuring or reviewing PDAs by including an easy-to-use self-assessment tool. This helps show how they have met standards essential in a PDA and identify further standards that might enhance the quality of their process or product.

What does this framework include?

The framework is divided into 2 sets of standards – essential and enhanced. Each set covers:

- the content of a PDA and its presentation, and
- the process for developing the PDA, including supporting information published alongside it to assess quality, rigour and reliability.

There are notes explaining each standard in the framework.

Essential standards

These are the fundamental requirements for a PDA. It cannot be considered a PDA if it does not meet these standards, and is high enough quality to use in practice if it does meet them.

- [Section 1](#) covers content and presentation of the information in a PDA.
- [Section 2](#) covers the essential processes and methods documentation about how a PDA was developed.

Enhanced standards

These are additional to the essential standards and indicate that the PDA aims to be of the highest quality. Some of these additional standards may not apply to all PDAs.

- [Section 3](#) contains enhanced content standards.
- [Section 4](#) contains enhanced process standards.

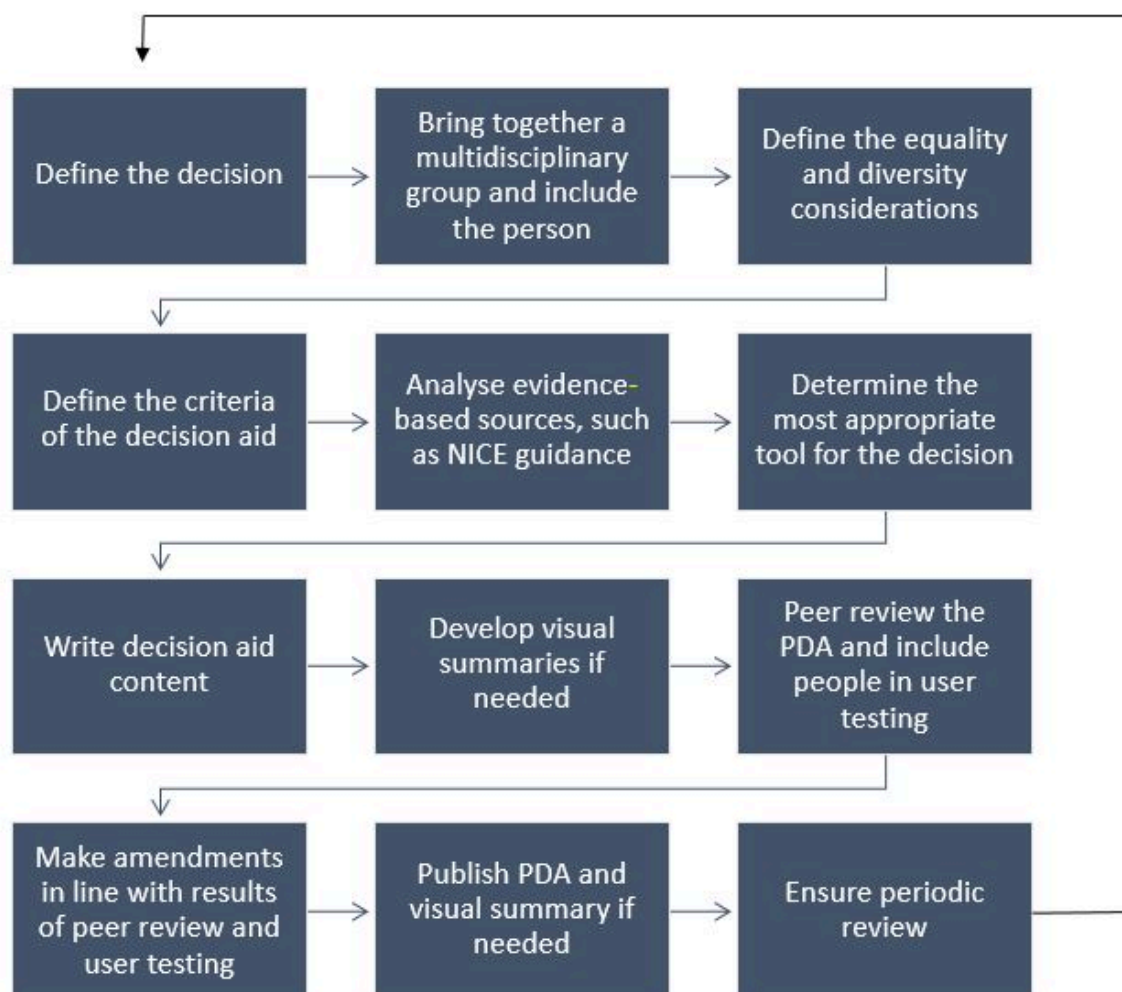
Sources

This framework draws from a number of sources, in particular:

- [NICE's guideline on shared decision making](#)
- [International Patient Decision Aid Standards \(IPDAS\) framework](#)
- [Washington State Health Care Authority's patient decision aid certification criteria](#).

Patient decision aid development process

The diagram below outlines a suggested sequence of activities to develop a patient decision aid (PDA). It is presented as a cycle to encourage regular review of the underpinning evidence and any necessary changes to the PDA.



Content and process standards for patient decision aids

The tables in this section list the essential and enhanced standards, with notes on how to use them. There is also [an assessment checklist and a self-assessment](#) that you can download in Word files to record your notes on a patient decision aid (PDA):

- The assessment checklist is for people using or delivering healthcare services to check the quality of individual PDAs.
- The self-assessment is for commissioners and developers to check their PDAs and the processes they use to develop them. This includes space to record whether a standard is met, partially met or not met.

See the [visual summary for an overview of the essential and enhanced standards supported with visual icons](#). Each of the standards have links to further information.

Section 1: essential content standards

Essential content standards

Health condition, decision and available options	Notes
<p>The patient decision aid (PDA) states:</p> <ul style="list-style-type: none"> • the symptom, condition, disease or illness the person is experiencing • that a decision about treatment or investigation is needed, and indicates which aspect of care this relates to • what evidence-based treatment or investigation options are available including all reasonable alternatives and the option of doing nothing. 	<p>The PDA should clearly outline:</p> <ul style="list-style-type: none"> • the issue at hand for the patient in terms of their health state, that is their illness, condition or potential diagnosis • what decision needs to be taken by the patient in collaboration with their healthcare professional • what options are available to the patient, based on the best available evidence. <p>A good PDA will include all reasonable alternative courses of action available to the person making the choice, and will always include the option for them to choose no intervention.</p>
Details of the available options	Notes

Health condition, decision and available options	Notes
<p>The PDA presents detailed information about the options to enable the person to make an informed decision in an unbiased way. This includes:</p> <ul style="list-style-type: none"> • detailed information about the potential consequences, benefits and harms of each option • an even-handed approach to how the options are displayed and framed, for example, using the same sized font or neutral language • the option of doing nothing new or different, for example, what happens if the person chooses to continue with their current treatment, chooses not to have further treatment or chooses no treatment at all. 	<p>In presenting the options the PDA should include possible outcomes depending on the option chosen. This could include information about what will happen to the course of their illness or disease, what side effects they might experience, and what impact the choice might have on their quality of life.</p> <p>A high-quality PDA will present the options in an unbiased way and will not attempt to influence the person making the decision. This can be shown by the use of font size, emboldening, colours, and the use of unbiased language.</p>
Support for the person's values, circumstances and preferences	Notes
<p>The PDA supports understanding by:</p> <ul style="list-style-type: none"> • helping people to prioritise what matters most to them in terms of the positive and negative features of the available options • supporting people to communicate these priorities with others, such as health professionals. 	<p>A high-quality PDA will support people to identify the things that matter to them most in relation to their health state by providing them with a clear set of options for treatment or investigation.</p> <p>In helping people to focus on their key priorities the PDA will help people shape the conversations they may choose to have with their healthcare professionals, their friends and family members about the choices they need to make.</p>
Use of language and numbers	Notes

Health condition, decision and available options	Notes
<p>The PDA is written in the most accessible way, by:</p> <ul style="list-style-type: none"> • using everyday language that is widely understood, or simpler language where necessary • using language equivalent to a reading age of 9 to 11 confirmed by a validated instrument such as the readability statistics within Word, or the Flesch Kincaid tool. Where this is not possible, and the PDA is intended to be explained by a healthcare professional, a reading age of 11 to 14 should be used • explaining information in a way that is meaningful to people without a background in health • explaining quantitative information about risks, benefits, chance and uncertainty in a way that is understandable to people with low levels of numeracy. 	<p>It is widely acknowledged that there are relatively low levels of health and general literacy among the UK population, and even lower levels of numeracy.</p> <p>PDA's should be written in clear, straightforward, everyday language to enable the largest number of people to be able to benefit from them. This includes techniques such as using short sentences, simple words, using the 'active' voice.</p> <p>This can be further enhanced if the PDA specifies that they have deployed a validated tool to determine the reading age of their content.</p> <p>A high-quality PDA will use simple everyday language to explain concepts such as diagnostic tests, surgical interventions and medication regimens, with a minimal use of technical terms. Where technical terms are used these are explained.</p> <p>Concepts such as risk probability and chance are also poorly understood, and a high-quality PDA will explain these in a comprehensible way.</p>
<p>For PDA's that include screening and diagnostic tests</p>	<p>Notes</p>

Health condition, decision and available options	Notes
<p>If the PDA relates to screening and diagnostic tests, it provides details about:</p> <ul style="list-style-type: none"> • what the test is designed to measure • how likely the test is to accurately identify what is being tested for • what (if any) intervention could follow from any result and the implications of that for example further investigations or treatments • the consequences of detecting a disease or condition that would not have caused any problems if the test had not been done. 	<p>Screening tests would include examples such as cervical smear, screening mammography.</p> <p>Diagnostic tests would include examples such as a polymerase chain reaction test for COVID-19, a sentinel node biopsy.</p> <p>Diagnostic tests would include examples such as a polymerase chain reaction test for COVID-19, sentinel node biopsy.</p> <p>High-quality PDAs will clearly define what the test is intended to be looking for, such as the likelihood of a fetus having a chromosomal anomaly. It will also be clear about how likely the test is to accurately give the person a definitive answer.</p> <p>A high-quality PDA will also be clear about what (if any) interventions might follow the results of a test, and what these might mean for the person being tested.</p>
Formats and availability of PDAs aimed at patients	Notes
<p>Where the PDA is intended for a patient audience it addresses the needs of the patient through:</p> <ul style="list-style-type: none"> • providing the PDA in a variety of sources such as websites, apps or by providing hard copies • providing a step-by-step guide to making a decision, and then explaining how to discuss that decision with family, friends, carers and healthcare professionals, if they wish. 	<p>To aid accessibility, an enhanced PDA should be made available in a variety of different formats and on a variety of different platforms. An enhanced PDA will also give people support in making a decision and in discussing this decision with their friends, family members and health professionals if they wish to do so.</p>

Section 2 essential process standards

Essential process standards

Evidence sources	Notes
<p>The patient decision aid (PDA) or supporting documentation provides information about:</p> <ul style="list-style-type: none"> • how evidence was found, appraised and summarised • how certain the evidence is about the likelihood of the outcomes described • the sources of evidence – citing NICE guidance where applicable. 	<p>The importance of providing people with evidence-based options cannot be overstated. For assurance that a PDA is based on the best possible evidence, its supporting documentation needs to outline its evidence sourcing, appraising and summarising approaches.</p> <p>It also needs to give an assessment of the certainty of the evidence and how reliable its findings can be considered.</p> <p>The evidence that underpins a PDA needs to be cited and should always include relevant NICE guidance where appropriate.</p>
<p>Patient involvement and co-production</p>	<p>Notes</p>

Evidence sources	Notes
<p>The supporting documentation demonstrates that the PDA focuses on the needs of the person. This is by confirming that:</p> <ul style="list-style-type: none"> • a clear need for the PDA has been established through dialogue with people with lived experience of the condition • the PDA has been co-produced with professionals and a range of people with lived experience, to ensure the tone is acceptable to patients, and the information presented is balanced and easy to understand. • the PDA has been peer-reviewed by both people with lived experience and professionals. 	<p>The involvement of patients in the development of PDAs is essential. In any supporting material the PDA developers need to demonstrate how their tool meets patients' needs, possibly through a needs assessment.</p> <p>The supporting materials also need to show how people with lived experience were involved in developing and coproducing the PDA. This needs to be in addition to any peer-review process before publication and should involve lay and professional contributors.</p>
<p>Neutral presentation of risks and benefits</p>	<p>Notes</p>

Evidence sources	Notes
<p>The developers have considered the presentation of risks and benefits to ensure they are neutral, consistent and unbiased. They ensure this by:</p> <ul style="list-style-type: none"> • using absolute risk rather than relative risk • using natural frequency • using data consistently • presenting risk over a defined period of time such as months or years, if appropriate • using numerical data, where possible, to describe risk, not terms such as rare, unusual, common as these are open to interpretation • inclusion of both positive and negative framing where possible. 	<p>Given that many people struggle with the concepts of risk and probability, as has already been stated, it is important that these are presented clearly and neutrally to remove any risk of bias. Absolute risk should be used rather than relative – for example the risk of an event increasing from 1 in 1,000 to 2 in 1,000, rather than the risk of the event doubling.</p> <p>In addition, it is important that risk and probability data are presented in a consistent manner throughout the PDA – for example by using the same denominator when comparing risk: 7 in 100 for one risk and 20 in 100 for another, rather than 1 in 14 and 1 in 5.</p> <p>Percentages are difficult for people and so natural frequencies are more suitable – for example 10 in 100 rather than a percentage such as 10%.</p> <p>The use of a defined period of time can be helpful – for example, if 100 people are treated for 1 year, 10 will experience a given side effect.</p> <p>Although numeracy can be a problem for some people, it is preferable and sometimes necessary to use numerical data, in a health literate way, rather than ambiguous terms or analogies.</p> <p>The framing of the information is also important and should be presented both positively and negatively where possible. For example, treatment will be successful for 97 out of 100 people and unsuccessful for 3 out of 100 people.</p>
<p>Review cycle and declaration of interests</p>	<p>Notes</p>

Evidence sources	Notes
<p>The PDA includes:</p> <ul style="list-style-type: none"> the date it was last updated and the nature of the updating process in the future, for example on a regular cycle or when new evidence emerges a declaration of the source of funding to develop the PDA and any potential conflicts of interest the authors' and developers' qualifications. 	<p>It is important that a PDA is kept up to date and aligned with the most recent evidence, so a high-quality PDA will include a publication date and an indication of when it will be reviewed.</p> <p>It is also important that the organisations funding the development of the PDA are stated openly, particularly if the funding comes from outside of the public sector. Any conflicts of interest relating to the PDA's authors should also be declared.</p> <p>The qualifications or the host organisation for the PDA's authors should be clearly stated.</p>

Section 3 enhanced content standards

Enhanced content standards

Experience of treatments	Notes
<p>The PDA describes what the person's experience might be depending on which option they choose.</p>	<p>An enhanced PDA might, as well as discussing the possible clinical consequences of each option available, describe the likely experience the person might expect, depending on the option they choose.</p>

Section 4 enhanced process standards

Enhanced process standards

Presentation of data	Notes
<p>The supporting documentation demonstrates that the patient decision aid (PDA) focuses on the needs of the person. It confirms that:</p> <ul style="list-style-type: none"> • alternative formats are available, for example in audio or video format, as needed by the Accessible Information Standard • there is a mixed approach to displaying data and multiple descriptive methods such as words, numbers, diagrams, pictograms and icon arrays • risks and benefits are personalised where possible. 	<p>The people using the PDA will have different communication needs and so the supporting documentation needs to describe what alternative formats are available. A national standardised approach, such as the Accessible Information Standard, should be used where possible.</p> <p>Where possible, developers should:</p> <ul style="list-style-type: none"> • use data that can be converted into a variety of display formats to accommodate different learning and information gathering styles • enable personal data to be included so that risks and benefits can be tailored to the individual.
<p>Field testing and validation with users</p>	<p>Notes</p>

Presentation of data	Notes
<p>The supporting documentation verifies that through the use of the PDA, people can:</p> <ul style="list-style-type: none"> • recognise the need for a decision • know what options are available to them • understand how their preferences, values and circumstances affect their decisions • identify what matters most to them in terms of outcomes, and can choose the option most aligned with this • discuss their values and preferences with their healthcare professionals • be involved in decision making to the extent that they wish to. 	<p>It is essential that any PDA delivers on its intention, which is to support people to make decisions about their treatment or other care options. Field testing and validating the PDA with people with lived experience are important aspects of the development process.</p> <p>The supporting documentation should include details of how this was done and the extent to which the PDA delivers against the bullet points in the column to the left.</p>
<p>Equality, diversity and health inequalities</p>	<p>Notes</p>

Presentation of data	Notes
<p>The developers have taken into consideration equality, diversity and health inequalities, through:</p> <ul style="list-style-type: none"> • a thorough equality impact assessment looking at the protected characteristics in the Equality Act 2010, to avoid discrimination and promote equality • assessing whether the PDA could reduce health inequalities, or make them worse • a consideration of cultural diversity in terms of decision-making and risk analysis. 	<p>The Equality Act 2010 provides a legal framework to avoid discrimination and promote equality across the population. Those working in the public sector are also bound by the Public sector equality duty.</p> <p>PDA developers need to demonstrate that they have undertaken some form of equality impact assessment. This should include an assessment of how likely the PDA is to address or compound health inequalities in the intended population.</p> <p>Cultural aspects of decision making (such as whether to take medicine containing porcine products for Muslim or Jewish people) may also need to be taken into account, and the developers' sensitivities to these aspects should be documented.</p>

Appendix 1 – Framework development process

Commission and funding source

This piece of work has been commissioned and funded by NHS England and Improvement. The project sponsors are:

- Jonathan Berry, personalisation and control specialist, NHS England and NHS Improvement
- Paul Chrisp, director of the centre for guidelines, NICE.

The NICE project leads are:

- Andy Hutchinson, medicines education technical adviser, NICE
- Victoria Thomas, head of public involvement, NICE.

Oversight

Oversight of the work was undertaken by a group of experts:

- Adrian Edwards, University of Cardiff
- Angela Coulter, academic
- Carole Pitkeathley, lay contributor
- Helen Morgan, palliative care consultant, Northumbria Healthcare NHS Trust
- Hilary Bekker, University of Leeds
- Louisa Polak, GP, Cambridge Primary Care Unit
- Natalie Joseph-Williams, University of Cardiff
- Richard Thomson, University of Newcastle
- Sophie Randall, Patient Information Forum.

Production

The project was delivered through the collaborative work of the following people:

- Jonathan Berry, personalisation and control specialist, NHS England and NHS Improvement
- Chris Carmona, senior technical analyst, NICE
- Deborah Collis, associate director of system engagement, NICE
- Amy Finnegan, information specialist, NICE
- Andy Hutchinson, medicines education technical adviser, NICE
- Johanna Hulme, associate director of medicines evidence and advice, NICE
- Setal Bachelard, medical editor, NICE
- Laura Norburn, senior operations manager, NICE
- Trudie Pandolfo, business manager, NICE
- Victoria Thomas, head of public involvement, NICE.

COVID -19 process

The process to develop this framework largely followed the process developed for [NICE's COVID-19 rapid guidance development](#).

Literature review

The literature review is detailed in [Appendix 2](#).

Peer and patient review

Drafts of the framework were reviewed by the oversight and delivery groups, and a targeted consultation took place with [members of the NICE shared decision making collaborative](#) and other key experts in the field.

Appendix 2 - References

Summary of topics of included and excluded references

Attribute Name	Count
Include - Standards for PDAs	27
Include - Models for testing PDAs	1
Include - Quality of reporting of PDAs	6
Include - Measures of PDA effectiveness	4
Exclude - Theory about PDAs	4
Exclude - Content of PDAs	6
Exclude - Development/appraisal/validation of PDA	155
Exclude - Identification of PDAs	32
Exclude - Not about patient decision aids	210
Exclude - Implementing PDAs	11
Exclude - Effectiveness of PDAs	29
Exclude - Discussion/opinion	8
Exclude - No abstract	1
None of the above	0

Included studies – decision aid standards

1. Abhyankar, Purva, Volk, Robert J, Blumenthal-Barby, Jennifer et al. (2013) Balancing the presentation of information and options in patient decision aids: an updated review. *BMC medical informatics and decision making* 13 (Suppl.2): 6
2. Bekker, Hilary L (2010) The loss of reason in patient decision aid research: do checklists damage the quality of informed choice interventions? *Patient education and counseling* 78(3): 357-64

3. Charvet-Berard AI; Chopard P; Perneger TV (2008) Measuring quality of patient information documents with an expanded EQIP scale. *Patient education and counseling* 70(3): 407-411
4. Coulter, Angela, Stilwell, Diana, Kryworuchko, Jennifer et al. (2013) A systematic development process for patient decision aids. *BMC medical informatics and decision making* 13 (Suppl.2): 2
5. Dowie, Jack; Kaltoft, Mette Kjer; Rajput, Vije Kumar (2020) Measures of Decision Aid Quality Are Preference-Sensitive and Interest-Conflicted - 1: Normative Measures. *Studies in health technology and informatics* 275: 47-51
6. Dowie, Jack; Kaltoft, Mette Kjer; Rajput, Vije Kumar (2020) Measures of Decision Aid Quality Are Preference-Sensitive and Interest-Conflicted - 2: Empirical Measures. *Studies in health technology and informatics* 275: 52-56
7. Durand, Marie-Anne, Dannenberg, Michelle D, Saunders, Catherine H et al. (2019) Modified Delphi survey for the evidence summarisation of patient decision aids: Study protocol. *BMJ open* 9(3): e026701
8. Durand, Marie-Anne, Witt, Jana, Joseph-Williams, Natalie et al. (2015) Minimum standards for the certification of patient decision support interventions: feasibility and application. *Patient education and counseling* 98(4): 462-8
9. Elwyn, Glyn, Burstin, Helen, Barry, Michael J et al. (2018) A proposal for the development of national certification standards for patient decision aids in the US. *Health policy (Amsterdam, Netherlands)* 122(7): 703-706
10. Elwyn, Glyn, O'Connor, Annette M, Bennett, Carol et al. (2009) Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi). *PloS one* 4(3): e4705
11. Elwyn, Glyn, O'Connor, Annette, Stacey, Dawn et al. (2006) Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ (Clinical research ed.)* 333(7565): 417
12. Fagerlin, Angela, Pignone, Michael, Abhyankar, Purva et al. (2013) Clarifying values: an updated review. *BMC medical informatics and decision making* 13 (Suppl.2): 8

13. Hoefel L, Lewis KB, O'Connor A et al. (2020) 20th Anniversary Update of the Ottawa Decision Support Framework: Part 2 Subanalysis of a Systematic Review of Patient Decision Aids. *Medical decision making : an international journal of the Society for Medical Decision Making* 40(4): 522-539
14. Hoefel L, O'Connor AM, Lewis KB et al. (2020) 20th Anniversary Update of the Ottawa Decision Support Framework Part 1: A Systematic Review of the Decisional Needs of People Making Health or Social Decisions. *Medical decision making : an international journal of the Society for Medical Decision Making* 40(5): 555-581
15. Joseph-Williams, Natalie, Newcombe, Robert, Politi, Mary et al. (2014) Toward Minimum Standards for Certifying Patient Decision Aids: A Modified Delphi Consensus Process. *Medical decision making : an international journal of the Society for Medical Decision Making* 34(6): 699-710
16. Koon, Sean (2020) Important Considerations for Design and Implementation of Decision Aids for Shared Medical Decision Making. *The Permanente journal* 24
17. Lenz M and Kasper J (2007) MATRIX - development and feasibility of a guide for quality assessment of patient decision aids. *Psycho-social medicine* 4: Doc09
18. McDonald, Heather; Charles, Cathy; Gafni, Amiram (2014) Assessing the conceptual clarity and evidence base of quality criteria/standards developed for evaluating decision aids. *Health expectations : an international journal of public participation in health care and health policy* 17(2): 232-43
19. Montori, Victor M, LeBlanc, Annie, Buchholz, Angela et al. (2013) Basing information on comprehensive, critically appraised, and up-to-date syntheses of the scientific evidence: a quality dimension of the International Patient Decision Aid Standards. *BMC medical informatics and decision making* 13 (Suppl.2): 5
20. Poddar, Urbashi, Brownlee, Shannon, Stacey, Dawn et al. (2015) Patient Decision Aids: A Case for Certification at the National Level in the United States. *The Journal of clinical ethics* 26(4): 306-11
21. Stacey D, Légaré F, Boland L et al. (2020) 20th Anniversary Ottawa Decision Support Framework: Part 3 Overview of Systematic Reviews and Updated Framework. *Medical decision making : an international journal of the Society for Medical Decision Making* 40(3): 379-398

22. Stevens, G., Theiler, R., Washburn, H. et al. (2018) Is honesty the best policy? The adequacy of disclosure as a strategy for addressing competing interests in patient decision aid development. *BMJ Evidence-Based Medicine* 23 (Suppl.1): a19
23. Thompson, R., Stevens, G., Washburn, H. et al. (2019) Is disclosure of financial conflicts of interest in patient decision aids effective? insights from a simulated pilot. *BMJ Evidence-Based Medicine* 24 (Suppl.1): a30
24. van der Weijden, Trudy, Dreesens, Dunja, Faber, Marjan J et al. (2019) Developing quality criteria for patient-directed knowledge tools related to clinical practice guidelines. A development and consensus study. *Health expectations : an international journal of public participation in health care and health policy* 22(2): 201-208
25. Volk, Robert J, Llewellyn-Thomas, Hilary, Stacey, Dawn et al. (2013) Ten years of the International Patient Decision Aid Standards Collaboration: evolution of the core dimensions for assessing the quality of patient decision aids. *BMC medical informatics and decision making* 13 (Suppl.2): 1
26. Vromans, Ruben D, van Eenbergen, Mies C, Pauws, Steffen C et al. (2019) Communicative aspects of decision aids for localized prostate cancer treatment - A systematic review. *Urologic oncology* 37(7): 409-429
27. Wieringa, Thomas H, Rodriguez-Gutierrez, Rene, Spencer-Bonilla, Gabriela et al. (2019) Decision aids that facilitate elements of shared decision making in chronic illnesses: a systematic review. *Systematic reviews* 8(1): 121

Included studies – model for field testing

1. Evans, Rhodri, Elwyn, Glyn, Edwards, Adrian et al. (2007) Toward a model for field-testing patient decision-support technologies: a qualitative field-testing study. *Journal of medical Internet research* 9(3): e21

Included studies – quality of reporting

1. Bonner, Carissa, Patel, Pinika, Fajardo, Michael Anthony et al. (2019) Online decision aids for primary cardiovascular disease prevention: systematic search, evaluation of quality and suitability for low health literacy patients. *BMJ open* 9(3): e025173

2. Hoffman, Aubri S, Sepucha, Karen R, Abhyankar, Purva et al. (2018) Explanation and elaboration of the Standards for UNiversal reporting of patient Decision Aid Evaluations (SUNDAE) guidelines: examples of reporting SUNDAE items from patient decision aid evaluation literature. *BMJ quality & safety* 27(5): 389-412
3. Lewis, Krystina B, Wood, Brianne, Sepucha, Karen R et al. (2017) Quality of reporting of patient decision aids in recent randomized controlled trials: A descriptive synthesis and comparative analysis. *Patient education and counseling* 100(7): 1387-1393
4. O'Connor, Annette M, Bennett, Carol, Stacey, Dawn et al. (2007) Do patient decision aids meet effectiveness criteria of the international patient decision aid standards collaboration? A systematic review and meta-analysis. *Medical decision making : an international journal of the Society for Medical Decision Making* 27(5): 554-74
5. Sepucha, Karen R, Abhyankar, Purva, Hoffman, Aubri S et al. (2018) Standards for UNiversal reporting of patient Decision Aid Evaluation studies: the development of SUNDAE Checklist. *BMJ quality & safety* 27(5): 380-388
6. Sepucha, Karen R, Matlock, Daniel D, Wills, Celia E et al. (2014) "It's Valid and Reliable" Is Not Enough: Critical Appraisal of Reporting of Measures in Trials Evaluating Patient Decision Aids. *Medical decision making : an international journal of the Society for Medical Decision Making* 34(5): 560-6

Included studies – measures of PDA effectiveness

1. Bekker, Hilary L, Legare, France, Stacey, Dawn et al. (2003) Is anxiety a suitable measure of decision aid effectiveness: a systematic review?. *Patient education and counseling* 50(3): 255-62
2. Kryworuchko, Jennifer, Stacey, Dawn, Bennett, Carol et al. (2008) Appraisal of primary outcome measures used in trials of patient decision support. *Patient education and counseling* 73(3): 497-503
3. Rutherford, Claudia, King, Madeleine T, Butow, Phyllis et al. (2019) Is quality of life a suitable measure of patient decision aid effectiveness? Sub-analysis of a Cochrane systematic review. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 28(3): 593-607
4. Scholl I, Koelewijn-van Loon M, Sepucha K et al. (2011) Measurement of shared decision making - a review of instruments. *Zeitschrift fur Evidenz, Fortbildung und Qualitat im Gesundheitswesen* 105(4): 313-324

ISBN: 978-1-4731-4171-1