NICE National Institute for Health and Care Excellence

NICE decision aid: process guide

Process and methods

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1 Introduction

1.1 What is this guide for?

This process guide provides an overview of the key principles used for developing NICE decision aids. It ensures that robust, quality-assured decision aids for people using and providing health and social care services are developed in an open, transparent and timely way, with appropriate input from key groups. Decision aids produced under this process will comply with the standards framework for shared-decision-making support tools, including patient decision aids.

1.2 Background

All NICE guidance states that professionals and practitioners should take into account the individual needs, preferences and values of their patients or the people using their service, alongside the guidance recommendations.

Some decisions are particularly preference-sensitive; that is, the possible treatment or care options have possible harms, benefits and consequences which people value differently and so the best choice for an individual depends on the emphasis that person places on each of them and the trade-offs they are willing to make. Decisions may be preference-sensitive for individuals even if, at a population level, there is evidence favouring one option.

NICE decision aids support shared decision making about the preference-sensitive decisions to which they relate. They are intended to support conversations between professionals or practitioners and people in their care, not replace them.

1.3 Aim

The aim of NICE decision aids is to help people facing a decision about treatment or care options (and their family and carers, as appropriate) make an informed choice based on which of the different options' advantages and disadvantages matter most to them. They do this by:

- describing what the options involve and summarising the best available evidence relating to their possible harms, benefits and consequences, including the option of having no treatment or not changing what the person is currently doing.
- presenting that information in a way that is easy for people facing the decision (and their family and carers, as appropriate) to understand, with support from their health or care practitioner.

1.4 Who are NICE decision aids for?

The primary audiences for NICE decision aids are people facing decisions (and their family and carers, as appropriate) and the professionals and practitioners involved in their care. Secondary audiences are organisations commissioning or providing care (which may include decision aids in policies and pathways), and voluntary and community sector organisations (which may promote them to the people with whom they work).

1.5 Key activities

Producing NICE decision aids involves:

- identifying the possible options and the possible harms, benefits and consequences of them that are important to most people facing the decision
- describing what the options involve and identifying and summarising the best available evidence relating to their possible harms, benefits and consequences
- presenting the information in a suitable format, including visual representations of the chance of benefits or harms where possible.
- reviewing and updating the decision aid.

See the section on developing a patient decision aid for more details.

2 Who is involved in producing NICE decision aids?

2.1 Development team

The development team is made up of pharmacists and technical, project and administrative staff who are responsible for:

- coordinating work, agreeing timelines and liaising with external partners as needed
- scoping and writing decision aids in line with this process, the standards framework for shared-decision-making support tools, including patient decision aids and evolving best practice in shared decision making and risk communication. This includes selecting the evidence on which a decision aid is based and identifying and working with the project group
- quality assuring decision aids
- updating decision aids.

The development team works with other NICE teams to:

- identify, select and prioritise possible topics for decision aids
- liaise with guidance committee members
- identify and work with project group members
- support clear and effective presentation and publication of decision aids
- conduct literature searches if these are needed.

2.2 Project group

A project group is identified and established to guide development of each NICE decision aid. This includes topic experts and relevant members of NICE staff. Topic experts are people with professional expertise or lived experience relevant to the topic of the decision

aid. They include patients or people who use services (or organisations that represent them), carers, and health or care professionals.

Topic experts are usually guidance committee members or are recruited via voluntary and community sector organisations and professional organisations. The role of the topic experts is to:

- inform the scope of the decision aid; in particular to identify the possible options and the possible harms, benefits and consequences of them that are important to most people facing the decision
- ensure the decision aid is fair, balanced and reflects the evidence, and is consistent with current NHS practice
- help ensure the decision aid is easy for people facing the decision (and their family and carers, as appropriate) to understand and use
- help ensure the decision aid is acceptable to and easy to use by professionals and practitioners supporting people facing the decision.

The project group is identified early in the production process to provide comments within an agreed timeframe.

2.3 External commissioners or partners

NICE decision aids may be commissioned by external organisations or developed in partnership with external partners such as NHS England. The commissioning arrangements are agreed between NICE and the commissioner or partner organisation.

3 Conflicts of interest

NICE staff and topic expert members of the project group are required to comply with the NICE conflicts of interest policy.

4 Topic selection

Selection and prioritisation decisions are informed by the NICE topic selection process and take into account the following criteria:

- Needs of people using services. Factors might include:
  - the complexity of the issues or the number of options from which to choose
  - whether or not the decision is likely to have life-changing or irreversible consequences
  - the value of a visual representation of the absolute chance of benefits or harms.
- Other unmet need, such as unwarranted variation in access to the treatment or care options.
- System priority, such as how frequently the decision is likely to be encountered by patients and users of services.

Selection and prioritisation will also take account of the availability of evidence on which to base a decision aid and available NICE resources.

If a decision aid has been commissioned by an external organisation, a process for topic selection is agreed as part of the commission arrangements.

5 Developing a patient decision aid

5.1 Equality and diversity

NICE decision aids are developed in line with NICE's equality scheme and declaration of interests policy.

5.2 Process overview and timelines

The key steps in developing a NICE decision aid

Timeline	Process overview
Weeks 1 to 3	Confirm the project aim and specification, including liaison with any external commissioner or partner
Weeks 1 to 3	Form the scoping group – identify clinical and patient experts
Weeks 4 to 6	Scope the decision aid with the scoping group
Additional 4 to 7 weeks	Evidence update completed between these steps if needed.
Weeks 7 to 8	Confirm project group and produce first draft
Weeks 9 to 10	Project group review and amend draft decision aid to reflect project group comments
Week 11	Project group meeting
Weeks 12 to 14	Amend draft after project group meeting, further project group review and amends made
Weeks 14 to 17	Technical accuracy check. Decision aid produced in InDesign format ready for stakeholder review

Timeline	Process overview
Weeks 18 to 21	Stakeholder review and user testing
Weeks 22 to 24	Amendments following stakeholder review and user testing made and reviewed by project group. Decision aid updated and prepared for sign-off
Week 25	Internal team sign-off
Weeks 26 to 28	Executive sign off and publication

5.3 Scoping

The development team agrees the aim and specifications of the decision aid with the relevant NICE team and the commissioner or partner (as appropriate). This includes agreeing the aim (user need) and the MoSCoW criteria.

The user need is stated as:

As [specify the population, for example 'an adult newly diagnosed with chronic primary pain'] facing the decision about [specify options, including the option of having no treatment or not changing what the person is currently doing], I need clear, understandable information about what the options involve and the associated possible risks, benefits and consequences; so that I can make an informed choice knowing which of those matter most to me.

The MoSCoW criteria specify content that:

- Must be included: omitting any of these would constitute project failure
- Should be included: things that would ideally be included but are not essential in the same way as must-haves and the need for which may be met in a different way
- Could be included: things that are desirable but not necessary, things that would improve the user experience
- Will Not be included: things that are out of scope.

The project group then defines the detailed content (for example, which possible harms,

benefits and consequences to cover), and advises on other information that the writers need, such as language to use. All NICE-produced decision aids are consistent with relevant NICE guidance.

5.4 Evidence for use in NICE decision aids

NICE decision aids are based on the best available evidence. The primary evidence source is normally the evidence review or submission used in developing the relevant NICE guidance. Where necessary, individual studies included in evidence reviews or submissions may be examined for further data. Studies excluded by the guidance development process are not used. Additional information may be taken from other NICE guidance and advice, and from standard reference sources including the NHS website (www.nhs.uk), NICE Clinical Knowledge Summaries (CKS) and (for information on adverse effects, monitoring requirements and similar matters relating to medicines) manufacturers' summaries of product characteristics (SPCs) and the BNF.

In exceptional circumstances a targeted literature search is undertaken by NICE's information services. This step will be considered only if:

- evidence to address an essential component of the scope has not been identified within the evidence reviews or submission used in the development process for the guidance, or
- the relevant part of the guidance was last updated more than 3 years previously or more recent evidence has been highlighted to NICE's guideline surveillance process, or
- the topic for an externally commissioned decision aid has not been the subject of NICE guidance published in the previous 3 years.

The process for searching for and selecting the evidence is described in appendix A: Searching for and selecting evidence for use in NICE decision aids. The rationale for including or excluding evidence is recorded. All evidence used in the decision aid is agreed with the project group. NICE decision aids use only evidence that is in the public domain.

6 Writing the decision aid

The lead author drafts the decision aid in accordance with the scope. The diverse nature of topics covered by NICE decision aids means that a formal template cannot be specified. For externally commissioned decision aids, the format or template is agreed with the commissioning organisation. The lead author drafts the decision aid such that its content meets at least the essential standards of the standards framework for shared-decision-making support tools, including patient decision aids. The decision aid will usually include the following information:

- an explanation of the intended audience and context of the decision aid.
- sufficient information about the condition or health problem and the aims of treatment or care options to orient readers
- a summary of the options, including the option of having no treatment or not changing what the person is currently doing.
- a description of the possible harms, benefits and consequences of the options. This will usually involve a visual representation of the chance of benefits or harms.
- support to help the person think about which of the risks, benefits and possible consequences of the options matter most to them and communicate these with others.

Other information may be included as appropriate to the topic. NICE decision aids are focussed on supporting informed decision making about options; they do not contain background information on the condition or health problem beyond that necessary to orient users.

7 Quality assuring the decision aid

The NICE decision aid is quality assured by the development team.

7.1 Technical accuracy

A detailed accuracy check is conducted by a member of the development team who was not involved in drafting the decision aid. This is to ensure the content is fair, balanced and accurate.

7.2 Peer review

Stakeholders are invited to comment on a draft of the decision aid:

- for decision aids relating to NICE guidelines, registered stakeholders from the current or last update of the NICE guideline are invited to review the draft
- for decision aids relating to NICE technology appraisal guidance, commentators and consultees are invited to review the draft
- for externally commissioned decision aids, the commissioning organisation is invited to review the draft and is responsible for identifying other stakeholders to review it to the development team.

Stakeholders include patient and professional groups. Additional stakeholders may be identified and invited to review the draft by the project group. For decision aids relating to fully published NICE guidance, user testing may be conducted.

The lead author amends the draft to respond to comments from stakeholders and results from user testing. This revised draft is reviewed by and agreed with the project group.

7.3 Sign-off and approval

The near-final decision aid is signed off by the programme director, clinical adviser or associate director. This near-final version is sent in confidence for a final opportunity to identify any outstanding issues to the project group and, for externally commissioned

decision aids, the commissioning organisation.

NICE's guidance executive or a NICE Director reviews the decision aid and, if appropriate, approves it for publication, ensuring that the process has been followed in its development.

For externally commissioned decision aids, arrangements for sign-off by the commissioning organisation after NICE executive sign-off are agreed as part of the commission arrangements.

8 Publication of the decision aid

The decision aid is published on the tools and resources tab of the NICE guidance. It is publicised through NICE's communications routes, including the NICE field team and NICE medicines and prescribing associates.

For externally commissioned decision aids, arrangements for publication are agreed as part of the commission arrangements.

9 Review and update

NICE decision aids are reviewed as part of the surveillance process for the guidance to which they relate. If the guidance and the relevant recommendations are modified, the decision aid is updated or withdrawn. The decision aid may also be updated or withdrawn before the guideline is updated if there are changes to the licensing arrangements for medicines to which the decision aid refers, relevant safety warnings are issued by the MHRA or there are changes to relevant legislation or usual NHS practice.

Appendix A: Searching for and selecting evidence for use in NICE decision aids

In exceptional circumstances a targeted literature search is undertaken by NICE's information services. This step will be considered only if:

- evidence to address an essential component of the scope has not been identified within the evidence reviews or submission used in the development process for the guidance, or
- the relevant part of the guidance was last updated more than 3 years previously or more recent evidence has been highlighted to NICE's guideline surveillance process, or
- the topic for an externally commissioned decision aid has not been the subject of NICE guidance published in the previous 3 years.

Reviewing surveillance reports

In any of the circumstances described, surveillance reports for the relevant guidance are first reviewed, if they have been conducted. A targeted literature search is not undertaken if either of the following circumstances apply and there is also no other reason to think that more recent evidence is available:

- evidence which addresses the relevant components of the scope is contained within the evidence reviews or submission used in the development process for the guidance and the surveillance review(s) indicate that no more recent relevant evidence has been published within the past 3 years, or
- the surveillance review(s) identify evidence which addresses components of the scope published within the past 3 years.

Searching for evidence

If, after available surveillance reports have been reviewed, an evidence search is needed, one or more search questions are developed by the decision aid development team that

describe the evidence needed to address the relevant components of the scope. These specify the population, intervention, comparators and outcomes (PICO). NICE's information services do a literature search according to the agreed scope and PICO. The search strategy and quality assurance of the search process is recorded.

Selecting the evidence

Evidence identified from the literature search is reviewed to either:

- confirm that no more recent or better evidence than that which is in the evidence reviews or submission is available, or
- identify evidence to address the relevant components of the scope.

First sift

The first sift reviews the title and abstract of the study against the scope and PICO and removes evidence of low relevance. This may include non-English language studies, conference abstracts or studies that have not been published in full (because these cannot be critically appraised).

Second sift

The second sift of full papers further excludes articles that do not meet the criteria in the scope and PICO.

Prioritisation

When all relevant studies have been identified, the best available evidence is selected, taking into account:

- Applicability: the ability to generate absolute rates of benefits or harms from the study results.
- Risk of bias: this includes an assessment of the quality of the study size and design. For comparisons between options, systematic reviews of randomised controlled trials (RCTs) are prioritised first, followed by single RCTs and then large observational studies.

- Precision: this includes a review of the 95% confidence interval around the best estimate of the absolute effect.
- Consistency: this includes considering similarities and differences in relative effects if several studies are identified which potentially provide evidence.
- Directness: how closely the population in the study matches the population in the aim for the decision aid and the study interventions match UK practice.

If evidence is identified which might impact on the guidance recommendations, the surveillance team is informed and the guideline surveillance process is followed.

The rationale for including or excluding evidence is recorded, but a narrative evidence review is not written. All evidence used in the decision aid is agreed with the project group.

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