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Study protocol: A modified Delphi survey for the evidence summarization of patient decision aids

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Study protocol: A modified Delphi survey for the evidence summarization of patient decision aids

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21
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23 [Decision Making](#)

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ABSTRACT FOR PROTOCOL

Introduction

Information included in a PDA can significantly influence patients' decisions and is, therefore, expected to be evidence based and rigorously selected and summarized. Yet patient decision aid developers have not yet agreed on a standardized process for the selection and summarization of the supporting evidence. We intend to generate consensus on a process (and related steps and criteria) for selecting and summarizing evidence for patient decision aids using a modified Delphi survey.

Methods and Analysis

We will develop an evidence summarization process specific to PDA development by using a consensus-based Delphi approach, surveying international experts and stakeholders with two to three rounds. To increase generalizability and acceptability, we will distribute the survey to the following stakeholder groups: patient decision aid developers, researchers with expertise in shared decision making, patient decision aid development and evidence summarization, members of the International Patient Decision Aid Standards group, policy makers with expertise in patient decision aid certification, and patient stakeholder groups. For each criterion, if at least 80% of survey participants rank the criterion as most important/least important, we will consider consensus achieved.

Ethics and Dissemination

It is critical for patient decision aids to have accurate and trustworthy evidence-based information about the risks and benefits of health treatments and tests, as these decision aids help patients make important choices. We want to generate consensus on an approach for selecting and summarizing the evidence included in patient decision aids, which can be widely implemented by decision aid developers. Dartmouth College's Committee for the Protection of Human Subjects approved this protocol. We will publish our results in a peer-reviewed journal.

Words: 265

Article Summary

- Gap: There is no standardized method for selecting and summarizing the evidence in patient decision aids.
- Solution: We're developing a process to ensure patient decision aids have the most up-to-date, trustworthy evidence available.
- Clinical implications: This will help patients and clinicians know they can trust the information in patient decision aids, so they can make the best decisions together.
- Health systems implications: Knowing that the evidence selection and summarization process is rigorous, healthcare systems may feel more comfortable including patient decision aids in routine care.
- Strengths: Systematic involvement of patient stakeholders.
- Limitations: Limitations of online surveys include selection bias.

INTRODUCTION

Patient Decision Aids (PDAs) are tools that help patients and their clinicians make preference-sensitive decisions together. They provide information about the harms and benefits of reasonable health-care options and help patients compare options and clarify their values and preferences. They promote patient engagement in medical decision making, collaboration between patients and their care team, increase knowledge and align patients' choices with their preferences [1]. Therefore, the information included in PDAs can significantly impact patients' decisions. For this reason, patients and clinicians expect the information in PDAs to be evidence based and rigorously selected and summarized.

1
2 The approach that PDA developers use to select and summarize the evidence in PDAs, however, appears
3 inconsistent. A recent international cross sectional survey of 15 PDA developers confirms that they do not have
4 an agreed-upon, standardized process to select and summarize evidence. They also do not always document the
5 evidence selection and summarization process [2]. Most organizations reported using existing systematic
6 reviews and clinical practice guidelines to select and summarize information for PDAs. Less than half reported
7 using a standard, documented approach to guide the evidence selection and summarization. When the
8 approach was documented, the documents offered varying levels of detail. Common evidence summarization
9 steps identified were: tool-relevant question formation, search strategies, evidence appraisals, and updating
10 policies. There was no standardized process across organizations to summarize evidence for PDAs. Although
11 agreed-upon approaches and tested methods for evidence summarization exist in other areas, such as clinical
12 practice guidelines, there is no agreed process (including steps and criteria within each step) for the selection
13 and summarization of evidence for PDAs.
14
15

16 The International Patient Decision Aids Standards (IPDAS) collaboration developed criteria for assessing the
17 quality of PDAs [3]. These criteria are also used by PDA producers to guide the development of the
18 interventions. However, only six items of the IPDAS checklist cover the selection and synthesis of evidence, and
19 do not provide any guidance about recommended methods for the evidence selection and summarization of
20 PDAs [3]. Further, the IPDAS instrument and the IPDAS minimum standards do not offer additional information
21 or guidance on the steps required to select and summarize evidence-based information for PDAs [4, 5]. Other
22 efforts to evaluate or certify the quality of PDAs have emerged [6], but none of those standards or certification
23 bodies describe recommended methods and criteria that PDAs producers should follow when selecting and
24 summarizing evidence for patient-facing interventions.
25
26

27 Evidence synthesis in other medical contexts is increasingly standardized, such as the selection and
28 summarization of evidence for clinical practice guidelines and systematic reviews. This process minimizes the
29 risk of bias in the end product [7-16]. The same level of scrutiny is justified when developing PDAs, as they may
30 directly influence patient care and decision making. Tasks such as the selection and identification of patient-
31 relevant outcomes, analysis of patient concerns and priorities, description of the quality of evidence, and
32 communication of uncertainty in ways that patients understand warrants the development of an agreed process
33 and related steps and criteria that are specific to PDAs. Efforts to develop an agreed evidence summarization
34 process for PDAs should incorporate the substantial body of related evidence summarization guidance
35 previously developed by other groups, and notably for clinical practice guidelines [9].
36
37

38 **Objective**

39 The purpose of the study is to generate consensus on a process (and related steps and criteria) for selecting and
40 summarizing evidence for patient decision aids using a modified Delphi survey.
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44

45 **2 METHODS**

46 **Study Design and Procedures**

47 We will develop an evidence summarization process specific to PDA development by using a consensus-based
48 Delphi approach previously used in the development of a quality criteria framework for PDAs [17, 18].
49 Consensus methods can harness the views of international experts on a wide range of information and
50 questions in order to make decisions that are based on expert consensus [19]. We will conduct a multi-round
51 modified Delphi survey (two to three rounds). Compared to the nominal group technique, it is the most practical
52 and scalable method to obtain feedback from a large number of stakeholders in different geographic locations.
53 During the multiple rounds of online questionnaires, relevant stakeholders will be consulted to provide feedback
54 about the evolving set of evidence summarization steps and criteria. The anonymous responses from
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1 participants will be fed back to them in subsequent rounds. Depending on the level of consensus after two
2 rounds (see Data Analysis section), we will determine whether to conduct a third survey round.
3
4

5 **Study Management**

6 To oversee the tasks of 1) generating an initial set of criteria for the Delphi process and 2) managing the Delphi
7 survey distribution and analysis, we convened a steering group. This group will oversee the project and will
8 make strategic decisions about the study design, data collection and analysis processes, as well as agree a final
9 process and related set of steps and criteria. An invitation to join this group was posted on social media
10 (Shared@Shared Decision Making Network Facebook group: 745 members) on 30 June 2017. The post invited all
11 Facebook group members to join an in-person meeting about evidence summarization during the International
12 Shared Decision Making conference, held in Lyon, France, between July 2, and July 5, 2017. For those who were
13 not able to join the meeting but expressed an interest in evidence summarization of PDAs, a high-level summary
14 was posted on Facebook. The steering group was convened in September 2017. The study steering group
15 includes international experts in PDA development, evaluation and implementation, evidence summarization
16 and clinical practice guidelines, and patient representation. Google drive will be used to facilitate the exchange
17 and review of information and documents as well as facilitate real-time collaboration and version-control.
18
19

20 **Participants**

21 To maximize the generalizability and applicability of the criteria, we plan to invite participation in the survey
22 from the following groups: 1) all known developers of PDAs who created or updated a tool within last five
23 calendar years (using existing inventory), 2) all members of the of the IPDAS group, 3) the Shared Decision
24 Making listserv; 4) the Society for Participatory Medicine listserv ; 5) an overdiagnosis google group ; 6) the
25 evidence-based healthcare listserv ; 7) the Society for Medical Decision Making ; the 8) the Society of Behavioral
26 Medicine (Health Decision Making Interest Group) , 9) HTAi-ISG Patient Involvement listserv, 10) GRADE Working
27 group, 11) the Guidelines International Network, 12) convenience sample of policy makers with interest and
28 expertise in PDA certification; 13) the BMJ patient group; 14) the ProPublica Patient Safety Community.
29
30

31 For all participants, the survey invitation (Supplementary File 1) will provide a brief outline of the study, a link to
32 the online survey (Supplementary File 2), and a brief participant information sheet as the first page of the
33 survey. Consent will be inferred by participants' completion of the survey. The ethics application form and
34 protocol were submitted to Dartmouth College's committee for the protection of human subjects on 27 April
35 2018. Approval was granted on 23 May 2018 (STUDY00031042).
36
37

38 **Patient and Public Involvement**

39 **Design**

40 Our patient partner, SC, was involved in the development of the Delphi survey and provided meaningful
41 feedback on iterative drafts of the online questionnaire. SC is a core member of our study steering group and an
42 author on this manuscript.
43
44

45 **Participants**

46 We also plan to make a concerted effort to recruit patient participants. We will reach out to online patient
47 groups, including the BMJ Patient group, the ProPublica Patient Safety Community (more than 6,000 members).
48 We will also engage a patient and family advisor group at Dartmouth-Hitchcock Medical Center.
49
50

51 **Analysis**

52 Our patient partner will be a critical part of our analysis team, and will be involved in all steering group
53 meetings.
54

55 **Survey Development**

1
2 The main output of the original Lyon evidence summarization meeting was the creation of a spreadsheet that
3 detailed all evidence-summarization steps inherent to PDA development. The first draft of this spreadsheet,
4 iteratively developed by the steering group members, included 18 criteria. Combining those 18 criteria with the
5 eight existing standards for the summarization of clinical practice guidelines as outlined by the National
6 Academy of Medicine (formerly IOM) & US Preventive Services Task Force Standards led to the creation of the
7 first draft of the proposed process and steps. This draft was shared in a Google doc with all members of the
8 steering group and iteratively refined and finalized. Three separate iterations of the process (phases, steps and
9 criteria) were created, reviewed and discussed by the steering group members until no additional revisions were
10 suggested. A final internal version of the criteria (n=48), categorized into four phases and 13 steps was finalized
11 in April 2018 (see Supplementary File 3).
12

13 14 **Data Collection**

15 16 **Round One Survey**

17 The round one survey will include a brief information page and a summary of the process that led to the
18 development of the phases, steps and criteria. Participants will be asked to provide their input on the phases,
19 steps and criteria (including inclusion, wording, grouping, order and any other comments). Specifically, they will
20 be asked to indicate using a four-point Likert scale (omit, possible, desirable, essential) whether each criterion
21 included in the proposed process should be omitted or kept (and whether it is considered possible, desirable or
22 essential). The criteria will be grouped into relevant phases and steps. For each phase and for each step,
23 participants will be given the opportunity to provide rewording suggestions, suggest additional phases, steps or
24 criteria, comment on the order of those elements or provide additional comments, or questions. Email
25 addresses will be collected so participants can participate in further rounds. At the end of each round, we will
26 confirm participants' interest to participate in the next round. Participants will also be asked to complete basic
27 demographic questions. Each round of the survey will be open for three weeks, and two reminders will be sent.
28
29

30 31 **Round Two Survey (and round three, as necessary)**

32 Round one participants will be invited to complete a second survey, in which feedback will be provided about
33 the results of the first round (percentage of participants who thought a criterion should be included or excluded)
34 and about the changes made based on the qualitative feedback. Participants will be invited to indicate whether
35 to omit or include (omit, possible, desirable, essential) the items, including the new items proposed by
36 participants in the first round, and to provide additional rewording suggestions, comments, or questions. As
37 mentioned above, the survey will be open for three weeks, and two email reminders will be sent. Depending on
38 the level of consensus, a third round may be conducted.
39

40 41 **Data Analysis**

42 Following round one, the ratings will be summarized using percentages. If at least 80% of participants rate the
43 item in the lower two categories (omit, possible) or in the higher two categories (desirable, essential), we will
44 consider consensus to be achieved and the item will be removed or retained, respectively. The steering group
45 will discuss the ratings and qualitative feedback received, including rewording suggestions per criterion,
46 suggestions to add new phases, steps or criteria and more general comments or questions. Criteria will be
47 revised if two or more respondents suggest it, or if the steering group members agree that the item would
48 benefit from rewording or merging.
49

50
51 Following the second survey round, a consensus meeting involving the steering group will be held. Decisions on
52 whether to conduct a third round and retain items in the scale will be made based on the ratings in the survey
53 rounds and feedback/comments from participants. The ratings will be summarized using percentages and the
54 views of all participants will be given equal weight. If at least 80% of participants rate the importance of the item
55 in the lower two categories, or in the higher two categories, we will consider consensus to be achieved and the
56 item will be removed or retained, respectively. If no consensus is achieved, the steering group will decide
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1
2 whether or not to retain a criterion, basing this decision on qualitative feedback from the participants where
3 possible, and the steering group's views.
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6

7 **DISCUSSION**

8 Patient decision aids must have accurate and trustworthy evidence-based information about the risks and
9 benefits of health treatments and tests, as these tools help patients make important healthcare choices. We
10 want to generate consensus on an approach for selecting and summarizing the evidence included in patient
11 decision aids, which we hope can be widely adopted by decision aid developers.
12

13 **STRENGTHS AND LIMITATIONS**

14 A strength of this study is the systematic involvement of patients and relevant stakeholders in planning the
15 modified Delphi survey. We plan to include a diverse sample of participant stakeholders including patients,
16 researchers, patient decision aid developers and health policy makers. Limitations of online surveys always
17 include the possibility of selection biases, meaning participants who opt to take the survey may be
18 systematically different than the target population. In our case, the participants may be more engaged and more
19 interested in the outcome of the Delphi survey. There is also a possibility that their views will be stronger than
20 those who opted not to participate.
21
22

23 **CONCLUSION**

24 Patients should be able to trust the information they receive from patient decision aids. Together with their
25 clinicians, family and caregivers, they rely on these tools to make decisions that are aligned with their informed
26 preferences. We believe standardizing a process for selecting and summarizing the evidence included in patient
27 decision aids is therefore a worthwhile effort. Bringing all relevant stakeholders to the table - patients,
28 researchers, patient decision aid developers, and healthcare policy makers - will ensure that the ultimate
29 outcome is rigorous and rooted in consensus, to promote widespread adoption.
30
31

32 **ETHICS AND DISSEMINATION**

33 Dartmouth College's Committee for the Protection of Human Subjects approved this protocol. We plan to
34 publish our results in a peer-reviewed journal.
35
36

37 **FUNDING**

38 We did not receive funding for this project.
39
40

41 **COMPETING INTERESTS**

42 Glyn Elwyn and Marie-Anne Durand have developed the Option Grid patient decision aids, and EBSCO
43 Information Services sells subscription access to Option Grid patient decision aids. They receive consulting
44 income from EBSCO Health, and may receive royalties in the future. Glyn Elwyn and Marie-Anne Durand are
45 consultant for ACCESS Community Health Network. Brian S. Alper is employed full-time by EBSCO Information
46 Services which is a for-profit company that publishes patient decision aids. No other competing interests
47 declared.
48

49 **AUTHORSHIP CONTRIBUTIONS**

50 Marie-Anne Durand, Glyn Elwyn and Michelle D. Dannenberg planned and designed the study. Catherine H.
51 Saunders, Anik Giguère, Brian S. Alper, Tammy Hoffmann, Lilisbeth Perestelo Perez and Stephen T. Campbell
52 provided advice and guidance on the design. Marie-Anne Durand drafted the manuscript and all authors
53 contributed to writing and approved the final draft of the manuscript.
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1
2 **Supplementary File 1: Survey Invitation**

3
4 SUBJ: Help us make more trustworthy patient materials: provide your feedback through a survey

5
6 To the members of [group name/list-serv name] –

7
8
9 We are an international workgroup, led by Marie-Anne Durand and Glyn Elwyn at The Dartmouth Institute for Health Policy and
10 Clinical Practice in Lebanon, N.H. We noticed a need for more clarity about how to select and summarize the evidence included
11 in patient decision aids. Patient decision aids influence the decisions that patients make - so the need for trustworthy tools is
12 important.
13

14
15 We wish to have your perspective, as an expert, patient, or other stakeholder.
16

17
18 **Please could you provide feedback via 2-3 surveys over the next few weeks?** Each survey should take less than 25
19 minutes.
20

21
22 Please click the link below for more information and the first survey.
23

24
25 Many thanks,
26

27
28 The Evidence Summarization workgroup
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For peer review only

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Evidence Summarization Survey

Information Sheet

SURVEY INFORMATION

What is the study about?

We want to generate consensus on an approach for selecting and summarizing the evidence included in patient decision aids. Our workgroup developed a proposed set of Phases, Steps and Criteria, based on the methods used to develop trustworthy clinical practice guidelines. The purpose of this survey is to gain your perspective, as an expert, patient or other stakeholder.

What is involved?

If you participate, we'll ask you to complete two or three surveys. In the first survey, we'll ask for your perspective on the proposed Phases, Steps and Criteria. This will include rating importance, suggesting wording changes and suggesting additional items. In the second and third surveys, we'll ask similar questions except we'll also share some results from the first survey.

How long will it take?

Completing this survey should take less than 25 minutes.

Do I have to take part?

No. Taking part is voluntary.

Will I be compensated?

You won't be compensated. However, we hope you'll take part. Your contributions

will improve the process of developing reliable, high-quality decision aids for patients.

Are there any risks?

We don't anticipate any risks from participating in the study.

How will my privacy be protected?

We won't name any individuals in any publications or presentations.

How can I contact you?

If you have questions, please feel free to contact Michelle Dannenberg (Michelle.D.Dannenberg@dartmouth.edu), Research Coordinator, The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth College.

If you would like to speak to the researchers leading this study, please contact Prof. Marie-Anne Durand (Marie-Anne.Durand@dartmouth.edu) or Prof. Glyn Elwyn (glynelwyn@gmail.com), The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth College.

What happens if I do not respond?

You'll receive two automated email reminders to complete the survey.

Do you want to participate?

Yes

No

Background Questions

BACKGROUND QUESTIONS

1 Which of the following best describes you? Please select all that apply.
2
3

- 4 Patient Decision Aid (PDA) developer
- 5
- 6 Researcher
- 7
- 8 International Patient Decision Aids Standards (IPDAS) collaboration member
- 9
- 10 Policy maker
- 11
- 12 Patient
- 13
- 14
- 15 Clinician, please specify specialty:
- 16
- 17
- 18 Other, please specify:
- 19
- 20
- 21
- 22

23 Which country do you live in?
24

25

26

27

28

29

30 What is your gender?
31

- 32
- 33 Male
- 34
- 35 Female
- 36
- 37 Other
- 38
- 39
- 40
- 41

42 What is your race/ethnicity? Please select all that apply.
43

- 44
- 45 American Indian or Alaska Native
- 46
- 47 Asian
- 48
- 49 Black or African American
- 50
- 51 Native Hawaiian or Other Pacific Islander
- 52
- 53 Hispanic, Latino/a or Spanish Origin
- 54
- 55 White
- 56
- 57
- 58

Other, please specify:

BACKGROUND QUESTIONS

We're requesting your email address so we can contact you for the next phase of this project. We will not share your email with anyone outside the study team, and we will not contact you about anything other than the study.

Please provide your email:

Overall Proposed Phases, Steps and Criteria

INFORMATION ON PROPOSED PROCESS

Decision aids are tools that help patients make choices. They provide information about the risks and benefits of health treatments and tests.

Accurate and clear information is critical. It's important for decision aids to have accurate and trustworthy information from research evidence about the risks and benefits of health treatments and tests.

We're trying to make evidence summarization easier. We're doing this by developing a process to guide decision aid developers in evidence summarization.

We're building on the good work that's already been done. This process includes the existing work of the International Patient Decision Aid Standards (IPDAS) collaboration.

We sketched out a proposed process, see Figure below. We are interested in your feedback on ALL elements of this, including the Phases, Steps and Criteria, as

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

well as the order and grouping.

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3 **Here's how you can help.** In the questions that follow, we will ask for your
4 perspective on **how important each criterion is to include in the proposed**
5 **process.** We will also ask for feedback on the wording of all parts. Nothing is final.
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7 Everything is up for discussion, and we are looking forward to hearing from you.
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11 **Below is a visual representation of the proposed process.** Review it carefully.
12 There are four proposed phases, each with one to five proposed steps. Each step
13 has a number of proposed Criteria. In the visual representation below, we show the
14 first Criteria for each step. The tabs represent additional Criteria.
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20 Feel free to [click here](#) to view the representation of the proposed Phases, Steps
21 and Criteria in a separate window. You can click on the image to zoom. You can
22 refer back to this image as you answer questions about the proposed process. Don't
23 worry, if you accidentally close the window, there are links to the figure on each page
24 of the survey.
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Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

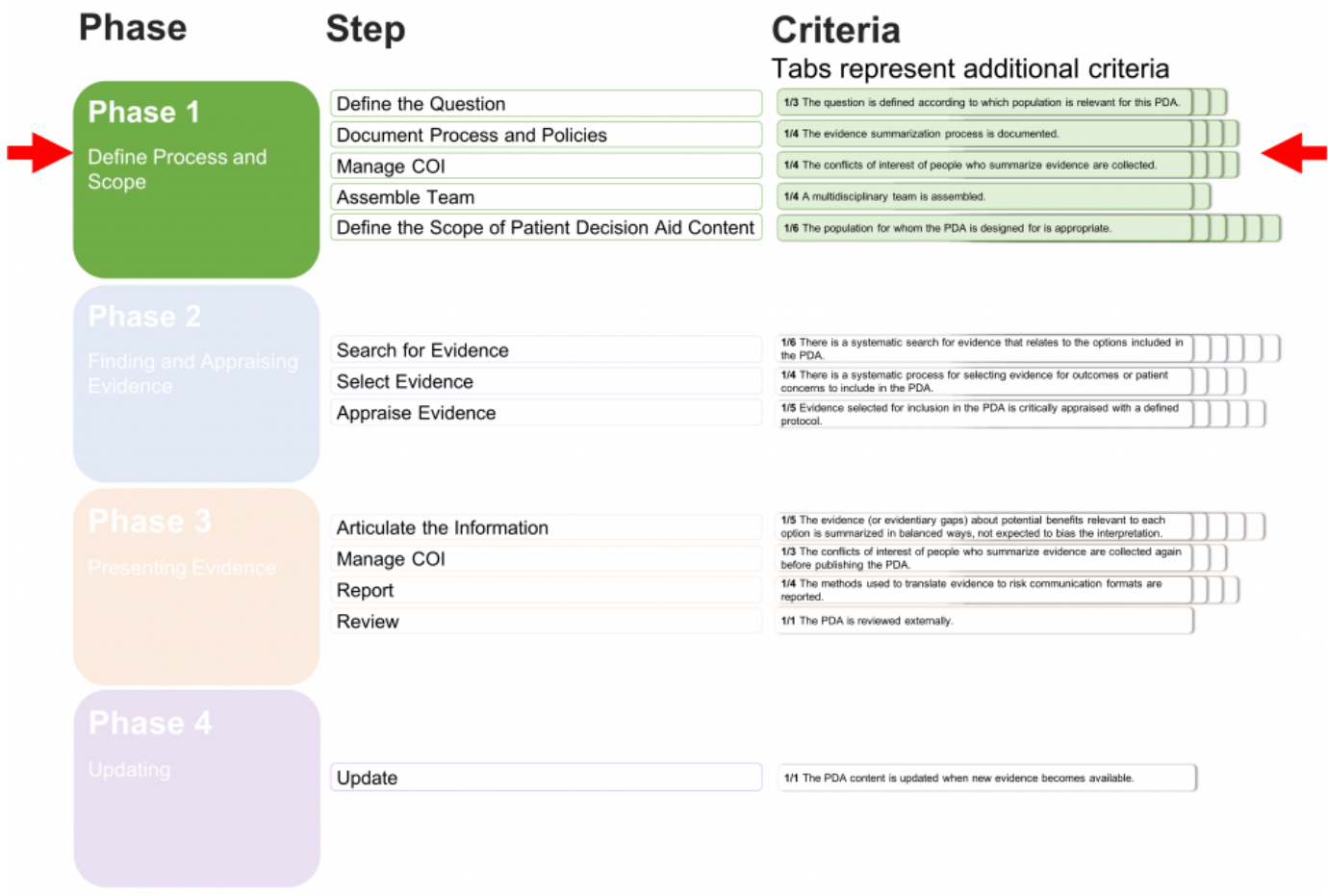
Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.

Phase 1

PROPOSED PHASE 1

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Phase below? If so, please share them.

- Phase 1: Defining Process and Scope**

1 Do you have any comments on the Steps below, including their wording or order? Or
2 suggestions for additional steps? If so, please share them.
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- 5 • **Step 1: Define the Question**
- 6 • **Step 2: Document Process and Policies**
- 7 • **Step 3: Manage COI**
- 8 • **Step 4: Assemble Team**
- 9 • **Step 5: Define the Scope of Patient Decision Aid Content**
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20 **PROPOSED PHASE 1 STEP 1**

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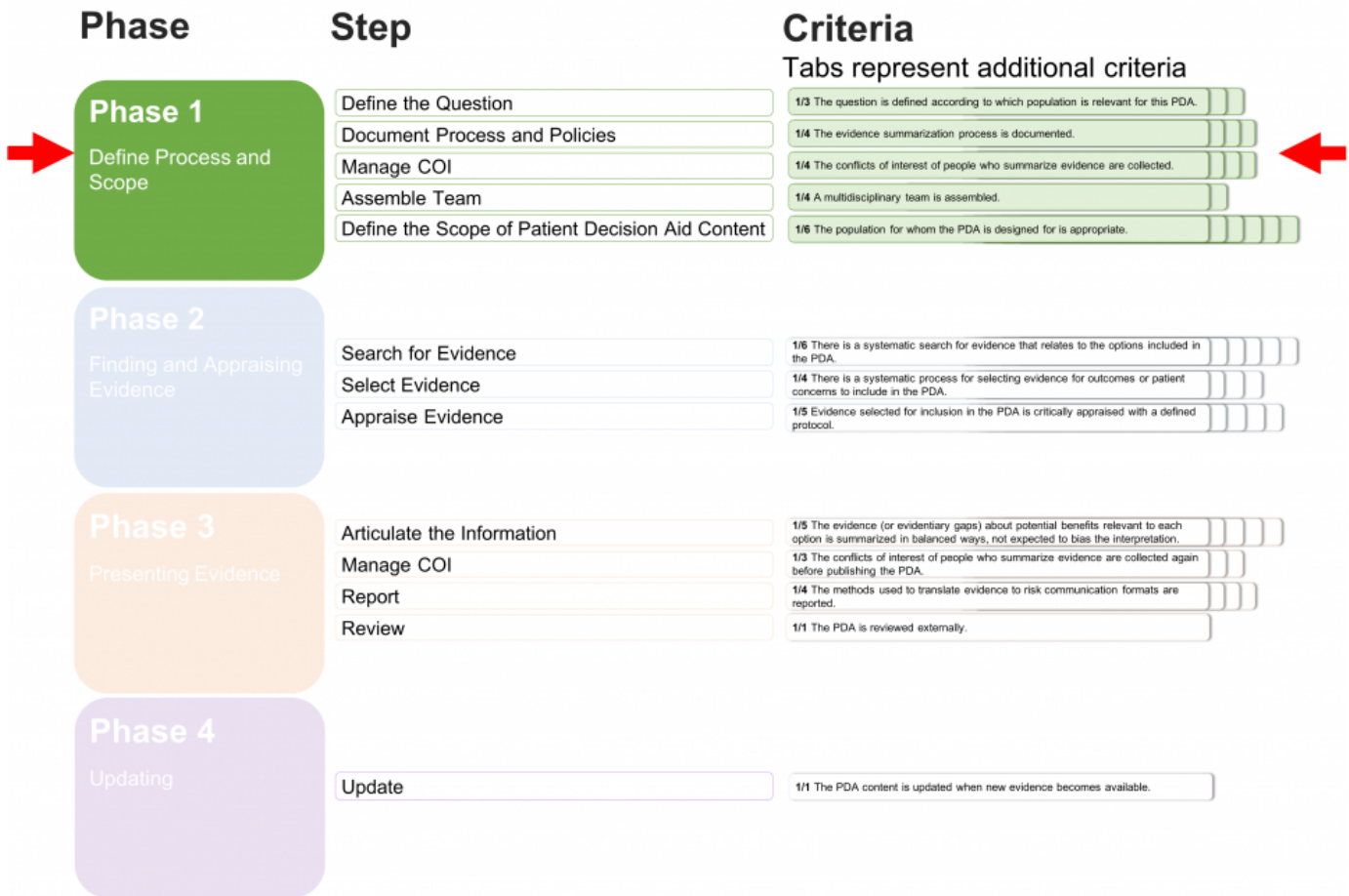
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Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- Step 1: Define the Question**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible Desira

The question is defined according to which population is relevant for this PDA.

The question is defined according to which options are relevant for this PDA.

The question is defined according to which outcomes or patient concerns are relevant for this PDA.

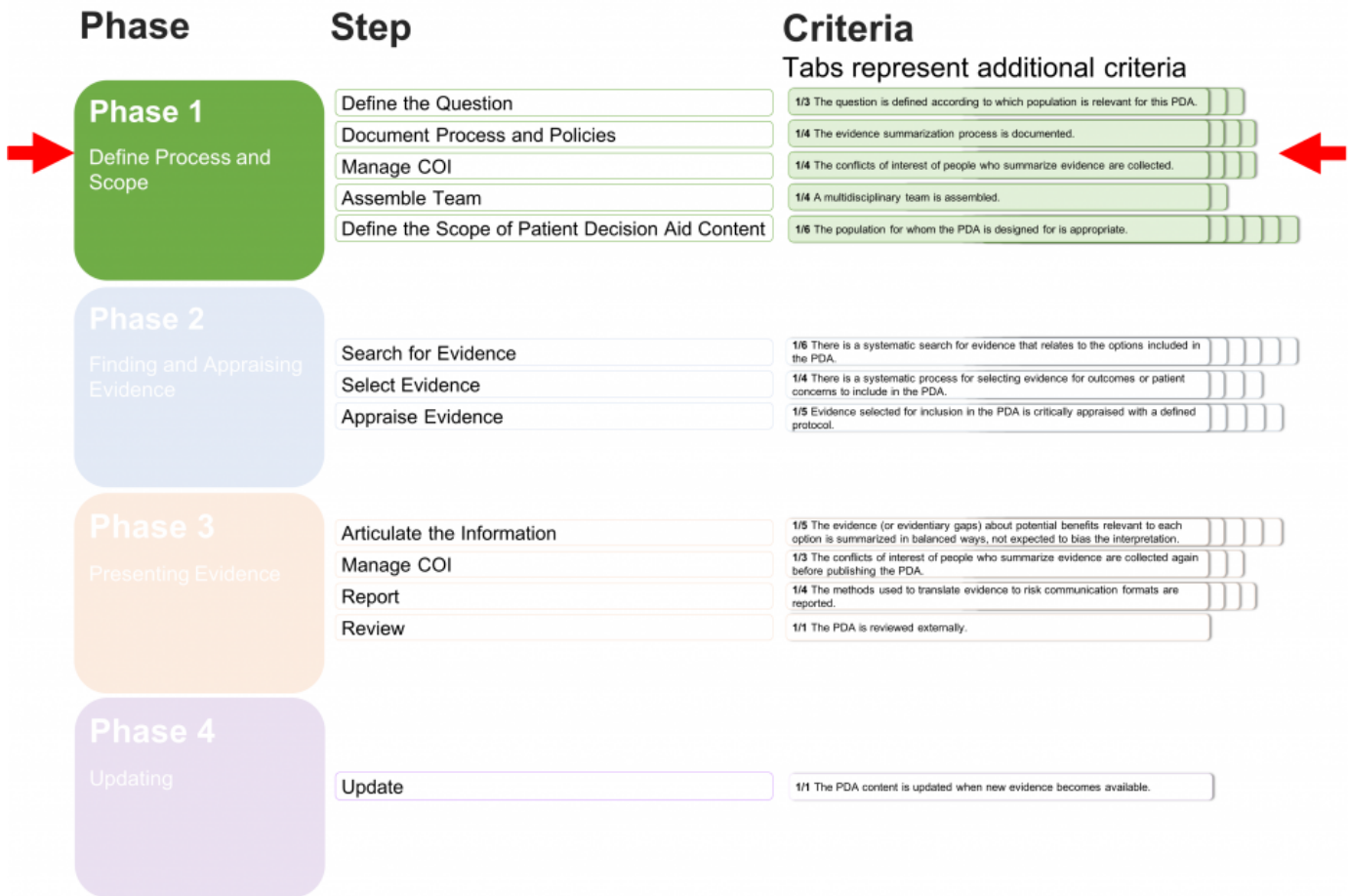
Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 1 STEP 2

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on this Step? If so, please share them.

- **Step 2: Document Process and Policies**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

- The evidence summarization process is documented.
- The evidence summarization process minimizes bias.
- The evidence summarization process minimizes conflicts of interest.
- The conflict of interest policy applying to people who summarize evidence is documented.

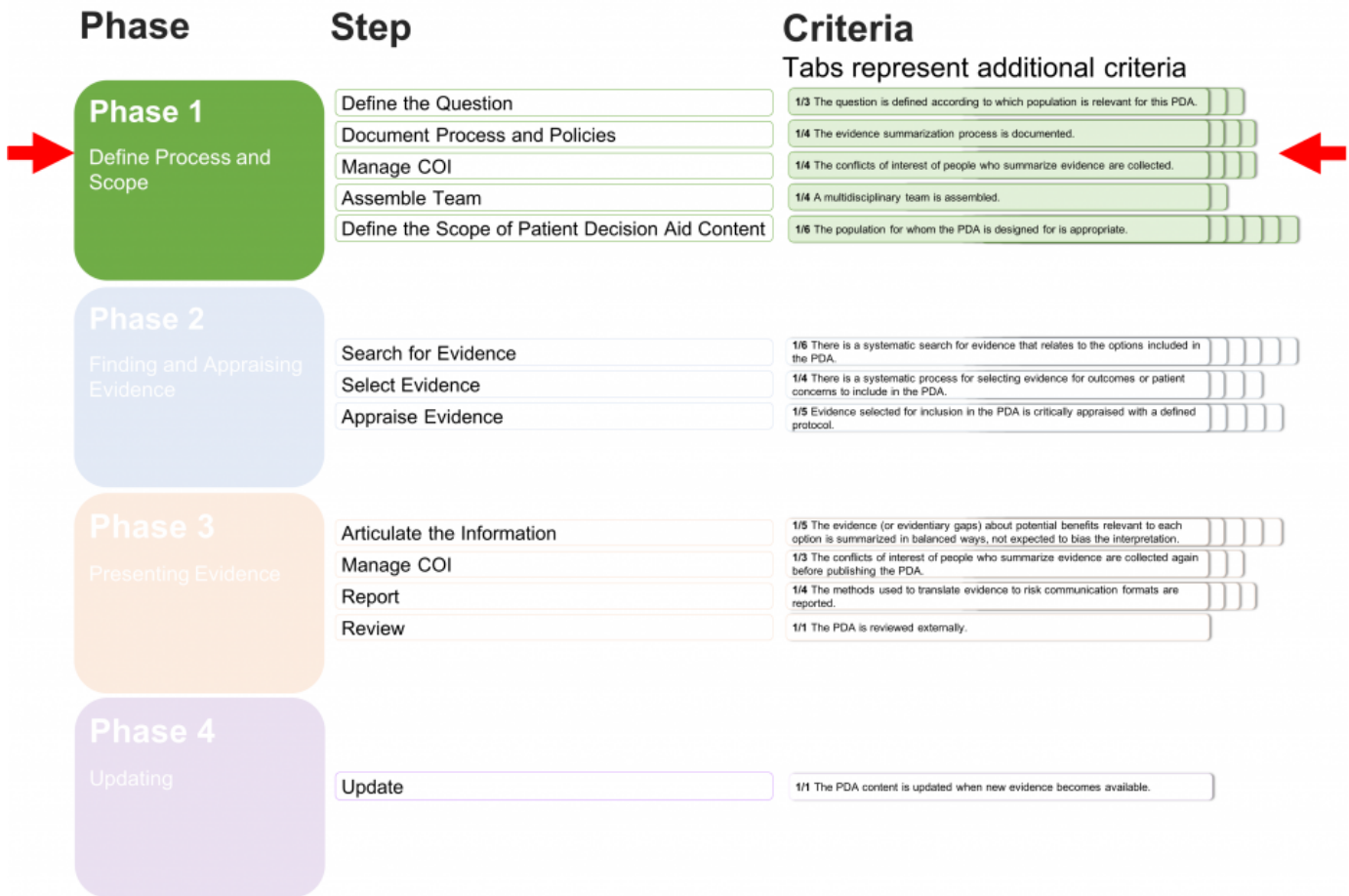
Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 1 STEP 3

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on this Step? If so, please share them.

- **Step 3: Manage COI**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

The conflicts of interest of people who summarize evidence are collected.

Actions are taken to manage relevant conflicts of interest.

The actions taken on relevant conflicts of interest are documented.

Conflicts of interest are monitored over the course of PDA development.

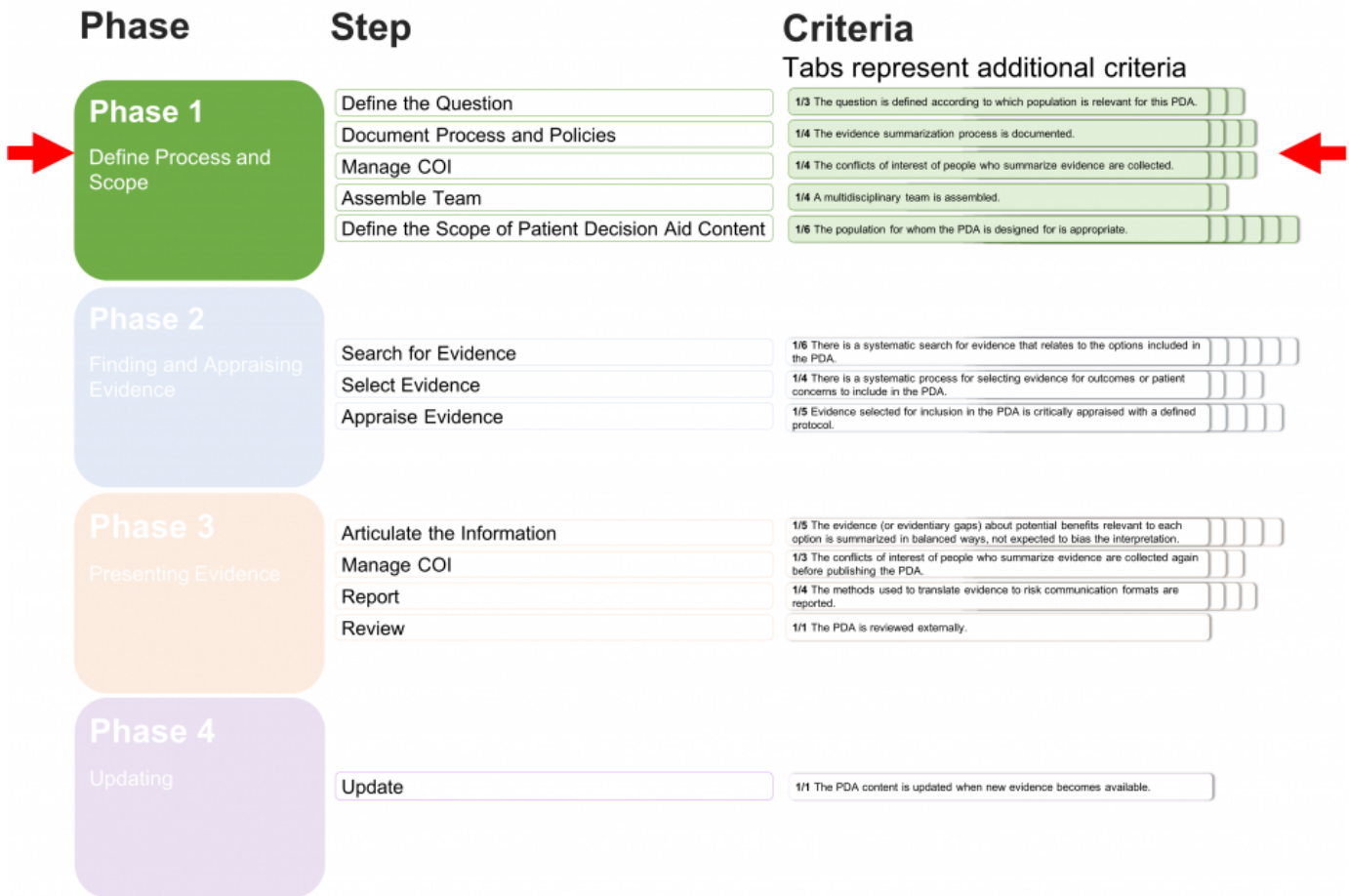
Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 1 STEP 4

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 4: Assemble Team**

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The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible [

A multidisciplinary team is assembled.

The team comprises clinicians.

The team comprises methodological experts.

The team comprises patient or consumer representatives.

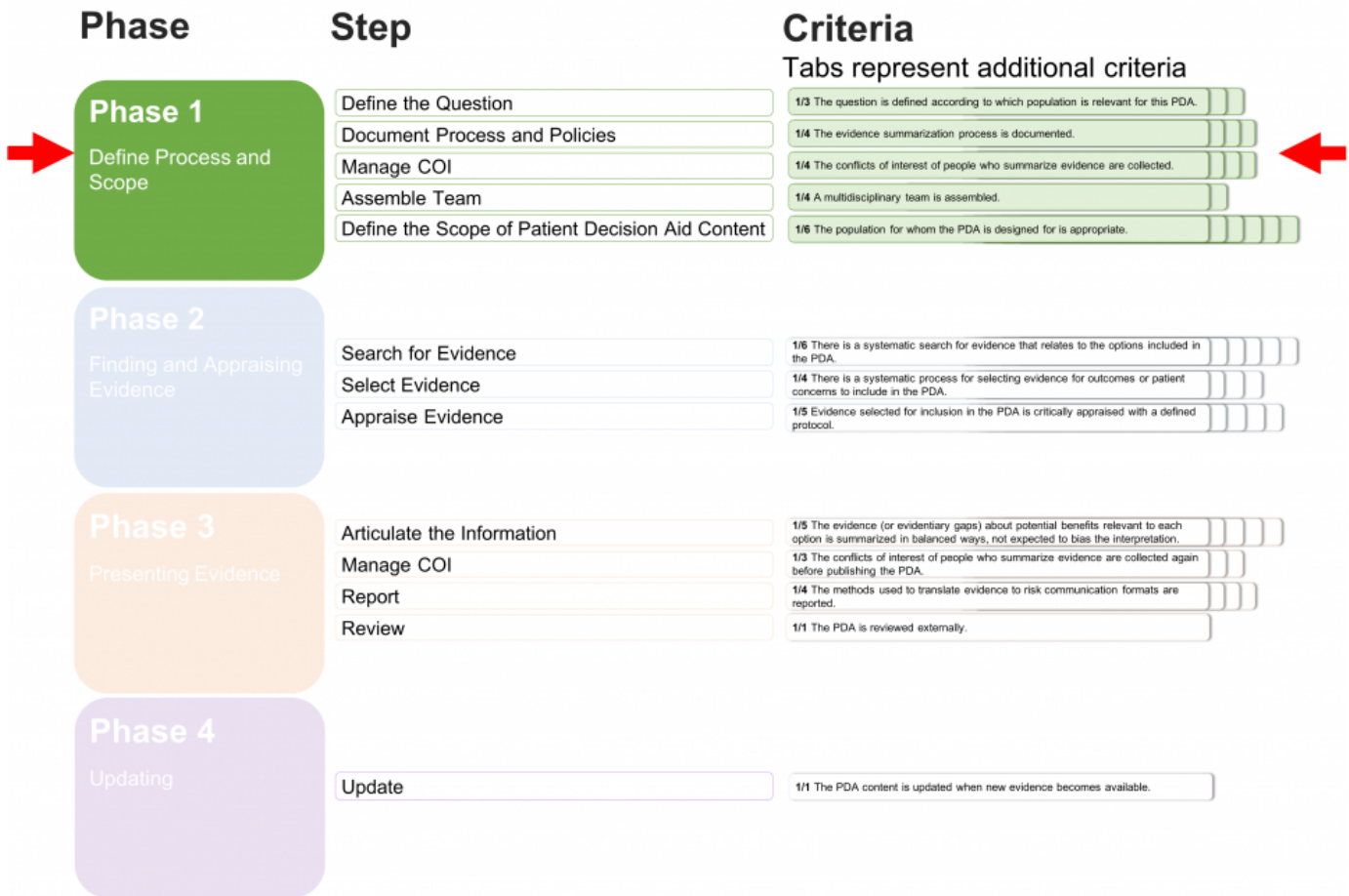
Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 1 STEP 5

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- Step 5: Define the Scope of Patient Decision Aid Content**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible C

The population for whom the PDA is designed for is appropriate.

There is a systematic process to reduce bias in the definition of the population for the PDA.

The options for inclusion in the PDA are appropriate for the intended population.

There is a systematic process to reduce bias in the definition of the options for the PDA.

The outcomes or patient concerns for inclusion in the PDA are appropriate for the intended population and options.

There is a systematic process to reduce bias in the definition of the outcomes or patient concerns for the PDA.

Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

Phase 2

PROPOSED PHASE 2

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase

Step

Criteria

Tabs represent additional criteria

Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.

Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

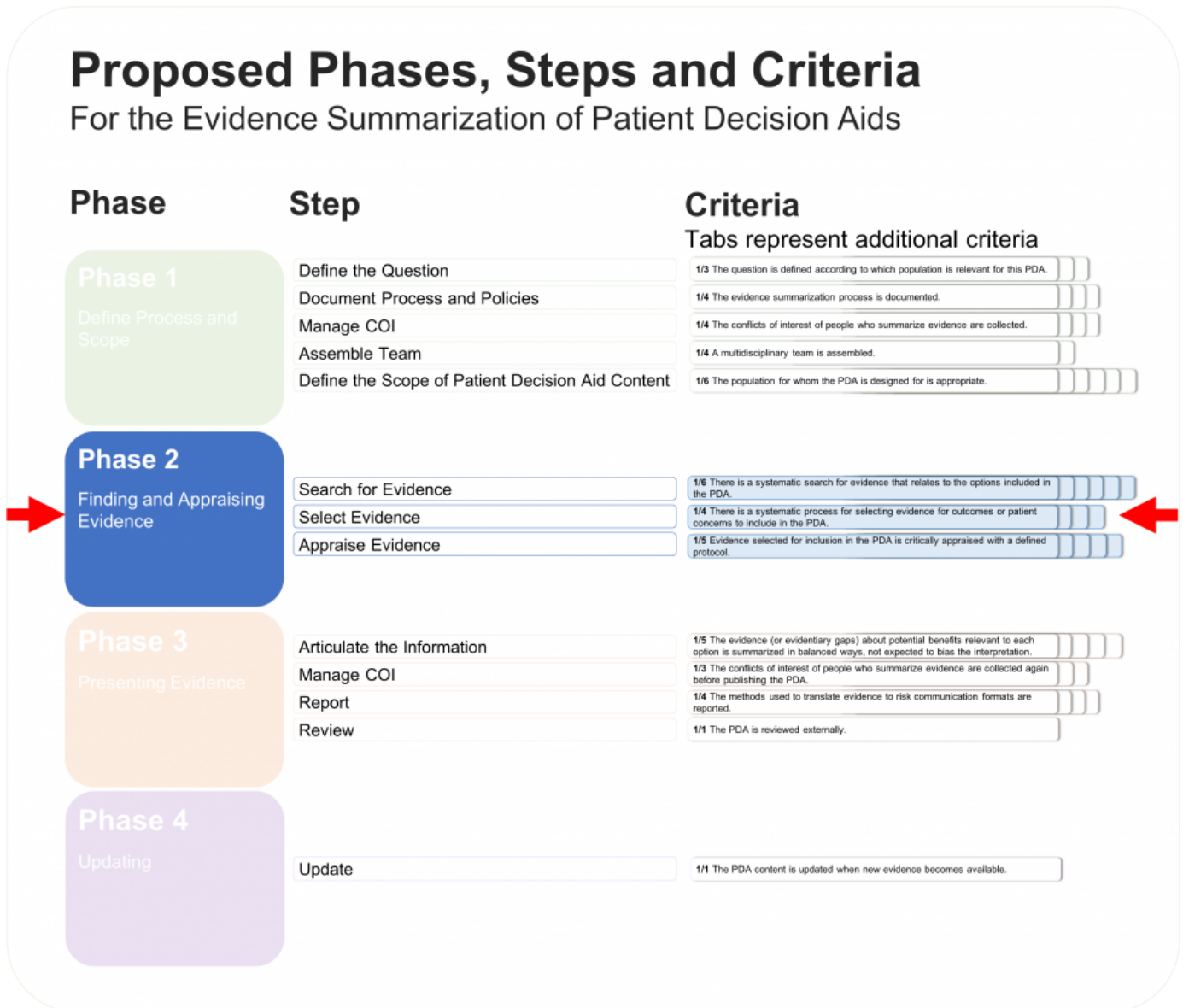
Do you have any comments or suggestions on the Phase below? If so, please share them.

- Phase 2: Finding & Appraising Evidence**

Do you have any comments on the Steps below, including their wording or order? Or suggestions for additional steps? If so, please share them.

- Step 1: Search for Evidence
- Step 2: Select Evidence
- Step 3: Appraise Evidence

PROPOSED PHASE 2 STEP 1



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Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on this Step? If so, please share them.

- Step 1: Search for Evidence**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	Essential
There is a systematic search for evidence that relates to the options included in the PDA.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
There is a systematic search for evidence that relates to the outcomes or patient concerns included in the PDA.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If the PDA is customizable to individual patient factors, there is a systematic search for evidence of how individual patient factors influence the expected outcomes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 2 STEP 2

Proposed Phases, Steps and Criteria For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.

Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 2: Select Evidence**

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4 The proposed Criteria for this step are below. Please indicate whether each
5 Criterium should be omitted, or whether it is a possible candidate for inclusion,
6 a desirable candidate for inclusion or is essential for inclusion.
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	Omit	Possible	Essential
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Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 2 STEP 3

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
	Update	1/1 The PDA content is updated when new evidence becomes available.

Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 3: Appraise Evidence**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

Evidence selected for inclusion in the PDA is critically appraised with a defined protocol (such as GRADE).

The protocol for critical appraisal of evidence accounts for risks of bias in study design.

The protocol for critical appraisal of evidence accounts for risks of bias in study analysis and reporting.

The protocol for critical appraisal of evidence accounts for assessment of certainty of evidence with attention to risk of bias, precision, directness, consistency, and publication bias.

The conflicts of interest of study authors related to selected evidence is appraised.

Do you have any comments or suggestions on the Criteria above? If so, please share them.

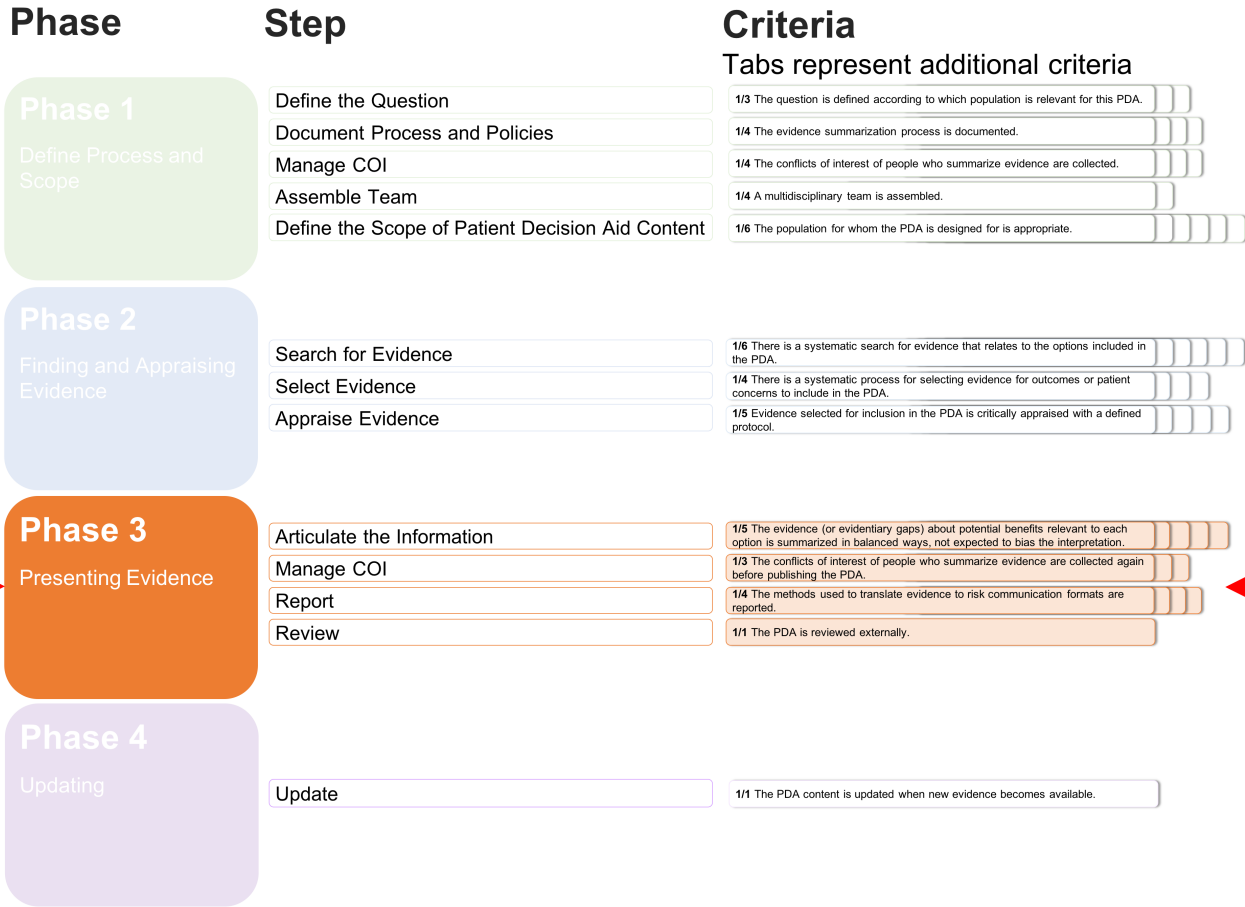
Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

Phase 3

PROPOSED PHASE 3

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Phase below? If so, please share them.

- Phase 3: Presenting Evidence

Do you have any comments on the Steps below, including their wording or order? Or do you have suggestions for additional steps? If so, please share them.

- Step 1: Articulate the Information
- Step 2: Manage COI
- Step 3: Report
- Step 4: Review

PROPOSED PHASE 3 STEP 1

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.



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Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

• **Step 1: Articulate the Information**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	Essential
The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The evidence (or evidentiary gaps) about potential harms relevant to each option is summarized in balanced ways, not expected to bias the interpretation.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The evidence (or evidentiary gaps) is summarized in ways that are easy to understand.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The certainty of the evidence is described in ways that are easy to understand.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The evidence summarization process is described in ways that are easy to understand.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The funding used to summarize the evidence (and develop the PDA) is reported.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

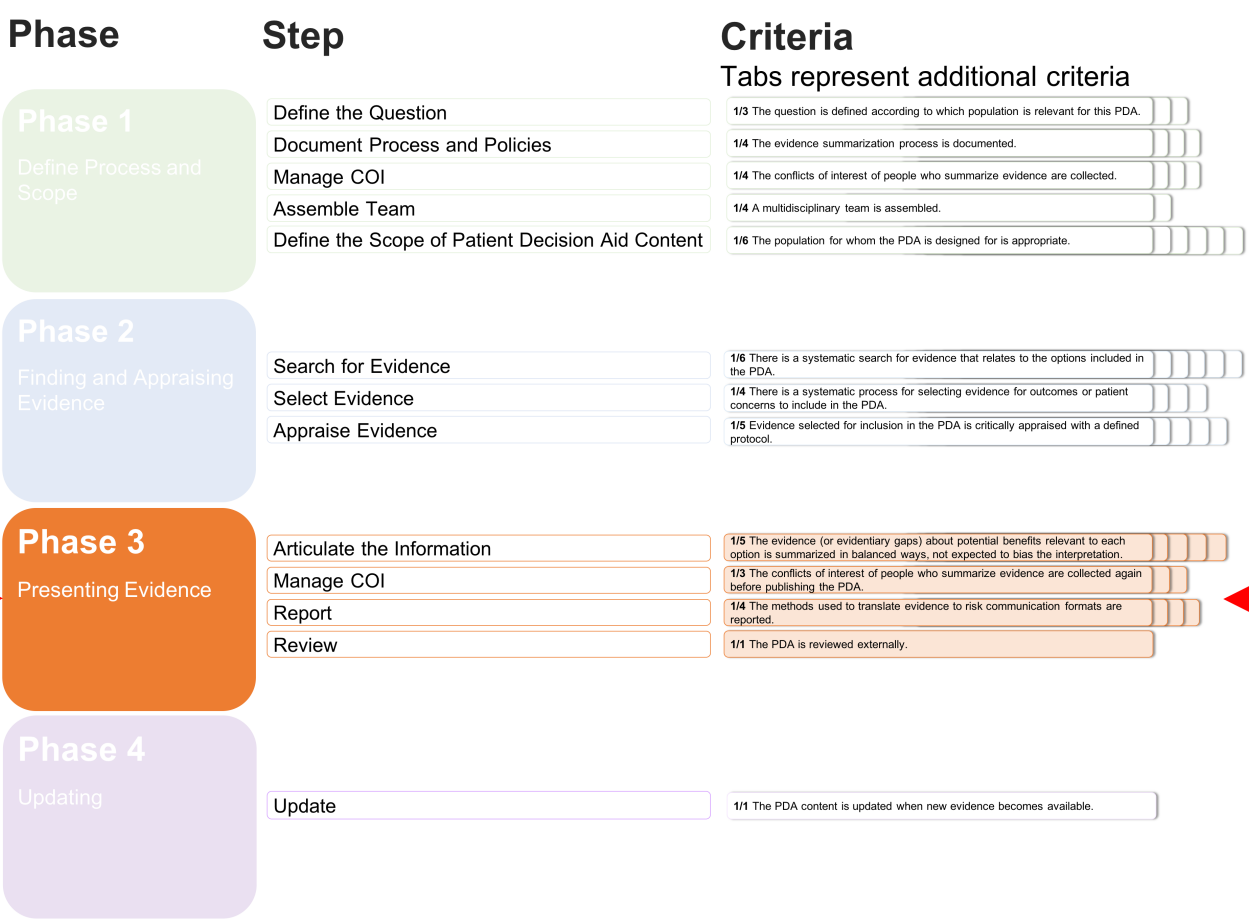
Do you have any comments or suggestions on the wording or order of any of the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 3 STEP 2

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

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3 them.
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7 • **Step 2: Manage COI**
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16 Criterium should be omitted, or whether it is a possible candidate for inclusion,
17 a desirable candidate for inclusion or is essential for inclusion.
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22 Omit Possible E

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24 The conflicts of interest of people who summarize evidence are
25 collected again before publishing the PDA.

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27 Any change to the conflicts of interest of people who summarize
28 evidence are reported.

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30 Actions are taken to manage relevant conflicts of interest.

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35 Do you have any comments or suggestions on the wording or order of any of the
36 Criteria above? If so, please share them.
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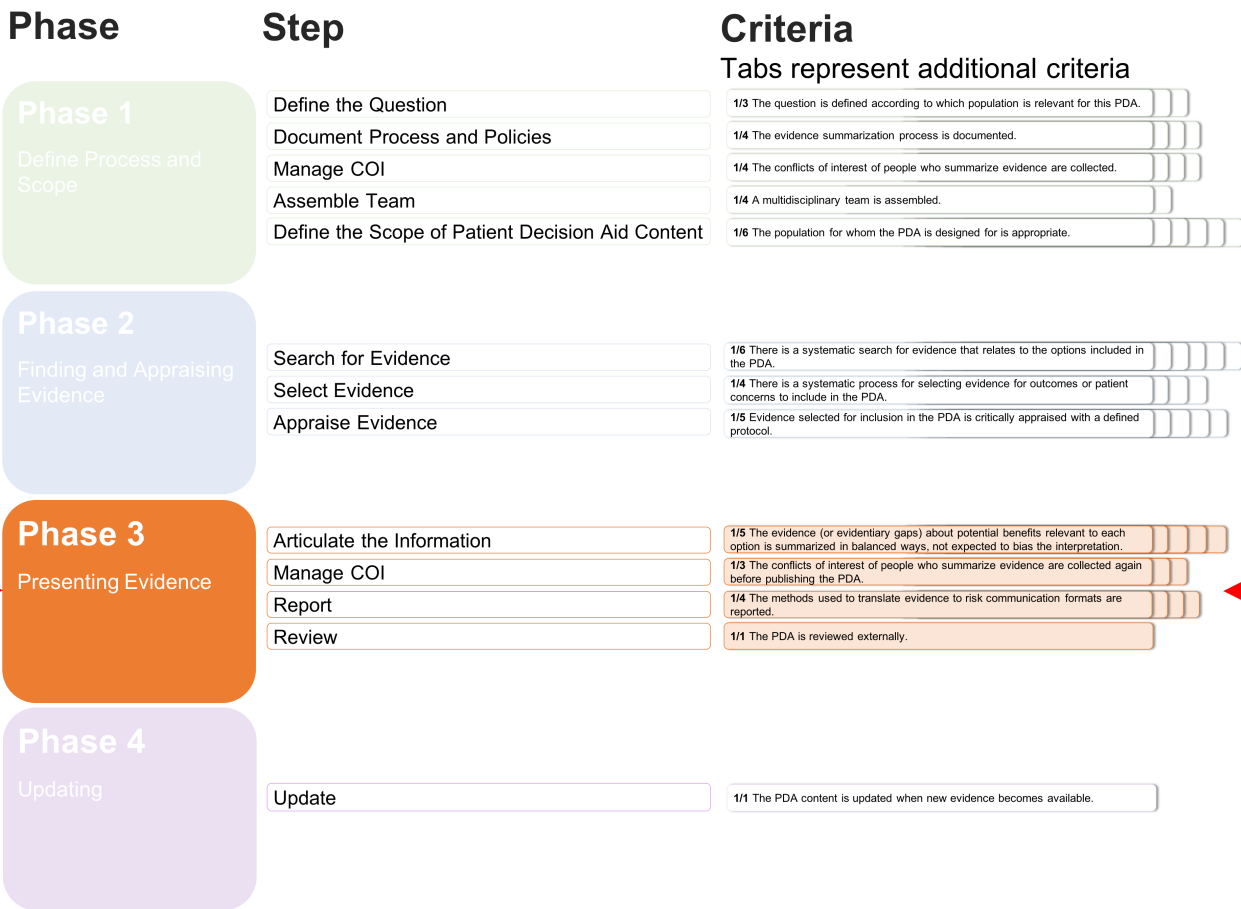
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44 Do you have any suggestions for additional Criteria to include in this Step? If so,
45 please share them.
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53 **PROPOSED PHASE 3 STEP 3**
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Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 3: Report**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

The methods used to translate evidence to risk communication formats are reported.

The approach to readability of summarized evidence is reported.

The summarization process is reported publicly.

The conflict of interest of people who summarize evidence are reported publicly.

Do you have any comments or suggestions on the wording or order of any of the Criteria above? If so, please share them.

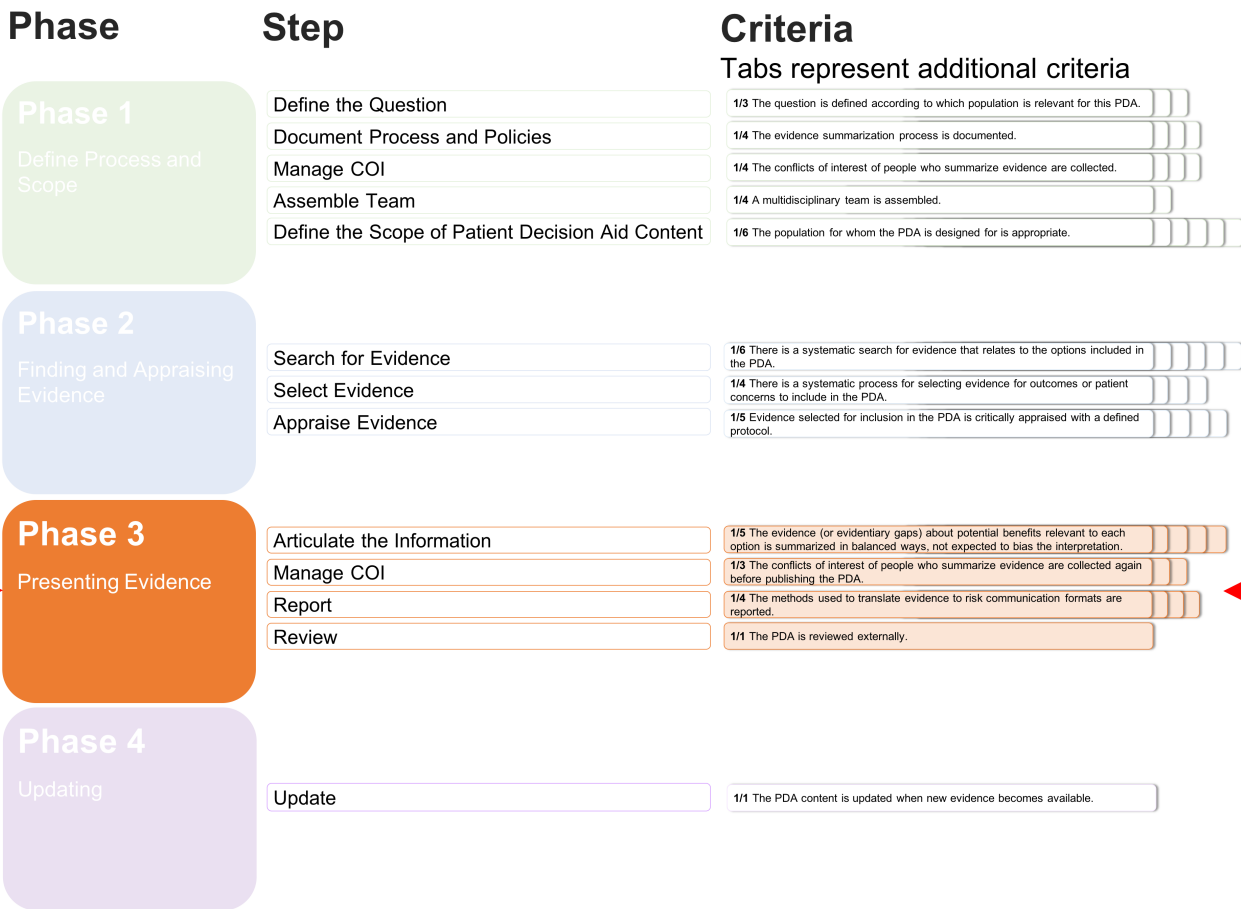
Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 3 STEP 4

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Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 4: Review**

The proposed Criteria for this step are below. Please indicate whether each criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit F

The PDA is reviewed externally.

Do you have any comments or suggestions on the wording or order of any of the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

Phase 4

PROPOSED PHASE 4

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Phase below? If so, please share them.

- Phase 4: Updating**

1 Do you have any comments or suggestions on the Step below. If so, please share
2 them.
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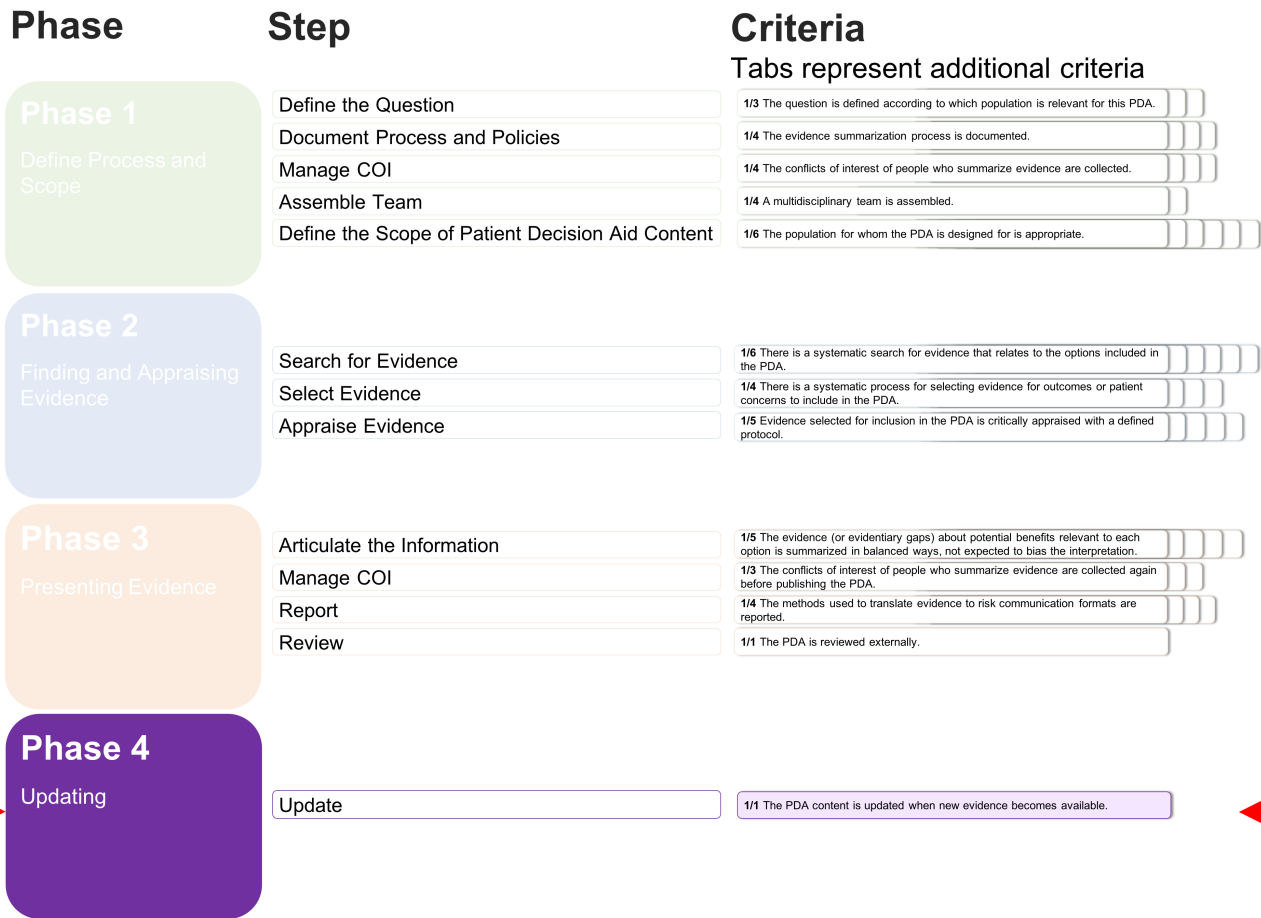
5 • **Step 1: Update**
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13 **PROPOSED PHASE 4 STEP 1**
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19 **Proposed Phases, Steps and Criteria**

20 For the Evidence Summarization of Patient Decision Aids
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1 Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and
2 Criteria in a separate window while you complete the questions below.
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6 Do you have any comments or suggestions on the Step below? If so, please share
7 them.
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10 • **Step 1: Update**
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19 The proposed Criteria for this step are below. Please indicate whether each criterium
20 should be omitted, or whether it is a possible candidate for inclusion,
21 a desirable candidate for inclusion or is essential for inclusion.
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27 The PDA content is updated when new evidence becomes
28 available.
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33 Do you have any comments or suggestions on the wording of the criterion above? If
34 so, please share them.
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42 Do you have any suggestions for additional criteria to include in this Step? If so,
43 please share them.
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Supplementary File 3: Proposed Phases, Steps, and Criteria

Existing standard (from IOM & USPSTF)	Phase	Step	Criteria
Establishing transparency	Phase I: Define Process and Scope	Define the question	The question is defined according to which population is relevant for this PDA.
			The question is defined according to which options are relevant for this PDA.
			The question is defined according to which outcomes or patient concerns are relevant for this PDA.
		Document process and policies	The evidence summarization process is documented.
			The evidence summarization process minimizes bias.
			The evidence summarization process minimizes conflicts of interest.
			The conflict of interest policy applying to people who summarize evidence is documented.
Management of conflict of interest	Manage COI	The conflicts of interest of people who summarize evidence are collected.	
		Actions are taken to manage relevant conflicts of interest.	
		The actions taken on relevant conflicts of interest are documented.	
		Conflicts of interest are monitored over the course of PDA development.	
Guideline development group composition	Assemble team	A multidisciplinary team is assembled.	
		The team comprises clinicians.	
		The team comprises methodological experts.	
		The team comprises patient or consumer representatives.	
	Define the scope of patient decision aid content	The population for whom the PDA is designed for is appropriate.	
		There is a systematic process to reduce bias in the definition of the population for the PDA.	
		The options for inclusion in the PDA are appropriate for the intended population.	
		There is a systematic process to reduce bias in the definition of the options for the PDA.	
		The outcomes or patient concerns for inclusion in the PDA are appropriate for the intended population and options.	

			There is a systematic process to reduce bias in the definition of the outcomes or patient concerns for the PDA.
Guideline and systematic review intersection	PHASE II: Finding & Appraising Evidence	Search for evidence	There is a systematic search for evidence that relates to the options included in the PDA.
			There is a systematic search for evidence that relates to the outcomes or patient concerns included in the PDA.
			If the PDA is customizable to individual patient factors, there is a systematic search for evidence of how individual patient factors influence the expected outcomes.
Establishing evidence foundations and rating strength of recommendation		Select evidence	There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA (where evidence is not available, can directly ask patients).
			There is a systematic process for selecting evidence (or evidentiary gaps) about potential benefits relevant to each option.
			There is a systematic process for selecting evidence (or evidentiary gaps) about potential harms relevant to each option.
			If the PDA is customizable to individual patient factors, there is a systematic process for selecting relevant risk predictors to include in the PDA.
		Appraise evidence	Evidence selected for inclusion in the PDA is critically appraised with a defined protocol (such as GRADE).
			The protocol for critical appraisal of evidence accounts for risks of bias in study design.
			The protocol for critical appraisal of evidence accounts for risks of bias in study analysis and reporting.
Articulation of information	PHASE III: Presenting Evidence	Articulate the information	The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
			The evidence (or evidentiary gaps) about potential harms relevant to each option is summarized in balanced ways, not expected to bias the interpretation.

			The evidence (or evidentiary gaps) is summarized in ways that are easy to understand.
			The certainty of the evidence is described in ways that are easy to understand.
			The evidence summarization process is described in ways that are easy understand.
			The funding used to summarize the evidence (and develop the PDA) is reported.
		Manage COI	The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
			Any change to the conflicts of interest of people who summarize evidence are reported.
			Actions are taken to manage relevant conflicts of interest.
		Report	The methods used to translate evidence to risk communication formats are reported.
			The approach to readability of summarized evidence is reported.
			The summarization process is reported publicly.
			The conflict of interest of people who summarize evidence are reported publicly.
		Review	The PDA is reviewed externally.
Updating	PHASE IV: Post-publication update	Update	The PDA content is updated when new evidence becomes available.

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BMJ Open

Study protocol: A modified Delphi survey for the evidence summarization of patient decision aids

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Manuscript ID	bmjopen-2018-026701.R1
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SCHOLARONE™
Manuscripts

Study protocol: A modified Delphi survey for the evidence summarization of patient decision aids

Running heading: Evidence summarization Delphi survey

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ABSTRACT FOR PROTOCOL

Introduction

Information included in a Patient Decision Aid (PDA) can significantly influence patients' decisions and is, therefore, expected to be evidence based and rigorously selected and summarized. Yet patient decision aid developers have not yet agreed on a standardized process for the selection and summarization of the supporting evidence. We intend to generate consensus on a process (and related steps and criteria) for selecting and summarizing evidence for patient decision aids using a modified Delphi survey.

Methods and Analysis

We will develop an evidence summarization process specific to PDA development by using a consensus-based Delphi approach, surveying international experts and stakeholders with two to three rounds. To increase generalizability and acceptability, we will distribute the survey to the following stakeholder groups: patient decision aid developers, researchers with expertise in shared decision making, patient decision aid development and evidence summarization, members of the International Patient Decision Aid Standards group, policy makers with expertise in patient decision aid certification, and patient stakeholder groups. For each criterion, if at least 80% of survey participants rank the criterion as most important/least important, we will consider consensus achieved.

Ethics and Dissemination

It is critical for patient decision aids to have accurate and trustworthy evidence-based information about the risks and benefits of health treatments and tests, as these decision aids help patients make important choices. We want to generate consensus on an approach for selecting and summarizing the evidence included in patient decision aids, which can be widely implemented by decision aid developers. Dartmouth College's Committee for the Protection of Human Subjects approved this protocol. We will publish our results in a peer-reviewed journal.

Words: 265

Article Summary

- Gap: There is no standardized method for selecting and summarizing the evidence in patient decision aids.
- Solution: We're developing a process to ensure patient decision aids have the most up-to-date, trustworthy evidence available.
- Clinical implications: This will help patients and clinicians know they can trust the information in patient decision aids, so they can make the best decisions together.
- Health systems implications: Knowing that the evidence selection and summarization process is rigorous, healthcare systems may feel more comfortable including patient decision aids in routine care.
- Strengths: Systematic involvement of patient stakeholders.
- Limitations: Limitations of online surveys include selection bias.

INTRODUCTION

Patient Decision Aids (PDAs) are tools that help patients and their clinicians make preference-sensitive decisions together. They are typically defined as: “evidence-based tools designed to help patients make specific and deliberated choices among healthcare options. Patient decision aids supplement (rather than replace) clinicians' counselling about options”[1][2]. They promote patient engagement in medical decision making, collaboration between patients and their care team, increase knowledge and align patients' choices with their preferences [1]. Therefore, the information included in PDAs can significantly impact patients' decisions. For this reason, patients and clinicians expect the information in PDAs to be evidence based and rigorously selected and summarized.

The approach that PDA developers use to select and summarize the evidence in PDAs, however, appears inconsistent. A recent international cross sectional survey of 15 PDA developers confirms that they do not have an agreed-upon, standardized process to select and summarize evidence. They also do not always document the evidence selection and summarization process [3]. Most organizations reported using existing systematic reviews and clinical practice guidelines to select and summarize information for PDAs. Less than half reported using a standard, documented approach to guide the evidence selection and summarization. When the approach was documented, the documents offered varying levels of detail. Common evidence summarization steps identified were: tool-relevant question formation, search strategies, evidence appraisals, and updating policies. There was no standardized process across organizations to summarize evidence for PDAs. Although agreed-upon approaches and tested methods for evidence summarization exist in other areas, such as clinical practice guidelines, there is no agreed process (including steps and criteria within each step) for the selection and summarization of evidence for PDAs.

The International Patient Decision Aids Standards (IPDAS) collaboration developed criteria for assessing the quality of PDAs [4]. These criteria are also used by PDA producers to guide the development of the interventions. However, only six items of the IPDAS checklist cover the selection and summarization of evidence, and do not provide any guidance about recommended methods for the evidence selection and summarization of PDAs [4]. A 2013 review of the literature conducted by the IPDAS working group on the synthesis of scientific evidence highlighted the importance of rigorously selecting and summarizing evidence used to populate a patient decision aid. They did not provide clear practical guidance on how to conduct evidence summarization for the development of patient decision aids except recommending that developers apply the GRADE methodology [5]. Further, the IPDAS instrument and the IPDAS minimum standards do not offer additional information or guidance on the steps required to select and summarize evidence-based information for PDAs [6][7]. Other efforts to evaluate or certify the quality of PDAs have emerged [8], but none of those standards or certification bodies describe recommended methods and criteria that PDAs producers should follow when selecting and summarizing evidence for patient-facing interventions.

Evidence summarization in other medical contexts is increasingly standardized, such as the selection and summarization of evidence for clinical practice guidelines and systematic reviews. This process promotes transparency, rigor, and minimizes the risk of bias in the end product [2] [9][10][11][12][13][14][15][16][17]. The same level of scrutiny is justified when developing PDAs, as they may directly influence patient care and decision making. Tasks such as the selection and

1 identification of patient-relevant outcomes, analysis of patient concerns and priorities, description of
2 the quality of evidence, and communication of uncertainty in ways that patients understand warrants
3 the development of an agreed process and related steps and criteria that are specific to PDAs. For
4 those reasons, it would not be appropriate to apply evidence summarization processes developed for
5 clinical guidelines without integrating the evidence summarization steps and components that are
6 specific to the development of interventions that target patients. The target group, scope and content
7 differ significantly enough from clinical practice guidelines development, thus requiring a tailored
8 evidence summarization process. Additionally, the IPDAS standards impose some prerequisites on the
9 evidence summarization process on which the decision aid will be based. For example, IPDAS requires
10 that the decision aid summarizes the evidence regarding all health options available to a patient facing
11 a specific health problem, and that decision aids present positive and negative features of each option
12 with an equal amount of details, among other specificities [18]. Efforts to develop an agreed evidence
13 summarization process for PDAs should incorporate the substantial body of related evidence
14 summarization guidance previously developed by other groups, and notably for clinical practice
15 guidelines previously mentioned [11].

21 **Objective**

22 The purpose of the study is to generate consensus on a process (and related steps and criteria) for
23 selecting and summarizing evidence for patient decision aids using a modified Delphi survey. This will
24 in turn improve transparency, rigor and minimize the risk of bias of the evidence summarization
25 processes leading to the development of patient decision aids.

28 **2 METHODS**

31 **Study Design and Procedures**

32 We will develop an evidence summarization process specific to PDA development by using a
33 consensus-based Delphi approach previously used in the development of a quality criteria framework
34 for PDAs [2] [19]. Consensus methods can harness the views of international experts on a wide range
35 of information and questions in order to make decisions that are based on expert consensus [20]. We
36 will conduct a multi-round modified Delphi survey (two to three rounds). Compared to the nominal
37 group technique, it is the most practical and scalable method to obtain feedback from a large number
38 of stakeholders in different geographic locations. During the multiple rounds of online questionnaires,
39 relevant stakeholders will be consulted to provide feedback about the evolving set of evidence
40 summarization steps and criteria. The anonymous responses from participants will be fed back to them
41 in subsequent rounds. Depending on the level of consensus after two rounds (see Data Analysis
42 section), we will determine whether to conduct a third survey round.

47 **Study Management**

48 To oversee the tasks of 1) generating an initial set of criteria for the Delphi process and 2) managing
49 the Delphi survey distribution and analysis, we convened a steering group. This group will oversee the
50 project and will make strategic decisions about the study design, data collection and analysis
51 processes, as well as agree a final process and related set of steps and criteria. An invitation to join this
52 group was posted on social media (Shared@Shared Decision Making Network Facebook group: 745
53 members) on 30 June 2017. The post invited all Facebook group members to join an in-person meeting
54 about evidence summarization during the International Shared Decision Making conference, held in
55 Lyon, France, between July 2, and July 5, 2017. For those who were not able to join the meeting but
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1 expressed an interest in evidence summarization of PDAs, a high-level summary was posted on
2 Facebook. The steering group was convened in September 2017. The study steering group includes
3 nine international experts in PDA development, evaluation and implementation, evidence
4 summarization and clinical practice guidelines, and one patient representative. Six steering group
5 members are based in the US, one in Canada, one in Australia and one in Spain Google drive and
6 video-conferencing facilities will be used to facilitate the exchange and review of information and
7 documents, virtual meetings, as well as real-time collaboration and version-control.
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10 11 **Participants**

12 To maximize the generalizability and applicability of the criteria, we plan to invite participation in the
13 survey from the following groups: 1) all known developers of PDAs who created or updated a tool
14 within last five calendar years (using existing inventory), 2) all members of the of the IPDAS group, 3)
15 the Shared Decision Making listserv; 4) the Society for Participatory Medicine listserv ; 5) an
16 overdiagnosis google group ; 6) the evidence-based healthcare listserv ; 7) the Society for Medical
17 Decision Making ; the 8) the Society of Behavioral Medicine (Health Decision Making Interest Group) ,
18 9) HTAi-ISG Patient Involvement listserv, 10) GRADE Working group, 11) the Guidelines International
19 Network, 12) convenience sample of policy makers with interest and expertise in PDA certification; 13)
20 the BMJ patient group; 14) the ProPublica Patient Safety Community. We have no other eligibility
21 criteria.
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26 For all participants, the survey invitation (Supplementary File 1) will provide a brief outline of the
27 study, a link to the online survey (Supplementary File 2), and a brief participant information sheet as
28 the first page of the survey. Consent will be inferred by participants' completion of the survey. The
29 ethics application form and protocol were submitted to Dartmouth College's committee for the
30 protection of human subjects on 27 April 2018. Approval was granted on 23 May 2018
31 (STUDY00031042).
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34
35 In order not to contaminate the Delphi survey results and express their views twice (in developing the
36 original items and taking the surveys), the steering group members have unanimously decided not to
37 complete the Delphi surveys.
38

39 **Patient and Public Involvement**

40 **Design**

41 Our patient partner, SC, was involved in the development of the Delphi survey and provided
42 meaningful feedback on iterative drafts of the online questionnaire. SC is a core member of our study
43 steering group and an author on this manuscript.
44
45

46 **Participants**

47 We also plan to make a concerted effort to recruit patient participants. We will reach out to online
48 patient groups, including the BMJ Patient group, the ProPublica Patient Safety Community (more than
49 6,000 members). We will also engage a patient and family advisor group at Dartmouth-Hitchcock
50 Medical Center.
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53 **Analysis**

54 Our patient partner will be a critical part of our analysis team, and will be involved in all steering group
55 meetings.
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Survey Development

The main output of the original Lyon evidence summarization meeting was the creation of a spreadsheet that detailed all evidence-summarization steps inherent to PDA development. The first draft of this spreadsheet, iteratively developed by the steering group members, included 18 criteria. Combining those 18 criteria with the eight existing standards for the summarization of clinical practice guidelines as outlined by the National Academy of Medicine (formerly IOM) & US Preventive Services Task Force Standards led to the creation of the first draft of the proposed process and steps. This draft was shared in a Google doc with all members of the steering group and iteratively refined and finalized. Three separate iterations of the process (phases, steps and criteria) were created, reviewed and discussed by the steering group members until no additional revisions were suggested. A final internal version of the criteria (n=48), categorized into four phases and 13 steps was finalized in April 2018 (see Supplementary File 3).

Data Collection

Round One Survey

The round one survey will include a brief information page and a summary of the process that led to the development of the phases, steps and criteria. Participants will be asked to provide their input on the phases, steps and criteria (including inclusion, wording, grouping, order and any other comments). Specifically, they will be asked to indicate using a four-point Likert scale (omit, possible, desirable, essential) whether each criterion included in the proposed process should be omitted or kept (and whether it is considered possible, desirable or essential). The criteria will be grouped into relevant phases and steps. For each phase and for each step, participants will be given the opportunity to provide rewording suggestions, suggest additional phases, steps or criteria, comment on the order of those elements or provide additional comments, or questions. Email addresses will be collected so participants can participate in further rounds. At the end of each round, we will confirm participants' interest to participate in the next round. Participants will also be asked to complete basic demographic questions. Each round of the survey will be open for three weeks, and two reminders will be sent.

Round Two Survey (and round three, as necessary)

Round one participants will be invited to complete a second survey, in which feedback will be provided about the results of the first round (percentage of participants who thought a criterion should be included or excluded) and about the changes made based on the qualitative feedback. Participants will be invited to indicate whether to omit or include (omit, possible, desirable, essential) the items, including the new items proposed by participants in the first round, and to provide additional rewording suggestions, comments, or questions. As mentioned above, the survey will be open for three weeks, and two email reminders will be sent. Depending on the level of consensus (see data analysis section), a third round may be conducted. This will be determined by the steering group after round 2 data analysis is completed.

Data Analysis

Following round one, the ratings will be summarized using percentages and the views of all participants will be given equal weight. If at least 80% of participants rate the item in the lower two categories (omit, possible) or in the higher two categories (desirable, essential), we will consider consensus to be achieved and the item will be removed or retained, respectively. Items where ratings

1 do not meet the consensus threshold and conflict with open text comments will be grouped together
2 and explained to round 2 participants. They will be asked to re-rate those items taking the qualitative
3 feedback into account. Following the first survey round, a consensus meeting involving the steering
4 group will be held. The steering group will review and discuss the ratings and qualitative feedback
5 received, including rewording suggestions per criterion, suggestions to add new phases, steps or
6 criteria and more general comments or questions. The wording or order of the phases, steps or criteria
7 will be revised if two or more respondents suggest it or if the steering group members agree that the
8 phase, step or criterion would benefit from rewording, reordering or merging.
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12 Following the second survey round, a second consensus meeting will be held. Decisions on whether to
13 conduct a third round and retain items in the scale will be made based on the ratings in the survey
14 rounds and feedback/comments from participants. The ratings will be summarized using percentages
15 and the views of all participants will be given equal weight. If at least 80% of participants rate the
16 importance of the item in the lower two categories, or in the higher two categories, we will consider
17 consensus to be achieved and the item will be removed or retained, respectively. If no consensus is
18 achieved or the consensus ratings are contradicted by recurring open text comments, the steering
19 group will decide whether or not to retain a criterion, basing this decision on qualitative feedback from
20 the participants where possible, and the steering group's views. We have successfully used this
21 approach before [21].
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25 Only complete surveys will be included in the analysis. We will report the amount of missing data in
26 the manuscript reporting the results of the Delphi survey.
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29 **Data Management and Safety**

30 Data to be collected include information about the participant's role as it relates to patient decision
31 aids, general demographics, and their opinion of what to add/change/include in an evidence
32 summarization process. We are careful to protect the identity of all study participants. We will store
33 the data securely in accordance with standard human subject research protocols. All data will be
34 retained for three years, per the Dartmouth College data retention policy (or for the period specified
35 by journals in which arising manuscripts are published, if longer) and then destroyed securely.
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39 **DISCUSSION**

40 Patient decision aids must have accurate and trustworthy evidence-based information about the risks
41 and benefits of health treatments and tests, as these tools help patients make important healthcare
42 choices. We want to generate consensus on an approach for selecting and summarizing the evidence
43 included in patient decision aids, which we hope can be widely adopted by decision aid developers.
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46 **STRENGTHS AND LIMITATIONS**

47 A strength of this study is the systematic involvement of patients and relevant stakeholders in planning
48 the modified Delphi survey. We plan to include a diverse sample of participant stakeholders including
49 patients, researchers, patient decision aid developers and health policy makers. Limitations of online
50 surveys always include the possibility of selection biases, meaning participants who opt to take the
51 survey may be systematically different than the target population. In our case, the participants may be
52 more engaged and more interested in the outcome of the Delphi survey. There is also a possibility that
53 their views will be stronger than those who opted not to participate.
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57 **CONCLUSION**

1 Patients should be able to trust the information they receive from patient decision aids. Together with
2 their clinicians, family and caregivers, they rely on these tools to make decisions that are aligned with
3 their informed preferences. We believe standardizing a process for selecting and summarizing the
4 evidence included in patient decision aids is therefore a worthwhile effort. Bringing all relevant
5 stakeholders to the table - patients, researchers, patient decision aid developers, and healthcare policy
6 makers - will ensure that the ultimate outcome is rigorous and rooted in consensus, to promote
7 widespread adoption.
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11 **ETHICS AND DISSEMINATION**

12 Dartmouth College's Committee for the Protection of Human Subjects approved this protocol. We plan
13 to publish our results in a peer-reviewed journal.
14
15

16 **FUNDING**

17 We did not receive funding for this project.
18
19

20 **COMPETING INTERESTS**

21 Glyn Elwyn and Marie-Anne Durand have developed the Option Grid patient decision aids, and EBSCO
22 Information Services sells subscription access to Option Grid patient decision aids. They receive
23 consulting income from EBSCO Health, and may receive royalties in the future. Glyn Elwyn and Marie-
24 Anne Durand are consultant for ACCESS Community Health Network. Brian S. Alper is employed full-
25 time by EBSCO Information Services which is a for-profit company that publishes patient decision aids.
26 No other competing interests declared.
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29

30 **AUTHORSHIP CONTRIBUTIONS**

31 Marie-Anne Durand, Glyn Elwyn and Michelle D. Dannenberg planned and designed the study.
32 Catherine H. Saunders, Anik Giguère, Brian S. Alper, Tammy Hoffmann, Lilisbeth Perestelo Perez and
33 Stephen T. Campbell provided advice and guidance on the design. Marie-Anne Durand drafted the
34 manuscript and all authors contributed to writing and approved the final draft of the manuscript.
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2 **Supplementary File 1: Survey Invitation**

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4 SUBJ: Help us make more trustworthy patient materials: provide your feedback through a survey

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6 To the members of [group name/list-serv name] –

7
8
9 We are an international workgroup, led by Marie-Anne Durand and Glyn Elwyn at The Dartmouth Institute for Health Policy and
10 Clinical Practice in Lebanon, N.H. We noticed a need for more clarity about how to select and summarize the evidence included
11 in patient decision aids. Patient decision aids influence the decisions that patients make - so the need for trustworthy tools is
12 important.
13

14
15 We wish to have your perspective, as an expert, patient, or other stakeholder.
16

17
18 **Please could you provide feedback via 2-3 surveys over the next few weeks?** Each survey should take less than 25
19 minutes.
20

21
22 Please click the link below for more information and the first survey.
23

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25 Many thanks,
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28 The Evidence Summarization workgroup
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For peer review only

Evidence Summarization Survey

Information Sheet

SURVEY INFORMATION

What is the study about?

We want to generate consensus on an approach for selecting and summarizing the evidence included in patient decision aids. Our workgroup developed a proposed set of Phases, Steps and Criteria, based on the methods used to develop trustworthy clinical practice guidelines. The purpose of this survey is to gain your perspective, as an expert, patient or other stakeholder.

What is involved?

If you participate, we'll ask you to complete two or three surveys. In the first survey, we'll ask for your perspective on the proposed Phases, Steps and Criteria. This will include rating importance, suggesting wording changes and suggesting additional items. In the second and third surveys, we'll ask similar questions except we'll also share some results from the first survey.

How long will it take?

Completing this survey should take less than 25 minutes.

Do I have to take part?

No. Taking part is voluntary.

Will I be compensated?

You won't be compensated. However, we hope you'll take part. Your contributions

1 will improve the process of developing reliable, high-quality decision aids for
2 patients.

3
4
5 **Are there any risks?**

6 We don't anticipate any risks from participating in the study.
7
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10 **How will my privacy be protected?**

11 We won't name any individuals in any publications or presentations.
12
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15 **How can I contact you?**

16 If you have questions, please feel free to contact Michelle Dannenberg
17 (Michelle.D.Dannenberg@dartmouth.edu), Research Coordinator, The Dartmouth
18 Institute for Health Policy and Clinical Practice, Dartmouth College.
19
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23

24 If you would like to speak to the researchers leading this study, please contact Prof.
25 Marie-Anne Durand (Marie-Anne.Durand@dartmouth.edu) or Prof. Glyn Elwyn
26 (glynelwyn@gmail.com), The Dartmouth Institute for Health Policy and Clinical
27 Practice, Dartmouth College.
28
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33 **What happens if I do not respond?**

34 You'll receive two automated email reminders to complete the survey.
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41 Do you want to participate?

42
43 Yes

44 No
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51 **Background Questions**

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55 **BACKGROUND QUESTIONS**
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1 Which of the following best describes you? Please select all that apply.
2

- 3 Patient Decision Aid (PDA) developer
- 4 Researcher
- 5
- 6 International Patient Decision Aids Standards (IPDAS) collaboration member
- 7
- 8 Policy maker
- 9
- 10 Patient
- 11
- 12 Clinician, please specify specialty:
- 13
- 14 Other, please specify:
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23 Which country do you live in?
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30 What is your gender?
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- 32 Male
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- 34 Female
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- 36 Other
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42 What is your race/ethnicity? Please select all that apply.
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- 44 American Indian or Alaska Native
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- 46 Asian
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- 48 Black or African American
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- 50 Native Hawaiian or Other Pacific Islander
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- 52 Hispanic, Latino/a or Spanish Origin
- 53
- 54 White
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1 Other, please specify:

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4 **BACKGROUND QUESTIONS**

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9 We're requesting your email address so we can contact you for the next phase of
10 this project. We will not share your email with anyone outside the study team, and
11 we will not contact you about anything other than the study.
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16 Please provide your email:

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23 **Overall Proposed Phases, Steps and Criteria**

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27 **INFORMATION ON PROPOSED PROCESS**

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32 **Decision aids are tools that help patients make choices.** They provide
33 information about the risks and benefits of health treatments and tests.

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37 **Accurate and clear information is critical.** It's important for decision aids to have
38 accurate and trustworthy information from research evidence about the risks and
39 benefits of health treatments and tests.
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45 **We're trying to make evidence summarization easier.** We're doing this by
46 developing a process to guide decision aid developers in evidence summarization.
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50 **We're building on the good work that's already been done.** This process
51 includes the existing work of the International Patient Decision Aid Standards
52 (IPDAS) collaboration.
53
54

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56
57 **We sketched out a proposed process,** see Figure below. We are interested in
58 your feedback on ALL elements of this, including the Phases, Steps and Criteria, as
59

60 For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

well as the order and grouping.

1
2
3 **Here's how you can help.** In the questions that follow, we will ask for your
4 perspective on **how important each criterion is to include in the proposed**
5 **process.** We will also ask for feedback on the wording of all parts. Nothing is final.
6
7 Everything is up for discussion, and we are looking forward to hearing from you.
8
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11
12 **Below is a visual representation of the proposed process.** Review it carefully.
13
14 There are four proposed phases, each with one to five proposed steps. Each step
15 has a number of proposed Criteria. In the visual representation below, we show the
16 first Criteria for each step. The tabs represent additional Criteria.
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21 Feel free to [click here](#) to view the representation of the proposed Phases, Steps
22 and Criteria in a separate window. You can click on the image to zoom. You can
23 refer back to this image as you answer questions about the proposed process. Don't
24 worry, if you accidentally close the window, there are links to the figure on each page
25 of the survey.
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Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

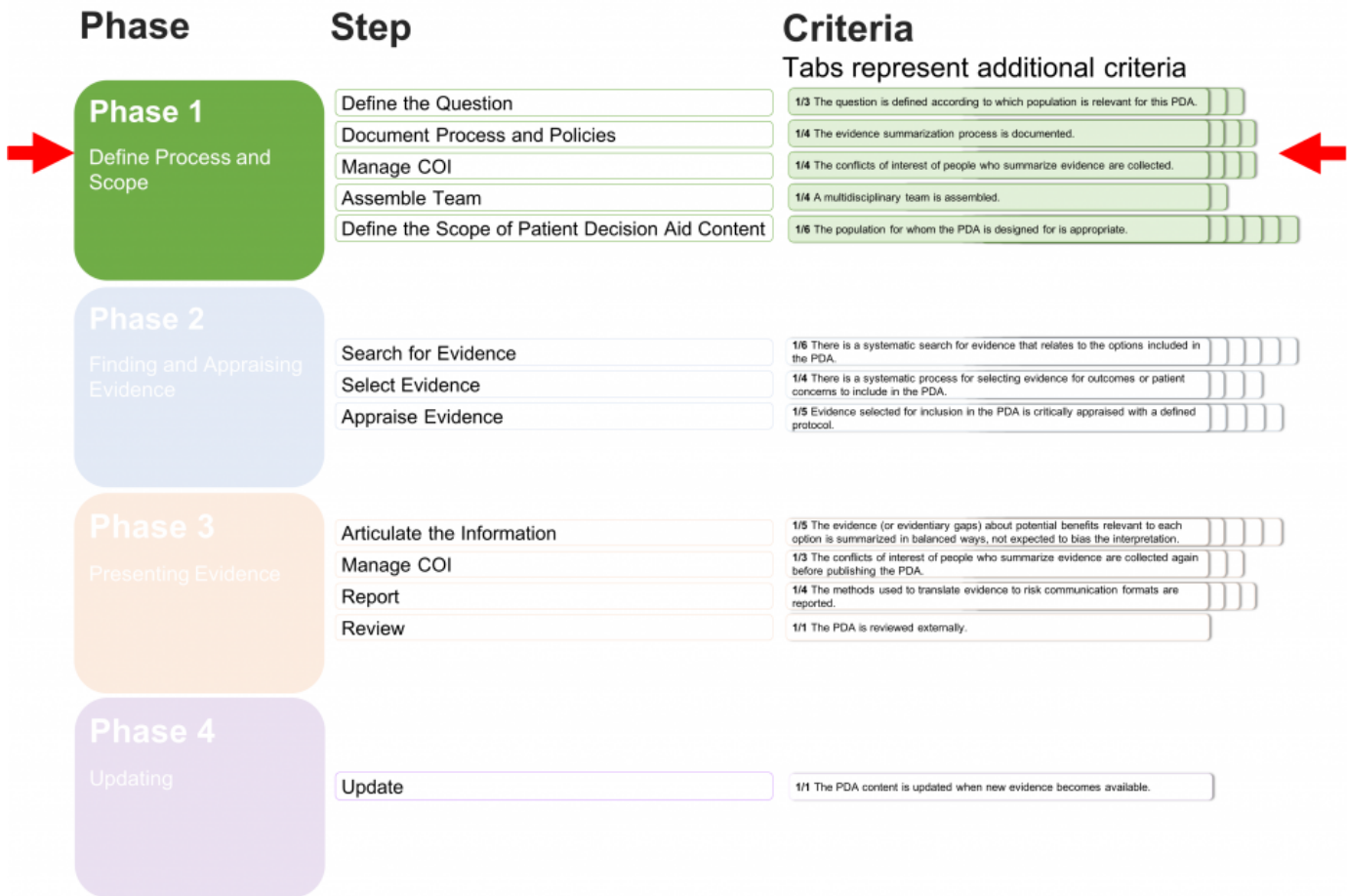
Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.

Phase 1

PROPOSED PHASE 1

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Phase below? If so, please share them.

- Phase 1: Defining Process and Scope**

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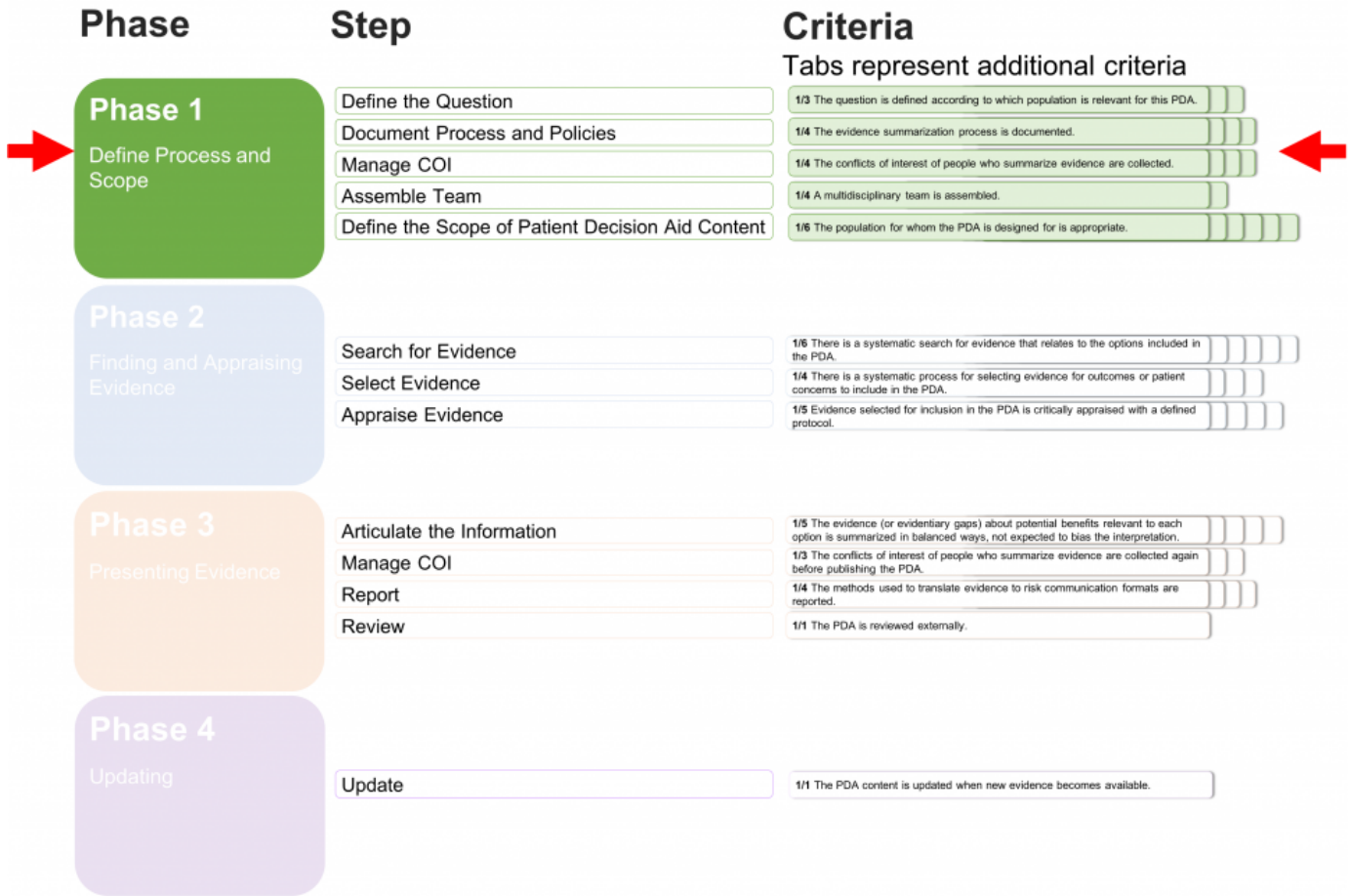
Do you have any comments on the Steps below, including their wording or order? Or suggestions for additional steps? If so, please share them.

- **Step 1: Define the Question**
- **Step 2: Document Process and Policies**
- **Step 3: Manage COI**
- **Step 4: Assemble Team**
- **Step 5: Define the Scope of Patient Decision Aid Content**

PROPOSED PHASE 1 STEP 1

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 1: Define the Question**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible Desira

The question is defined according to which population is relevant for this PDA.

The question is defined according to which options are relevant for this PDA.

The question is defined according to which outcomes or patient concerns are relevant for this PDA.

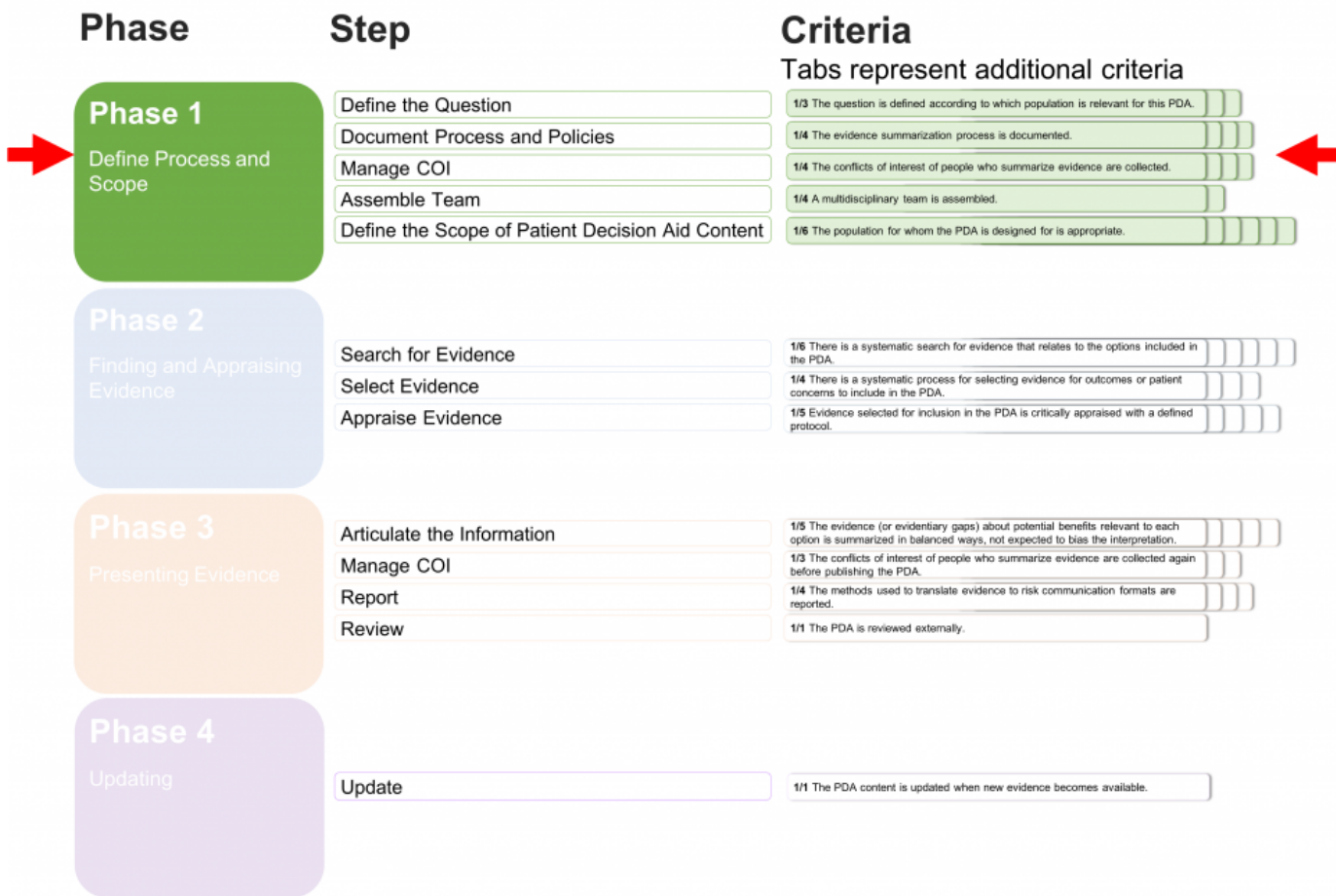
Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 1 STEP 2

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on this Step? If so, please share them.

- Step 2: Document Process and Policies**

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The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible C

- The evidence summarization process is documented.
- The evidence summarization process minimizes bias.
- The evidence summarization process minimizes conflicts of interest.
- The conflict of interest policy applying to people who summarize evidence is documented.

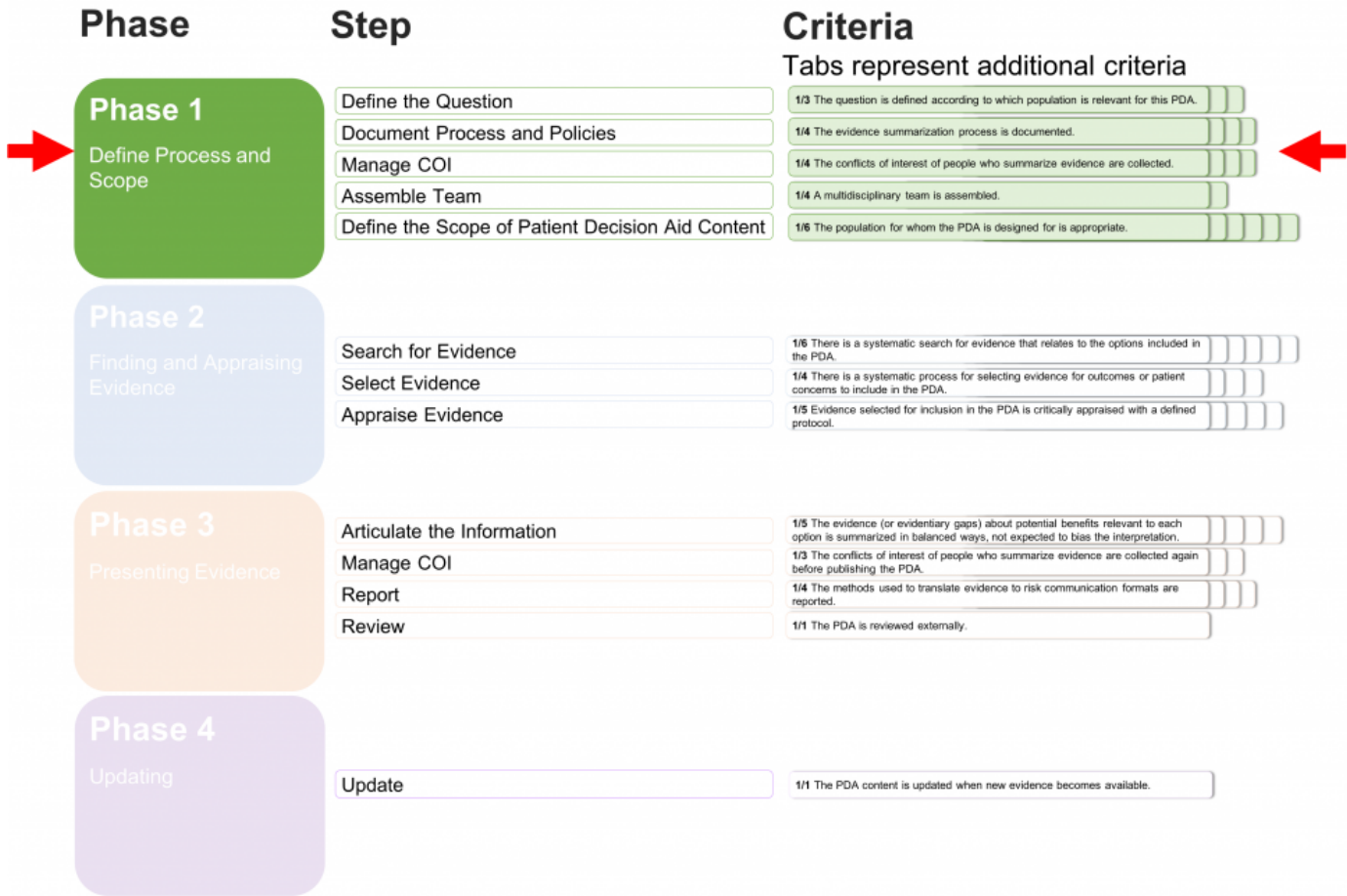
Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 1 STEP 3

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on this Step? If so, please share them.

- **Step 3: Manage COI**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

The conflicts of interest of people who summarize evidence are collected.

Actions are taken to manage relevant conflicts of interest.

The actions taken on relevant conflicts of interest are documented.

Conflicts of interest are monitored over the course of PDA development.

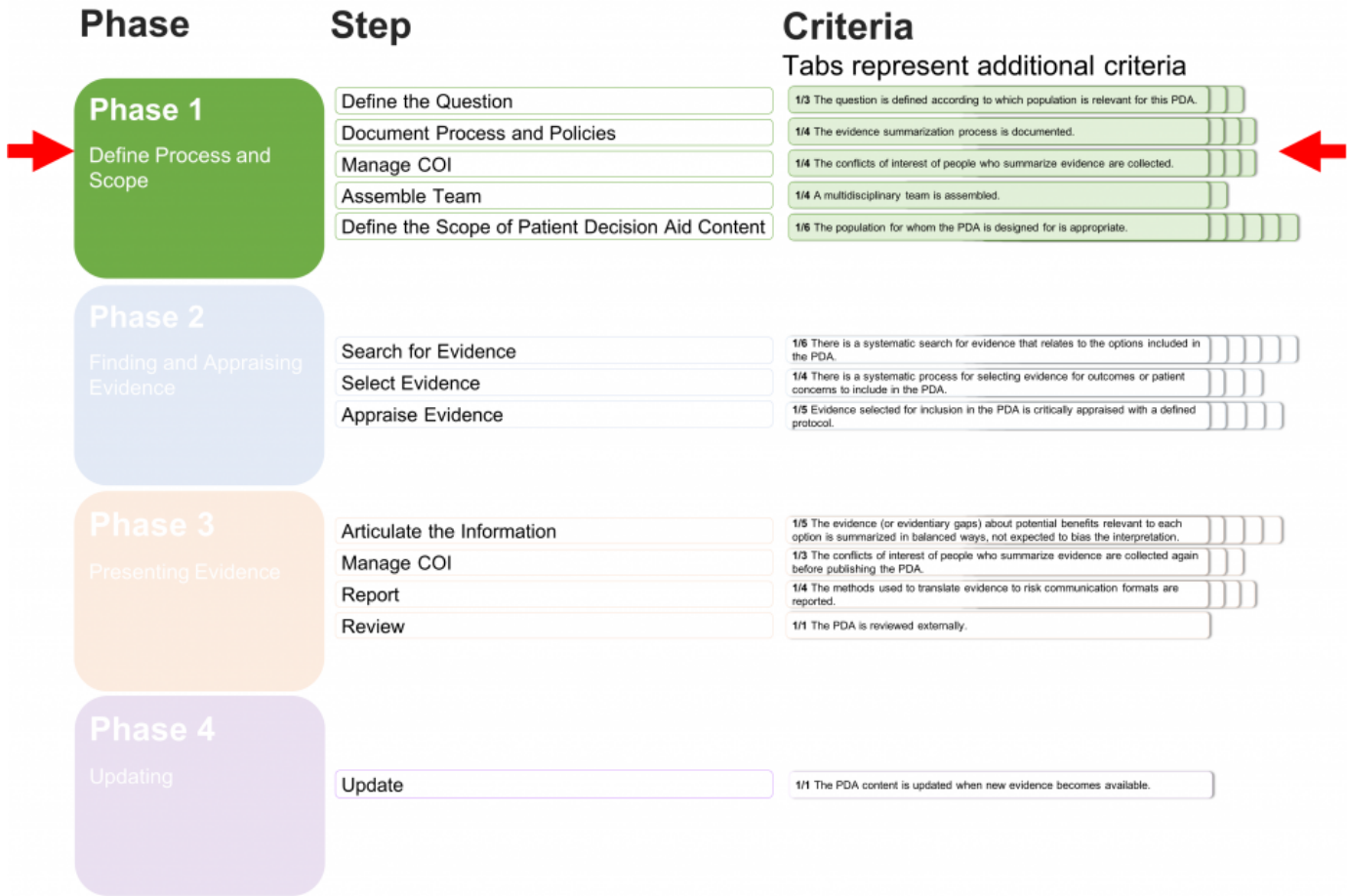
Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 1 STEP 4

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- Step 4: Assemble Team**

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The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible [

- A multidisciplinary team is assembled.
- The team comprises clinicians.
- The team comprises methodological experts.
- The team comprises patient or consumer representatives.

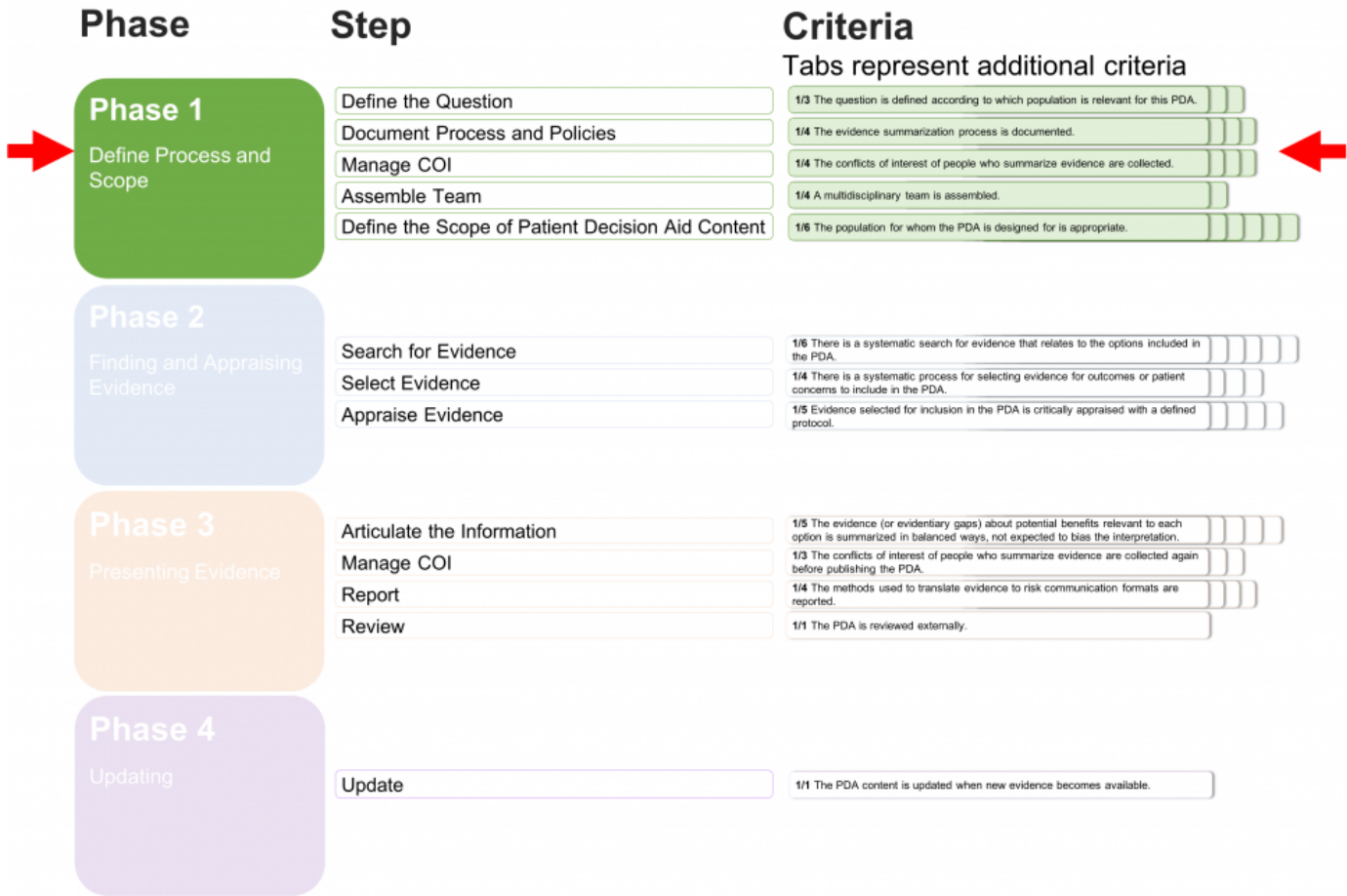
Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 1 STEP 5

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 5: Define the Scope of Patient Decision Aid Content**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible C

The population for whom the PDA is designed for is appropriate.

There is a systematic process to reduce bias in the definition of the population for the PDA.

The options for inclusion in the PDA are appropriate for the intended population.

There is a systematic process to reduce bias in the definition of the options for the PDA.

The outcomes or patient concerns for inclusion in the PDA are appropriate for the intended population and options.

There is a systematic process to reduce bias in the definition of the outcomes or patient concerns for the PDA.

Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

Phase 2

PROPOSED PHASE 2

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.

Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

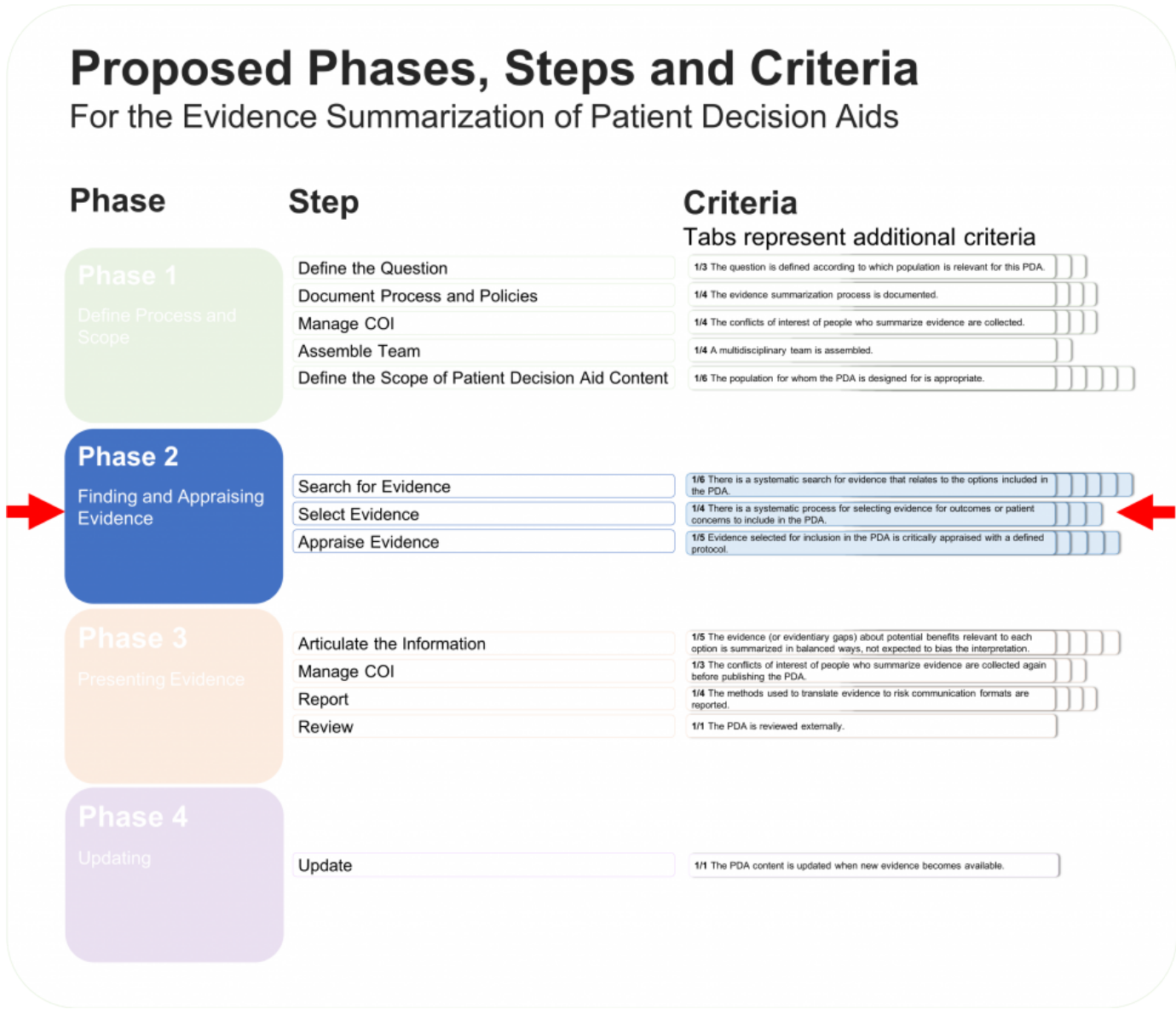
Do you have any comments or suggestions on the Phase below? If so, please share them.

- Phase 2: Finding & Appraising Evidence

Do you have any comments on the Steps below, including their wording or order? Or suggestions for additional steps? If so, please share them.

- Step 1: Search for Evidence
- Step 2: Select Evidence
- Step 3: Appraise Evidence

PROPOSED PHASE 2 STEP 1



1 Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and
2 Criteria in a separate window while you complete the questions below.
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7 Do you have any comments or suggestions on this Step? If so, please share them.
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10 • **Step 1: Search for Evidence**
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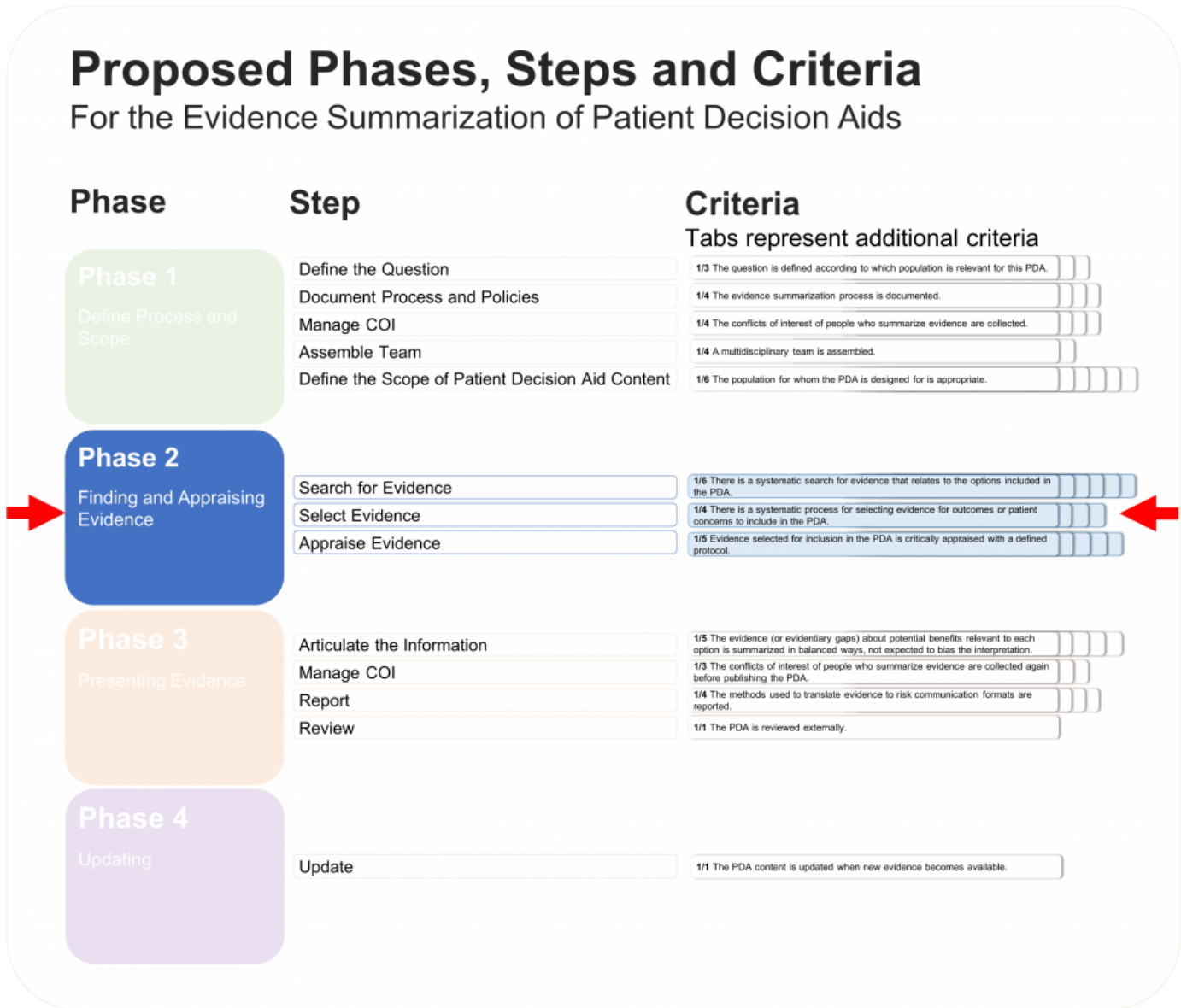
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20 The proposed Criteria for this step are below. Please indicate whether each
21 Criterium should be omitted, or whether it is a possible candidate for inclusion,
22 a desirable candidate for inclusion or is essential for inclusion.
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	Omit	Possible	Essential
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Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 2 STEP 2



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 2: Select Evidence**

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The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA (where evidence is not available, can directly ask patients).

There is a systematic process for selecting evidence (or evidentiary gaps) about potential benefits relevant to each option.

There is a systematic process for selecting evidence (or evidentiary gaps) about potential harms relevant to each option.

If the PDA is customizable to individual patient factors, there is a systematic process for selecting relevant risk predictors to include in the PDA.

Do you have any comments or suggestions on the Criteria above? If so, please share them.

[Empty text box]

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

[Empty text box]

PROPOSED PHASE 2 STEP 3

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.

Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- Step 3: Appraise Evidence**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

Evidence selected for inclusion in the PDA is critically appraised with a defined protocol (such as GRADE).

The protocol for critical appraisal of evidence accounts for risks of bias in study design.

The protocol for critical appraisal of evidence accounts for risks of bias in study analysis and reporting.

The protocol for critical appraisal of evidence accounts for assessment of certainty of evidence with attention to risk of bias, precision, directness, consistency, and publication bias.

The conflicts of interest of study authors related to selected evidence is appraised.

Do you have any comments or suggestions on the Criteria above? If so, please share them.

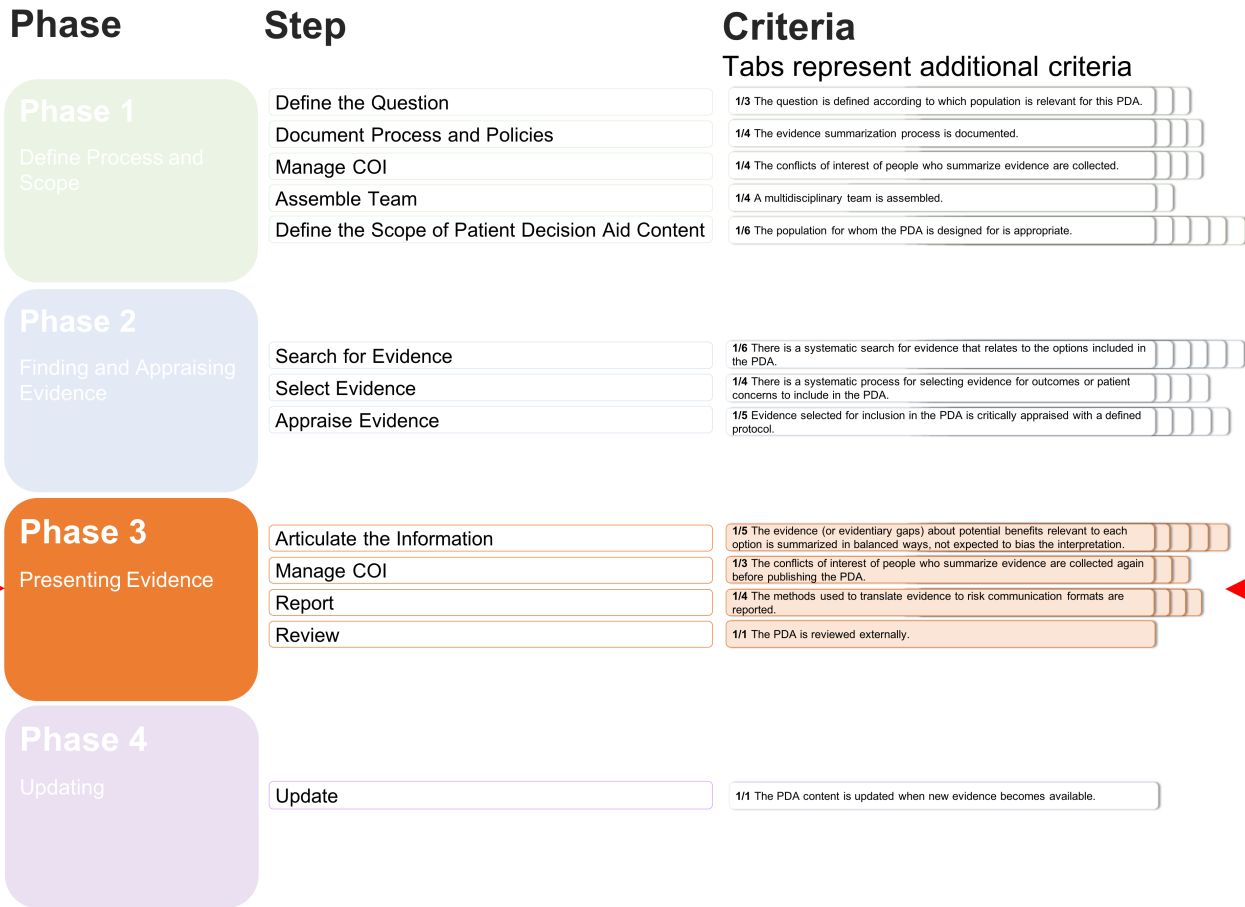
Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

Phase 3

PROPOSED PHASE 3

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Phase below? If so, please share them.

- Phase 3: Presenting Evidence

Do you have any comments on the Steps below, including their wording or order? Or do you have suggestions for additional steps? If so, please share them.

- Step 1: Articulate the Information
- Step 2: Manage COI
- Step 3: Report
- Step 4: Review

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PROPOSED PHASE 3 STEP 1

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.



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Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

• **Step 1: Articulate the Information**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	I
The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.	<input type="radio"/>	<input type="radio"/>	
The evidence (or evidentiary gaps) about potential harms relevant to each option is summarized in balanced ways, not expected to bias the interpretation.	<input type="radio"/>	<input type="radio"/>	
The evidence (or evidentiary gaps) is summarized in ways that are easy to understand.	<input type="radio"/>	<input type="radio"/>	
The certainty of the evidence is described in ways that are easy to understand.	<input type="radio"/>	<input type="radio"/>	
The evidence summarization process is described in ways that are easy to understand.	<input type="radio"/>	<input type="radio"/>	
The funding used to summarize the evidence (and develop the PDA) is reported.	<input type="radio"/>	<input type="radio"/>	

Do you have any comments or suggestions on the wording or order of any of the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 3 STEP 2

Proposed Phases, Steps and Criteria

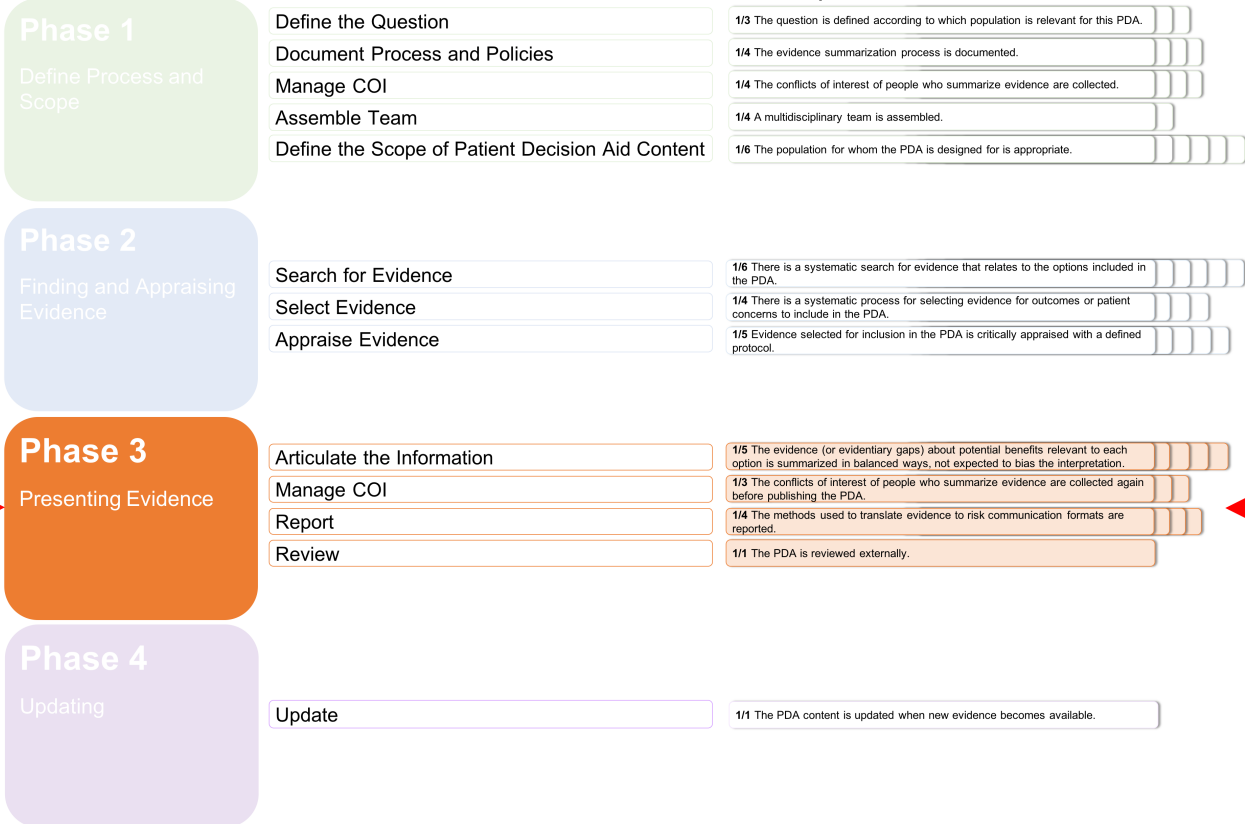
For the Evidence Summarization of Patient Decision Aids

Phase

Step

Criteria

Tabs represent additional criteria



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

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Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 2: Manage COI**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.

Any change to the conflicts of interest of people who summarize evidence are reported.

Actions are taken to manage relevant conflicts of interest.

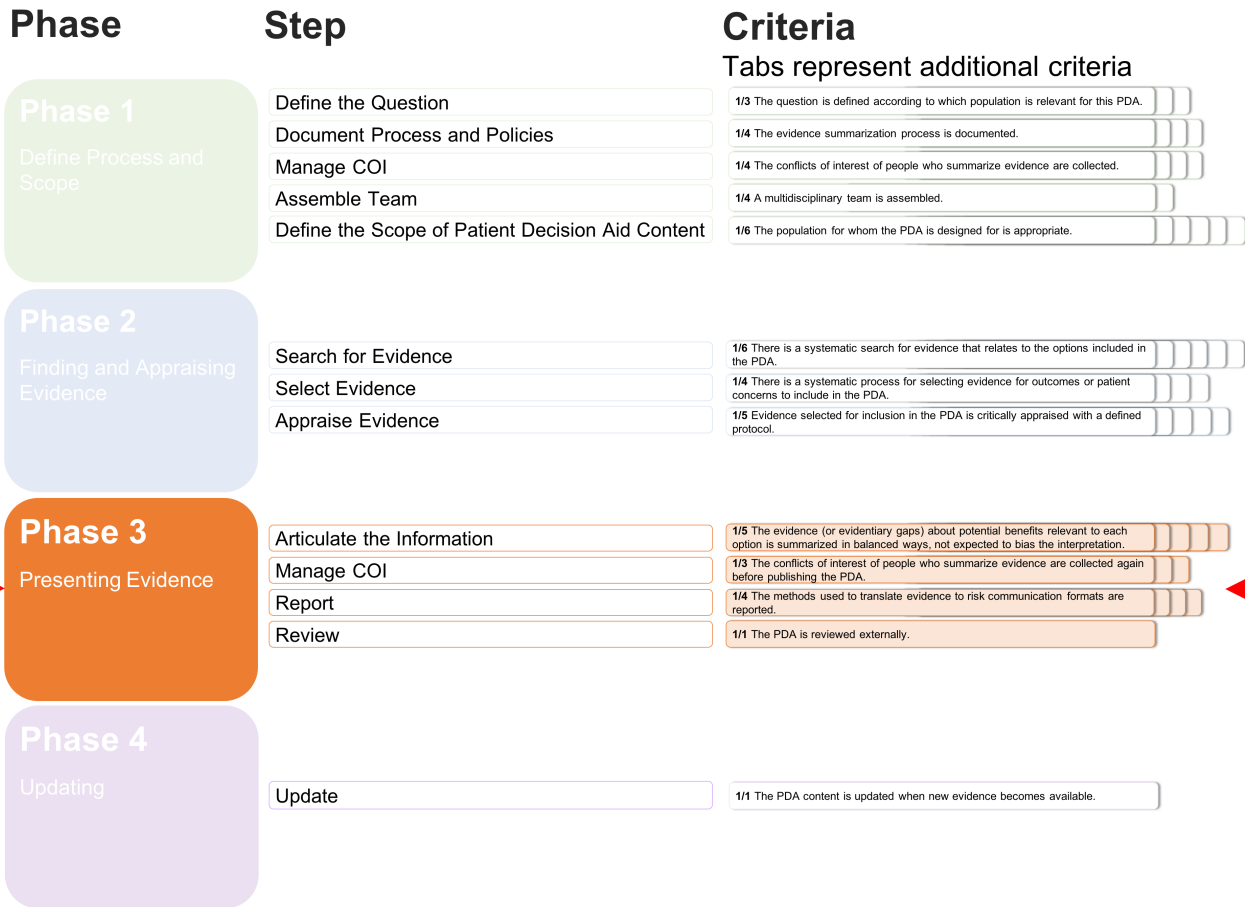
Do you have any comments or suggestions on the wording or order of any of the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 3 STEP 3

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 3: Report**

1 The proposed Criteria for this step are below. Please indicate whether each
2 Criterium should be omitted, or whether it is a possible candidate for inclusion,
3 a desirable candidate for inclusion or is essential for inclusion.
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7 Omit Possible E

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9 The methods used to translate evidence to risk communication
10 formats are reported.

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12 The approach to readability of summarized evidence is reported.

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14 The summarization process is reported publicly.

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16 The conflict of interest of people who summarize evidence are
17 reported publicly.

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22 Do you have any comments or suggestions on the wording or order of any of the
23 Criteria above? If so, please share them.
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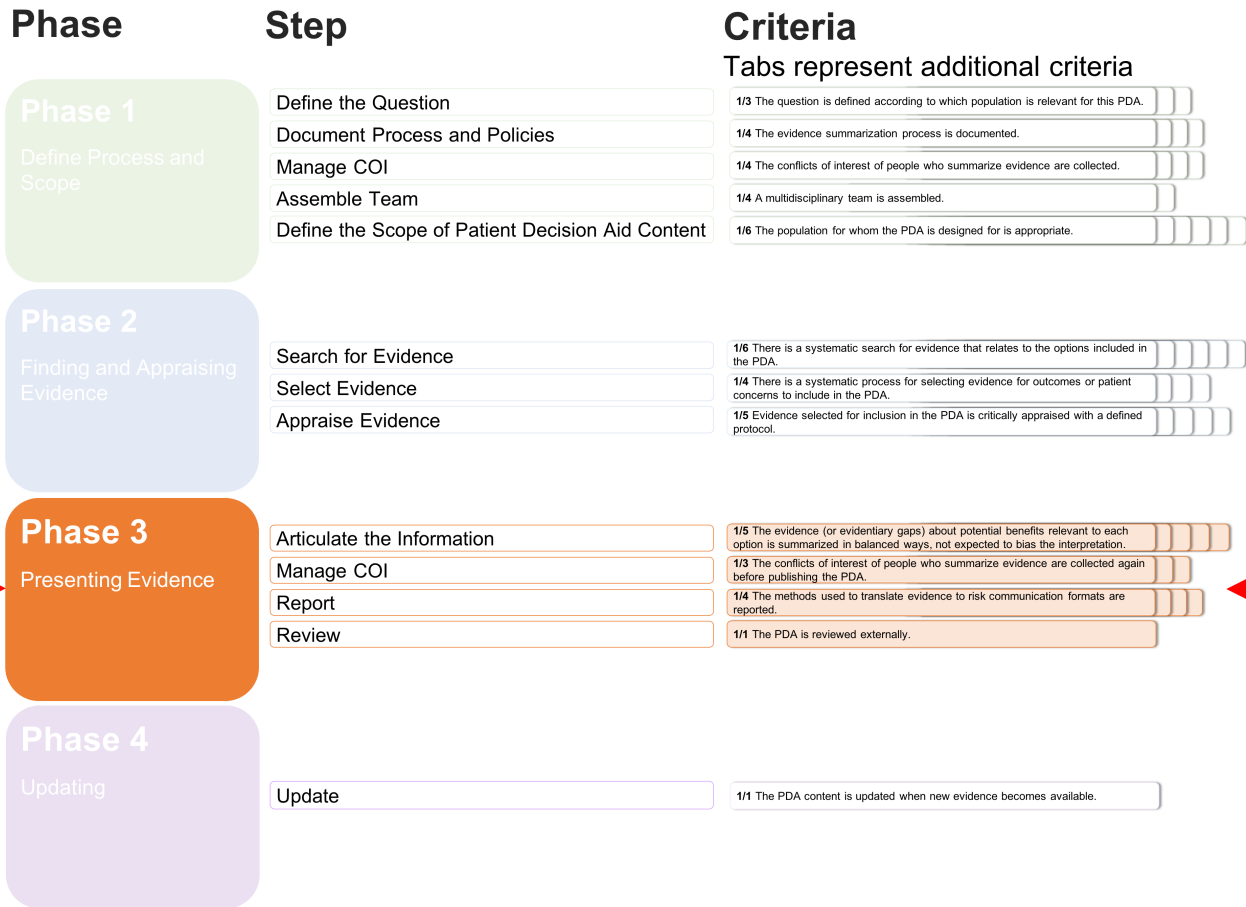
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31 Do you have any suggestions for additional Criteria to include in this Step? If so,
32 please share them.
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36 37 38 39 40 **PROPOSED PHASE 3 STEP 4**

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 4: Review**

1 The proposed Criteria for this step are below. Please indicate whether each criterium
2 should be omitted, or whether it is a possible candidate for inclusion,
3 a desirable candidate for inclusion or is essential for inclusion.
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Omit F

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9 The PDA is reviewed externally.

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13 Do you have any comments or suggestions on the wording or order of any of the
14 Criteria above? If so, please share them.
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22 Do you have any suggestions for additional Criteria to include in this Step? If so,
23 please share them.
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31 **Phase 4**

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35 **PROPOSED PHASE 4**

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Phase below? If so, please share them.

- Phase 4: Updating**

Do you have any comments or suggestions on the Step below. If so, please share them.

• Step 1: Update

PROPOSED PHASE 4 STEP 1

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.



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Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 1: Update**

The proposed Criteria for this step are below. Please indicate whether each criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

The PDA content is updated when new evidence becomes available.

Do you have any comments or suggestions on the wording of the criterion above? If so, please share them.

Do you have any suggestions for additional criteria to include in this Step? If so, please share them.

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Supplementary File 3: Proposed Phases, Steps, and Criteria

Existing standard (from IOM & USPSTF)	Phase	Step	Criteria
Establishing transparency	Phase I: Define Process and Scope	Define the question	The question is defined according to which population is relevant for this PDA.
			The question is defined according to which options are relevant for this PDA.
			The question is defined according to which outcomes or patient concerns are relevant for this PDA.
		Document process and policies	The evidence summarization process is documented.
			The evidence summarization process minimizes bias.
			The evidence summarization process minimizes conflicts of interest.
			The conflict of interest policy applying to people who summarize evidence is documented.
Management of conflict of interest	Manage COI	The conflicts of interest of people who summarize evidence are collected.	
		Actions are taken to manage relevant conflicts of interest.	
		The actions taken on relevant conflicts of interest are documented.	
		Conflicts of interest are monitored over the course of PDA development.	
Guideline development group composition	Assemble team	A multidisciplinary team is assembled.	
		The team comprises clinicians.	
		The team comprises methodological experts.	
		The team comprises patient or consumer representatives.	
	Define the scope of patient decision aid content	The population for whom the PDA is designed for is appropriate.	
		There is a systematic process to reduce bias in the definition of the population for the PDA.	
		The options for inclusion in the PDA are appropriate for the intended population.	
		There is a systematic process to reduce bias in the definition of the options for the PDA.	
		The outcomes or patient concerns for inclusion in the PDA are appropriate for the intended population and options.	

			There is a systematic process to reduce bias in the definition of the outcomes or patient concerns for the PDA.
Guideline and systematic review intersection	PHASE II: Finding & Appraising Evidence	Search for evidence	There is a systematic search for evidence that relates to the options included in the PDA.
			There is a systematic search for evidence that relates to the outcomes or patient concerns included in the PDA.
			If the PDA is customizable to individual patient factors, there is a systematic search for evidence of how individual patient factors influence the expected outcomes.
Establishing evidence foundations and rating strength of recommendation		Select evidence	There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA (where evidence is not available, can directly ask patients).
			There is a systematic process for selecting evidence (or evidentiary gaps) about potential benefits relevant to each option.
			There is a systematic process for selecting evidence (or evidentiary gaps) about potential harms relevant to each option.
			If the PDA is customizable to individual patient factors, there is a systematic process for selecting relevant risk predictors to include in the PDA.
		Appraise evidence	Evidence selected for inclusion in the PDA is critically appraised with a defined protocol (such as GRADE).
			The protocol for critical appraisal of evidence accounts for risks of bias in study design.
			The protocol for critical appraisal of evidence accounts for risks of bias in study analysis and reporting.
Articulation of information	PHASE III: Presenting Evidence	Articulate the information	The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
			The evidence (or evidentiary gaps) about potential harms relevant to each option is summarized in balanced ways, not expected to bias the interpretation.

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			The evidence (or evidentiary gaps) is summarized in ways that are easy to understand.
			The certainty of the evidence is described in ways that are easy to understand.
			The evidence summarization process is described in ways that are easy understand.
			The funding used to summarize the evidence (and develop the PDA) is reported.
		Manage COI	The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
			Any change to the conflicts of interest of people who summarize evidence are reported.
			Actions are taken to manage relevant conflicts of interest.
		Report	The methods used to translate evidence to risk communication formats are reported.
			The approach to readability of summarized evidence is reported.
			The summarization process is reported publicly.
			The conflict of interest of people who summarize evidence are reported publicly.
		Review	The PDA is reviewed externally.
Updating	PHASE IV: Post-publication update	Update	The PDA content is updated when new evidence becomes available.

For peer review only

BMJ Open

Study protocol: A modified Delphi survey for the evidence summarization of patient decision aids

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-026701.R2
Article Type:	Protocol
Date Submitted by the Author:	06-Feb-2019
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Primary Subject Heading:	Communication
Secondary Subject Heading:	Evidence based practice
Keywords:	Decision Making, Delphi Technique, Patient Preference, Patient-Centered Care, Surveys and Questionnaires

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Manuscripts

Study protocol: A modified Delphi survey for the evidence summarization of patient decision aids

Running heading: Evidence summarization Delphi survey

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28 Keywords

29 [Decision Making](#)

30 [Delphi Technique](#)

31 [Patient Preference](#)

32 [Patient-Centered Care](#)

33 [Surveys and Questionnaires](#)
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ABSTRACT FOR PROTOCOL

Introduction

Information included in a Patient Decision Aid (PDA) can significantly influence patients' decisions and is, therefore, expected to be evidence based and rigorously selected and summarized. Yet patient decision aid developers have not yet agreed on a standardized process for the selection and summarization of the supporting evidence. We intend to generate consensus on a process (and related steps and criteria) for selecting and summarizing evidence for patient decision aids using a modified Delphi survey.

Methods and Analysis

We will develop an evidence summarization process specific to PDA development by using a consensus-based Delphi approach, surveying international experts and stakeholders with two to three rounds. To increase generalizability and acceptability, we will distribute the survey to the following stakeholder groups: patient decision aid developers, researchers with expertise in shared decision making, patient decision aid development and evidence summarization, members of the International Patient Decision Aid Standards group, policy makers with expertise in patient decision aid certification, and patient stakeholder groups. For each criterion, if at least 80% of survey participants rank the criterion as most important/least important, we will consider consensus achieved.

Ethics and Dissemination

It is critical for patient decision aids to have accurate and trustworthy evidence-based information about the risks and benefits of health treatments and tests, as these decision aids help patients make important choices. We want to generate consensus on an approach for selecting and summarizing the evidence included in patient decision aids, which can be widely implemented by decision aid developers. Dartmouth College's Committee for the Protection of Human Subjects approved this protocol. We will publish our results in a peer-reviewed journal.

Words: 268

Article Summary

- Gap: There is no standardized method for selecting and summarizing the evidence in patient decision aids.
- Solution: We are developing a process to ensure patient decision aids have the most up-to-date, trustworthy evidence available.
- Clinical implications: This will help patients and clinicians know they can trust the information in patient decision aids, so they can make the best decisions together.
- Strengths: Systematic involvement of patient stakeholders.
- Limitations: Limitations of online surveys include selection bias.

INTRODUCTION

Patient Decision Aids (PDAs) are tools that help patients and their clinicians make preference-sensitive decisions together. They are typically defined as: “evidence-based tools designed to help patients make specific and deliberated choices among healthcare options. Patient decision aids supplement (rather than replace) clinicians' counselling about options”[1][2]. They promote patient engagement in medical decision making, collaboration between patients and their care team, increase knowledge and align patients' choices with their preferences [1]. Therefore, the information included in PDAs can significantly impact patients' decisions. For this reason, patients and clinicians expect the information in PDAs to be evidence based and rigorously selected and summarized.

The approach that PDA developers use to select and summarize the evidence in PDAs, however, appears inconsistent. A recent international cross sectional survey of 15 PDA developers confirms that they do not have an agreed-upon, standardized process to select and summarize evidence. They also do not always document the evidence selection and summarization process [3]. Most organizations reported using existing systematic reviews and clinical practice guidelines to select and summarize information for PDAs. Less than half reported using a standard, documented approach to guide the evidence selection and summarization. When the approach was documented, the documents offered varying levels of detail. Common evidence summarization steps identified were: tool-relevant question formation, search strategies, evidence appraisals, and updating policies. There was no standardized process across organizations to summarize evidence for PDAs. Although agreed-upon approaches and tested methods for evidence summarization exist in other areas, such as clinical practice guidelines, there is no agreed process (including steps and criteria within each step) for the selection and summarization of evidence for PDAs.

The International Patient Decision Aids Standards (IPDAS) collaboration developed criteria for assessing the quality of PDAs [4]. These criteria are also used by PDA producers to guide the development of the interventions. However, only six items of the IPDAS checklist cover the selection and summarization of evidence, and do not provide any guidance about recommended methods for the evidence selection and summarization of PDAs [4]. A 2013 review of the literature conducted by the IPDAS working group on the synthesis of scientific evidence highlighted the importance of rigorously selecting and summarizing evidence used to populate a patient decision aid. They did not provide clear practical guidance on how to conduct evidence summarization for the development of patient decision aids except recommending that developers apply the GRADE methodology [5]. Further, the IPDAS instrument and the IPDAS minimum standards do not offer additional information or guidance on the steps required to select and summarize evidence-based information for PDAs [6][7]. Other efforts to evaluate or certify the quality of PDAs have emerged [8], but none of those standards or certification bodies describe recommended methods and criteria that PDAs producers should follow when selecting and summarizing evidence for patient-facing interventions.

Evidence summarization in other medical contexts is increasingly standardized, such as the selection and summarization of evidence for clinical practice guidelines and systematic reviews. This process promotes transparency, rigor, and minimizes the risk of bias in the end product [2] [9][10][11][12][13][14][15][16][17]. The same level of scrutiny is justified when developing PDAs, as they may directly influence patient care and decision making. Tasks such as the selection and

1 identification of patient-relevant outcomes, analysis of patient concerns and priorities, description of
2 the quality of evidence, and communication of uncertainty in ways that patients understand warrants
3 the development of an agreed process and related steps and criteria that are specific to PDAs. For
4 those reasons, it would not be appropriate to apply evidence summarization processes developed for
5 clinical guidelines without integrating the evidence summarization steps and components that are
6 specific to the development of interventions that target patients. The target group, scope and content
7 differ significantly enough from clinical practice guidelines development, thus requiring a tailored
8 evidence summarization process. Additionally, the IPDAS standards impose some prerequisites on the
9 evidence summarization process on which the decision aid will be based. For example, IPDAS requires
10 that the decision aid summarizes the evidence regarding all health options available to a patient facing
11 a specific health problem, and that decision aids present positive and negative features of each option
12 with an equal amount of details, among other specificities [18]. Efforts to develop an agreed evidence
13 summarization process for PDAs should incorporate the substantial body of related evidence
14 summarization guidance previously developed by other groups, and notably for clinical practice
15 guidelines previously mentioned [11].

21 **Objective**

22 The purpose of the study is to generate consensus on a process (and related steps and criteria) for
23 selecting and summarizing evidence for patient decision aids using a modified Delphi survey. This will
24 in turn improve transparency, rigor and minimize the risk of bias of the evidence summarization
25 processes leading to the development of patient decision aids.

28 **2 METHODS**

31 **Study Design and Procedures**

32 We will develop an evidence summarization process specific to PDA development by using a
33 consensus-based Delphi approach previously used in the development of a quality criteria framework
34 for PDAs [2] [19]. Consensus methods can harness the views of international experts on a wide range
35 of information and questions in order to make decisions that are based on expert consensus [20]. We
36 will conduct a multi-round modified Delphi survey (two to three rounds). Compared to the nominal
37 group technique, it is the most practical and scalable method to obtain feedback from a large number
38 of stakeholders in different geographic locations. During the multiple rounds of online questionnaires,
39 relevant stakeholders will be consulted to provide feedback about the evolving set of evidence
40 summarization steps and criteria. The anonymous responses from participants will be fed back to them
41 in subsequent rounds. Depending on the level of consensus after two rounds (see Data Analysis
42 section), we will determine whether to conduct a third survey round.

47 **Study Management**

48 To oversee the tasks of 1) generating an initial set of criteria for the Delphi process and 2) managing
49 the Delphi survey distribution and analysis, we convened a steering group. This group will oversee the
50 project and will make strategic decisions about the study design, data collection and analysis
51 processes, as well as agree a final process and related set of steps and criteria. An invitation to join this
52 group was posted on social media (Shared@Shared Decision Making Network Facebook group: 745
53 members) on 30 June 2017. The post invited all Facebook group members to join an in-person meeting
54 about evidence summarization during the International Shared Decision Making conference, held in
55 Lyon, France, between July 2, and July 5, 2017. For those who were not able to join the meeting but
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1 expressed an interest in evidence summarization of PDAs, a high-level summary was posted on
2 Facebook. The steering group was convened in September 2017. The study steering group includes
3 nine international experts in PDA development, evaluation and implementation, evidence
4 summarization and clinical practice guidelines, and one patient representative. Six steering group
5 members are based in the US, one in Canada, one in Australia and one in Spain Google drive and
6 video-conferencing facilities will be used to facilitate the exchange and review of information and
7 documents, virtual meetings, as well as real-time collaboration and version-control.
8
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10 11 **Participants**

12 To maximize the generalizability and applicability of the criteria, we plan to invite participation in the
13 survey from members of the following groups: 1) all known developers of PDAs who created or
14 updated a tool within last five calendar years (using existing inventory), 2) all members of the of the
15 IPDAS group, 3) the Shared Decision Making listserv; 4) the Society for Participatory Medicine listserv ;
16 5) an overdiagnosis google group ; 6) the evidence-based healthcare listserv ; 7) the Society for Medical
17 Decision Making ; the 8) the Society of Behavioral Medicine (Health Decision Making Interest Group) ,
18 9) HTAi-ISG Patient Involvement listserv, 10) GRADE Working group, 11) the Guidelines International
19 Network, 12) convenience sample of policy makers with interest and expertise in PDA certification; 13)
20 the BMJ patient group; 14) the ProPublica Patient Safety Community. We have no other eligibility
21 criteria (except for membership to one of the above listed groups).
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26 For all participants, the survey invitation (Supplementary File 1) will provide a brief outline of the
27 study, a link to the online survey (Supplementary File 2), and a brief participant information sheet as
28 the first page of the survey. Consent will be inferred by participants' completion of the survey. The
29 ethics application form and protocol were submitted to Dartmouth College's committee for the
30 protection of human subjects on 27 April 2018. Approval was granted on 23 May 2018
31 (STUDY00031042).
32
33

34 In order not to contaminate the Delphi survey results and express their views twice (in developing the
35 original items and taking the surveys), the steering group members have unanimously decided not to
36 complete the Delphi surveys.
37
38

39 **Patient and Public Involvement**

40 **Design**

41 Our patient partner, SC, was involved in the development of the Delphi survey and provided
42 meaningful feedback on iterative drafts of the online questionnaire. SC is a core member of our study
43 steering group and an author on this manuscript.
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46

47 **Participants**

48 We also plan to make a concerted effort to recruit patient participants. We will reach out to online
49 patient groups, including the BMJ Patient group, the ProPublica Patient Safety Community (more than
50 6,000 members). We will also engage a patient and family advisor group at Dartmouth-Hitchcock
51 Medical Center.
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54 **Analysis**

55 Our patient partner will be a critical part of our analysis team, and will be involved in all steering group
56 meetings.
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Survey Development

The main output of the original Lyon evidence summarization meeting was the creation of a spreadsheet that detailed all evidence-summarization steps inherent to PDA development. The first draft of this spreadsheet, iteratively developed by the steering group members, included 18 criteria. Combining those 18 criteria with the eight existing standards for the summarization of clinical practice guidelines as outlined by the National Academy of Medicine (formerly IOM) & US Preventive Services Task Force Standards led to the creation of the first draft of the proposed process and steps. This draft was shared in a Google doc with all members of the steering group and iteratively refined and finalized. Three separate iterations of the process (phases, steps and criteria) were created, reviewed and discussed by the steering group members until no additional revisions were suggested. A final internal version of the criteria (n=48), categorized into four phases and 13 steps was finalized in April 2018 (see Supplementary File 3).

Data Collection

Round One Survey

The round one survey will include a brief information page and a summary of the process that led to the development of the phases, steps and criteria. Participants will be asked to provide their input on the phases, steps and criteria (including inclusion, wording, grouping, order and any other comments). Specifically, they will be asked to indicate using a four-point Likert scale (omit, possible, desirable, essential) whether each criterion included in the proposed process should be omitted or kept (and whether it is considered possible, desirable or essential). The criteria will be grouped into relevant phases and steps. For each phase and for each step, participants will be given the opportunity to provide rewording suggestions, suggest additional phases, steps or criteria, comment on the order of those elements or provide additional comments, or questions. Email addresses will be collected so participants can participate in further rounds. At the end of each round, we will confirm participants' interest to participate in the next round. Participants will also be asked to complete basic demographic questions. Each round of the survey will be open for three weeks, and two reminders will be sent.

Round Two Survey (and round three, as necessary)

Round one participants will be invited to complete a second survey, in which feedback will be provided about the results of the first round (percentage of participants who thought a criterion should be included or excluded) and about the changes made based on the qualitative feedback. Participants will be invited to indicate whether to omit or include (omit, possible, desirable, essential) the items, including the new items proposed by participants in the first round, and to provide additional rewording suggestions, comments, or questions. As mentioned above, the survey will be open for three weeks, and two email reminders will be sent. Depending on the level of consensus (see data analysis section), a third round may be conducted. This will be determined by the steering group after round 2 data analysis is completed. We will use open debate and discussion followed by a democratic consensus.

Data Analysis

Following round one, the ratings will be summarized using percentages and the views of all participants will be given equal weight. If at least 80% of participants rate the item in the lower two categories (omit, possible) or in the higher two categories (desirable, essential), we will consider

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2 consensus to be achieved and the item will be removed or retained, respectively. Items where ratings
3 do not meet the consensus threshold and conflict with open text comments will be grouped together
4 and explained to round 2 participants. They will be asked to re-rate those items taking the qualitative
5 feedback into account. Following the first survey round, a consensus meeting involving the steering
6 group will be held. The steering group will review and discuss the ratings and qualitative feedback
7 received, including rewording suggestions per criterion, suggestions to add new phases, steps or
8 criteria and more general comments or questions. The wording or order of the phases, steps or criteria
9 will be revised if two or more respondents suggest it or if the steering group members agree that the
10 phase, step or criterion would benefit from rewording, reordering or merging.
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14 Following the second survey round, a second consensus meeting will be held. Decisions on whether to
15 conduct a third round and retain items in the scale will be made based on the ratings in the survey
16 rounds and feedback/comments from participants. The ratings will be summarized using percentages
17 and the views of all participants will be given equal weight. If at least 80% of participants rate the
18 importance of the item in the lower two categories, or in the higher two categories, we will consider
19 consensus to be achieved and the item will be removed or retained, respectively. If no consensus is
20 achieved or the consensus ratings are contradicted by recurring open text comments, the steering
21 group will decide whether or not to retain a criterion, basing this decision on qualitative feedback from
22 the participants where possible, and the steering group's views. We have successfully used this
23 approach before [21].
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27 Only complete surveys will be included in the analysis. We will report the amount of missing data in
28 the manuscript reporting the results of the Delphi survey.
29

30 **Data Management and Safety**

31
32 Data to be collected include information about the participant's role as it relates to patient decision
33 aids, general demographics, and their opinion of what to add/change/include in an evidence
34 summarization process. We are careful to protect the identity of all study participants. We will store
35 the data securely in accordance with standard human subject research protocols. All data will be
36 retained for three years, per the Dartmouth College data retention policy (or for the period specified
37 by journals in which arising manuscripts are published, if longer) and then destroyed securely.
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40 **DISCUSSION**

41 Patient decision aids must have accurate and trustworthy evidence-based information about the risks
42 and benefits of health treatments and tests, as these tools help patients make important healthcare
43 choices. We want to generate consensus on an approach for selecting and summarizing the evidence
44 included in patient decision aids, which we hope can be widely adopted by decision aid developers.
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47 **STRENGTHS AND LIMITATIONS**

48
49 A strength of this study is the systematic involvement of patients and relevant stakeholders in planning
50 the modified Delphi survey. We plan to include a diverse sample of participant stakeholders including
51 patients, researchers, patient decision aid developers and health policy makers. Limitations of online
52 surveys always include the possibility of selection biases, meaning participants who opt to take the
53 survey may be systematically different than the target population. In our case, the participants may be
54 more engaged and more interested in the outcome of the Delphi survey. There is also a possibility that
55 their views will be stronger than those who opted not to participate.
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CONCLUSION

Patients should be able to trust the information they receive from patient decision aids. Together with their clinicians, family and caregivers, they rely on these tools to make decisions that are aligned with their informed preferences. We believe standardizing a process for selecting and summarizing the evidence included in patient decision aids is therefore a worthwhile effort. Bringing all relevant stakeholders to the table - patients, researchers, patient decision aid developers, and healthcare policy makers - will ensure that the ultimate outcome is rigorous and rooted in consensus, to promote widespread adoption.

ETHICS AND DISSEMINATION

Dartmouth College's Committee for the Protection of Human Subjects approved this protocol. We plan to publish our results in a peer-reviewed journal.

FUNDING

We did not receive funding for this project.

COMPETING INTERESTS

Glyn Elwyn and Marie-Anne Durand have developed the Option Grid patient decision aids, and EBSCO Information Services sells subscription access to Option Grid patient decision aids. They receive consulting income from EBSCO Health, and may receive royalties in the future. Glyn Elwyn and Marie-Anne Durand are consultant for ACCESS Community Health Network. Brian S. Alper is employed full-time by EBSCO Information Services which is a for-profit company that publishes patient decision aids. No other competing interests declared.

AUTHORSHIP CONTRIBUTIONS

Marie-Anne Durand, Glyn Elwyn and Michelle D. Dannenberg planned and designed the study. Catherine H. Saunders, Anik Giguère, Brian S. Alper, Tammy Hoffmann, Lilisbeth Perestelo Perez and Stephen T. Campbell provided advice and guidance on the design. Marie-Anne Durand drafted the manuscript and all authors contributed to writing and approved the final draft of the manuscript.

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2 **Supplementary File 1: Survey Invitation**

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4 SUBJ: Help us make more trustworthy patient materials: provide your feedback through a survey

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6 To the members of [group name/list-serv name] –

7
8
9 We are an international workgroup, led by Marie-Anne Durand and Glyn Elwyn at The Dartmouth Institute for Health Policy and
10 Clinical Practice in Lebanon, N.H. We noticed a need for more clarity about how to select and summarize the evidence included
11 in patient decision aids. Patient decision aids influence the decisions that patients make - so the need for trustworthy tools is
12 important.
13

14
15 We wish to have your perspective, as an expert, patient, or other stakeholder.
16

17
18 **Please could you provide feedback via 2-3 surveys over the next few weeks?** Each survey should take less than 25
19 minutes.
20

21
22 Please click the link below for more information and the first survey.
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25 Many thanks,
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28 The Evidence Summarization workgroup
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For peer review only

Evidence Summarization Survey

Information Sheet

SURVEY INFORMATION

What is the study about?

We want to generate consensus on an approach for selecting and summarizing the evidence included in patient decision aids. Our workgroup developed a proposed set of Phases, Steps and Criteria, based on the methods used to develop trustworthy clinical practice guidelines. The purpose of this survey is to gain your perspective, as an expert, patient or other stakeholder.

What is involved?

If you participate, we'll ask you to complete two or three surveys. In the first survey, we'll ask for your perspective on the proposed Phases, Steps and Criteria. This will include rating importance, suggesting wording changes and suggesting additional items. In the second and third surveys, we'll ask similar questions except we'll also share some results from the first survey.

How long will it take?

Completing this survey should take less than 25 minutes.

Do I have to take part?

No. Taking part is voluntary.

Will I be compensated?

You won't be compensated. However, we hope you'll take part. Your contributions

1 will improve the process of developing reliable, high-quality decision aids for
2 patients.

3 4 5 **Are there any risks?**

6 We don't anticipate any risks from participating in the study.
7
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9

10 **How will my privacy be protected?**

11 We won't name any individuals in any publications or presentations.
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15 **How can I contact you?**

16 If you have questions, please feel free to contact Michelle Dannenberg
17 (Michelle.D.Dannenberg@dartmouth.edu), Research Coordinator, The Dartmouth
18 Institute for Health Policy and Clinical Practice, Dartmouth College.
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24 If you would like to speak to the researchers leading this study, please contact Prof.
25 Marie-Anne Durand (Marie-Anne.Durand@dartmouth.edu) or Prof. Glyn Elwyn
26 (glynelwyn@gmail.com), The Dartmouth Institute for Health Policy and Clinical
27 Practice, Dartmouth College.
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33 **What happens if I do not respond?**

34 You'll receive two automated email reminders to complete the survey.
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41 Do you want to participate?

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43 Yes

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45 No
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51 **Background Questions**

52 **BACKGROUND QUESTIONS**

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1 Which of the following best describes you? Please select all that apply.
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- 3 Patient Decision Aid (PDA) developer
- 4 Researcher
- 5
- 6 International Patient Decision Aids Standards (IPDAS) collaboration member
- 7
- 8 Policy maker
- 9
- 10 Patient
- 11
- 12 Clinician, please specify specialty:
- 13
- 14 Other, please specify:
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23 Which country do you live in?
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30 What is your gender?
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- 32 Male
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- 34 Female
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- 36 Other
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42 What is your race/ethnicity? Please select all that apply.
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- 44 American Indian or Alaska Native
- 45
- 46 Asian
- 47
- 48 Black or African American
- 49
- 50 Native Hawaiian or Other Pacific Islander
- 51
- 52 Hispanic, Latino/a or Spanish Origin
- 53
- 54 White
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Other, please specify:

BACKGROUND QUESTIONS

We're requesting your email address so we can contact you for the next phase of this project. We will not share your email with anyone outside the study team, and we will not contact you about anything other than the study.

Please provide your email:

Overall Proposed Phases, Steps and Criteria

INFORMATION ON PROPOSED PROCESS

Decision aids are tools that help patients make choices. They provide information about the risks and benefits of health treatments and tests.

Accurate and clear information is critical. It's important for decision aids to have accurate and trustworthy information from research evidence about the risks and benefits of health treatments and tests.

We're trying to make evidence summarization easier. We're doing this by developing a process to guide decision aid developers in evidence summarization.

We're building on the good work that's already been done. This process includes the existing work of the International Patient Decision Aid Standards (IPDAS) collaboration.

We sketched out a proposed process, see Figure below. We are interested in your feedback on ALL elements of this, including the Phases, Steps and Criteria, as

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

well as the order and grouping.

Here's how you can help. In the questions that follow, we will ask for your perspective on **how important each criterion is to include in the proposed process.** We will also ask for feedback on the wording of all parts. Nothing is final. Everything is up for discussion, and we are looking forward to hearing from you.

Below is a visual representation of the proposed process. Review it carefully. There are four proposed phases, each with one to five proposed steps. Each step has a number of proposed Criteria. In the visual representation below, we show the first Criteria for each step. The tabs represent additional Criteria.

Feel free to [click here](#) to view the representation of the proposed Phases, Steps and Criteria in a separate window. You can click on the image to zoom. You can refer back to this image as you answer questions about the proposed process. Don't worry, if you accidentally close the window, there are links to the figure on each page of the survey.

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

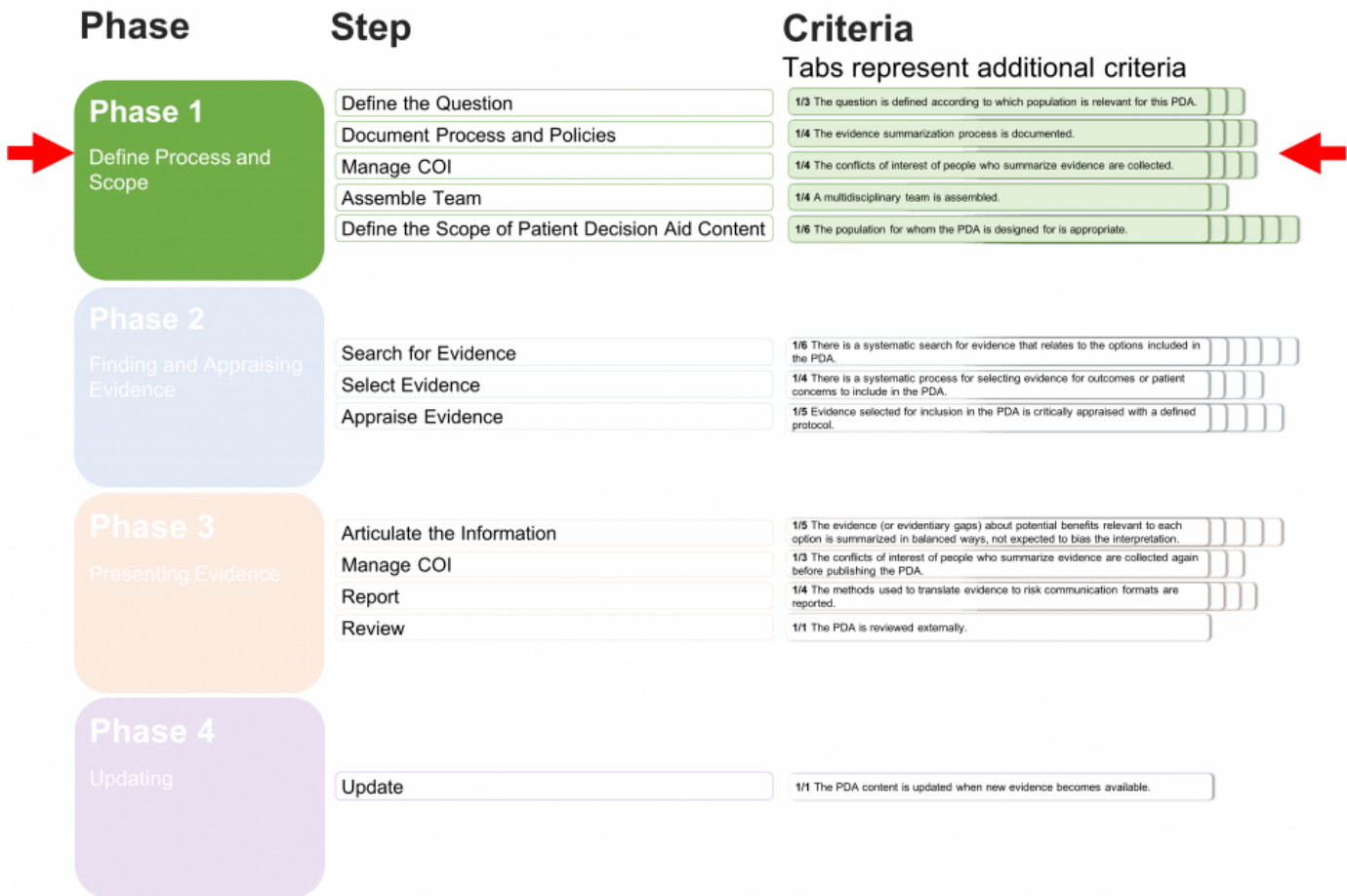
Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.

Phase 1

PROPOSED PHASE 1

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Phase below? If so, please share them.

- Phase 1: Defining Process and Scope**

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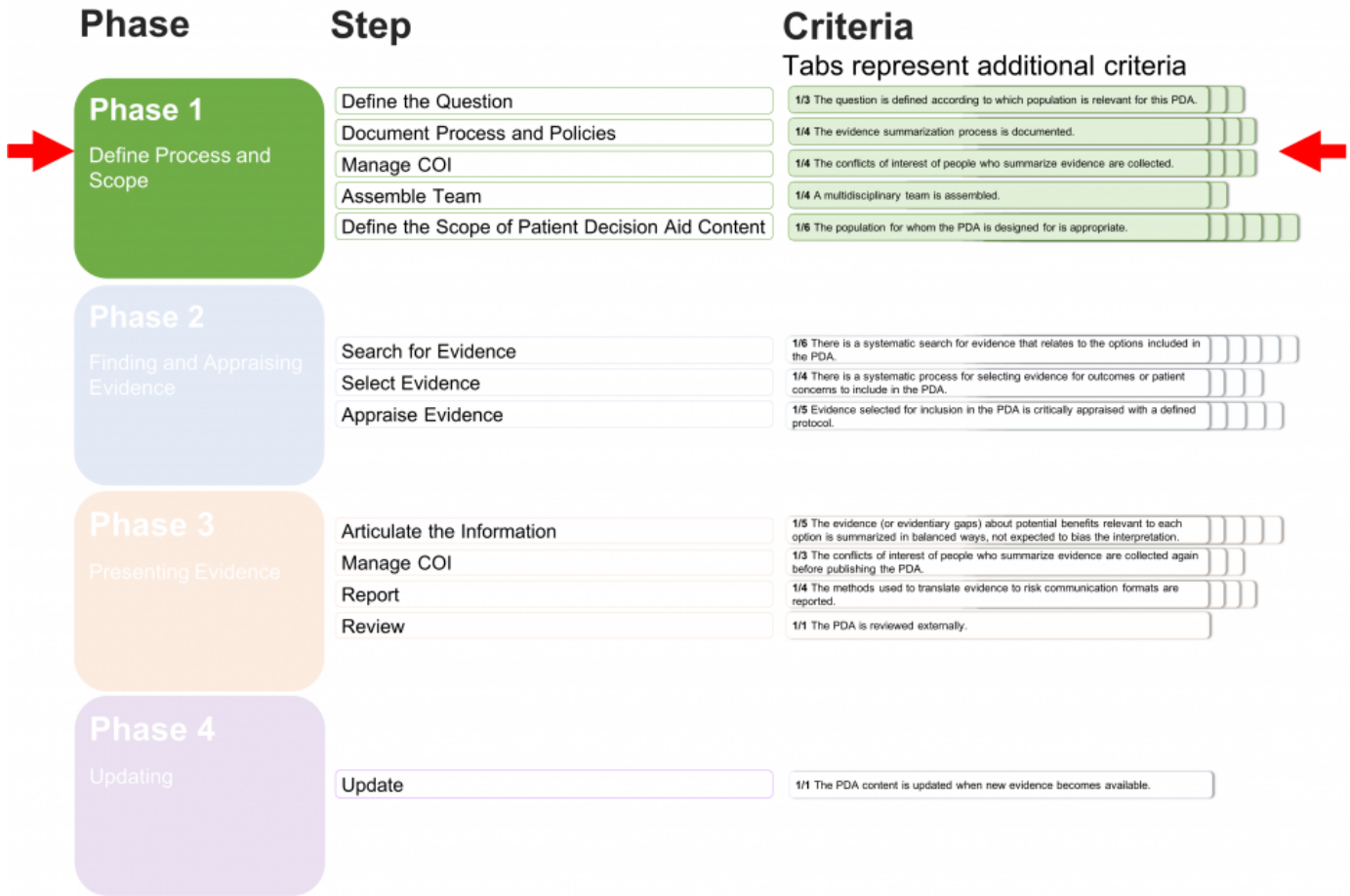
Do you have any comments on the Steps below, including their wording or order? Or suggestions for additional steps? If so, please share them.

- **Step 1: Define the Question**
- **Step 2: Document Process and Policies**
- **Step 3: Manage COI**
- **Step 4: Assemble Team**
- **Step 5: Define the Scope of Patient Decision Aid Content**

PROPOSED PHASE 1 STEP 1

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 1: Define the Question**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible Desira

The question is defined according to which population is relevant for this PDA.

The question is defined according to which options are relevant for this PDA.

The question is defined according to which outcomes or patient concerns are relevant for this PDA.

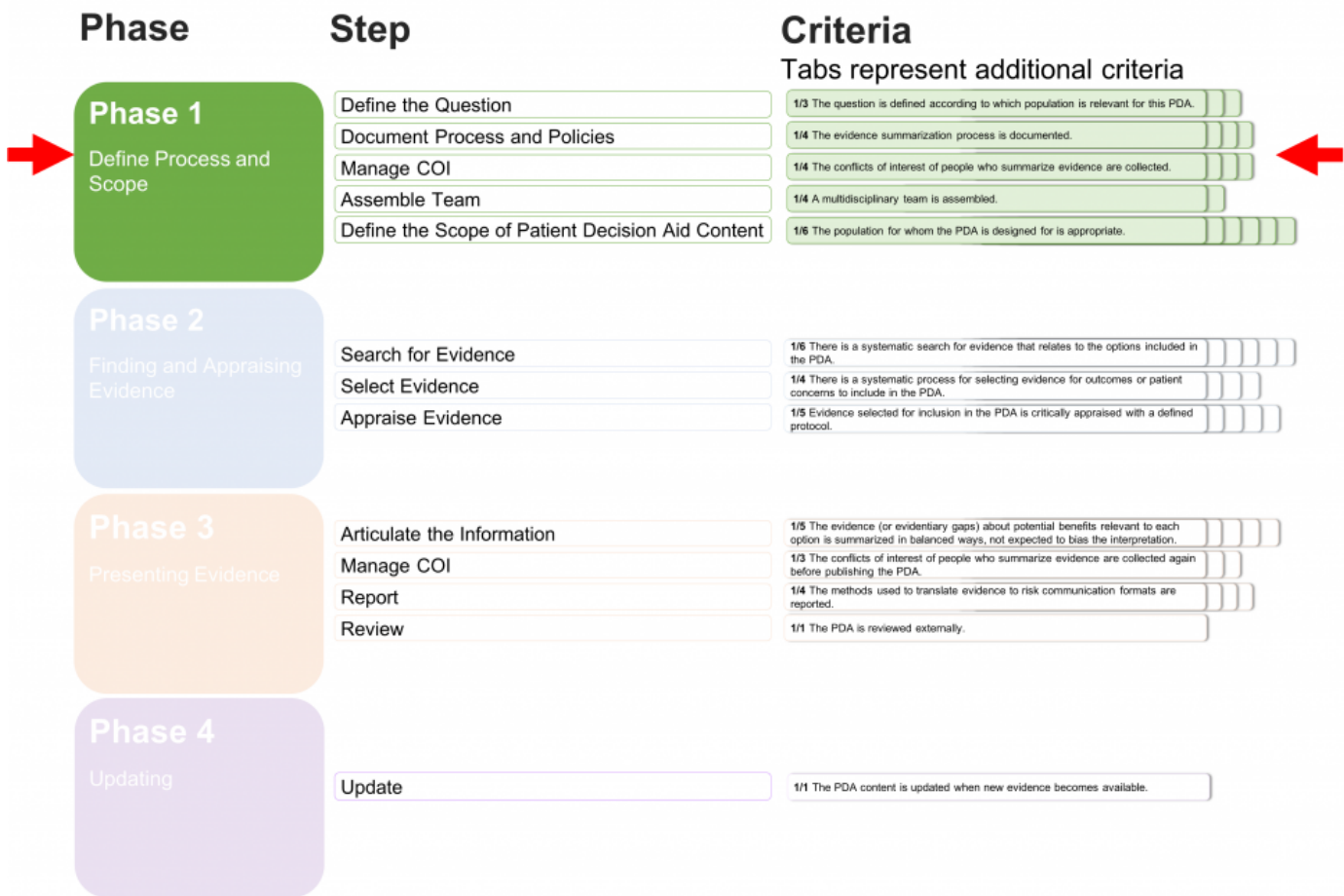
Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 1 STEP 2

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on this Step? If so, please share them.

- **Step 2: Document Process and Policies**

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The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible C

- The evidence summarization process is documented.
- The evidence summarization process minimizes bias.
- The evidence summarization process minimizes conflicts of interest.
- The conflict of interest policy applying to people who summarize evidence is documented.

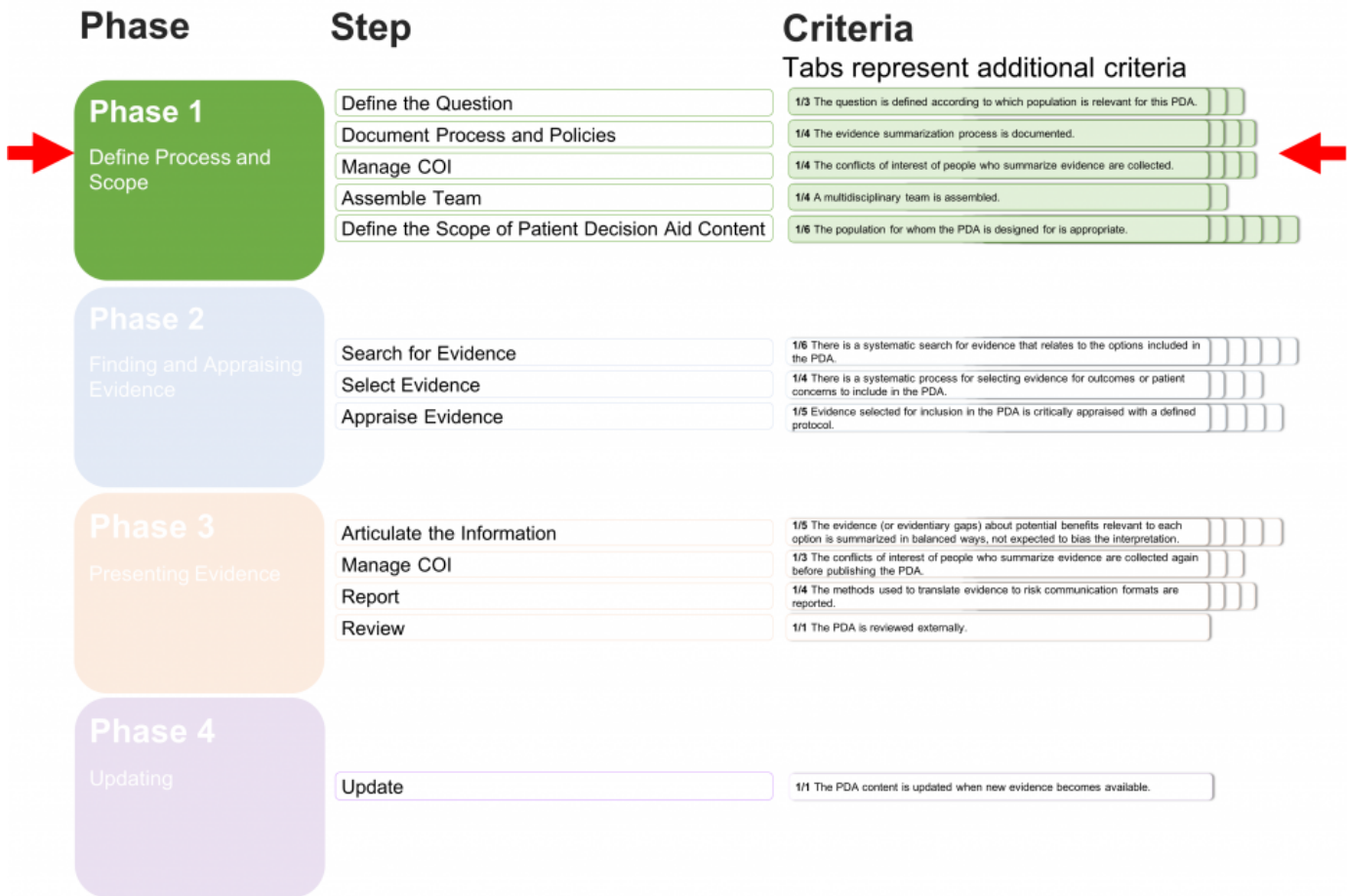
Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 1 STEP 3

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on this Step? If so, please share them.

- **Step 3: Manage COI**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

The conflicts of interest of people who summarize evidence are collected.

Actions are taken to manage relevant conflicts of interest.

The actions taken on relevant conflicts of interest are documented.

Conflicts of interest are monitored over the course of PDA development.

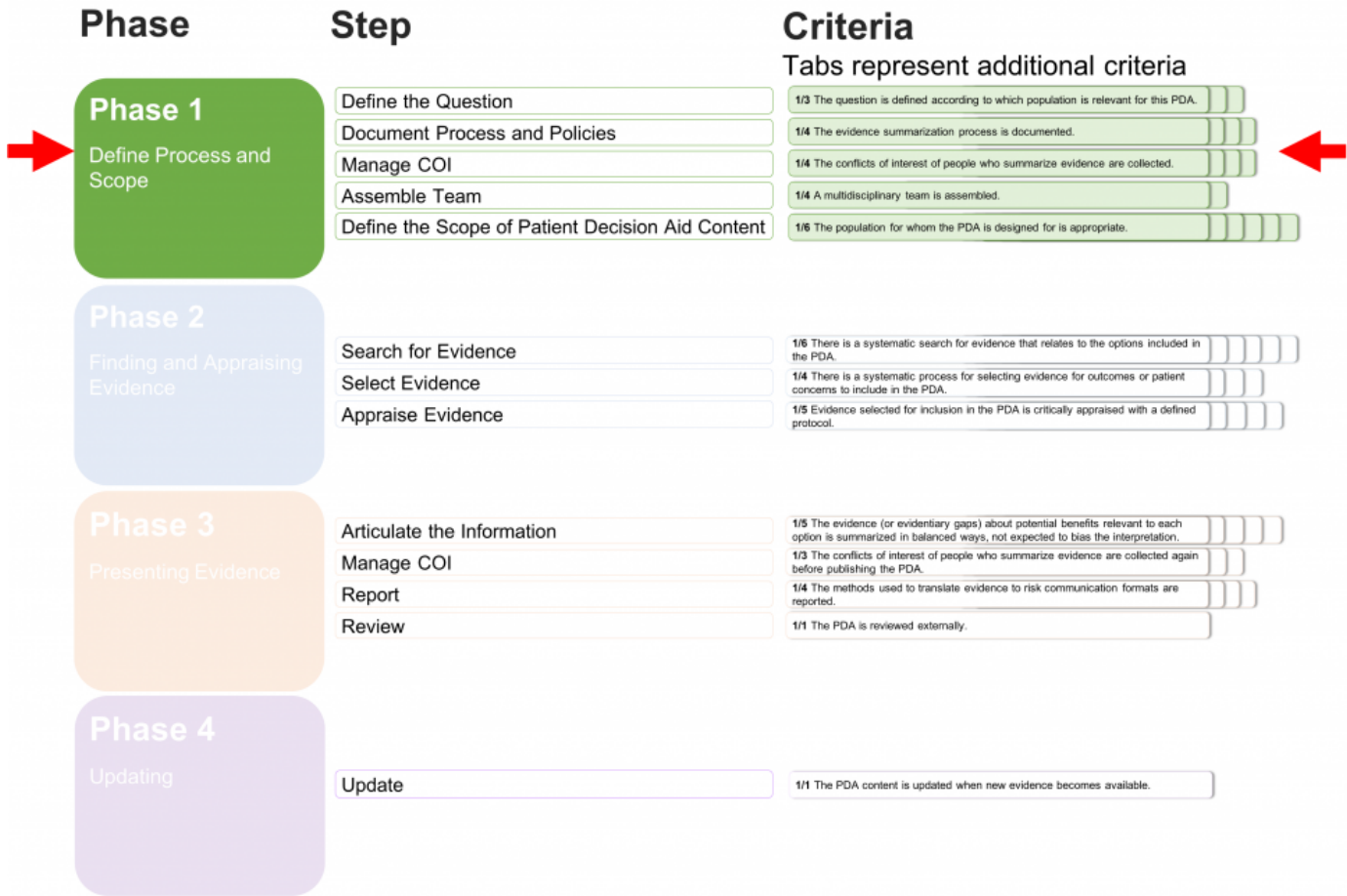
Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 1 STEP 4

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- Step 4: Assemble Team**

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The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible [

- A multidisciplinary team is assembled.
- The team comprises clinicians.
- The team comprises methodological experts.
- The team comprises patient or consumer representatives.

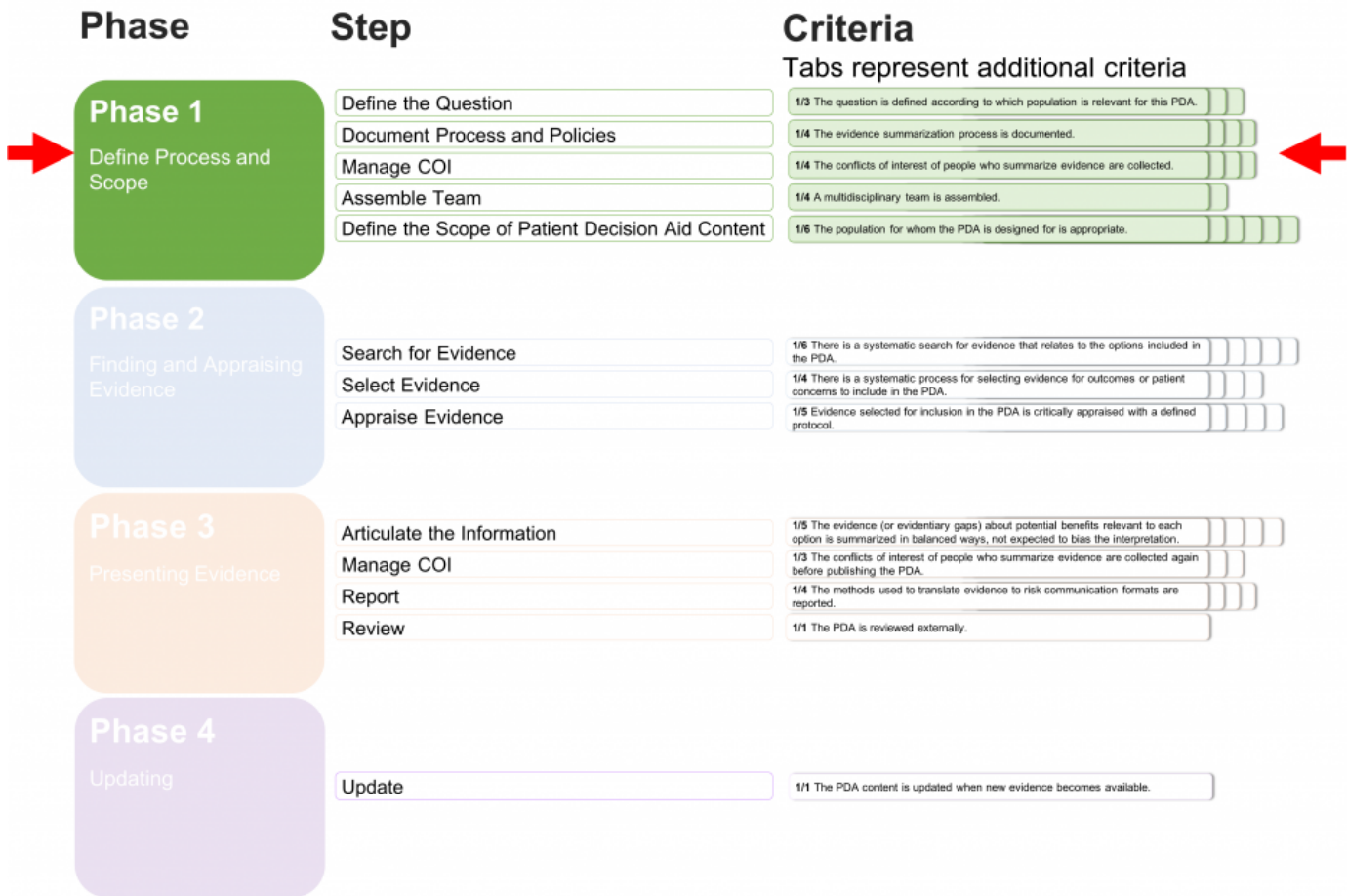
Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 1 STEP 5

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 5: Define the Scope of Patient Decision Aid Content**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

The population for whom the PDA is designed for is appropriate.

There is a systematic process to reduce bias in the definition of the population for the PDA.

The options for inclusion in the PDA are appropriate for the intended population.

There is a systematic process to reduce bias in the definition of the options for the PDA.

The outcomes or patient concerns for inclusion in the PDA are appropriate for the intended population and options.

There is a systematic process to reduce bias in the definition of the outcomes or patient concerns for the PDA.

Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

Phase 2

PROPOSED PHASE 2

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.

Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

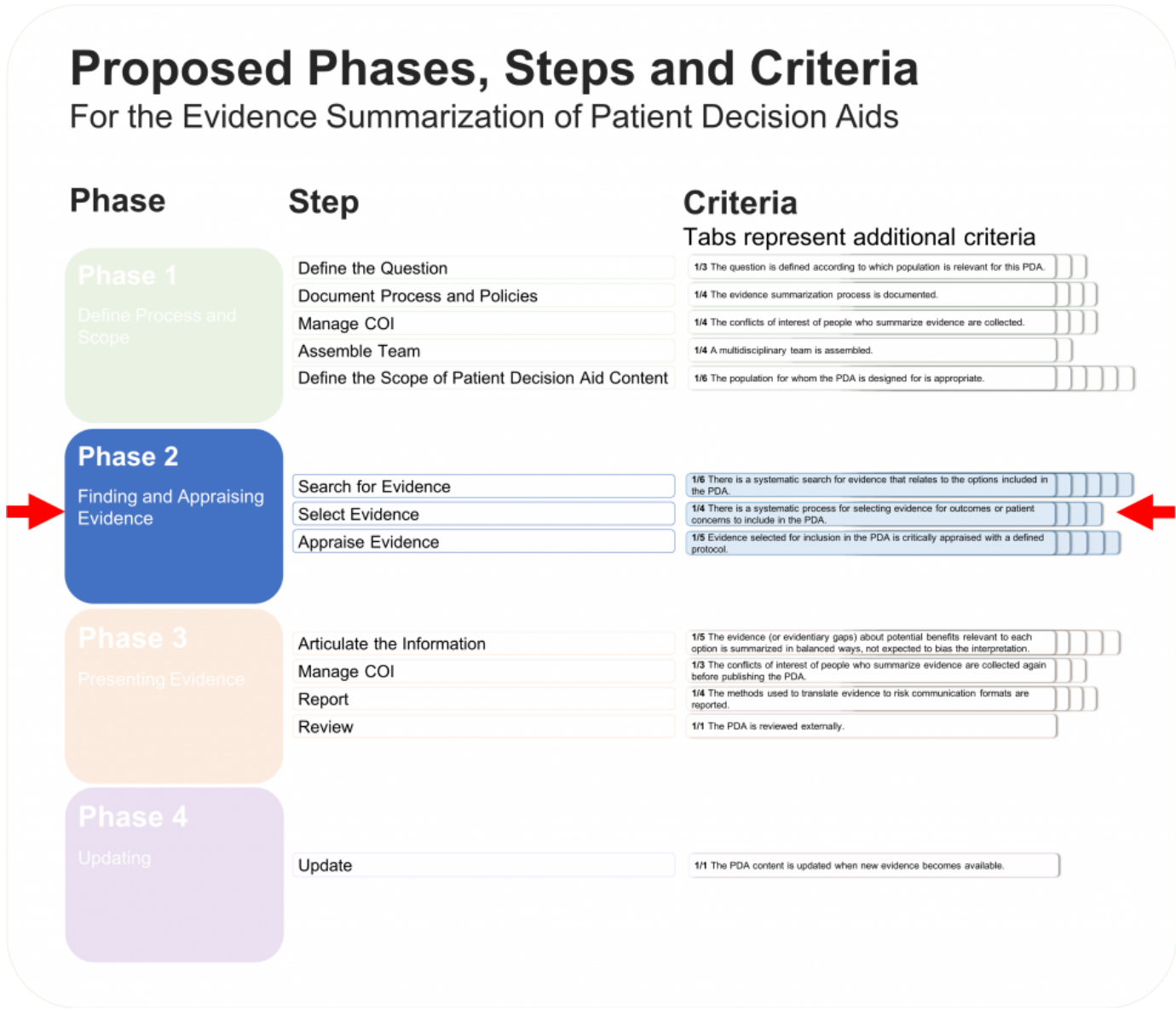
Do you have any comments or suggestions on the Phase below? If so, please share them.

- Phase 2: Finding & Appraising Evidence

Do you have any comments on the Steps below, including their wording or order? Or suggestions for additional steps? If so, please share them.

- Step 1: Search for Evidence
- Step 2: Select Evidence
- Step 3: Appraise Evidence

PROPOSED PHASE 2 STEP 1



1 Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and
2 Criteria in a separate window while you complete the questions below.
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7 Do you have any comments or suggestions on this Step? If so, please share them.
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10 • **Step 1: Search for Evidence**
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20 The proposed Criteria for this step are below. Please indicate whether each
21 Criterium should be omitted, or whether it is a possible candidate for inclusion,
22 a desirable candidate for inclusion or is essential for inclusion.
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	Omit	Possible	Essential
26 27 28 29 There is a systematic search for evidence that relates to the options 30 included in the PDA.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
31 32 33 There is a systematic search for evidence that relates to the 34 outcomes or patient concerns included in the PDA.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
35 36 37 If the PDA is customizable to individual patient factors, there is a 38 systematic search for evidence of how individual patient factors 39 influence the expected outcomes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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43 Do you have any comments or suggestions on the Criteria above? If so, please
44 share them.
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52 Do you have any suggestions for additional Criteria to include in this Step? If so,
53 please share them.
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PROPOSED PHASE 2 STEP 2

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.

Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 2: Select Evidence**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA (where evidence is not available, can directly ask patients).

There is a systematic process for selecting evidence (or evidentiary gaps) about potential benefits relevant to each option.

There is a systematic process for selecting evidence (or evidentiary gaps) about potential harms relevant to each option.

If the PDA is customizable to individual patient factors, there is a systematic process for selecting relevant risk predictors to include in the PDA.

Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 2 STEP 3

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.

Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- Step 3: Appraise Evidence**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

Evidence selected for inclusion in the PDA is critically appraised with a defined protocol (such as GRADE).

The protocol for critical appraisal of evidence accounts for risks of bias in study design.

The protocol for critical appraisal of evidence accounts for risks of bias in study analysis and reporting.

The protocol for critical appraisal of evidence accounts for assessment of certainty of evidence with attention to risk of bias, precision, directness, consistency, and publication bias.

The conflicts of interest of study authors related to selected evidence is appraised.

Do you have any comments or suggestions on the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

Phase 3

PROPOSED PHASE 3

Proposed Phases, Steps and Criteria

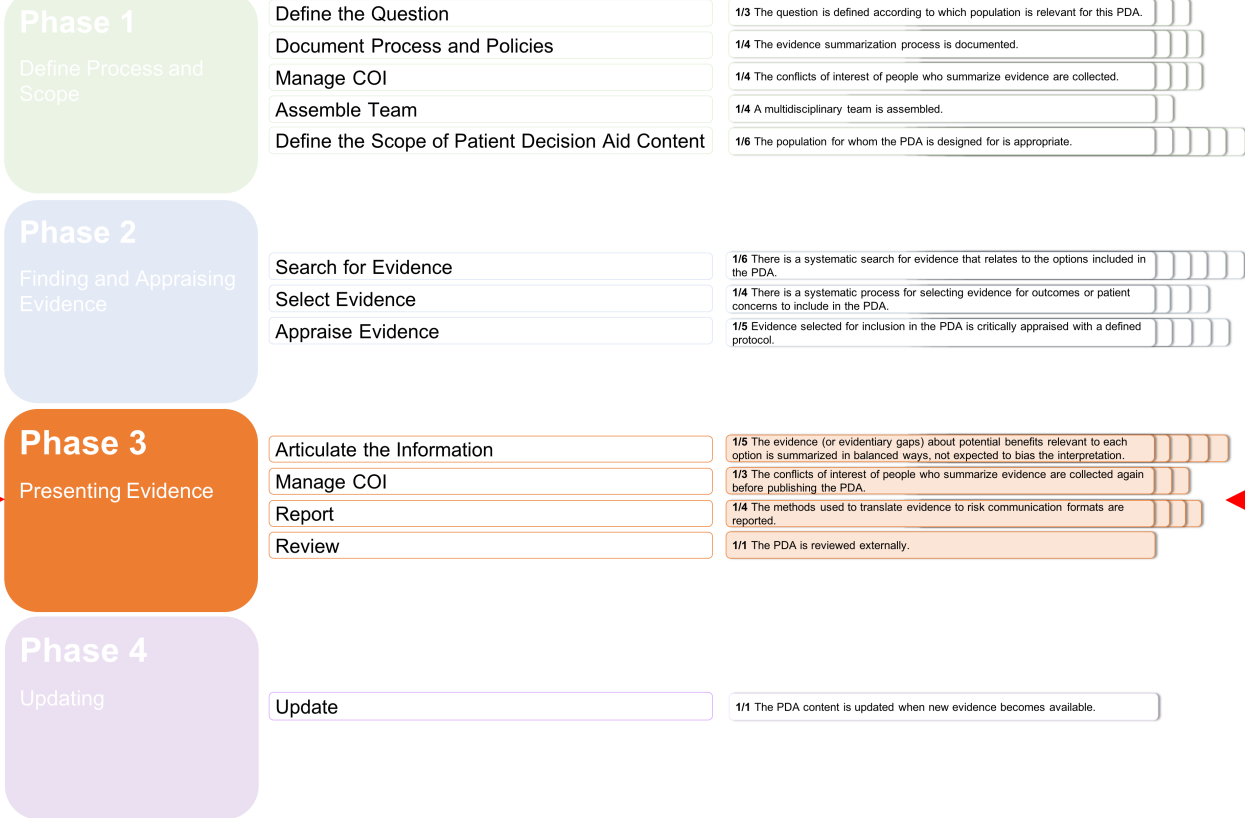
For the Evidence Summarization of Patient Decision Aids

Phase

Step

Criteria

Tabs represent additional criteria



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Phase below? If so, please share them.

- **Phase 3: Presenting Evidence**

Do you have any comments on the Steps below, including their wording or order? Or do you have suggestions for additional steps? If so, please share them.

- Step 1: Articulate the Information
- Step 2: Manage COI
- Step 3: Report
- Step 4: Review

Empty text input box for comments.

PROPOSED PHASE 3 STEP 1

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.



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Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

• **Step 1: Articulate the Information**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible I
The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.	<input type="radio"/>	<input type="radio"/>
The evidence (or evidentiary gaps) about potential harms relevant to each option is summarized in balanced ways, not expected to bias the interpretation.	<input type="radio"/>	<input type="radio"/>
The evidence (or evidentiary gaps) is summarized in ways that are easy to understand.	<input type="radio"/>	<input type="radio"/>
The certainty of the evidence is described in ways that are easy to understand.	<input type="radio"/>	<input type="radio"/>
The evidence summarization process is described in ways that are easy to understand.	<input type="radio"/>	<input type="radio"/>
The funding used to summarize the evidence (and develop the PDA) is reported.	<input type="radio"/>	<input type="radio"/>

Do you have any comments or suggestions on the wording or order of any of the Criteria above? If so, please share them.

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4 Do you have any suggestions for additional Criteria to include in this Step? If so,
5 please share them.
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13 **PROPOSED PHASE 3 STEP 2**
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19 **Proposed Phases, Steps and Criteria**

20 For the Evidence Summarization of Patient Decision Aids

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23
24 **Phase**

Step

Criteria

25 Tabs represent additional criteria

26 **Phase 1**

27 Define Process and
28 Scope

- 29 Define the Question
- 30 Document Process and Policies
- 31 Manage COI
- 32 Assemble Team
- 33 Define the Scope of Patient Decision Aid Content

- 34 1/3 The question is defined according to which population is relevant for this PDA.
- 35 1/4 The evidence summarization process is documented.
- 36 1/4 The conflicts of interest of people who summarize evidence are collected.
- 37 1/4 A multidisciplinary team is assembled.
- 38 1/6 The population for whom the PDA is designed for is appropriate.

39 **Phase 2**

40 Finding and Appraising
41 Evidence

- 42 Search for Evidence
- 43 Select Evidence
- 44 Appraise Evidence

- 45 1/6 There is a systematic search for evidence that relates to the options included in the PDA.
- 46 1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
- 47 1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.

48 **Phase 3**

49 Presenting Evidence

- 50 Articulate the Information
- 51 Manage COI
- 52 Report
- 53 Review

- 54 1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
- 55 1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
- 56 1/4 The methods used to translate evidence to risk communication formats are reported.
- 57 1/1 The PDA is reviewed externally.

58 **Phase 4**

59 Updating

- 60 Update

- 1/1 The PDA content is updated when new evidence becomes available.



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2 Do you have any comments or suggestions on the Step below? If so, please share
3 them.
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7 • **Step 2: Manage COI**
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15 The proposed Criteria for this step are below. Please indicate whether each
16 Criterium should be omitted, or whether it is a possible candidate for inclusion,
17 a desirable candidate for inclusion or is essential for inclusion.
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	Omit	Possible	Essential
20 21 22 23 24 The conflicts of interest of people who summarize evidence are 25 collected again before publishing the PDA.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
26 27 Any change to the conflicts of interest of people who summarize 28 evidence are reported.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29 30 31 Actions are taken to manage relevant conflicts of interest.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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35 Do you have any comments or suggestions on the wording or order of any of the
36 Criteria above? If so, please share them.
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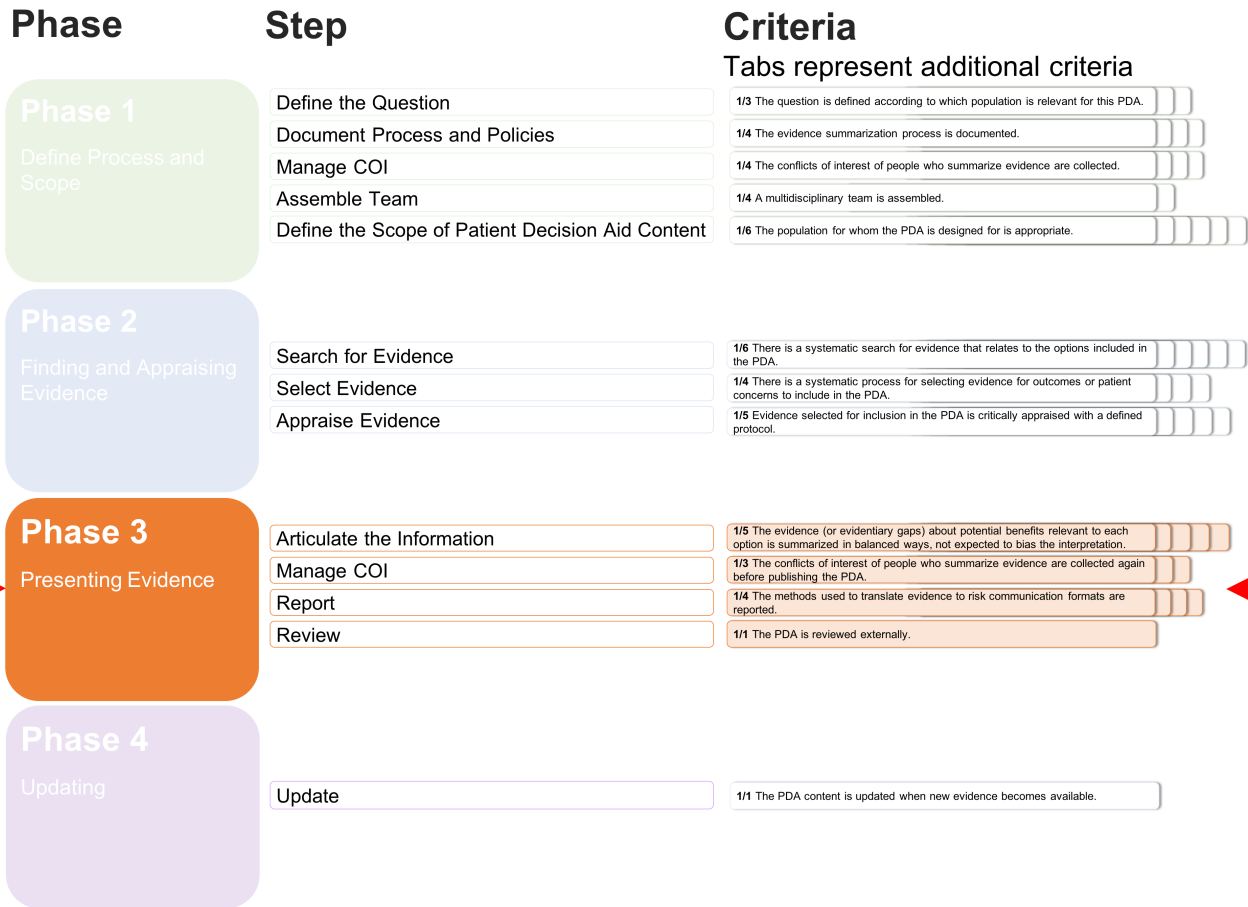
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44 Do you have any suggestions for additional Criteria to include in this Step? If so,
45 please share them.
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53 **PROPOSED PHASE 3 STEP 3**
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Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 3: Report**

The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible E

The methods used to translate evidence to risk communication formats are reported.

The approach to readability of summarized evidence is reported.

The summarization process is reported publicly.

The conflict of interest of people who summarize evidence are reported publicly.

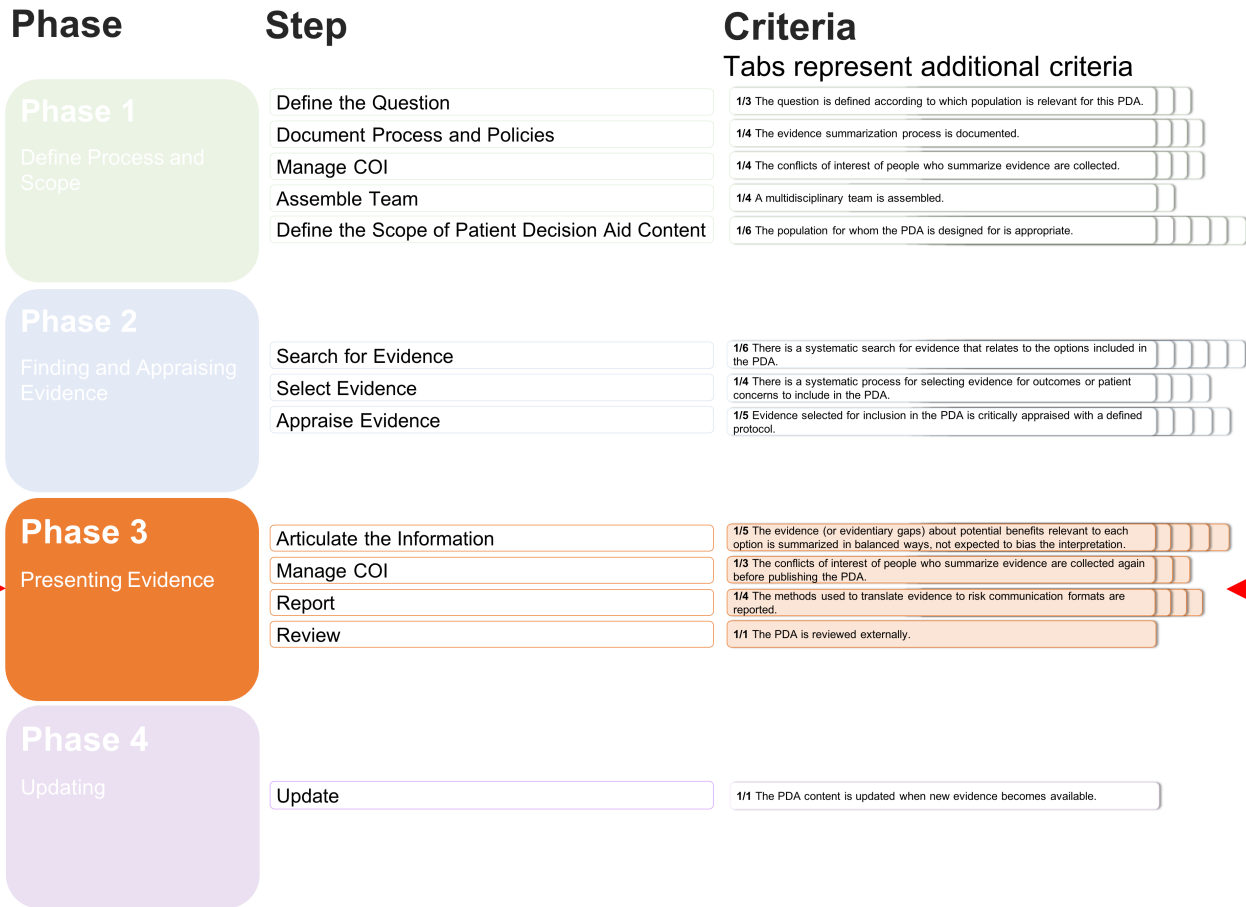
Do you have any comments or suggestions on the wording or order of any of the Criteria above? If so, please share them.

Do you have any suggestions for additional Criteria to include in this Step? If so, please share them.

PROPOSED PHASE 3 STEP 4

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 4: Review**

1 The proposed Criteria for this step are below. Please indicate whether each criterium
2 should be omitted, or whether it is a possible candidate for inclusion,
3 a desirable candidate for inclusion or is essential for inclusion.
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Omit F

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8 The PDA is reviewed externally.

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13 Do you have any comments or suggestions on the wording or order of any of the
14 Criteria above? If so, please share them.
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22 Do you have any suggestions for additional Criteria to include in this Step? If so,
23 please share them.
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31 **Phase 4**

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35 **PROPOSED PHASE 4**

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.



Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Phase below? If so, please share them.

- Phase 4: Updating**

Do you have any comments or suggestions on the Step below. If so, please share them.

• Step 1: Update

PROPOSED PHASE 4 STEP 1

Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids

Phase	Step	Criteria
Phase 1 Define Process and Scope	Define the Question	1/3 The question is defined according to which population is relevant for this PDA.
	Document Process and Policies	1/4 The evidence summarization process is documented.
	Manage COI	1/4 The conflicts of interest of people who summarize evidence are collected.
	Assemble Team	1/4 A multidisciplinary team is assembled.
	Define the Scope of Patient Decision Aid Content	1/6 The population for whom the PDA is designed for is appropriate.
Phase 2 Finding and Appraising Evidence	Search for Evidence	1/6 There is a systematic search for evidence that relates to the options included in the PDA.
	Select Evidence	1/4 There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA.
	Appraise Evidence	1/5 Evidence selected for inclusion in the PDA is critically appraised with a defined protocol.
Phase 3 Presenting Evidence	Articulate the Information	1/5 The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
	Manage COI	1/3 The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
	Report	1/4 The methods used to translate evidence to risk communication formats are reported.
	Review	1/1 The PDA is reviewed externally.
Phase 4 Updating	Update	1/1 The PDA content is updated when new evidence becomes available.



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Feel free to [click here](#) to view a visualization of the proposed Phases, Steps and Criteria in a separate window while you complete the questions below.

Do you have any comments or suggestions on the Step below? If so, please share them.

- **Step 1: Update**

The proposed Criteria for this step are below. Please indicate whether each criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

Omit Possible I

The PDA content is updated when new evidence becomes available.

Do you have any comments or suggestions on the wording of the criterion above? If so, please share them.

Do you have any suggestions for additional criteria to include in this Step? If so, please share them.

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Supplementary File 3: Proposed Phases, Steps, and Criteria

Existing standard (from IOM & USPSTF)	Phase	Step	Criteria
Establishing transparency	Phase I: Define Process and Scope	Define the question	The question is defined according to which population is relevant for this PDA.
			The question is defined according to which options are relevant for this PDA.
			The question is defined according to which outcomes or patient concerns are relevant for this PDA.
		Document process and policies	The evidence summarization process is documented.
			The evidence summarization process minimizes bias.
			The evidence summarization process minimizes conflicts of interest.
			The conflict of interest policy applying to people who summarize evidence is documented.
Management of conflict of interest	Manage COI	The conflicts of interest of people who summarize evidence are collected.	
		Actions are taken to manage relevant conflicts of interest.	
		The actions taken on relevant conflicts of interest are documented.	
		Conflicts of interest are monitored over the course of PDA development.	
Guideline development group composition	Assemble team	A multidisciplinary team is assembled.	
		The team comprises clinicians.	
		The team comprises methodological experts.	
		The team comprises patient or consumer representatives.	
	Define the scope of patient decision aid content	The population for whom the PDA is designed for is appropriate.	
		There is a systematic process to reduce bias in the definition of the population for the PDA.	
		The options for inclusion in the PDA are appropriate for the intended population.	
		There is a systematic process to reduce bias in the definition of the options for the PDA.	
		The outcomes or patient concerns for inclusion in the PDA are appropriate for the intended population and options.	

			There is a systematic process to reduce bias in the definition of the outcomes or patient concerns for the PDA.
Guideline and systematic review intersection	PHASE II: Finding & Appraising Evidence	Search for evidence	There is a systematic search for evidence that relates to the options included in the PDA.
			There is a systematic search for evidence that relates to the outcomes or patient concerns included in the PDA.
			If the PDA is customizable to individual patient factors, there is a systematic search for evidence of how individual patient factors influence the expected outcomes.
Establishing evidence foundations and rating strength of recommendation		Select evidence	There is a systematic process for selecting evidence for outcomes or patient concerns to include in the PDA (where evidence is not available, can directly ask patients).
			There is a systematic process for selecting evidence (or evidentiary gaps) about potential benefits relevant to each option.
			There is a systematic process for selecting evidence (or evidentiary gaps) about potential harms relevant to each option.
			If the PDA is customizable to individual patient factors, there is a systematic process for selecting relevant risk predictors to include in the PDA.
		Appraise evidence	Evidence selected for inclusion in the PDA is critically appraised with a defined protocol (such as GRADE).
			The protocol for critical appraisal of evidence accounts for risks of bias in study design.
			The protocol for critical appraisal of evidence accounts for risks of bias in study analysis and reporting.
Articulation of information	PHASE III: Presenting Evidence	Articulate the information	The evidence (or evidentiary gaps) about potential benefits relevant to each option is summarized in balanced ways, not expected to bias the interpretation.
			The evidence (or evidentiary gaps) about potential harms relevant to each option is summarized in balanced ways, not expected to bias the interpretation.

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			The evidence (or evidentiary gaps) is summarized in ways that are easy to understand.
			The certainty of the evidence is described in ways that are easy to understand.
			The evidence summarization process is described in ways that are easy understand.
			The funding used to summarize the evidence (and develop the PDA) is reported.
		Manage COI	The conflicts of interest of people who summarize evidence are collected again before publishing the PDA.
			Any change to the conflicts of interest of people who summarize evidence are reported.
			Actions are taken to manage relevant conflicts of interest.
		Report	The methods used to translate evidence to risk communication formats are reported.
			The approach to readability of summarized evidence is reported.
			The summarization process is reported publicly.
			The conflict of interest of people who summarize evidence are reported publicly.
		Review	The PDA is reviewed externally.
Updating	PHASE IV: Post-publication update	Update	The PDA content is updated when new evidence becomes available.

For peer review only