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

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Complete List of Authors:	Durand, Marie-Anne; The Dartmouth Institute for Health Policy & Clinical Practice, Dannenberg, Michelle; Dartmouth College, The Dartmouth Institute for Health Policy and Clinical Practice Saunders, Catherine; Dartmouth College, The Dartmouth Institute for Health Policy & Clinical Practice Giguère, Anik; Universite Laval Faculte de medecine Alper, Brian; EBSCO Health, DynaMed Plus; University of Missouri Columbia School of Medicine, Family and Community Medicine Hoffman, Tammy; Bond University, Perestelo-Pérez, L; Evaluation Unit of the Canary Islands Health Service Campbell, Stephen; Dartmouth College Geisel School of Medicine Elwyn, Glyn; Dartmouth College,
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Study protocol: A modified Delphi survey for the evidence summarization of patient decision aids

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Authors:
Marie-Anne Durand[1]
Michelle D. Dannenberg[2]
Catherine H. Saunders[3]
Anik Giguère[4]
Brian S. Alper[5]
Tammy Hoffmann[6]
Lilisbeth Perestelo-Perez[7]
Stephen T. Campbell[8]
Glyn Elwyn[9]

1 Associate Professor
The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States
2 Research Assistant/Research Coordinator
The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States
3 Doctoral Student
The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States
4 Associate Professor
Department of Family Medicine
Université Laval, C.A.
2325 Rue de l'Université, Québec, QC G1V 0A6, Canada
5 Vice President of Innovations and EBM Development
EBSCO Health Innovations, Department of Innovations and EBM Development
10 Estes Street, Ipswich, MA 01938, United States
6 Professor of Clinical Epidemiology
Centre for Research in Evidence-Based Practice (CREBP)
Faculty of Health Sciences & Medicine
Level 2, Building 5, Faculty of Health Sciences & Medicine, Bond University
14 University Dr, Robina QLD 4226, Australia
7 Researcher
Evaluation AND Planning Unit – Directorate of the Canary Islands Health Service
Camino de Candelaria s/n. El Chorrillo
38109
El Rosario, Spain
8 Patient Partner
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States

9 Professor
The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States

Correspondence to: Marie-Anne Durand:
Phone: 603-653-0851
Email: marie-anne.durand@dartmouth.edu
Address: The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
Level 5, Williamson Translational Research Building
One Medical Center Drive
Lebanon, NH 03756

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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.

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 [2]. 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 [3]. 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 synthesis of evidence, and do not provide any guidance about recommended methods for the evidence selection and summarization of PDAs [3]. 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 [4, 5]. Other efforts to evaluate or certify the quality of PDAs have emerged [6], 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 synthesis in other medical contexts is increasingly standardized, such as the selection and summarization of evidence for clinical practice guidelines and systematic reviews. This process minimizes the risk of bias in the end product [7-16]. 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 identification of patient-relevant outcomes, analysis of patient concerns and priorities, description of the quality of evidence, and communication of uncertainty in ways that patients understand warrants the development of an agreed process and related steps and criteria that are specific to PDAs. Efforts to develop an agreed evidence summarization process for PDAs should incorporate the substantial body of related evidence summarization guidance previously developed by other groups, and notably for clinical practice guidelines [9].

Objective

The purpose of the study is 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.

2 METHODS

Study Design and Procedures

We will develop an evidence summarization process specific to PDA development by using a consensus-based Delphi approach previously used in the development of a quality criteria framework for PDAs [17, 18]. Consensus methods can harness the views of international experts on a wide range of information and questions in order to make decisions that are based on expert consensus [19]. We will conduct a multi-round modified Delphi survey (two to three rounds). Compared to the nominal group technique, it is the most practical and scalable method to obtain feedback from a large number of stakeholders in different geographic locations. During the multiple rounds of online questionnaires, relevant stakeholders will be consulted to provide feedback about the evolving set of evidence summarization steps and criteria. The anonymous responses from

participants will be fed back to them in subsequent rounds. Depending on the level of consensus after two rounds (see Data Analysis section), we will determine whether to conduct a third survey round.

Study Management

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

Participants

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

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

Patient and Public Involvement

Design

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

Participants

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

Analysis

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

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, a third round may be conducted.

Data Analysis

Following round one, the ratings will be summarized using percentages. 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. The steering group will discuss the ratings and qualitative feedback received, including rewording suggestions per criterion, suggestions to add new phases, steps or criteria and more general comments or questions. Criteria will be revised if two or more respondents suggest it, or if the steering group members agree that the item would benefit from rewording or merging.

Following the second survey round, a consensus meeting involving the steering group will be held. Decisions on whether to conduct a third round and retain items in the scale will be made based on the ratings in the survey rounds and feedback/comments from participants. 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 importance of the item in the lower two categories, or in the higher two categories, we will consider consensus to be achieved and the item will be removed or retained, respectively. If no consensus is achieved, the steering group will decide

whether or not to retain a criterion, basing this decision on qualitative feedback from the participants where possible, and the steering group's views.

DISCUSSION

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

STRENGTHS AND LIMITATIONS

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

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.

REFERENCES

1. Stacey D, Legare F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. The Cochrane database of systematic reviews. 2017;4:CD001431.
2. Michelle D. Dannenberg M-AD, Clifford Reilly, Victor Montori, Glyn Elwyn., editor Comparative Analysis of Evidence Synthesis Methods by Organizations that Produce Patient-facing Decision Aids. . International Shared Decision Making Conference; 2017 July 2-5 2017; Lyon, France.
3. Elwyn G, O'Connor AM, Bennett C, Newcombe RG, Politi M, Durand MA, et al. Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi). PLoS ONE. 2009;4(3):e4705.
4. Durand MA, Witt J, Joseph-Williams N, Newcombe RG, Politi MC, Sivell S, et al. Minimum standards for the certification of patient decision support interventions: feasibility and application. Patient Educ Couns. 2015;98(4):462-8.
5. Joseph-Williams N, Newcombe R, Politi M, Durand MA, Sivell S, Stacey D, et al. Toward Minimum Standards for Certifying Patient Decision Aids: A Modified Delphi Consensus Process. Med Decis Making. 2014;34(6):699-710.
6. Authority WSHC. Patient decision aids certification 2018 [Available from: https://www.hca.wa.gov/about-hca/healthier-washington/patient-decision-aids-pdas.
7. Higgins JG, S. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0. 2011.
8. Schünemann H, Brożek J, Guyatt G, Oxman A. GRADE Handbook: The GRADE Working Group; 2013.
9. Qaseem A, Forland F, Macbeth F, Ollenschlager G, Phillips S, van der Wees P, et al. Guidelines International Network: toward international standards for clinical practice guidelines. Ann Intern Med. 2012;156(7):525-31.
10. Schunemann HJ, Al-Ansary LA, Forland F, Kersten S, Komulainen J, Kopp IB, et al. Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines. Ann Intern Med. 2015;163(7):548-53.
11. Institute of Medicine. Standards for systematic reviews 2011 [Available from: http://www.nationalacademies.org/hmd/Reports/2011/Finding-What-Works-in-Health-Care-Standards-for-Systematic-Reviews/Standards.aspx.
12. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med. 2009;6(7):e1000097.
13. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. The Global Rating Scale complements the AGREE II in advancing the quality of practice guidelines. J Clin Epidemiol. 2012;65(5):526-34.
14. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. Development of the AGREE II, part 1: performance, usefulness and areas for improvement. CMAJ. 2010;182(10):1045-52.
15. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. Development of the AGREE II, part 2: assessment of validity of items and tools to support application. CMAJ. 2010;182(10):E472-8.
16. Cluzeau F, Trust AR. Conflicting recommendations. Let's not forget AGREE. BMJ. 2009;338:b407.
17. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. BMJ. 2006;333(7565):417.
18. Murphy MK, Black NA, Lamping DL, McKee CM, Sanderson CF, Askham J, et al. Consensus development methods, and their use in clinical guideline development. Health Technol Assess. 1998;2(3):i-iv, 1-88.
19. Jones J, Hunter D. Consensus methods for medical and health services research. BMJ. 1995;311(7001):376-80.

Supplementary File 1: Survey Invitation

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

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

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

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

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

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

Many thanks,

The Evidence Summarization workgroup

Evidence Summarization Survey

THE Dartmouth INSTITUTE FOR HEALTH POLICY & CLINICAL PRACTICE GEISEL SCHOOL OF MEDICINE AT DARTMOUTH

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

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

- [ ] Patient Decision Aid (PDA) developer
- [ ] Researcher
- [ ] International Patient Decision Aids Standards (IPDAS) collaboration member
- [ ] Policy maker
- [ ] Patient
- [ ] Clinician, please specify specialty:
- [ ] Other, please specify:

Which country do you live in?

What is your gender?

- ○ Male
- ○ Female
- ○ Other

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

- [ ] American Indian or Alaska Native
- [ ] Asian
- [ ] Black or African American
- [ ] Native Hawaiian or Other Pacific Islander
- [ ] Hispanic, Latino/a or Spanish Origin
- [ ] White

☐ 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

well as the order and grouping.

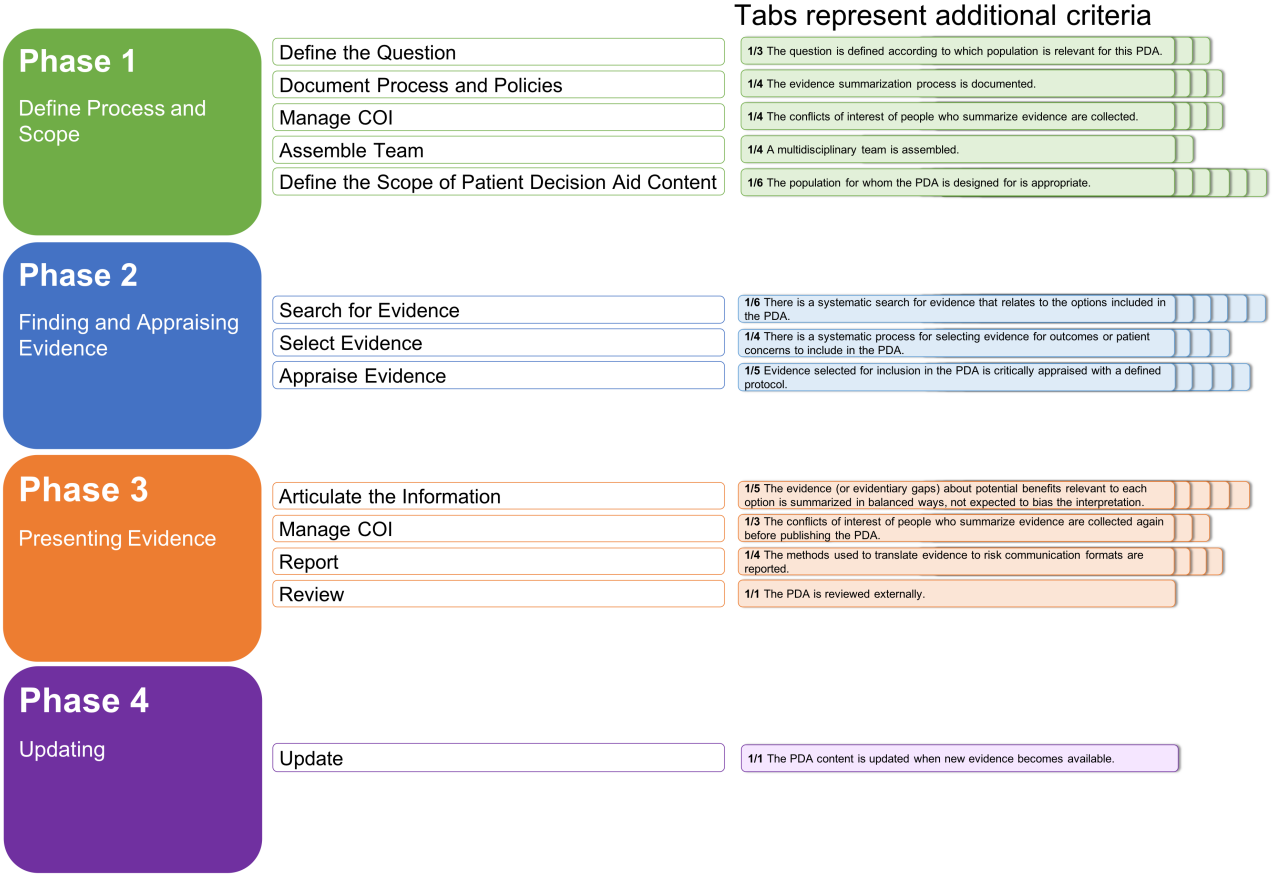
Here's how you can help. In the questions that follow, we will ask for your perspective on **how important each criterion is to include in the proposed process**. We will also ask for feedback on the wording of all parts. Nothing is final. Everything is up for discussion, and we are looking forward to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

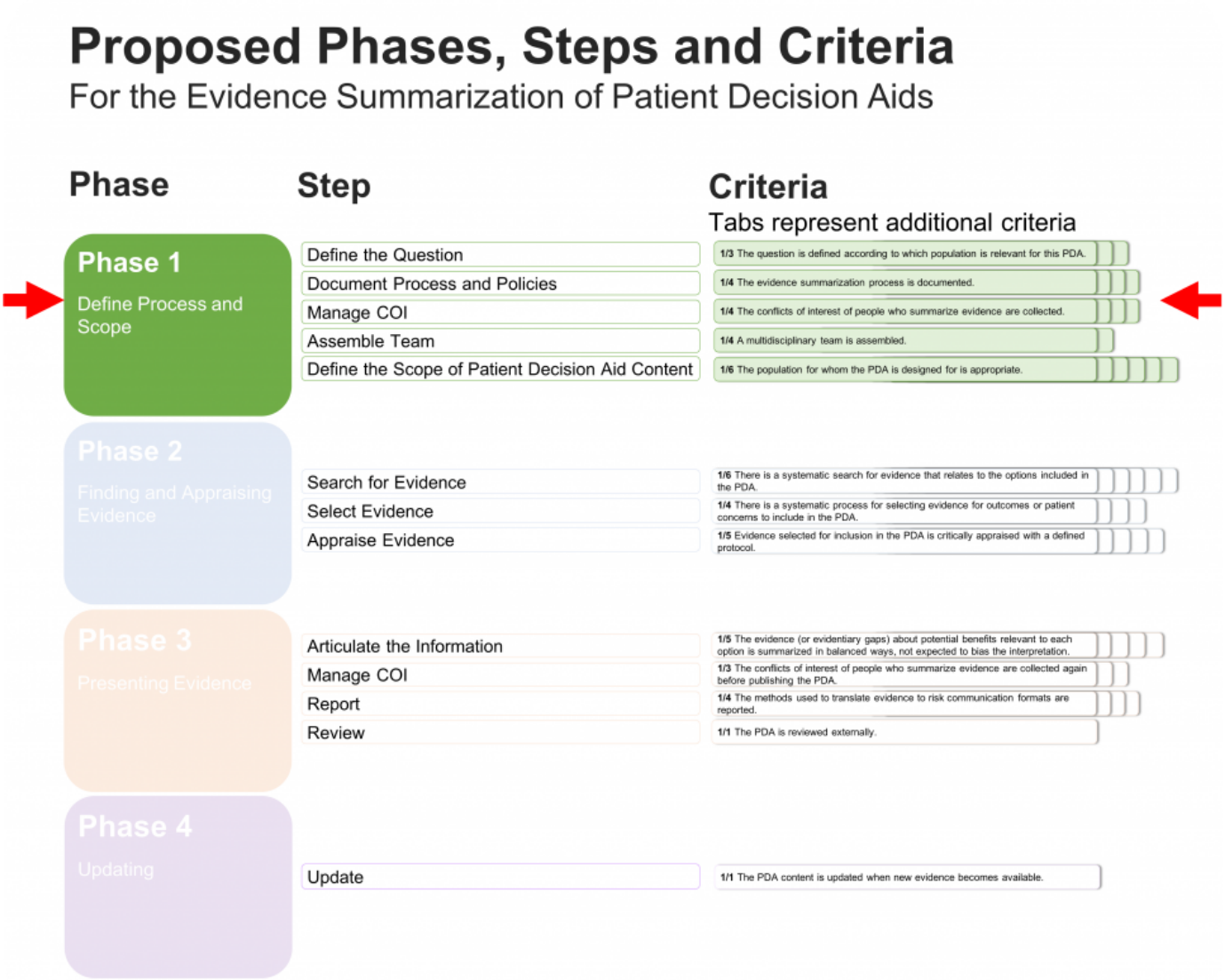
Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Phase 1

PROPOSED PHASE 1



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.

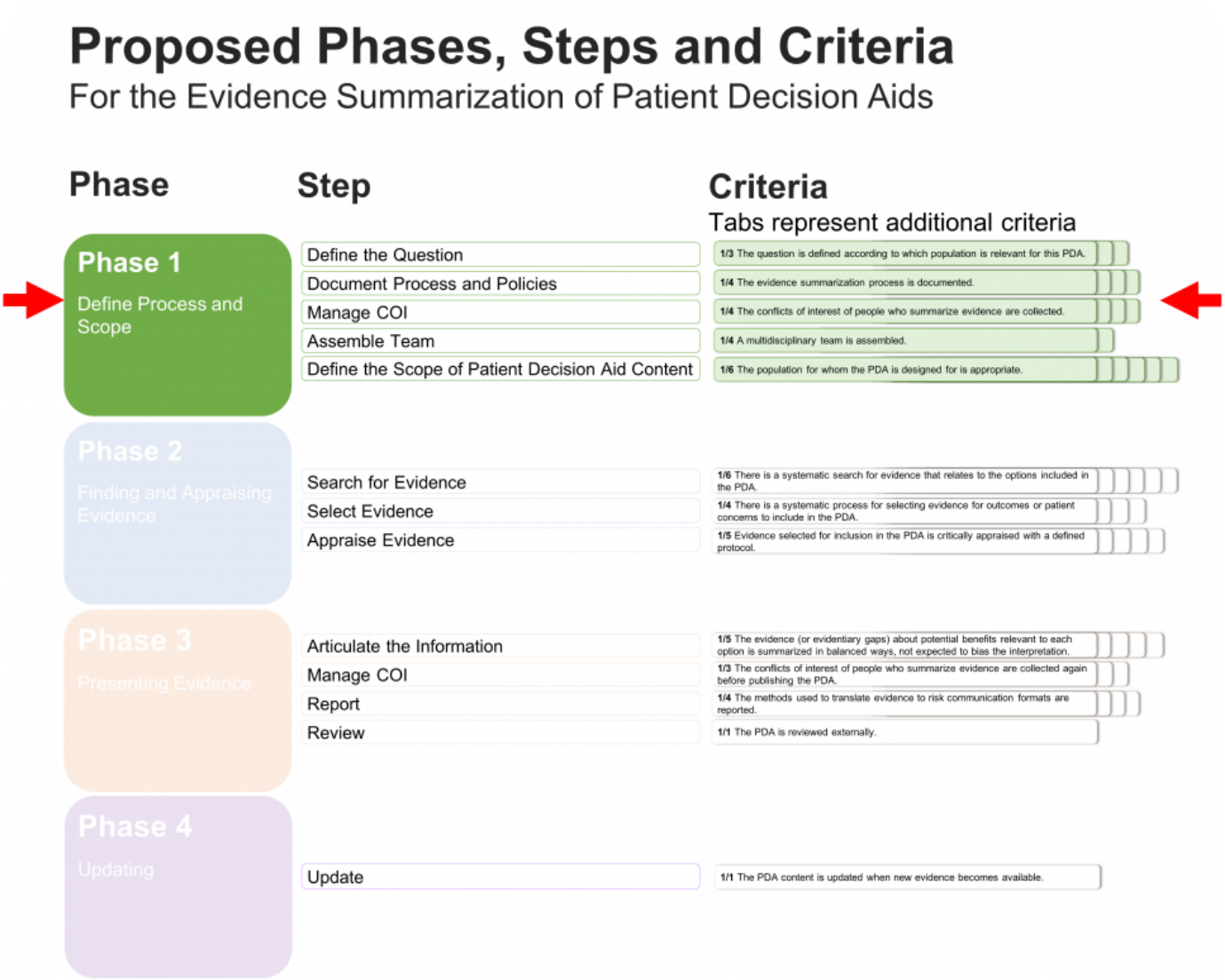
Do you have any comments or suggestions on the Phase below? If so, please share them.

- **Phase 1: Defining Process and Scope**

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



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**

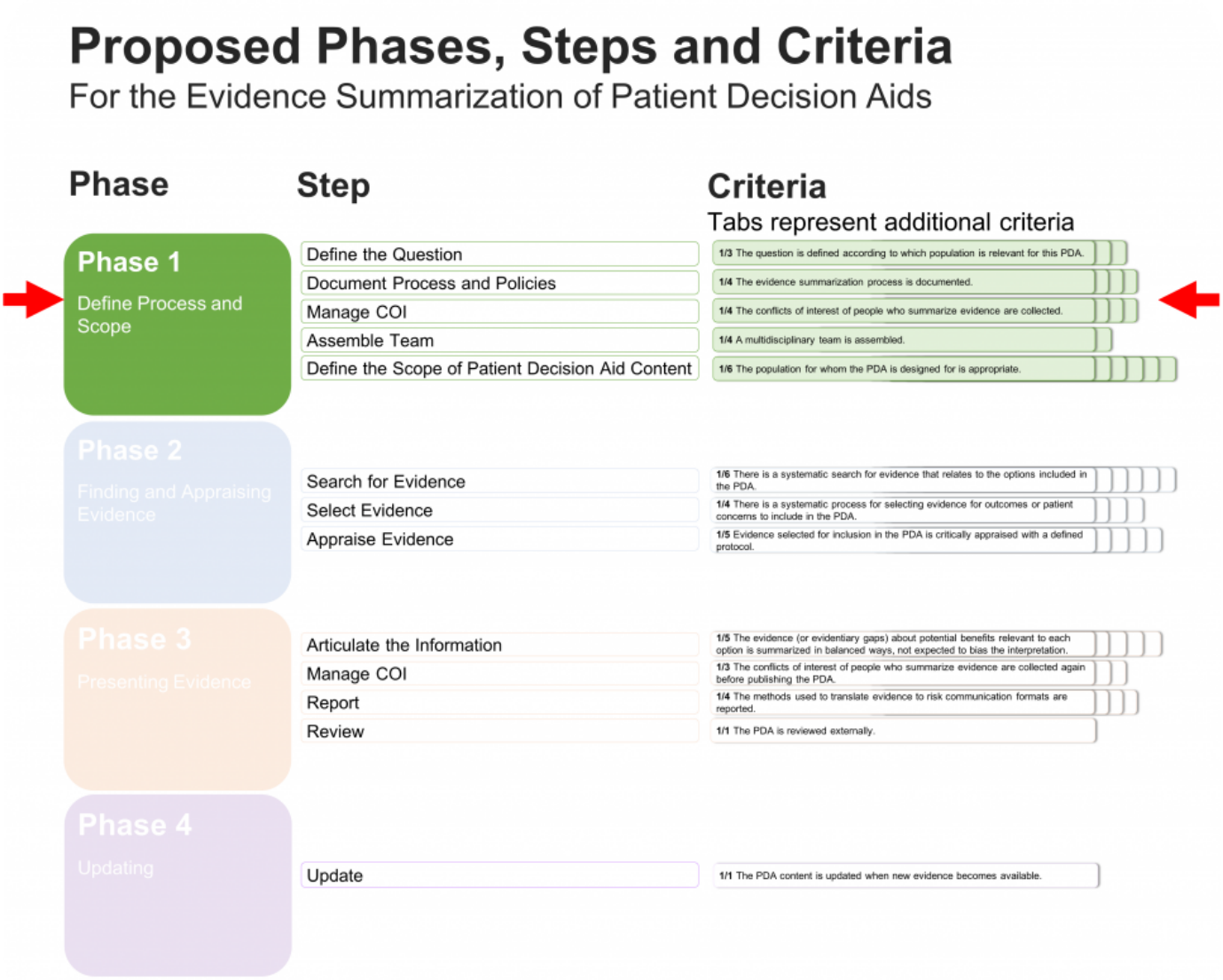
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	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



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**

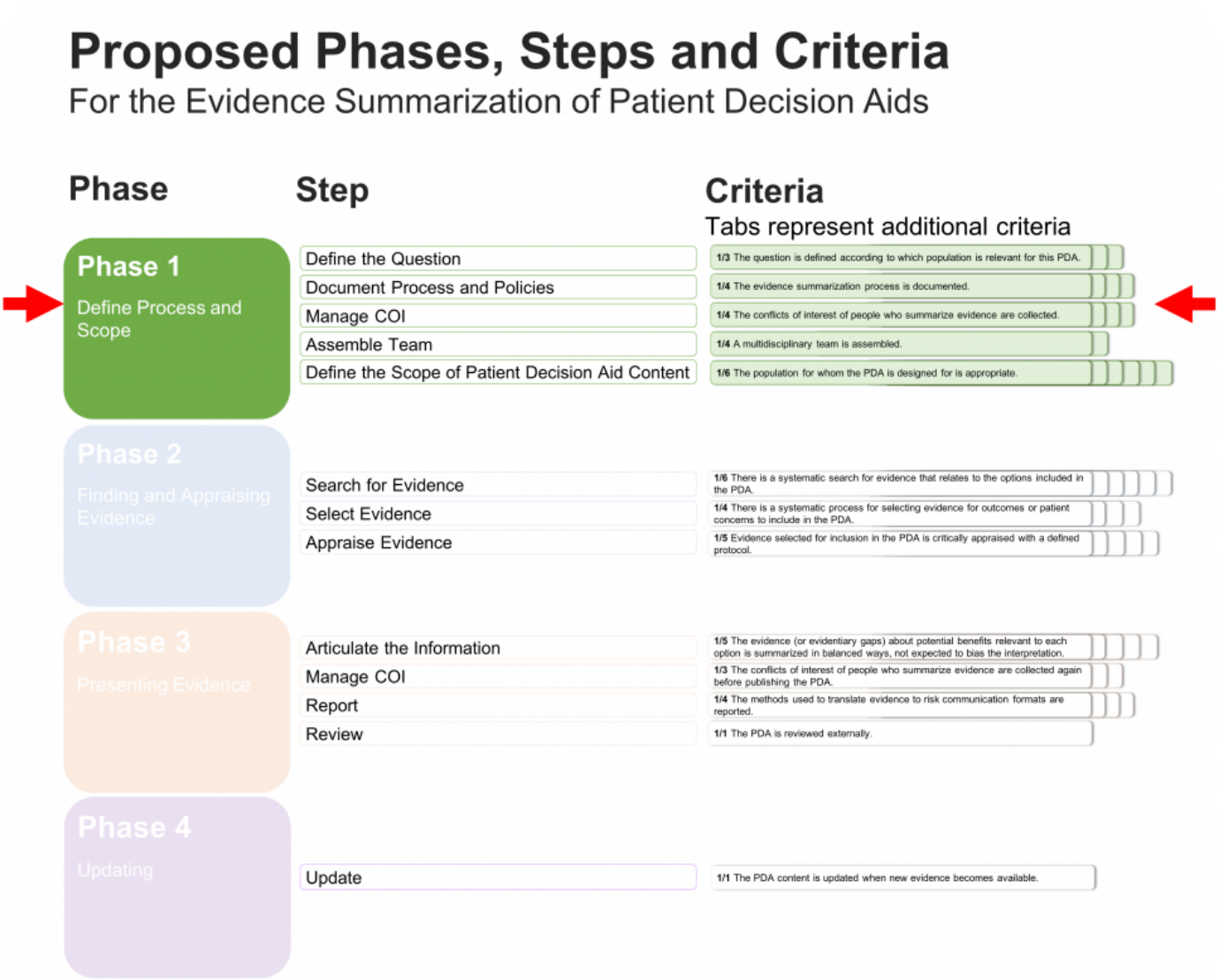
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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**

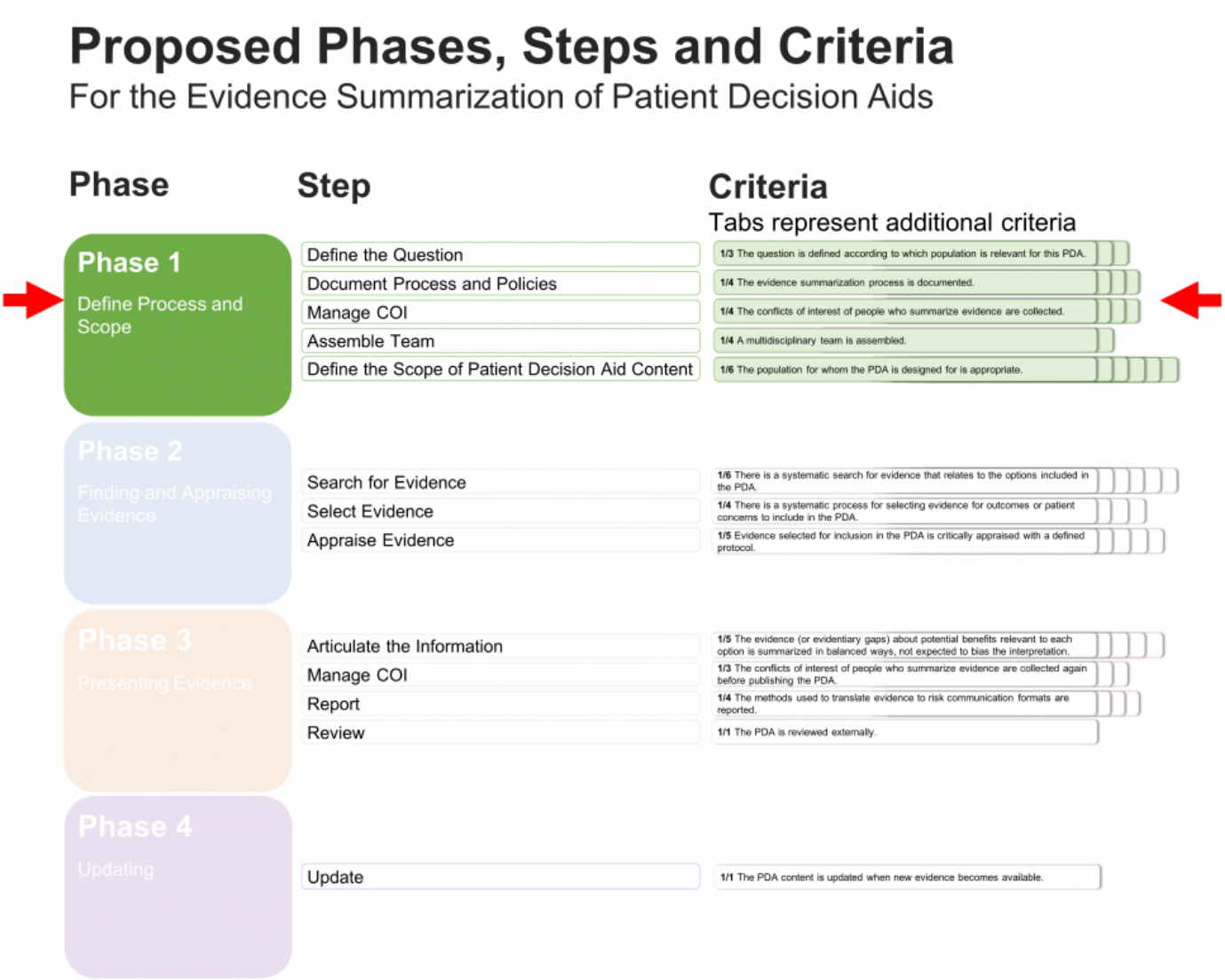
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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**

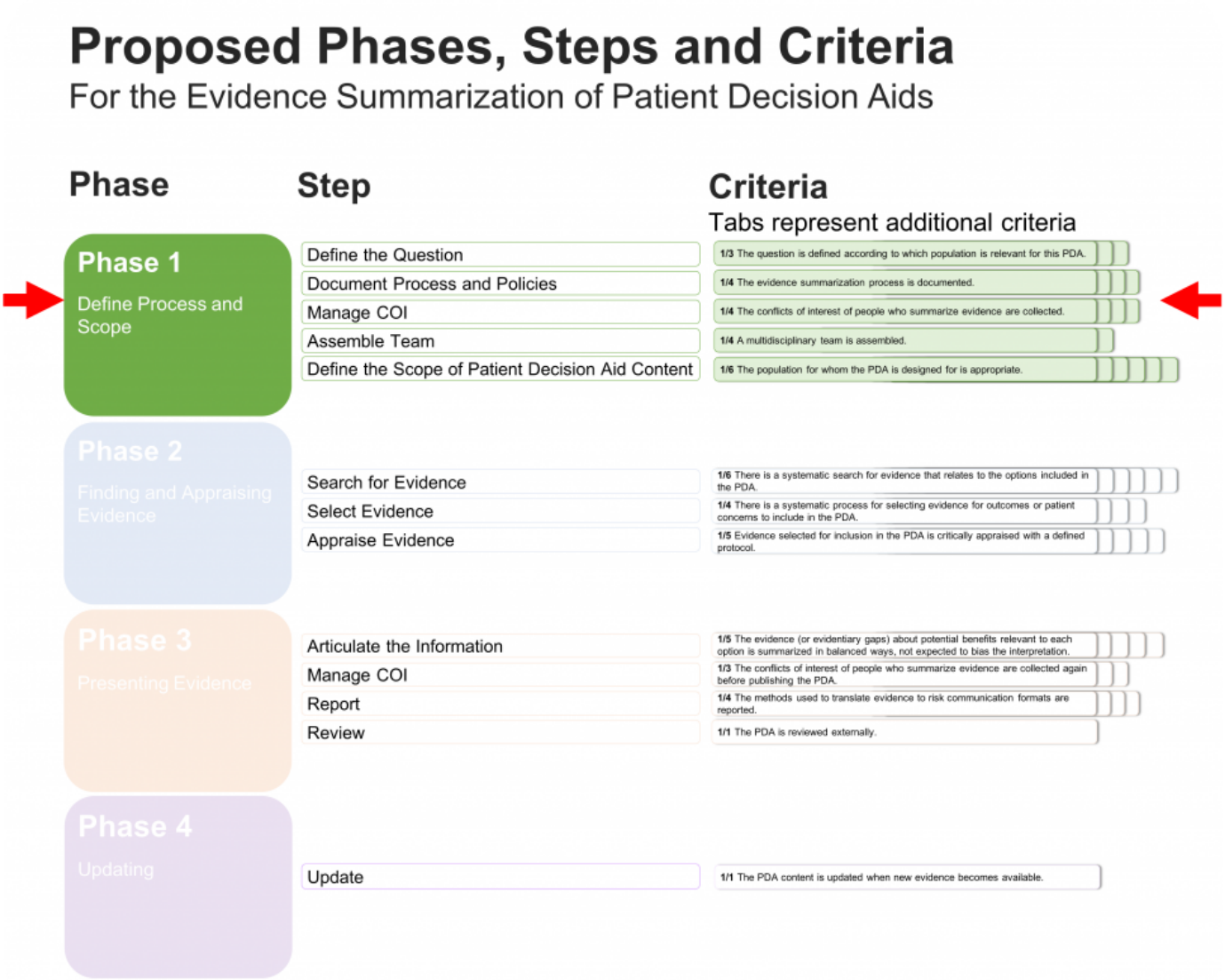
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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.

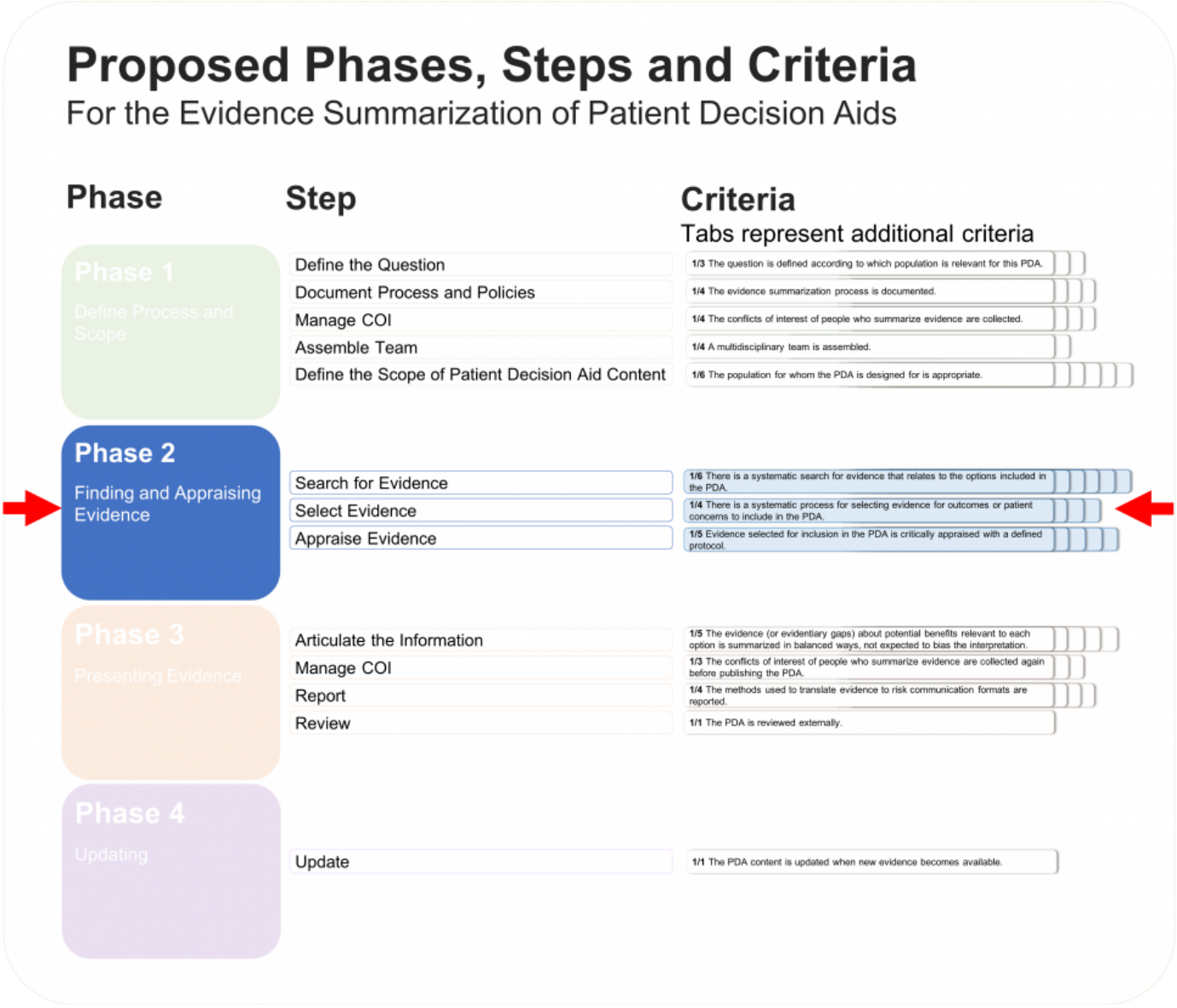
	Omit	Possible	D
The population for whom the PDA is designed for is appropriate.	○	○	
There is a systematic process to reduce bias in the definition of the population for the PDA.	○	○	
The options for inclusion in the PDA are appropriate for the intended population.	○	○	
There is a systematic process 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



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.

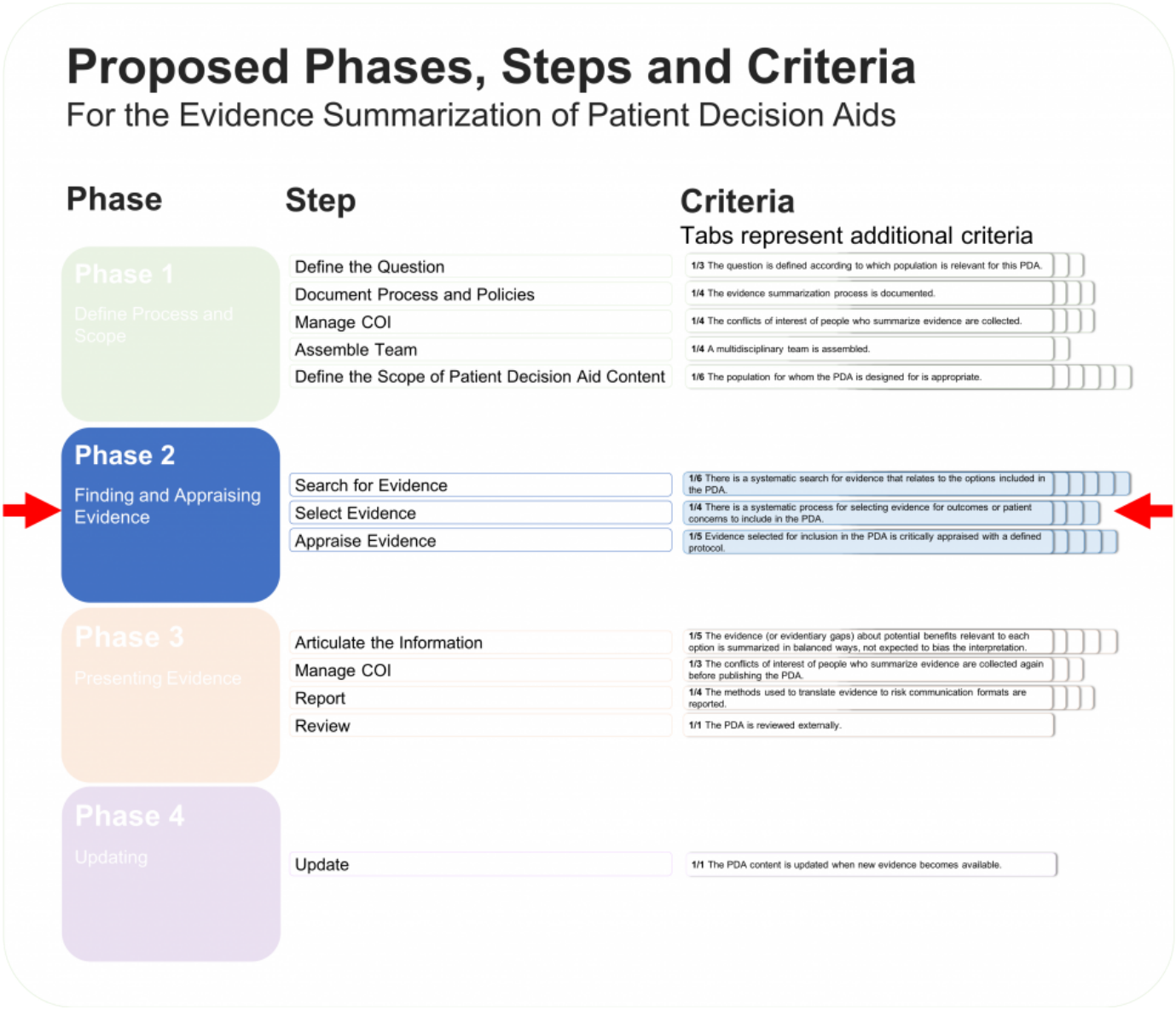
Do you have any comments or suggestions on the Phase below? If so, please share them.

- **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



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**

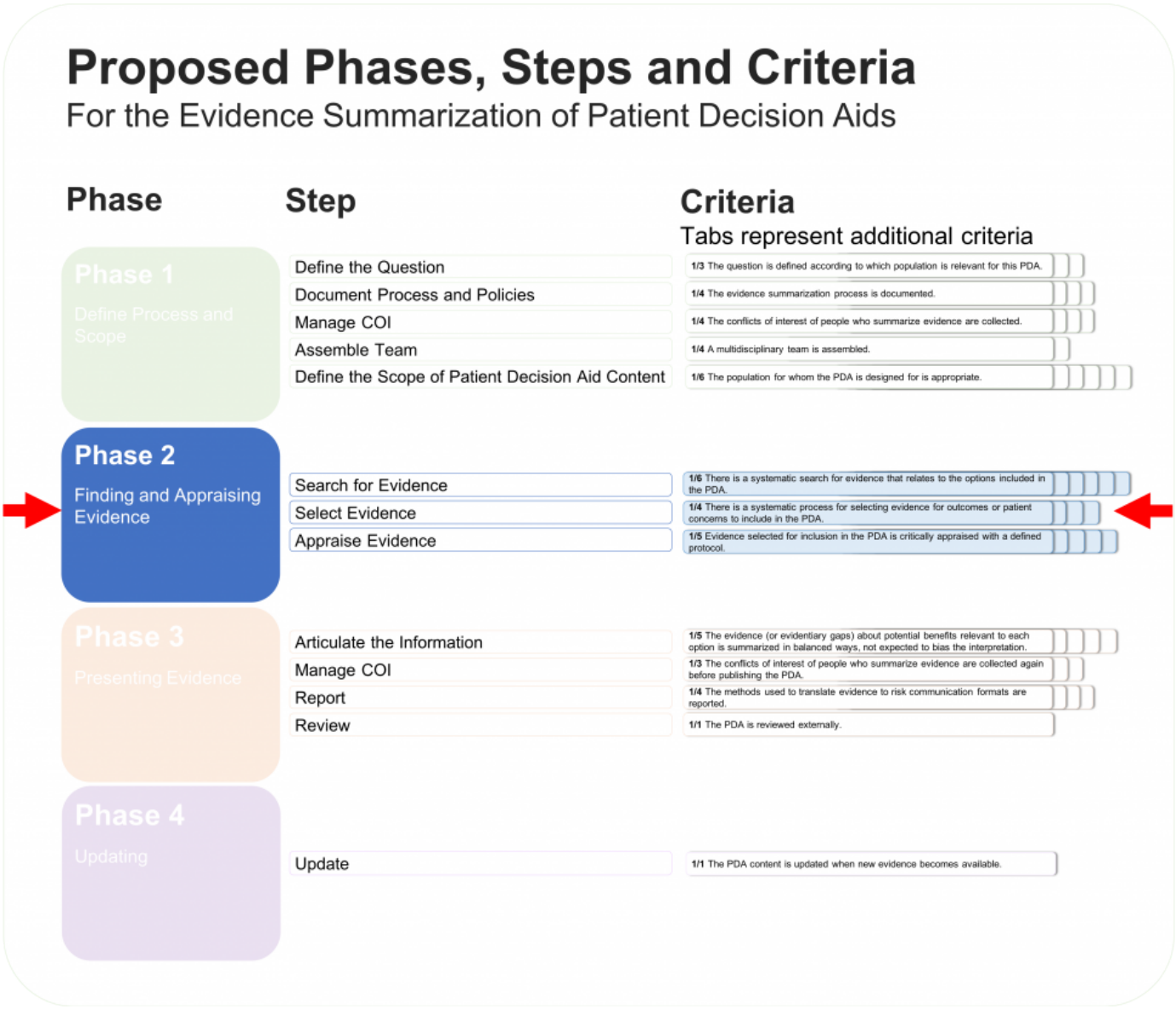
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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.	○	○	

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**

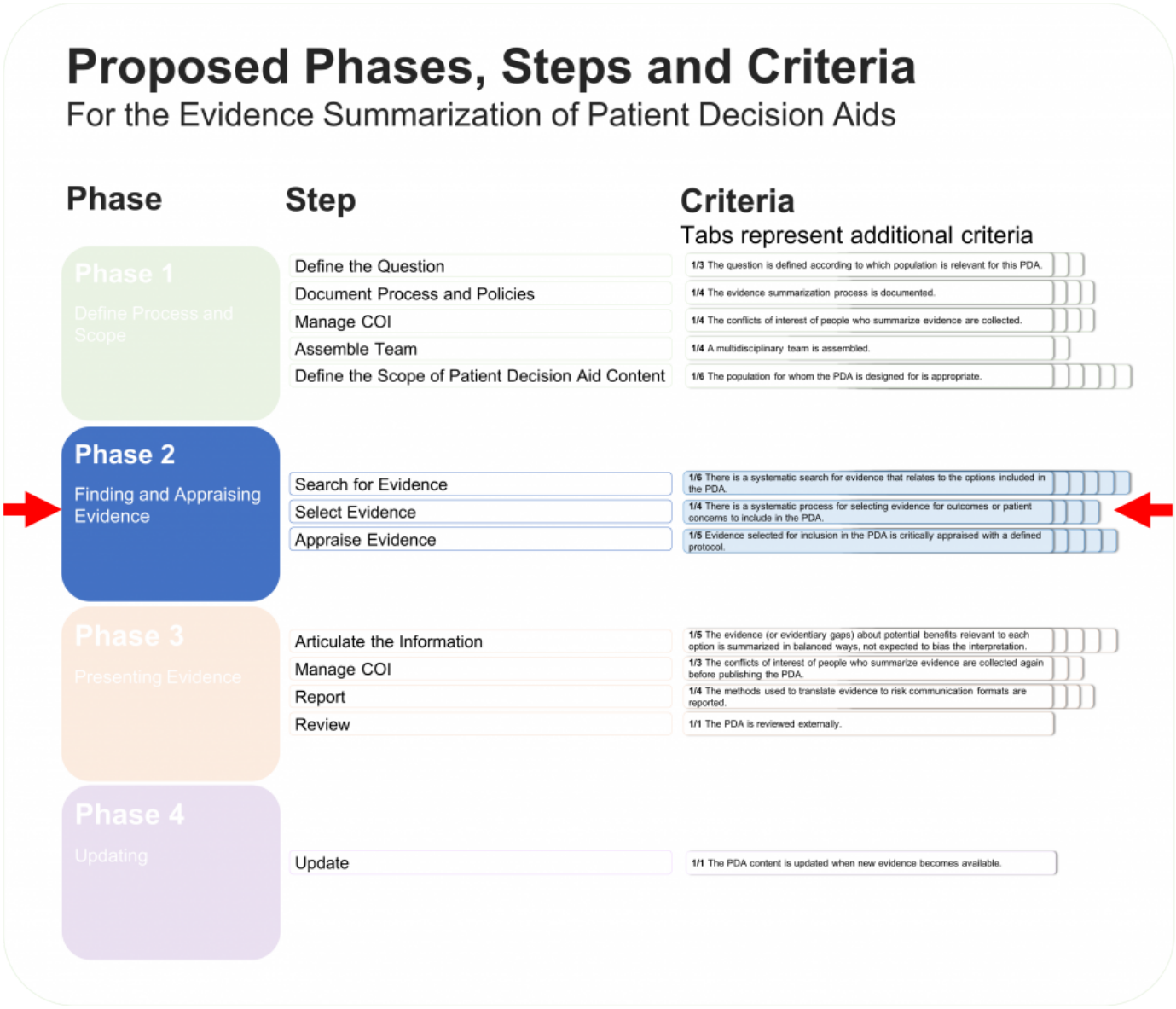
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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.

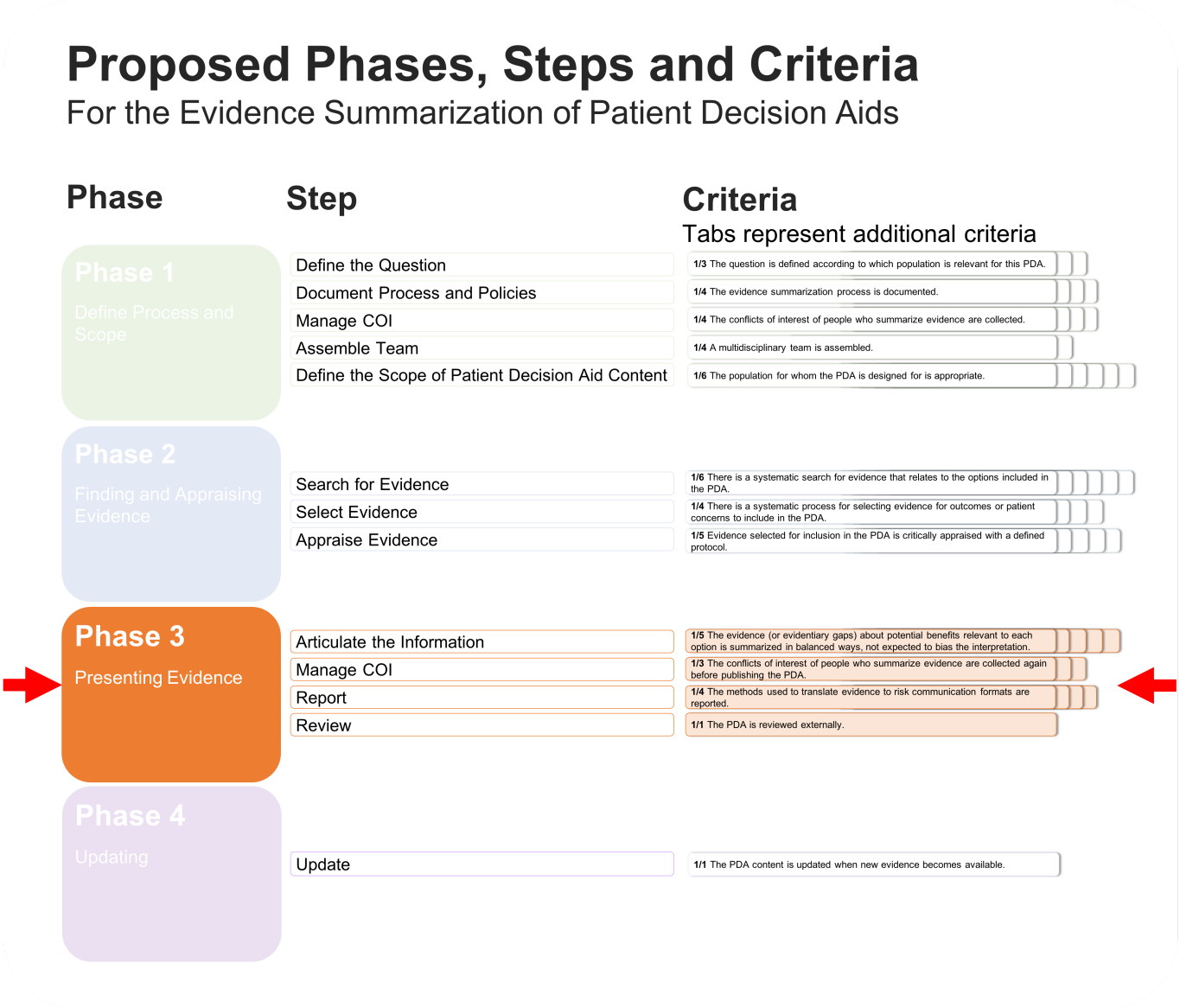
	Omit	Possible	D
Evidence selected for inclusion in the PDA is critically appraised with a defined protocol (such as GRADE).	○	○	
The protocol for critical appraisal of evidence accounts for risks of bias in study design.	○	○	
The protocol for critical appraisal of evidence accounts for risks of bias 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



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.

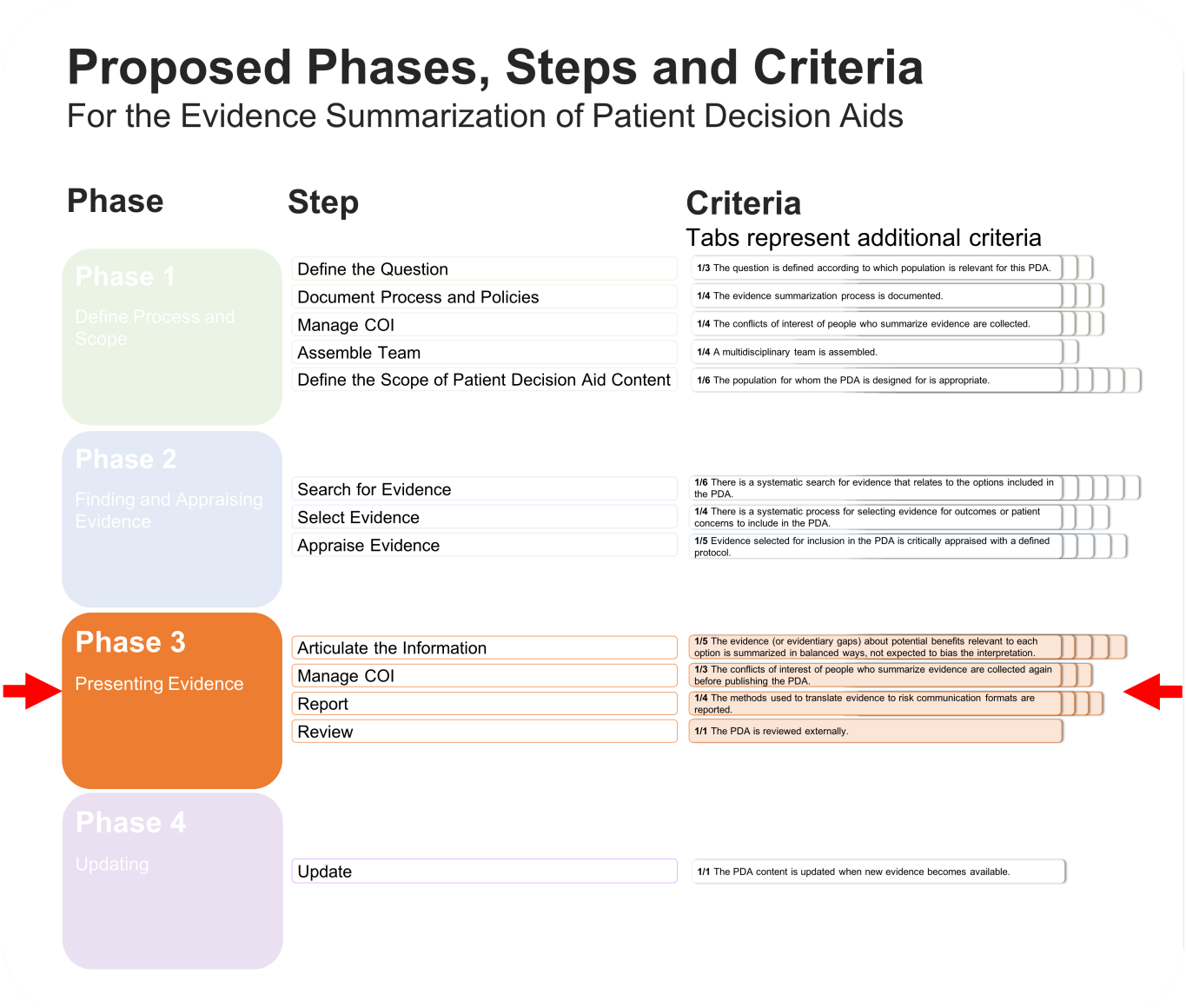
Do you have any comments or suggestions on the Phase below? If so, please share them.

- **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



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**

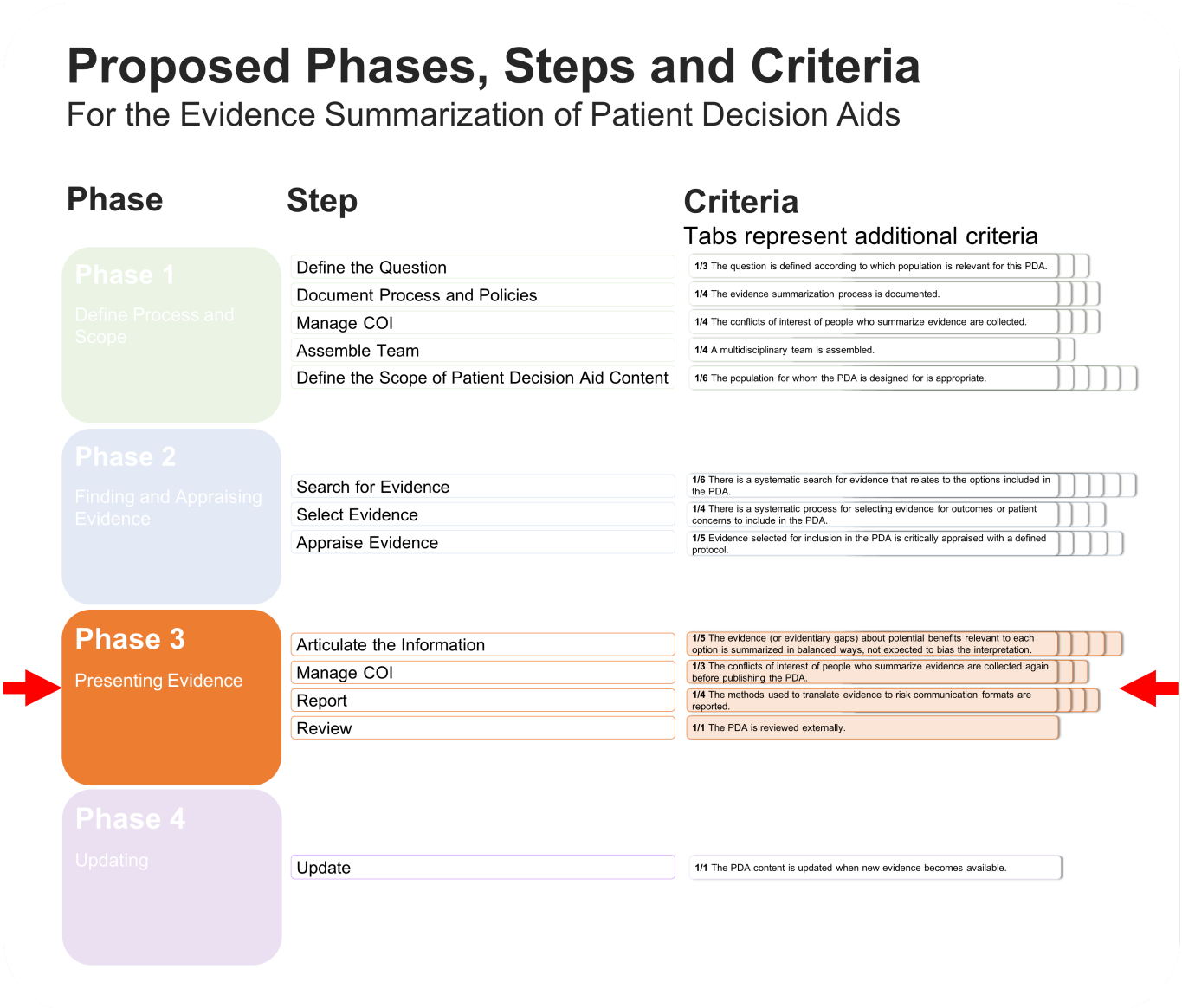
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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 to understand.	○	○	
The funding used to summarize the evidence (and develop the PDA) is reported.	○	○	

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



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: Manage COI**

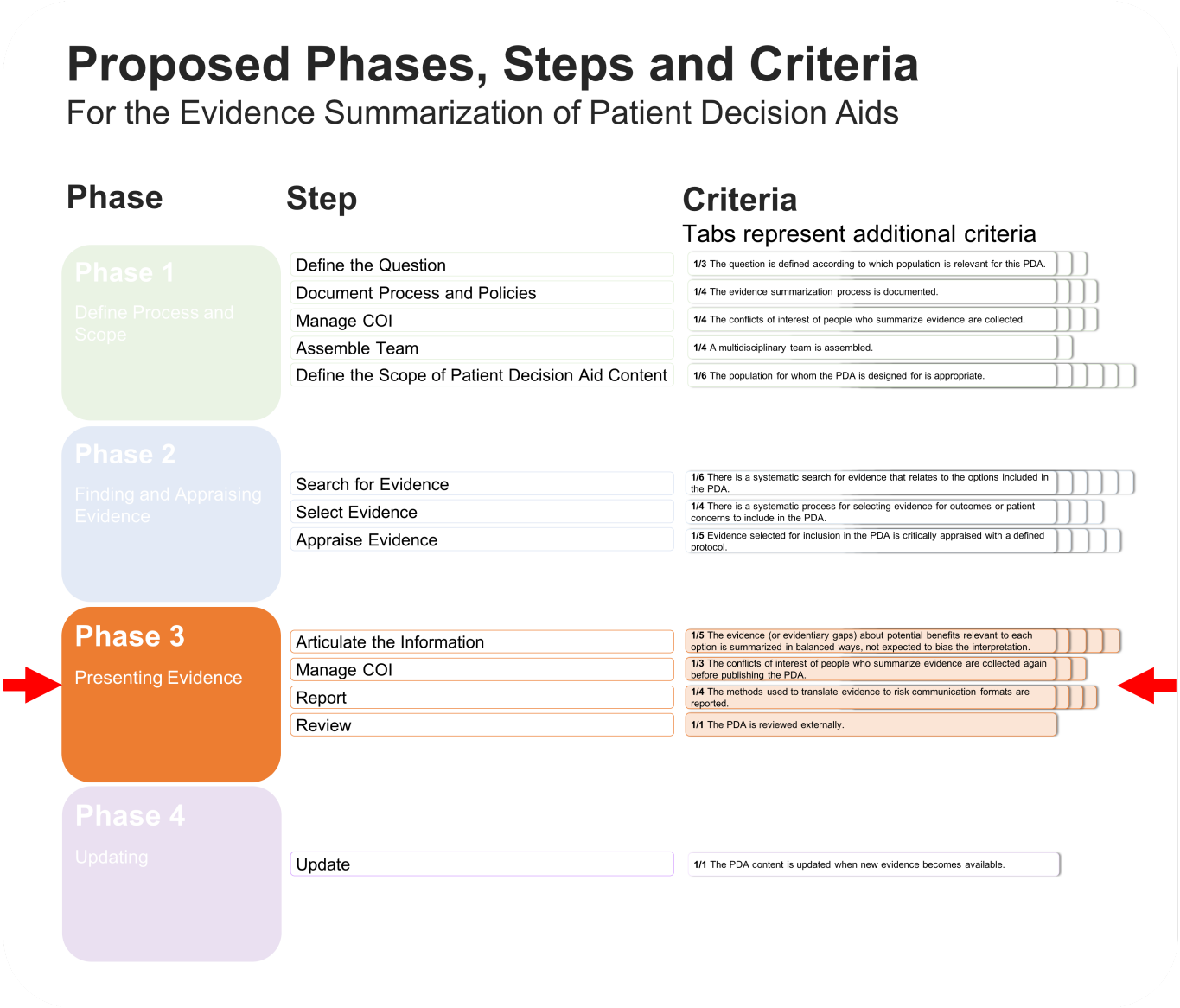
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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**

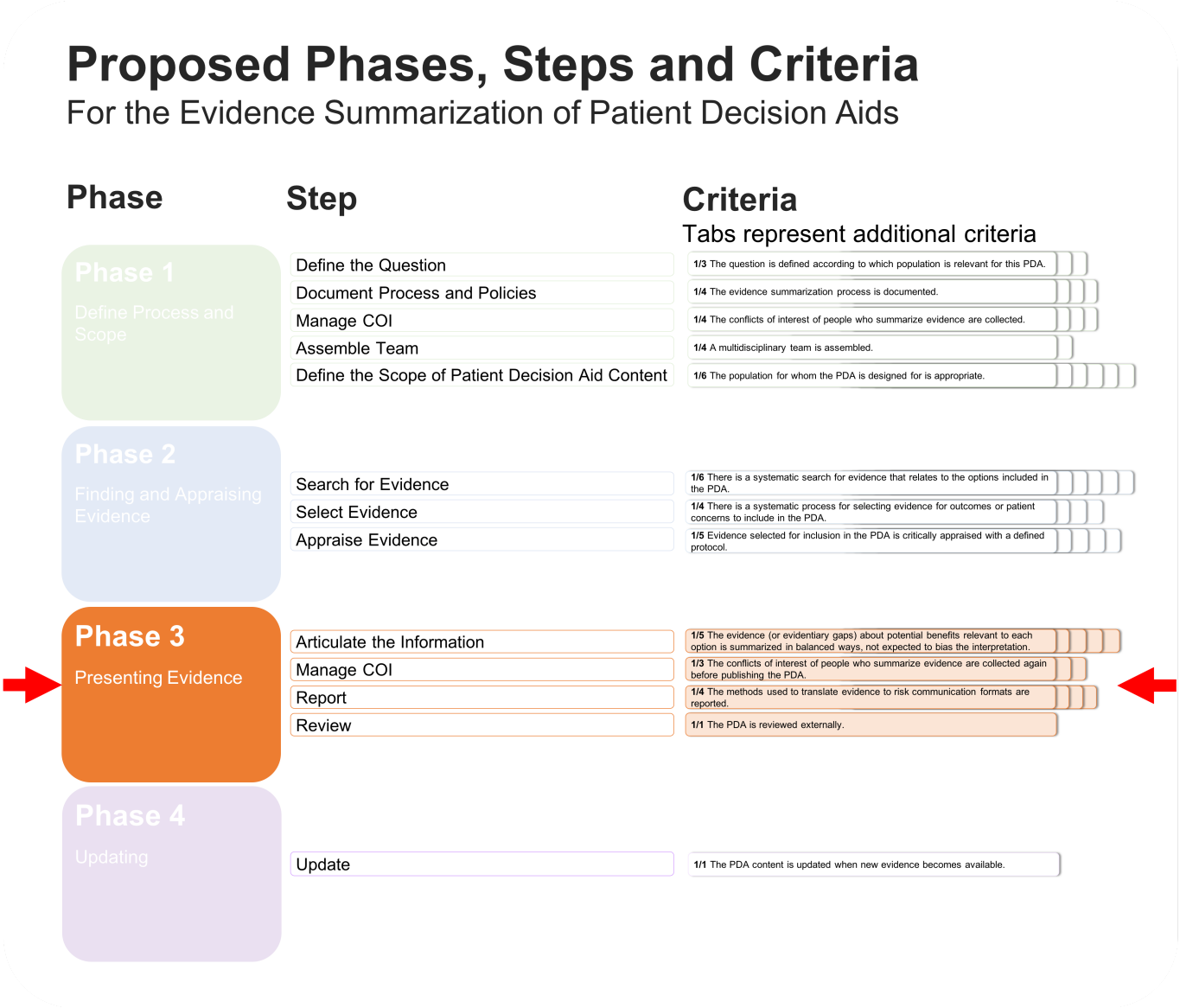
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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.

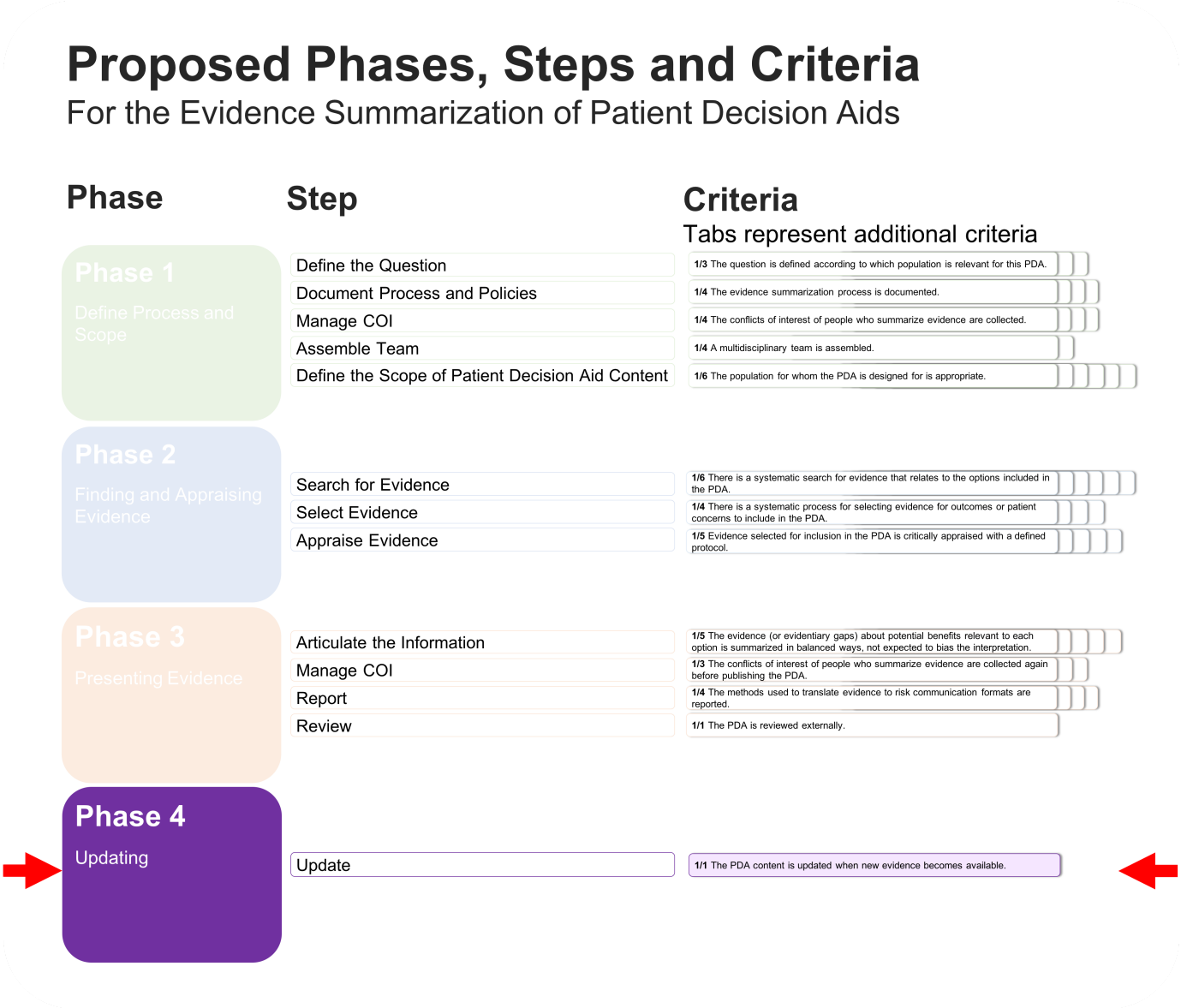
	Omit	F
The PDA is reviewed externally.	○	

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



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.

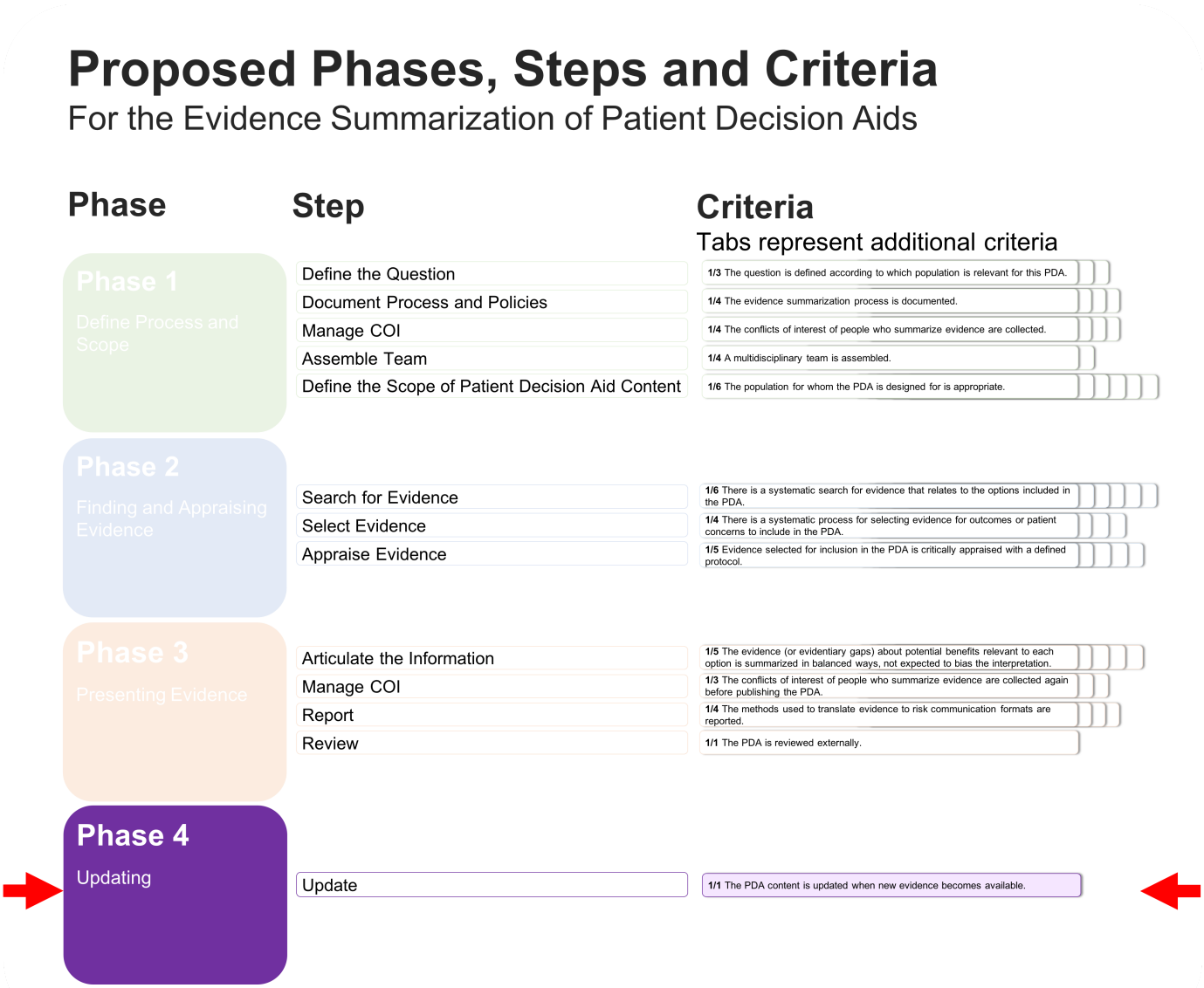
Do you have any comments or suggestions on the Phase below? If so, please share them.

- **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



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	D
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.
			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.
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.

BMJ Open

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

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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

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

Running heading: Evidence summarization Delphi survey

Authors:
Marie-Anne Durand[1]
Michelle D. Dannenberg[2]
Catherine H. Saunders[3]
Anik Giguère[4]
Brian S. Alper[5]
Tammy Hoffmann[6]
Lilisbeth Perestelo-Perez[7]
Stephen T. Campbell[8]
Glyn Elwyn[9]

1 Associate Professor
The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States
2 Research Assistant/Research Coordinator
The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States
3 Doctoral Student
The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States
4 Associate Professor
Department of Family Medicine
Université Laval, C.A.
2325 Rue de l'Université, Québec, QC G1V 0A6, Canada
5 Vice President of Innovations and EBM Development
EBSCO Health Innovations, Department of Innovations and EBM Development
10 Estes Street, Ipswich, MA 01938, United States
6 Professor of Clinical Epidemiology
Centre for Research in Evidence-Based Practice (CREBP)
Faculty of Health Sciences & Medicine
Level 2, Building 5, Faculty of Health Sciences & Medicine, Bond University
14 University Dr, Robina QLD 4226, Australia
7 Researcher
Evaluation AND Planning Unit – Directorate of the Canary Islands Health Service
Camino de Candelaria s/n. El Chorrillo
38109

El Rosario, Spain

8 Patient Partner
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States

9 Professor
The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States

Correspondence to: Marie-Anne Durand:
Phone: 603-653-0851
Email: marie-anne.durand@dartmouth.edu
Address: The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
Level 5, Williamson Translational Research Building
One Medical Center Drive
Lebanon, NH 03756

Keywords
Decision Making
Delphi Technique
Patient Preference
Patient-Centered Care
Surveys and Questionnaires

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

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

Objective

The purpose of the study is 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. This will in turn improve transparency, rigor and minimize the risk of bias of the evidence summarization processes leading to the development of patient decision aids.

2 METHODS

Study Design and Procedures

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

Study Management

To oversee the tasks of 1) generating an initial set of criteria for the Delphi process and 2) managing the Delphi survey distribution and analysis, we convened a steering group. This group will oversee the project and will make strategic decisions about the study design, data collection and analysis processes, as well as agree a final process and related set of steps and criteria. An invitation to join this group was posted on social media (Shared@Shared Decision Making Network Facebook group: 745 members) on 30 June 2017. The post invited all Facebook group members to join an in-person meeting about evidence summarization during the International Shared Decision Making conference, held in Lyon, France, between July 2, and July 5, 2017. For those who were not able to join the meeting but

expressed an interest in evidence summarization of PDAs, a high-level summary was posted on Facebook. The steering group was convened in September 2017. The study steering group includes nine international experts in PDA development, evaluation and implementation, evidence summarization and clinical practice guidelines, and one patient representative. Six steering group members are based in the US, one in Canada, one in Australia and one in Spain Google drive and video-conferencing facilities will be used to facilitate the exchange and review of information and documents, virtual meetings, as well as real-time collaboration and version-control.

Participants

To maximize the generalizability and applicability of the criteria, we plan to invite participation in the survey from the following groups: 1) all known developers of PDAs who created or updated a tool within last five calendar years (using existing inventory), 2) all members of the of the IPDAS group, 3) the Shared Decision Making listserv; 4) the Society for Participatory Medicine listserv ; 5) an overdiagnosis google group ; 6) the evidence-based healthcare listserv ; 7) the Society for Medical Decision Making ; the 8) the Society of Behavioral Medicine (Health Decision Making Interest Group) , 9) HTAi-ISG Patient Involvement listserv, 10) GRADE Working group, 11) the Guidelines International Network, 12) convenience sample of policy makers with interest and expertise in PDA certification; 13) the BMJ patient group; 14) the ProPublica Patient Safety Community. We have no other eligibility criteria.

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

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

Patient and Public Involvement

Design

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

Participants

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

Analysis

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

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

do not meet the consensus threshold and conflict with open text comments will be grouped together and explained to round 2 participants. They will be asked to re-rate those items taking the qualitative feedback into account. Following the first survey round, a consensus meeting involving the steering group will be held. The steering group will review and discuss the ratings and qualitative feedback received, including rewording suggestions per criterion, suggestions to add new phases, steps or criteria and more general comments or questions. The wording or order of the phases, steps or criteria will be revised if two or more respondents suggest it or if the steering group members agree that the phase, step or criterion would benefit from rewording, reordering or merging.

Following the second survey round, a second consensus meeting will be held. Decisions on whether to conduct a third round and retain items in the scale will be made based on the ratings in the survey rounds and feedback/comments from participants. 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 importance of the item in the lower two categories, or in the higher two categories, we will consider consensus to be achieved and the item will be removed or retained, respectively. If no consensus is achieved or the consensus ratings are contradicted by recurring open text comments, the steering group will decide whether or not to retain a criterion, basing this decision on qualitative feedback from the participants where possible, and the steering group's views. We have successfully used this approach before [21].

Only complete surveys will be included in the analysis. We will report the amount of missing data in the manuscript reporting the results of the Delphi survey.

Data Management and Safety

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

DISCUSSION

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

STRENGTHS AND LIMITATIONS

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

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.

REFERENCES

[1] D. Stacey, F. Légaré, K. Lewis, M.J. Barry, C.L. Bennett, K.B. Eden, M. Holmes-Rovner, H. Llewellyn-Thomas, A. Lyddiatt, R. Thomson, L. Trevena, F. Legare, N.F. Col, C.L. Bennett, M.J. Barry, K.B. Eden, M. Holmes-Rovner, H. Llewellyn-Thomas, A. Lyddiatt, R. Thomson, L. Trevena, J.H.C. Wu, F. Légaré, K. Lewis, M.J. Barry, C.L. Bennett, K.B. Eden, M. Holmes-Rovner, H. Llewellyn-Thomas, A. Lyddiatt, R. Thomson, L. Trevena, Decision aids for people facing health treatment or screening decisions, Cochrane Database Syst. Rev. 4 (2017) CD001431. doi:10.1002/14651858.CD001431.pub5.

[2] G. Elwyn, A.M.A. O'Connor, D. Stacey, R. Volk, A.G.K.A.G. Edwards, A. Coulter, R. Thomas, A.L. Barratt, M. Barry, S.J. Bernstein, P.N. Butow, A. Clarke, V.A. Entwistle, D. Feldman-Stewart, M. Holmes-Rovner, A. Mulley, H.A. Llewellyn-Thomas, N. Moumjid, C. Ruland, K.R. Sepucha, A. Sykes, T. Whelan, R. Thomson, Developing a quality criteria framework for patient decision aids: online international Delphi consensus process, BMJ. 333 (2006) 417–423. doi:10.1136/bmj.38926.629329.AE.

[3] M.D. Dannenberg, M.-A. Durand, V.M. Montori, C. Reilly, G. Elwyn, Existing evidence summarization methods cannot guarantee trustworthy patient decision aids., J. Clin. Epidemiol. 102 (2018) 69–77. doi:10.1016/j.jclinepi.2018.06.003.

[4] G. Elwyn, A.M.A.M.A.M. O'Connor, C.L. Bennett, R.G.R.G.R.G. Newcombe, M. Politi, M.-A.M.M.-A. Durand, E. Drake, N. Joseph-Williams, S. Khangura, A. Saarimaki, S. Sivell, M. Stiel, S.J.S.J. Bernstein, N. Col, A. Coulter, K. Eden, M. Härter, M.H.M.H.M.H. Rovner, N. Moumjid, D. Stacey, R. Thomson, T. Whelan, T. van der Weijden, A.G.K.A. Edwards, O'Connor AM, Bennett C, Newcombe RG, Politi M, Durand MA, Drake E, Joseph-Willams N, Khangura S, Anton Saarimaki A, Stephanie Sivell S, Stiel M, Col N, Coulter A, Eden K, Holmes Rovner M, Moumjid N, Thomson R, Whelan T, van der Weijden T, A.G.K. Edward, A. Khangura, Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi), PLoS One. 4 (2009) e4705. doi:10.1371/journal.pone.0004705.

[5] V.M. Montori, A. LeBlanc, A. Buchholz, D.L. Stilwell, A. Tsapas, Basing information on comprehensive, critically appraised, and up-to-date syntheses of the scientific evidence: a quality dimension of the International Patient Decision Aid Standards., BMC Med. Inform. Decis. Mak. 13 Suppl 2 (2013) S5. doi:10.1186/1472-6947-13-S2-S5.

[6] M.-A. Durand, J. Witt, N. Joseph-Williams, R.G. Newcombe, M.C. Politi, S. Sivell, G. Elwyn, Minimum standards for the certification of patient decision support interventions: Feasibility and application, Patient Educ. Couns. 98 (2015). doi:10.1016/j.pec.2014.12.009.

[7] N. Joseph-Williams, R. Newcombe, M. Politi, M.-A. Durand, S. Sivell, D. Stacey, A. O'Connor, R.J. Volk, A. Edwards, C. Bennett, M. Pignone, R. Thomson, G. Elwyn, Toward Minimum Standards for Certifying Patient Decision Aids, Med. Decis. Mak. 34 (2014) 699–710. doi:10.1177/0272989X13501721.

[8] A. WSHC, Patient decision aids certification 2018, (n.d.). https://www.hca.wa.gov/about-hca/healthier-washington/patient-decision-aids-pdas.

[9] J.P.T. Higgins, S. Green, Cochrane handbook for systematic reviews of interventions version 5.0. 2 [updated September 2009], The Cochrane Collaboration, York, 2009.

[10] O.A. Schünemann H, Brożek J, Guyatt G, ed., GRADE Handbook for Grading Quality of Evidence and Strength of Recommendations, The GRADE Working Group, n.d. Available from gdt.guidelinedevelopment.org/app/handbook/handbook.html .

[11] A. Qaseem, F. Forland, F. Macbeth, G. Ollenschlager, S. Phillips, P. van der Wees, Guidelines International Network: toward international standards for clinical practice guidelines., Ann. Intern. Med. 156 (2012) 525–531. doi:10.7326/0003-4819-156-7-201204030-00009.

[12] Standards for systematic reviews 2011, n.d. http://www.nationalacademies.org/hmd/Reports/2011/Finding-What-Works-in-Health-Care-Standards-for-Systematic-Reviews/Standards.aspx.

[13] D. Moher, A. Liberati, J. Tetzlaff, D.G. Altman, Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement., PLoS Med. 6 (2009) e1000097. doi:10.1371/journal.pmed.1000097.

[14] M.C. Brouwers, M.E. Kho, G.P. Browman, J.S. Burgers, F. Cluzeau, G. Feder, B. Fervers, I.D. Graham, J. Grimshaw, S.E. Hanna, P. Littlejohns, J. Makarski, L. Zitzelsberger, The Global Rating Scale complements the AGREE II in advancing the quality of practice guidelines., J. Clin. Epidemiol. 65 (2012) 526–534. doi:10.1016/j.jclinepi.2011.10.008.

[15] M.C. Brouwers, M.E. Kho, G.P. Browman, J.S. Burgers, F. Cluzeau, G. Feder, B. Fervers, I.D. Graham, S.E. Hanna, J. Makarski, Development of the AGREE II, part 1: performance, usefulness and areas for improvement., CMAJ. 182 (2010) 1045–1052. doi:10.1503/cmaj.091714.

[16] M.C. Brouwers, M.E. Kho, G.P. Browman, J.S. Burgers, F. Cluzeau, G. Feder, B. Fervers, I.D. Graham, S.E. Hanna, J. Makarski, Development of the AGREE II, part 2: assessment of validity of items and tools to support application., CMAJ. 182 (2010) E472-8. doi:10.1503/cmaj.091716.

[17] F. Cluzeau, Conflicting recommendations. Let's not forget AGREE., BMJ. 338 (2009) b407. doi:10.1136/bmj.b407.

[18] M.A. Lawani, B. Valera, E. Fortier-Brochu, F. Legare, P.-H. Carmichael, L. Cote, P. Voyer, E. Kroger, H. Witteman, C. Rodriguez, A.M.C. Giguere, Five shared decision-making tools in 5 months: use of rapid reviews to develop decision boxes for seniors living with dementia and their caregivers., Syst. Rev. 6 (2017) 56. doi:10.1186/s13643-017-0446-2.

[19] M.K. Murphy, N.A. Black, D.L. Lamping, C.M. McKee, C.F. Sanderson, J. Askham, T. Marteau, Consensus development methods, and their use in clinical guideline development., Health Technol. Assess. 2 (1998) i–iv, 1-88.

[20] J. Jones, D. Hunter, Jones J, Hunter D, J. J, H. D, Consensus methods for medical and health services research, BMJ. 311 (1995) 376–380. isi:A1995RN46900025.

[21] L.J.M. Oostendorp, M.-A. Durand, A. Lloyd, G. Elwyn, Measuring organisational readiness for patient engagement (MORE): an international online Delphi consensus study, BMC Health Serv. Res. 15 (2015) 61. doi:10.1186/s12913-015-0717-3.

Supplementary File 1: Survey Invitation

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

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

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

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

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

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

Many thanks,

The Evidence Summarization workgroup

Evidence Summarization Survey

THE Dartmouth INSTITUTE FOR HEALTH POLICY & CLINICAL PRACTICE GEISEL SCHOOL OF MEDICINE AT DARTMOUTH

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

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

- [ ] Patient Decision Aid (PDA) developer
- [ ] Researcher
- [ ] International Patient Decision Aids Standards (IPDAS) collaboration member
- [ ] Policy maker
- [ ] Patient
- [ ] Clinician, please specify specialty:
- [ ] Other, please specify:

Which country do you live in?

What is your gender?

- ○ Male
- ○ Female
- ○ Other

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

- [ ] American Indian or Alaska Native
- [ ] Asian
- [ ] Black or African American
- [ ] Native Hawaiian or Other Pacific Islander
- [ ] Hispanic, Latino/a or Spanish Origin
- [ ] White

☐ 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

well as the order and grouping.

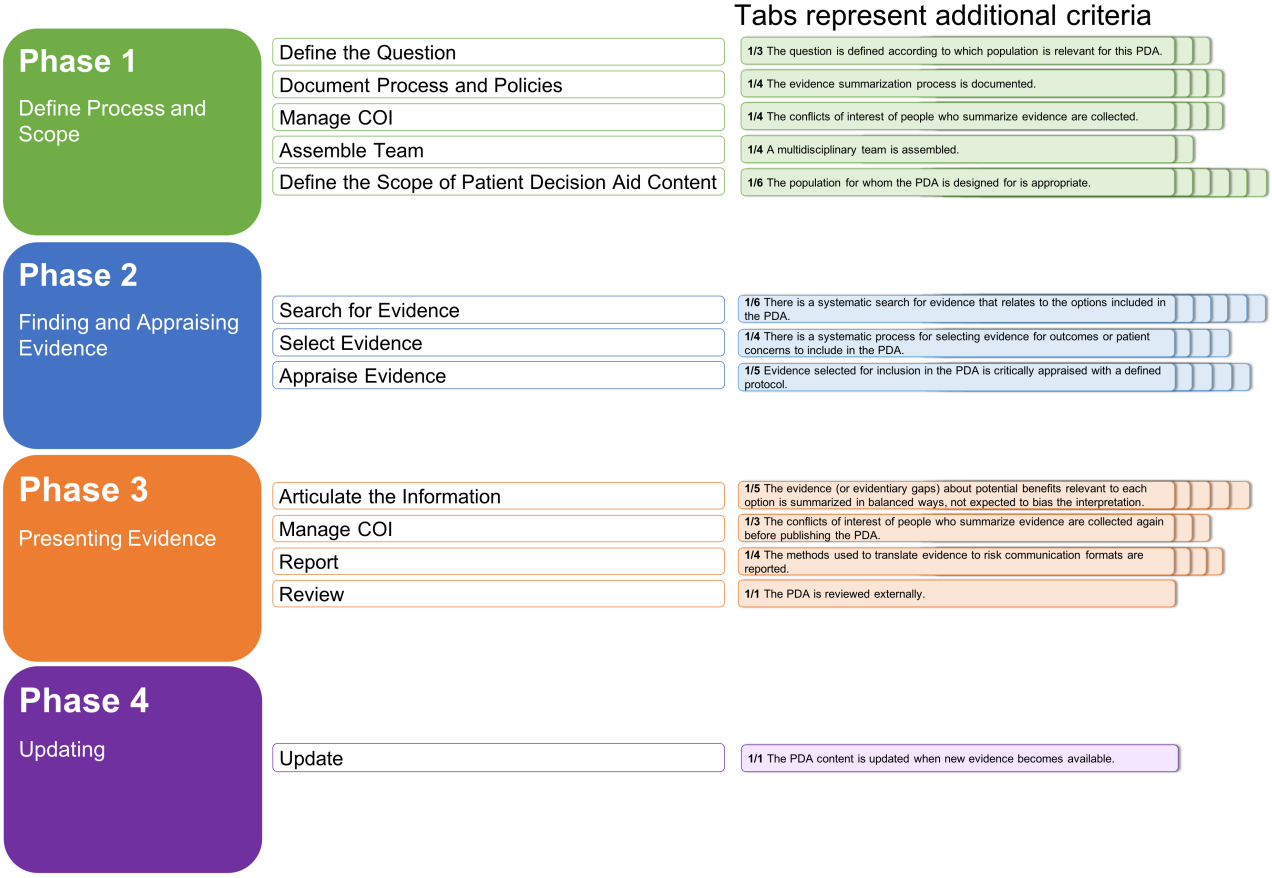
Here's how you can help. In the questions that follow, we will ask for your perspective on **how important each criterion is to include in the proposed process**. We will also ask for feedback on the wording of all parts. Nothing is final. Everything is up for discussion, and we are looking forward to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

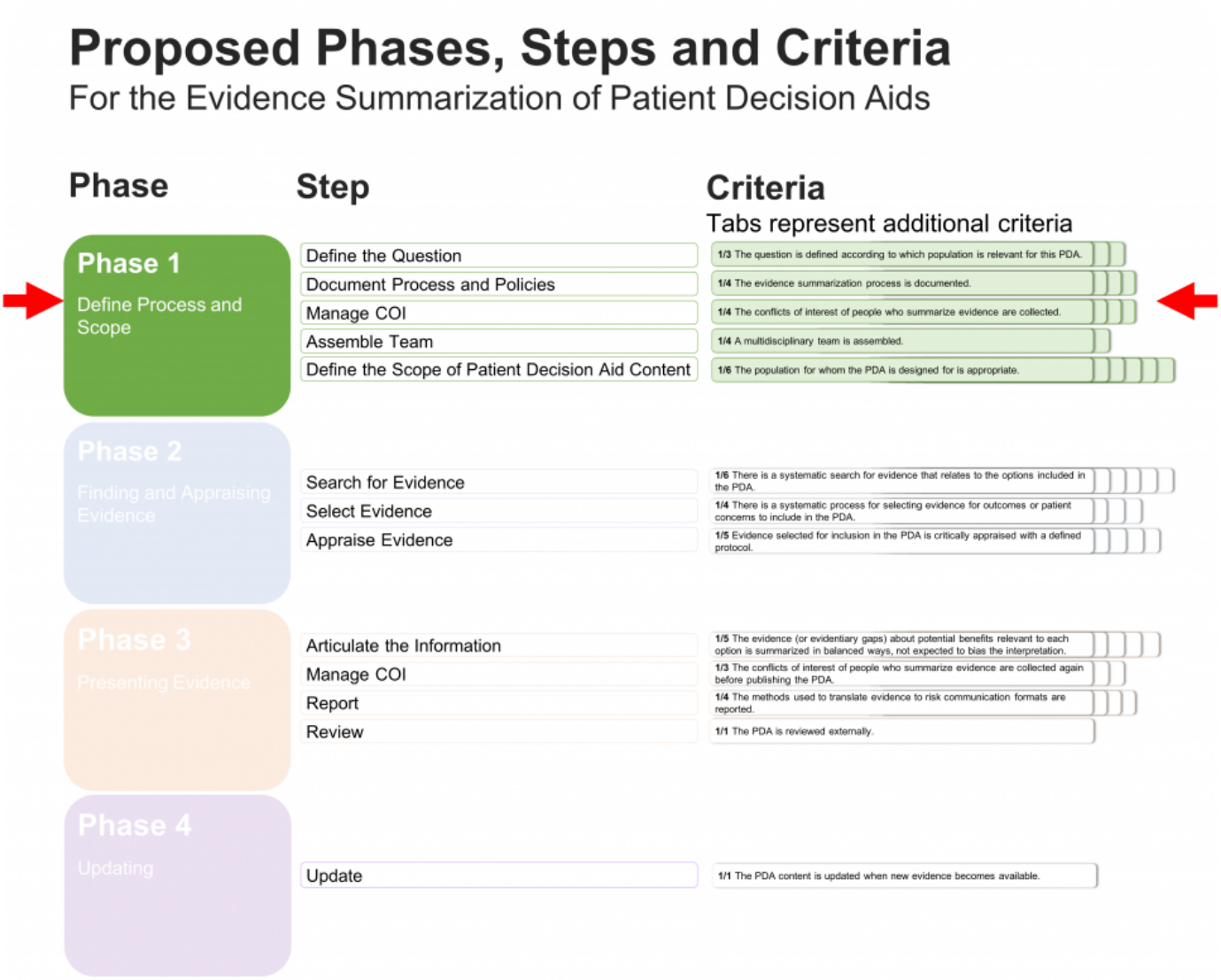
Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Phase 1

PROPOSED PHASE 1



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.

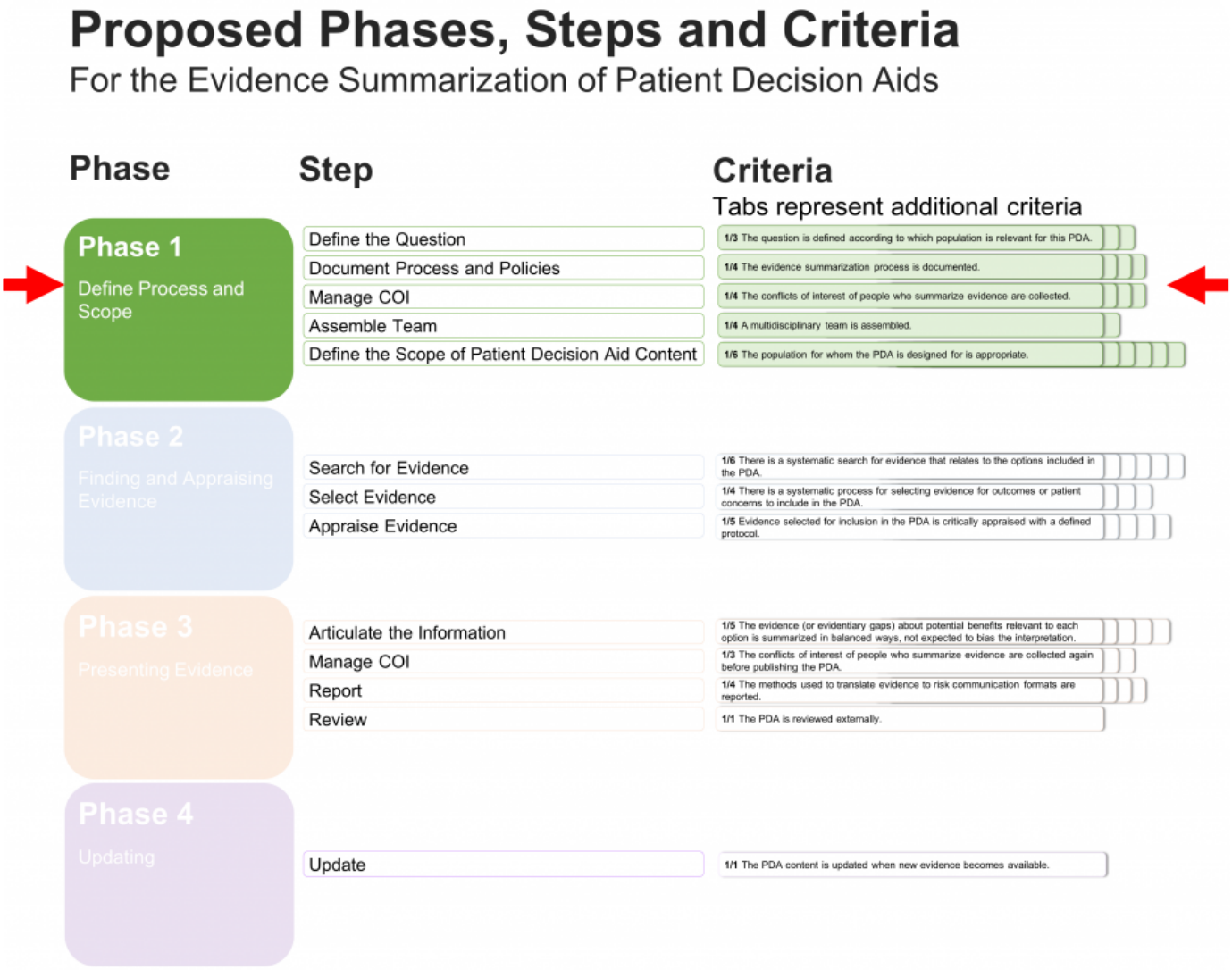
Do you have any comments or suggestions on the Phase below? If so, please share them.

- **Phase 1: Defining Process and Scope**

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



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**

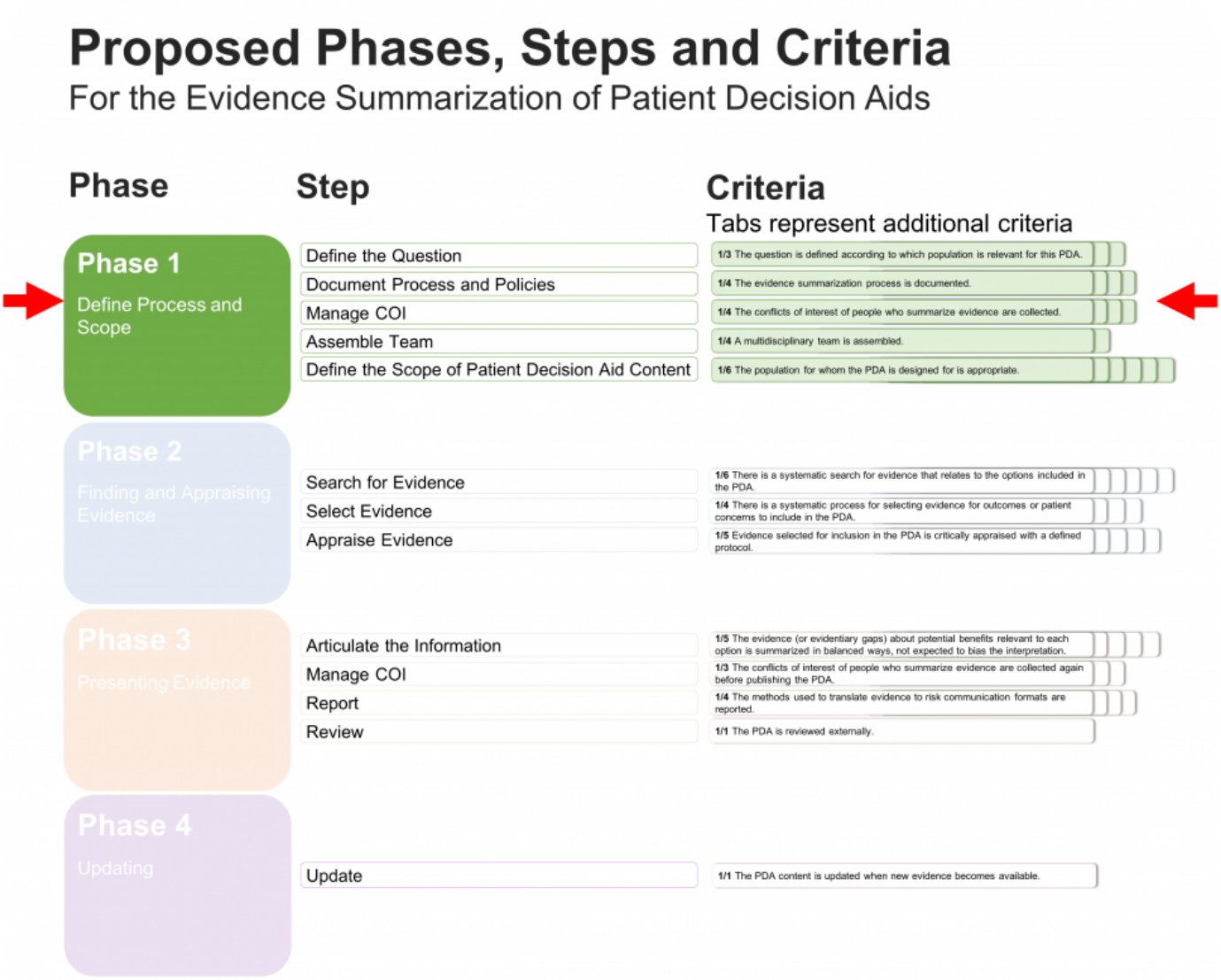
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	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



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**

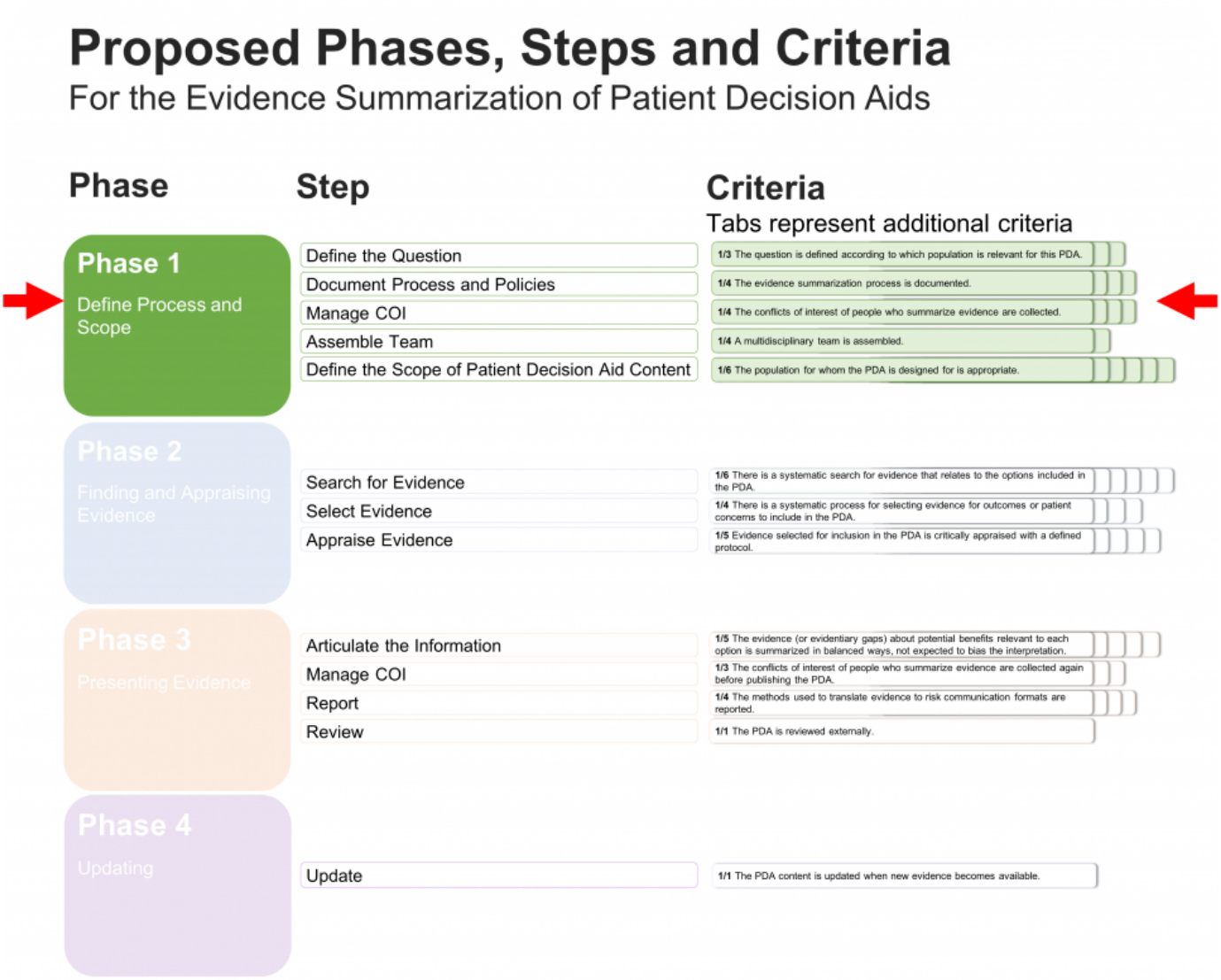
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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**

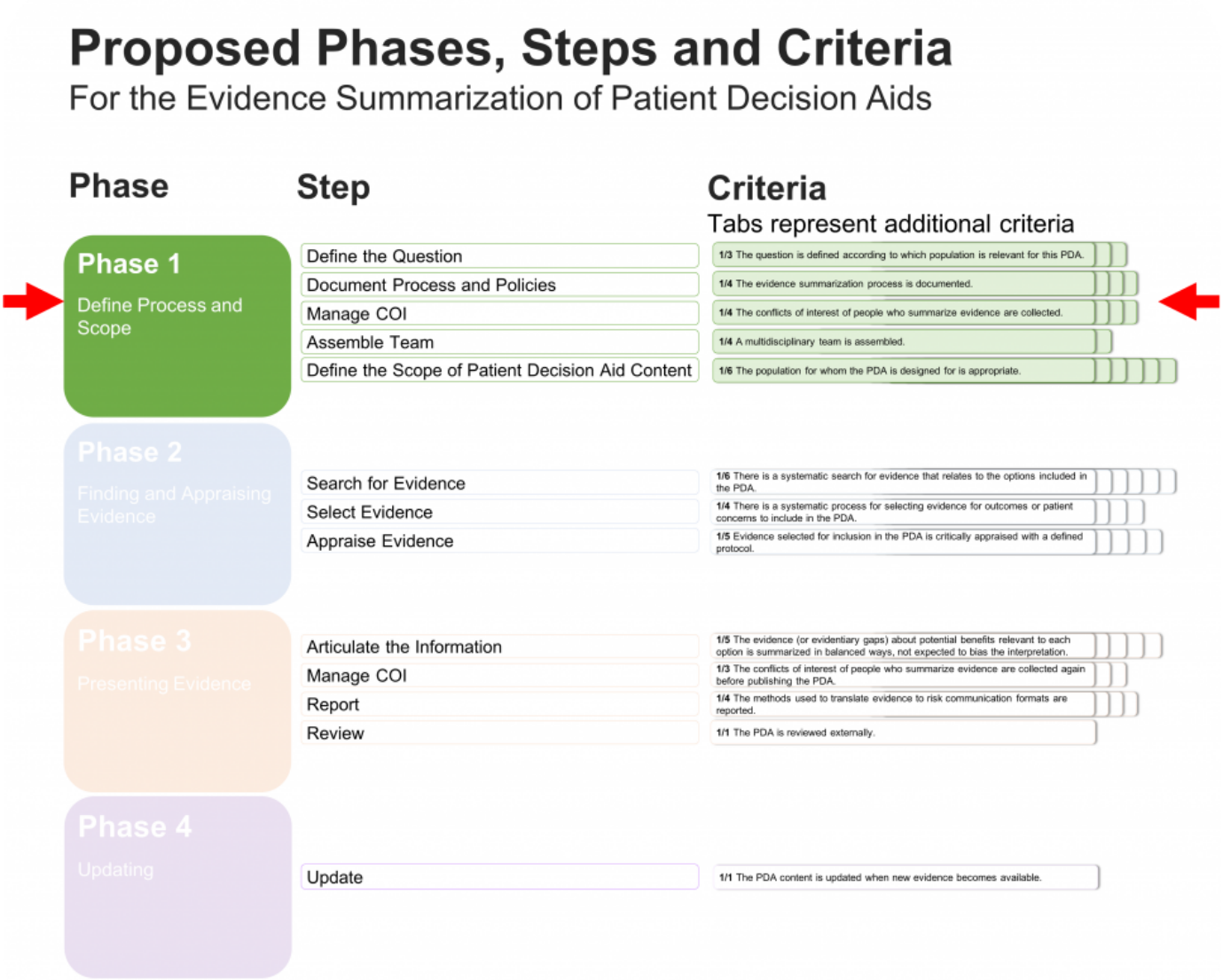
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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**

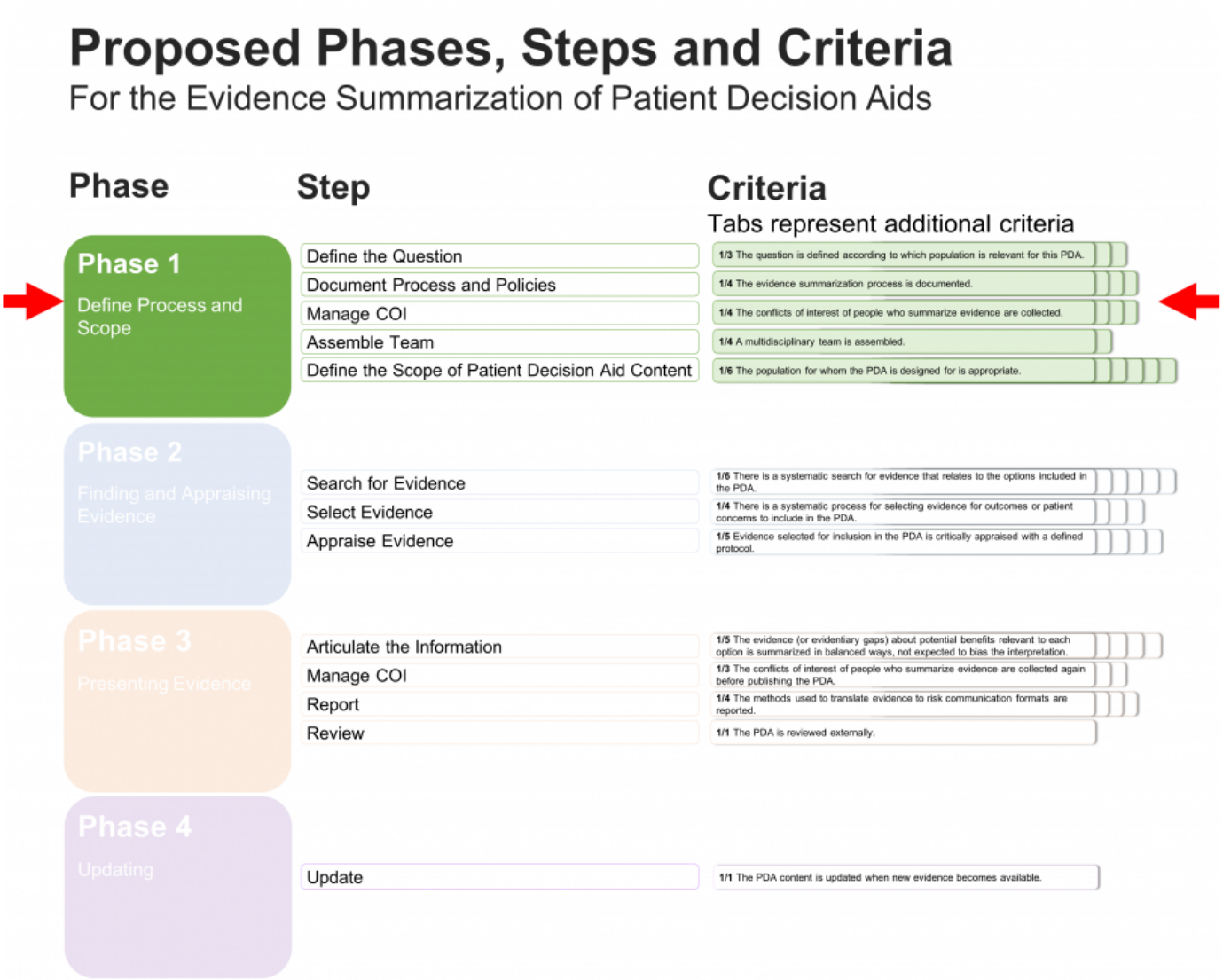
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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.

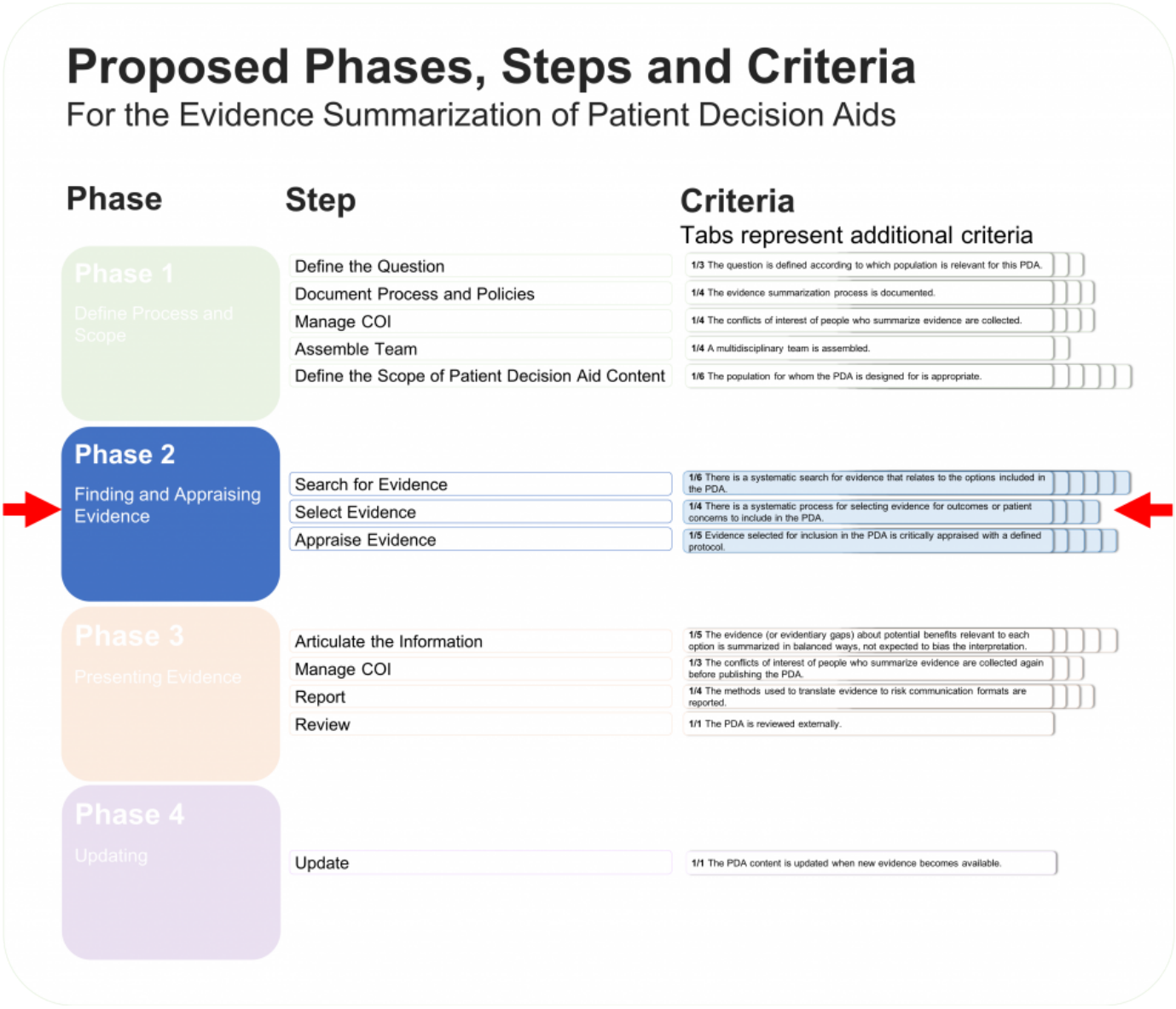
	Omit	Possible	D
The population for whom the PDA is designed for is appropriate.	○	○	
There is a systematic process to reduce bias in the definition of the population for the PDA.	○	○	
The options for inclusion in the PDA are appropriate for the intended population.	○	○	
There is a systematic process 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



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.

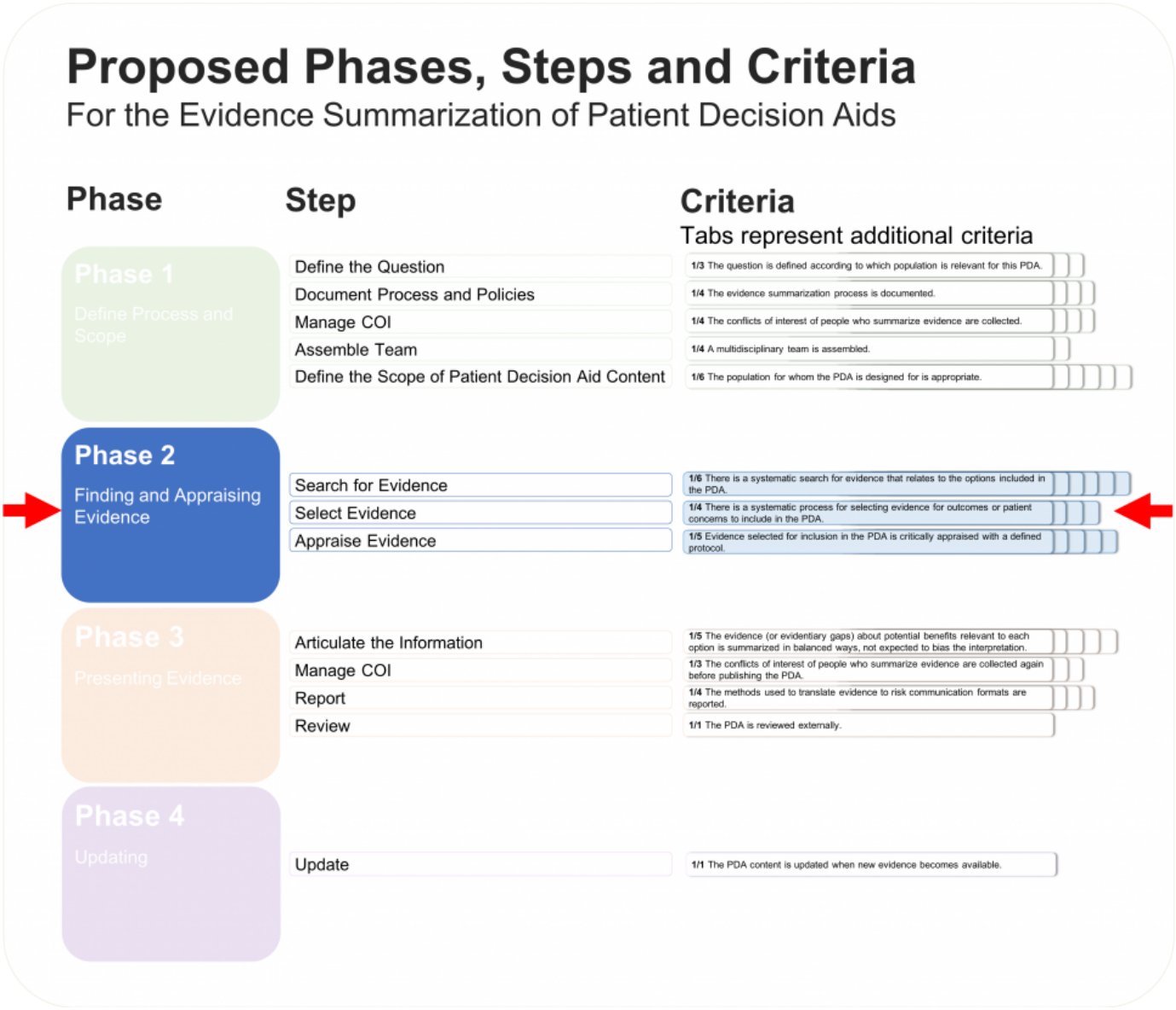
Do you have any comments or suggestions on the Phase below? If so, please share them.

- **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



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**

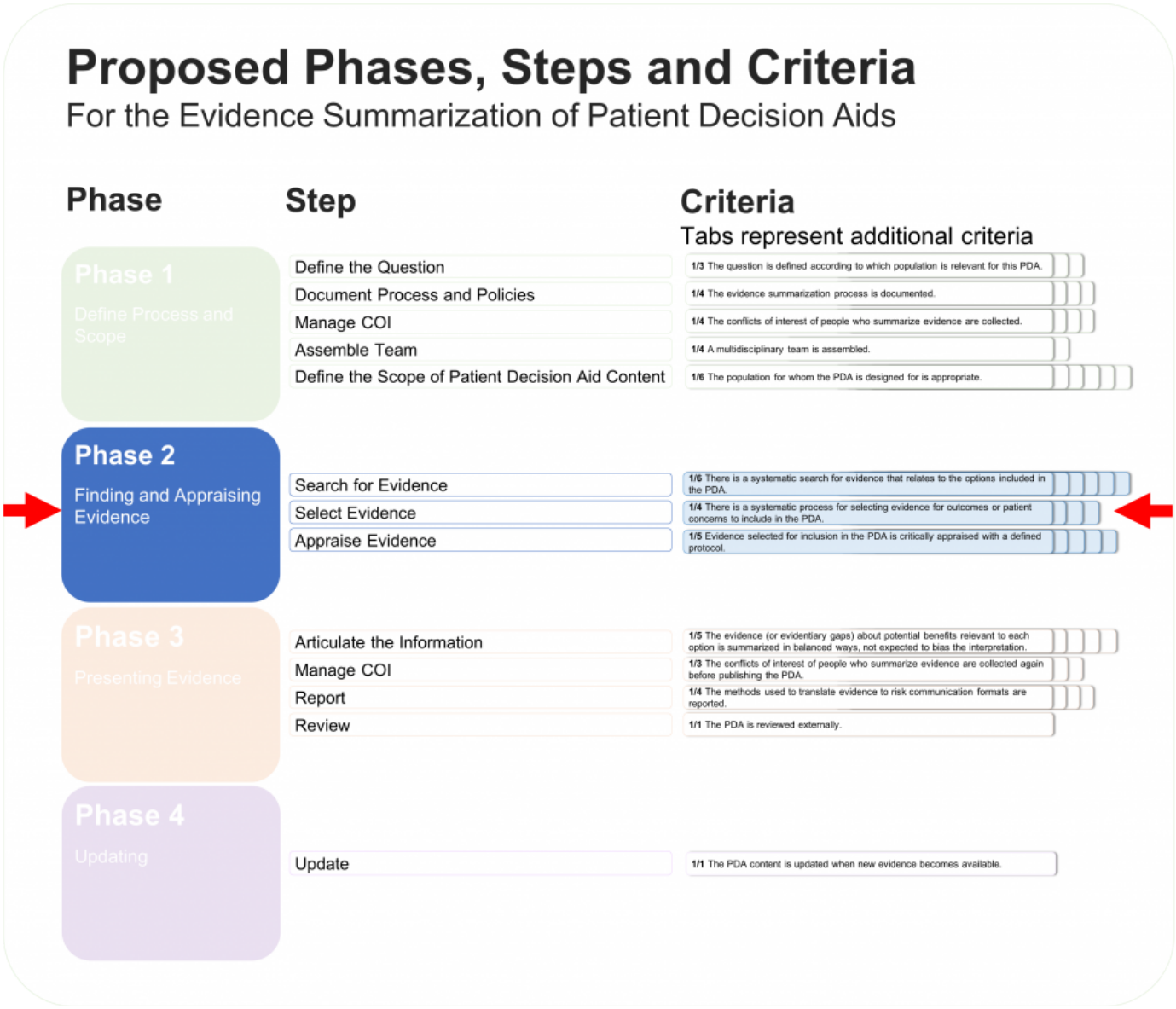
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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.	○	○	

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**

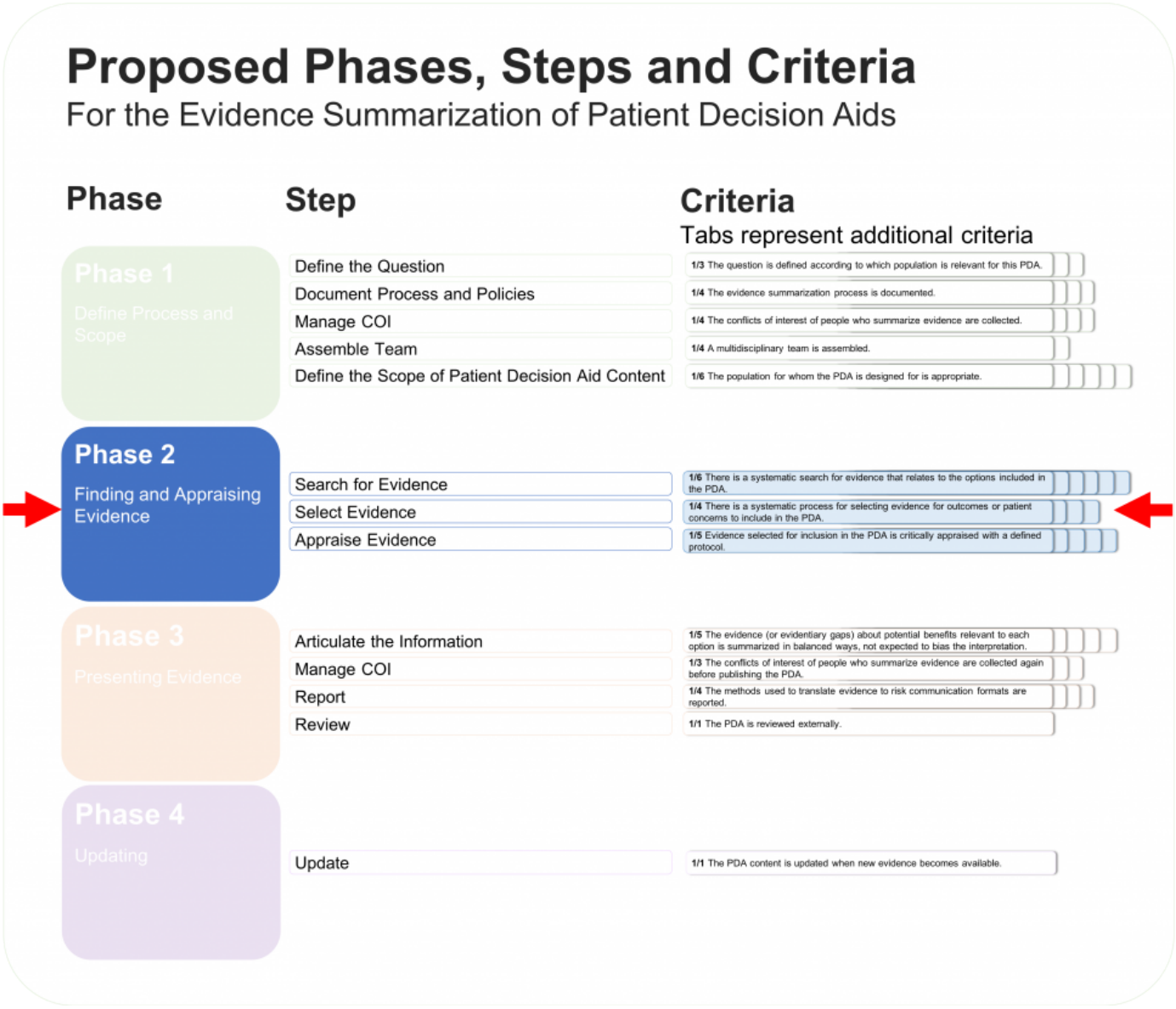
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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.

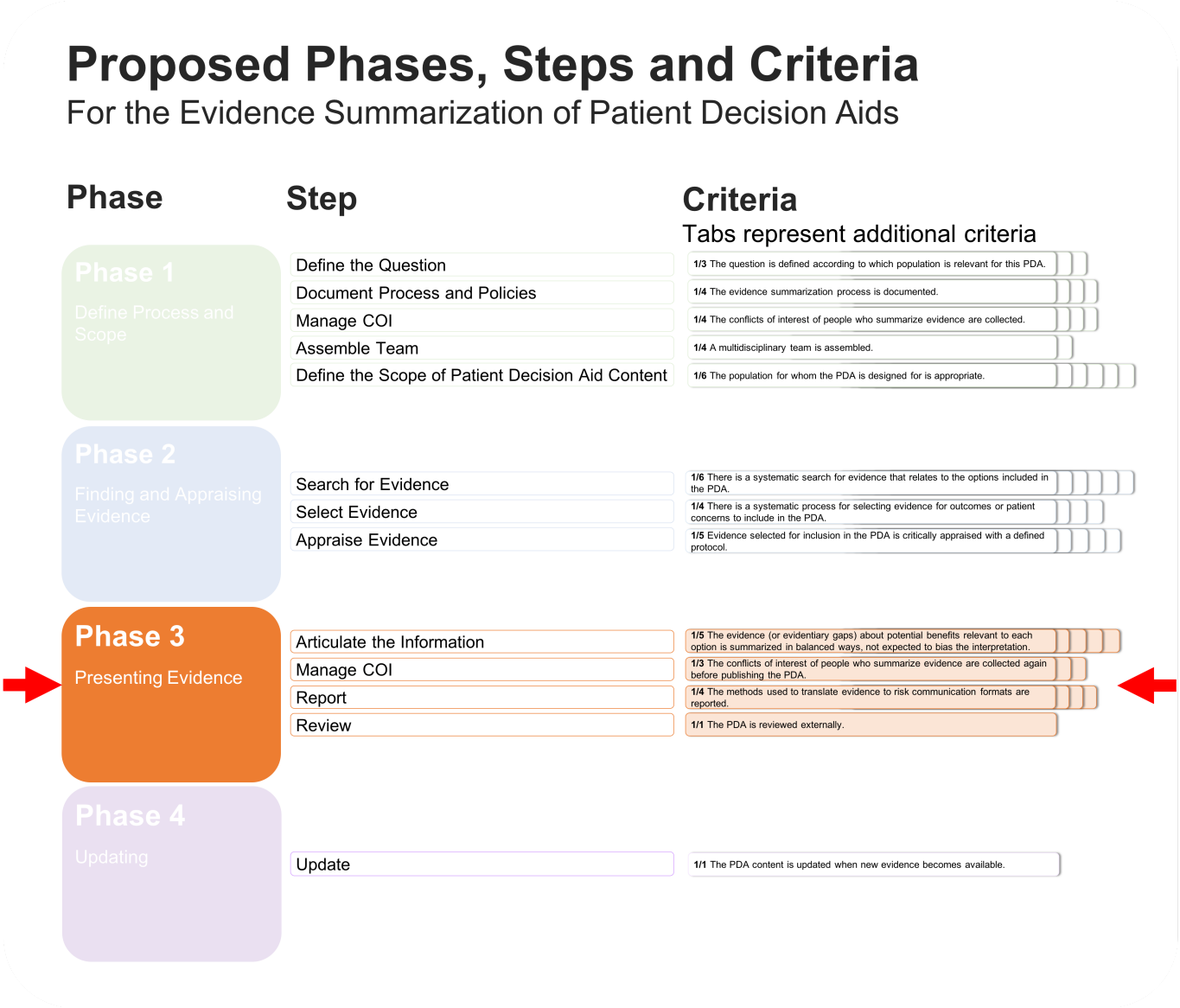
	Omit	Possible	D
Evidence selected for inclusion in the PDA is critically appraised with a defined protocol (such as GRADE).	○	○	
The protocol for critical appraisal of evidence accounts for risks of bias in study design.	○	○	
The protocol for critical appraisal of evidence accounts for risks of bias 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



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.

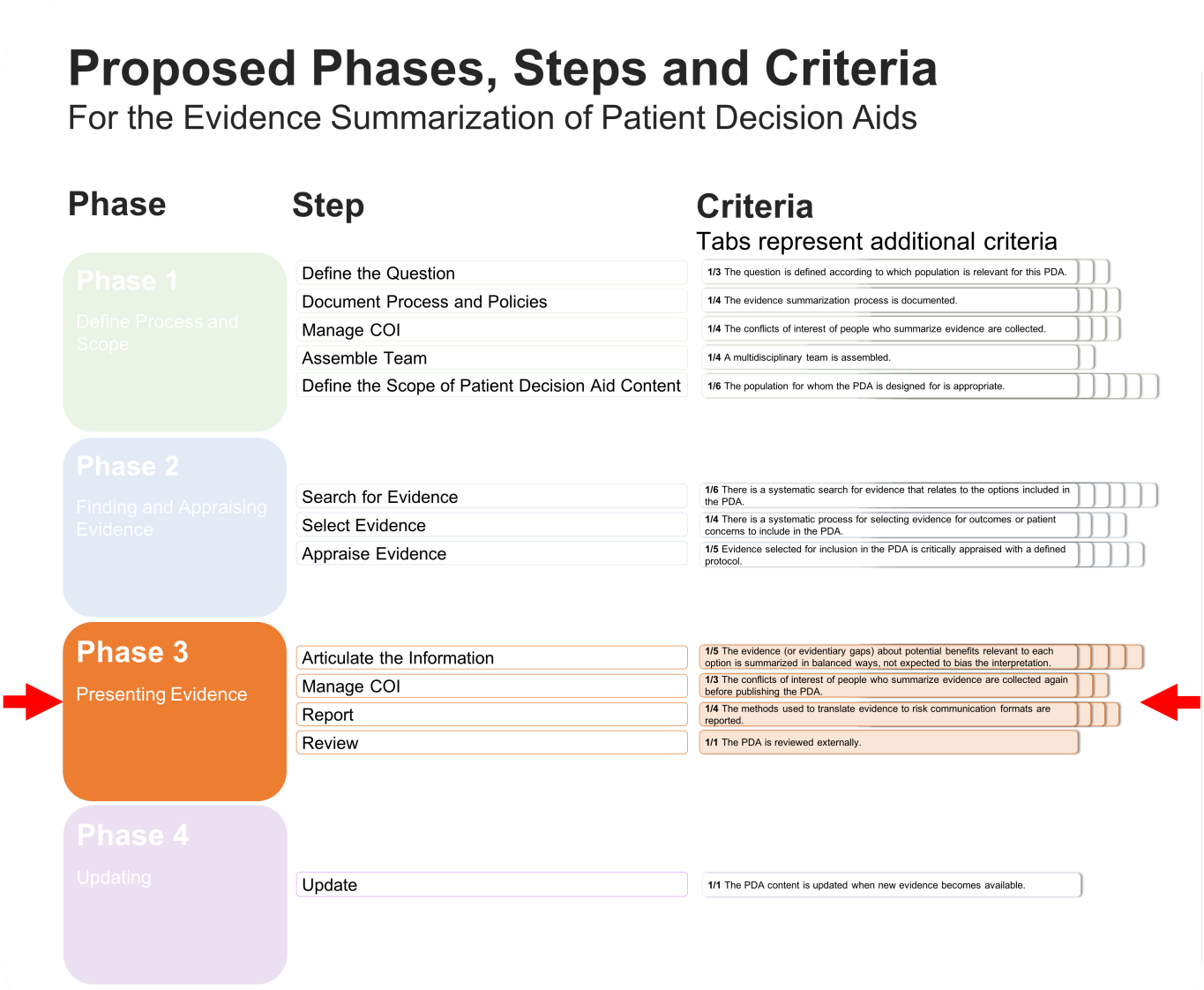
Do you have any comments or suggestions on the Phase below? If so, please share them.

- **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



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**

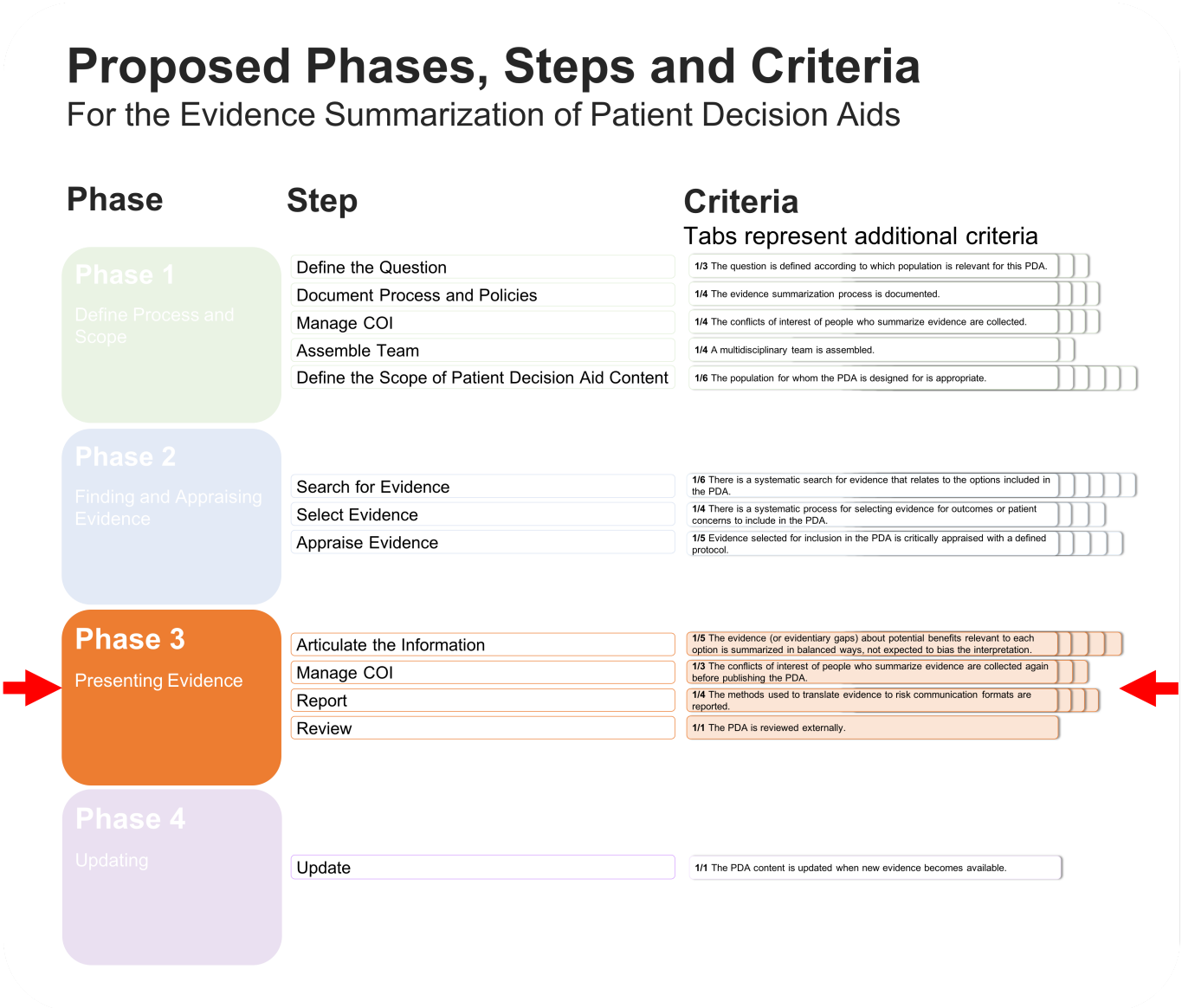
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	[
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 to understand.	○	○	
The funding used to summarize the evidence (and develop the PDA) is reported.	○	○	

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



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: Manage COI**

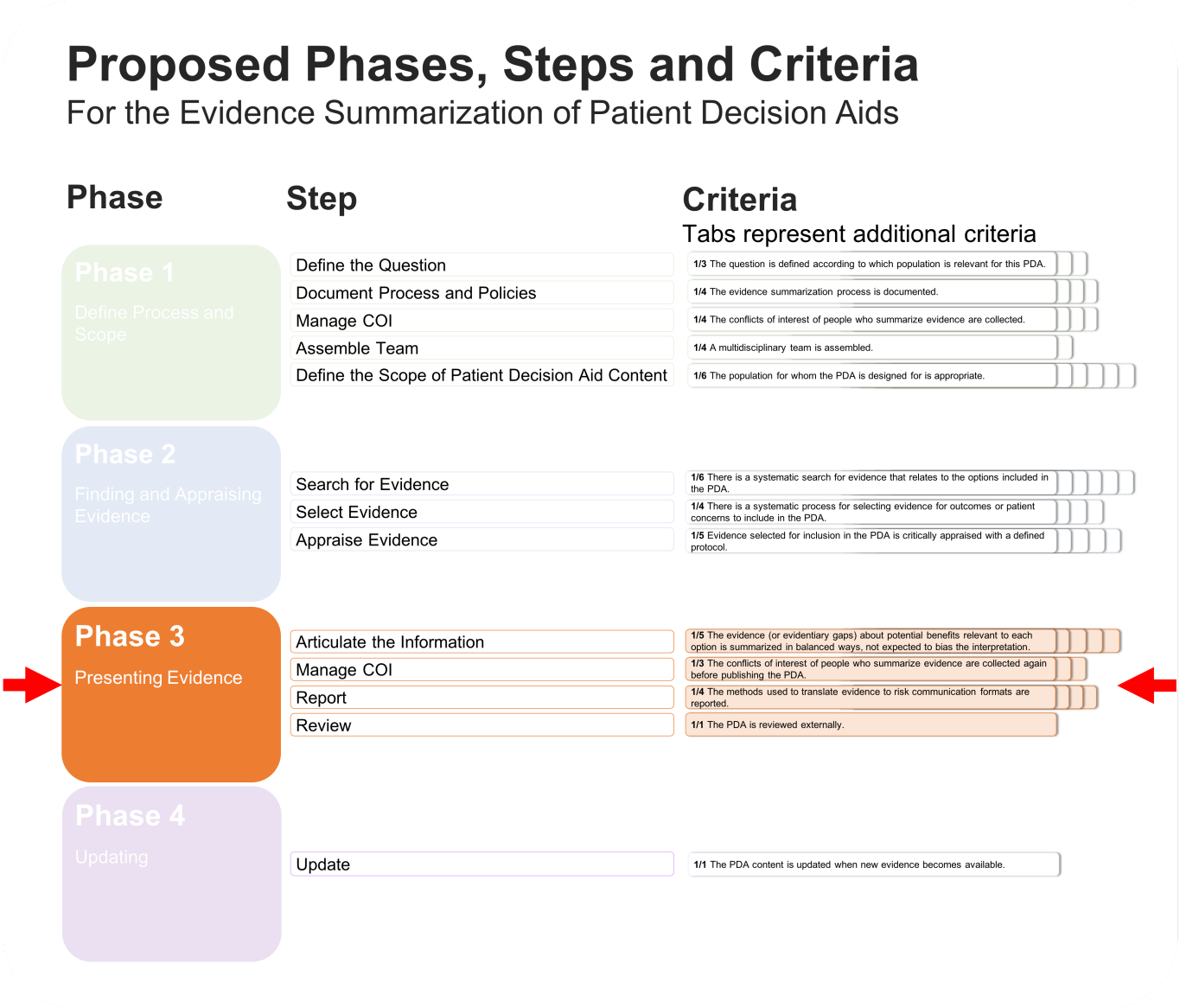
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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**

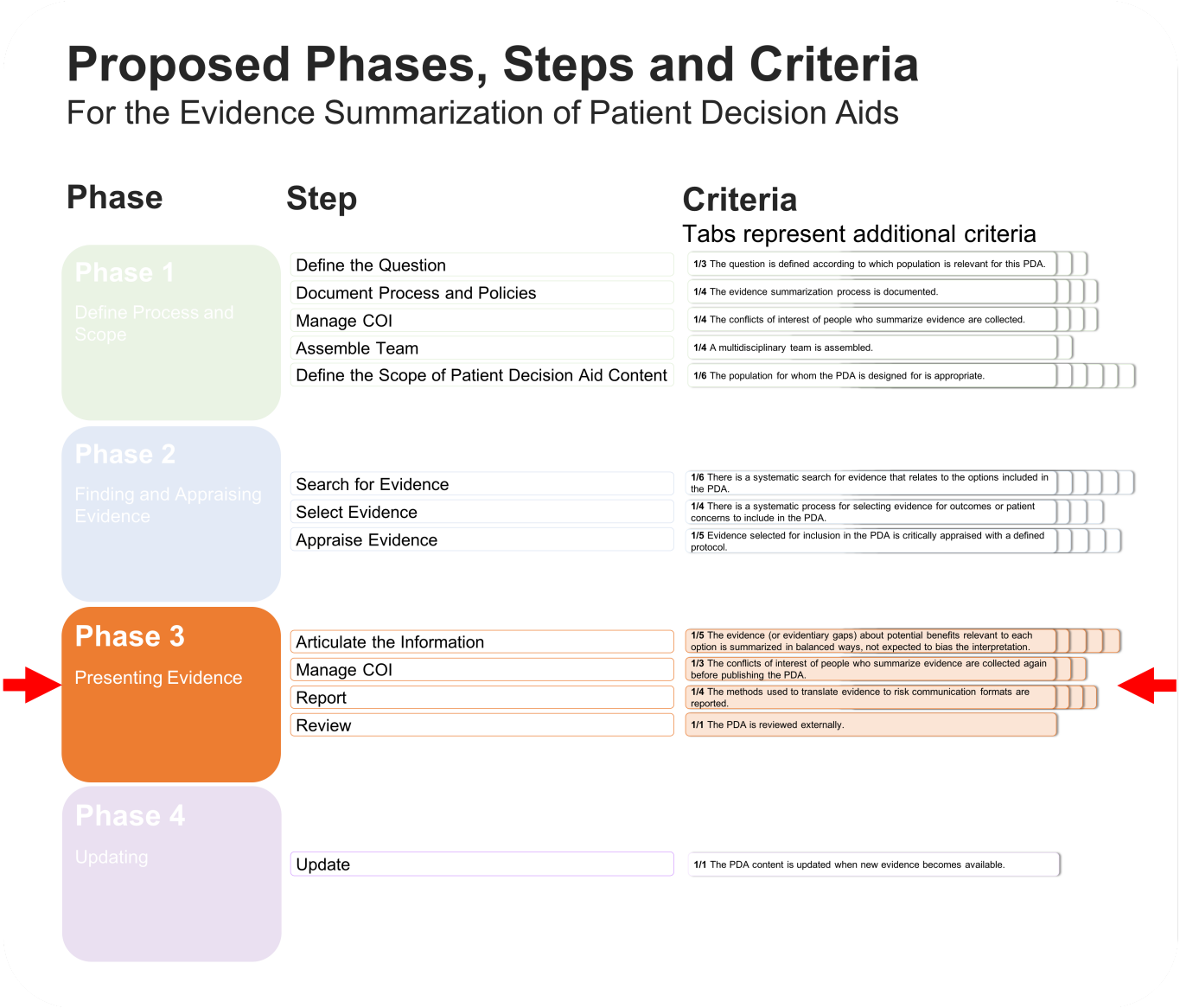
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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.

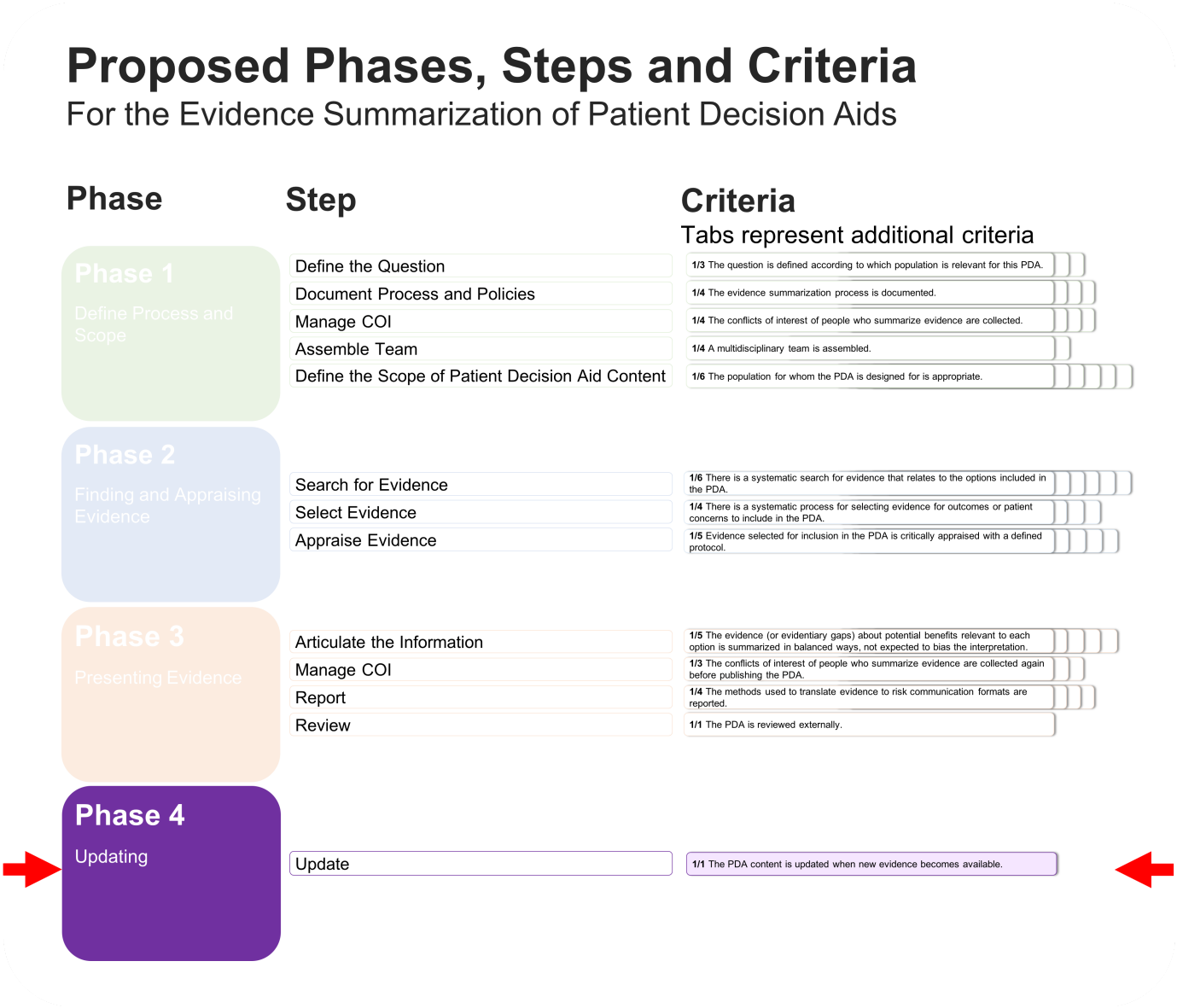
	Omit	F
The PDA is reviewed externally.	○	

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



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.

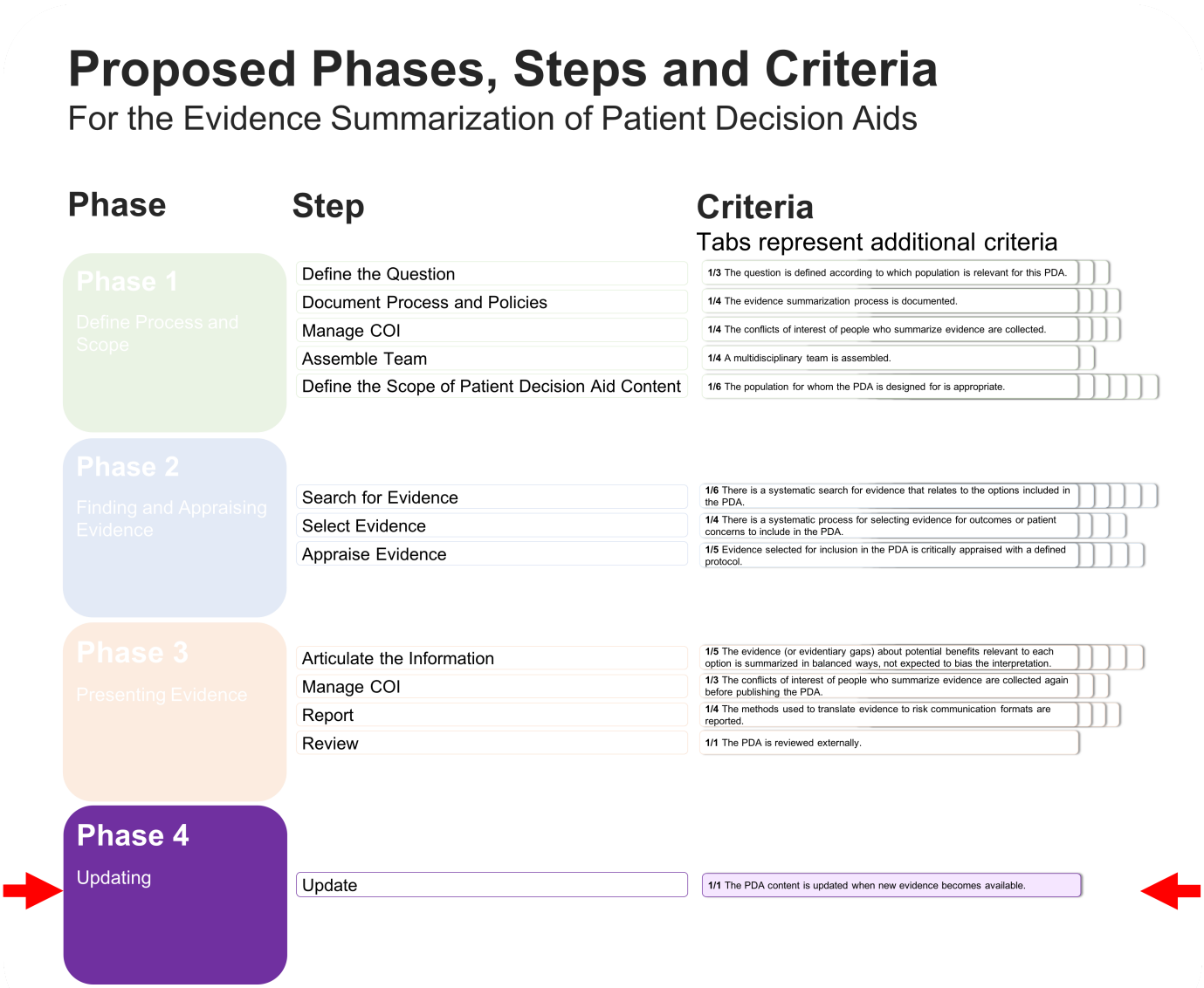
Do you have any comments or suggestions on the Phase below? If so, please share them.

- **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



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	[
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.
			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.
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.

BMJ Open

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

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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

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

Running heading: Evidence summarization Delphi survey

Authors:
Marie-Anne Durand[1]
Michelle D. Dannenberg[2]
Catherine H. Saunders[3]
Anik Giguère[4]
Brian S. Alper[5]
Tammy Hoffmann[6]
Lilisbeth Perestelo-Perez[7]
Stephen T. Campbell[8]
Glyn Elwyn[9]

1 Associate Professor
The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States
2 Research Assistant/Research Coordinator
The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States
3 Doctoral Student
The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States
4 Associate Professor
Department of Family Medicine
Université Laval, C.A.
2325 Rue de l'Université, Québec, QC G1V 0A6, Canada
5 Vice President of Innovations and EBM Development
EBSCO Health Innovations, Department of Innovations and EBM Development
10 Estes Street, Ipswich, MA 01938, United States
6 Professor of Clinical Epidemiology
Centre for Research in Evidence-Based Practice (CREBP)
Faculty of Health Sciences & Medicine
Level 2, Building 5, Faculty of Health Sciences & Medicine, Bond University
14 University Dr, Robina QLD 4226, Australia
7 Researcher
Evaluation AND Planning Unit – Directorate of the Canary Islands Health Service
Camino de Candelaria s/n. El Chorrillo
38109

El Rosario, Spain

8 Patient Partner
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States

9 Professor
The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
One Medical Center Drive, Lebanon, NH 03766, United States

Correspondence to: Marie-Anne Durand:
Phone: 603-653-0851
Email: marie-anne.durand@dartmouth.edu
Address: The Preference Laboratory
The Dartmouth Institute for Health Policy & Clinical Practice
Level 5, Williamson Translational Research Building
One Medical Center Drive
Lebanon, NH 03756

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Patient-Centered Care
Surveys and Questionnaires

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

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

Objective

The purpose of the study is 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. This will in turn improve transparency, rigor and minimize the risk of bias of the evidence summarization processes leading to the development of patient decision aids.

2 METHODS

Study Design and Procedures

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

Study Management

To oversee the tasks of 1) generating an initial set of criteria for the Delphi process and 2) managing the Delphi survey distribution and analysis, we convened a steering group. This group will oversee the project and will make strategic decisions about the study design, data collection and analysis processes, as well as agree a final process and related set of steps and criteria. An invitation to join this group was posted on social media (Shared@Shared Decision Making Network Facebook group: 745 members) on 30 June 2017. The post invited all Facebook group members to join an in-person meeting about evidence summarization during the International Shared Decision Making conference, held in Lyon, France, between July 2, and July 5, 2017. For those who were not able to join the meeting but

expressed an interest in evidence summarization of PDAs, a high-level summary was posted on Facebook. The steering group was convened in September 2017. The study steering group includes nine international experts in PDA development, evaluation and implementation, evidence summarization and clinical practice guidelines, and one patient representative. Six steering group members are based in the US, one in Canada, one in Australia and one in Spain Google drive and video-conferencing facilities will be used to facilitate the exchange and review of information and documents, virtual meetings, as well as real-time collaboration and version-control.

Participants

To maximize the generalizability and applicability of the criteria, we plan to invite participation in the survey from members of the following groups: 1) all known developers of PDAs who created or updated a tool within last five calendar years (using existing inventory), 2) all members of the of the IPDAS group, 3) the Shared Decision Making listserv; 4) the Society for Participatory Medicine listserv ; 5) an overdiagnosis google group ; 6) the evidence-based healthcare listserv ; 7) the Society for Medical Decision Making ; the 8) the Society of Behavioral Medicine (Health Decision Making Interest Group) , 9) HTAi-ISG Patient Involvement listserv, 10) GRADE Working group, 11) the Guidelines International Network, 12) convenience sample of policy makers with interest and expertise in PDA certification; 13) the BMJ patient group; 14) the ProPublica Patient Safety Community. We have no other eligibility criteria (except for membership to one of the above listed groups).

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

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

Patient and Public Involvement

Design

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

Participants

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

Analysis

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

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

consensus to be achieved and the item will be removed or retained, respectively. Items where ratings do not meet the consensus threshold and conflict with open text comments will be grouped together and explained to round 2 participants. They will be asked to re-rate those items taking the qualitative feedback into account. Following the first survey round, a consensus meeting involving the steering group will be held. The steering group will review and discuss the ratings and qualitative feedback received, including rewording suggestions per criterion, suggestions to add new phases, steps or criteria and more general comments or questions. The wording or order of the phases, steps or criteria will be revised if two or more respondents suggest it or if the steering group members agree that the phase, step or criterion would benefit from rewording, reordering or merging.

Following the second survey round, a second consensus meeting will be held. Decisions on whether to conduct a third round and retain items in the scale will be made based on the ratings in the survey rounds and feedback/comments from participants. 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 importance of the item in the lower two categories, or in the higher two categories, we will consider consensus to be achieved and the item will be removed or retained, respectively. If no consensus is achieved or the consensus ratings are contradicted by recurring open text comments, the steering group will decide whether or not to retain a criterion, basing this decision on qualitative feedback from the participants where possible, and the steering group's views. We have successfully used this approach before [21].

Only complete surveys will be included in the analysis. We will report the amount of missing data in the manuscript reporting the results of the Delphi survey.

Data Management and Safety

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

DISCUSSION

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

STRENGTHS AND LIMITATIONS

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

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.

REFERENCES

[1] D. Stacey, F. Légaré, K. Lewis, M.J. Barry, C.L. Bennett, K.B. Eden, M. Holmes-Rovner, H. Llewellyn-Thomas, A. Lyddiatt, R. Thomson, L. Trevena, F. Legare, N.F. Col, C.L. Bennett, M.J. Barry, K.B. Eden, M. Holmes-Rovner, H. Llewellyn-Thomas, A. Lyddiatt, R. Thomson, L. Trevena, J.H.C. Wu, F. Légaré, K. Lewis, M.J. Barry, C.L. Bennett, K.B. Eden, M. Holmes-Rovner, H. Llewellyn-Thomas, A. Lyddiatt, R. Thomson, L. Trevena, Decision aids for people facing health treatment or screening decisions, Cochrane Database Syst. Rev. 4 (2017) CD001431. doi:10.1002/14651858.CD001431.pub5.

[2] G. Elwyn, A.M.A. O'Connor, D. Stacey, R. Volk, A.G.K.A.G. Edwards, A. Coulter, R. Thomas, A.L. Barratt, M. Barry, S.J. Bernstein, P.N. Butow, A. Clarke, V.A. Entwistle, D. Feldman-Stewart, M. Holmes-Rovner, A. Mulley, H.A. Llewellyn-Thomas, N. Moumjid, C. Ruland, K.R. Sepucha, A. Sykes, T. Whelan, R. Thomson, Developing a quality criteria framework for patient decision aids: online international Delphi consensus process, BMJ. 333 (2006) 417–423. doi:10.1136/bmj.38926.629329.AE.

[3] M.D. Dannenberg, M.-A. Durand, V.M. Montori, C. Reilly, G. Elwyn, Existing evidence summarization methods cannot guarantee trustworthy patient decision aids., J. Clin. Epidemiol. 102 (2018) 69–77. doi:10.1016/j.jclinepi.2018.06.003.

[4] G. Elwyn, A.M.A.M.A.M. O'Connor, C.L. Bennett, R.G.R.G.R.G. Newcombe, M. Politi, M.-A.M.M.-A. Durand, E. Drake, N. Joseph-Williams, S. Khangura, A. Saarimaki, S. Sivell, M. Stiel, S.J.S.J. Bernstein, N. Col, A. Coulter, K. Eden, M. Härter, M.H.M.H.M.H. Rovner, N. Moumjid, D. Stacey, R. Thomson, T. Whelan, T. van der Weijden, A.G.K.A. Edwards, O'Connor AM, Bennett C, Newcombe RG, Politi M, Durand MA, Drake E, Joseph-Willams N, Khangura S, Anton Saarimaki A, Stephanie Sivell S, Stiel M, Col N, Coulter A, Eden K, Holmes Rovner M, Moumjid N, Thomson R, Whelan T, van der Weijden T, A.G.K. Edward, A. Khangura, Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi), PLoS One. 4 (2009) e4705. doi:10.1371/journal.pone.0004705.

[5] V.M. Montori, A. LeBlanc, A. Buchholz, D.L. Stilwell, A. Tsapas, Basing information on comprehensive, critically appraised, and up-to-date syntheses of the scientific evidence: a quality dimension of the International Patient Decision Aid Standards., BMC Med. Inform. Decis. Mak. 13 Suppl 2 (2013) S5. doi:10.1186/1472-6947-13-S2-S5.

[6] M.-A. Durand, J. Witt, N. Joseph-Williams, R.G. Newcombe, M.C. Politi, S. Sivell, G. Elwyn, Minimum standards for the certification of patient decision support interventions: Feasibility and application, Patient Educ. Couns. 98 (2015). doi:10.1016/j.pec.2014.12.009.

[7] N. Joseph-Williams, R. Newcombe, M. Politi, M.-A. Durand, S. Sivell, D. Stacey, A. O'Connor, R.J. Volk, A. Edwards, C. Bennett, M. Pignone, R. Thomson, G. Elwyn, Toward Minimum Standards for Certifying Patient Decision Aids, Med. Decis. Mak. 34 (2014) 699–710. doi:10.1177/0272989X13501721.

[8] A. WSHC, Patient decision aids certification 2018, (n.d.). https://www.hca.wa.gov/about-hca/healthier-washington/patient-decision-aids-pdas.

[9] J.P.T. Higgins, S. Green, Cochrane handbook for systematic reviews of interventions version 5.0. 2 [updated September 2009], The Cochrane Collaboration, York, 2009.

[10] O.A. Schünemann H, Brożek J, Guyatt G, ed., GRADE Handbook for Grading Quality of Evidence and Strength of Recommendations, The GRADE Working Group, n.d. Available from gdt.guidelinedevelopment.org/app/handbook/handbook.html .

[11] A. Qaseem, F. Forland, F. Macbeth, G. Ollenschlager, S. Phillips, P. van der Wees, Guidelines International Network: toward international standards for clinical practice guidelines., Ann. Intern. Med. 156 (2012) 525–531. doi:10.7326/0003-4819-156-7-201204030-00009.

[12] Standards for systematic reviews 2011, n.d. http://www.nationalacademies.org/hmd/Reports/2011/Finding-What-Works-in-Health-Care-Standards-for-Systematic-Reviews/Standards.aspx.

[13] D. Moher, A. Liberati, J. Tetzlaff, D.G. Altman, Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement., PLoS Med. 6 (2009) e1000097. doi:10.1371/journal.pmed.1000097.

[14] M.C. Brouwers, M.E. Kho, G.P. Browman, J.S. Burgers, F. Cluzeau, G. Feder, B. Fervers, I.D. Graham, J. Grimshaw, S.E. Hanna, P. Littlejohns, J. Makarski, L. Zitzelsberger, The Global Rating Scale complements the AGREE II in advancing the quality of practice guidelines., J. Clin. Epidemiol. 65 (2012) 526–534. doi:10.1016/j.jclinepi.2011.10.008.

[15] M.C. Brouwers, M.E. Kho, G.P. Browman, J.S. Burgers, F. Cluzeau, G. Feder, B. Fervers, I.D. Graham, S.E. Hanna, J. Makarski, Development of the AGREE II, part 1: performance, usefulness and areas for improvement., CMAJ. 182 (2010) 1045–1052. doi:10.1503/cmaj.091714.

[16] M.C. Brouwers, M.E. Kho, G.P. Browman, J.S. Burgers, F. Cluzeau, G. Feder, B. Fervers, I.D. Graham, S.E. Hanna, J. Makarski, Development of the AGREE II, part 2: assessment of validity of items and tools to support application., CMAJ. 182 (2010) E472-8. doi:10.1503/cmaj.091716.

[17] F. Cluzeau, Conflicting recommendations. Let's not forget AGREE., BMJ. 338 (2009) b407. doi:10.1136/bmj.b407.

[18] M.A. Lawani, B. Valera, E. Fortier-Brochu, F. Legare, P.-H. Carmichael, L. Cote, P. Voyer, E. Kroger, H. Witteman, C. Rodriguez, A.M.C. Giguere, Five shared decision-making tools in 5 months: use of rapid reviews to develop decision boxes for seniors living with dementia and their caregivers., Syst. Rev. 6 (2017) 56. doi:10.1186/s13643-017-0446-2.

[19] M.K. Murphy, N.A. Black, D.L. Lamping, C.M. McKee, C.F. Sanderson, J. Askham, T. Marteau, Consensus development methods, and their use in clinical guideline development., Health Technol. Assess. 2 (1998) i–iv, 1-88.

[20] J. Jones, D. Hunter, Jones J, Hunter D, J. J, H. D, Consensus methods for medical and health services research, BMJ. 311 (1995) 376–380. isi:A1995RN46900025.

[21] L.J.M. Oostendorp, M.-A. Durand, A. Lloyd, G. Elwyn, Measuring organisational readiness for patient engagement (MORE): an international online Delphi consensus study, BMC Health Serv. Res. 15 (2015) 61. doi:10.1186/s12913-015-0717-3.

Supplementary File 1: Survey Invitation

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

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

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

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

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

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

Many thanks,

The Evidence Summarization workgroup

Evidence Summarization Survey

THE Dartmouth INSTITUTE FOR HEALTH POLICY & CLINICAL PRACTICE GEISEL SCHOOL OF MEDICINE AT DARTMOUTH

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

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

- [ ] Patient Decision Aid (PDA) developer
- [ ] Researcher
- [ ] International Patient Decision Aids Standards (IPDAS) collaboration member
- [ ] Policy maker
- [ ] Patient
- [ ] Clinician, please specify specialty:
- [ ] Other, please specify:

Which country do you live in?

What is your gender?

- ○ Male
- ○ Female
- ○ Other

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

- [ ] American Indian or Alaska Native
- [ ] Asian
- [ ] Black or African American
- [ ] Native Hawaiian or Other Pacific Islander
- [ ] Hispanic, Latino/a or Spanish Origin
- [ ] White

☐ 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

well as the order and grouping.

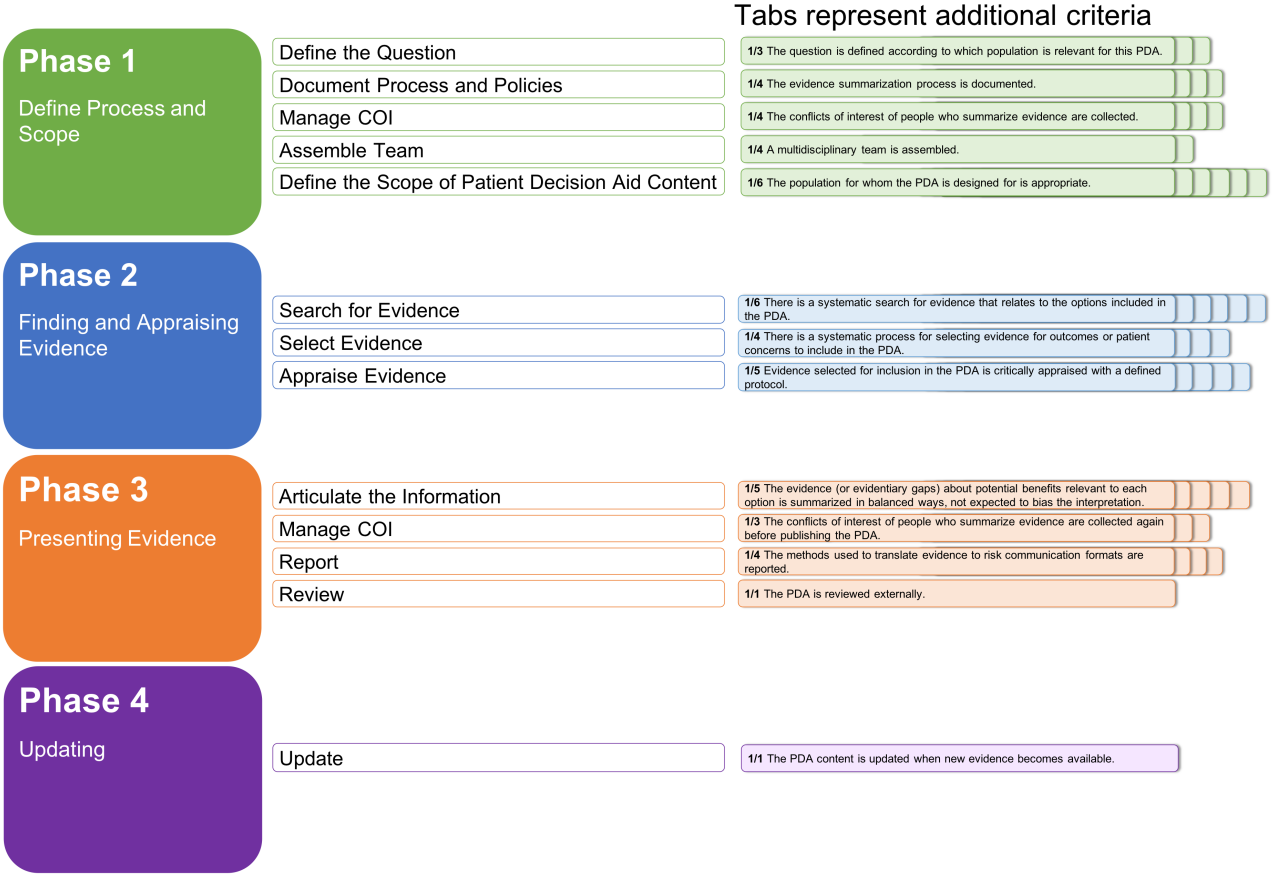
Here's how you can help. In the questions that follow, we will ask for your perspective on **how important each criterion is to include in the proposed process**. We will also ask for feedback on the wording of all parts. Nothing is final. Everything is up for discussion, and we are looking forward to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

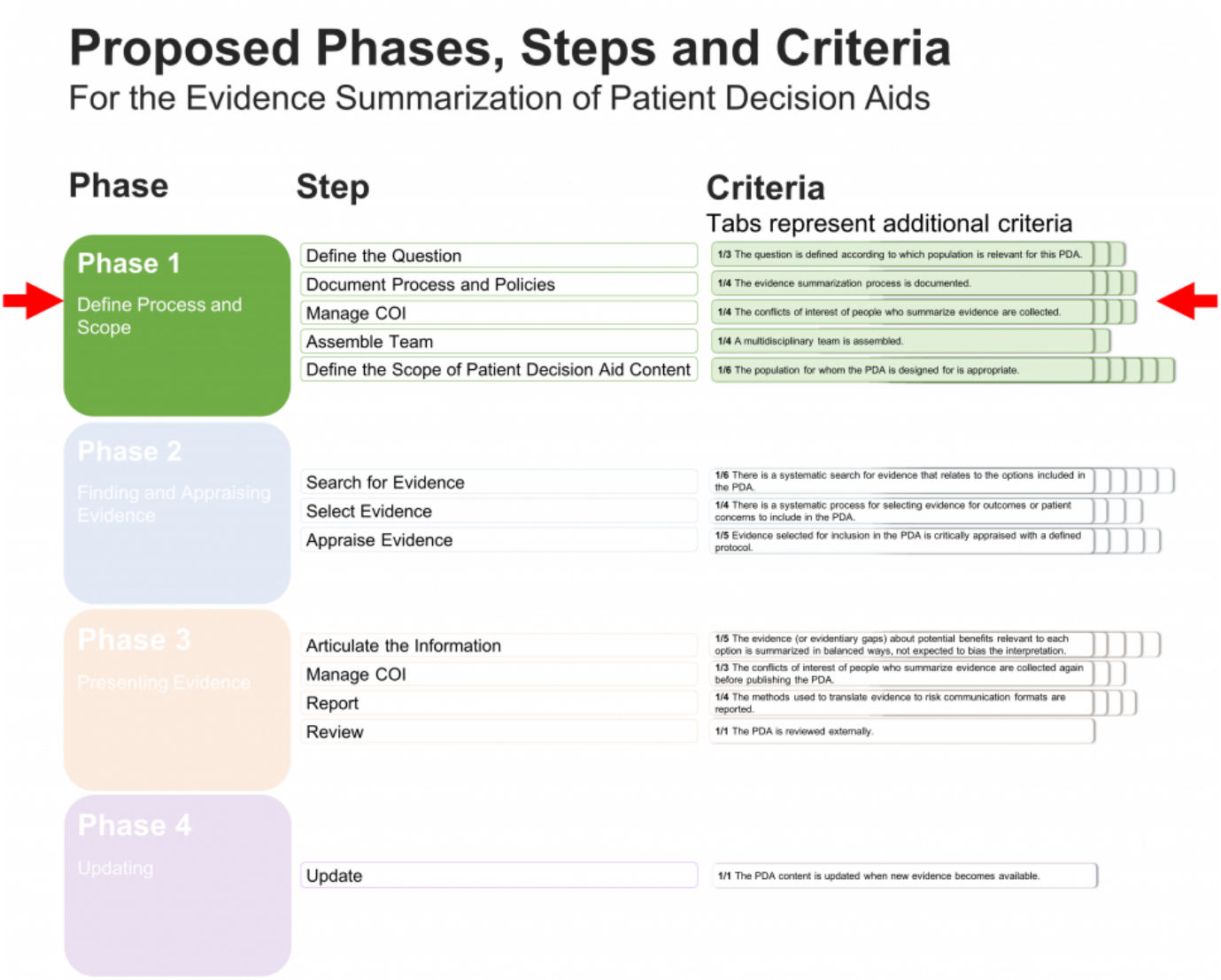
Proposed Phases, Steps and Criteria

For the Evidence Summarization of Patient Decision Aids



Phase 1

PROPOSED PHASE 1



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.

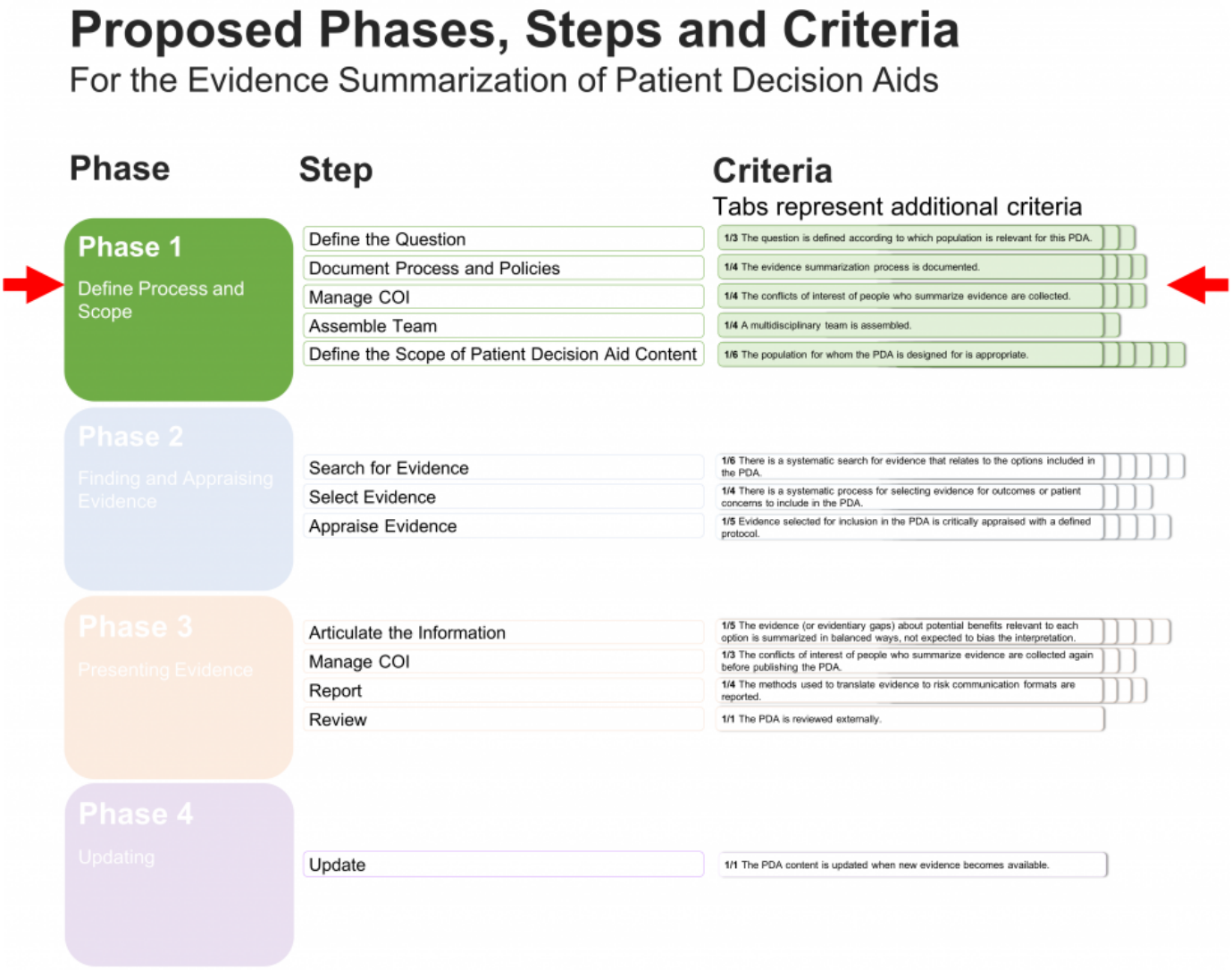
Do you have any comments or suggestions on the Phase below? If so, please share them.

- **Phase 1: Defining Process and Scope**

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



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**

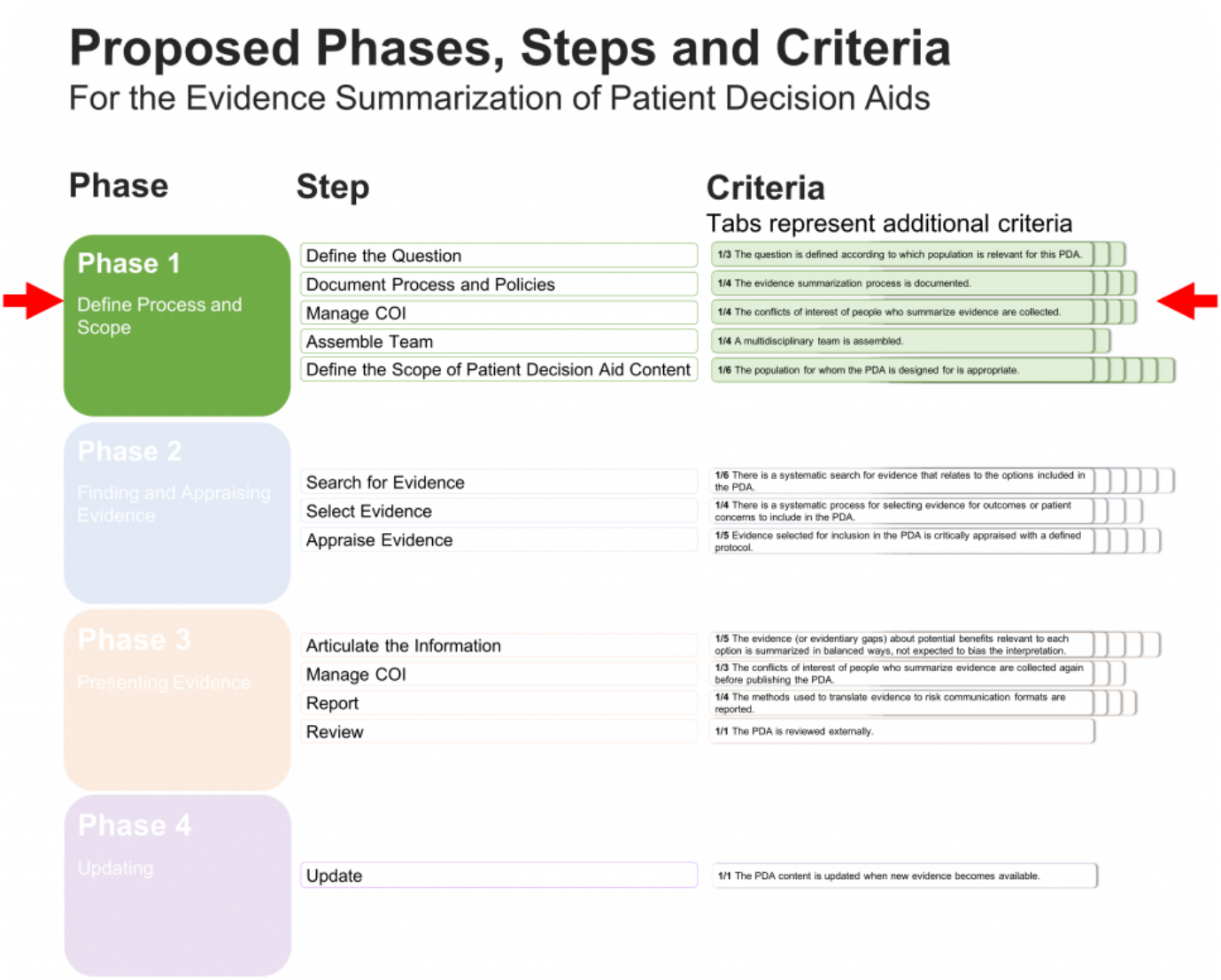
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	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



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**

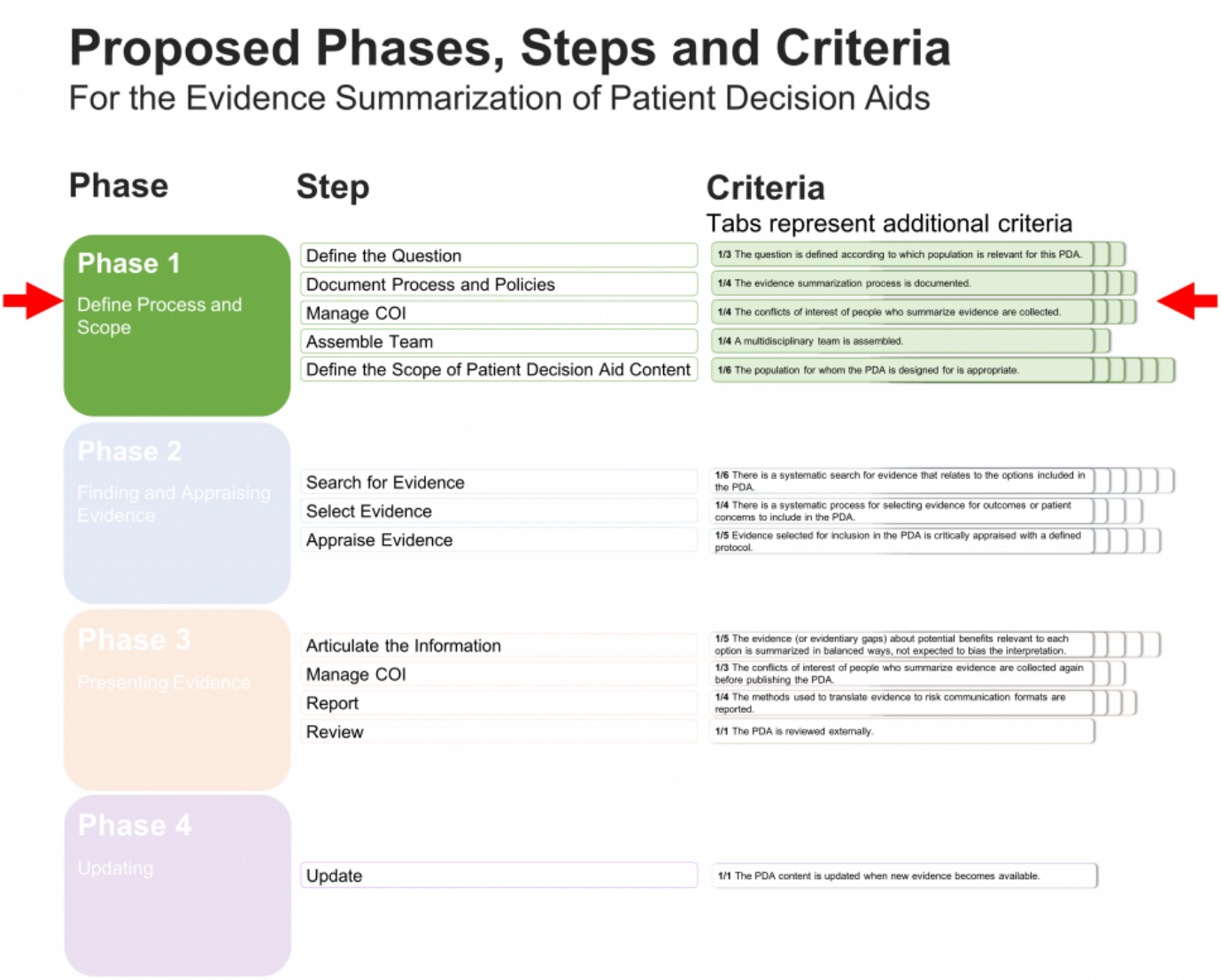
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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**

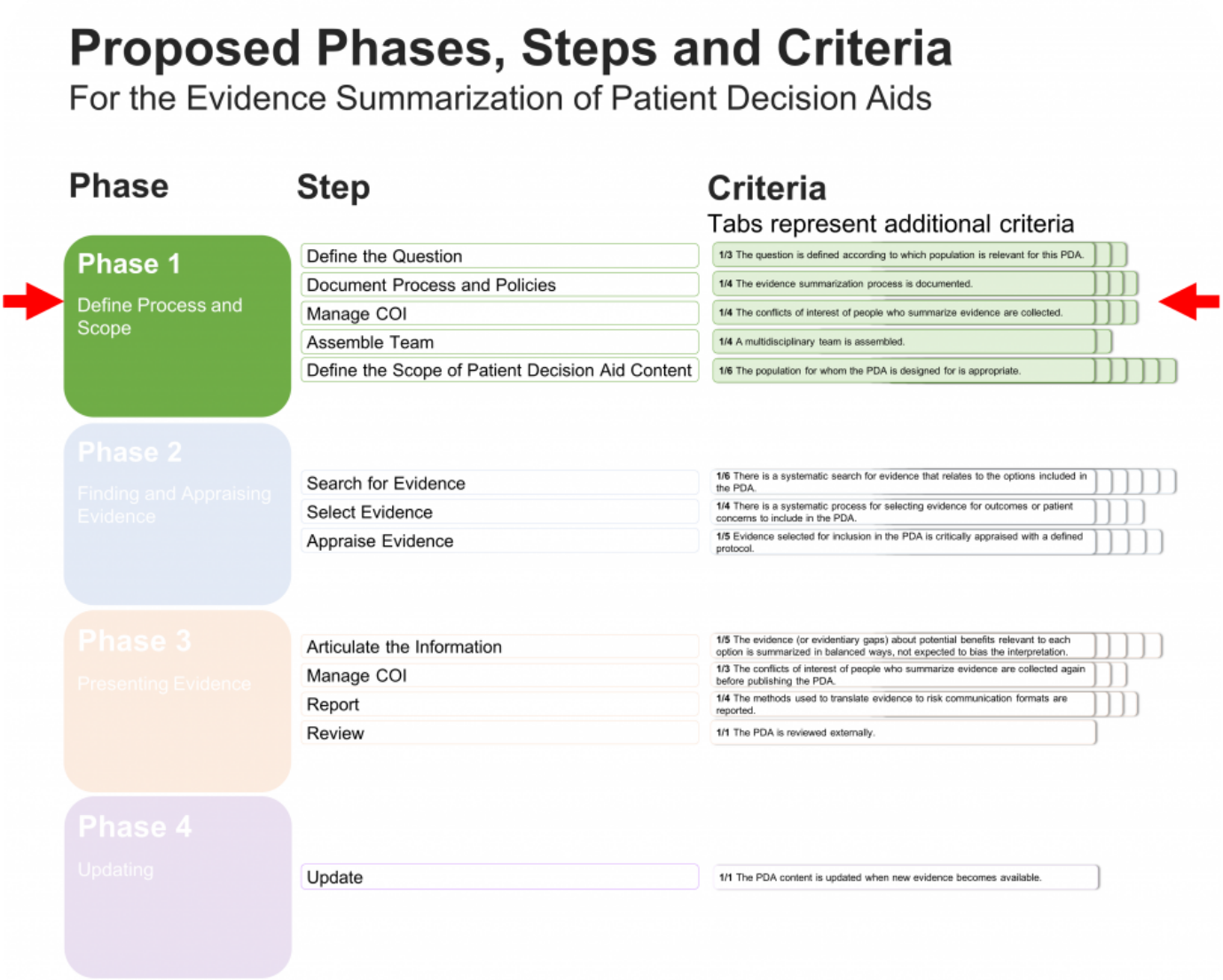
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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**

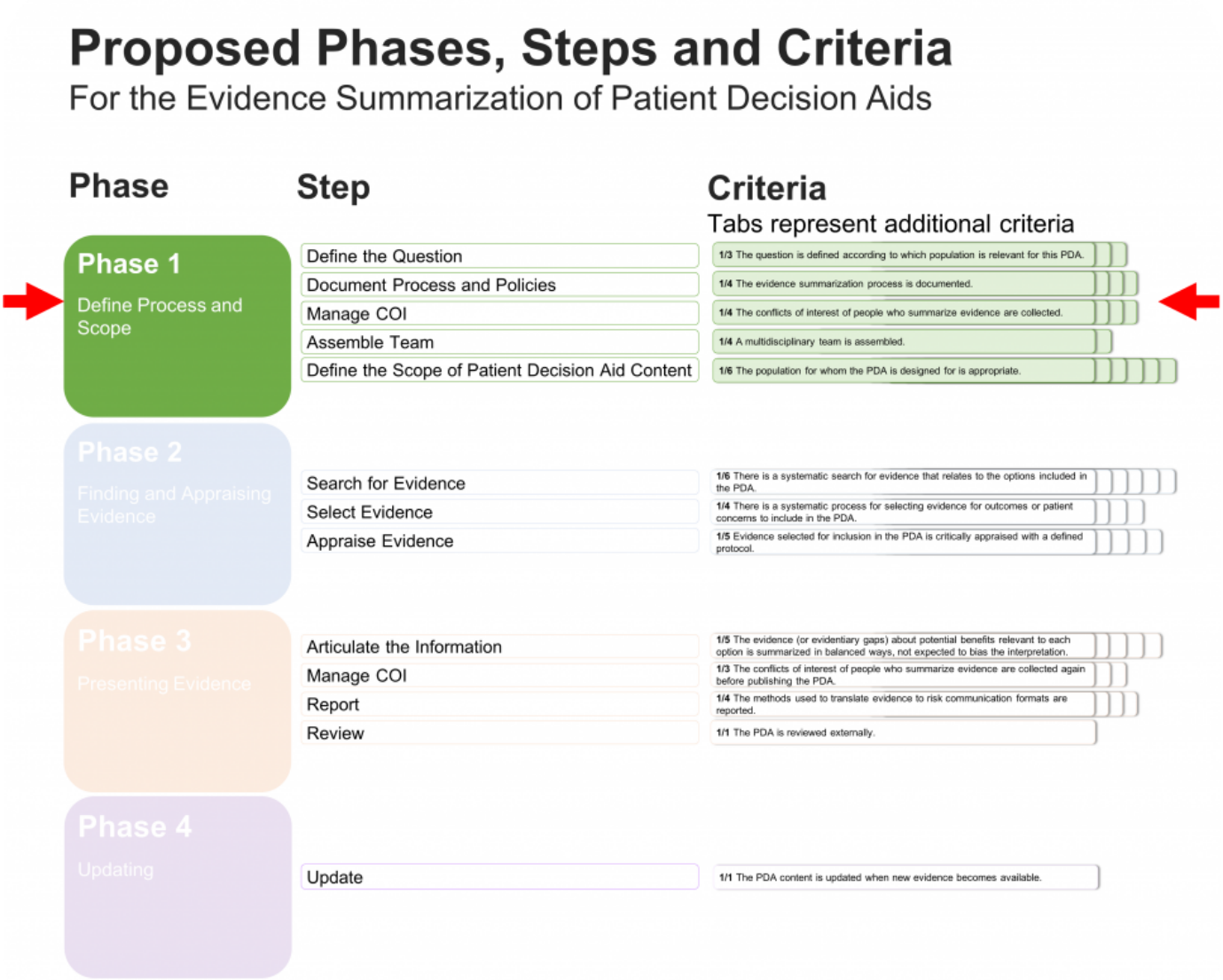
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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.

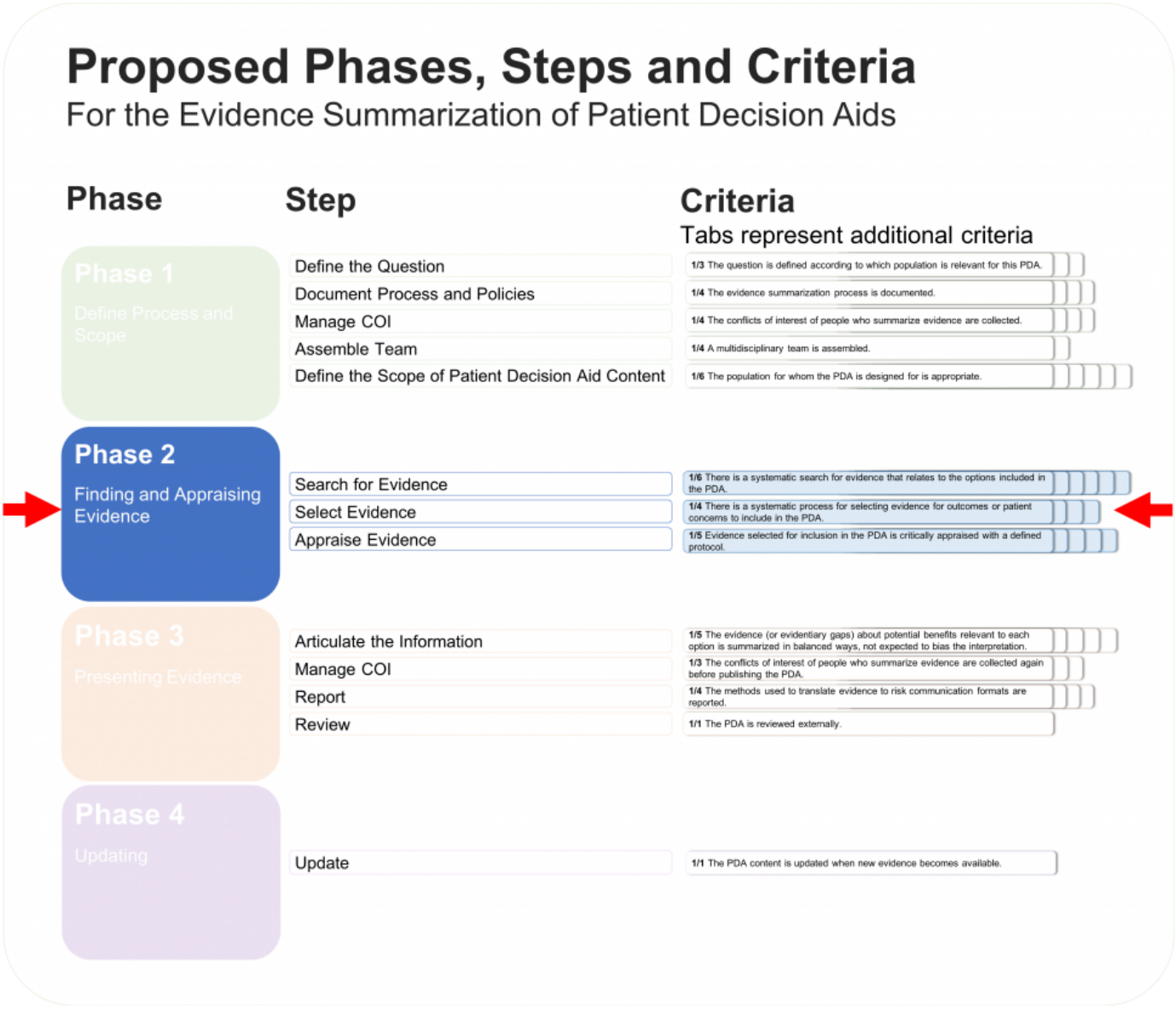
	Omit	Possible	D
The population for whom the PDA is designed for is appropriate.	○	○	
There is a systematic process to reduce bias in the definition of the population for the PDA.	○	○	
The options for inclusion in the PDA are appropriate for the intended population.	○	○	
There is a systematic process 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



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.

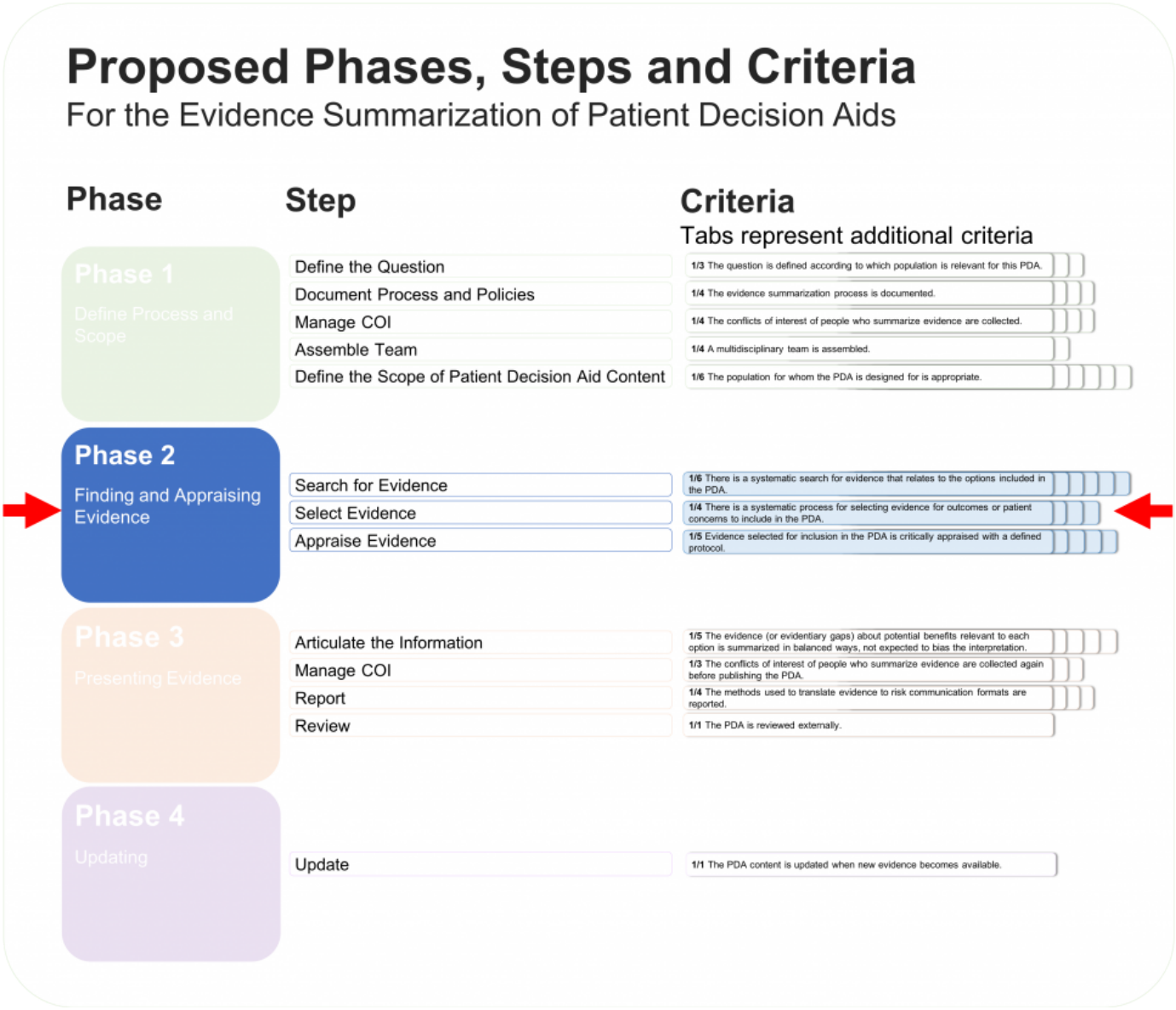
Do you have any comments or suggestions on the Phase below? If so, please share them.

- **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



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**

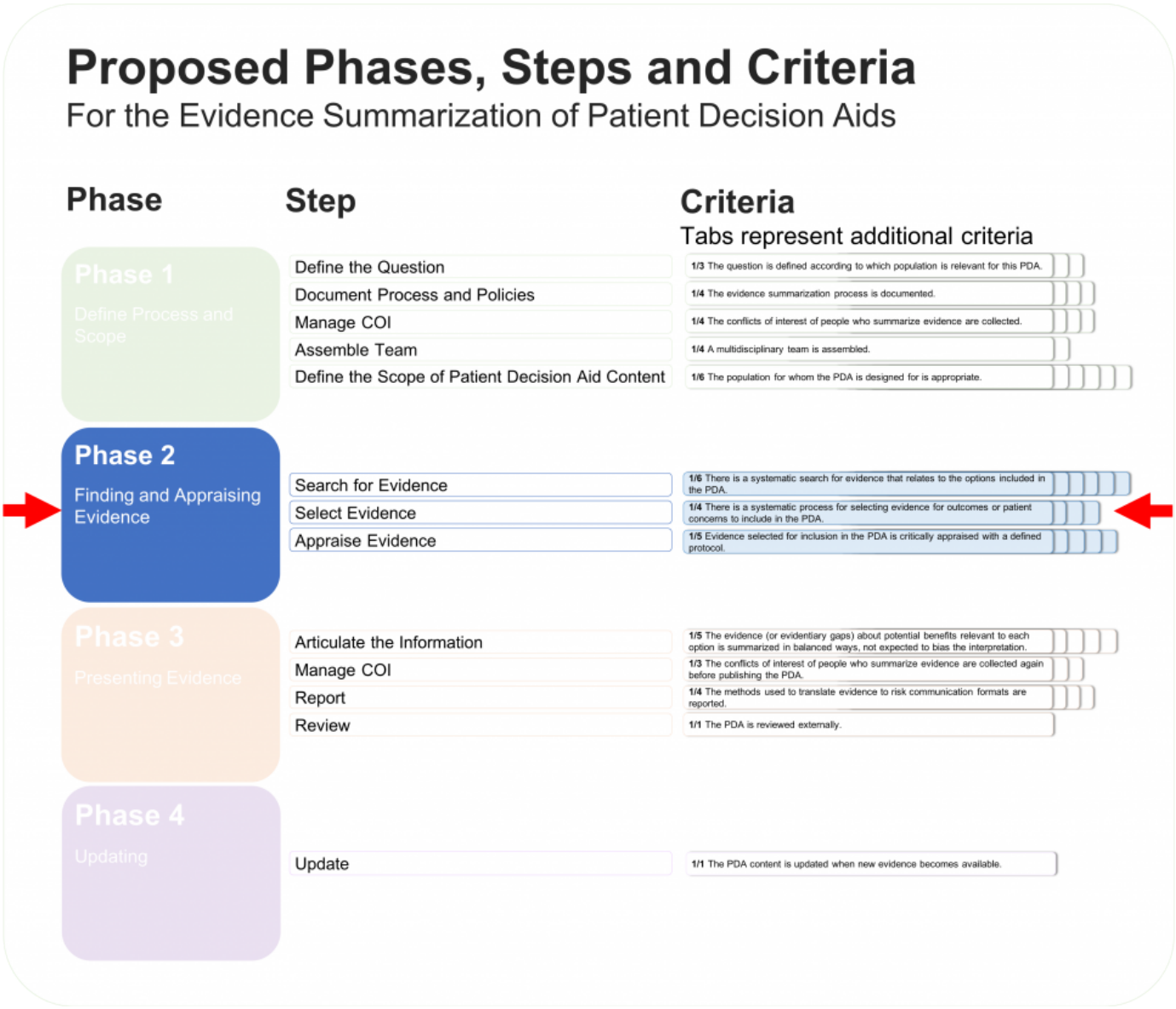
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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.	○	○	

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**

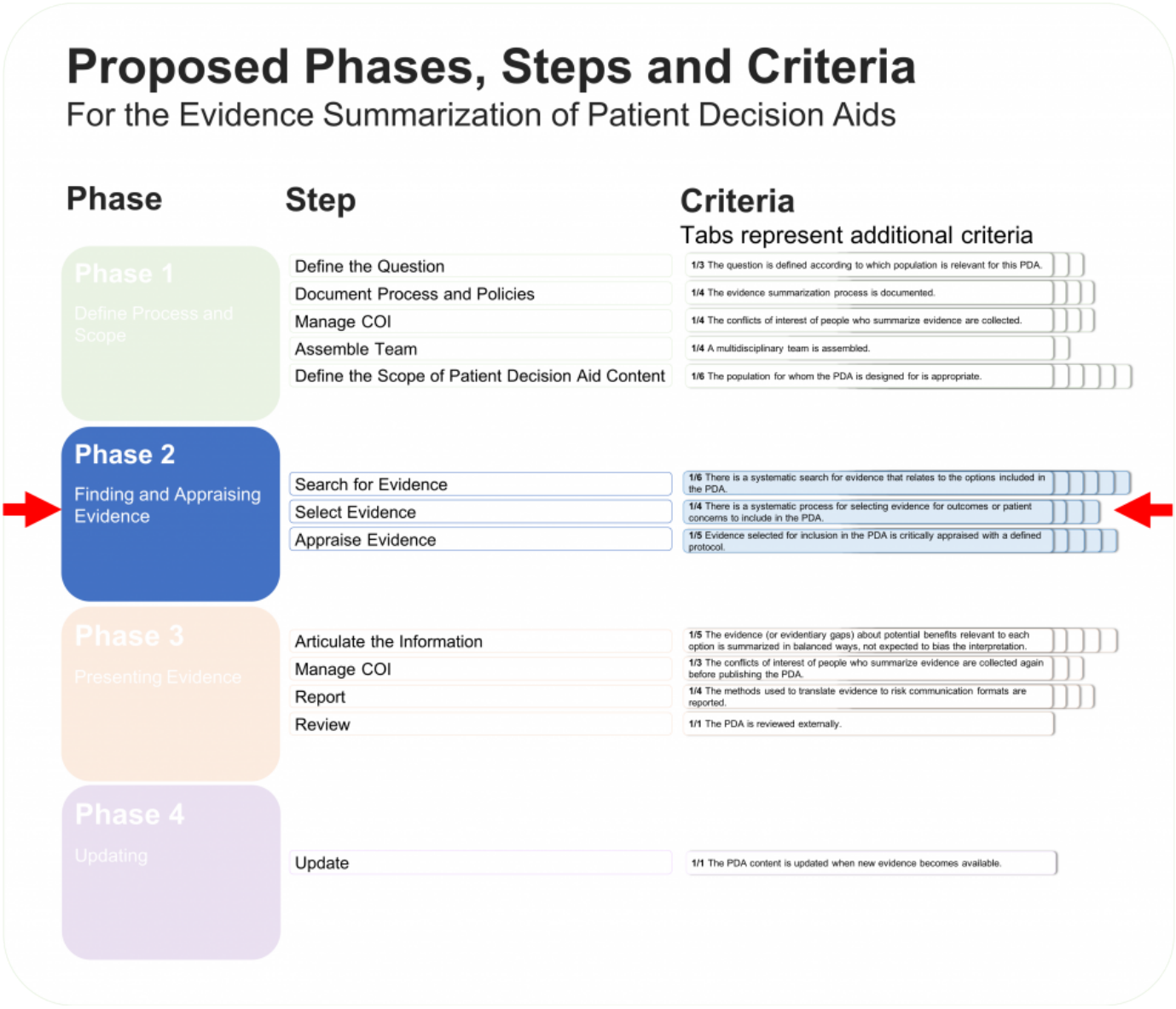
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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.

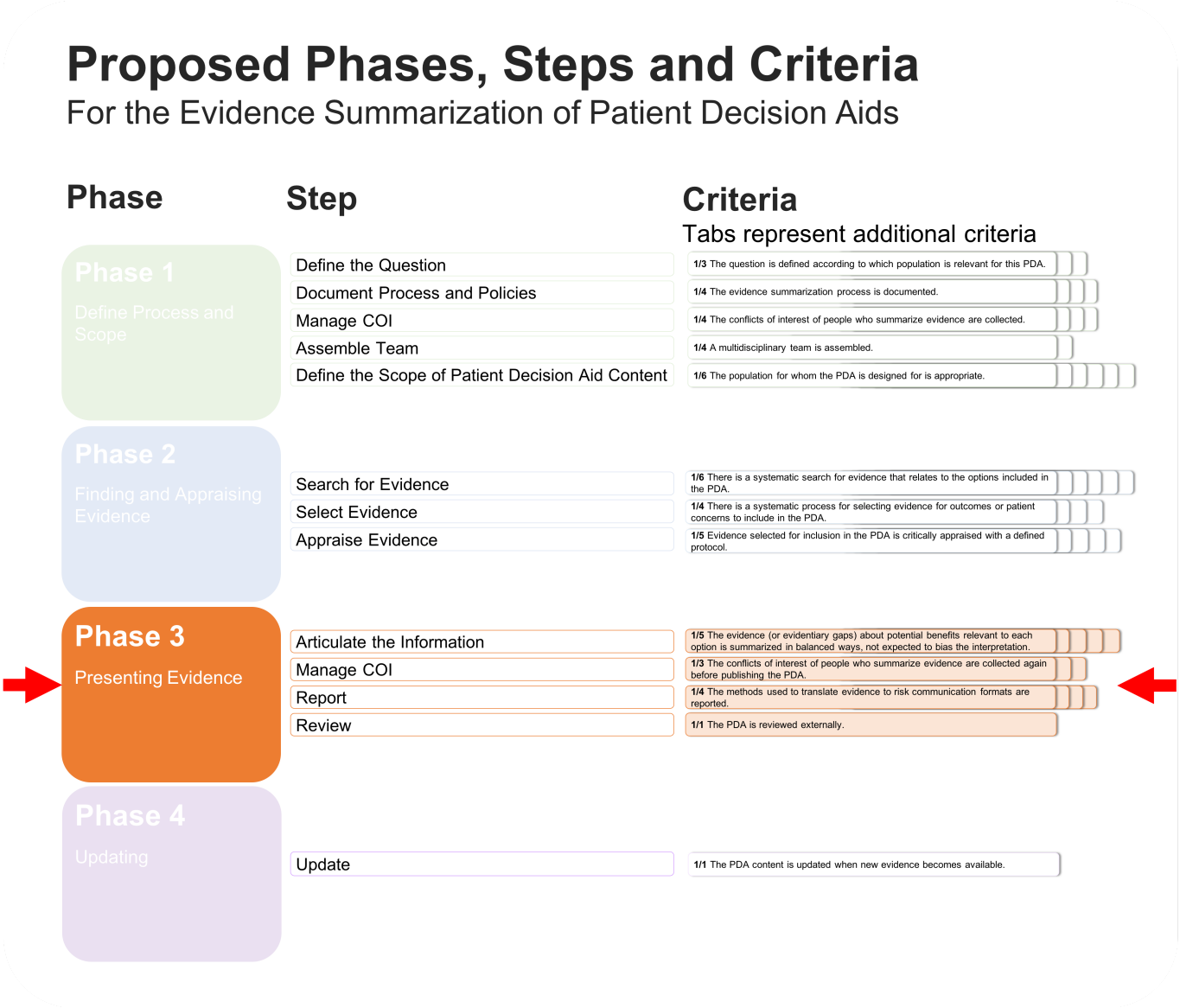
	Omit	Possible	D
Evidence selected for inclusion in the PDA is critically appraised with a defined protocol (such as GRADE).	○	○	
The protocol for critical appraisal of evidence accounts for risks of bias in study design.	○	○	
The protocol for critical appraisal of evidence accounts for risks of bias 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



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.

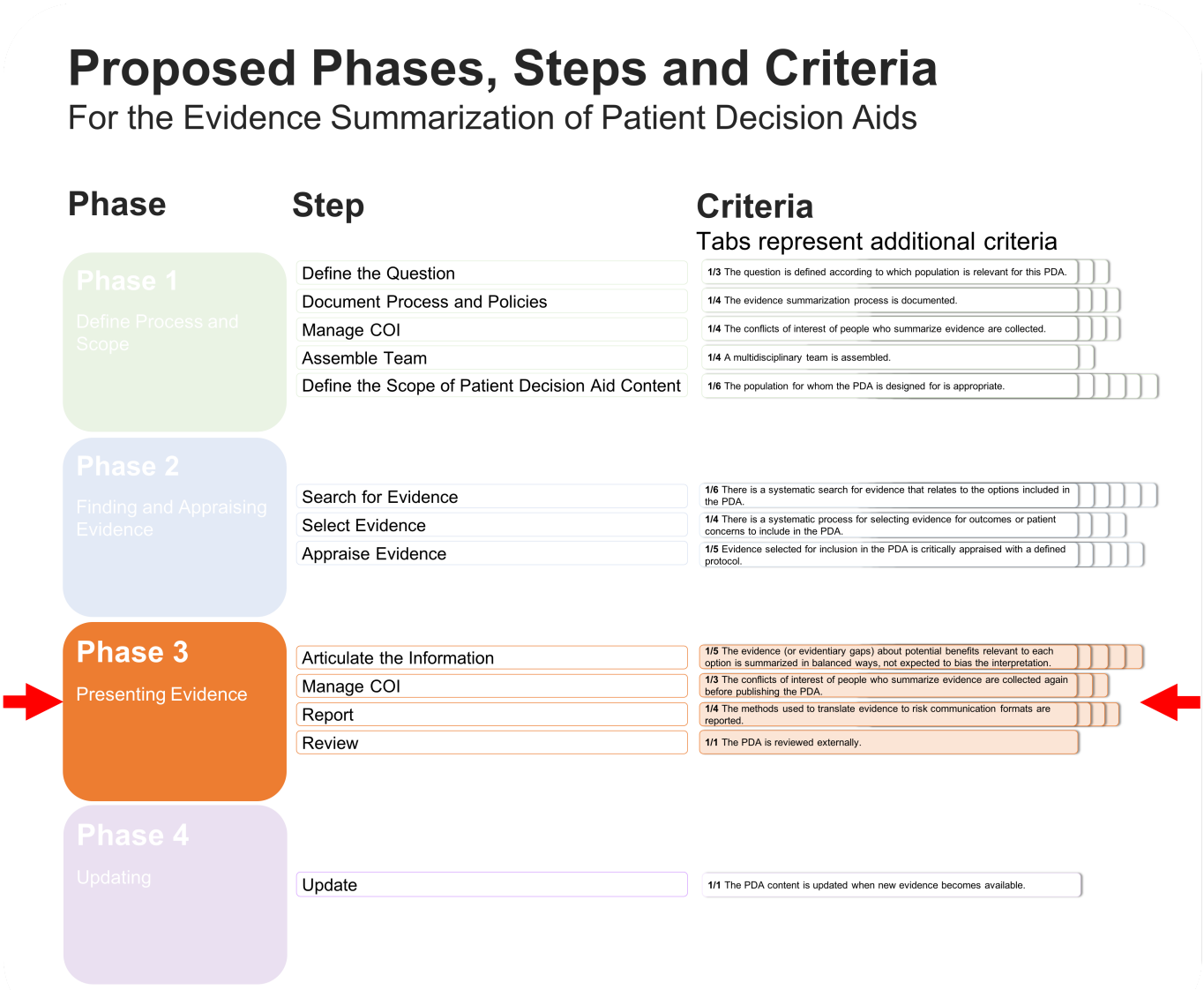
Do you have any comments or suggestions on the Phase below? If so, please share them.

- **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



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**

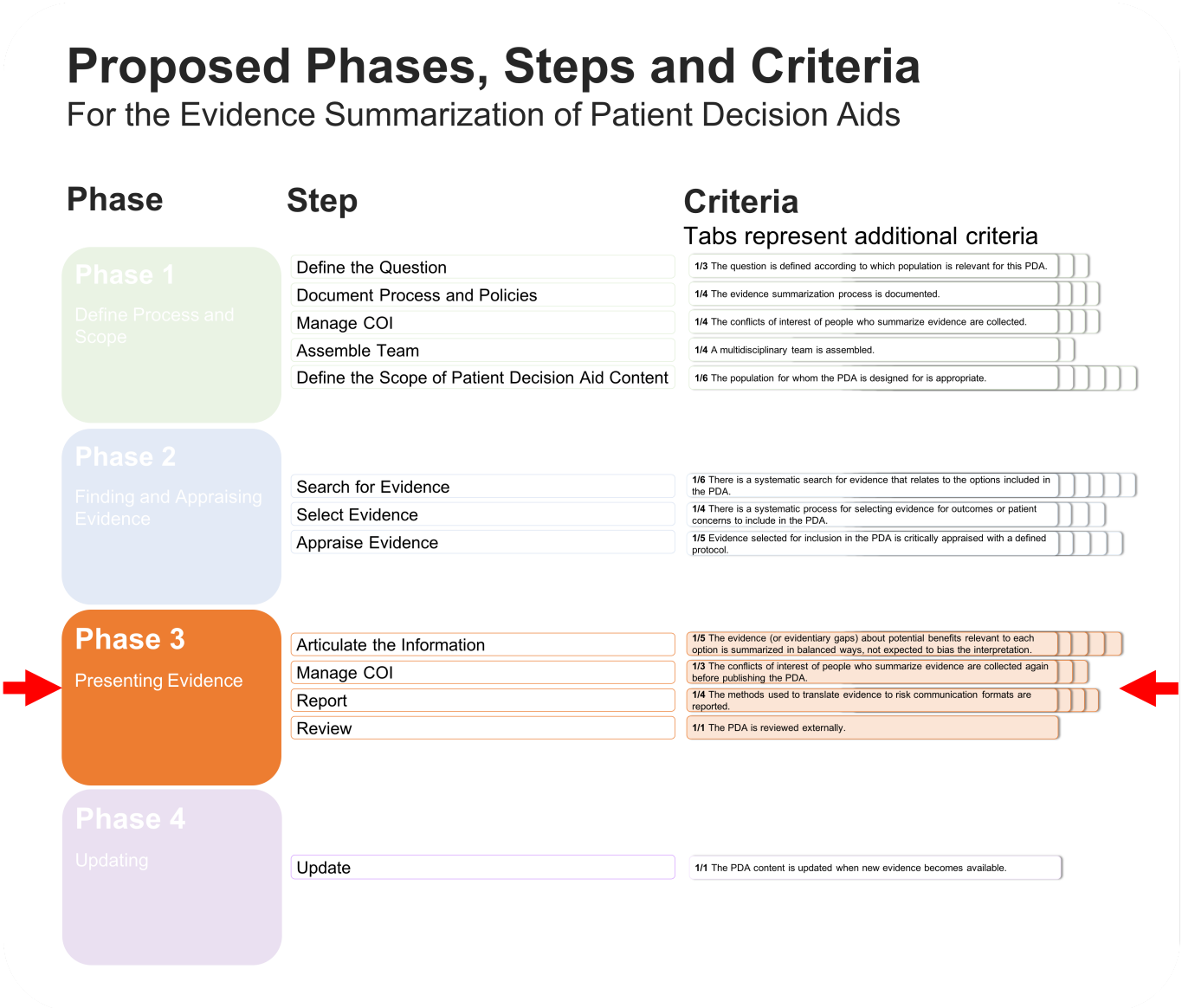
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	[
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 to understand.	○	○	
The funding used to summarize the evidence (and develop the PDA) is reported.	○	○	

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



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: Manage COI**

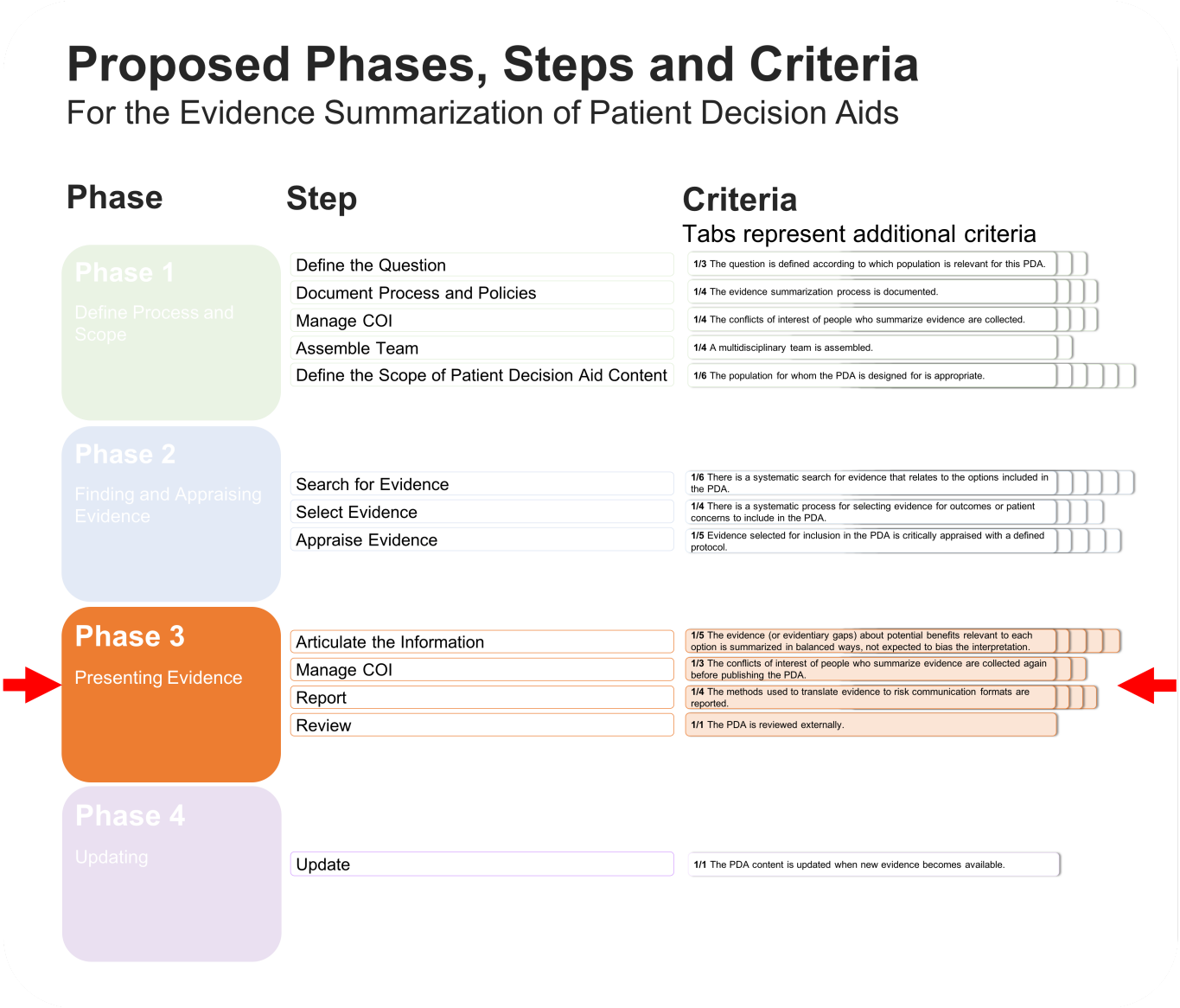
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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**

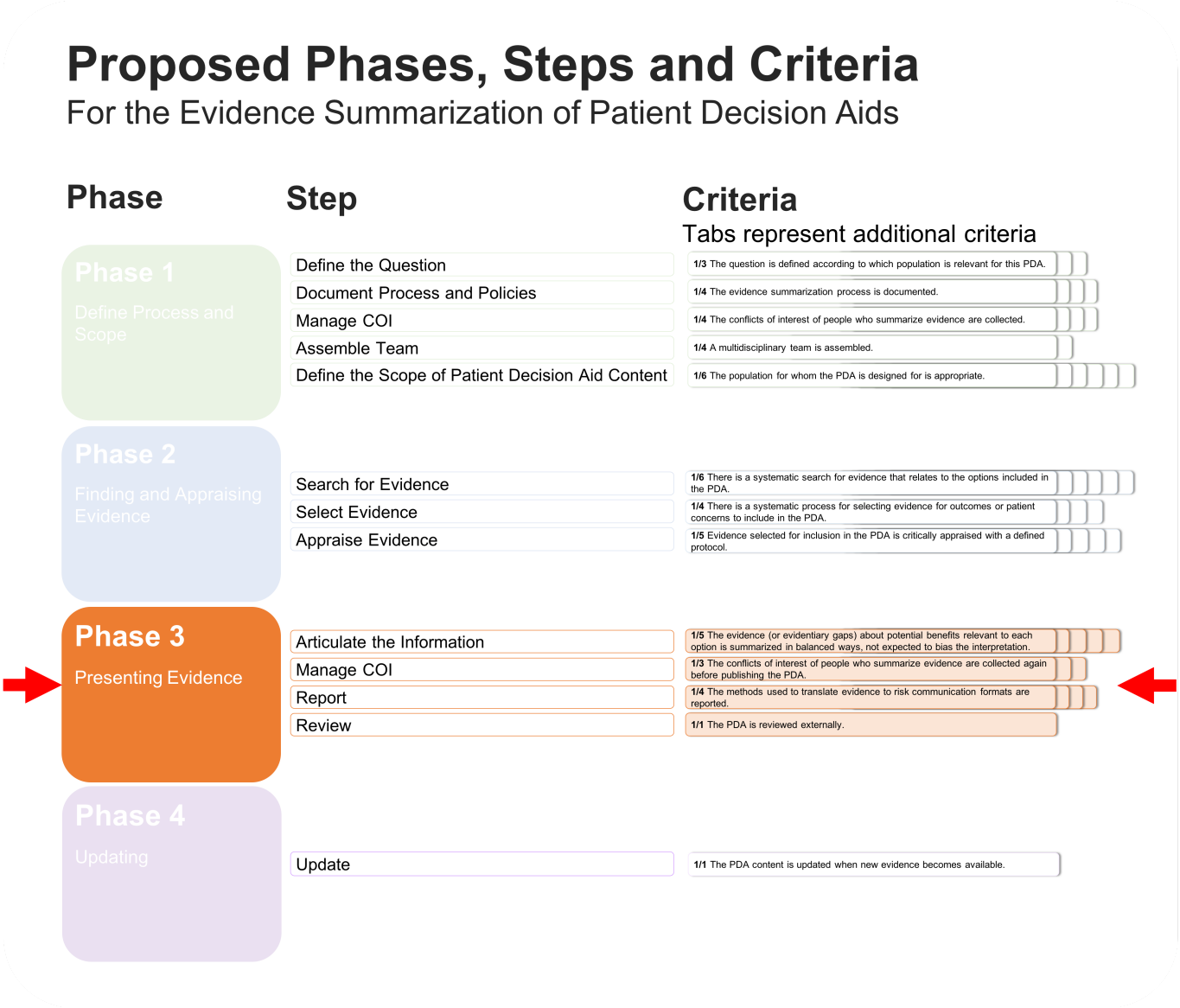
The proposed Criteria for this step are below. Please indicate whether each Criterium should be omitted, or whether it is a possible candidate for inclusion, a desirable candidate for inclusion or is essential for inclusion.

	Omit	Possible	D
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



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.

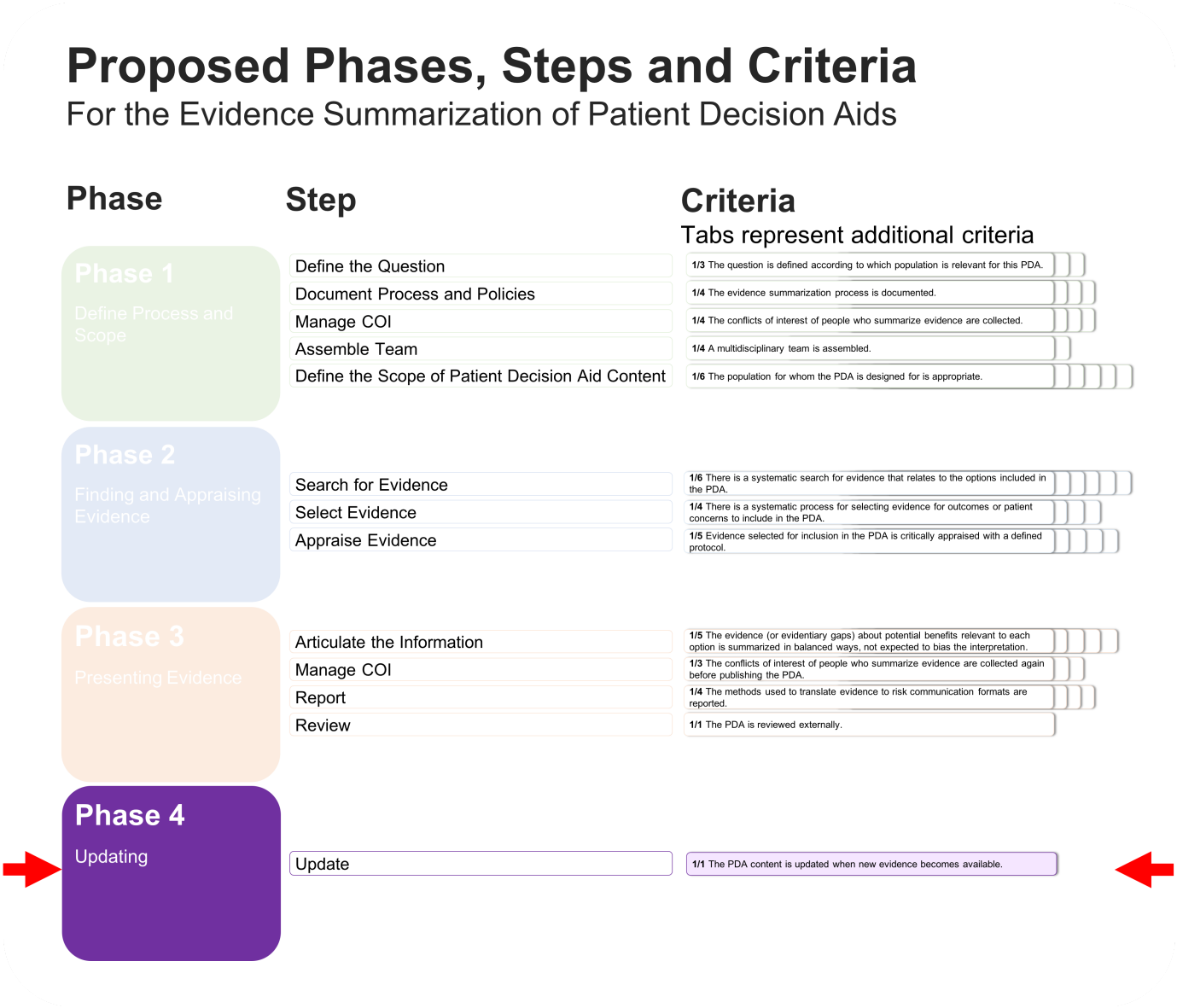
	Omit	F
The PDA is reviewed externally.	○	

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



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.

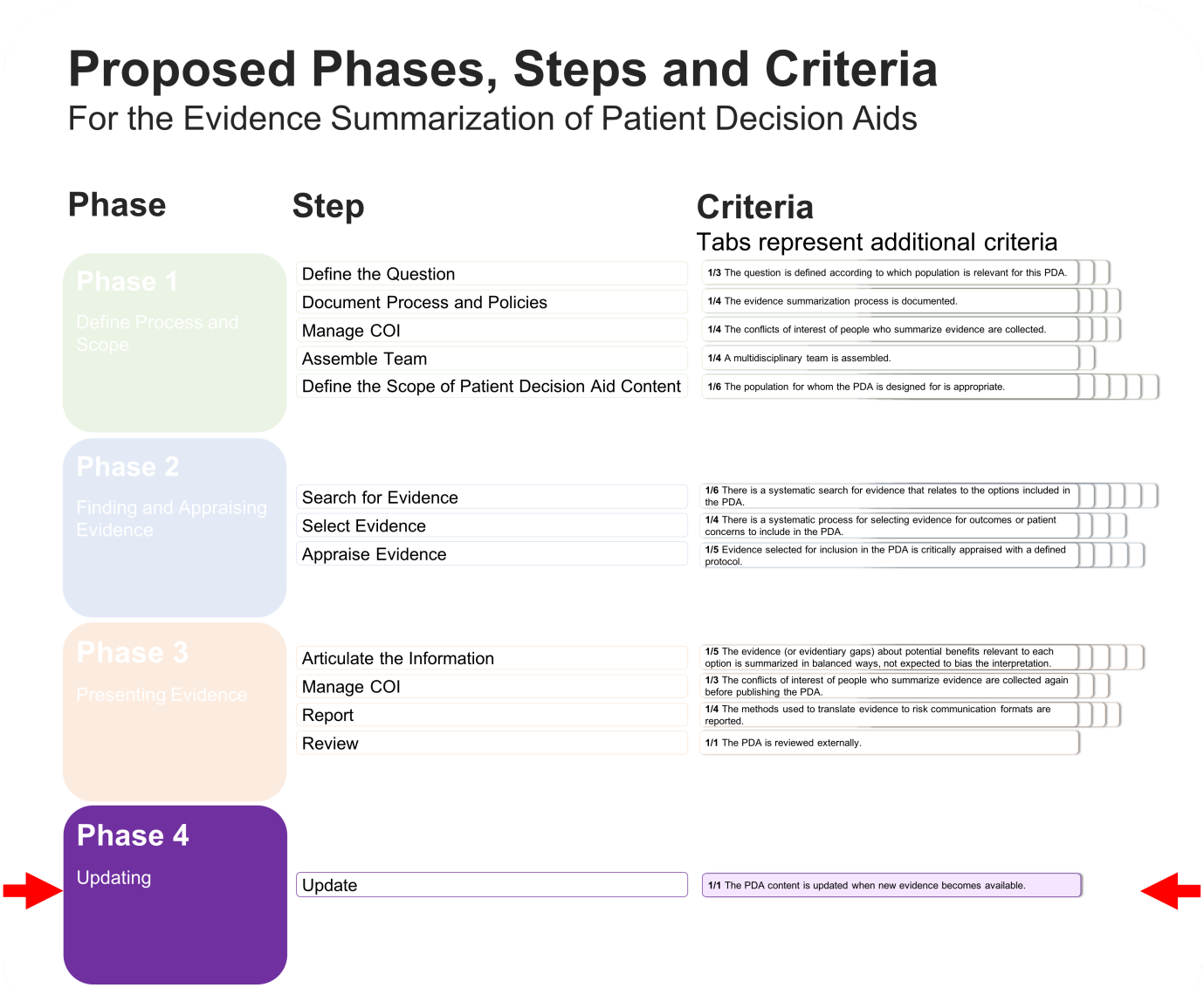
Do you have any comments or suggestions on the Phase below? If so, please share them.

- **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



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	[
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.
			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.
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.