

# Development of guidance for Multi-Stakeholder Engagement in Guidelines and Recommendations

*Presented on behalf of the MuSE Consortium by:*

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## Outline

- 1. Introduction to MuSE**
2. Definitions
3. MuSE Project progress

# The MuSE Consortium



**GRADE**



**ACTIVE**  
Authors & Consumers Together Impacting on eVidencE



S.T.A.R. Initiative®  
STRATEGICALLY TARGETING  
APPROPRIATE RESEARCHERS



Health Canada  
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Public Health  
Ontario  
PARTNERS FOR HEALTH

Santé  
publique  
Ontario  
PARTENAIRES POUR LA SANTÉ

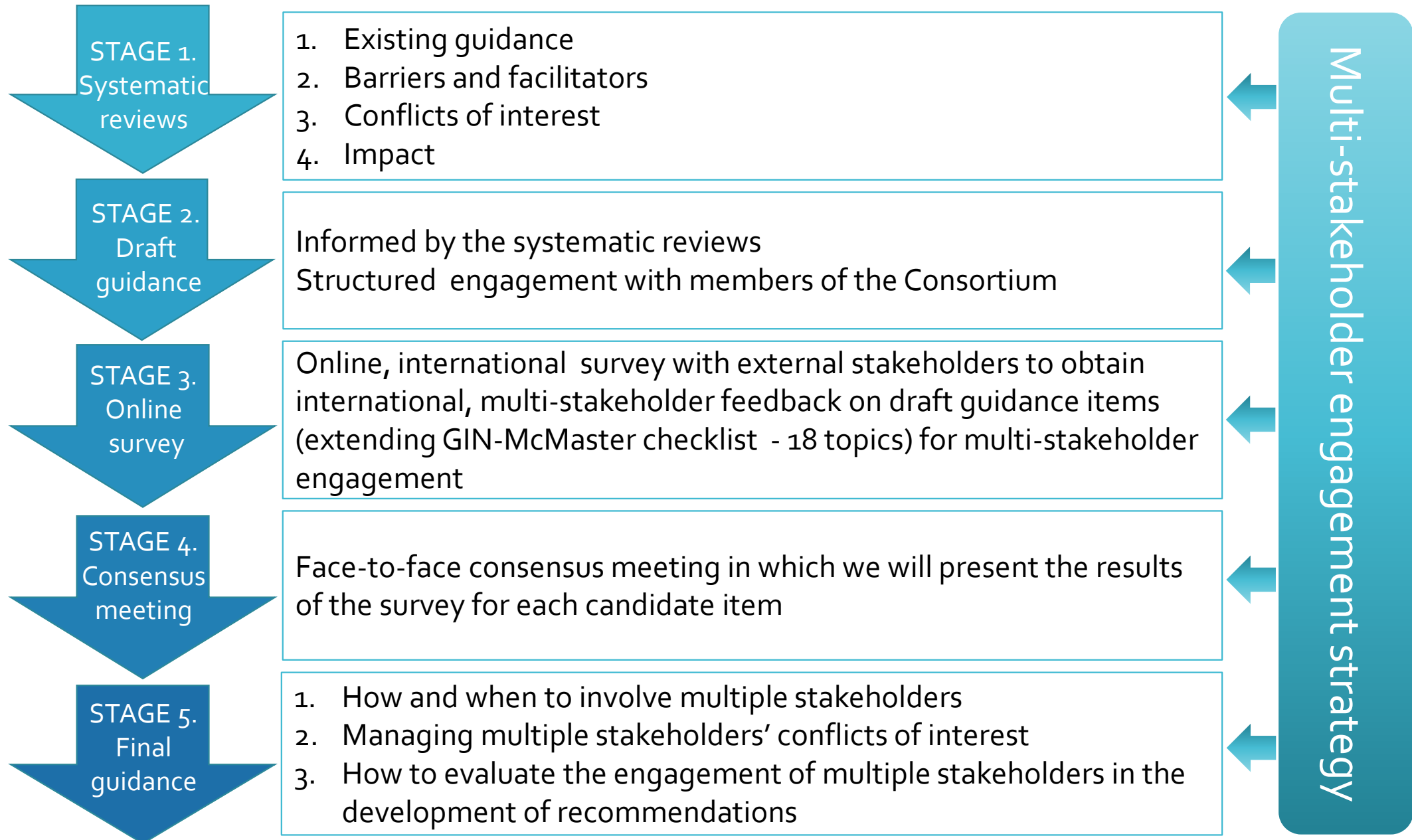


## Project objective

This project aims to develop guidance for developers of recommendations that supports the equitable and meaningful engagement of multiple stakeholders throughout the development and implementation of recommendations.

**Goal:** A stakeholder engagement extension of the GIN-McMaster Guideline Development Checklist

# PROJECT OVERVIEW



## Outline

1. Introduction to MuSE
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# Definitions



# 1. GIN-McMaster Guideline Development Checklist



# Methods for Development of the European Commission Initiative on Breast Cancer Guidelines

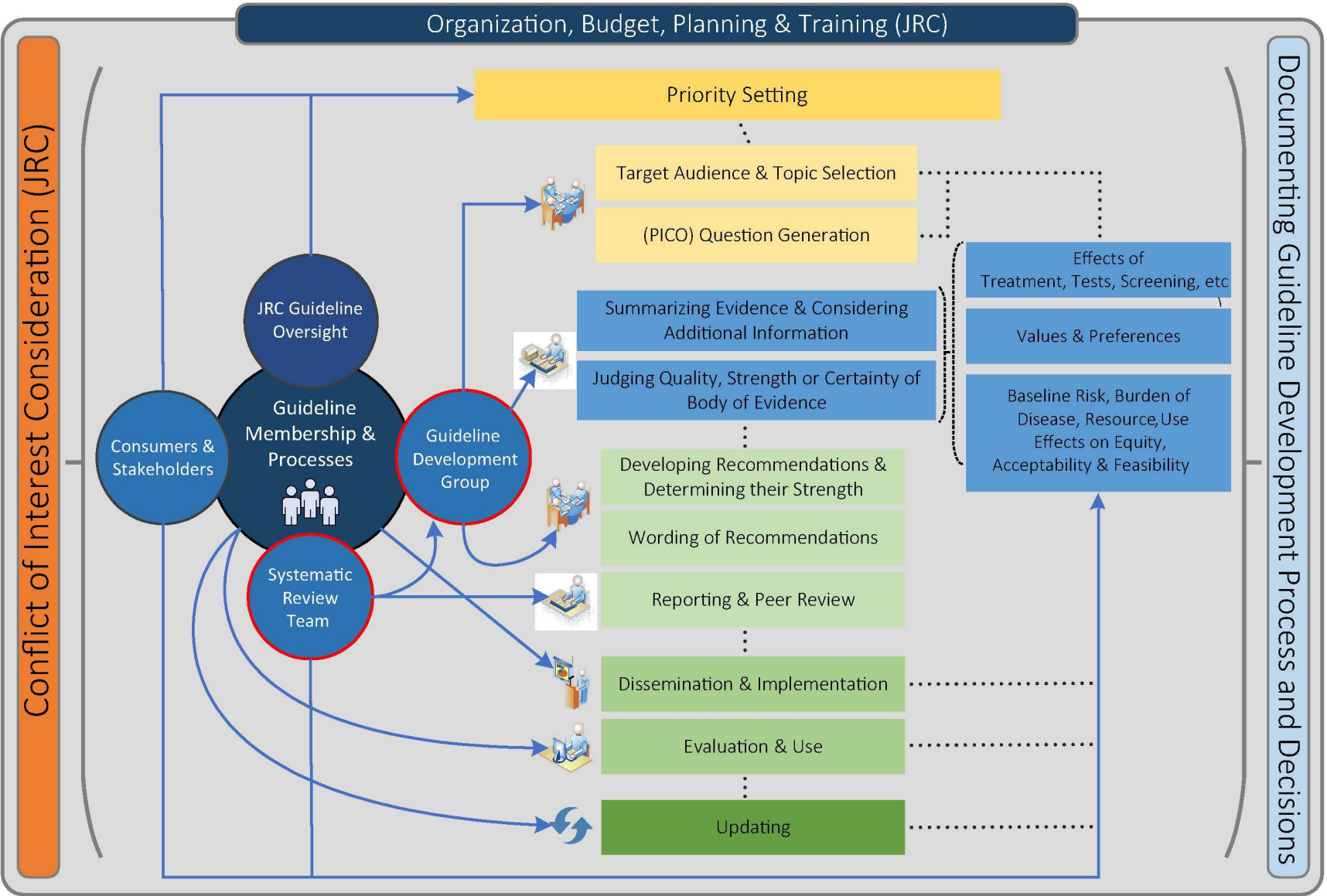
## Recommendations in the Era of Guideline Transparency

Holger J. Schünemann, MD, PhD, MSc; Donata Lerda, PhD; Nadya Dimitrova, PhD; Pablo Alonso-Coello, MD, PhD; Axel Gräwingholt, MD; Cecily Quinn, MD; Markus Follmann, MD, MPH, MSc; Robert Mansel, MD; Francesco Sardanelli, MD; Paolo Giorgi Rossi, PhD; Annette Lebeau, MD; Lennarth Nyström, PhD; Mireille Broeders, PhD; Lydia Ioannidou-Mouzaka, MD; Stephen W. Duffy, BSc, MSc, CStat.; Bettina Borisch, MD; Patricia Fitzpatrick, MD; Solveig Hofvind, PhD; Xavier Castells, MD, PhD; Livia Giordano, MD; Sue Warman, MEd; and Zuleika Saz-Parkinson, PhD; for the European Commission Initiative on Breast Cancer Contributor Group\*

Neither breast cancer prevention and early-detection programs, nor their outcomes, are uniform across Europe. This article describes the rationale, methods, and process for development of the European Commission (EC) Initiative on Breast Cancer Screening and Diagnosis Guidelines. To be consistent with standards set by the Institute of Medicine and others, the EC followed 6 general principles. First, the EC selected, via an open call, a panel with broad representation of areas of expertise. Second, it ensured that all recommendations were supported by systematic reviews. Third, the EC separately considered impor-

Evidence to Decision frameworks were used to structure the process and minimize the influence of competing interests. Fifth, it focused its recommendations on outcomes that matter to women, and certainty of the evidence is rated for each. Sixth, the EC elicited stakeholder feedback to ensure that the recommendations remain up to date and relevant to practice. This article describes the approach and highlights ways of disseminating and adapting the recommendations both within and outside Europe, using innovative information technology tools.

Figure 3. Approach to guideline development used by the European Commission Initiative on Breast Cancer.



## Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise

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### Box 2: Topics included in checklist for guideline development

Topic	Description
1. Organization, budget, planning and training	Involves laying out a general but detailed plan describing what is feasible, how it will be achieved and what resources are required to produce and use the guideline. The plan should refer to a specific period and be expressed in formal, measurable terms.
2. Priority setting	Refers to the identification, balancing and ranking of priorities by stakeholders. Priority setting ensures that resources and attention are devoted to those general areas (e.g., chronic obstructive pulmonary disease, diabetes, cardiovascular disease, cancer, prevention) where health care recommendations will provide the greatest benefit to the population, a jurisdiction or a country. A priority-setting approach needs to contribute to future plans while responding to existing, potentially difficult circumstances. <sup>100,101</sup>
3. Guideline group membership	Defines who is involved, in what capacity, and how the members are selected for the guideline development and at other steps of the guideline enterprise.
4. Establishing guideline group processes	Defines the steps to be followed, how those involved will interact and how decisions will be made.
5. Identifying target audience and topic selection	Involves describing the potential users or consumers of the guideline and defining the topics to be covered in the guideline (e.g., diagnosis of chronic obstructive pulmonary disease).
6. Consumer and stakeholder involvement	Describes how relevant people or groups who are not necessarily members of the panel but are affected by the guideline (e.g., as target audience or users) will be engaged.
7. Conflict of interest considerations	Focuses on defining and managing the potential divergence between an individual's interests and his or her professional obligations that could lead to questioning whether the actions or decisions are motivated by gain, such as financial, academic advancement, clinical revenue streams or community standing. Financial or intellectual or other relationships that may affect an individual's or organization's ability to approach a scientific question with an open mind are included.
8. Question generation	Focuses on defining key questions the recommendations should address using the PICO (patient/problem, intervention, comparison, outcome) framework, including the detailed population, intervention (including diagnostic tests and strategies) and outcomes that will be relevant for decision-making (e.g., should test A be used, or should treatments B, C, D or E be used in chronic obstructive pulmonary disease?).

# GIN-McMaster GDC

## Box 3 (part 1 of 10): Checklist for guideline development

The checklist is organized into 18 topics, each with corresponding items to consider. Users of the checklist should review all topics and items before applying them, because the items are not necessarily sequential and many are interconnected. The brief examples included with some items are for clarification and elaboration; they are not meant to be extensive instructions for how to accomplish the steps. Instructions and suggestions for accomplishing the steps can be found in the source documents referenced and in the resources suggested in the interactive online version of the checklist (<http://cebgrade.mcmaster.ca/guidecheck.html>). See Appendix 1 (available at [www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.131237/-/DC1](http://www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.131237/-/DC1)) for a glossary of terms appearing in the checklist.

Completed  
Not applicable

Guideline development steps

Sources, reference nos.

### 1. Organization, budget, planning and training

- |                          |                          |   |   |
|--------------------------|--------------------------|---|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 1. Establish the structure of the guideline development group and determine the roles, tasks and relationships among the various groups to be involved (e.g., oversight committee or body to direct guideline topic selection and group membership, a working group consisting of experts and methodologists to synthesize evidence, a secretariat to provide administrative support, a guideline panel to develop recommendations, and stakeholders and consumers for consultation). <i>See also topics 3, 4 and 6</i> | 20, 32–36, 39, 42–45, 56, 57, 72, 88          |
| <input type="checkbox"/> | <input type="checkbox"/> | 2. Perform a thorough assessment of the proposed guideline development project with respect to financial and feasibility issues concerning the guideline development group (e.g., availability of resources to complete the project, expected commitment from guideline panel and staff).   | 20, 32, 35, 37, 40, 42–46, 47, 57, 58, 71, 88 |
| <input type="checkbox"/> | <input type="checkbox"/> | 3. Obtain organizational approval to proceed with the guideline project.  | 2, 20, 33–35, 37, 42, 43, 45, 46, 58          |

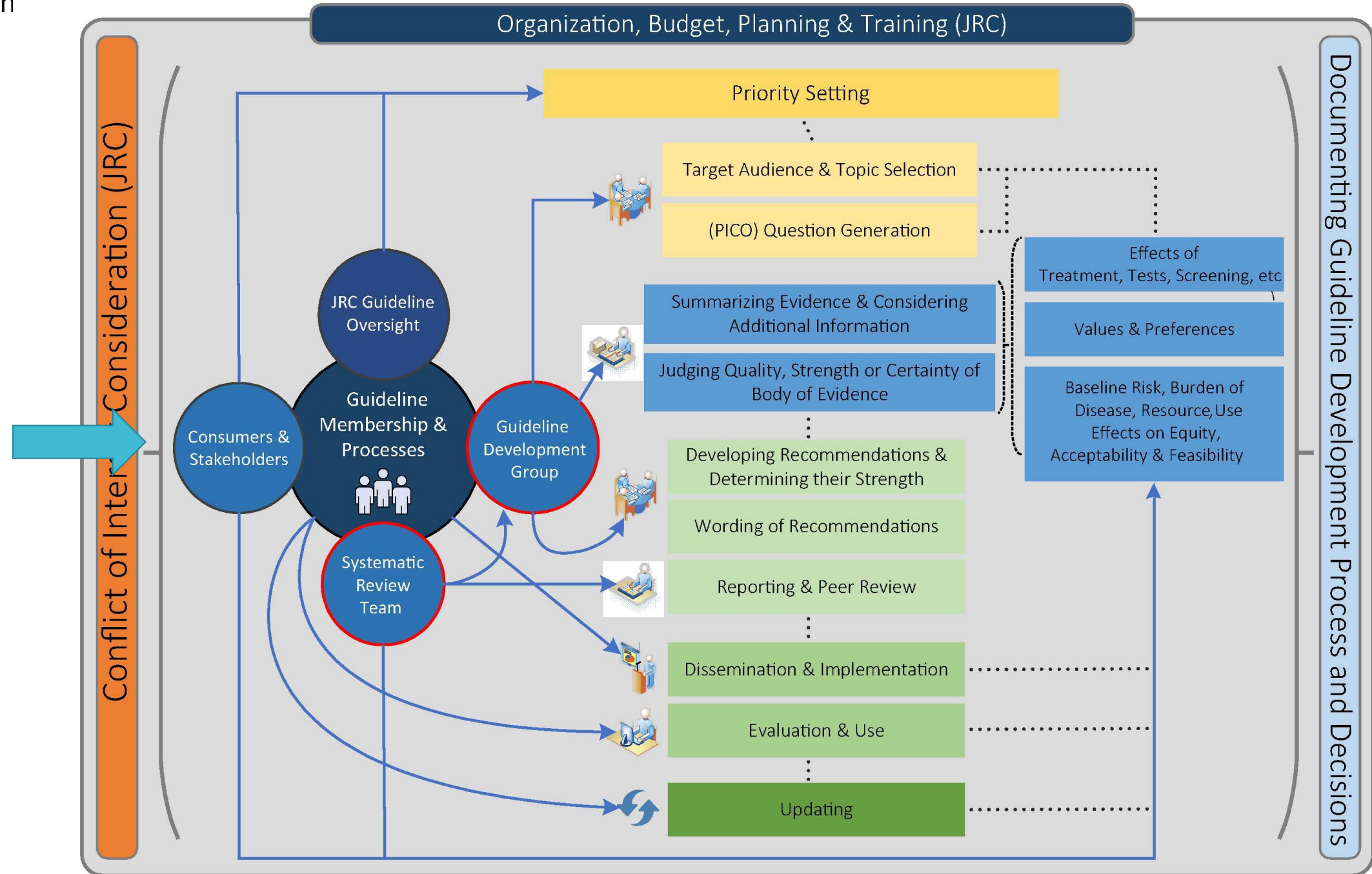
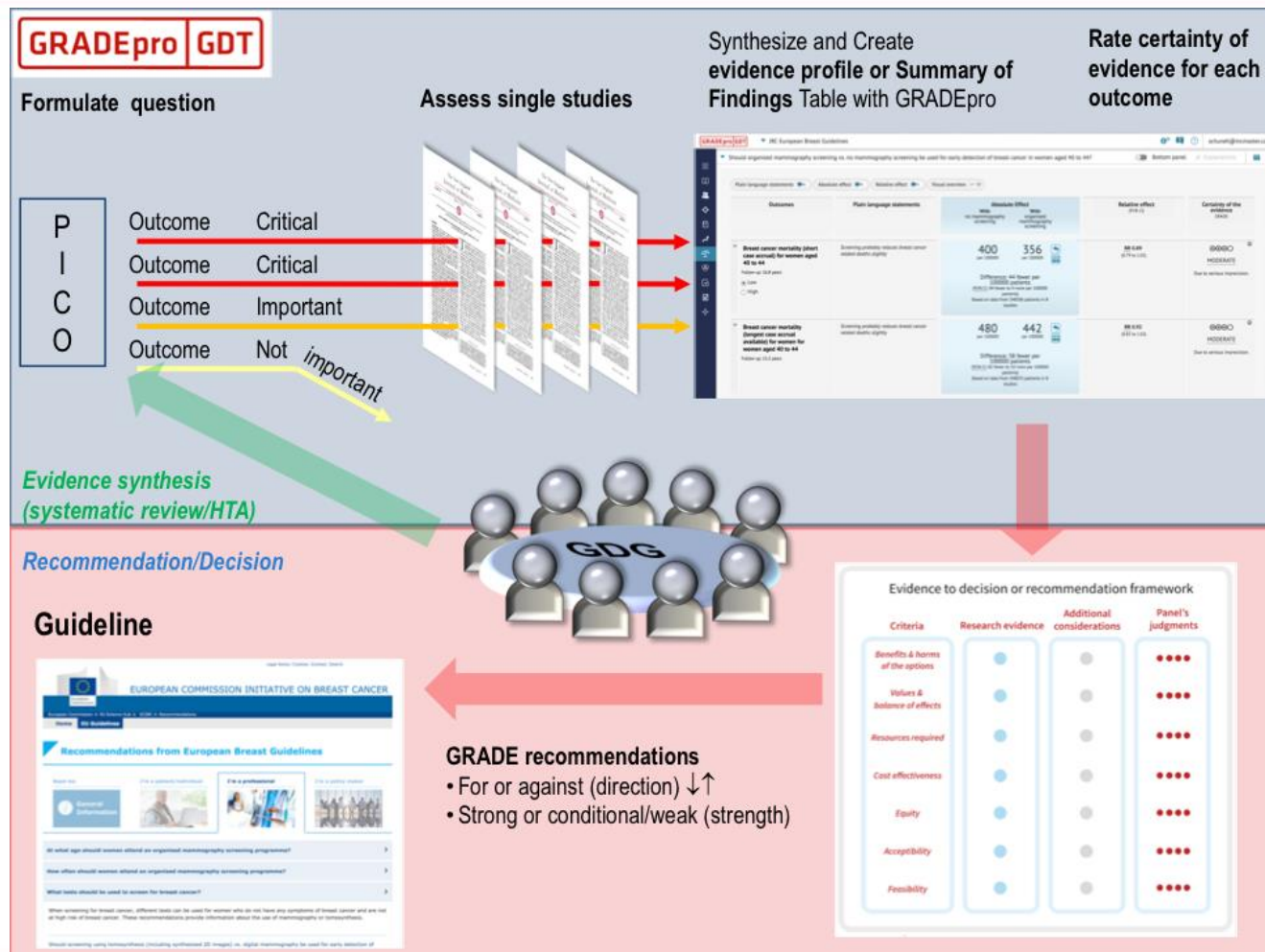


Figure 1. According to GRADE, certainty, quality, strength of evidence, or confidence in the estimate of effect is determined on the basis of a systematic review of the evidence for each outcome (based on the domains risk of bias, indirectness, imprecision, inconsistency, and publication bias that lower certainty and, usually only for nonrandomized studies, large effects, dose-response relations and opposing plausible residual confounding that may increase the certainty).



For recommendations, the overall certainty is determined across outcomes based on the lowest certainty outcome among those critical for decision making for the specific context. The guidelines development group applies the GRADE Evidence-to-Decision frameworks to make recommendations that are made available on the European Commission Web site. (Reproduced from reference 15, with permission from Schünemann HJ.).



## 2. Recommendations

## Recommendation

- An evidence-based statement that assists providers and recipients of care with making informed decisions





## 3. Stakeholders



# Stakeholder

- A stakeholder is any individual or group who is responsible for or affected by health- and healthcare-related decisions that can be informed by research evidence. (Concannon 2012, Tugwell 2006)

- 1. Patients, Patient caregivers, Patient advocates/ organizations**
- 2. Public**
- 3. Providers**
- 4. Purchasers, Payers of health services**
- 5. Policy makers**
- 6. Program managers**
- 7. Product makers**
- 8. Principal investigators**
- 9. Payers of research**
- 10. Peer review editors and science writers**



**10 Ps**

(Sources: Concannon et al. 2011, Tugwell et al. 2006)



## 4. Engagement

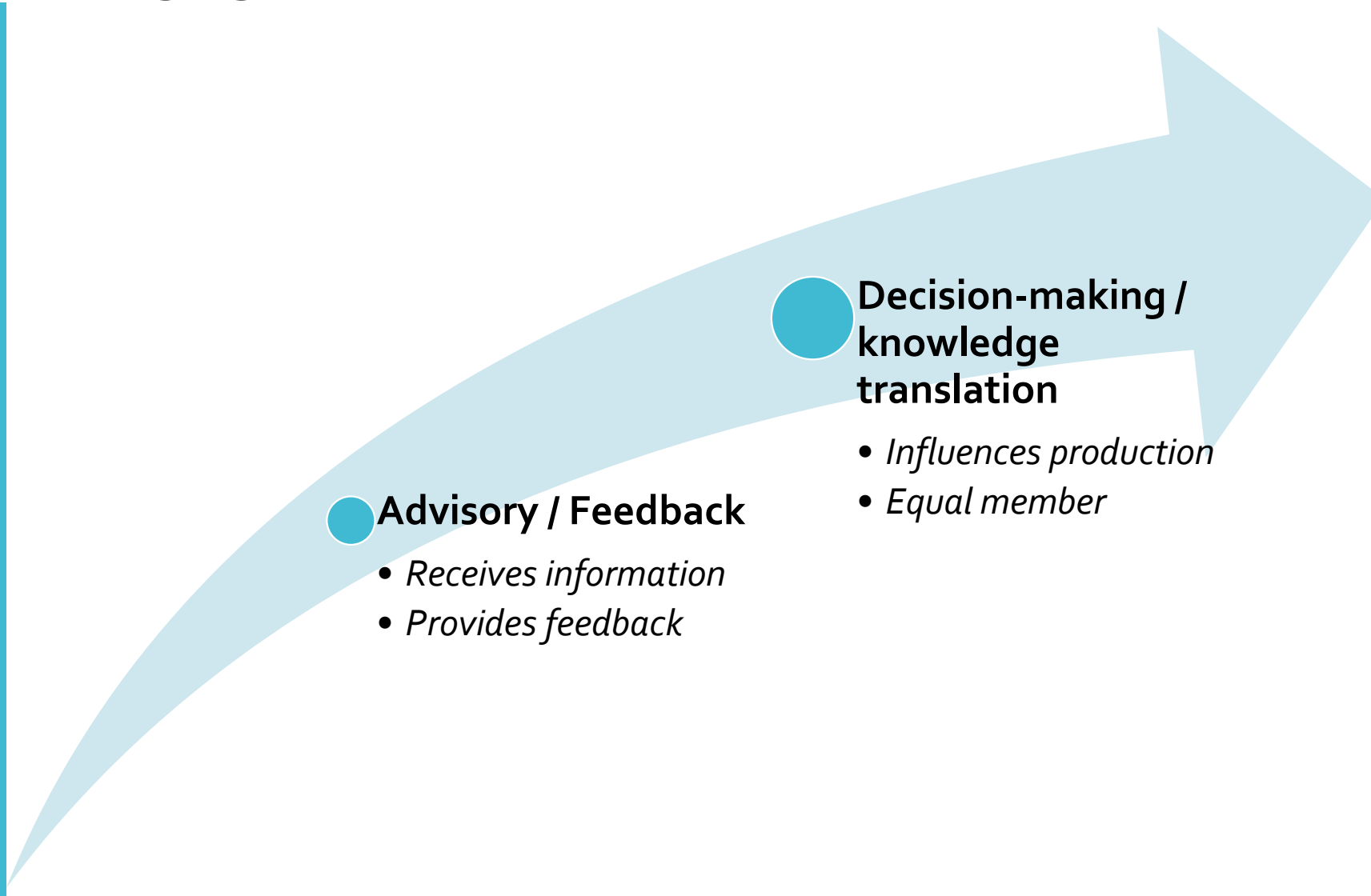
# Engagement

- An approach to ensure the contribution of stakeholders toward the development of the recommendation, completion of any of the stages of the guideline, or dissemination of the guideline and/or recommendations).
- Terms such as involvement, collaboration, or partnership are also used to refer to engagement
- [Pollock 2018](#); [Frank 2020](#); [Hoddinott 2018](#)



## 5. Levels of engagement

# Levels of engagement



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1. Introduction to MuSE
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GIN-McMaster  
GDC  
18 topics

1. Organization, budget, planning, training
2. Priority setting
3. Guideline group membership
4. Establishing group processes
5. Identifying target audience and topic selection
6. Consumer and stakeholder involvement
7. Conflict of interest considerations
8. Question formulation
9. Considering importance of outcomes and interventions, values, preferences, and utilities
10. Deciding what evidence to include and searching for evidence

GIN-McMaster  
GDC  
18 topics

11. Summarizing evidence and considering additional information
12. Judging quality, strength or certainty of a body of evidence
13. Developing recommendations and determining their strength
14. Wording of recommendations and of considerations about implementation, feasibility and equity
15. Reporting and peer review
16. Dissemination and implementation
17. Evaluation and use
18. Updating

# PROJECT GOAL:

How and when to include different stakeholder groups, facilitate equitable engagement, manage conflicts of interest, and evaluate impact for all 18 steps in the GIN-McMaster Guideline Development checklist

**PROJECT GOAL:** How and when to include different stakeholder groups, facilitate equitable engagement, manage conflicts of interest, and evaluate impact for all 18 steps in the checklist

Step

1. Organization, budget, planning and training

2. Priority setting

3. Guideline group membership

...

16. Dissemination & implementation

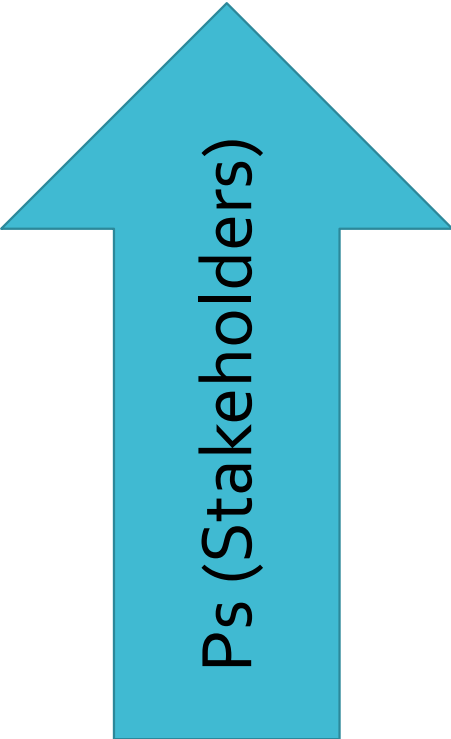
17. Evaluation and use

18. Updating



**PROJECT GOAL:** How and when to include different stakeholder groups, facilitate equitable engagement, manage conflicts of interest, and evaluate impact for all 18 steps in the checklist

Step	Patients	Caregivers	Patient advocates/ organizations	Public	Providers	Purchasers	Payers of health services	Payers of health research	Policy makers	Program managers	Product makers	Principal investigators	Peer review editors and science writers
1. Organization, budget, planning and training													
2. Priority setting													
3. Guideline group membership													
...													
16. Dissemination & implementation													
17. Evaluation and use													
18. Updating													



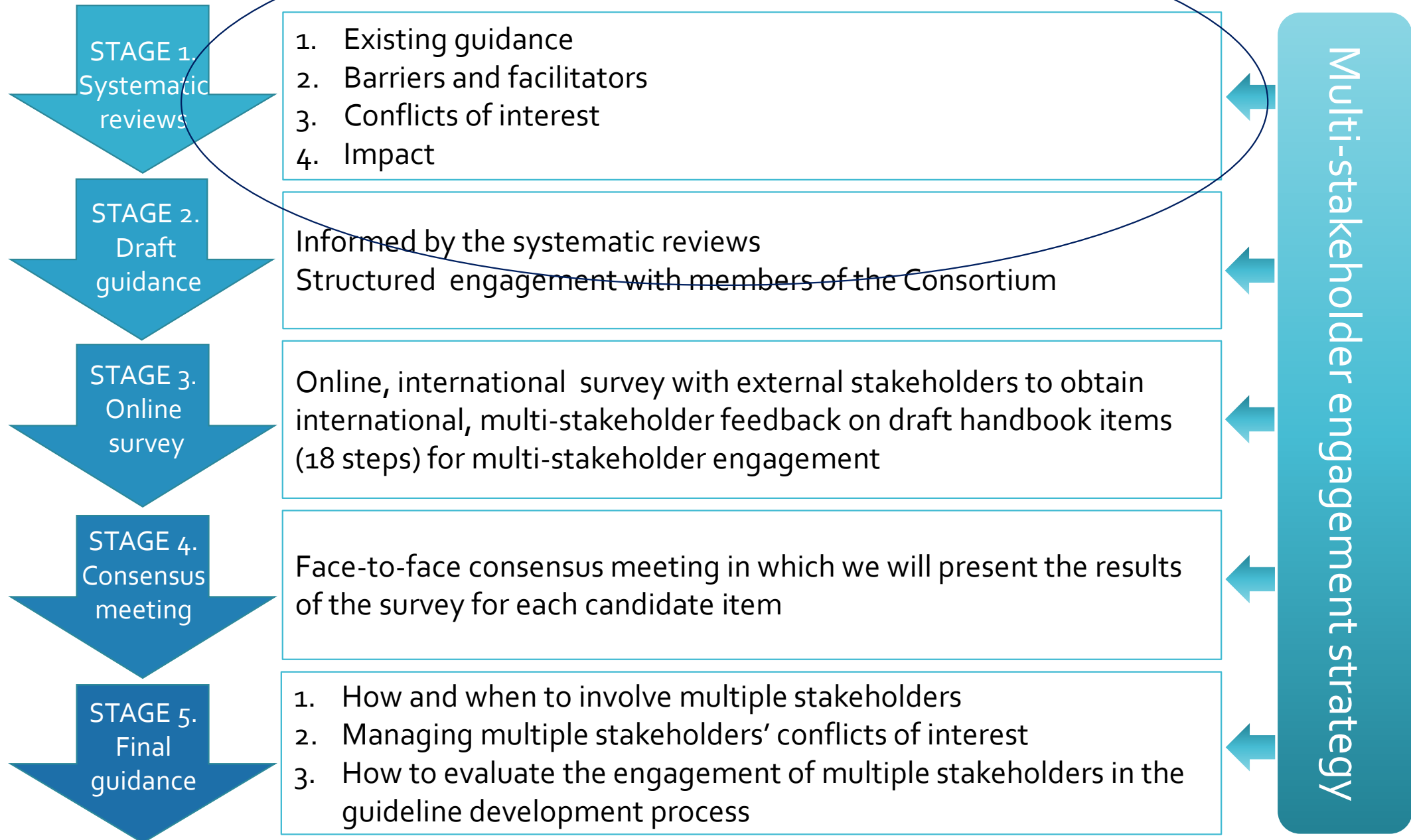
**PROJECT GOAL:** How and when to include different stakeholder groups, facilitate equitable engagement, manage conflicts of interest, and evaluate impact for all 18 steps in the checklist

Step	Patients	Caregivers	Patient advocates/ organizations	Public	Providers	Purchasers	Payers of health services	Payers of health research	Policy makers	Program managers	Product makers	Principal investigators	Peer review editors and science writers
1. Organization, budget, planning and training													
2. Priority setting													
3. Guideline group membership													
...													
16. Dissemination & implementation													
17. Evaluation and use													
18. Updating													

Identify roles and modes  
 Facilitate equitable engagement  
 Manage conflicts of interest  
 Evaluate impact

*Source: adapted from Schünneman et al. 2014.*

# PROJECT OVERVIEW



# Systematic reviews

Systematic review	Number of included studies
Existing guidance	19
Barriers and facilitators	23
Conflicts of Interest	7
Impact	35



Example –  
existing  
evidence for  
stakeholder  
engagement

GDC Steps

Summary of guidance

4. Establishing guideline group processes

4.1 Establish how and how often communication with guideline panel members and other groups will take place

- Decide on communication modes and frequency and time commitment required.
- Establish a system for group communication.

**FACILITATOR:** Engage an experienced facilitator / committee chair to manage power/group dynamics

Example –  
existing  
evidence for  
stakeholder  
engagement

GDC Steps	Summary of guidance
4. Establishing guideline group processes	
4.2 Set expectations and awareness of the group process through an introduction, training, and support	<ul style="list-style-type: none"><li>– Introduce members at the start of meetings</li><li>– Create an agenda to facilitate discussions</li></ul>

Example –  
existing  
evidence for  
stakeholder  
engagement

GDC Steps

Summary of guidance

4. Establishing guideline group processes

4.3 As part of the training for the guideline development group, ensure that group members understand what the process and proposed methods will be and that they need to be adhered to

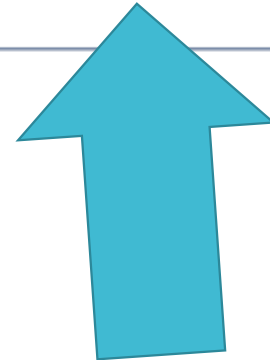
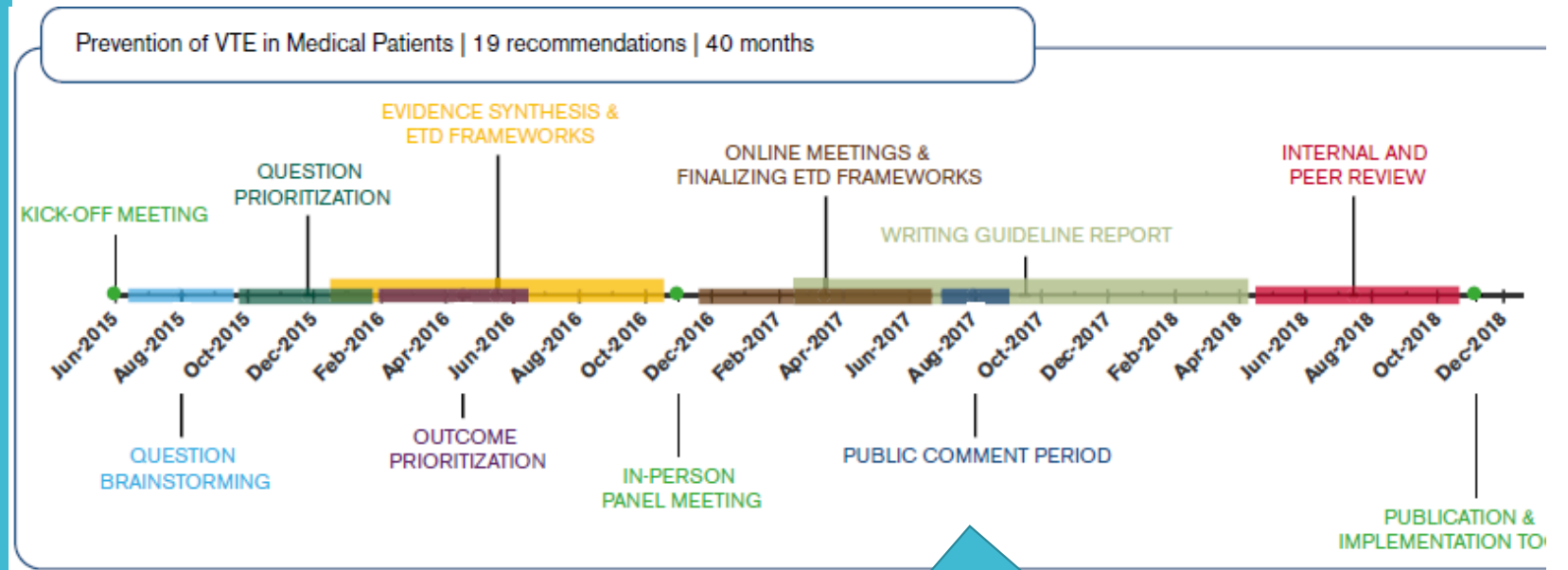
- Discuss voting roles of patient members, avoid jargon and confirm patient understanding regularly, take breaks regularly
- FACILITATOR:** Comprehensive and early training for patients on guideline topic and methods including evaluating and synthesizing evidence

## EXAMPLE:

American  
Society of  
Hematology  
(ASH)

- Stakeholder feedback sought:
  - Draft recommendations are posted online with a 4-6 week public consultation period.

# ASH example



Source:  
Izkovich et al. 2020: A user guide to the American Society of Hematology clinical practice guidelines

# ASH Example

## Methodology for ASH VTE Guidelines

### Supplement 10: ASH guidelines public comment survey questions

Respondents are asked as background questions:

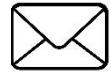
1. Contact Information
2. Which of the following options best describes your role in relation to this guideline? Please select all that apply:
  - Hematologist or oncologist
  - Internal medicine specialist or hospitalist
  - Primary care physician
  - OB-GYN
  - Surgeon
  - Pharmacist
  - Research scientist
  - Allied professional
  - Government employee
  - Industry representative
  - Laboratory technician
  - Patient
  - None of the above
3. Would you agree to be contacted by ASH about implementation of these guidelines? Method of follow-up could include brief survey or brief phone interview. (Yes/No)
4. Are you a member, representative, or employee of any of the following [medical specialty society] organizations? (Note: you do not need to be a member to comment.)
5. Do you have any conflicts of interest relevant to the guideline topic? Conflicts could include employment or direct financial relationships or interests in companies affected by the recommendations, research funding by such companies, or professional or career interests that could be affected by the recommendations. (Yes/No/Maybe)

*The survey provides a link to (optionally) download a document with a list of all guideline recommendations and corresponding Evidence-to-Decision Frameworks.*

# MuSE Timeline

- Systematic review drafts: December 2020
- Interim consensus meeting: February 2021
- Draft guidance items (for survey): March 2021

## Contact us!



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<https://methods.cochrane.org/equity/projects/stakeholder-engagement-guideline-development>



@GuidelinesMuse



# GIN-McMaster GDC

- List of 18 topics (146 items) outlining the practical steps to consider for developing guideline and recommendations
- Intended for use by guideline developers to plan and track the process of guideline development
- <https://www.cmaj.ca/content/186/3/E123>