Country-led Assessment for Prioritization in Immunization (CAPACITI)

Decision-support framework
Version 2.0

Guidance manual

Date of this version: 19 September 2020

For support using the CAPACITI decision-support framework, please contact
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Contents

OVERVIEW: CAPACITI decision-support framework

Purpose

The decision-support framework of the Country-led Assessment for Prioritization in Immunization (CAPACITI) outlines the steps of a structured recommendation process that is evidence based, context specific and well documented. The framework is appropriate for decision questions that require comparison of two or more options, may involve input from multiple stakeholders, use evidence from across disciplines and/or indicate significant data uncertainty.

Types of questions addressed by the framework

1) Selecting between multiple options

Potential applications of the framework include:

- *product choice*, as when choosing which rotavirus vaccine product to procure;
- *schedule choice*, as when deciding whether to follow a 2+1 or 3+0 schedule for PCV vaccination;
- *delivery strategy*, as when determining whether to introduce controlled temperature chain (CTC) delivery of birth dose hepatitis B vaccine, and under which conditions.

2) Ranking multiple options

Potential applications of the framework include:

- *vaccine prioritization,* as when comparing PCV, HPV and rotavirus vaccines;
- *vaccine introduction or delivery strategies*, as when prioritizing regions for phased introduction of a vaccine;
- *prioritization of immunization and non-immunization alternatives*, as when considering investment in rotavirus vaccine introduction compared with other diarrhoeal disease prevention and control measures.

Five full worked examples of different types of policy and programmatic questions can be found in **Appendix 1: Worked examples**

Difference between the CAPACITI decision-support framework and the GRADE Evidence to Recommendation framework

The GRADE Evidence to Recommendation (EtR) framework supports the work of the expert panels by providing guidance for using evidence in a structured and transparent way to inform recommendations.[1] It is the framework that the WHO Strategic Advisory Group of Experts (SAGE) and many national immunization technical advisory groups (NITAGs) use to make recommendations.

The GRADE EtR framework evaluates a single intervention in relation to a comparator, whereas the CAPACITI decision-support framework is designed for choices involving multiple interventions. The table below compares the types of policy questions addressed by the two frameworks.

GRADE Evidence to Recommendation (EtR) framework: example questions	CAPACITI decision-support framework: example questions
New vaccine introduction	
Should rotavirus vaccination be introduced into the national immunization programme (NIP)?	Which new vaccine(s) should be prioritized for introduction into the NIP? *E.g. comparison among HPV, PCV, rotavirus vaccines*
Vaccine product procurement	
Should the immunization programme switch procurement from the quadrivalent HPV vaccine to the nine-valent HPV vaccine?	Which of the available HPV vaccine products should be procured for the NIP?
Vaccine delivery strategy	
Should hepatitis B birth dose be delivered under controlled temperature chain (CTC) conditions?	Under which scenarios should controlled temperature chain (CTC) delivery be recommended for birth dose hepatitis B vaccination?

[1] Alonso-Coello P, Schünemann H, Moberg J, Brignardello-Petersen R, Akl E, Davoli M et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. BMJ. 2016;353:i2016.

Target audience

The CAPACITI decision-support framework is aimed at a secretariat or core team within the national immunization programme or ministry of health (MOH) that is tasked with coordinating the recommendation process. This team should have knowledge of the national immunization programme and policy processes within the country. If the framework's accompanying decision-support tool is used, it will be beneficial for at least one member of the team to be proficient in Excel.

> The CAPACITI decision-support framework can be used by standing committees, such as the National Immunization Technical Advisory Group (NITAG), the Inter-agency Coordination Committee (ICC) or a national benefits package selection committee. It can also be used in settings in which a recommendation committee or panel has not yet been identified. In both cases, it is important to consider how to adapt the framework to align with local guidelines and procedures.

Structure of the framework

The CAPACITI decision-support framework is structured into the following five sections (see Box 1 for further details).

1. Decision question – articulates the recommendation objectives and outlines how the recommendation process will be conducted.
2. Criteria for decision-making – sets out the principles for comparing and evaluating each of the options.
3. Evidence assessment – collects, synthesizes and assesses the quality of available evidence, for presentation to the recommendation committee.
4. Appraisal – assesses the merits and drawbacks of each option, in accordance with the criteria determined in Section 2.
5. Recommendation – agrees upon, finalizes and communicates the recommendation.

Methodology for the framework: multi-criteria decision analysis (MCDA)

The CAPACITI decision-support framework is based on multi-criteria decision analysis (MCDA) – a structured methodology that brings together different viewpoints and sources of evidence to compare options.

There are three different types of MCDA: quantitative, qualitative and rule-based.

- Quantitative MCDA – a total score is calculated per option by combining weights and scores. To come to a recommendation, the committee deliberates on the rank order of the options.
- Qualitative MCDA – weights are not assigned to criteria, and options are not scored. Instead, the committee comes to a judgement by deliberating the evidence according to the criteria.
- Rule-based MCDA – instead of considering all criteria simultaneously, the committee specifies the priority order in which criteria will be considered.

See Step 1.5 for more information on MCDA. It is also important to note that it is possible to follow a hybrid approach in the CAPACITI decision-support framework, by combining elements of two or all three types of MCDA.

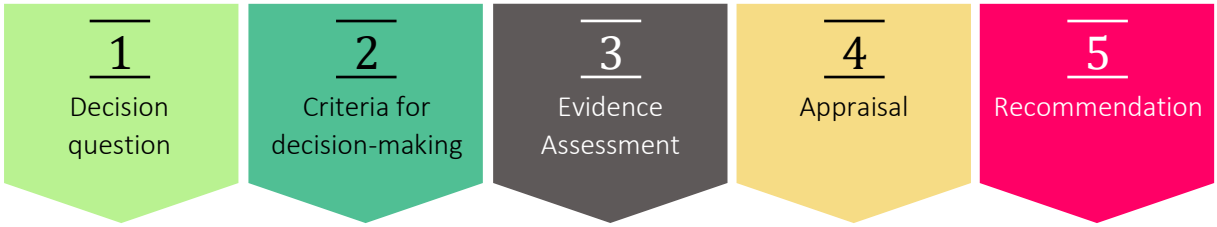
BOX 1: Steps of the CAPACITI decision-support framework

1) DECISION QUESTION	1.1) Objectives – articulates the recommendation objectives and frames the role of the recommendation within the broader policy environment
	1.2) Context – outlines the programme context and potential implications of the recommendation
	1.3) Options – scopes and shortlists from two to five options in order to compare
	1.4) Participation – identifies which stakeholders to engage, mechanisms for stakeholder participation, and composition of the recommendation committee
	1.5) Priority-setting process – selects the most appropriate MCDA methods, group techniques, and operational procedures
2) CRITERIA FOR DECISION-MAKING	2.1) Criteria – selects or adapts a list of criteria relevant for the decision question
	2.2) Weights – indicates the relative importance of the criteria
	2.3) Rules for interpreting evidence – outlines scoring scales and, if relevant, determines rules or sequences for considering criteria
3) EVIDENCE ASSESSMENT	3.1) Evidence collection – documents available evidence and research methods
	3.2) Evidence statements – synthesizes available evidence and assesses its quality
	3.3) Performance matrix – summarizes the performance of each option by criterion
4) APPRAISAL	4.1) Comparison by criterion – scores and compares the performance of each option on a criterion-by-criterion basis
	4.2) Comparison across criteria – considers the trade-offs between each option, which option(s) perform best overall and the impact of data uncertainty
5) RECOMMENDATION	5.1) Formulation of recommendation – formulates a preliminary recommendation and considers the implications of data quality
	5.2) Supplementary considerations – considers notable implications of the recommendation and mitigation measures, if relevant
	5.3) Final recommendation – agrees and rationalizes the final recommendation
	5.4) Audit, monitoring and evaluation – reviews the recommendation process and makes provisions for review and monitoring of the recommendation
	5.5) Communication – communicates the recommendation and rationale to the final decision-maker and interested parties

Indicative timelines

There is no prescribed length for the process, which can vary from a couple of weeks to over a year. The exact timeline is likely to depend on a number of factors, including the nature of the decision question, the urgency and importance of the recommendation, the number and profile of stakeholders involved in the process, and the availability of evidence and of resources to coordinate the process.

As a rough guide, a typical recommendation is expected to take from 4 to 6 months. However, the duration can be reduced to 1 to 2 weeks for urgent decision questions, or last more than a year for high profile, strategic questions requiring extensive data collection and analysis. An indicative breakdown of the timing for each step is given below.



1-2 months	0.5-1 day (discussion)	1-3 months	1 day (discussion)	1 month
For high priority questions or settings with a well-established process, this step may take as little as 1 week.	This step can be shorter if there is an established set of criteria, weights and/or scales.	Duration depends on the bandwidth of technical focal points, number of data points and level of analysis required.	A full day is recommended, but it can be shorter if the committee reviews evidence in advance.	Duration mainly depends on time needed to write the final report; it can be as little as 1 week.

Supporting materials

The CAPACITI decision-support framework toolkit includes the following materials.

Decision-support tool (Excel-based)

The decision-support tool guides the user through the steps of the decision-support framework, documenting discussions at each step of the process.

Guidance manual (this document)

The manual details the steps of the decision-support framework. It includes guidance for streamlining and adapting the process, as well as tips for completing the decision-support tool.

Worked examples (Appendix 1)

Worked examples for different types of decision questions are provided, with screenshots from the Excel-based CAPACITI decision-support tool.

Template report (Appendix 2)

The template report provides a draft structure to communicate the final recommendation. It references the relevant sheets of the decision-support tool and can be adapted as much as necessary.

Getting started

The CAPACITI decision-support tool opens on the home page. Before moving past the home sheet, ensure that the following steps have been completed.

1) **Check that you are using the most recent version of the tool.**

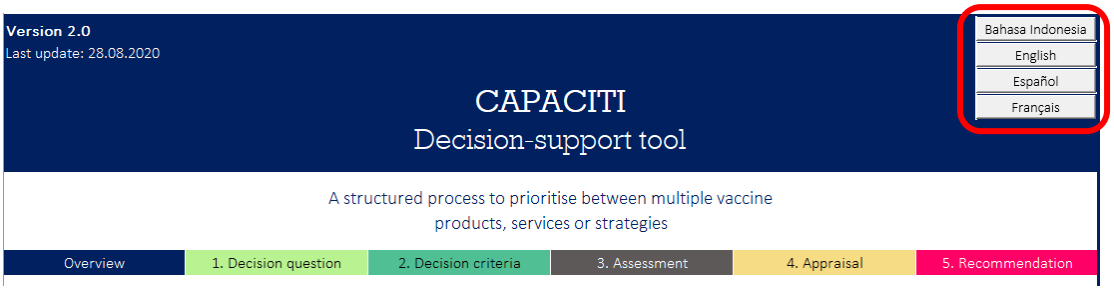
   Note 1: the version of the tool is noted on the home page (see screenshot below).
   Note 2: the most recent update of the tool can be accessed here.

2) **Ensure that macros are enabled in the tool**, by clicking "Enable Content" if the following message bar appears:

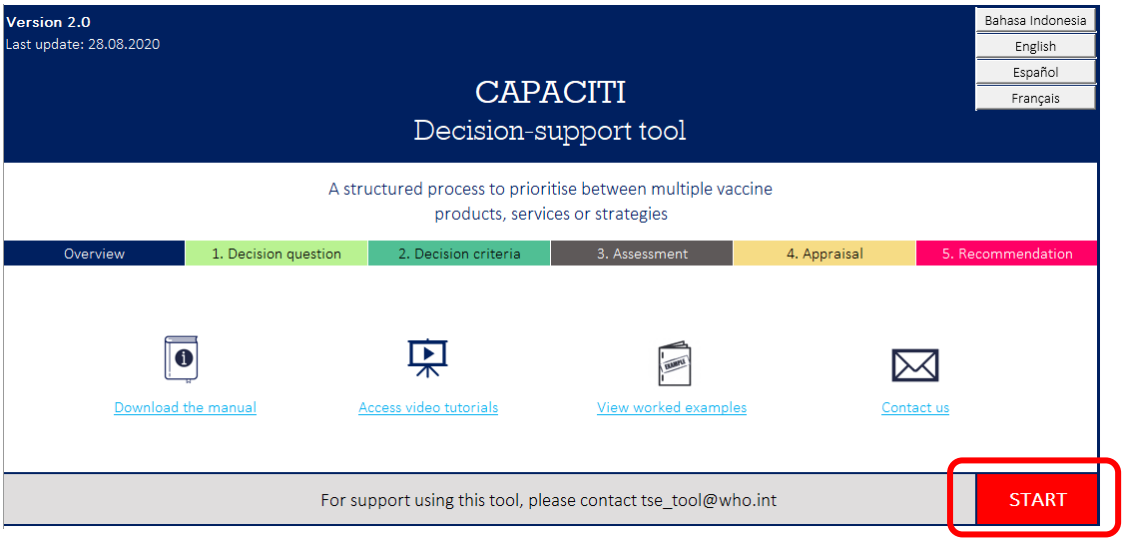
> Excel for the Web and versions of Excel before Excel 2007 do not support macros. If possible, find a laptop with a desktop version of Excel (2007 or later) to run the tool. It is possible to use the tool in English if macros do not function. However, the translation functions and buttons to export to .pdf or Word will not work properly.

3) **Save the tool on your local drive** with an appropriate name specific to the recommendation, such as CAPACITI decision-support tool_v2.0_Mali_HPV_May2019.xlsm.

4) **Select the appropriate language** from the menu bar at the top of the page.



5) **Click on the start button to begin.**

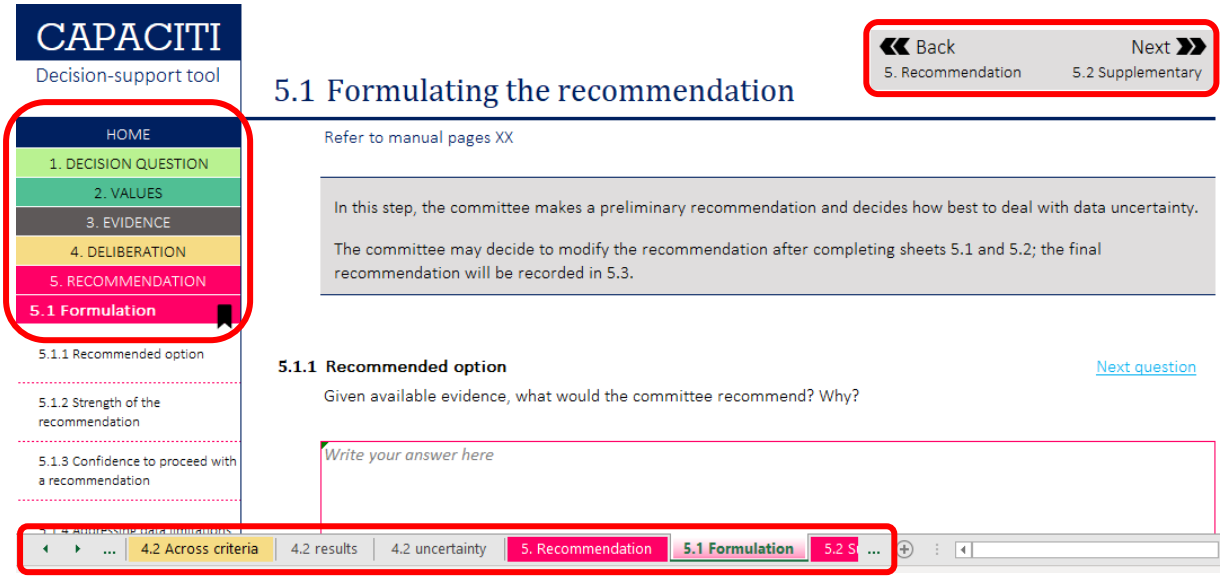


Structure of the tool

The decision-support tool is structured according to the five sections of the CAPACITI decision-support framework shown in Box 1. Each section of the tool starts with an overview page, followed by a series of worksheets.

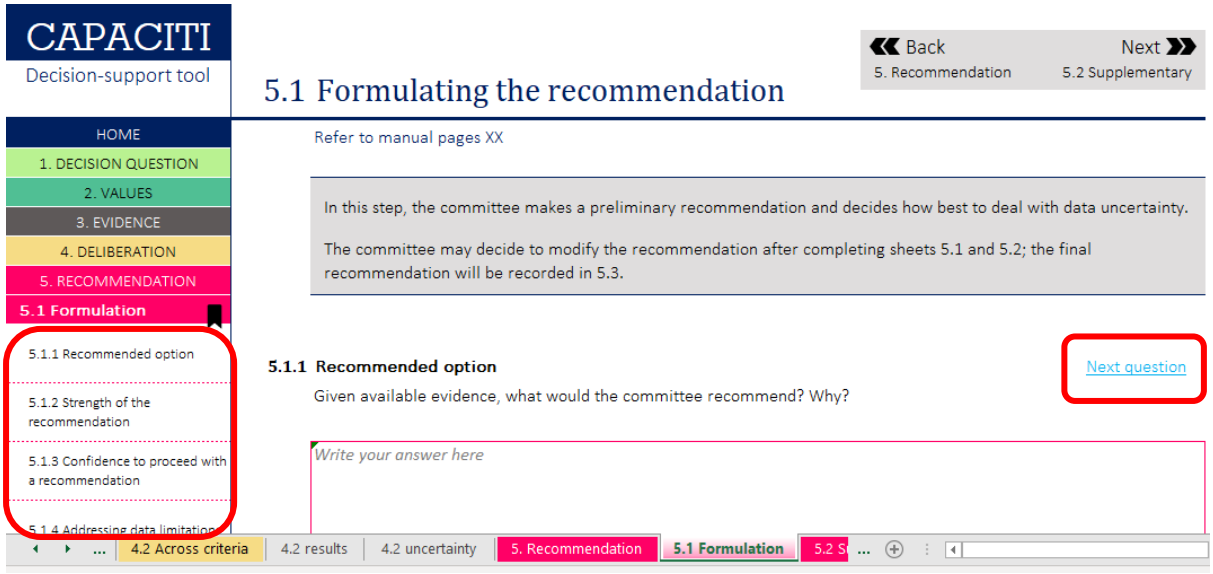
Navigate between sheets. There are three ways to navigate between sheets of the tool, as shown in screenshot below.

- Use the navigation pane on the left-hand side of each sheet.
  Note 1: the bookmark icon indicates the current page.
  Note 2: only worksheets in the current section are shown in the navigation pane. To select a worksheet in another section, go to the relevant section first.
- Use the **Back/Next** buttons at the top and bottom of each page.
- Use **Tabs** at the bottom of the window.



Navigate between questions. Within the worksheets themselves, it is possible to navigate between questions in three ways.

- Use the navigation pane on the left-hand side of each sheet.
  Note: the navigation pane shows all questions (sub-steps) in the current sheet.
- Use the "Next question" link.
- Scroll down the page using the mouse/keyboard.



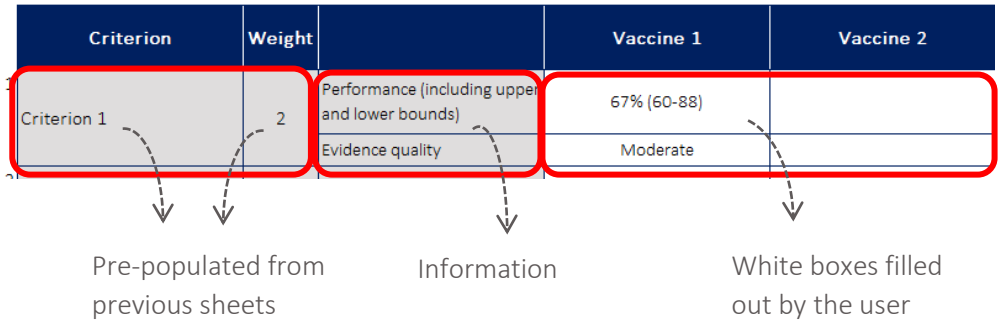
Identify essential steps. While it is highly recommended to complete all steps in the tool, the essential steps are highlighted with a black triangle.

Information sheets provide additional guidance on completing certain questions. It is advisable to read these sheets the first time using the tool.

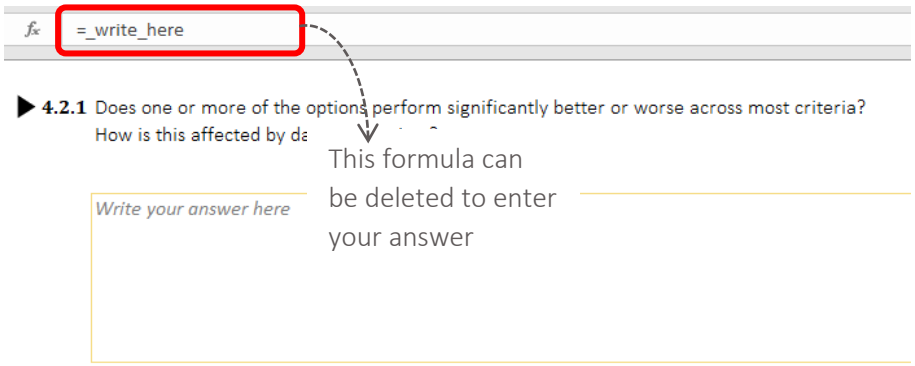
Supplementary sheets are additional resources that can be filled out if helpful to the secretariat or committee. Information and supplementary sheets are linked to worksheets in the tool (see page 14-Icons in the tool).

Entering information

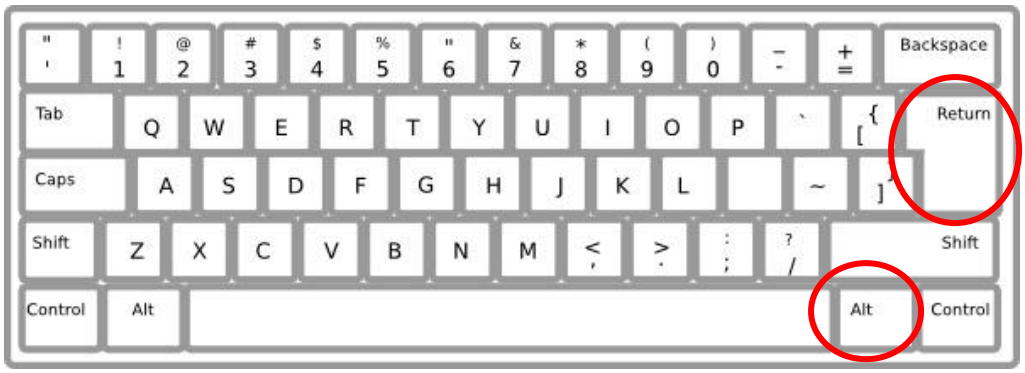
In the tool, grey cells include information or are pre-populated from previous sheets, while white boxes are filled out by the user. All cells in the tool are locked except white boxes.



Certain unlocked cells in the tool contain guidance text, which can be over-written to enter information in the tool.

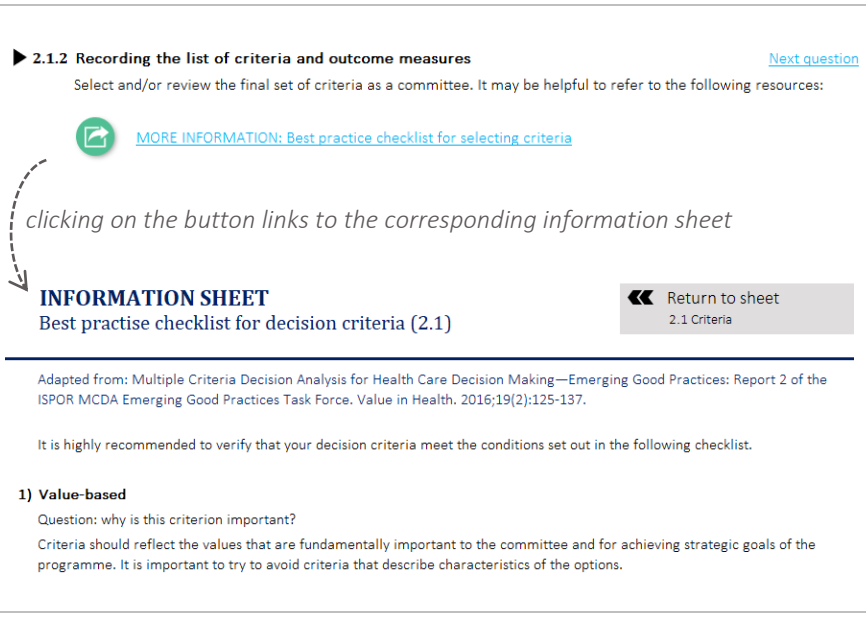
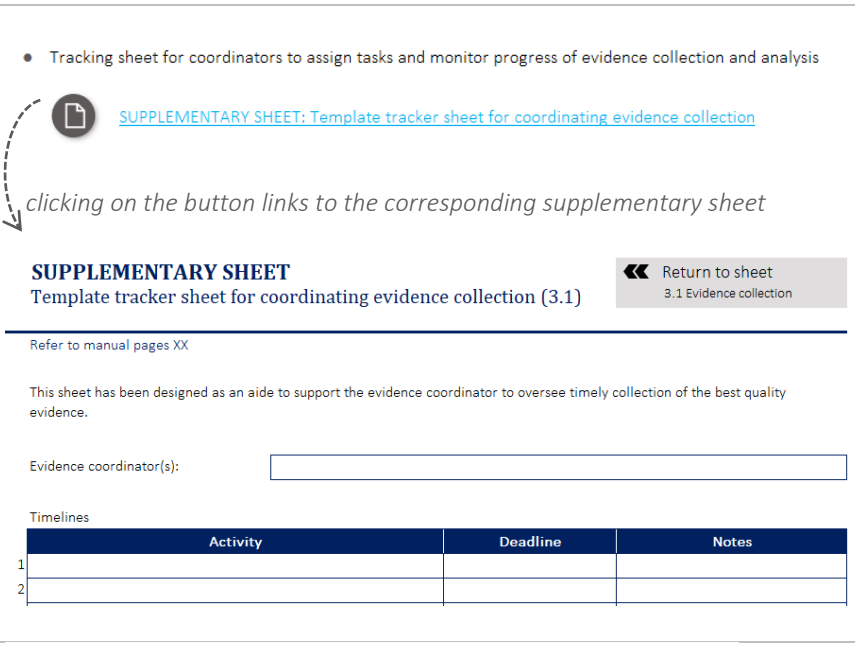


If you wish to have a line break within a box in the tool, press **Alt** and **Return** on the keyboard. In Excel, press **Return** by itself in order to move to the next cell.



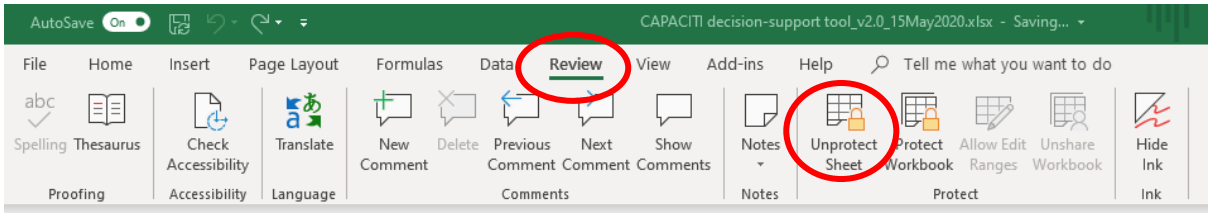
Key to icons in the tool

Icon	Meaning	Example from the tool
	Current page (used in navigation pane)	HOME 1. DECISION QUESTION 2. VALUES 3. EVIDENCE 4. DELIBERATION 5. RECOMMENDATION **5.1 Formulation** 5.1.1 Recommended option 5.1.2 Strength of the recommendation 5.1.3 Confidence to proceed with a recommendation 5.1.4 Addressing data limitations
	Important step: highlights essential steps to complete	**1.4.4 Members of the recommendation committee** Record the members of the recommendation committee (or working group). It is advisable to include between 6 and 15 members. Name | Position (job title) | Affiliation(s) | Voting rights 1
	Important information	**IMPORTANT: for quantitative MCDA, review the links below before proceeding with this worksheet**

	Information sheet: links to a sheet in the tool with further details	
	Supplementary sheet: links to an optional sheet in the tool that can be used as an extra resource	
	Download Word/.pdf: exports to a file on your drive; requires macros	
	External link: links to an external site with further information	

Unlocking the tool

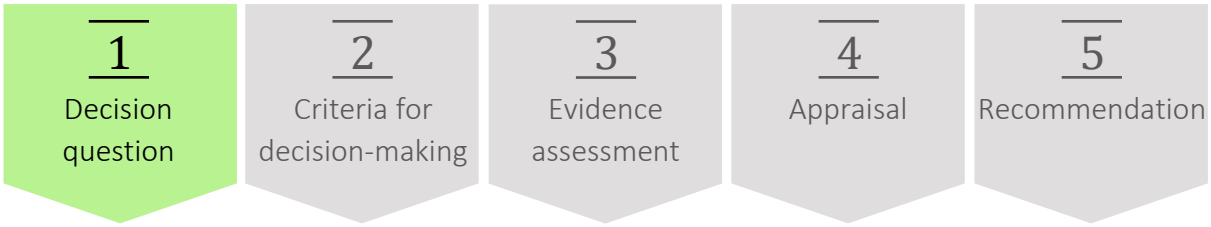
All sheets in the tool are locked to avoid accidental deletion of the formulas. If you wish to modify a sheet, it can be unlocked by selecting **Review > Unprotect Sheet** in the Excel menu bar (see below). It is highly recommended to lock the sheet again after finishing the changes.



Troubleshooting and support

For help using the tool or fixing errors, please contact tse_tool@who.int.

1. DECISION QUESTION



The role of this section is to articulate the purpose of the recommendation and to outline how the recommendation process will be conducted. In this section, a secretariat or core team based within the MOH will:

- characterize the decision problem within the existing programme and policy environment
- define the decision question and its scope
- outline the recommendation process, including methods for stakeholder engagement and evidence interpretation.

IN THIS SECTION

1.1 Framing the objectives

This step is completed by the secretariat.

PURPOSE:

- The secretariat articulates the policy or programmatic question that needs to be addressed and how the recommendation will inform the final decision.
- This step is important, as it ascertains that the committee or working group making the recommendation is well-briefed on the mandate of the recommendation.

ESSENTIAL TO COMPLETE:

- Define the policy or programmatic question clearly (1.1.1).
- Document any points that are important for briefing the committee or working group.

COUNTRY ADAPTATION:

- It is recommended to define the remit of the CAPACITI decision-support framework in your country, in terms of the types of questions it will address and where it sits within your existing processes (see Box 2, page 21).
- This may allow you to bypass 1.1.3 and 1.1.4, provided they remain constant across all recommendations.

IMPORTANT

1.1.1 What is the decision question?

The decision question influences which options are compared, as well as the criteria that are used to assess the options. It is therefore important to ensure that the decision question accurately captures the objectives of the recommendation and that the question is clearly documented.

When articulating the decision question, it may be helpful to consider the following points.

- **What is the problem being addressed?**

  It is advisable to write an objectives-based decision question, as opposed to framing the question around alternatives. This ensures that no relevant options are missed, and will demonstrate that a thorough, unbiased process has been followed to scope the options.

  The table below gives examples of alternatives-based questions which are framed around options, and how they can be re-phrased as objectives-based questions by identifying the problem that needs to be addressed.

	Alternatives-based question (not recommended)	Objectives-based question (recommended)
1	Should HPV or rotavirus vaccine be introduced?	*Problem: budget restrictions mean that not all new vaccines can be introduced* Which new vaccine is highest priority to introduce into the national immunization programme?
2	Should the EPI programme procure the quadrivalent monodose or bivalent two-dose vial presentation?	*Problem: selecting the best product for the country, since many products with different characteristics are available* Which HPV vaccine presentation should be procured?

- **What is the emphasis of the question?**

  The phrasing of the decision question will influence the factors considered by the committee and, ultimately, the outcome of the recommendation. The example below illustrates different ways in which a question on new vaccine introduction could be phrased.

	Examples: phrasing the question for new vaccine introduction
1	What is the order in which to prioritize new vaccine introduction? *Ranks new vaccines in terms of priority for the country*
2	Which (if any) of the new vaccines should be introduced? *Includes an option of no vaccine introduction*
3	Which portfolio of vaccines should be provided through the national immunization programme? *Requires evaluation of both new vaccines and vaccines currently provided through the national immunization programme*
4	Which of the new vaccines offer best value for money? *Requires evaluation of cost against other criteria*

- **Will the question be interpreted in the same way by all stakeholders?**

  Ensure that the question is sufficiently precise and unambiguous, so that all members of the recommendation committee or working group, as well as the final decision-maker, have the same understanding of the remit. In the new vaccine prioritization example above, it may be worth clarifying whether the scope of the question includes all new vaccines, or only those that would be introduced in routine immunization or nationwide.

1.1.2 Why is the recommendation being considered?

Understanding the reason that the decision question is important and why it is being addressed now can inform the subsequent steps that scope the options and define the list of criteria for the recommendation. For example, is a new vaccine prioritization exercise being conducted because a new window of funding has opened from Gavi, has it been prompted by a recent WHO SAGE recommendation, or is the purpose to plan programme activities for the next five years?

1.1.3 Who requested the recommendation?

It is important to understand who articulated the question, so that the recommendation adequately addresses their concerns. If not covered in 1.1.2, it is worth outlining the responsibility of this person and the motivation for the request.

> In countries with an established process for identifying questions addressed by the CAPACITI decision-support framework, this part may be pre-filled.

1.1.4 How will the recommendation be used?

This step outlines both the implications of the recommendation and factors influencing its successful implementation. This information will support the secretariat in setting the scope and process for the recommendation. It also sets the scene for the committee, so that it can decide whether to take account of the recommendation's feasibility and its likelihood for implementation.

It may be helpful to consider the following points.

- End goal of the recommendation: for example, will the recommendation be used for an application to Gavi or to inform the national immunization strategy (NIS)?
- Type of recommendation: is this a policy, planning, budget allocation or procurement decision?
- Implementation of the recommendation:
  - What are the subsequent steps between this recommendation and the final decision? *The committee may wish to consider factors that will be important to the final decision-maker.*
  - Which stakeholders are responsible for the funding, implementation and uptake of the recommendation? This includes government agencies as well as sub-national stakeholders and the caregiver or person being vaccinated. *The committee may wish to consider the perspective of these stakeholders when making a recommendation.*

These points will influence the options that are compared (1.3), stakeholders who are engaged throughout the recommendation process (1.4), criteria selected by the committee (2.1), type of evidence collected (3.1), and discussions of the committee to come to a recommendation (4.1, 4.2).

1.1.5 Timeline for the recommendation

Aside from supporting planning, outlining the timelines at a high level can give the committee a sense of the urgency of the decision. For example, if there is a high-priority decision that has to be made within a short timeline, it is more likely that the committee will proceed with a recommendation, even in the absence of poor quality evidence.

Similarly, detailing the expected timeline for implementation is important, as it enables the committee to take relevant factors into consideration. For example, product choice for a new vaccine introduction in the next six months is much more likely to consider supply availability than an introduction in a year or more.

BOX 2: Identifying the remit of the CAPACITI decision-support tool within existing priority-setting and decision-making processes

Before implementing the decision-support framework, it is important to consider the types of decisions for which it could be useful, and at which stage the framework will be implemented within the decision-making process. It can be beneficial to consider national processes for conducting health technology assessments (HTAs) and mechanisms for selecting benefits packages, in order to ensure that the priority-setting process for immunization is aligned.

The following steps may be helpful in considering when to use the CAPACITI decision-support framework.

1. Map the types of questions for which the framework may be helpful. This can include new vaccine introduction, vaccine schedules, product choice or delivery strategy selection.
2. Map the pathway for each of the questions identified, from identifying a decision question to approval for the final decision and implementation. Note which groups are involved at each step.
3. Discuss at which stage of the process the decision-support framework would be most relevant. Outline if the framework is used by a standing committee, the scope of questions addressed with the framework and how the process is triggered.

1.2 Context

This step is completed by the secretariat.

PURPOSE:

The secretariat summarizes any background that is relevant to contextualize and understand potential implications of the recommendation.

ESSENTIAL TO COMPLETE:

Note any significant health, economic or social consequences of a recommendation (1.2.4).

1.2.1 Background: disease and programme performance

The purpose of this step is to include any relevant background pertaining to disease epidemiology, existing control measures, and capacity of the immunization programme. Depending on the question, this may include the following.

- Country-specific data on burden of disease, including its variation across populations and regions of the country, and comparison with other countries.
- Current prevention and control measures, including non-vaccination interventions, and any local data on the impact of these measures.
- National strategic goals that are aligned with the decision question, such as disease elimination targets or goals to raise immunization coverage.
- Immunization programme performance, strengths and weaknesses. It can be important to consider whether recent programme reviews, such as the EPI review, have highlighted any systems challenges or barriers to immunization that could be affected, either positively or negatively, by the recommendation.

There should be sufficient detail for the recommendation committee to understand the current situation in the country.

1.2.2 Background: existing policy and practice

This step outlines any existing guidance or policy recommendations that are in place, and the extent to which they influence current practice or health outcomes. It may be helpful to summarize the following points, if relevant.

- Previous recommendations. Are there previous recommendations related to the decision question? What was the rationale for the recommendation? For example, it may be helpful to provide the rationale for a new vaccine introduction recommendation for a decision question

that concerns which product to procure. If relevant, discuss the extent to which the recommendation has been followed.

- Current practice. Outline current practice, if relevant, the extent to which it is aligned with existing guidelines, and whether it is effective.

As before, the purpose is to ensure that the committee is sufficiently briefed on the current situation in the country.

1.2.3 Recommendations from other jurisdictions

It can be helpful to outline the recommendations made in other jurisdictions, with the rationale, so that the committee understands factors that have been taken into consideration by other groups. In particular, it may be helpful to highlighting global, regional and national-level recommendations.

- Global, such as recommendations from WHO SAGE. It is important to consider the extent to which such guidance is applicable to the country context.
- Regional, such as recommendations from neighbouring countries and/or the Regional Immunization Technical Advisory Group (RITAG). Consider whether the rationale for the recommendations is relevant for your setting.
- National, such as any recommendations already made within the country. It may be that professional associations have already made a recommendation on the topic, or individual states/provinces in decentralized systems may already have addressed the decision question.

IMPORTANT

1.2.4 Potential consequences

At the start of the recommendation process, it is important to consider whether any significant health, economic or social implications could result from the recommendation. It is not expected for the secretariat to predict the outcome of the recommendation. The purpose of this step is to ensure that the committee is cognizant of any potential consequences – either positive or negative – that its recommendation may have.

1.3 Scope

This step is completed by the secretariat.

PURPOSE:

- The secretariat selects which interventions the committee will compare to address the decision question.
- Following a scoping exercise to identify possible interventions, the secretariat uses a quick set of procedures to shortlist the interventions. This ensures options are not missed and reduces bias.

ESSENTIAL TO COMPLETE:

- Document the options that have been selected to compare (1.3.2).
- Document any options that were identified during the scoping exercise but will not be evaluated by the committee, and explain why (1.3.3).

1.3.1 Types of interventions

The committee will compare from two to five options ("interventions") in order to come to a recommendation. However, for many decision questions, there will be more than five possible options that could be compared. For example, when considering which rotavirus vaccine product to procure, there are more than five products that have received WHO prequalification.

Scoping review. The first part of this step is to conduct a scoping review to map all possible options that may address the decision question. Although the secretariat may already have a good grasp of the possible options, this can ensure that the process is transparent and that no options are missed. It is recommended to document any parameters used during this scoping review, such as:

- Example 1. A list of new vaccines was obtained from the list of WHO SAGE-recommended vaccines.
- Example 2. A list of new vaccines was generated based on vaccines for which there is a NITAG recommendation, but the vaccine has not been introduced into the national immunization programme.

Shortlisting. If there are more than five options at the end of this scoping stage, the secretariat shortlists a maximum of five options using quick procedures. As far as possible, this should be according to a simple, objective rule that is appropriate for the decision question, such as:

- Example 1. The final list of vaccines was generated by shortlisting the vaccines protecting against diseases with the greatest burden of disease in the country (measured in DALYs, data from the Institute for Health Metrics and Evaluation (IHME) Global Burden of Disease (GBD) database.

- **Example 2.** The final list of vaccines was generated by shortlisting all vaccines that meet the national cost-effectiveness threshold, as defined by the national health technology assessment (HTA) agency.

At this stage, it is important not to shortlist options using rules that may be disputed or considered subjective.

IMPORTANT

1.3.2 Options included within scope

This step records the final list of interventions that have been selected for comparison by the committee.

Include a description. For each option, it is advisable to include a concise and unambiguous description to ensure that the secretariat and all committee members have the same understanding. For example, when selecting a vaccine product, specify the number of doses per vial for each of the options. For recommending a new vaccine, specify the target population and whether the vaccine would be introduced nationally.

Explain the reason. It is important to document why the option has been selected, referring to the parameters and shortlisting rules defined in 1.3.1. Thorough documentation of decisions taken at each step of the process enhances legitimacy and credibility of the final recommendation and provides a written record to defend the final recommendation.

IMPORTANT

1.3.3 Options excluded from scope

It is highly recommended to document any options that will not be compared by the committee and explain why they have been excluded. This is especially important for any options that were identified through the scoping review but then were excluded from the final shortlist, as well as options that the final decision-maker may expect to see but which have not been included.

1.4 Participation

This step is completed by the secretariat.

PURPOSE:

- The secretariat identifies members of the recommendation committee or working group, in line with existing processes and policy bodies, and determines whether there are other important stakeholder perspectives to include in the recommendation process.
- The final recommendation depends on the value judgement of individuals on the committee and how they interpret the evidence. It is therefore important to ensure those included have the right perspectives and expertise.

ESSENTIAL TO COMPLETE:

- • Record members of the recommendation committee or working group (1.4.4).

COUNTRY ADAPTATION:

- If the decision-support framework will always be used by a standing committee in the country, such as the NITAG or ICC, parts 1.4.2 to 1.4.4 can be pre-filled. However, it is still recommended to discuss 1.4.1 when considering whether the decision question at hand requires additional perspectives or expertise to be included.
- In order to streamline this step over time, it is recommended to either identify an existing committee to use the decision-support framework, or develop a standard operating procedure for the formation of the recommendation committee, with appropriate conflict-of-interest management procedures.

1.4.1 Stakeholder identification

Since the recommendation ultimately depends on the members of the committee and stakeholders consulted during the recommendation process, it is worth considering the profile of stakeholders who should be engaged in making a good recommendation. At this stage it is recommended to consider the best stakeholders to address the decision question and not focus on members of a specific body or committee (this will be addressed in subsequent steps).

While a greater number of stakeholders increases the diversity of perspectives and expertise, too many stakeholders can impede or bias the recommendation. The following principles may be helpful in achieving a balance that includes all relevant stakeholders without overly prolonging or complicating the process.

- Information

  Determine if there are stakeholders with expertise or knowledge that will inform selection of the decision criteria, bring information that is not available in reports, and/or provide insight that would otherwise be missed when collecting and interpreting evidence.

- **Legitimacy**

  Consider which stakeholders will enhance credibility of the recommendation. These may be stakeholders that represent an important perspective, such as caregivers, nomads or indigenous groups, stakeholders with a given expertise, or representatives from relevant government departments or technical agencies.

- **Ownership**

  Consider which stakeholders will be responsible for implementing the recommendation, including budget holders, departments involved in planning and delivery, and health care staff. Engagement with such stakeholders can ensure that they are in agreement with, and understand the rationale for, the final recommendation.

Even if the recommendation committee is already fixed, it is strongly recommended to complete this step. If it is determined that the committee would benefit from additional insights or expertise, there can be other ways to engage the relevant stakeholders throughout the process, aside from representation on the committee itself (1.4.3).

1.4.2 Policy environment and organizational aspects

This step identifies where the decision question sits within the existing decision-making processes in the country. It may be that there is already a standing committee – such as the NITAG, ICC or EPI planning unit – that already has a mandate to address this type of decision question. It is also possible the secretariat may feel that the decision question warrants the formation of an ad hoc committee or working group.

Existing committee. If the decision question fits within the remit of an existing committee or working group, consider the rules around engaging external stakeholders in the recommendation process. It is likely that this can be found in the terms of reference of the committee. For example, it may be that the NITAG can invite external stakeholders to form part of a working group, but these stakeholders cannot vote on the final recommendation.

Ad hoc committee. If there is not an existing committee or working group that is well-placed to address the decision question, an ad hoc committee may be formed. If so, it is highly advisable to draw up terms of reference for the group, outlining the functions, duration, duties of members and the process for appointing members and the chair. In this instance, it is especially important to ensure that there is a conflict-of-interest management policy in place.

1.4.3 Mechanisms for participation

Relevant stakeholders can participate in the recommendation process as members of the committee, or through other means, such as consultation or by joining selected steps of the process. This step identifies how the stakeholders identified in 1.4.1 will be involved in the recommendation process, given the guidelines around stakeholder engagement identified in 1.4.2.

Existing committee. If there is an existing committee or working group making the recommendation:

- Review whether there are important stakeholders – as identified in 1.4.1 – missing from the make-up of the committee.
- Consider why and when input from these stakeholders is beneficial. For example, is specific expertise required for the full recommendation process, or only to inform selection of criteria, review of evidence or another step?
- Identify how best to engage the additional stakeholders, according to rules set out in the committee's terms of reference.

Ad hoc committee. If an ad hoc committee will be formed specifically for this recommendation:

- Consider whether all stakeholders identified in 1.4.1 will be included as part of the recommendation committee or engaged through other means.

IMPORTANT

1.4.4 Members of the recommendation committee

It is recommended for the committee to include six to fifteen members. If there are fewer than six people, there is a risk that there may be insufficient diversity of perspectives, while if there are more than fifteen, it can be difficult to attain consensus and ensure that all committee members share their perspective.

For transparency purposes, it is important to record the members of the recommendation committee. It is advisable to include any non-voting members, since they will influence discussions even if they cannot participate in the final vote. In the decision-support tool, there is space to note whether a member has voting rights or not.

1.5 Priority-setting process

This step is completed by the secretariat.

PURPOSE:

- The secretariat sets out how the recommendation process will be conducted, in terms of group techniques, methods for evidence interpretation and operational procedures.
- The final part of this step is to generate a briefing document for the committee, including relevant information from steps 1.1 to 1.5.

ESSENTIAL TO COMPLETE:

- Decide whether the committee will consider an analysis of "total score" per option to guide their discussion of the evidence (quantitative MCDA) (1.5.1).

COUNTRY ADAPTATION:

- While the secretariat may trial different MCDA approaches to identify which works best in your setting, it is recommended to identify one approach to consistently apply across recommendations (1.5.1).
- It is anticipated that operational procedures (1.5.2) and group techniques (1.5.3) will remain constant across recommendations.
- If a template briefing document for the recommendation committee does not already exist, it is recommended to adapt the template in 1.5.4 to create a country-specific template that can be used across all recommendations.

IMPORTANT

1.5.1 Multi-criteria decision analysis (MCDA) methods

In order to develop a recommendation using the CAPACITI decision-support framework, options are compared according to a common set of criteria along with discussion of evidence quality. However, there are different methods by which this can be done. In this step, the secretariat decides which approach to use, based on members' knowledge of the committee and the decision question.

While it may be helpful to trial different approaches the first few times using the framework, it is recommended to identify an approach to consistently follow across recommendations. This will enable stakeholders to become familiar with the approach and enable the secretariat to tailor the approach to the country context.

1.5 Priority-setting process

Background: overview of MCDA methods

The framework is based on multi-criteria decision analysis (MCDA) which provides a structured way to incorporate multiple sources of evidence and stakeholder perspectives. In strict MCDA methodology, one of three approaches – quantitative, qualitative or rule-based – is followed.

- **Quantitative MCDA.** Each criterion is assigned a weight and, after evidence collection, each option is assigned a score per criterion. A total score is calculated per option by combining the weights and scores, and a sensitivity analysis is conducted on the total scores to assess data uncertainty in weights and scores. To come to a recommendation, the committee deliberates on the rank order of the total score of the options.
- **Qualitative MCDA**. Criteria are not assigned weights and no scores are assigned. Instead, the committee comes to a judgement by deliberating the performance of each option according to the defined criteria.
- **Rule-based MCDA.** Instead of considering all criteria simultaneously, the committee specifies the priority order in which criteria will be considered, with the most important criterion considered first.

It is important to note that, in the interests of practicality, it is possible to follow a hybrid approach in the CAPACITI decision-support framework that combines elements of two or even all three types of MCDA.

Selecting the most suitable MCDA approach

Any type of MCDA method or a hybrid approach may be followed in the tool. All approaches have their advantages and limitations. It is therefore important for the secretariat to justify its reason for selecting a given approach and consider ways in which to address limitations of the approach. The table below summarizes the main differences between the three types of MCDA and the recommended approach in the tool.

The steps included in each MCDA method are indicated by a tick (✓). Steps that are not included in a given MCDA method are indicated by a cross (✕).

		MCDA methods			CAPACITI decision-support framework
		Quanti-tative	Qualit-ative	Rule-based	
1) Objectives					
2) Decision criteria	Select criteria (2.1)	✓	✓	✓	**Mandatory** The committee may use an existing criteria list or select criteria de novo.
	Assign weights to criteria (2.2)	✓	✕	✕	**Recommended** Discussing weights can promote a shared understanding of which criteria are most important across the committee.
	Set a scoring scale (2.3.1)	✓	✕	May use threshold	**Recommended**

					Agreeing to the scale by which to assess the options can remove bias and enhance consistency in interpreting the evidence.
	Define rules (2.3.2)	✗	✗	✓	**Optional** It is possible to state whether certain criteria will be considered before/after the total scores in quantitative MCDA (for example, cost-effectiveness).
3) Evidence assessment					
4) Appraisal	Assign scores (4.1)	✓	✗	✗	**Recommended** Facilitates reporting of the recommendation and aligns with the GRADE EtR framework.
	Calculate total scores (4.2)	✓	✗	✗	**Optional** (for quantitative MCDA only)
	Sensitivity analysis (4.2)	✓	✗	✗	**Optional** (for quantitative MCDA only)
	Deliberation across criteria (4.2)	From total score	From summary matrix	In order stated by rules	For all approaches, it is strongly recommended to refer to the evidence statements (3.2) during appraisal.
5) Recommendation					

It may be helpful to decide whether to follow a more discussion-based approach to interpret the evidence, or whether an analysis of total score per option (quantitative MCDA) would support committee discussions. There is space in the decision-support tool to record whether a quantitative MCDA approach is being followed.

You may wish to consider the following points.

- **Balance between transparency and thorough consideration of the evidence**

  Quantitative approach. There is greater transparency in how criteria and evidence lead to a recommendation, but the committee may overly focus on the numbers (total scores) as opposed to the evidence. Thus, it is important for the facilitator to ensure the committee refers to evidence statements as well as total scores in the discussions.

  Discussion-based approach. It is important that there is thorough documentation of discussions leading to the recommendation for transparency. This approach may be more appropriate if a detailed evaluation is needed because of complex evidence and/or conflicting stakeholder interest.

- **Number of options and committee power dynamics**

  Quantitative approach. There is a lower cognitive burden on committee members and discussions are less likely to be dominated by vocal committee members. A quantitative approach may be more suitable if a large number of options is being compared.

Discussion-based approach. Group techniques can be used to reduce domination. Setting up a scoring scale can reduce cognitive burden on the committee by consistently assessing and documenting performance of the options.

- Inclusion of economic criteria

  Quantitative approach. It is recommended to consider "constraints" criteria separately, either before or after discussing total scores.
  Discussion-based approach. It is less important to select independent criteria than in quantitative MCDA. With this approach, criteria that reflect constraints, such as cold chain capacity, budget or cost-effectiveness thresholds, can be considered alongside criteria that reflect values, such as health benefit, equitable coverage and ease of administration.

If the secretariat decides instead to follow a discussion-based approach, it can then discuss whether it will follow the recommended approach in the tool, a strict qualitative approach or a strict rules-based approach. It is strongly recommended to document the rationale for selecting a given approach, and to evaluate whether the approach was fit-for-purpose at the end of the recommendation process presented in 5.4-Audit, monitoring and evaluation.

1.5.2 Meetings and operational procedures

This step outlines the roles of various stakeholders and how the recommendation process will be conducted in terms of in-person or virtual meetings, or other communication forums.

The decision-support framework identifies three primary groups and their roles.

- Secretariat. The secretariat is responsible for defining the decision question, coordinating the recommendation process, documenting discussions and outcomes at each step by completing the decision-support tool, and writing the final report.
- Committee. The committee comprises a group of stakeholders responsible for making the recommendation. With support from the secretariat, the committee reviews the decision criteria for the recommendation and interpret the evidence to come to a recommendation.
- Technical team. The technical team is responsible for collecting, analysing and reporting evidence. It may or may not be composed of members of the secretariat and/or committee.

Discuss any changes to the roles of the secretariat, committee and technical team. This step can be skipped if there are well-established processes in the country.

It is recommended, where possible, to conduct steps involving the committee via a facilitated in-person workshop, to allow the committee to fully consider important aspects of the recommendation. However, in many situations, this is not possible due to budget or time limitations. It is advisable that the committee consider which steps will be conducted in-person and which are best conducted virtually.

Whether conducted in person or virtually, it is strongly recommended that an impartial facilitator lead discussions (see Box 3).

BOX 3: Role of the facilitator

It is strongly recommended to have an impartial facilitator lead group discussions. The role of the facilitator is to encourage open dialogue and input from all participants, to steer the conversation so that the committee stays focused on the recommendation, and to provide reassurance through conversations with opposing viewpoints or significant uncertainty. While it is possible for a committee chair to play the role of the facilitator, it is essential that the facilitator remain neutral throughout discussions.
Although the facilitator requires sufficient subject knowledge to follow discussions, it is equally important for the facilitator to be calm, good at listening to and understanding diverse viewpoints, and able to moderate group dynamics by, for example, dealing with dominant members or protecting minority viewpoints. To be able to lead group discussions and intervene when necessary, the facilitator should ideally have respect from the group.

1.5.3 Group techniques

To ensure that the group functions productively, it can be helpful to set out ways of working for the group, if they do not already exist. You may wish to consider the following points:

- How will the group come to an agreement? Is consensus needed or will voting be used?
- How will the facilitator ensure equal contribution from all members of the group? It can be helpful, for example, for all members to give their perspective before starting the discussion, or for all members to write down and present their perspective.
- How will the secretariat ensure that all members of the group have sufficient background knowledge to fully contribute? Do specific group members require additional briefing or background to come up to speed on the subject?

1.5.4 Briefing document for the committee

It is recommended to provide committee members with a brief that outlines the decision question and background, scope and timelines. In the decision-support tool, it is possible to export text from Section 1 into a Word document, which can be modified or pasted into an existing template for distribution to committee members.

To save a template report to your computer, click on the button in 1.5.4 of the CAPACITI decision-support tool (see below). Note that text in the Word document is automatically populated from the information you have entered into the tool. If parts of the tool have been skipped, there will be blank spaces in the document.

1.5.4 Briefing document for the committee

It is recommended to summarise the recommendation objectives and context in a briefing document for committee members.

Template briefing document for the committee

EPI	Expanded Programme on Immunization
HPV	Human Papillomavirus
HTA	Health Technology Assessment
ICC	Inter-agency Coordinating Committee
MCDA	Multi-criteria decision analysis
NITAG	National immunization technical advisory group
WHO SAGE	WHO Strategic Advisory Group of Experts on immunization

1.4 Participation

Fung A. Varieties of Participation in Complex Governance. Public Administration Review. 2006;66(s1):66-75.

Greer S, Wismar M, Figueras J. Strengthening health governance. Maidenhead: Open University Press; 2016.

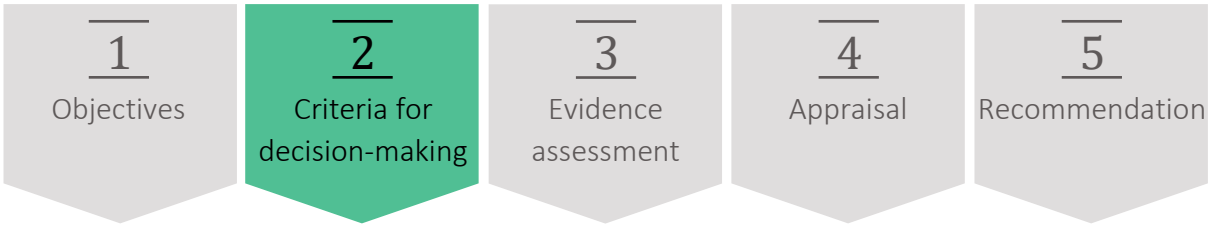
Phillips LD and Phillips MC. Facilitated Work Groups: Theory and Practice. The Journal of the Operational Research Society, Vol. 44, No. 6, pp. 533-549.

1.5 Priority-setting process

Baltussen R, Marsh K, Thokala P, Diaby V, Castro H, Cleemput I et al. Multicriteria Decision Analysis to Support Health Technology Assessment Agencies: Benefits, Limitations, and the Way Forward. Value in Health. 2019;22(11):1283-1288.

Phillips LD and Phillips MC. Facilitated Work Groups: Theory and Practice. The Journal of the Operational Research Society, Vol. 44, No. 6, pp. 533-549.

2. CRITERIA FOR DECISION-MAKING



The role of this section is to lay out the principles for comparing and evaluating each of the options, according to local values and specific requirements of the decision question. In this section, the committee will:

- identify (as a group) the criteria for decision-making, either de novo or by reviewing an existing set of criteria;
- assign weights to reflect the relative importance of each criterion;
- determine how options will be assessed against the criteria.

IN THIS SECTION

2.1 Criteria

 This step is completed by the committee.

PURPOSE:

- The committee refines the list of criteria that will be used to assess the different options in order to arrive at a recommendation.
- Depending on the country context and decision question, this may involve reviewing an existing list of criteria or developing a list of criteria specifically for this decision question.

ESSENTIAL TO COMPLETE:

- Document the final list of criteria (2.1.2).

COUNTRY ADAPTATION:

- If there is already an established list of criteria for this type of decision question, this can be used. In countries without an established set of criteria, it is recommended to develop a standardized set of criteria for use across different recommendations.

2.1.1 Process for criteria selection

The process that the committee will use to finalize the list of criteria for the recommendation will depend on a number of factors, such as:

- Is there already an established set of criteria for this type of decision question in the country? For example, many NITAGs and health technology assessment (HTA) agencies have established lists of criteria. In this case, the committee will review whether the criteria are appropriate to the decision question and identify whether any modifications need to be made.
- Is the decision question similar to other decision questions that the committee typically addresses? If the question is similar to other decision questions, it is recommended to develop a standard set of criteria to apply across different recommendations. However, if the decision question is very specialized, it is instead advisable to develop a set of criteria specific to the decision question.
- Is the importance of stakeholder engagement during the process sufficiently recognized? For high-profile decision questions, it may be important to increase buy-in from key stakeholders by engaging them in the criteria selection process. This may warrant developing a set of criteria specific to the decision question.

2.1 Criteria

Decide which of the following approaches the committee will follow for criteria selection.

1. Review and adapt an existing set of criteria. The criteria may be country-specific or from global-level guidance.
2. Develop a set of criteria de novo that is specific to this decision question.

Establish a set of criteria to apply to this recommendation and all future recommendations for this type of decision question. It can include, for example, product choice or new vaccine introduction.

TIP: deciding which approach to take for criteria selection

INSTITUTIONALIZED APPROACH

In general, it is recommended to use (or establish) a set of criteria that is consistently applied across recommendations. Doing so will give the flexibility to tailor the set of criteria to the decision question if needed.

- **It will increase the legitimacy of recommendations**, because the process to select criteria is separated from the process to make the recommendation. It also decreases the risk that criteria are selected (whether consciously or not) to favour a certain outcome.
- **It will improve consistency across recommendations**, especially if care is taken to align immunization decision criteria with any criteria used for health technology assessments (HTAs) and/or benefits package selection for UHC in the country.
- **It will streamline the process and reduce time requirements**, since the committee only reviews and adapts the list of criteria, instead of having to draw up a new list of criteria each time.

However, occasionally a standard set of criteria may not be appropriate if the decision question is atypical of the type of decision question normally addressed.

To follow this approach, see the following items.

- ❖ *"Using an existing set of criteria" (page 39), if there is already an established set of criteria that is used for immunization or health sector decisions in the country.*
- ❖ *"Establishing a set of criteria for use across recommendations" (page 41), if no set of criteria for this type of decision question exists in the country.*

ONE-OFF APPROACH

In certain situations, the committee may wish to develop a set of criteria specifically for a single recommendation.

- **It will require more time and may be susceptible to bias.**
- **It will offer greater flexibility to the decision question** and can increase stakeholder ownership of the recommendation.

This approach is only recommended for high priority questions in which stakeholder buy-in is critical, or for specialized questions that cannot be addressed using the existing set of criteria. This approach may also be followed in the short-term while a standardized set of criteria is being established in the country.

To follow this approach, see the following items.

- ❖ *"Using an existing set of criteria" (page 39), if a generic global set of criteria will be adapted.*
- ❖ *"Developing a set of criteria specific to the decision question" (page 39), if you wish to develop a list of criteria de novo with the committee.*

Regardless of the approach taken, it is strongly advised to ensure that the criteria adhere to the best practice checklist outlined in Box 4. It can also be beneficial, for purposes of transparency, to explain the reason for following a certain approach, particularly if the committee decided against using an established set of criteria.

Using an existing set of criteria

There are many potential sources of criteria. Depending on the country, there may be an established list of decision criteria used by the NITAG or HTA agency.

Before using an existing set of criteria, it is recommended to review the following requirements:

- Are the criteria suitable for the decision question?
- Are the criteria suitable for your country context? In particular, consider whether the criteria reflect the strategic priorities of the immunization programme and any programme priorities identified in the programme review.
- Do the criteria adhere to the best practice checklist in Box 4?

You may wish to adapt the set of criteria, if necessary to meet these three requirements.

Developing a set of criteria specific to the decision question (one-off approach)

The points below outline a process that can be used to jointly develop a set of criteria as a group. A benefit of actively engaging all committee members in the process is that everyone understands the meaning of each criterion and why it is important. If the input from certain stakeholders outside of the committee is very important, you may wish to involve them in the criteria selection stage.

1) Develop a complete list of criteria

   It is recommended to ensure all participants put forward criteria that they think are important to address the decision question. This will give the group a holistic set of criteria that covers all perspectives and expertise in the room. At this stage, there is no limit on the maximum number of criteria.

- Ask all participants to put forward the criteria that they think are important for making this specific recommendation. This can either be through writing one criterion per post-it note, or by asking each participant to write down a list of criteria individually and writing all responses on a flipchart.
- When participants share their list of criteria, ask them to explain what they mean by each criterion. For example, "financial sustainability" may mean budget impact analysis to one participant, but guaranteed pricing agreement to another.
- Encourage participants to focus on criteria that will discriminate between the options. For example, while safety is a very important aspect, if all options being compared already have received WHO pre-qualification, it may not be essential to include incidence of adverse events following immunization (AEFI) as a criterion.

2) Group the criteria

Once all participants have put forward criteria, the group synthesises them into a comprehensive list.

- Group similar criteria together. Ensure that all committee members have the same understanding of each criterion. To ensure there is a common understanding in the group, it may be helpful to jot down a brief definition or unit of measurement for the criteria.
- Examine the list of criteria. Identify any criteria that describe the options instead of emphasizing what is important to the committee. For example, "wastage rate" is ambiguous – leaving open whether it is important because of financial considerations, cold chain constraints, supply forecasting, health worker reluctance to open vials, and/or other reasons. Thus it is important to phrase all criteria to reflect what is important to the committee (see Box 4).
- Remove any overlapping options. Make sure that they truly are overlapping rather than a matter of two committee members expressing different ideas with the same phrase.
- Remove any criteria that the committee already knows will not discriminate between the options. For example, if it is known that there is no evidence suggesting significant difference in effectiveness between the options, effectiveness can be removed as a criterion.
- View the list of remaining criteria as a whole. Discuss as a group whether all important elements for the recommendation have been included, or whether major considerations are missing.

3) Refine the list of criteria

Before finalizing the criteria, it is advisable to ensure that they follow best practices (Box 4).

- Review the criteria. Are they all unique, meaning there is no double counting? And, are they all independent, meaning that the importance of one criterion does not affect how the committee will judge the importance of another?
- Rephrase all criteria so that they are consistently phrased in terms of gains or losses. This will reduce the risk of framing bias (2.2-Weights).

4) Finalize the list of criteria

Choose a maximum of eight criteria. As a group, it is recommended to remove the least important criteria, and to document why they were removed (2.1.3).

Establishing a set of criteria for use across recommendations (institutionalized approach)

The following steps outline a process that can be used to select a set of criteria for repeated use across multiple recommendations in a country. It is important to note that the points below are not prescriptive and can be modified as needed.

1) Articulate the scope

Since the final set of criteria will be applied across a range of decision questions, it is important to define the scope in terms of which types of decision questions this set of criteria is intended to address. For example, will the criteria be used for new vaccine introduction, product selection, or all immunization policy and programmatic questions?

2) Identify whether there is already a set of criteria in the health programme that is fit-for-purpose

In many countries, a national HTA agency, or the committee that selects the products and services included within UHC, will have a defined set of criteria for decision-making. It may be helpful to review such a list (if it exists) and judge whether it is suitable for immunization.

- More information on HTA in your country can be found on the Decide Health Decision Hub at www.DecideHealth.world.

3) Identify the relevant stakeholders to engage

The set of criteria will ultimately depend on the value judgement of the stakeholders involved and the factors that are important to them. For example, it is likely that a clinician will place more emphasis on health outcomes, a logistician will be more concerned with supply issues, and a budget or planning representative will consider economic impact and financial sustainability.

- Follow the principles outlined in 1.4.1-Participation to identify a set of stakeholders to establish the set of criteria.

4) Map strategic goals of the immunization programme

Decision-making in the immunization programme should ultimately support the country in achieving its health sector, and immunization programme goals and targets. It is therefore important for the set of criteria to reflect national strategic goals.

- With all relevant stakeholders, use the national immunization strategy and national health sector plans to identify 3–4 overarching goals. These will act as the overarching domains for the criteria selected.

5) Identify criteria based on the strategic goals

At this stage, the stakeholders come up with a proposed set of criteria, ensuring that they are appropriate to the scope while also contributing to the 3–4 goals.

- Refer to the scope outlined above in item 1. Identify 3–4 example decision questions that are included within this scope, making the examples as diverse as possible. These could be illustrative examples or reflect decision questions that have already been addressed in the country.
- Generate a list of criteria that you think should address the decision question, mapping each of the criteria to one of the goals identified above in item 4. Do this for each of the example decision questions. You may wish to split the stakeholders into groups for this exercise, with each group working on one of the decision questions.
- Review the lists of criteria. Are there criteria that are common across all decision questions? If so, they can be grouped into "generic" criteria that will be relevant for all decision questions and "contextual" criteria, which may or may not be relevant for the decision question.
- Consider the full set of generic and contextual criteria. Ensure that they meet the conditions set out in the best practice checklist (Box 4).

6) Continue to evaluate and revise the set of criteria

Normally, an established set of criteria should be reviewed and amended every 3 to 5 years. However, during the first few uses, it can be beneficial for the secretariat to evaluate and review the set of criteria. Over time, it is also recommended to define the extent to which criteria can be modified by the committee to fit a specific decision question.

BOX 4: BEST PRACTICE CHECKLIST FOR CRITERIA

It is highly recommended to ensure that the final list of criteria adheres to the following principles.

1) **Values based**

Criteria should reflect what is important to the committee, as opposed to describing the differences between options. This is because the criteria articulate a set of *values* by which the recommendation will be made.

To ensure that criteria are values-based, it can be helpful to ask, for each criterion: Why is this criterion important?

Example: "Number of doses per vial"
This is a weak criterion, as it does not explain what is important to the committee. Are the committee members concerned about doses per vial because:

- They wish to increase coverage rates?
- There is limited cold chain capacity?
- They are concerned about procurement costs with high wastage?
- They want to reduce contamination risk, as the multi-dose vial policy is often not followed?

In this example, the underlying reason(s) should be listed as the criteria – presented, for example, as vaccine coverage, cold chain burden, budget impact and contamination risk. If more than one reason is identified, each reason should be listed as a separate criterion.

2) **Relevant to the decision question**

Each criterion should differentiate between the options. Otherwise, the criterion will increase evidence collection requirements without influencing the final recommendation.

For each criterion, it can be helpful to discuss: Will this criterion discriminate between the options?

Examples:

- "WHO pre-qualification", if all of the options being compared are already WHO pre-qualified
- "Vaccine efficacy", if WHO SAGE guidelines state that there is no evidence that there is significant difference in efficacy between available products

3) **Complete**

The final set of criteria should cover all important considerations for the recommendation, including those that the final decision-maker may expect to see addressed.

It may be helpful to group similar criteria, in order to discuss: Are any important factors missing?

4) **Unique**

Care should be taken to make sure that criteria do not overlap, to avoid double-counting. Otherwise one or more factors may be playing a greater role in the final recommendation than is indicated by the weights.

Examples:

- "Herd immunity" and "effectiveness" are not unique, since herd immunity is included within vaccine effectiveness. The committee could either remove the criterion "herd immunity" or change "effectiveness" to "efficacy".
- "Budget impact" and "cost-effectiveness" both include procurement and delivery costs. If cost-effectiveness is included, it is often considered separately to other criteria (this is covered in 2.3-Rules).

Important note: It is possible to incorporate criteria that violate the unique or independent rules. However, these criteria should be considered separately for quantitative MCDA. This is covered in more detail in 2.2-Weights and 2.3-Rules.

5) Independent

As far as possible, the committee should try to ensure that there is no interdependence between the criteria. It may be helpful for the committee to consider: Is the importance of any criteria dependent on other criteria?

Example: vaccine efficacy/burden of disease

These criteria are independent, since many people would accept a lower vaccine efficacy for protection against a high burden disease. Instead, these criteria could be combined into a measure such as "Deaths averted by vaccination".

6) Phrased to avoid framing bias

The wording of criteria, particularly whether phrased in a positive or negative manner, can influence the relative importance that people assign to them. It is important to ensure that criteria are consistently phrased according to either gains or losses, to avoid bias in the weighting step.

Example: deaths averted/lives saved

Most people are risk averse, so place greater weight (importance) on "deaths averted" than "lives saved", even though the outcome of both is the same.

IMPORTANT

1.1.2 Recording the list of criteria and outcome measures

The committee should seek to ensure that the criteria capture all important considerations. However, as the number of criteria increases, so do evidence collection requirements, while at the same time, the contribution of each criterion to the final recommendation decreases. This can make it harder for the committee to keep track of all criteria during discussions. It is therefore recommended to select a maximum of eight criteria.

It is important to document the final list of criteria that have been selected, together with the rationale (justification) for why they are important. At this stage, it is beneficial for the committee to agree on the outcome measure for each criterion.

To decide on the outcome measure, it may be helpful to think about the data that you would use to measure the criterion. For example:

- **budget impact –** total procurement and delivery costs over 5 years (US$)
- **ease of administration –** expert opinion based on product profile
- **safety –** incidence of severe adverse events following immunization (AEFI)
- **fit with existing schedule –** number and timing of doses

If the committee is unsure if the data exists for the preferred outcome measure, it is possible to note a secondary outcome measure, which will only be used if there are no available data for the primary outcome measure.

The example below is a screenshot from the table in the CAPACITI decision-support tool:

The outcome measure (indicator) will determine the data collection and analysis needed to measure the performance of options against this criterion.

Criterion	Justification	1º outcome measure (indicator)	2º outcome measure (indicator)
Local manufacture	Domestically produced vaccines are cheaper and better supply security	Whether a domestically produced vaccine exists with sufficient supply	N/A
Benefit of vaccination	To maximise public health impact	QALY gained	DALY averted

The justification explains why this criterion is considered important by the committee.

A secondary outcome measure can be included if the committee thinks that there may be insufficient evidence for the primary outcome measure.

2.1.3 Documenting excluded criteria/outcome measures

It can be important to keep a record of any criteria that have not been selected by the committee, in order to defend the rationale for the final recommendation.

If the committee has developed a set of criteria specifically for this decision question, record any criteria that were:

- **Discussed by the committee, but not included in the final list.** Include the reason why the committee decided it was not relevant for the question.

  Example 1: "Political will" was considered as a factor that would increase the likelihood of uptake of the recommendation, but it was excluded as the role of the NITAG is to make an independent recommendation to the Ministry of Health.

  Example 2: "Political will" was considered as a necessary factor for implementation, but it was excluded on the basis that it cannot be measured subjectively by the committee.

- **Removed from the final list to reduce the number of criteria**. Include the reason why these criteria were not considered as important as the final criteria.

  Example 3: "Ease of administration" was initially included but was removed to reduce the list to eight criteria, as it was felt to be less important than the other criteria included in the final list.

- **Not included, even though the final decision-maker would expect to see this criterion in the evaluation.**

  Example 4: "Vaccine efficacy" was not included, as the WHO SAGE position paper states that there is no evidence to suggest a difference in the efficacy of WHO pre-qualified rotavirus vaccine products.

If the committee is using an existing list of criteria, document whether any criteria on the list will not be used for this specific recommendation and why. For example, certain criteria in the list may have been removed because they do not discriminate between options or are not applicable for this decision question.

2.2 Weights

This step is completed by the committee.

PURPOSE:

- The committee comes to an agreement on whether certain criteria are more important in contributing to the final recommendation, by assigning weights to criteria.

ESSENTIAL TO COMPLETE:

- Assign a weight to each criterion. If all criteria are judged to be equally important, the same weight can be assigned to each criterion.

COUNTRY ADAPTATION:

- Certain countries may wish to define a standardized weight to each criterion, which will remain constant across recommendations. In this case, it is highly recommended that the committee review the weights to ensure that they are applicable to this specific decision question before proceeding to 2.3.

IMPORTANT

The committee should discuss the relative importance of the criteria and assign a weight to each. Although weights are not assigned in strict qualitative MCDA, it can be beneficial to complete this step, in order for the committee members to understand each other's perspective in terms of which criteria are more important than others.

The default scale in the CAPACITI decision-support tool is from 1 (least important) to 5 (most important). Any weighting scale can be used, as long as higher weights indicate greater importance. The group can either assign weights through simple discussion, or use established methods to assign weights (refer to the ISPOR MCDA Emerging Good Practices Task Force, report 2, for further details).

While it is strongly recommended for the committee to come to an agreement on weights, it is also possible to record an alternate weight.

IMPORTANT NOTE: in the case that any of the criteria are interdependent or reflect fixed capacity (constraints)

If quantitative MCDA is being used, it is very important to make sure that inter-dependent criteria and criteria that relate to fixed capacity (referred to as "constraints") are considered separately from other criteria.

Constraints – criteria related to fixed capacity – may include: budget, cold chain capacity, cost-effectiveness threshold and human resources.

2.2 Weights

If you are following a quantitative MCDA approach, assign all constraints a weight of zero (see 1.5.1). This means that they will not contribute to the total score, and can be considered either before or after the committee discusses the total score before coming to a recommendation.

The example below is a screenshot from the table in the CAPACITI decision-support tool.

Criterion	Weight	Justification	Alternate weight (optional)
Local manufacture	2	Local manufacture is less important than public health impact	1
Benefit of vaccination	5	The main goal of vaccination is to improve health	

If weights are being used, it is encouraged to use the full range of weights from 1 to 5 (there may be a tendency not to assign lower weights).

The justification can be brief. It is most important to capture the rationale for weights if there was disagreement, so that the committee does not revisit the weighting again in the appraisal step.

Only complete this column if a disagreement could not be resolved.

2.3 Rules for interpreting evidence

This step is completed by the committee.

PURPOSE:

- The committee decides how the evidence will be assessed against each of the criteria.
- The scoring scale serves as a reference for the committee to evaluate each of the options. This ensures that each option is evaluated in the same way, while decision rules determine how criteria will be considered.

ESSENTIAL TO COMPLETE:

- To improve consistency and reduce bias in interpreting the evidence, it is highly recommended to define the scoring scale in 2.3.1.
- If rules-based MCDA has been selected, or if the committee is following quantitative MCDA and has chosen interdependent on "constraints" (fixed capacity) criteria, it is necessary to explain the sequence for considering criteria in 2.3.2.

COUNTRY ADAPTATION:

- If the country has a fixed set of criteria, it may be beneficial to define a standardized scoring scale for use across recommendations.
- Similarly, decision rules – the process for dealing with "constraints" in quantitative MCDA – are expected to remain fixed across recommendations.

IMPORTANT

2.3.1 Scoring scale

Since each criterion is measured with a different unit, a scoring scale standardizes interpretation of the evidence by putting all criteria on a common scale. Using the scale enables a comparison across criteria.

Although scores are normally only assigned for quantitative MCDA, it is highly recommended to set up a scoring scale in the CAPACITI decision-support framework, regardless of the approach being followed. Scoring can support the committee deliberations and improve consistency in committee interpretation of the evidence. It is also consistent with the GRADE evidence to recommendation (EtR) framework, commonly used by NITAGs for yes/no decisions. In the CAPACITI decision-support framework, the scoring scale is set up before evidence collection, in order to reduce bias.

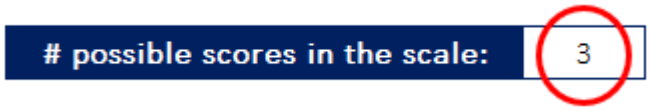
There are three components to this step:

- deciding the range of the scale
- assigning labels to the scale
- defining the scale for each criterion.

2.3 Rules for interpreting evidence

Deciding the range of the scoring scale

The range of the scoring scale is the number of scores that can be assigned. For example, a scoring scale "Bad", "Average", "Good" has a range of 3. In the tool, the range can be modified in the following cell:



It may be helpful to consider the following points when deciding on the range of the scale.

- **What level of detail does the scale need to capture between options?**
  If the options are expected to be very similar, a greater level of precision (greater range) will allow better discrimination between options. If the scores will be used to give the committee a sense of whether there are major differences between options, a smaller range may be more appropriate.
- **What is the appropriate balance between weights and scores?**
  For quantitative MCDA, a smaller scoring scale range will increase the contribution of weights to the total score. Conversely, a greater scoring scale range will increase the contribution of scores to the total score per option.

Assigning labels to the scoring scale

The labels of the scoring scale can be numerical (see Example 1) or descriptive (see Example 2). You can either add labels in the decision-support tool or leave the boxes blank. In the latter case, the tool will automatically assign a numerical scale.

IMPORTANT NOTE: The tool is configured so that a lower score denotes poorer performance

Example 1: descriptive scale

# possible scores in the scale:	4

1	2	3	4
Poor	Average	Good	Very good

Example 2: numerical scale

# possible scores in the scale:	6

1	2	3	4	5	6
0	1	2	3	4	5

2.3 Rules for interpreting evidence

Defining the scoring scale for each criterion

Once the common scale has been decided, the committee defines the scoring scale for each criterion. There is no correct way to set up a scoring scale, and the definition of the scale should depend on the expert judgement of the committee.

It is recommended to use the full range of the scale for each criterion. For example, if the general scale is from 0 to 5, it is not advisable to define the scale for one of the criteria from 1 to 3. Otherwise, the committee is affecting the importance of the criterion, which should be captured in the weights and not the score.

The table below outlines some different ways of defining the scoring scale, with examples. These examples are illustrative and do not show a correct way to set up the scale.

Note that different scales are used in the examples for illustrative purposes, but the scale should stay constant across criteria.

2.3 Rules for interpreting evidence

Example	Criterion	Outcome	Scale
1) Linear scale	Financial sustainability	# years fixed pricing agreement	**Poor:** 1 year or less **Average:** 2 years **Good:** 3 years **Very good:** 4 years or more
2) Varied intervals	Protection against disease	Vaccine efficacy	**0:** <50% efficacy **1:** 50–80% efficacy **2** 80–95% efficacy **3:** >95% efficacy
3) Proportional to goals (in this *example, averting deaths from VPD)*	Lives saved	# deaths averted per year	Proportional to the total disease burden for HPV, rotavirus and PCV **Low:** <20% deaths averted **Medium:** 20–40% deaths averted **High:** 40–60% deaths averted **Very high:** >80% deaths averted
4) Proportional to capacity/ constraints	Budget impact	Total vaccine procurement cost	**Unacceptable:** more than 10% increase in EPI procurement budget required **Acceptable:** exceeds current EPI procurement budget by less than 10% **Preferred:** no change in budget required
5) Dichotomous criteria	Religious acceptance	Halal/not halal	**1:** not halal **5:** halal *In this example, the range of the scale is from 1 to 5.*
6) Combination scales (Example 1)	Protection against prevalent strains in the country	# circulating strains covered by the vaccine	The score will be calculated as a composite sum of the strains covered by the vaccine, with **2 points** if the vaccine protects against strain A (over 50% prevalence in our country), **1 point** each for protection against strains B/C/D (each has 10–15% prevalence), **0 points** for all other strains (less than 4% prevalence). *For example, a vaccine protecting against strains A, C, F, G receives a score of **3** (2+1+0+0)*
7) Combination scales (example 2)	Supply availability	Local manufacture and available supply	**1:** Foreign manufacturer and no guaranteed supply for the next 2 years **3:** Either local manufacture or guaranteed supply for the next 2 years **5:** Local manufacturers can guarantee supply for the next 2 years
8) Judgement-based scale	Acceptability to health workers	Complexity to store at the health facility and administer	**Poor:** product features that make the existing product more difficult to store and administer **Average:** similar complexity to the existing product

			Good: significant improvements in ease of storing and administering compared with existing product

2.3.2 Decision rules and ordering criteria (optional)

2.3.1 explains the rules for individual criteria, whereas **2.3.2** explains the rules that will be applied across criteria.

The purpose of this step is to lay out any rules that will be applied when the committee compares the options across all criteria.

It is only necessary to complete if the committee is following either rules-based MCDA or quantitative MCDA, and if it has selected criteria that are either interdependent or reflect constraints, such as the budget or cold chain capacity.

For rules-based MCDA, record any thresholds that will be applied, such as a requirement to meet a minimum cost-effectiveness threshold. Also, record any rules in terms of the sequence for considering criteria.

- **Example: F**irst, exclude any options that do not meet the cost-effectiveness threshold of US$ 20 000. Options will then be compared according to budget impact, and the top ranking options will be compared according to the remaining criteria to make a recommendation.

For quantitative MCDA, identify any criteria that are not independent and/or unique, such as cost-effectiveness, or any criteria that represent constraints, such as fixed capacity. Specify whether these criteria will be considered before or after considering other criteria.

- **Example 1. S**ince the budget is fixed, budget impact will be considered before other criteria, to shortlist affordable options for further consideration.
- **Example 2.** Budget impact will be considered after other criteria, so that the committee can highlight if there is insufficient budget for the best performing.

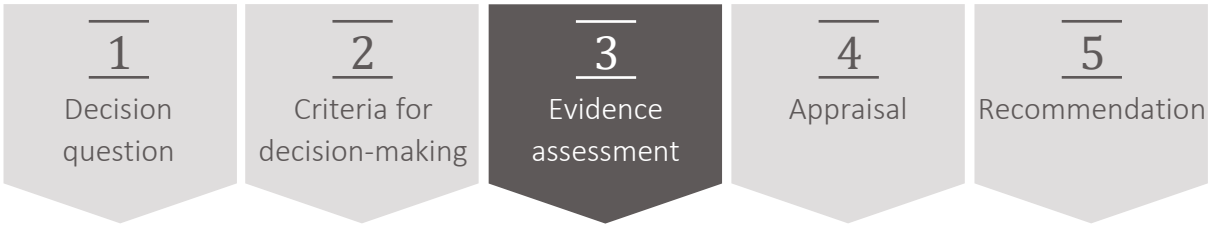
DALY	Disability adjusted life years
EPI	Expanded programme on immunization
HTA	Health technology assessment
NITAG	National immunization technical advisory group
QALY	Quality adjusted life years
UHC	Universal health coverage
VPD	Vaccine preventable disease

2.1 Criteria

Evidence-informed deliberative processes. A practical guide for HTA agencies to enhance legitimate decision-making. Version 1.0. Nijmegen: Radboud university medical center; 2019.

Multiple Criteria Decision Analysis for Health Care Decision Making—Emerging Good Practices: Report 2 of the ISPOR MCDA Emerging Good Practices Task Force. Value in Health. 2016;19(2):125-137.

3. EVIDENCE ASSESSMENT



The role of this section is to collect, synthesise and assess the quality of available evidence for the committee. For this section, a technical team, which may or may not comprise members of the secretariat and/or committee, will:

- document methods for data collection and analysis;
- synthesize multiple evidence sources to generate one or more evidence statements per criterion;
- summarize the performance of each option, with an assessment of evidence quality, in a performance matrix.

IN THIS SECTION

3.1 Evidence collection

This step is completed by the technical team.

PURPOSE:

The technical team collects and analyses available data for all options according to each of the criteria defined in 2.1.

COUNTRY ADAPTATION:

Certain countries may already have national guidelines for evidence and interpretation, either for the NITAG or as defined by a national health technology assessment (HTA) agency.

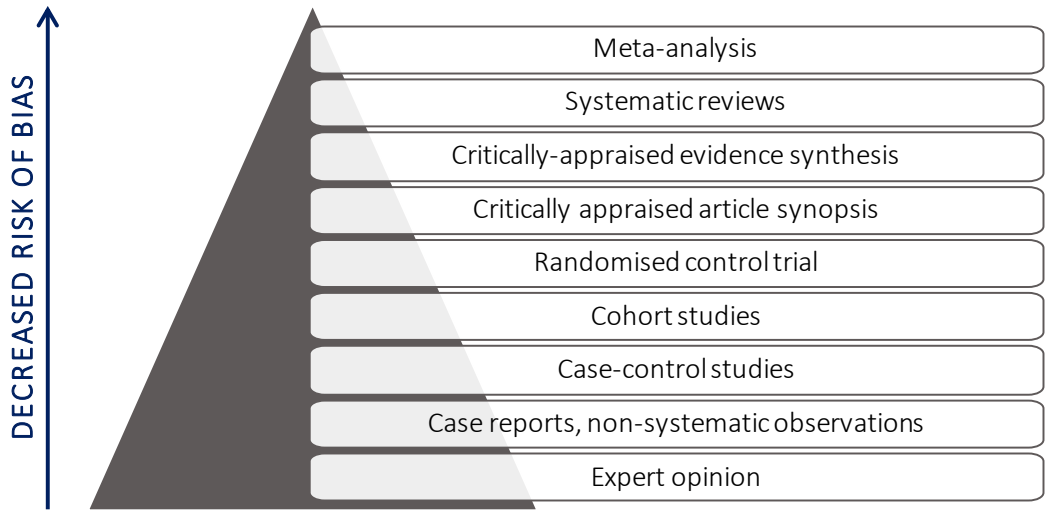
To collect the best quality evidence possible, it is recommended to consider its risk of bias, applicability and relevance for implementation.

- Risk of bias

  The source and type of evidence can both influence risk of bias.

  Source of evidence. When collecting evidence, it is important to consider any potential vested interest that the authors, publishers or funders may have. WHO position papers, for example, are less likely to be biased than studies funded by the manufacturer.

  Type of evidence. For type of evidence, data aggregated across multiple studies and assessed for quality is less likely to be biased than individual studies. The evidence-based pyramid can be a helpful reference in considering bias for clinical data. In general, it is advisable to seek to use types of evidence closer to the top of the pyramid.



Evidence-based pyramid for clinical studies

- **Applicability**

  It is important to consider the relevance of evidence for the decision question. For example, it may be helpful to consider the target population and country setting of clinical studies and the assumptions in delivery costs for economic analysis. Certain data, such as effectiveness, are more difficult to extrapolate to other settings than others, such as efficacy.

  It is highly advisable to ensure that the most recent data is being used.

- **Relevance for implementation**

  Consider the extent to which the evidence is representative of real-world implementation. For example, when considering behaviour change or adherence, an observational study of real-world use may be more representative than data collected during a clinical study.

Guidance on conducting literature reviews and access to systematic reviews are available on the NITAG resource center website. The CAPACITI resource of tools is under development to provide a reference of available data sources and analysis tools.

> Supplementary sheets in the CAPACITI decision-support tool
>
> The CAPACITI decision-support tool contains two supplementary sheets to support the evidence collection process. Both sheets are optional.
>
> - **The template tracker sheet for coordinating evidence collection** can be used to record key activities and deadlines, assign focal points to collect evidence for each criterion and record any notes on evidence collection methods that are decided as a group. It also can track the status of evidence collection, marking it as: “in progress”, “completed – needs revision” or “completed – satisfactory”.
> - **The template sheet for evidence collection** has been designed to be completed per criterion. It provides space to document the methods for data collection and analysis, and space to record the data and references collected for each of the options.

3.2 Evidence statements

This step is completed by the technical team.

PURPOSE:

- The evidence statements provide a concise overview of available evidence and its quality.
- This step ensures that the committee has a good understanding of the evidence and its limitations.

ESSENTIAL TO COMPLETE:

- It is highly recommended to complete this step in full.

COUNTRY ADAPTATION:

- Certain countries may have existing guidelines for reporting of evidence. Those guidelines should be followed in this step.

IMPORTANT

The evidence statement is a succinct summary of the evidence identified for each criterion. Since committee members seldom have the time to review the original evidence sources in full, the role of the evidence statement is to make committee members aware of the available evidence (or lack thereof), concordance between different evidence sources, and any limitations in the evidence. In general, a single evidence statement will summarize evidence for all options.

If there is very complex data or a large number of options, the technical team may wish to write a separate evidence statement per option.

In the decision-support framework, the evidence statement and summary of evidence quality are separated. While labelling evidence as “high” or “low” quality is helpful to a certain extent – especially if following established guidelines such as GRADE or CHEERS – it does not mean the committee will understand specific limitations of the evidence. It is therefore highly recommended to provide a separate overview of evidence quality.

Writing an evidence statement

To support the committee in understanding the data that has been collected and any analysis conducted, it is recommended to cover the following points in the evidence statement.

- **Number of evidence sources identified, with references and date.** In the CAPACITI decision-support tool, there is a separate column to record each of the evidence sources.
- **Type of evidence.** This can include, for example, meta-analyses, expert opinions or a costing study using data from two provinces.

- **Brief overview of methods and study design for the evidence sources.** It is most important to focus on elements that will allow the committee to judge the extent to which the evidence is appropriate for the decision question. In particular, you may wish to highlight:
    - population, country and setting, such as: girls aged 9 years in Uganda, or vaccine delivered through health facilities on 6-month schedule;
    - intervention and comparator, for clinical studies;
    - sample size and any major limitations in methodology.
- **A summary of the main outcomes (results)**. This can, for example, include the direction and size of the effect or uncertainty bounds. It also can check consistency across data sources, which may be consistency across studies or consistency across different experts for expert opinion.

Considering evidence quality

There are some overarching principles that can be used to consider evidence quality.

1) Study limitations
    - Are there any shortcomings in the evidence identified?
    - Is there a high risk of bias, either from the type of evidence or source?
2) Quantity and consistency of results
    - How many evidence sources have been identified? Is this sufficient?
    - What is the level of concordance between data sources? For expert opinion, do the experts tend to agree or do they have very divergent responses?
3) Applicability of evidence
    - To what extent is the data reflective of the decision question?
    - Can you extrapolate the findings to your country?
4) Precision
    - Are there wide confidence intervals or significant data uncertainty?

Specific guidelines for clinical data, economic evaluations, and data based on expert opinion can be found in the references (page 61).

3.3 Performance matrix

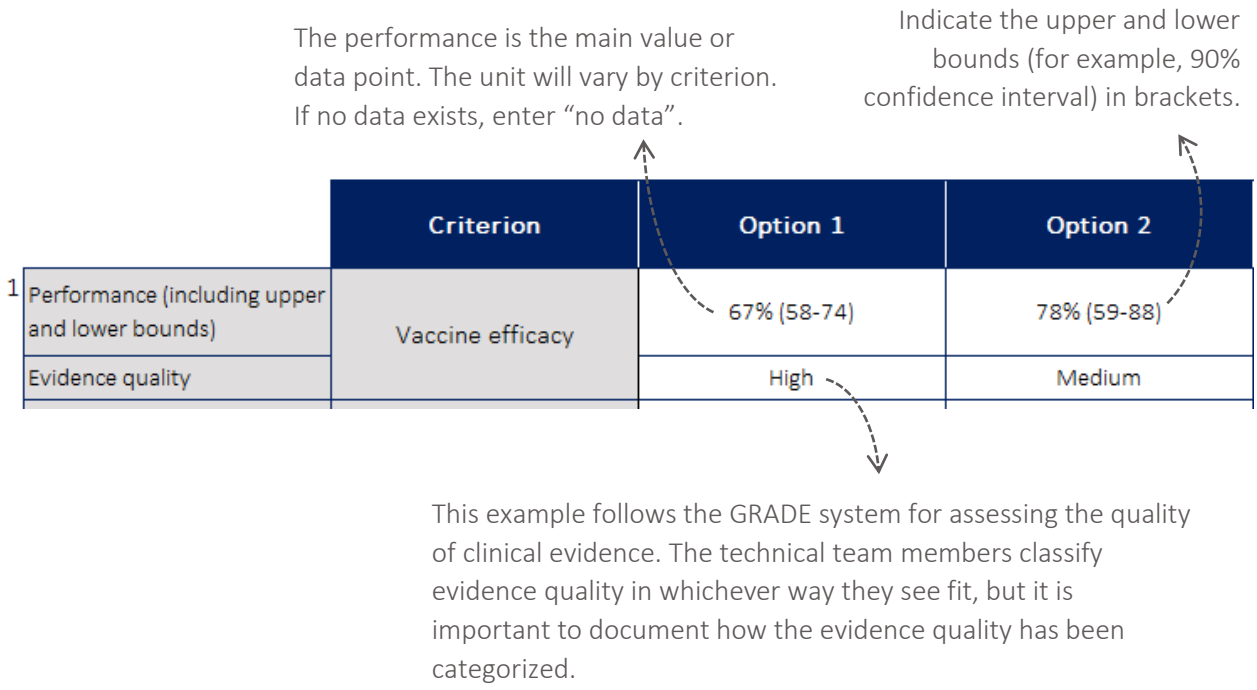
This step is completed by the technical team.

PURPOSE:

- The performance matrix gives a high-level comparison of the performance of the options by each criterion, with an indication of evidence quality.
- It is intended to serve as a reference for the committee in discussions and should not replace the evidence statements.

If the committee is not following a quantitative MCDA approach, the performance matrix serves as a reference by which to compare the options during the appraisal step. However, it is important that the committee review the evidence statements fully, as the performance matrix does not give the same level of detail on variation and limitations in the evidence as the evidence statements.

The example below is a screenshot from the table in the CAPACITI decision-support tool.



CHEERS	Consolidated Health Economic Evaluation Reporting Standards (Guidelines for reporting economic evaluations)
EPI	Expanded Programme on Immunization
GRADE	Grading of Recommendations, Assessment, Development and Evaluation (Guidelines for assessing the quality of clinical evidence)
HTA	Health technology assessment
MCDA	Multi-criteria decision analysis
NITAG	National immunization technical advisory group

3.1 Evidence collection

NITAG Resource Center (2020) Training Modules. Available at: http://www.nitag-resource.org/training/strengthen/training-modules

5 Reviewing the scientific evidence. Methods for the development of NICE public health guidance (third edition). 2012. Available from: www.nice.org.uk/process/pmg4/chapter/reviewing-the-scientific-evidence#assessing-the-quality-of-the-evidence

3.2 Evidence statements

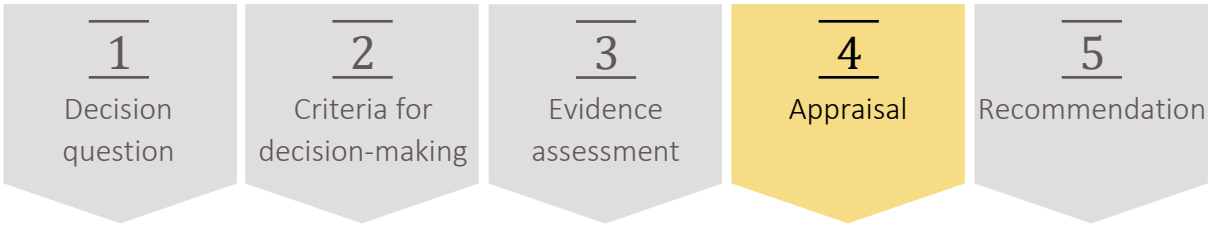
Information on the GRADE system to categorise quality of clinical evidence: Guyatt G, Oxman A, Vist G, Kunz R, Falck-Ytter Y, Alonso-Coello P et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008;336(7650):924-926.

Information on the CHEERS checklist for assessing the quality of economic analysis: Husereau D, Drummond M, Petrou S, et al. Consolidated health economic evaluation reporting standards (CHEERS)—explanation and elaboration: a report of the ISPOR Health Economic Evaluations Publication Guidelines Good Reporting Practices Task Force. Value Health. 2013;16(2):231-250.

Information on collecting and assessing the quality of expert opinion (1): Concannon T, Grant S, Welch V, Petkovic J, Selby J, Crowe S et al. Practical Guidance for Involving Stakeholders in Health Research. Journal of General Internal Medicine. 2018;34(3):458-463.

Information on collecting and assessing the quality of expert opinion (2): Cooke, R.M. and Goossens, L.H.J. (2000), "A Procedures Guide for Structured Expert Judgment," EUR 18820, European Commission Report.

4. APPRAISAL



The role of this section is for the committee to come to a shared understanding of the evidence and its limitations, in order to jointly assess the merits and drawbacks of each option. In this section, the committee will:

- critically review the evidence and compare how the options perform against each criterion;
- consider the implications of data uncertainty and the extent to which it may influence the relative performance of the options;
- come to a common understanding of the relative trade-offs between the options, using the criteria set up in Section 2.

IN THIS SECTION

4.1 Comparison by criterion

This step is completed by the committee.

PURPOSE:

- The committee reviews the evidence statements provided by the technical team, in order to compare the different options according to each criterion.
- At the end of this step, the committee should have a thorough understanding of the available evidence and its limitations, and whether there are significant differences between the options.

ESSENTIAL TO COMPLETE:

- It is highly recommended to complete this step in full.

COUNTRY ADAPTATION:

- If the country has already established a fixed scoring scale for generic criteria, it is possible for the technical team to pre-populate the scores for the committee. However, it is important that the committee still review the evidence statements and complete the discussion points in this step.

IMPORTANT

For the committee to make a balanced and well-informed recommendation, it is important that all committee members have a good understanding of the evidence for each criterion. This improves the quality of committee deliberations as, regardless of their area of expertise, all members will be fully briefed to weigh up the trade-offs between options in Step 4.2. For example, an economist from the planning department will have better appreciation of the clinical and logistical issues.

Throughout this step, the committee considers each of the criteria in turn, to review the evidence and compare the different options on a criterion-by-criterion basis. It may facilitate the committee's understanding if the relevant focal point in the technical team provides a brief overview of the evidence statement(s) and data quality summary for the criterion before committee discussions. This should provide the opportunity for the committee to ask for clarification on the data.

Once the committee has reviewed the evidence statement for a criterion, the committee refers to the evidence to assign a score for the performance of each option, using the scoring scale set up in 2.3.1. In the tool, there is a summary of data from the performance matrix and the scoring scale for the committee to use as a reference (see example below).

4.1 Comparison by criterion

Important note: in the decision-support tool, the committee should always assign a score. If there is no data, the score can be assigned based on committee expert judgement. The committee can note why it has assigned the given score in the comments box.

Cells in grey are pre-populated with data from the performance matrix (sheet 3.3) and the scoring scale (sheet 2.3).

Vaccine efficacy	Rota1	Rota2	Rota3
Performance (including upper and lower bound)	67% (60-88)	49% (47-59)	81% (75-88)
Evidence quality	Moderate	Moderate	High
Score	**Average**	**Poor**	**Good**
Scale	Under 50% is poor, from 50-70% is average, 70-90% is good, above 90% is very good		

According to the scoring scale set-up by the committee in 2.3.1, performance of 67% is "average" as it is between 50% and 70%.

Information from the performance matrix is summarized as a reminder to the committee. It does not provide sufficient detail to inform committee discussions and should not replace consideration of the evidence statements (3.2).

For each criterion, after assigning scores for each of the options, it can be beneficial for the committee to discuss and document the following points about the options.

- **Magnitude of the difference.** Discuss whether, for this criterion, there are significant differences between options, or whether differences between the options are negligible.
- **Low scores.** If any of the options receive a low score for this criterion, consider whether this is acceptable or whether the low score means that the option is not feasible, regardless of performance against other criteria.
- **Evidence limitations.** Consider any limitations in the available evidence for this criterion, including significant uncertainty or data gaps. What impact could this have on the relative performance of the options?
- **External factors.** Discuss the extent to which this criterion is dependent on the choice made by the committee. For example, the criterion "efficacy" will be solely determined by vaccine product choice, whereas "community acceptance" could also be dependent on communication and social mobilization activities.

4.1 Comparison by criterion

It is strongly recommended for the committee to complete this exercise for all criteria, so that all committee members fully understand the evidence before coming to a recommendation. In *exceptional* circumstances, the technical team may complete this step for the committee, provided that the technical team provides a full briefing to committee members in advance of the next step.

TIP: dealing with missing data

There is rarely a situation in which the committee has all the required data for a recommendation. If there are criteria or options for which there is no data or the data is of such poor quality that the committee does not think it is informative, it is recommended to follow these steps.

- **Do not change the weight assigned to the criterion.** If there is no data for a criterion that the committee judged to be very important, this is important to communicate to the final decision-maker. It may affect the committee's confidence in the recommendation, determine when the recommendation should next be reviewed, and/or inform priority research areas.
- **Assign a score based on expert committee judgement**, noting the rationale for selecting the score.

  If certain committee members have better knowledge of this criterion than others, it is best to come to an agreement on the score in discussion with the more knowledgeable members of the group.

  If committee members have a similar level of knowledge for this criterion, it can be helpful for all members to assign a score separately. Assign the average score and take the range to be the upper and lower bounds when considering data uncertainty. *For example, if committee members select 2, 3, 3, 4, 4, a score of "3" would be assigned and the committee would discuss whether a score of "2" or "4" would change how this option compares relative to the other options.*

  If the committee does not feel able to assign a score, it can observe one of the two following approaches:

  i) Assign a score that is an average of the scores for the other options. *For example, if option A receives a score of "good", option B receives a score of "average", option C is unknown and option D received a score of "average", the committee would assign a score of "average" for option C.*

  ii) Assign the lowest possible score. This represents the worst case scenario. In the discussion box, the committee should also note the highest possible score.

- **Consider the realistic range of scores when considering uncertainty**. If there is no data, it may be that the committee wants to assume that the score could be the minimum or maximum possible score. However, it is important to consider whether this is realistic and to base discussions around what the committee feels are the likely upper and lower bounds. Further, committee assumptions on the upper and lower bounds should be documented.

4.2 Comparison across criteria

This step is completed by the committee.

PURPOSE:

- The committee compares the performance of each option across all criteria, in order to consider whether one or more of the options performs better than others.
- At the end of this step, the committee will agree whether one or more option(s) is better than the others, or agree on a ranking of the options from best to worst (depending on the decision question).

ESSENTIAL TO COMPLETE:

- It is highly recommended to complete this step in full.

IMPORTANT

After having reviewed the evidence for each criterion separately, the committee now takes account of all criteria simultaneously, applying the weights and decision rules assigned in Section 2 “Criteria for decision-making” to guide discussions.

A key consideration in this step is the importance of missing or poor quality data. It may be that a missing data point does not influence which option(s) perform best overall, or the missing data may have a significant impact on the rank order of the options.

Specific details for this step, provided below, are based on the type of MCDA approach being followed by the committee.

- For a quantitative approach, the scores and weights will be combined to give a total score per option. The committee will use the total scores to guide discussions around the trade-offs between the options, and examine the impact of data uncertainty (and, if relevant, disagreement on weights) by conducting a one-way sensitivity analysis.

  There are two supplementary sheets in the decision-support tool for a quantitative approach: total scores and modelling uncertainty (see pages 67-68).

- For a qualitative approach, the committee will refer to the performance matrix to inform its discussions.
- For a rules-based approach, the committee will refer to the performance matrix and apply the decision rules defined in 2.3.2 to structure its discussions.

SUPPLEMENTARY SHEET 1: Total scores (QUANTITATIVE MCDA)

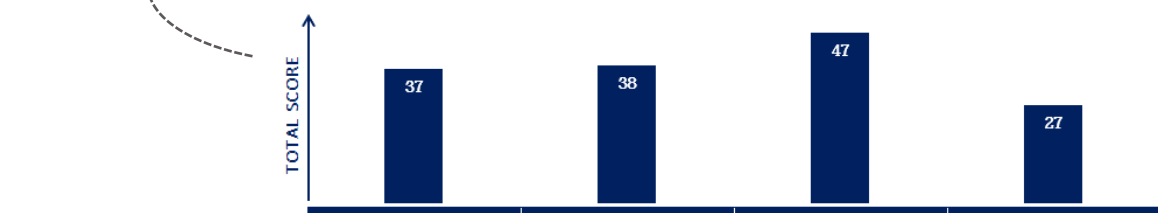
For quantitative MCDA, the tool summarizes the overall performance of each option across all criteria by calculating a total score per option:

- Weighted score = criterion weight x score
- Total score = sum of weighted scores

The total score is intended to guide committee discussions. It does not dictate which option(s) the committee should prioritize.

The graphics in the tool have been designed to support the committee's understanding of the reason for the differences in total scores. Ultimately, the committee members will use their expert judgement to make the prioritization, which may or may not be the same as the ranking given in the tool.

The bar chart shows the total score per option. Higher scores indicate better performance. It is important to note whether there are major differences between options. *In the example below, the difference in score between Rota1 and Rota2 is negligible.*



	Criterion	Weight	Rota1 Score	Rota1 Weight x Score	Rota2 Score	Rota2 Weight x Score	Rota3 Score	Rota3 Weight x Score	Rota4 Score	Rota4 Weight x Score
1	Cold chain burden	5	2	10	3	15	4	20	1	5
2	Ease of administration	3	4	12	4	12	2	6	1	3
3	Potential for high coverage	4	3	12	2	8	4	16	4	16
4	Guarantee of supply	1	3	3	3	3	5	5	3	3

The scores are highlighted using a traffic-lighting system: low scores are red, medium scores are yellow, high scores are green. *Of note: the tool transforms descriptive scales into a numerical score.*

The length of the grey bar is proportional to the weighted score. Longer bars indicate criteria that contribute most to the total score. *In this example, the high score for Rota3 is driven by good performance on cold chain and coverage criteria.*

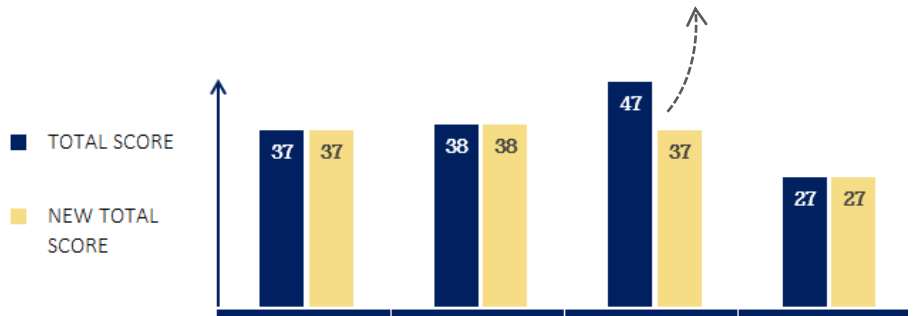
SUPPLEMENTARY SHEET 2: Modelling uncertainty (QUANTITATIVE MCDA)

For quantitative MCDA, the tool includes a sheet for the committee to conduct one-way sensitivity analysis, in order to examine the implications of uncertainty in weights and data.

- **Weights.** If alternative weights were recorded in worksheet 2.2 of the tool, the alternative weights are automatically entered in this sheet. The committee can modify the weights to see the role of weighting in the total scores.
- **Scores.** If there is uncertainty in the data, the committee can modify the scores to identify whether the best performing option(s) or rank order may change with better quality data, or whether data gaps are not important in the context of this specific recommendation.

In committee discussions, it is most important to focus on changes to weights or scores that affect the ranking of options.

The navy bars show the original total score, while the yellow bars show the new total score after changing the weights and/or scores. It is important to note which changes in weights or scores alter the rank order of the options.



				Rota1		Rota2		Rota3		Rota4	
	Criterion	Weight	New weight	Score	New score	Score	New score	Score	New score	Score	New score
1	Cold chain burden	5	5	2	2	3	3	4	2	1	1
2	Ease of administration	3	3	4	4	4	4	2	2	1	1
3	Potential for high coverage	4	4	3	3	2	2	4	4	4	4
4	Guarantee of supply	1	1	3	3	3	3	5	5	3	3

Weights and scores that have been modified will be highlighted in pink. Note that the tool automatically enters the alternative weights from worksheet 2.2.

4.2.1 Identifying "dominated" options

First, it can be helpful for the committee to identify any options that are "dominated", or options that consistently perform worse than another option across all criteria. Unless there is significant data uncertainty, it is possible for the committee to exclude this option if the decision question requires the committee to select the best-performing option. This will reduce the number of options for the committee to compare in the following steps.

> **Quantitative MCDA.** In supplementary sheet 1, the colour-coding for scores may help the committee identify if there are dominated options.

4.2.2 Applying weights and rules

If the committee has assigned weights to criteria. The committee discusses which options perform best on higher weighted criteria. Importantly, the committee should take account of uncertainty in the data and any disagreements on weights, in order to identify whether this impacts the better performing options.

> Quantitative MCDA
>
> - The committee should refer to supplementary sheet 1: total scores to guide discussions (see page 67 for guidance in interpreting total scores).
> - The committee can examine whether better quality data or disagreements on weights could influence the prioritization of options by conducting a sensitivity analysis, using supplementary worksheet 2: modelling uncertainty (see page 68 for further details).

If the committee is using decision rules or a set order in which to consider criteria. The committee applies the rules or order defined in 2.3.2. It is important to document the outcomes after applying each rule. *For example: option A was excluded because it did not meet the cost-effectiveness threshold; options B and C performed significantly better than option D on the budget impact analysis, so only options B and C were compared using the other criteria; while option B received a slightly higher total score overall (43 compared with 40), option C performed more consistently across all criteria and the high score for option B was mainly driven by better anticipated health impact.*

4.2.3 Selecting or ranking options

After having analysed the overall performance of each option, the committee now considers which option(s) will be prioritized. Although the committee may choose to select/rank the options according to the discussions in 4.2.3, there are a number of legitimate reasons why the committee may not prioritize options that have the best overall performance. Most notably, the committee:

- may not prioritize an option if it received an unacceptably low score on one or more criteria, even if it performs best overall;
- may decide that it is better to select/prioritize options that perform consistently across all criteria, rather than options that only perform well on higher weighted criteria;
- may feel that there is too much risk for options with missing or poor quality data and instead choose to prioritize options with better quality data – it is recommended to only follow this approach if the uncertainty in the data has a significant impact on the rank order of the options.

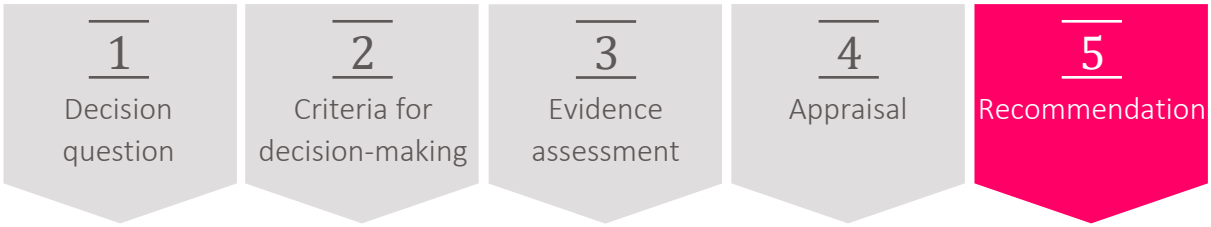
If there is discordance between 4.2.2 and 4.2.3, it is important for the committee to document why it is not prioritizing the options according to overall performance.

4.2.4 Documenting contextual criteria

During committee discussions, there will often be additional factors considered that are not in the original list of criteria defined in 2.1. These factors are referred to as “contextual criteria”. For the purposes of transparency, it is strongly recommended that any contextual criteria be documented, outlining the extent to which they influenced committee discussions.

EPI	Expanded Programme on Immunization
MCDA	Multi-criteria decision analysis

5. RECOMMENDATION



The role of this section is to finalize and communicate the recommendation. In this section, the committee, supported by the secretariat will:

- come to an agreement on the final recommendation, review the strength of the recommendation, and consider the need for any supplementary and/or research recommendations;
- communicate the recommendation to the final decision-maker and other audiences (as relevant); and
- evaluate the recommendation process and set provisions to monitor implementation of the recommendation.

IN THIS SECTION

This step is completed by the committee.

PURPOSE:

- The committee reviews the strength of the recommendation to determine whether it feels confident to proceed with a recommendation.
- The committee also prioritizes any key research questions or data gaps that need to be addressed to inform future country policy or decision-making.

ESSENTIAL TO COMPLETE:

- Strength of the recommendation (5.1.2).

COUNTRY ADAPTATION:

- There may be existing guidelines used by the NITAG or HTA agency to assess the strength of a recommendation.

5.1.1 Preliminary recommendation

The committee sets out a preliminary recommendation to address the decision question. It is possible that the committee may modify the recommendation after completing steps 5.1 and 5.2, so it is not recommended to spend a long time justifying the recommendation at this stage.

IMPORTANT

5.1.2 Strength of the recommendation

The strength of the recommendation will influence whether the committee decides to proceed with a recommendation at this stage. It supports the final decision-maker in deciding whether to implement the recommendation and also supports the secretariat in arranging the timelines and preparatory activities required for the next review of the recommendation.

The committee may wish to discuss the following points.

- Quality of the evidence. Is it likely that better quality evidence would change the recommendation? It is most important to consider the *implications* of data uncertainty: if data gaps would not change the preliminary recommendation, the committee may still make a strong recommendation.
- Difference between the options. Is there significant difference between the options? A recommendation is often considered to be stronger if there is more a pronounced difference between options.

- **Major disadvantages to the selected/more highly prioritized options.** If there are significant drawbacks to the recommended option(s), this may weaken the strength of the recommendation.

The GRADE system uses the classifications “strong recommendation” and “weak recommendation”. The committee can classify strength of recommendation however it sees fit, but it is recommended to document and apply the same principles for assessing the strength of a recommendation across decision questions.

5.1.3 Confidence to proceed with a recommendation

Given the strength of the recommendation, the committee members decide whether they feel that they are able to address the decision question at this stage. It may be that the committee wishes to recommend further data collection or consultation with a broader group of stakeholders instead of making a recommendation on the options.

> Note that confidence to proceed with a recommendation may be influenced by the urgency of the decision question (refer to 1.1.5). For urgent decisions, it is important for the committee to clearly communicate the strength of the recommendation, when the recommendation should next be reviewed (refer to 5.4.1) and the priority data gaps to address (if any, refer to 5.1.4 and 5.3.3).

5.1.4 Addressing data limitations

In their deliberations, the committee members will have identified whether there are any data gaps that are high priority to address, either for the decision question at hand or for future recommendations. It is advisable for the committee to identify any high priority data gaps for policy or decision-making. These can be formulated as specific research questions in 5.3.3.

5.2 Supplementary considerations

This step is completed by the committee.

PURPOSE:

- The committee considers whether there are any issues with the preliminary recommendation or its implementation and how these can be addressed.
- The outputs from this step will be used to inform supplementary recommendations in 5.3.2.

5.2.1 Mitigating against poor performance

If there are any major drawbacks to the recommendation, such as poor performance on one or more criteria, the committee can consider whether there are any measures that could mitigate against this.

- **Example 1.** If there is no post-licensure safety data, the committee may wish to discuss surveillance requirements.
- **Example 2.** If the preliminary recommendation is for a product that is not halal, the committee may discuss how to engage religious leaders and measures for community acceptance.

5.2.2 Implications for practice, training, funding, policy

If not yet discussed, it can be helpful for the committee to review whether the preliminary recommendation would require any major changes in practice, training, funding or policy.

- **Practice –** for example, controlled temperature chain (CTC) delivery of birth dose hepatitis B vaccine may require training of midwives to deliver the vaccine.
- **Training –** especially if this is beyond the normal training requirements.
- **Funding –** for example, increased budget allocation or fund harmonization between different departments or budget lines.
- **Policy –** for example, allowing lesser trained health workers to deliver vaccines.

5.2.3 Further implementation challenges

Before proceeding with the final recommendation, it is advised for the committee to review whether there are any additional challenges for implementation that have not yet been discussed, and how these could be addressed.

5.3 Final recommendation

This step is completed by the committee.

PURPOSE:

The committee articulates and documents the final recommendation together with any supplementary or research recommendations.

ESSENTIAL TO COMPLETE:

Documentation of the recommendation and rationale (5.3.1).

IMPORTANT

5.3.1 Recommendation and rationale

Once the committee has agreed on the final recommendation, it is important to clearly document the recommendation and the main reasons for the recommendation. Ideally, the recommendation should stand alone and be understandable to someone with limited background knowledge. It is advisable to avoid jargon as much as possible. The main recommendation should directly answer the decision question, noting that there is space to document supplementary recommendations in 5.3.2.

5.3.2 Supplementary recommendations

If the committee identified any measures to facilitate implementation of the recommendation or to overcome any drawbacks to the recommended option(s), the committee can document these as supplementary recommendations.

5.3.3 Research recommendations

Research recommendations specify priority data gaps to address and justify why they are important. It is recommended to formulate each of the priority data gaps from 5.1.4 as a research question and to outline the rationale for investing in answering the research question by briefly outlining:

- Why is the research question important for policy questions?
- Why is the current evidence inadequate? What are the implications of not addressing the research question?
- What level of resourcing is required to address the research question? Can the committee already identify potential funding sources and/or institutions to undertake the work?

The research recommendations should make a strong argument for filling the data gaps with a concrete proposal.

This step is completed by the secretariat.

PURPOSE:

The recommendation process has greater legitimacy and will be more effective if there is a system to evaluate and improve the recommendation process itself, and to monitor and review individual recommendations.

COUNTRY ADAPTATION:

Certain countries may already have processes in place to monitor implementation of recommendations and to evaluate the recommendation process, which can be applied in 5.4.2 and 5.4.3 respectively.

5.4.1 Next review of the recommendation

For many recommendations, it may be beneficial to review the recommendation in 1 to 5 years, especially if additional data are expected to become available. In this step, the secretariat considers when the recommendation should be re-visited. In particular, if there are any post-introduction studies or data that are expected to become available which may inform the recommendation, the secretariat may wish to take the timing into consideration.

5.4.2 Monitoring implementation

The committee may wish to monitor whether the recommendation is implemented and has the expected impact. This may be particularly relevant if the committee has made assumptions that it wishes to monitor, such as expected coverage.

5.4.3 Improving the process

The CAPACITI decision-support framework outlines a generic process for making a recommendation, and it is highly recommended to adapt and modify the process to fit the needs of individual countries and advisory or decision-making bodies. The secretariat can either evaluate the process informally, or request input from the committee.

A template evaluation form can be downloaded from the decision-support tool. The evaluation form is in Word and can be adapted by the committee. To download the form, click on the following button in worksheet 5.4-Audit monitoring and evaluation, in the tool.

5.4.3 Improving the process

Summarise any key changes to the recommendation process, including the action to take, rationale, and who is responsible

The tool also contains a table to track agreed changes to the process, why the change is being made, and who is responsible for ensuring that the change is made before the next decision question.

This step is completed by the secretariat.

PURPOSE:

- The secretariat, in collaboration with the committee, drafts and communicates the final recommendation.

ESSENTIAL TO COMPLETE:

- Writing the final report (5.5.1).

COUNTRY ADAPTATION:

- The secretariat can use an existing report template in 5.5.1, if it exists.
- It is expected that the communication plan (5.5.2) and appeal process (5.5.3) will remain constant across recommendations and can be pre-filled. If there are already standard operating procedures for communication and appeal of recommendations, these should be followed.

IMPORTANT

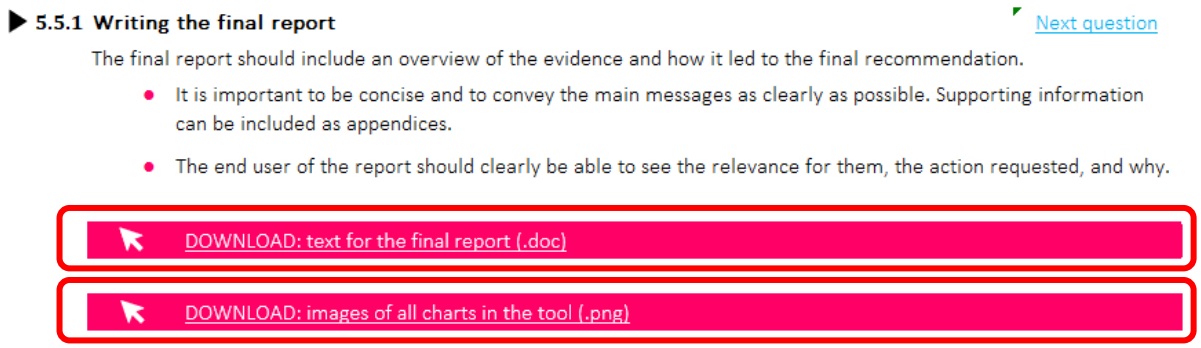
5.5.1 Writing the final report

The role of the final report is to succinctly communicate the recommendation to the final decision-maker or the next advisory body in the policy process. The report will outline the key reasons and evidence that led the committee to the recommendation.

It is also important that the report provide a succinct overview of the trade-offs (advantages and disadvantages) of each option, so that the decision-maker makes an informed decision, whether the committee's recommendation is followed or not.

In the tool, it is possible to download a Word document containing information entered into the tool throughout the recommendation process. The secretariat can cut-and-paste information from this document into an existing report template, if it exists, or into the CAPACITI decision-support template report (LINK). The decision-support template report is intended to provide a draft structure for the secretariat and can be amended however the secretariat sees fit.

To download the text from the tool and to download the charts from the tool (quantitative MCDA), click on the following buttons in sheet 5.5.



5.5.2 Communication plan

The communication plan outlines to whom the final recommendation will be communicated. It also identifies the means for the communications, such as by sharing the final report, publishing the final report online, or conducting a briefing meeting. Further, it indicates the timelines. For example, it may be that the recommendation is made public after the final decision-maker has decided whether to implement the recommendation.

5.5.3 Appeal process

An appeal process is a mechanism that allows defined stakeholders to provide input into the recommendation, as well as outlining how their comments will be addressed, by whom, and according to what timeline. Establishing an appeal process can lend credibility to the recommendation, but should be weighed against the time and resourcing of the secretariat to conduct an appeal process. If the secretariat has limited bandwidth, any appeal process should be light and open to a select, but representative, group of stakeholders.

HTA	Health technology assessment
NITAG	National immunization technical advisory group

5. Recommendation (in full)

7 Developing Recommendations. National Institute for Health and Care Excellence. Methods for the development of NICE public health guidance (third edition). Process and methods [PMG4] [Internet]. NICE; 2012. Available from: https://www.nice.org.uk/process/pmg4/chapter/developing-recommendations

5.1 Formulating the recommendation

Guyatt G, Oxman A, Vist G, Kunz R, Falck-Ytter Y, Alonso-Coello P et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008;336(7650):924-926.

5.5 Communication

Guidance on stakeholder engagement and appeal processes: Greer S, Wismar M, Figueras J. Strengthening health governance. Maidenhead: Open University Press; 2016.