

This is a repository copy of *The CAPACITI decision-support tool for national immunization programs*.

White Rose Research Online URL for this paper: https://eprints.whiterose.ac.uk/175960/

Version: Accepted Version

Article:

Botwright, S., Giersing, B.K., Meltzer, M.I. et al. (10 more authors) (2021) The CAPACITI decision-support tool for national immunization programs. Value in Health, 24 (8). pp. 1150-1157. ISSN 1098-3015

https://doi.org/10.1016/j.jval.2021.04.1273

Article available under the terms of the CC-BY-NC-ND licence (https://creativecommons.org/licenses/by-nc-nd/4.0/).

Reuse

This article is distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs (CC BY-NC-ND) licence. This licence only allows you to download this work and share it with others as long as you credit the authors, but you can't change the article in any way or use it commercially. More information and the full terms of the licence here: https://creativecommons.org/licenses/

Takedown

If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.



Title

The CAPACITI decision-support tool for national immunisation programmes

Running title

CAPACITI decision-support tool for immunisation

Abstract

Objectives: Immunisation programmes in low-income and middle-income countries (LMICs) are faced with an ever-growing number of vaccines of public health importance recommended by the World Health Organization, whilst also financing a greater proportion of the programme through domestic resources. More than ever, national immunisation programmes must be equipped to contextualise global guidance and make choices that are best suited to their setting. The CAPACITI decision-support tool has been developed in collaboration with national immunisation programme decision-makers in LMICs to structure and document an evidencebased, context-specific process for prioritising or selecting between multiple vaccination products, services, or strategies. Methods: The CAPACITI decision-support tool is based on multi-criteria decision analysis (MCDA), as a structured way to incorporate multiple sources of evidence and stakeholder perspectives. The tool has been developed iteratively in consultation with 12 countries across Africa, Asia, and the Americas. **Results:** The tool is flexible to existing country processes and can follow any type of MCDA or a hybrid approach. It is structured into five sections: decision question, criteria for decision-making, evidence assessment, appraisal, recommendation. The Excel-based tool guides the user through the steps and document discussions in a transparent manner, with an emphasis on stakeholder engagement and country ownership. Conclusion: Pilot countries valued the CAPACITI decision-support tool as a means to consider multiple criteria and stakeholder perspectives, and to evaluate trade-offs and the impact of low-quality data. With use, it is expected that LMICs will tailor steps to their context and streamline the tool for decision-making.

Highlights

- The CAPACITI decision-support tool applies MCDA to immunisation decisions
- It emphasises stakeholder engagement, country contextualisation and deliberation
- It has been well received in pilot countries across Africa, Asia and the Americas

Article

Introduction

Achieving the goals set out in the 2012 United Nations resolution on Universal Health Coverage (UHC) will require countries to set context-specific priorities through an explicit, transparent and accountable process [1]. Traditionally, decisions on the introduction of new vaccines in low-income and middle-income countries (LMICs) have been guided by global recommendations and facilitated by global financing and supply agencies [2]. However, as more countries transition towards domestic financing of immunisation programmes, and as the range of available vaccines and vaccine products grows, it is increasingly important to strengthen the capacity of national immunisation programmes (NIPs) to contextualise global guidance as they choose between vaccination products, services, and strategies.

The World Health Organization (WHO) 3D framework outlines three components for evidenceinformed decision-making: data (information, analysis and criteria for decisions), dialogue (stakeholder participation and engagement in the recommendation process), and decision (organisational structures, governance and legal frameworks) [3]. In the ISPOR report on Good Practices in HTA, the data component of the 3D framework is concerned with evidence synthesis, whilst dialogue is concerned with evidence-based decision-making, requiring contextualisation and deliberation a broad range of considerations, including affordability, feasibility, and socio-ethical factors [4].

The previous decade has seen considerable progress towards improving immunisation decisionmaking capacity in LMICs on the data and decision components of the 3D framework. In many countries, national immunisation technical advisory groups (NITAGs) have been established as

independent advisory bodies to the immunisation programme, and an increasing number of tools and information databases are available to support evidence collection and synthesis [Steffen et al, in progress]. However, many countries lack a strong, legitimate process for structured dialogue and interpretation of evidence to compare among multiple interventions [4,5,6]. This paper describes the development of the CAPACITI decision-support tool as a means to explicitly structure and document the process for prioritising across vaccination products, services, or strategies. We describe how the structure of the tool has been informed by best practice in the fields of health technology assessment (HTA) and multi-criteria decision analysis (MCDA), as well as how the tool balances best practice with practicality and how this has been informed by country pilots.

Purpose and scope of the CAPACITI decision-support tool

The decision-support tool structures and documents an evidence-based, context-specific process for prioritising or selecting among multiple vaccination products, services, or strategies [7]. The target audience is the immunisation programme or advisory bodies in LMICs, to address decisions devolved to the immunisation programme by the Minister of Health. Similar to the GRADE Evidence to Recommendation (EtR) framework, the decision-support tool supports panels to use evidence in a structured and transparent way to inform decisions [8]. However, whereas the EtR framework is designed to evaluate a single intervention in relation to a comparator, the CAPACITI decision-support tool is designed for choices among multiple options (Table 1). Accordingly, the decision-support tool is based on multi-criteria decision analysis (MCDA), as a structured way to incorporate different types of evidence (such as clinical trial data, economic analysis and expert opinion) and stakeholder perspectives (for example, clinicians, budget holders, logisticians and disease programme managers). Most relevant for immunisation programmes, MCDA can incorporate criteria which cannot be fully measured, such as alignment of a proposed new vaccine with the existing immunisation programme or ease of administration, alongside measurable considerations, such as reduction in morbidity [9]. The CAPACITI decision-support tool is oriented towards national advisory and decision-making bodies in LMICs, with a practical, stepwise, Excel-based tool that explicitly outlines mechanisms for stakeholder involvement, allows consideration of operational and social/political aspects (including guidance to incorporate expert opinion), and transparently documents the recommendation process. Typically, the recommendation process using the CAPACITI decisionsupport tool would be expected to take around six months, but timelines are highly dependent on country context and complexity of the decision question. The full process could foreseeably be condensed to one week for urgent decisions or may take more than a year for complex decisions. The main determinants of time are data collection and analysis requirements, personnel availability and number of in-person meetings. It is expected that countries using the tool for the first time, and those with weaker priority-setting infrastructure, may take longer to complete the process, since many of the steps will be completed *de novo*.

Development of the CAPACITI decision-support tool

The CAPACITI decision-support tool, and the underlying methodology, has been developed through an iterative approach from 2018 to 2020, in consultation with 13 countries across the World Health Organization (WHO) regions of Africa, the Americas, Southeast Asia, and the Western Pacific, as well as technical agencies and advisory committees to WHO [5]. Table 2 lists the countries involved and the pilot topics examined using the CAPACITI tool. This section

summarises iterations of the tool and lessons learned, before presenting a description of the final tool in the results.

Version 2018: Quantitative MCDA model for evidence assessment with fixed criteria In response to calls to look beyond the traditional measures of efficacy and cost-effectiveness [10], an Excel tool was developed to analyse vaccine products across five criteria determined through global consultations (health impact, coverage and equity, safety, delivery cost, procurement cost), incorporate country-specific weights, and aggregate the output into a ranking of options [5]. Piloting found that greater emphasis was needed on the social aspects of MCDA – namely stakeholder engagement and guiding discussions to interpret the output – as well as greater flexibility to incorporate country criteria and data. This is in line with a consensus development paper on the use of MCDA in HTA, which underlines the importance of incorporating deliberation [11].

Version 2019: Tool for quantitative MCDA incorporating procedural aspects

A revised tool was developed based the ISPOR best practice checklist for MCDA [12]. The tool was developed through two in-person workshops: one workshop for criteria selection, followed by a period of evidence collection, and a second workshop for interpreting evidence to come to a recommendation. In this revised approach, the tool and accompanying Excel tool did not determine the output at any stage: country users defined the options, criteria, and evidence requirements. There is no minimum set of evidence requirements. The tool supports the committee to understand limitations in available evidence and whether better quality data would change the final recommendation (for example, a committee may lack data on acceptability, but

determine that such data is unlikely to change their recommendation). Users attached weights to criteria and scores to options, using scales fixed to a 1 to 5 and a 0 to 10 absolute scale, respectively, since early testing suggested that more extensive scales gave the committee a false sense of precision. During the appraisal stage, aggregate scores for each option were calculated and presented graphically, and users adjusted weights or scores in real time to examine the implications of data uncertainty. In line with best practice [11], 'cost' and 'cost-effectiveness' criteria were excluded from the value measurement model and considered during a separate value for money step, which compared total cost against the total (aggregate) score of each option.

This version was well-received during orientation workshops in eight African countries and was successfully piloted in Mali to support the NITAG recommendation on HPV product choice. However, there was concern around sustainability of using the tool and approach, since many advisory bodies in LMICs are severely resource-constrained, in terms of funding, secretariat function and time. Moreover, the tool took a one-off approach, in which members of the committee, criteria and evidence requirements are newly defined with each use. It was highlighted that this may become burdensome over a series of recommendations, and a one-off approach may lead to poor consistency and transparency in settings with weak governance [13]. Many policymakers found it counter-intuitive to separate cost from other criteria. It was also highlighted that, from an economic perspective, all constraints (including, for example, cold chain capacity and health worker time) should be separated along with budget. Policymakers requested greater flexibility in assigning scores, with the possibility of using more qualitative scores instead of the 0-10 scale mandated in the tool. Finally, while there was a greater focus on

stakeholder engagement and discussion in this iteration, there was still a tendency to focus on total scores as opposed to evidence during appraisal.

Version 2020: Tool for deliberative decision-making

The current version of the CAPACITI decision-support tool (v2.0) incorporates elements of the Public Health England prioritisation tool as a user-friendly tool to simply convey the concepts behind MCDA [14]; the evidence-informed deliberative processes (EDP) as a sequential overview of procedural aspects for making recommendations [15]; the AGREE II instrument to ensure documentation of important aspects during the recommendation process [16]; and the National Institute for Health and Care Excellence (NICE) guideline development methods, for specific guidance on evidence assessment [17]. Since NITAGs are a potential end-user, the tool seeks to align with the GRADE EtR tool, which is frequently used by NITAGs. The tool has been reviewed by teams in Cuba, Indonesia and Zambia, as well as technical agencies supporting immunisation priority-setting. The Excel tool was circulated to focal points based in NIPs, NITAGs or WHO country offices (5 countries) and WHO regional offices (Central Africa, the Americas, West Africa, Western Pacific) for beta testing (Table 2). Feedback was that the tool is very useful, especially for new vaccine introduction and product choice decisions, as it is responsive to country context and brings stakeholders together. Guidance to streamline the process will be important, and the tool should be provided alongside existing resources for interpreting evidence and data quality.

Structure of the CAPACITI decision-support tool

The tool is based in Excel and structured into five sections: decision question, criteria for decision-making, evidence assessment, appraisal, recommendation (Table 3). The tool seeks to adhere to principles set out in the ISPOR reports on good practices in MCDA and HTA [4,12], whilst allowing flexibility to different decision-making processes within countries. Figure 1 summarises the differences between each type of MCDA. All types of MCDA follow common steps to define the decision problem, select decision criteria, and assemble data to construct a performance matrix that compares, using selected criteria, between the options being evaluated [11]. In qualitative MCDA, the committee deliberates on the performance matrix. Compared to using no explicit decision criteria, this improves the quality, consistency and transparency of recommendations. In contrast, quantitative MCDA employs a value measurement model (using weighting and scoring) to interpret the performance matrix before deliberation, reducing cognitive burden on the committee and domination by vocal committee members, as well as improving consistency and transparency of recommendations. However, it can be difficult to construct scales and capture opportunity costs, and the committee may overly focus on weights and scores, instead of the evidence.

In the tool, users can follow any of the three MCDA approaches, or a hybrid-based approach. A strong focus of the tool and training materials is supporting countries to identify the MCDA and stakeholder engagement techniques that work best for their setting. The tool thereby covers a significant part of the decision-making continuum outlined by Ultsch et al [18]. Over time, country users will tailor and pre-fill certain steps to streamline the tool for future use and to improve transparency and consistency of recommendations. For example, criteria, weights and scoring scales may be pre-set for similar types of decision questions.

1) Decision Question

The purpose of this step is to articulate the recommendation objectives and to outline how the recommendation process will be conducted. It is completed by focal points coordinating the recommendation process.

The step includes a review of the decision context and country-specific background to the question, before defining the scope of the recommendation by shortlisting between two and eight options to compare. To ensure transparent documentation, any excluded options are noted with the reason. There is a maximum of eight options as it can be challenging for a committee to keep track of performance across multiple criteria when comparing many options.

Next, the committee considers which stakeholders to engage. Policy bodies, their mandates and guidelines vary across countries. The focal points therefore determine where the recommendation sits within the existing policy infrastructure, and identifies how best to engage relevant stakeholders, whether through participation on the committee or other means. In line with Fung's principles for effectively structured participation, it is advised to include stakeholders that will bring necessary expertise and knowledge, enhance legitimacy of the recommendation, or ensure ownership for successful implementation of the recommendation [19]. The tool recommends including between six and fifteen members for the recommendation committee, to ensure a sufficiently diverse range of perspectives, whilst also allowing all members to actively contribute to discussions, in order to foster shared understanding and ownership of the final recommendation [20].

The final part of this step is to consider how the evidence appraisal will be structured. The focal points outline the approach to be followed, techniques to support committee deliberations, and

develops a briefing document for the committee outlining the policy and programme context to the decision question.

2) Criteria for decision-making

The purpose of this step is to articulate how options will be compared and evaluated, according to local values and the decision question. This step is completed by the recommendation committee.

Firstly, the committee selects the criteria that will form the basis for choosing or prioritising among options. Whilst it is important to be comprehensive, it is recommended not to exceed eight criteria, so that the committee can keep track of all criteria during discussions [13]. To enhance legitimacy of the recommendation, it is encouraged to use a generic set of criteria, which are applicable across different decision questions, as this enhances consistency in decision-making. Generic criteria can be supplemented by context-specific criteria, which depend on the specific options being compared. In many countries, the NITAG or HTA agency may already have defined generic criteria. If an established list of criteria exists, this step reviews whether the criteria are fit for purpose (for example, criteria developed for new vaccine introduction decisions may be less relevant for selecting between delivery strategies) and if there are any question-specific modifications to the list (for example, valency is important when considering HPV vaccine product choice but less relevant for rotavirus vaccine product choice). If there is not an established list of criteria, or if the list is not fit for purpose, the committee develops and comes to an agreement on criteria for the recommendation. Whilst a bottom-up approach, in which the criteria are selected according to the question, may be appropriate for single uses of the tool, it is recommended to establish country-specific generic criteria through a

top-down approach based on the health sector strategic plan and national immunisation strategy. Criteria are not pre-set, because piloting found that countries wish to select criteria themselves [5], but it is suggested to consider criteria across the domains of health impact, economic impact and sustainability, operational (programmatic and supply) and socio-ethical factors [7]. The committee indicate whether certain criteria are more important than others by assigning weights. It is possible to weight all criteria equally. In qualitative MCDA, weights are not normally assigned. However, weighting is encouraged in the decision-support tool so that the committee to comes to an agreement on relative importance of criteria, increasing transparency and streamlining the appraisal step.

The committee then sets out the scoring scale that will be used to assess the evidence across criteria on a common scale. Whilst scoring is normally only used for quantitative MCDA, this step is recommended in the decision-support tool to improve consistency in the committee's interpretation of the evidence and to reduce bias in interpreting the evidence. In the Excel tool, the there is a maximum scoring scale range of 10. The scale can either be numerical (for example, assigning scores between 0 and 5) or descriptive (for example, assigning "poor", "average", "good"). In countries with stronger analytical capabilities, it is important to consider how the value of quantitative criteria maps to the scoring scale, as some criteria have ratio properties and should not be mapped linearly.

Within this step, it is possible to define decision rules, either in the sense of rules-based MCDA, which defines the priority order for criteria, or to separate inter-dependent criteria and "constraints" for quantitative MCDA. Constraints are criteria reflecting fixed capacity, such as budget and cold chain space, and should not be combined with other criteria to calculate the aggregate score in quantitative MCDA. Since piloting found it counter-intuitive to separate

constraints from other criteria, the tool recommends that the committee set the weight of constraints to zero and to state whether they will be considered before other criteria, to shortlist options, or after other criteria, to consider feasibility of top-ranking options during appraisal.

3) Evidence assessment

During this step, a technical team (which may comprise members of the committee in resourceconstrained settings) collects, synthesises and assesses the quality of available evidence. Since there are many existing resources for collecting and analysing data [5], the tool focusses on succinctly summarising the main findings for the committee, as well as reviewing confidence in the data. Across all types of evidence, it is recommended to consider risk of bias, quantity and consistency of results, applicability for the decision question and local context, and precision. This follows the principles set out in the GRADE system for assessing evidence quality [21], but allows comparison across different criteria (for example, to compare across clinical data, economic analyses, legal or ethical judgements, market data, and cold chain analyses). The team then completes a performance matrix, summarising the main data points by criterion for each option, together with uncertainty bounds. It is essential that the performance matrix is complementary to, and does not replace, the summary of evidence.

4) Appraisal

In the appraisal step, the committee comes to a shared understanding of the evidence and its limitations, in order to jointly assess the advantages and disadvantages of each option. Contrary to standard MCDA practice, the tool firstly involves a comparison of options by criterion, to encourage a detailed review of the evidence. This ensures that committees following a

quantitative MCDA approach do not overly focus on the total score, and that all criteria are duly taken into consideration for a qualitative MCDA approach. The committee considers whether there are significant differences between the options for each criterion, the impact of data uncertainty on relative performance, and whether any option performs unacceptably poorly. The committee then evaluates the performance of the options across all criteria, and considers whether there are additional factors that may influence the recommendation ("contextualised criteria"). If using decision rules, the committee considers the criteria in the specified order. For quantitative MCDA, interactive graphics in the tool guide discussions and committee understanding of the factors influencing the total score (figure 2a and 2b). Although there is no mathematical constraints optimisation step, the committee deals with constraints implicitly through their deliberations.

5) Recommendation

The purpose of this step is to finalise and communicate the recommendation. After considering whether there is sufficient evidence quality to proceed with a recommendation, the committee comes to a consensus on the final recommendation and documents the rationale, noting any supplementary or research recommendations. Focal points specify the timing to next review the recommendation, measures to monitor impact of the recommendation (for example, to determine whether assumptions around health impact or coverage are realised), and evaluates the recommendation process itself. The final component of this step is drafting the final report and outlining the communication and appeal process.

Discussion

For implementation, it is essential to embed the CAPACITI decision-support tool within the existing decision-making architecture of countries. To strengthen capabilities across all components of the WHO 3D framework (data, dialogue, decision), the decision-support tool should be implemented in tandem with other initiatives to build capacity for data analysis and evidence synthesis (moving towards the generation of country-specific reference cases) [22], provision of training on facilitation techniques, and establishment of adequate legal capacity and accountability mechanisms. It is encouraged to implement the tool within a system for routine horizon scanning by public health agencies, such that there is foresight and planning of decision questions.

The tool provides guidance on MCDA approaches and stakeholder engagement techniques, but ultimately implementation of the tool should be a learning process driven by national teams, who adapt the tool for their needs. The role of global and regional actors should be to provide technical support on functionality; countries themselves should choose the decision-making approach that works best for them.

As identified through piloting, the main value of the CAPACITI decision-support tool is in structuring dialogue across stakeholders to come to a context-specific recommendation. Whilst several MCDA software tools exist, including PriorityVax for immunization, these tools are limited to a quantitative MCDA approach and tend to provide less support for deliberation and country-led contextualisation – they allow adaptation of fixed stages but not the overall process [23,24]. These tools are more appropriate in settings with strong processes for stakeholder engagement and deliberation; the CAPACITI decision-support tool supports other countries to build such processes.

Recent outbreaks such as COVID-19 and other responses have brought to the forefront the increasingly complex decisions facing immunisation programmes. These include deciding which immunisation services to continue; identifying strategies to deliver non-COVID-19 vaccines given local restrictions; prioritisation of interventions with increasingly constrained government budgets and healthcare resources; and conducting early evaluation of COVID-19 vaccine candidates to support procurement negotiations and vaccine preparedness planning [25,26,27]. There is a rapidly evolving landscape of data from surveillance, modelling and clinical trials, with expectations for immunisation programmes and advisory bodies to continuously incorporate new data and analyses to update recommendations. It has been argued that recommendation processes must adapt from static to agile, with "living" recommendations and guidance [28]. The CAPACITI decision-support tool is well-suited to promote this shift: transparent documentation of each step in the process means it is simple to update and re-communicate recommendations, and the focus on evidence limitations supports policymakers to iteratively prioritise and address evidence needs with local researchers. Accompanied with resources to make data and modelling available and adaptable to country policymakers, the CAPACITI decision-support tool could be a valuable resource in supporting immunisation programmes to respond to the COVID-19 pandemic and other such public health emergencies.

Conclusion

The CAPACITI decision-support tool strengthens priority-setting in LMICs, by structuring the process for stakeholders to contextualise evidence across disciplines. Piloting across 12 countries has identified the need for, and benefits associated with using, the tool as part of a comprehensive package for LMICs to strengthen their decision-making processes.

References

- Chalkidou K, Glassman A, Marten R, et al. Priority-setting for achieving universal health coverage. Bulletin of the World Health Organization. 2016;94(6):462-467.
- Revill, P. & Glassman, A. (2019) Understanding the opportunity cost, seizing the opportunity: Report of the Working Group on Incorporating Economics and Modelling in Global Health Goals and Guidelines. Washington, DC: Center for Global Development.
- Kadandale S, Rajan D, Schmets G. Strategizing national health in the 21st century. Geneva: World Health Organization; 2016.
- 4) Kristensen F, Husereau D, Huić M, et al. Identifying the Need for Good Practices in Health Technology Assessment: Summary of the ISPOR HTA Council Working Group Report on Good Practices in HTA. Value in Health. 2019;22(1):13-20.
- 5) Botwright S, Kahn A, Hutubessy R, et al. How can we evaluate the potential of innovative vaccine products and technologies in resource constrained settings? A total systems effectiveness (TSE) approach to decision-making. Vaccine: X. 2020;6:100078.
- de Oliveira L, Toscano C, Sanwogou N, et al. Systematic documentation of new vaccine introduction in selected countries of the Latin American Region. Vaccine. 2013;31:C114-C122.
- 7) Vaccine Prioritization (CAPACITI) [Internet]. World Health Organization. 2021 [cited 22 January 2021]. Available from: https://www.who.int/teams/immunization-vaccines-andbiologicals/immunization-analysis-and-insights/vaccine-impact-value/economicassets/vaccine-prioritization/.

- Alonso-Coello P, Schünemann H, Moberg J, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. BMJ. 2016;:i2016.
- 9) Phelps C, Lakdawalla D, Basu A, Drummond M, Towse A, Danzon P. Approaches to Aggregation and Decision Making—A Health Economics Approach: An ISPOR Special Task Force Report [5]. Value in Health. 2018;21(2):146-154.
- 10) Wilder-Smith A, Longini I, Zuber PL, et al. The public health value of vaccines beyond efficacy: methods, measures and outcomes. BMC Med. 2017;15(1):138.
- 11) Baltussen R, Marsh K, Thokala P, 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.
- 12) Marsh K, IJzerman M, Thokala P, et al. 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.
- 13) Inotai A, Nguyen H, Hidayat B, et al. Guidance toward the implementation of multicriteria decision analysis framework in developing countries. Expert Review of Pharmacoeconomics & Outcomes Research. 2018;18(6):585-592.
- 14) Ultsch B, Damm O, Beutels P, et al. Methods for Health Economic Evaluation of Vaccines and Immunization Decision Frameworks: A Consensus Framework from a European Vaccine Economics Community. PharmacoEconomics. 2015;34(3):227-244.
- 15) GOV.UK. (2019). The Prioritisation Framework: making the most of your budget. [online] Available at: https://www.gov.uk/government/publications/the-prioritisation-frameworkmaking-the-most-of-your-budget [Accessed 23 May 2019].

- 16) Oortwijn W, Jansen M, Baltussen R. Evidence-informed deliberative processes. A practical guide for HTA agencies to enhance legitimate decision-making. Version 1.0. Nijmegen:
 Radboud University Medical Centre, Radboud Institute for Health Sciences; 2019. Available from: https://www.radboudumc.nl/en/research/research-groups/global-health-priorities
- 17) Brouwers M, Kho M, Browman G, et al. AGREE II: Advancing guideline development, reporting, and evaluation in health care. Preventive Medicine. 2010;51(5):421-424.
- 18) 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

- 19) Fung A. Varieties of Participation in Complex Governance. Public Administration Review.2006;66(s1):66-75.
- 20) Phillips L, Phillips M. Facilitated Work Groups: Theory and Practice. The Journal of the Operational Research Society. 1993;44(6):533.
- 21) Guyatt G, Oxman A, Vist G, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008;336(7650):924-926.
- 22) Wilkinson T, Sculpher M, Claxton K, et al. The International Decision Support Initiative Reference Case for Economic Evaluation: An Aid to Thought. Value in Health.
 2016;19(8):921-928.
- 23) Moreno-Calderón A, Tong T, Thokala P. Multi-criteria Decision Analysis Software in Healthcare Priority Setting: A Systematic Review. PharmacoEconomics. 2019;38(3):269-283.

- 24) McCormick BJJ, Waiswa P, Nalwadda C, Sewankambo N, Knobler S. SMART Vaccines 2.0 decision-support platform: a tool to facilitate and promote priority setting for sustainable vaccination in resource-limited settings. BMJ Global Health. 2020;5:e003587.
- 25) Adamu A, Jalo R, Habonimana D, Wiysonge C. COVID-19 and routine childhood immunization in Africa: Leveraging systems thinking and implementation science to improve immunization system performance. International Journal of Infectious Diseases. 2020;98:161-165.
- 26) Gheorghe A, Chalkidou K, Glassman A, Lievens T, McDonnell A. COVID-19 and Budgetary Space for Health in Developing Economies [Internet]. Center for Global Development; 2020. Available from: <u>https://www.cgdev.org/sites/default/files/Gheorghe-</u> Chalkidou-COVID-Budgetary-Space.pdf
- 27) WHO SAGE. WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply[Internet]. Geneva: World Health Organization; 2020. Available from: <u>https://www.who.int/docs/default-source/immunization/sage/covid/sage-prioritization-</u> roadmap-covid19-vaccines.pdf?Status=Temp&sfvrsn=bf227443_2&ua=1
- 28) Munn Z, Twaddle S, Service D, et al. Developing Guidelines Before, During, and After the COVID-19 Pandemic. Annals of Internal Medicine. 2020;0(0).

Table 1: a comparison between the types of policy questions addressed by the GRADE Evidence

 to Recommendation (EtR) framework and those addressed by the CAPACITI decision-support

 framework.

	Example of policy questions addressed	Example of policy questions addressed				
	by GRADE Evidence to	by CAPACITI decision-support				
	Recommendation (EtR) framework	framework				
Ne	w vaccine introduction					
1	Should rotavirus vaccination be	Which new vaccine(s) should be				
	introduced into the NIP?	prioritised for introduction into the NIP?				
		E.g. comparison between HPV, PCV,				
		rotavirus vaccines				
Va	accine product procurement					
2	Should the immunisation programme	Which of the available HPV vaccine				
	switch procurement from the quadrivalent	products should be procured for the NIP?				
	HPV vaccine to the nine-valent HPV					
	vaccine?					
Va	accine delivery strategy					
3	Should hepatitis B birth dose be delivered	Under which scenarios should controlled				
	under controlled temperature chain (CTC)	temperature chain (CTC) delivery be				
	conditions?	recommended for birth dose hepatitis B				
		vaccination?				

HPV - human papillomavirus, PCV - pneumococcal conjugate vaccine

Table 2: an overview of iterations in the development of the CAPACITI decision-support

 framework.

MCDA – multi-criteria decision analysis; NIP – national immunisation programme; NITAG – national immunisation technical advisory group; WHO – World Health Organization

	Version 2018	Version 2019	Version 2020
Scope	Selection of rotavirus	Prioritisation of 2-5	Prioritisation of 2-5
	vaccine products	immunisation	immunisation
		interventions	interventions
Output	Ranking of vaccines at	Document process and	Document process and
	national and sub-	rationale for final	rationale for final
	national level	recommendation	recommendation
Elements set by	Quantitative MCDA,	Quantitative MCDA, 0-	Minimal elements set
the framework	criteria, data inputs,	10 range for scoring	by the framework, with
	scoring scales	scale, separation of cost	flexibility for the user
		and non-cost criteria	to choose which steps
			are important for their
			recommendation
Elements set by	Weights, groups for	Stakeholders, options,	Stakeholders, options,
the user	equity analysis	criteria, weights,	type of MCDA, criteria,
		scoring scale definition,	weights (if relevant),
		outcome measures and	scoring scale and/or
		data sources	rules to interpret
			evidence (if relevant),
			outcome measures and
			data sources
Countries	Indonesia, Thailand	Mali (full pilot), Benin,	Indonesia (full pilot -
providing input		Burkina Faso, Côte	ongoing), Cuba,
(WHO country		d'Ivoire, Central	Nigeria, Vietnam,
office, NITAG,		African Republic,	Zambia
and/or NIP)		Democratic Republic of	

	the Congo, Ghana,	
	Indonesia, Nigeria	

Table 3: Steps in the CAPACITI decision-support framework. The framework outlines key

 considerations and questions under each step, but the fields in each step of the tool are left blank.

 Not all steps have to be completed. It is anticipated that certain steps will (and should) be pre

 filled at the country level to tailor to country context, streamline the process, and ensure

 consistency and accountability of recommendations.

MCDA – multi-criteria decision analysis

Step of the decision-support		Description				
framework						
	1.1 Framing the	Specifies the recommendation objectives, why a				
	objectives	recommendation is needed, how it will be used and by				
		whom				
	1.2 Context	Describes the current situation in the country and				
1. Decision question		potential implications of the recommendation				
on qu	1.3 Scope	Scopes possible options and uses quick procedures to				
Decisi		shortlist 2-5 options to evaluate				
	1.4 Participation	Maps important stakeholder perspectives and identifies				
		mechanisms for participation				
	1.5 Priority-setting	Considers which MCDA approach to follow and the				
	process	group techniques/discussion forums that will be used				
ria	2.1 Criteria	Documents the criteria and outcome measures to				
2. Criteria		evaluate options				

2.2 Rules	Determines whether all criteria will be considered
	simultaneously, or whether certain criteria will be
	considered before/after others
2.3 Weights	Assigns weights to each criterion to indicate their relative
	importance
2.4 Scoring scale	Defines how options will be scored against each
	criterion.
3.1 Evidence	Identifies and gathers available evidence
collection	
3.2 Evidence	Provides a concise overview of available evidence and its
statements	limitations
3.3 Performance	Summarises the performance of each option against each
matrix	criterion, for simple comparison across options
4.1 Comparison by	Reviews how the options compare on a criterion-by-
criterion	criterion basis
4.2 Comparison	Examines which option(s) perform best across all criteria
across criteria	and the extent to which this may be affected by data
	quality
5.1 Formulating the	Makes a preliminary recommendation and considers how
recommendation	to deal with data uncertainty
5.2 Supplementary	Considers any negative implications of the preliminary
considerations	recommendation and how these could be addressed
	2.3 Weights 2.4 Scoring scale 3.1 Evidence collection 3.2 Evidence statements 3.3 Performance matrix 4.1 Comparison by criterion 4.2 Comparison by criterion 5.1 Formulating the recommendation

	5.3 Final	Finalises and rationalises the recommendation
	recommendation	
	5.4 Audit,	Considers how the recommendation will be monitored
	monitoring and	and evaluated, and how to improve the recommendation
	evaluation	process
	5.5 Communication	Drafts the final report and describes the communication
		plan and appeal process

Figure 1

Title: a summary of the key differences between quantitative, qualitative and rule-based MCDA [11]. The CAPACITI decision-support framework (right side) allows the user to follow any of these three approaches, or to follow a hybrid-based approach. Specific details are in the text.

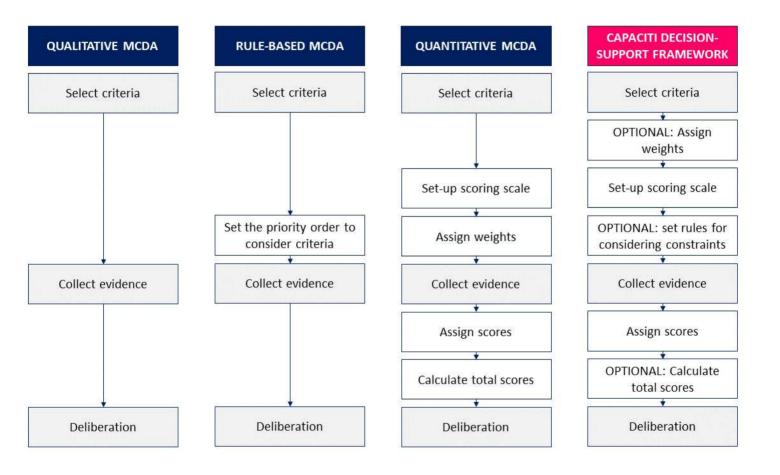


Figure 2a

Title: For quantitative MCDA, the tool produces a visual aid to guide committee discussion around factors driving the total scores. This figure is an illustrative example from a pilot country workshop to compare three HPV vaccine products. Workshop participants defined the criteria.

Legend: filled circles – indicate weight (full circle is higher weight); grey horizontal bars – weighted score; green to red scale – higher scores are green and lower scores are red; navy vertical bars – total score.

	 TOTAL SCORE NEW TOTAL SCORE 			207 216 227 227 218 22				227	
				HPV 1		HPV 2		HPV 3	
	Criterion	Weight	New weight	Score	New score	Score	New score	Score	New score
1	Rate of protection	3	3	9	9	9	9	9	9
2	Duration of protection	3	3	7	7	5	5	7	7
3	Valency	3	3	8	8	7	7	8	8
4	Safety	3	3	10	10	10	10	10	10
5	Availability	3	3	10	10	10	10	10	10
6	Temperature monitoring	3	3	10	10	10	10	10	10
7	Presentation	2	2	1	1	1	1	1	1
8	Storage	2	2	10	10	10	10	10	10
9	Presence of CTC	1	1	1	1	10	10	1	1
10	Storage volume	2	2	5	5	1	1	1	1
11	Experience	1	1	1	10	10	10	1	10

Figure 2b

Title: For quantitative MCDA, there is also an interactive sheet in which the committee can view the effect of changing scores and weights on the final result, to support discussions around confidence to proceed with a recommendation and the impact of data uncertainty or disagreement on weights. This figure is an illustrative example from a pilot country workshop to compare three HPV vaccine products, in which the score for the "experience" criterion has been modified to examine the impact of missing data.

Legend: blue bars – original total score; yellow bars – new total score in the uncertainty analysis; pink text – scores that have been modified in the uncertainty analysis

	TOTAL SCORE	Ň	207				218		
			HPV 1		HPV 2		HPV 3		
Criterion	Weight	Score	Weight x Score	Score	Weight x Score	Score	Weight x Score		
1 Rate of protection	• 3	9	27	9	27	9	27		
2 Duration of protection	• 3	7	21	5	15	7	21		
3 Valency	• 3	8	24	7	21	8	24		
4 Safety	• 3	10	30	10	30	10	30		
5 Availability	• 3	10	30	10	30	10	30		
6 Temperature monitoring	• 3	10	30	10	30	10	30		
7 Presentation) 2	1	2	1	2	1	2		
8 Storage	D 2	10	20	10	20	10	20		
9 Presence of CTC	0 1	1	1	10	10	1	1		
10 Storage volume	D 2	5	10	1	2	1	2		
11 Experience	O 1	1	1	10	10	1	1		