NEW VACCINES' INTRODUCTION PRIORITIZATION AND SEQUENCING TOOL (NVI-PST)

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Development Catalysts
JSI Research and Training Institute
International Vaccine Access Center at Johns Hopkins Bloomberg School of Public Health
McKing Consulting Corporation

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Introduction

With numerous newly-developed vaccines available on the market or expected in the next several years, countries face an increasingly complex decisions for their immunization programs. Gavi-supported countries, for example, can currently apply for seventeen vaccine programs[1]. As countries undertake the development and implementation of their National Immunization Strategy (NIS) as recommended by the WHO and additionally for some, a Full Portfolio Planning (FPP) as requested by Gavi, the Vaccine Alliance, they must consider which new vaccines to add to a national immunization program and the order they want to introduce them (new vaccine introduction prioritization and sequencing), as well as the optimization of existing vaccine programs by assessing change to vaccine products/presentations, schedules, and/or delivery strategies. Each country has a unique set of priorities and initiatives to consider with differential impact on disease burden, lives saved, health system cost savings, and feasibility/programmatic complexities. As countries consider new vaccine introductions, they must weigh their priorities in the context of increasing coverage of existing antigens, while also optimizing current programs and ensuring ongoing advocacy and improvements in their supply chain, data systems, communications and domestic financing.

The political process of introducing new vaccines in a country involves government and policymakers deciding on vaccine approval, distribution, and administration. In most countries, the National Immunization Technical Advisory Groups (NITAGs) are responsible for providing evidence-based recommendations to guide this decision-making, with the national immunization program as a key collaborator. Historically, most NITAGs review each new vaccine introduction individually, resulting in a recommended list of several new vaccines to be introduced over a short period without doing a preliminary prioritization exercise that would also consider the overall consequences on the financing, cold chain capacity and program delivery. This approach has sometimes required countries to delay vaccine introduction even if a NITAG recommendation was issued to introduce them.

Prioritization and sequencing exercises are needed in countries to make these recommendations and inform decision-making based on analysis of its epidemiological context, the capacity of its health system to absorb and maintain such introduction and the resources available. These processes must further optimize the chances of success by identifying programmatic synergies and streamlining processes and operations. However, existing prioritization processes and tools can be elaborate and time-consuming for countries, especially for Gavi-supported countries which face multiple priorities and constraints in human resources, technical capacity and time.

The Bill & Melinda Gates Foundation (BMGF) sought to address this challenge, working in close coordination with the WHO, Gavi, the Vaccine Alliance, UNICEF, and a core group of partners to develop this pragmatic and country-based vaccine prioritization and sequencing framework that can be implemented at the country level.

Intended use and complementarity with other tools

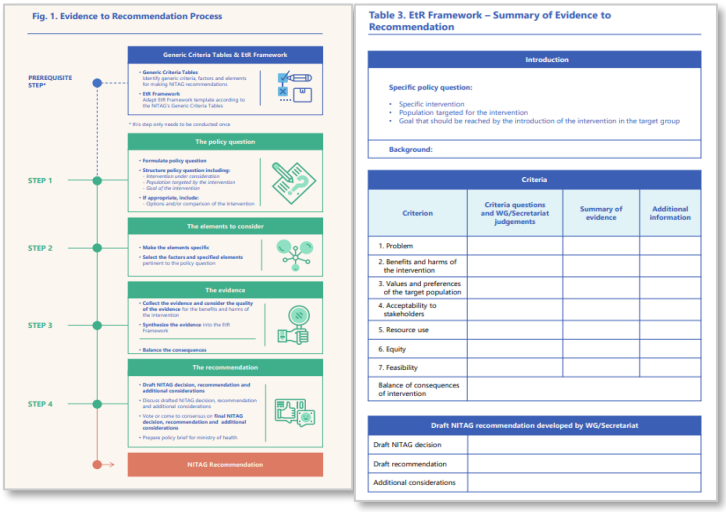
The NVI Prioritization and Sequencing Tool (NVI-PST) is designed specifically to guide a country's prioritization and sequencing of new vaccine introductions for a defined future period of time, through a structured yet streamlined decision-making process. The framework is not intended to replace existing vaccine introduction recommendation tools, but instead adds a tool that can be used specifically for **prioritization and sequencing of several vaccines for a defined future period of time**.

The following existing tools provide complementary decision-support guidance and information, but do not answer the same fundamental question:

[1] COVID-19 vaccine, Human papillomavirus vaccine (HPV), inactivated polio vaccine (IPV), Japanese encephalitis vaccine (JE), malaria vaccine, measles and measles-rubella vaccines, meningococcal A vaccine (MenA), oral cholera vaccine (OCV), pentavalent vaccine, pneumococcal conjugate vaccine (PCV), rotavirus vaccine, typhoid conjugate vaccine (TCV), yellow fever vaccine (YF), DTP-containing boosters, hepatitis B birth dose, hexavalent vaccine and Ebola vaccine.

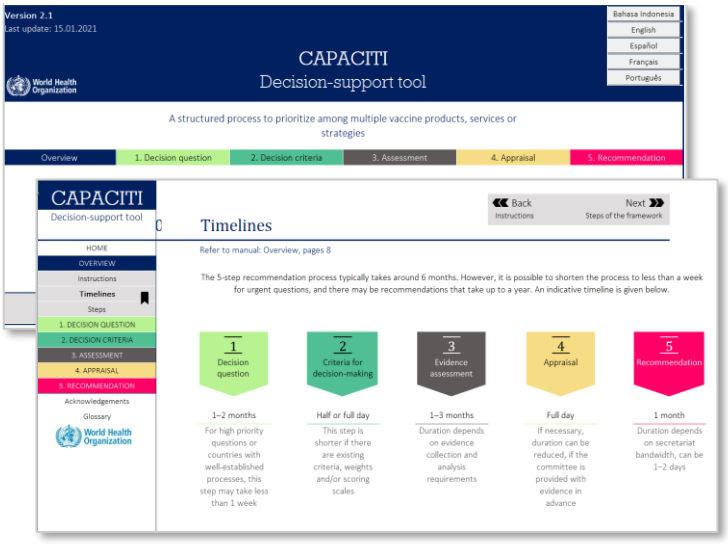
- **The CDC's Evidence-to-Recommendations (EtR) Framework is an important tool for considering the introduction of individual new vaccines or interventions, but does not incorporate comparison, prioritization and sequencing of new vaccines**. The framework enables the adoption of recommendation ns regarding potential interventions by NITAGs, based on a list of criteria representing aspects that need to be incorporated when considering introduction of a new vaccine or intervention. It is the sole tool to support the NITAG in making recommendations on whether and how individual vaccines should be introduced.

Figure 1 Evidence-to-Recommendations (EtR) Framework



- **WHO's Country-led Assessment for Prioritisation on Immunisation (CAPACITI) Decision-Support Tool is a complementary toolkit designed to compare interventions and select the best option - but it was not designed specifically for NVI introductions and does not include criteria for prioritization and sequencing**. CAPACITI is a comprehensive process tool that enables the comparison of interventions and the selection of the best option, leveraging a structured process tool that enables the grading of each option against predefined criteria.

Figure 2 CAPACITI Decision-Support Tool



Framework development and pilot

A working prioritization framework should be evidence-based, simple yet comprehensive, iterative and allow for tweaks based on countries' own priorities.

Focusing on these key principles, the Global NVI Prioritization and Sequencing Consortium - a collaboration between Development Catalysts, JSI Research and Training Institute (JSI), the International Vaccine Access Center at Johns Hopkins Bloomberg School of Public Health (IVAC), and McKing Consulting Corporation (McKing) – developed and piloted a comprehensive framework for new vaccine prioritization and sequencing. Development Catalysts spearheaded the framework development and coordinated and facilitated the implementation of the country pilots; JSI provided comprehensive technical expertise and, along with McKing, significant in-country technical facilitation, data collection, and stakeholder coordination; and IVAC similarly provided critical technical expertise with significant support to global data collection.

Following the development of a comprehensive framework, hierarchized list of criteria, and an innovative methodology that ensures the prioritization process is not only evidence-based but also simple, adaptive and iterative, the Global NVI Prioritization and Sequencing Consortium engaged the NITAGs in the Democratic Republic of the Congo (DRC) and Niger to pilot the new vaccine introduction prioritization and sequencing tool (NVI-PST). The methodology developed through this initiative for the prioritization of new vaccine introduction enabled the NITAGs in the DRC and Niger to make informed decisions based on international evidence and the analysis of their epidemiological contexts, health systems capacities

and available resources, resulting in recommendations for a well-defined, evidence-based sequencing of vaccine introductions.

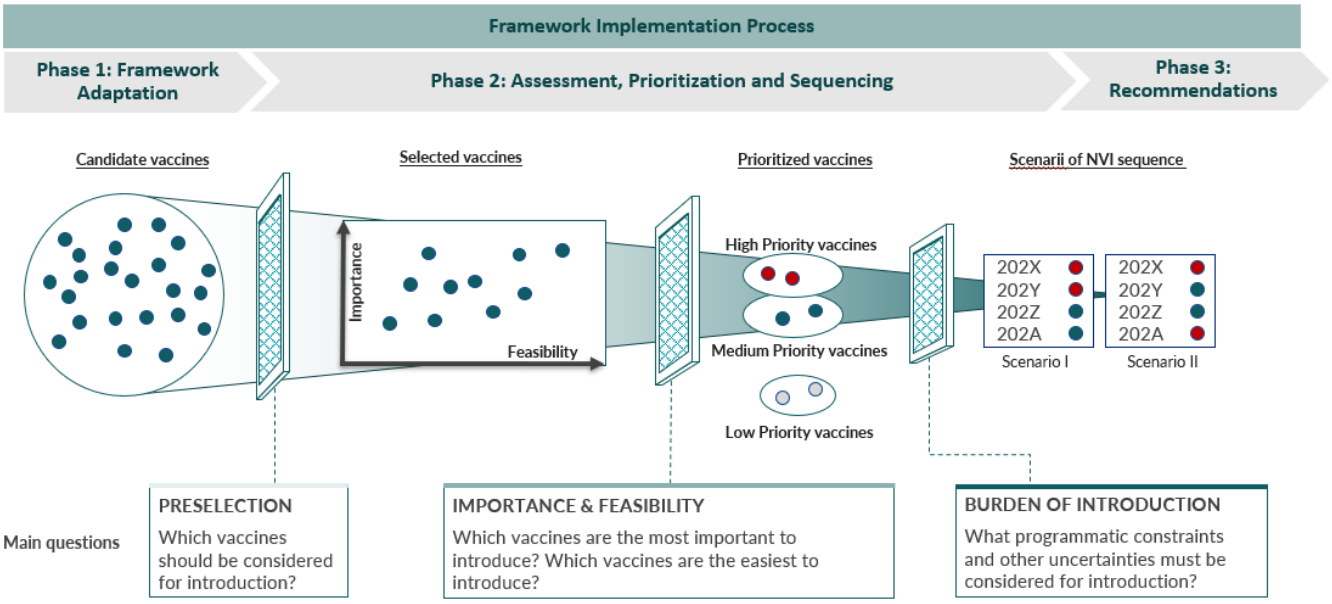
Methodology

The NVI Prioritization and Sequencing Tool (NVI-PST) is designed to be evidence-based, simple yet comprehensive, iterative and allow for tweaks based on countries' own priorities.

Beginning with a comprehensive list of all possible vaccine programs (available and near-future), the framework guides NITAGs through a series of decisions to select vaccines to consider and then prioritize vaccines based on pre-selected importance and feasibility criteria.

Prioritization and Sequencing Framework Guidelines	
Evidence-based	Rely on **measurable evidence** to ensure consistency of decision-making
Simple	Refer to a **limited number of criteria**
Comprehensive	Take into account **all potential vaccines** and **country context**
Adaptive	Enable **country** selection of **criteria** and **candidate vaccines**
Iterative	Be conducted on a **recurring basis** to ensure adaptation to **evolving local context, research, vaccines availability and potential funding**

Figure 3 Vaccine prioritization funnel and decision-points



Criteria selection

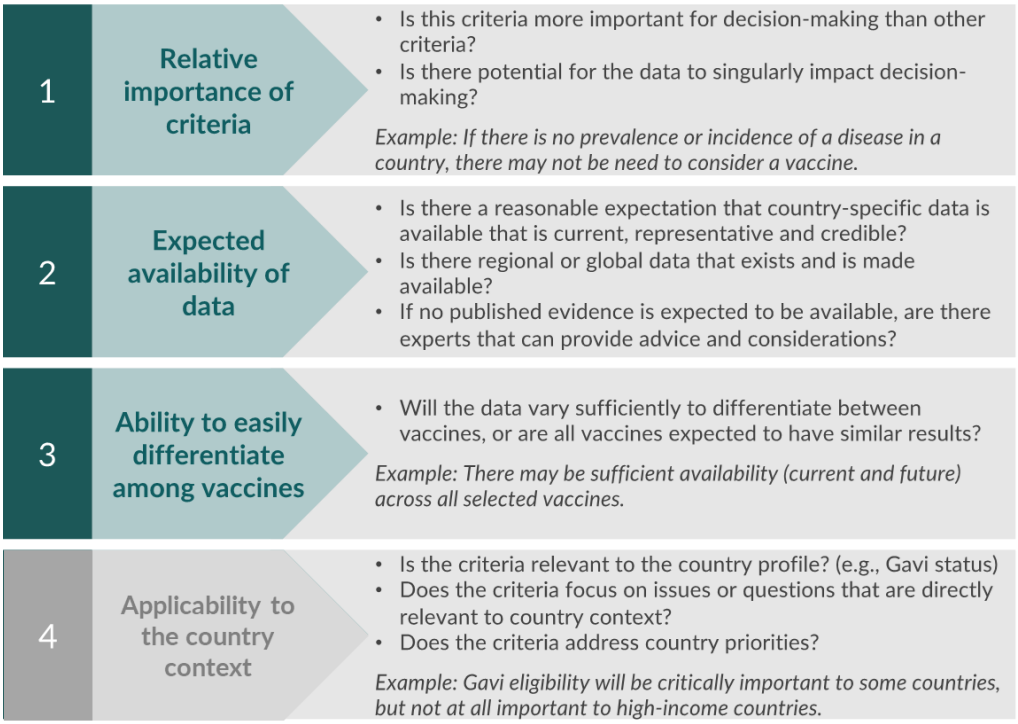
The framework is founded upon a list of 71 criteria (Appendix C and **"1.1 NVI-PST - Phase 1 - Prioritized list of criteria and indicators"**) that were identified through an exhaustive literature scan and review of existing tools and resources to ensure consistency, including the CAPACITI Decision-Support Tool, Vaccine Investment Strategy (VIS), and the Evidence to Recommendations (EtR) Framework. The literature review was conducted and vetted by experts, a list of the sources reviewed is included in Appendix A.

Each of 71 criteria identified were categorized based on 11 topics, including those focused on:

- Disease and vaccine: burden & epidemiology of the disease, benefits of the vaccine, safety of vaccine
- External factors: market availability, finances & economics, legal & ethical; and
- Program factors: strategy, logistics, service delivery, acceptability of the vaccine.

All criteria were then reviewed against the first three criteria selection benchmarks (Figure 4), including: relative importance as agreed by experts, expected availability of data (direct source vs. modeled), and the ability to easily differentiate among vaccines. Leveraging input from global stakeholders, the criteria are pre-classified into three groups: essential, significant and other, to provide NITAGs with a streamlined criteria list to be considered for the prioritization process. The fourth criteria selection benchmark (Applicability to the country context) will be considered by a country's NITAG prior to finalization of the criteria selection.

Figure 4 Criteria selection benchmarks for classification

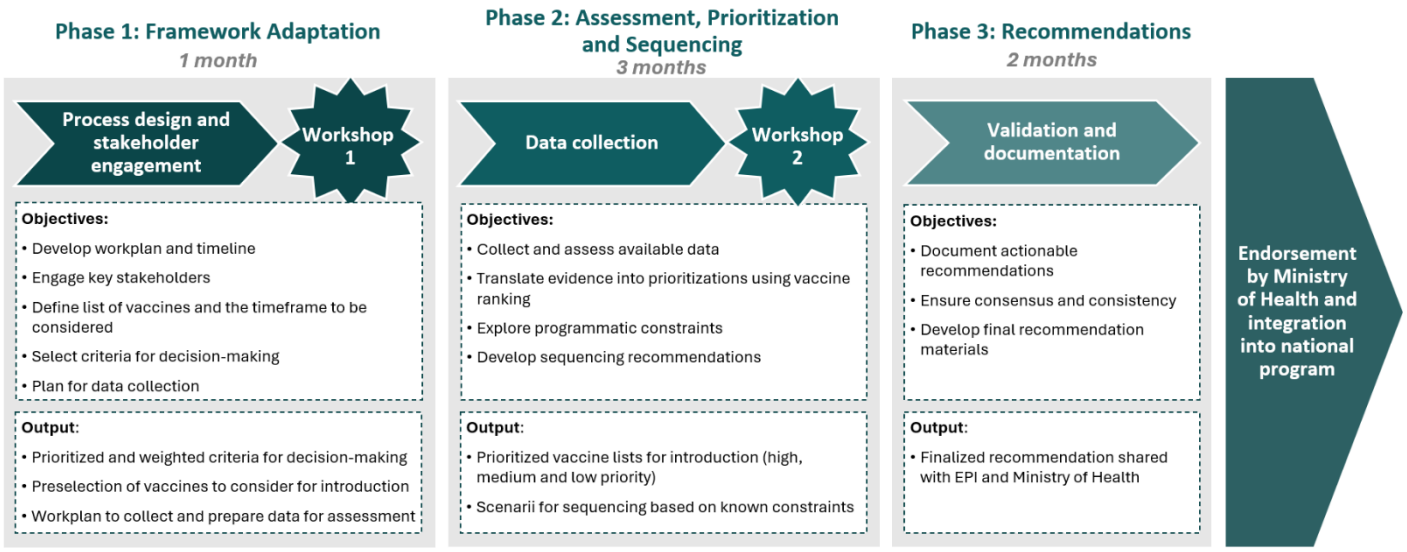


Considered for workshop #1

Framework implementation methodology

The NVI Prioritization and Sequencing Tool (NVI-PST) framework is implemented through a three-phase methodology (Figure 5) that is designed to support simple yet comprehensive analysis, remain adaptable to country priorities and context, and provide national ownership of the process, efficiency in proceedings, and consistency and replicability of outputs. This section provides an overview of these three phases; additional detail for implementation is included in the following sections.

Figure 5 NVI Prioritization and Sequencing Tool Methodology



Phase 1: Framework Adaptation

Beginning with a comprehensive process of stakeholder engagement, Phase 1 is intended to build alignment between stakeholders, enforce country ownership of the prioritization and sequencing process, and result in a clear path forward for assessing vaccine candidates. The NITAG is guided through a series of decisions to adapt the NVI Prioritization and Sequencing Tool framework to their country's specific context and needs – including:

- Defining the list of vaccines to be considered for the exercise,
- Defining the timeframe to be considered for the exercise,
- Selecting criteria to use to compare vaccines, and
- Determining a weighting scheme for the selected criteria to guide decision-making.

Conducted either through an online session or in-person workshop, an easy-to-use online voting tool[2] is used for each of these decision points to gather preferences and share results back with the NITAG so they can discuss each step.

An in-person one-day workshop at the end of Phase 1 brings together NITAG members, along with other key stakeholders such as the national immunization program, WHO and UNICEF, to finalize decision points and develop a plan for evidence collection. If not conducted in advance of the workshop, participants are first asked to respond to an online poll to provide feedback on the above key decision points. Once all feedback is received, members review and discuss the poll results, ultimately making final decisions on the vaccines and timeframe to be considered for the prioritization exercise and the prioritized and weighted criteria for decision-making.

The NITAG then develops a workplan to collect and prepare evidence for assessment. NITAG members, NITAG secretariat and/or other stakeholders (NITAG ex-officio and liaison members) can be assigned to collect individual data points (either by vaccine or by criteria, as relevant) with clear expectations of the timeline for evidence collection, who to provide the evidence to for coordination and preparation, and when the follow-on workshop will be to review the evidence.

Phase 2: Assessment, Prioritization and Sequencing

Following development of the evidence collection workplan, those assigned proceed with the evidence collection, exploring all known sources (including both country-specific and regional/global sources) to gather comprehensive

[2] Although using an online tool is highly recommended, this step can also be carried out using traditional methods, such as paper forms or other analog techniques, to gather and discuss preferences

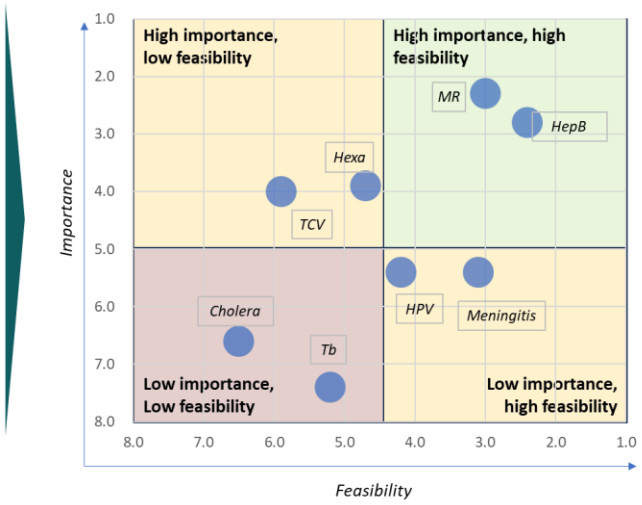
evidence to assess each criterion for each vaccine. An evidence collection coordinator – either a technical partner or the NITAG secretariat – should oversee this evidence collection, both to ensure accountability and to consolidate the evidence in an organized manner.

A second in-person workshop is held at the end of Phase 2, during which all the evidence gathered is assessed by the NITAG members over the course of three days. The first two days of the workshop focus on evidence assessment and vaccine ranking. NITAG members review the evidence gathered for each criterion individually, comparing indicators across vaccines, and use an online voting tool to rank[3] the vaccines – with the first day focused on importance criteria and the second day focused on feasibility criteria.

The results of this ranking exercise are used to inform both prioritization decisions and sequencing results, initiating in-depth discussion between the NITAG members - the results are presented as an aid to guide the discussion rather than an algorithm to make the decision for the NITAG. At the end of the second day of the workshop, members review and compare the importance and feasibility ranking results (weighted and unweighted). Average importance and feasibility rankings are computed for each of the vaccines considered and displayed in a four-quadrant scatter chart to enable a simple visualization of the discussion results (Figure 6). NITAG members then review the results and determine – based on the criteria discussed and their country priorities – which vaccines to prioritize, selecting both high and medium priority vaccines and defining which vaccines should be low priority and therefore not introduced in the proposed timeframe.

Figure 6 Sample vaccine ranking results and importance/feasibility assessment

Vaccine	Average Ranking - Importance	Average Ranking - Feasibility	Average Ranking - Combined
Hepatitis B at birth (HepB)	2.8	2.4	2.6
Measles-Rubella (MR)	3.0	2.3	2.7
Hexavalent	4.7	3.9	4.3
Meningitis Multivalent	3.1	5.4	4.3
Human Papillomavirus (HPV)	4.2	5.4	4.9
Typhoid (TCV)	5.9	4.0	4.9
Cholera	6.5	6.6	6.6
Tuberculosis	5.2	7.4	6.2

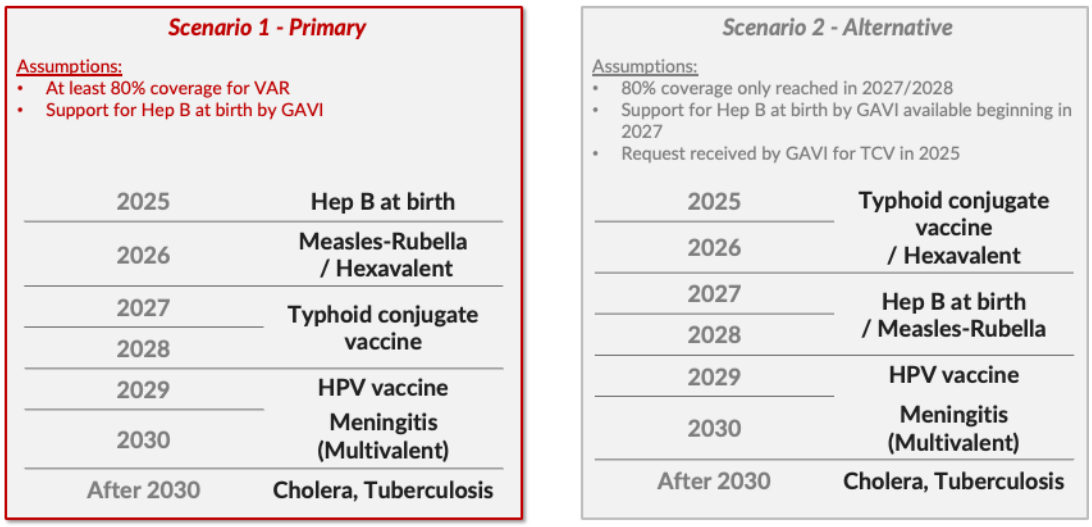


Following this prioritization exercise, the third day of the workshop focuses on sequencing. During this exercise, additional input is gathered from stakeholders – most importantly, from the national immunization program – on critical considerations for the introduction of each vaccine. This includes constraints of the immunization program, immunization campaigns already planned, the burden of introduction (additional programmatic requirements for introducing individual vaccines), and other uncertainties such as estimated availability of vaccines.

The NITAG is then able to develop sequencing scenarios for the prioritized vaccines. It is recommended that two or three scenarios are developed, outlining clear assumptions for each, to provide options if the context changes (e.g., availability of vaccines or funding).

[3] Although using an online tool is highly recommended, this step can also be carried out using traditional methods, for example using tables or worksheets to rank/rate vaccines and compute overall rankings/ratings

Figure 7 Sample sequencing scenarios



Phase 3: Recommendations

Clear documentation of the recommendations is crucial for presentation to the Ministry of Health and hopeful endorsement for integration into the national immunization program and by the Inter-agency Coordinating Committee (ICC). This process may vary based on the structure of each country's NITAG and their secretariat (as well as the level of engagement and acceptance by the ICC), but should include, at minimum, thorough documentation of recommendations and justification for decision-making, review and validation of the recommendations by the NITAG members, and preparation of a formal recommendations package to be submitted and presented to the national immunization program and the Ministry of Health.

Phase 0: Process Design and Preparation

The implementation of the NVI Prioritization and Sequencing Tool framework must be country-led to ensure the process and outcomes support country priorities and needs.

Thorough preparation for implementation of the NVI Prioritization and Sequencing Tool framework is important to increase the likelihood of success by:

- Ensuring alignment between key stakeholders on objectives and timeline,
- Identifying a core team and assign roles and responsibilities, and
- Developing a workplan that is feasible for the NITAG and addresses country-specific timelines.

Ensure alignment between key decision-makers

This toolkit is designed with the assumption that the NITAG Chair or secretariat will lead the implementation process, including initial process design and preparation; however this lead may vary based on the country. Regardless of the lead, it is critical to obtain buy-in from all national decision-makers prior to initiating the planning process and ensure alignment on the objectives and timeline. Successful implementation will depend on these stakeholders supporting the process, providing vital inputs where relevant, and being willing to advance the expected outputs for national-level decision-making. These key stakeholders include:

- The NITAG Chair (*if the process was not directly initiated by NITAG Chair)*
- The Director of the Immunization Program
- The Ministry of Health

Initial engagement should be conducted with these key stakeholders, including:

- Presentation of NVI Prioritization and Sequencing Tool framework and methodology
- Discussion of important dates or timelines of ongoing planning processes to incorporate into workplan
- Identification of existing plans for new vaccine introductions and/or national-level commitments for disease eradication/control
- Review of engagement opportunities throughout prioritization and sequencing process – in particular, highlighting the importance for ongoing participation from the Director of the Immunization Program.
- Identify upcoming meetings where the process and/or results of the NVI prioritization can be presented (e.g., the next ICC meeting).

Early identification of key opportunities to present the results of the NVI prioritization and sequencing will help align workplan development with key opportunities.

Identify core team and assign roles and responsibilities

The core team is responsible for guiding the implementation of the NVI Prioritization and Sequencing Tool framework and ensuring that the NITAG has sufficient capacity and/or support to conduct the prioritization and sequencing process. This team should consist of – at minimum – the NITAG Chair and the NITAG secretariat; additional individuals or technical partners may be engaged as appropriate to support this process.

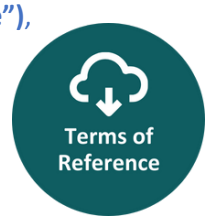
Once this core team is assembled, discuss and assign roles and responsibilities. Decide who will:

- Manage invitations and mobilize participants
- Arrange logistics for workshops
- Facilitate workshops
- Manage feedback and voting tools
- Oversee evidence collection
- Prepare supporting documents and presentations
- Develop recommendations
- Liaise with the Ministry of Health and present recommendations

Develop workplan and timeline

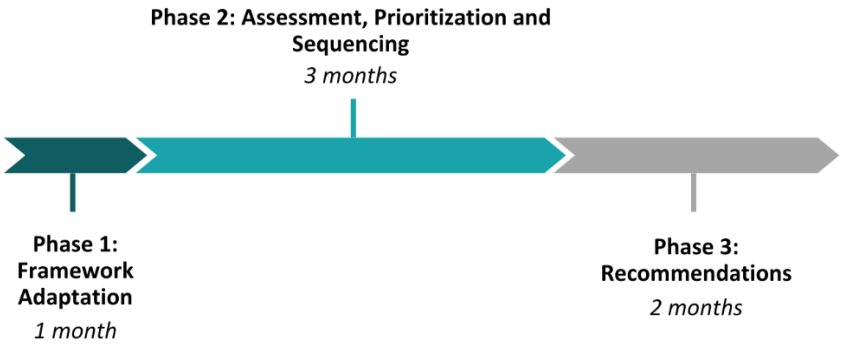
The core team begins by developing a workplan for implementing the NVI Prioritization and Sequencing Framework, including a schedule, budget and leads for individual activities. A template is provided for the workplan (**"0.3 NVI-PST Phase 0 - Workplan template**"), outlining the key tasks that are required for implementation of the NVI Prioritization and Sequencing Framework.

A generic Terms of Reference is also provided **("0.1 NVI-PST - Phase 0 - Partner Terms of Reference"),** which can be used as needed for technical or logistical support. The template includes a section on budgeting for the workshops; additional budgetary items may be required based on the NITAG's internal capacity (e.g., per diems for external experts), location of members (e.g., flights or alternate travel compensation for workshops), and other factors.



The schedule should include dates and times for all activities, including the initial online session, Workshop 1, evidence collection and preparation, Workshop 2, and development of recommendations. A recommended timeline is included in Figure 8, and countries should align these recommendations with external factors (e.g. NIS and FPP planning processes and any scheduled key meetings in which the process and/or results of the NVI prioritization and sequencing can be presented, as identified through the initial engagement with decision-makers.

Figure 8 Recommended 6-month timeline to implement the NVI Prioritization and Sequencing Framework



Phase 1: Framework Adaptation

Phase 1 is intended to build alignment between stakeholders, enforce country ownership of the prioritization and sequencing process, adapt the framework to country context, and result in a clear path forward for assessing vaccine candidates. This section provides a detailed description and instructions for each step in Phase 1: Framework Adaption.

Stakeholder Engagement

Following comprehensive planning and alignment from key decision-makers and finalization of workplan, a broader group of stakeholders are convened to introduce the initiative, present the methodology, and gather initial feedback to inform the Framework Adaption Workshop.

Arranged by the NITAG Chair with support from the core team, this initial engagement can be conducted virtually in advance of the Framework Adaption Workshop. *If an online session is not feasible, this input can be gathered during the Framework Adaption Workshop, but will require additional time.*

Planning for this stakeholder engagement session includes:

1. **Identification and invitation of relevant stakeholders:** Though the specific individuals will vary by country, this should include, at minimum, NITAG members (core and non-core), the NITAG secretariat, representatives from the Ministry of Health and the national immunization program, and key in-country partners such as WHO, Gavi and UNICEF.
2. **Preparation of methodology / process overview:** A generic slidedeck **("1.3 NVI-PST - Phase 1 - Online session slidedeck")** for this session is available via this link, containing both a general overview of the NVI Prioritization and Sequencing Tool framework and directions to provide feedback. Update these slides – including all designated slides - to include any country-specific information, such as the expected workplan and workshop dates for the prioritization and sequencing process, information on the NIS / FPP process, if relevant, and links or directions for providing feedback.

3. **Selection and preparation of a tool to gather feedback**: Using an online questionnaire[4] enables the facilitators to gather comprehensive input from both NITAG voting members and other participants on the timeline and vaccines to be considered, as well as the criteria to use for assessment. Select an online survey tool to use for this purpose - this can be any survey tool that is used by the organizing party (e.g., Survey Monkey, Microsoft Forms), or other free tools such as Google Forms. Prepare the online questionnaire in advance of the session; a template for this questionnaire is provided in the NVI-PST toolkit **("1.2 NVI-PST - Phase 1 - Criteria & Vaccines Questionnaire").**

[4] Although using an online tool is highly recommended, this step can also be carried out using traditional methods, such as paper forms or other analog techniques, to gather and discuss preferences

This virtual meeting should be facilitated by the NITAG Chair, with technical assistance provided as relevant. Key agenda items for this session include:

- Overview of methodology and workplan
- Review of the comprehensive criteria list
- Description of the process to collect feedback for key decision points, including:
    - Vaccines to be considered
    - Timeframe to be considered
    - Criteria to be used to compare vaccines

Immediately following the session, the link to the online questionnaire is shared with all relevant stakeholders to provide their input, highlighting the importance of receiving this feedback by the deadline to inform the Framework Adaptation Workshop (Workshop 1).

Framework Adaptation Workshop (Workshop 1)

An in-person 1.5 day workshop at the end of Phase 1 brings together NITAG members, along with other key stakeholders such as the national immunization program, WHO and UNICEF, to adapt the framework to country context and develop a comprehensive plan for evidence collection. The NITAG Chair may decide – depending on the NITAG's standard operating procedures – to allow virtual participation for those who are not able to attend in-person due to budget or time limitations.

Facilitated by the NITAG Chair and supported by the core team, this workshop serves several purposes:

- Defining the list of vaccines to be considered for the prioritization exercise,
- Defining the timeframe to be considered for the prioritization exercise,
- Selecting criteria to use to compare vaccines, and
- Determining a weighting scheme for the selected criteria to guide decision-making.

If not conducted in advance of the workshop as described above, participants should first be asked to respond to an questionnaire poll during this workshop to inform the key decision points, and this input can be incorporated into the slidedeck by a designated individual during initial agenda items.

Planning for the Framework Adaptation Workshop includes:

1. **Identification and invitation of relevant stakeholders:** Though the specific individuals will vary by country, this should include, at minimum, NITAG members (core and non-core), the NITAG secretariat, representatives from the Ministry of Health and the national immunization program, and key in-country partners such as WHO, UNICEF, CDC, BMGF and Gavi. Experts from other medical fields not represented in the NITAG but relevant to the exercise can also be invited to attend workshops and share views during the process.
2. **Management of logistics:** The assigned core team member manages all standard meeting logistics, including securing facility and catering, booking of travel/accommodations (if required / supported), management of A/V, and procurement of any identified supplies.
3. **Analysis and preparation of feedback:** A generic slidedeck for this session is provided **("1.4 NVI-PST - Phase 1 - Workshop 1 slidedeck")**, which contains both a review of the full criteria list and template slides to capture the feedback received through the online questionnaire. Update these slides – including all slides designated with a red stop shape - to include these results and any country-specific information, such as the expected workplan and workshop dates for the prioritization and sequencing process and information on the NIS / FPP process, if relevant. Instructions are included in the slide notes for updating the included chart templates.

4. **Identification of group decision-making techniques**: This workshop incorporates a number of critical decision points to adapt the NVI Prioritization and Sequencing Tool framework to the country's context; as such a clear and consistent process to make decisions is important. As the facilitator, the NITAG chair should identify the decision-

making mechanism to use in the workshop (e.g. show of hands, ballots, or roll call vote) and guidelines for decision-making (e.g., majority vote or consensus, process for tiebreakers). This should be guided by the NITAG's standard operating procedures, as relevant.

5. **Preparation for evidence collection workplan:** Following decisions on the vaccine candidates and criteria to be considered for the prioritization and sequencing exercise, the NITAG will develop an evidence collection plan. An evidence collection planning toolkit is provided to support this process, including an **evidence collection planning matrix, sample indicators for essential and significant criteria, and an optional template to use for evidence collection**. In advance of the workshop, the assigned core team member (Evidence Collection Lead) reviews the evidence collection planning toolkit and determines the process to use to conduct this evidence collection, leveraging pre-existing NITAG working groups as appropriate. Planning for evidence collection includes:
    a. Determining how evidence collection assignments will be made, including whether assignments should be made by vaccine (e.g., information on the benefits of the vaccine and vaccine safety), by criteria (e.g. burden of disease or expected availability of funding), by group of criteria (e.g. programmatic criteria), or using a mixed-methods approach. Additionally, some data points may be country-specific (e.g., perception of the target population of the disease risk) whereas others will be global (e.g., duration of protection); evidence that is not specific to the country may be collected by a global partner, if available.
    b. Determining the timeline and process for members to share the evidence they've collected with the Evidence Collection Lead. This must be completed in advance of the second workshop, with sufficient time to enable the Evidence Collection Lead to process the data and format it for sharing.
    c. Developing a process for dealing with evidence that members are unable to find/access, such as asking other technical partners or experts to assist, or discarding the criteria.
    d. Determining how and when the collected evidence will be shared back with the NITAG - for example, whether the evidence will be shared in advance of the second workshop or simply reviewed and discussed live in the workshop.

A mixed-methods approach to organizing data collection and assigning leads is recommended, based on the specifics of the data to be collected. Though this method requires more detailed planning, it will be most time-efficient for the evidence collection and synthesis.

The workshop begins with a review of the NVI Prioritization and Sequencing Tool framework and the methodology being applied for the country's prioritization and sequencing process; participants will then be guided through a series of decisions to adapt the framework to the country context. The workshop agenda is included in Figure 9, with details following.

Figure 9 Framework Adaptation Workshop (Workshop 1): Sample agenda

Time	Activity	Responsible
	Day 1	
30 minutes	Introductions and Objectives	TBD
1 hr	Review of the approach, methodology and criteria	TBD
30 minutes	Timeframe	TBD
1 hr 30 min	Vaccine candidates	TBD
3 hours	Criteria discussion	TBD
	Day 2	
2 hours	Plan for evidence collection	TBD
30 minutes	Workplan and conclusion	TBD

Workshop 1: Agenda details and facilitation process

1. Introductions and Objectives

The NITAG Chair convenes the workshop, providing opening remarks, making introductions as needed, and sharing any administrative/logistics needs.

Process:

- Introduce the purpose of the prioritization and sequencing exercise, including how it aligns with the country's NIS / FPP process, if relevant.
- Make introductions of attendees as needed.
- Provide any required information on logistics for the workshop.

2. Approach, Methodology and Criteria

The workshop begins with a comprehensive review of the NVI Prioritization and Sequencing Framework, including the methodology, expectations for adapting the framework to the country context, and an in-depth review of the framework's criteria. This review may be led by the NITAG Chair, secretariat, or any assigned technical partner.

Process:

- Review the NVI Prioritization and Sequencing Tool framework and its methodology.
- Review the comprehensive criteria list by category, including pre-classification of criteria.
- Discuss the process to adapt the framework to the country in this workshop.

3. Timeframe

The NITAG selects the time period to be considered for this prioritization exercise, ensuring that the timeframe selected is feasible and realistic for 5-7 vaccine introductions (some of which will be de-prioritized), given the status and constraints of both the EPI program and health system. This discussion and decision-making process should be led by the NITAG Chair.

Process:

- Introduce the questions to be decided upon – the selection of the time period to be considered for this prioritization exercise. Discuss the explain the importance of determining a time period that is feasible for 5-7 vaccine introductions, given the status and constraints of the EPI program.
- Present results from the (online) questionnaire and facilitate discussion.
- Finalize the timeframe to be considered using a show of hand or other decision-making mechanism.
- (Optional) The frequency of the prioritization exercise (e.g. every 2 years) can also be discussed at that time

4. Vaccine Candidates

From the initial list of vaccine candidates, the NITAG selects 5-7 vaccines to consider for the prioritization and sequencing exercise. This abbreviate list enables the NITAG to focus on what vaccines are most important for their country at this time.

To provide a foundation for this discussion, recognizing that many of the vaccines to be considered are new and may not be well known by all NITAG members, the NITAG Chair or other assigned technical partner begins with presenting basic information on each potential vaccine candidate. This ensures NITAG members have sufficient knowledge of the disease burden and vaccine itself to appropriately select vaccines to consider. The Chair then presents the feedback gathered through the (online) questionnaire and facilitates discussion on the vaccine candidates. Led by the NITAG Chair, the NITAG then discusses and selects vaccines leveraging the feedback gathered through the online questionnaire for in-depth discussion and decision-making.

Process:

- Introduce the vaccine candidates to be selected from for the prioritization exercise.
- Present information on the vaccine candidates and underlying disease burden.
- Present results from the (online) questionnaire and facilitate discussion.
- Finalize the selection of 5-7 vaccines to be considered in the prioritization exercise, using a show of hand or other decision-making mechanism.
- Identify if any future vaccines are of interest to the NITAG for future consideration.

5. Criteria Selection and Weighting

From the initial list of 71 criteria, the NITAG selects up to 16 criteria to use for the prioritization exercise and classifies the criteria as essential, significant or other. This abbreviated criteria list enables the NITAG to focus on what is most important for their country to consider and streamlines the follow-on evidence collection and assessment process. Using the feedback gathered through the (online) questionnaire to support the decision-making process and considering the criteria selection benchmarks, the NITAG discusses and selects essential criteria, significant criteria, and other criteria.

A mix of essential, significant and other criteria will enable the selected weighting scheme to inform prioritization discussions. It is recommended that countries should consider no more than 8 essential criteria, 5 significant criteria, and 3 other criteria.

After the essential, significant and other criteria are selected, the NITAG indicates the relative importance of the criteria for the prioritization exercise by assigning weights to each. To simplify this process, the NVI Prioritization and Sequencing Tool framework assigns weights by criteria group (essential, significant, other) rather than to each criteria individually; the default scale is 3.0 (essential) – 2.0 (significant) – 1.0 (other). Any weighting scale can be selected, as long as higher weights indicate greater importance. The NITAG discusses potential weighting scales and selects weights through approved decision-making mechanism.

These discussions and decision-making processes should be led by the NITAG Chair, though assigned partners may provide support by reviewing the criteria and questionnaire results.

Process:

- Introduce the process to be used to select criteria to be used for the prioritization exercise. Provide a reminder on the difference between essential, significant and other criteria. Provide a reminder of the criteria consideration benchmarks (the considerations to be used for selecting criteria): relative importance of the criteria, expected availability of the data, the ability to easily differentiate between vaccines, and applicability to the country's context.
- **[Essential criteria]** Present results from the (online) questionnaire and facilitate discussion.
- **[Essential criteria]** Select up to 8 essential criteria using a show of hand or other decision-making mechanism.
- **[Significant criteria]** Present results from the (online) questionnaire and facilitate discussion. Remind participants that this decision point should consider both the pre-classified essential criteria not selected **and** pre-classified significant criteria.
- **[Significant criteria]** Select up to 5 significant criteria using a show of hand or other decision-making mechanism.
- **[Other criteria]** Present results from the (online) questionnaire and facilitate discussion.
- **[Other criteria]** Select up to 5 other criteria using a show of hand or other decision-making mechanism.
- Review and finalize the selected criteria list.
- Introduce potential weighting schemes for the criteria list and facilitate discussion on preferred weighting.
- Select a weighting scheme through show of hands or other decision-making mechanism.

6. Plan for Evidence Collection

Following decisions on the vaccine candidates and criteria to be considered for the prioritization and sequencing exercise, the NITAG develops an evidence collection plan to ensure comprehensive evidence generation. The Evidence Collection Lead, in partnership with the NITAG Chair, leads this discussion and planning process, including describing the process to be undertaken. An evidence collection planning matrix is presented to the NITAG members, with in-depth discussion on indicators for each criteria and known available evidence and/or resources to access available evidence. Based on the approach to organizing evidence collection, as determined by the Evidence Collection Lead, the NITAG Chair makes evidence collection assignments, with 1 lead per group of data assigned for accountability and identified partner support, if available. Following evidence collection assignments, the Evidence Collection Lead provides specific instructions to those assigned, including the timeline and process to share the evidence collected and what to do should they not be able to find/access specific data points.

Evidence collection planning should address the level at which evidence should be collected. Clearly segmenting national-level data (e.g., perception of the population of the disease risk) and global-level data (e.g., duration of protection) protection) will guide appropriate assignments for evidence collection.

Process:

- Present the process to be used for evidence collection, including timeline, roles and responsibilities, and how evidence will be analyzed and presented.
- Review the evidence collection matrix. Discuss indicators of interest for each criteria. Discuss known available evidence and/or resources to access available data. *This can be done after the workshop by each work group*
- Assign leads for evidence collection – these may include NITAG members, NITAG secretariat and/or other stakeholders (NITAG ex-officio and liaison members).
- Discuss specific steps to be taken by the assigned leads, including a reminder of the timeline, instructions for who to provide the evidence to for coordination and preparation, and what to do should issues be encountered (e.g. unable to find/access the assigned evidence).

7. Workplan and Conclusion

The NITAG Chair closes the workshop with a review of the workplan, next steps and key dates.

Process:

- Review the NVI Prioritization and Sequencing Tool framework workplan, with a focus on evidence collection timeline and date for next workshop.
- Identify upcoming key meetings to present the process and/or prioritization and sequencing results.
- Address any general comments or questions.
- Thank participants and conclude.

Phase 2: Assessment, Prioritization and Sequencing

Phase 2 moves the adapted prioritization and sequencing framework from planning into execution through a comprehensive process of evidence collection, evidence assessment, and guided decision-making for prioritization and sequencing. This section provides a detailed description and instructions for each step in Phase 2: Assessment, Prioritization and Sequencing.

Evidence Collection

Comprehensive evidence collection is vital to guide robust evidence-based decision-making, and therefore the collection and synthesis of relevant data will serve as the foundation for the prioritization and sequencing process. A guide to

evidence collection and synthesis is provided in this toolkit (**"2.2 NVI-PST - Phase 2 – Guide to Collecting evidence and building content"**).

Following development of the evidence collection planning matrix, those assigned proceed with the data collection as directed. This process will include:

- The identification of relevant evidence,
- Assessment of the evidence quality,
- Preparation of an evidence synthesis for further review, discussion and decision-making.

The Evidence Collection Lead will oversee the process of data collection, including:

- Ensuring those assigned to evidence collection complete their assignments by the deadline, including issuing reminders and providing support, as needed.
- Determining path forward, in consultation with the NITAG chair, if relevant evidence is not available for some indicators. New studies or literature reviews may be conducted to obtain evidence if time and resources permits, otherwise this gap should be noted for this assessment process and considered for future evidence generation opportunities.
- Review the quality of evidence obtained and preparation of an evidence synthesis as described further below.

The use of a standard template for collecting evidence will enable straightforward assessment of the evidence quality and comparison between data sources and ultimately streamline the evidence synthesis process. An optional template is included in the evidence collection planning toolkit.

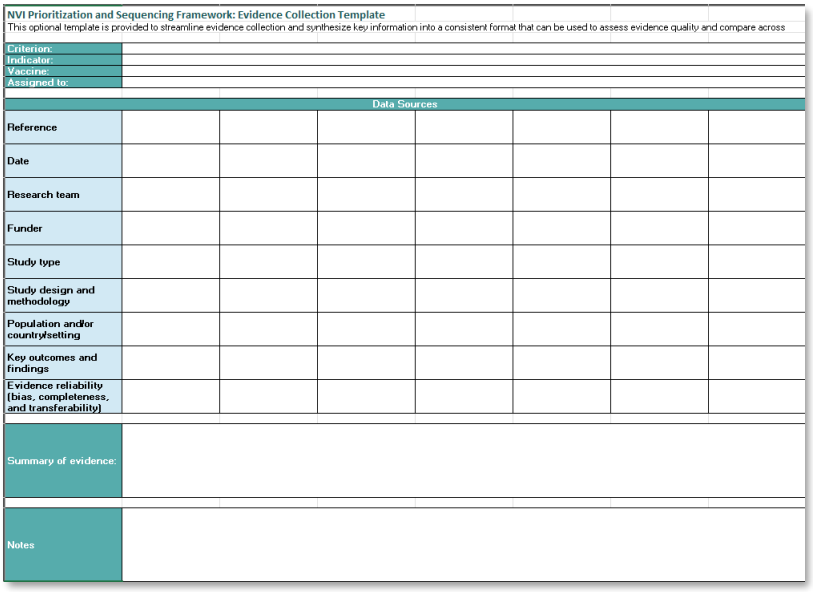
Identification of relevant evidence

Evidence should be collected for all identified indicators and data points, as identified in the evidence collection planning matrix (**"1.5 NVI-PST - Phase 1 - Data collection planning matrix"**), leveraging both the resources initially identified and any other available sources. Though specific sources will depend upon both the selected criteria, defined indicators and specific vaccine, the following sources may be considered to consult:

- Published and unpublished literature
- Statistical data or surveillance records
- WHO or WHO SAGE documents, publications and recommendations
- Documents published by other NITAGs or Regional Immunization Technical Advisory Groups (RITAGs)

The Global NITAG Network Resource Center can be leveraged as a key resource center to locate and access published recommendations from different NITAGs and WHO SAGE, as well as the SYSVAC registry to easily identify relevant existing systematic reviews.

Identified evidence should be entered into the prescribed format for collection, noting key attributes of the study and important information about the evidence, such as the date, research team, study type, study design, population and/or country setting and key outcomes. A shorter version of the template can be found in the same document.



NVI Prioritization and Sequencing Framework: Evidence Collection Template

This optional template is provided to streamline evidence collection and synthesize key information into a consistent format that can be used to assess evidence quality and compare across

Criterion:							
Indicator:							
Vaccine:							
Assigned to:							
Data Sources							
Reference							
Date							
Research team							
Funder							
Study type							
Study design and methodology							
Population and/or country/setting							
Key outcomes and findings							
Evidence reliability (bias, completeness, and transferability)							
Summary of evidence:							
Notes							

A shorter version of the data collection template is also available in the toolkit.

Assessment of evidence quality

As relevant evidence is identified, the quality and reliability of this evidence can be assessed by those conducting data collection.[5] There are several methods and tools available for assessing evidence quality and identifying evidence limitations. The WHO "Guidance for the development of evidence-based vaccination-related recommendations" provides several tools to consider for assessing evidence quality, including the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach and a template for applying this methodology. The evidence quality assessment conducted during the prioritization process should not replace the full evidence quality assessment conducted by NITAGs when considering and developing vaccine recommendations. The following could be considered for assessing evidence quality, accuracy and reliability during a prioritization exercise:

- Bias of the study or data: Are there any methodological limitations in the study design or execution that may have influenced the outcomes? Are these clearly described and are mitigation measures explained? More broadly, is the person evaluating the data able to discern the quality of the data?
- Conflicts of interest: Are there any potential vested interest that the authors, publishers or funders may have? Are any potential interests disclosed or acknowledged clearly? In that, case, these should recognized, acknowledged and discussed, while not necessarily leading to automatically downgrading these studies.
- Completeness: Is the study based on complete datasets (i.e., limited dropout or exclusion) or are there structural limitations that impact the results (i.e., in to lack of health care access or incomplete reporting)? Do studies report similar and homogenous effects of the vaccines? Are there concerns about underlying data quality?
- Transferability: Is the evidence representative of the target population and/or country context? Is the context in which the study was conducted relevant or comparable to the potential introducing country, or is there adequate information about the study population to allow for transferability to other settings?

The evidence quality and reliability assessment can be entered into the evidence collection template. Once all evidence has been collected and assessed, a summary of evidence should be developed to highlight the most reliable and relevant evidence available and any limitations in the evidence. For some indicators of interest, evidence may not yet be available

[5] The evidence quality assessment conducted during the prioritization process is optional due to time constraints and the extensive scope of the comparison, which involves multiple vaccines and criteria

(i.e., for vaccines still in clinical trials); it is important to note this and, where feasible, identify any ongoing studies or non-published data that could be reviewed.

Preparation of an evidence synthesis

As evidence is collected and assessed, it is submitted to the Evidence Collection Lead to review, validate assessments, and prepare an evidence synthesis to be used for the Prioritization and Sequencing Workshop (Workshop 2). The Evidence Collection Lead should review each evidence summary submitted and validate the assessment based on the data collected. Should there be any significant questions, concerns, or disagreements regarding the evidence summaries, the Evidence Collection Lead should discuss directly with those assigned to the evidence collection and come to a consensus regarding evidence reliability and/or detail any areas where questions remain and warrant further discussion. Once validated, evidence summaries can be input into the evidence synthesis template, to enable ease of review across vaccines and identify any evidence gaps. If significant gaps are identified, the Evidence Collection Lead may discuss with the NITAG Chair and potentially assign an alternate evidence collector to seek additional sources. In the case of evidence gaps resulting from vaccine options still in clinical trials or yet to be introduced (i.e., for vaccines expected to be available in the period of interest but still undergoing clinical trials or review for licensure, etc.), the Evidence Collection should note any available information on anticipated timeline for evidence/data availability. This may be gathered in consultation with key informants, through clinical trial databases (i.e., ClinicalTrials.gov, etc.), or pipeline tracking resources managed by partners.

The evidence synthesis should be provided to all NITAG members at least 48 hours before Workshop 2, though in-depth review and discussion of the evidence will occur during Workshop 2.

Prioritization and Sequencing Workshop (Workshop 2)

A two- to three-day in-person workshop provides the opportunity for all NITAG members and other key stakeholders to evaluate the evidence generated and prioritize and sequence the selected new vaccines.

As with the first workshop, the NITAG Chair may decide – depending on the NITAG's standard operating procedures – to allow virtual participation for those who are not able to attend in-person due to budget or time limitations. **However, it is strongly recommended to have all NITAG members present in-person due to the quantity of information to be discussed and for ease of facilitating the prioritization exercise.**

Facilitated by the NITAG Chair and supported by the core team, this workshop serves several purposes:

- Review and discuss the evidence generated across all criteria and vaccines,
- Conduct the prioritization exercise through a streamlined ranking process, and
- Develop sequencing recommendations.

Planning for the Prioritization and Sequencing Workshop includes:

1. **Identification and invitation of relevant stakeholders:** Though the specific individuals will vary by country, this should include, at minimum, NITAG members (core and non-core), the NITAG secretariat, representatives from the Ministry of Health and the national immunization program, and key in-country partners such as WHO, Gavi and UNICEF.
2. **Management of logistics:** The assigned core team member manages all standard meeting logistics, including securing facility and catering, booking of travel/accommodations (if required / supported), management of A/V, and procurement of any identified supplies.

Comprehensive input from EPI or the national immunization program is particularly important for this workshop to ensure the vaccine rankings and developed scenarios reflect program realities and expected burden of introduction.

3. **Selection and preparation of workshop tools[6]:** The NVI Prioritization and Sequencing methodology is based on ranking the selected vaccines for each criterion, weighting these results based on the criteria classification levels, and producing a combined weighted average vaccine ranking. This requires use of a tool that allows members to rank the vaccines against each criterion. The core team member responsible for the management of feedback and tools should identify an online or analog tool to be used and prepare a separate poll question for each criterion, listing the candidate vaccines for the individuals to rank based on either importance or feasibility (depending on the criteria category).
4. **Identification of group decision-making techniques**: The goal of this workshop is to develop recommendations regarding the prioritization and sequencing for new vaccine introductions. Though this workshop will rely on a vaccine ranking process to guide prioritization, a clear decision-making method must be used to make the final prioritization and sequencing decisions. As the facilitator, the NITAG chair should identify the decision-making mechanism to use in the workshop (e.g. show of hands, ballots, or roll call vote) and guidelines for decision-making (e.g., majority vote or consensus, process for tiebreakers). This should be guided by the NITAG's standard operating procedures, as relevant.

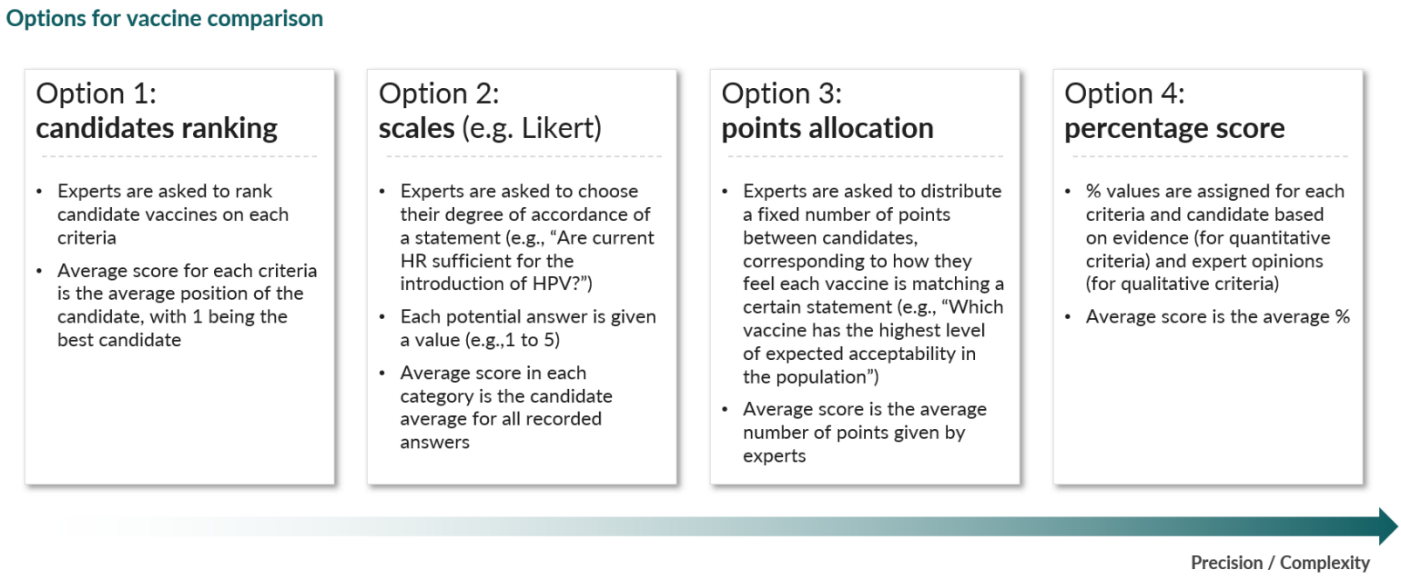
There are numerous online tools that can be used for vaccine ranking: for example, https://polleverywhere.com is a free tool that can be set up for this purpose. Important criteria for selecting this tool include:

- the capacity to set up as many live polls as the NITAG selected criteria,
- the ability to activate and deactivate questions throughout the duration of the workshop,
- the ability to trace who submitted each vote, and
- output calculations of the average ranking per vaccine for each criterion or the ability to export results to a CSV file for manual calculations.

[6] Although using an online tool is highly recommended, this step can also be carried out using traditional methods, for example using tables or worksheets to rank/rate vaccines and compute overall rankings/ratings

Vaccine Comparison – Options

While we recommend using ranking to facilitate vaccine comparisons, as the tool is designed around ranking mechanisms, the NITAG may choose an alternative comparison method, such as rating or scaling vaccines. Options for these approaches are outlined in the chart below. Decisions regarding the vaccine comparison process should be finalized by the end of the first workshop, particularly because the rules for *scales* or the translation of evidence into *percentage scores* must be established before evidence is gathered to maintain impartiality.



5. **Preparation of slides, including evidence synthesis:** A presentation template for this workshop is provided (**"2.3 NVI-PST - Phase 2 - Workshop 2 slidedeck"**), which contains a review of the overall NVI Prioritization and Sequencing Framework, an overview of the evidence synthesis and vaccine ranking process, template slides to synthesize evidence for review and discussion, and template slides to present the ranking results. In advance of the workshop:
    - **a.** Update slides on the vaccine ranking process to include voting tools and any other procedural elements,
    - **b.** Develop slides to clearly present the evidence synthesis, enabling a comparison across vaccines for each criterion, adding QR codes or links to access the ranking tool,
    - **c.** Prepare template slides to present ranking results and inform decision-making (these slides will be filled out in the workshop as votes are received), and
    - **d.** Update final slides on expected next steps, including the process for developing and finalizing the recommendations and any known dates for presenting the recommendations to national authorities.

The workshop begins with a review of the NVI Prioritization and Sequencing Tool framework and the methodology being applied for the country's prioritization and sequencing process; over the course of the next two days, participants will then be guided through discussion of each individual criterion and the evidence collected and the use of a live poll to rank vaccines for each criterion (considering criteria related to importance on the first day and criteria related to feasibility on the second day). Following this in-depth process, the third day focuses on reviewing the results of the ranking, making decisions regarding prioritized vaccines, and developing sequencing recommendations.

Vaccine Ranking – Process and Calculations

The ranking process used in this workshop - first ranking vaccine candidates against individual criteria and then developing aggregate rankings for both importance and feasibility criteria - provides a critical foundation for the NVI prioritization. Though the ultimate vaccine prioritization decisions will occur following discussion and group decision-making process, aggregate rankings for both importance and feasibility criteria enables participants to easily compare the results of the evidence generation across vaccines to inform final decision-making. A model facilitating these calculations is provided (**"2.1 NVI-PST - Phase 2 - Ranking Calculations model"**). As included in the description of the Workshop 2 agenda and facilitation process below, this includes the following steps:

1. **Participants rank vaccines for each criterion:** Following presentation of the evidence for each criterion, NITAG members complete a live poll to rank vaccines for the criterion. The focus on Day 1 will be on importance criteria, and participants will rank vaccines based on which is most important for each criterion; Day 2 will focus on feasibility criteria, and participants will rank vaccines based on which will be easiest to introduce.
   Example:
2. **Calculation of average vaccine rankings for each criterion:** The average vaccine rankings for each criterion are calculated by first calculating the count of how many times each vaccine was ranked in each position and multiplying this count by the number of the ranking position, calculating a sum of these ranking scores for each vaccine, and dividing this sum by the number of participants.
   Example: Participants submitted the vaccine rankings Figure 10*. The number of times each vaccine was ranked in each position is noted in* Figure 11*.*
   The ranking sum is calculated by multiplying the frequency of each rank by the number of the rank and adding across each vaccine (e.g., MR was ranked #1 by 2 participants and #2 by 2 participants, so the sum is (2 x 1) + (2 x 2) = 6.
   The sum of these scores for each vaccine are then divided by the number of participants to calculate the average ranking (e.g., as there were 4 participants in this example, the average ranking for MR is calculated as 6 / 4 = 1.5.

Figure 10 Sample vaccine rankings for one criterion

	Vaccine ranking results			
	1	2	3	4
Participant 1	MR	Hexavalent	TCV	HPV
Participant 2	MR	Hexavalent	HPV	TCV
Participant 3	Hexavalent	MR	TCV	HPV
Participant 4	TCV	MR	Hexavalent	HPV

Figure 11 Sample calculation of average vaccine ranking for one criterion

	Number of times vaccine is ranked in each position				Sum of ranking calculations	Average ranking
	1	2	3	4		
MR	2	2	0	0	6	1.5
Hexavalent	1	2	1	0	8	2
TCV	1	0	2	1	11	2.75
HPV	0	0	1	3	15	3.75

3. **Calculate a weighted average for each vaccine:** Once average rankings have been calculated for each individual criterion, weighted importance and feasibility averages are calculated for each vaccine using the assigned weights of the criteria by multiplying each average rank by its weight, adding together these values for each vaccine, and dividing by the total weight.

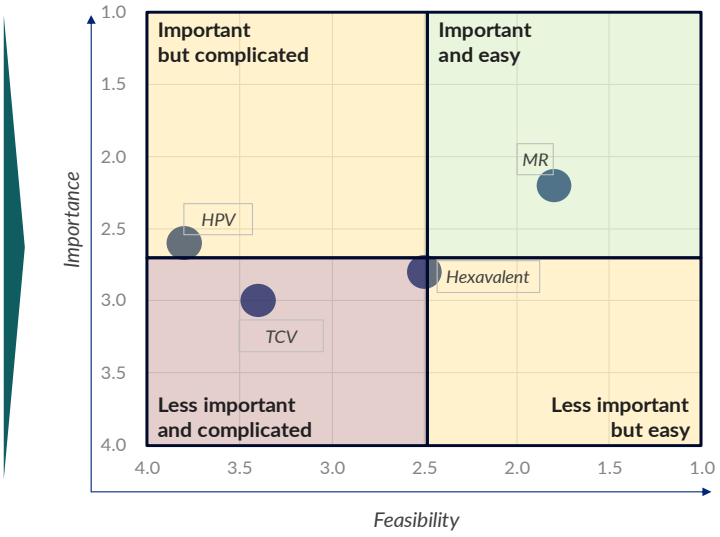
Example: Average rankings for 3 importance criteria (incidence, mortality and outbreak potential), along with the assigned weights, are included in Figure 12. *The weighted average for MR is calculated as: [(2.1 x 2.0) + (2.7 x 2.0) + (1.5 x 1.0)] / 5 = 2.2*

Figure 12 Sample importance criteria weighted averages

	Weighted average	Average	Incidence Weight: 2.0	Mortality Weight: 2.0	Outbreak potential Weight: 1.0
MR	2.2	2.1	2.1	2.7	1.5
Hexavalent	2.8	2.6	2.7	3.2	2.0
TCV	3.0	2.9	3.4	2.6	2.8
HPV	2.6	2.8	1.7	2.8	3.8

4. The average weighted importance and feasibility rankings are combined into an overall weighted ranking and are plotted in a four-quadrant chart, enabling simple visualization of the weighted importance and feasibility of each vaccine.

Vaccine	Average Ranking-Importance (weighted)	Average Ranking-Feasibility (weighted)	Average Ranking–Overall (weighted)
MR	2.2	1.8	2.0
Hexavalent	2.8	2.5	2.6
TCV	3.0	3.4	3.2
HPV	2.6	3.8	3.3



The workshop agenda is included in Figure 13, with details following.

Figure 13 Prioritization and Sequencing Workshop (Workshop 2): Sample agenda

Time	Activity	Responsible
	Day 1	
30 minutes	Welcome and introductions	TBD
30 minutes	Review of criteria and selected vaccines	TBD
4 hours	Presentation of evidence for importance criteria, with ranking of vaccines for each criterion	TBD
30 minutes	Presentation of results	TBD
	Day 2	
30 minutes	Welcome	TBD
30 minutes	Review of Day 1 results	TBD
4 hours	Presentation of evidence for importance criteria, with ranking of vaccines for each criterion	TBD
30 minutes	Presentation of results	TBD
1 hour	Prioritization of vaccines (high and medium priority lists selected)	TBD
	Day 3	
30 minutes	Welcome	TBD
30 minutes	Review of vaccine prioritization lists	TBD
1 hour	Discussion on the points of uncertainty to be integraqated into the scenarios	TBD
2 hours	Proposals and validation of sequencing scenarios	TBD
30 minutes	Plan for drafting of recommendations	TBD
30 minutes	Plan for scenario re-assessment	TBD
30 minutes	Next steps	TBD

Workshop 2: Agenda details and facilitation process

1. Introductions and Objectives

The NITAG Chair convenes the workshop, providing opening remarks, making introductions as needed, and sharing any administrative/logistics needs.

Process:

- Provide a review of the purpose of the prioritization and sequencing exercise, including how it aligns with the country's NIS / FPP process, if relevant.
- Make introductions of attendees as needed.
- Provide any required information on logistics for the workshop.

2. Approach

The workshop begins with a brief review of the NVI Prioritization and Sequencing Tool framework and the current status of the workplan, led by the NITAG Chair, secretariat, or any assigned technical partner. This individual will provide further detail on the approach for reviewing the evidence and process of ranking the vaccines for each criterion, including logistics for taking the polls.

Process:

- Review the NVI Prioritization and Sequencing Tool framework and its methodology.
- Remind participants of the decisions previously made, including the timeframe to be considered, the vaccines selected, the criteria selected, and the weighting scheme.
- Discuss the process to review the evidence for each criterion and the use of vaccine ranking to help inform prioritization.
- Provide instructions on how to use the polling tool for vaccine ranking.

Using an example poll may be helpful for participants to practice using the online tool for ranking. This could be relevant to the workshop topic or a fun icebreaker question.

3. Importance Criteria

The first day of the workshop covers the importance criteria. Facilitated by the Evidence Collection Lead with input by each individual assigned to evidence collection, criteria will be considered one-by-one. For each criterion, the individual(s) assigned to evidence collection will present the evidence and discuss the quality of that evidence, clearly identifying any concerns regarding bias, completeness and transferability, allowing for a thorough comparison and discussion across vaccines.

Process:

- For each criterion:
  - Present the evidence summary
  - Facilitate discussion of the evidence and comparison across vaccines
  - Conduct live poll to rank vaccines
  - Presentation of average ranking results (if selected tool provides live results – otherwise this will be calculated and presented during prioritization discussions)
- Repeat for each importance criteria.

4. Feasibility Criteria

The second day of the workshop covers the importance criteria. Following the same process as the importance criteria, the Evidence Collection Lead will facilitate the feasibility criteria discussions with input by each individual assigned to evidence collection. For each criterion, the individual(s) assigned to evidence collection will present the evidence and discuss the quality of that evidence, clearly identifying any concerns regarding bias, completeness and transferability, allowing for a thorough comparison and discussion across vaccines.

Process:

- For each criterion:
  - Present the evidence summary
  - Facilitate discussion of the evidence and comparison across vaccines
  - Conduct live poll to rank vaccines
  - Presentation of average ranking results (if selected tool provides live results – otherwise this will be calculated and presented during prioritization discussions)
- Repeat for each feasibility criteria.

5. Vaccine Ranking Summaries and Prioritization

The start of the third day of the workshop begins with a review of the vaccine ranking summaries. Facilitated by the NITAG Chair or assigned technical partner, the rankings for importance and feasibility criteria are first presented separately, and then combined into an overall weighted ranking.

Starting with the importance criteria, the average vaccine rankings for each criterion are converted into general rankings for each criterion (e.g., the lowest average ranking is ranked #1, the second-lowest average ranking is ranked #2, and

so-on). These general rankings are presented in a single table for ease of review and comparison. A weighted average is calculated for each vaccine using the assigned weights for each criterion, which are then assigned a weighted importance ranking using the same process described above (the lowest average ranking is ranked #1, etc.). These rankings are presented to workshop participants for review and discussion.

This same process is conducted for feasibility criteria, resulting in a weighted feasibility ranking being presented and discussed.

The average weighted importance and feasibility rankings can be considered in two manners for NITAG's prioritization consideration and discussion. First, the average importance and feasibility weighted rankings are combined into an overall weighted ranking. Second, the average importance and feasibility weighted rankings are plotted in a four-quadrant chart, enabling simple visualization of the weighted importance and feasibility of each vaccine.

With discussion led by the NITAG Chair, the NITAG reviews and discusses these results and prioritizes vaccines through the approved decision-making mechanism, identifying high, medium and low priority vaccines.

Capturing details on these discussions and justification for vaccine prioritization is critical for documenting clear and comprehensive recommendations for review by national authorities.

Process:

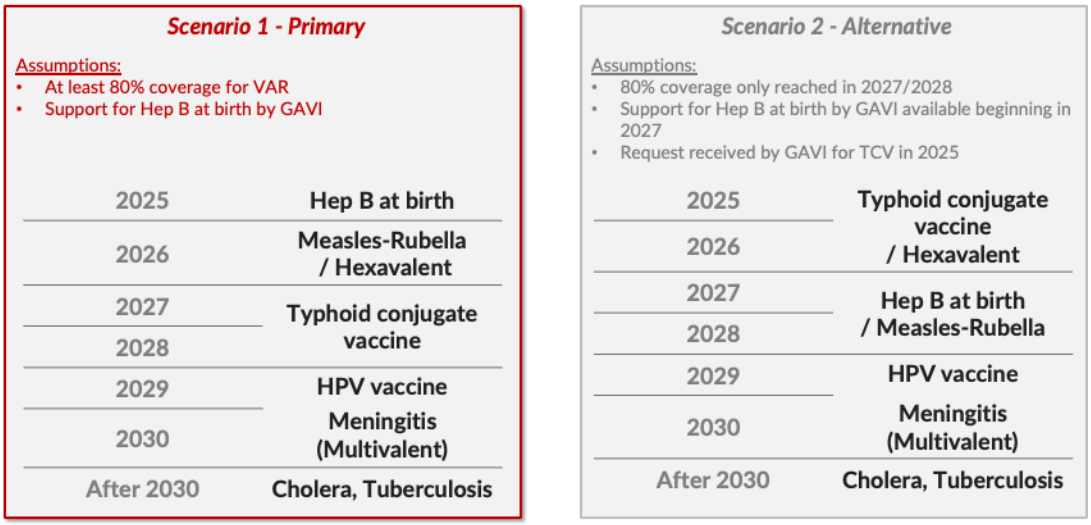
- Review vaccine rankings for importance criteria and facilitate discussion.
- Review vaccine rankings for feasibility criteria and facilitate discussion.
- Review combined weighted vaccine rankings for both importance and feasibility criteria and facilitate discussion.
- Select for high, medium and low priority vaccines using show of hand or other decision-making mechanism.

6. Sequencing

The recommended sequence for introducing the high, medium and low priority vaccines is also completed during the third day of the workshop. As with the feasibility criteria, **input from EPI / the national immunization program is absolutely critical for these discussions**, in order to understand and incorporate the burden of introduction as well as potential constraints or limitations on the EPI/MoH side. For example, NITAG members need to understand: what will be required to prepare for introduction of each vaccine and how long this process will take, how many new vaccines can feasibly be introduced in a year, and what campaigns are already planned and when. Additionally, they should consider any constraints or uncertainties regarding each individual vaccine – e.g., expected SAGE recommendations or availability of doses – to capture the earliest that each prioritized vaccine could possibly be introduced.

The NITAG Chair facilitates these discussions, ultimately developing two potential sequencing scenarios that address both the prioritization results and the burden of introduction. Assumptions for each scenario must be clearly documented, such that those reviewing the scenarios can understand the impact and potential options if assumptions that are not realized (e.g., if it is assumed that doses will be available by 20XX but market availability is delayed).

Figure 14 Sample sequencing scenarios



Scenario 1 - Primary

Assumptions:
- At least 80% coverage for VAR
- Support for Hep B at birth by GAVI

2025	Hep B at birth
2026	Measles-Rubella / Hexavalent
2027	Typhoid conjugate vaccine
2028	
2029	HPV vaccine
2030	Meningitis (Multivalent)
After 2030	Cholera, Tuberculosis

Scenario 2 - Alternative

Assumptions:
- 80% coverage only reached in 2027/2028
- Support for Hep B at birth by GAVI available beginning in 2027
- Request received by GAVI for TCV in 2025

2025	Typhoid conjugate vaccine / Hexavalent
2026	
2027	Hep B at birth / Measles-Rubella
2028	
2029	HPV vaccine
2030	Meningitis (Multivalent)
After 2030	Cholera, Tuberculosis

Process:

- For each high and medium priority vaccine, discuss the burden of introduction and any constraints/uncertainties.
- Through process of group consensus, develop two sequencing scenarios with varying assumptions.

7. Plan for Recommendation Development

The NITAG Chair discusses next steps for recommendation development, clearly identifying who is responsible for writing the recommendations, the process and timeline for reviewing the recommendations and providing feedback, and the process and timeline for finalization of the recommendations.

Process:

- Review the process for recommendation development, with individuals clearly designated to write the recommendations.

8. Scenario re-assessment

Led by the NITAG Chair, the NITAG additionally determines the process and timeline for reassessing the prioritization and sequencing results – both reassessment and minor updates to the sequence of introductions, as well as re-conducting the full prioritization and sequencing exercise to include comprehensive evidence generation and development of new recommendations. This should consider the capacity and budgetary constraints of the NITAG and expected timelines of future new vaccines.

Process:

- Through process of group consensus, determine the frequency to reassess the sequencing scenarios developed (e.g., every 1, 2 or 3 years) and the frequency to repeat this full prioritization and sequencing exercise (e.g., every 5, 7, or 10 years).

9. Conclusion

The NITAG Chair closes the workshop with a review of the workplan, next steps and key dates. The NITAG Chair should also gather feedback on the overall prioritization and sequencing process - conducted through either a brief online survey or group discussion, this information should be used to improve future prioritization and sequencing exercises.

Process:

- Review the NVI Prioritization and Sequencing Tool framework workplan, with a focus on recommendation development and key upcoming meetings.
- Gather feedback on the overall exercise and address any general comments or questions.
- Thank participants and conclude.

Phase 3: Recommendations

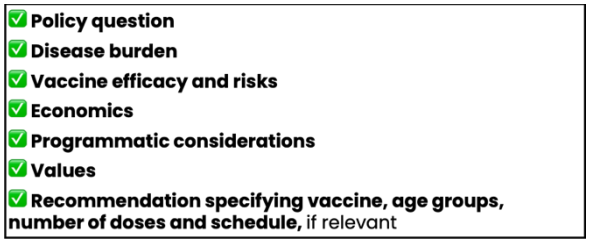
Clear documentation of the recommendations is crucial for presentation to the Ministry of Health and hopeful endorsement for integration into the national immunization program and by the Inter-agency Coordinating Committee (ICC). Immediate documentation ensures that all information discussed is captured and supports visibility and credibility of the NITAG and their recommendations. Though this process may vary based on the structure and standard operating practices of each country's NITAG and their secretariat, it should - at minimum - include thorough documentation of recommendations and justification for decision-making, review and validation of the recommendations by the NITAG members, and preparation of a formal recommendations.

The "Documenting NITAG work: best practices" training module provides standard recommendations for this process and expected output. According to this training module, the recommendations are drafted by the secretariat and should:

- Provide a **summary** of the evidence supporting the recommendation, rationale for decision to support **decision-making**
- Have a **consistent, clear, logical flow** and be **short** (ideally less than 2-4 pages)
- Be in a **standard format** for consistency, including specifying the MoH focal point and procedures of communications in the NITAG Charter or other documentation.

This training module also provides a standard outline for the recommendations report (Figure 15), however it is designed primarily for recommendations on whether or not to introduce single vaccines. For this purpose, the following sections are recommended:

Figure 15 Standard sections for the MoH report (NITAG Training Documentation)



- **Context of the question**: What is the question? Who added the topic to the NITAG agenda? Why was the topic added to the agenda?
- **Description of the prioritization process:** What importance and feasibility criteria were selected and what was the rationale for these selections?
- **Evidence search process**: How was the evidence generation process organized and conducted?
- **Evidence summary:** Findings on the disease, health systems and context issues, by criterion.
- **Defined priority lists**: What were the outcomes of the ranking and prioritization process?
- **Implementation considerations**: What is the burden of introduction for these prioritized vaccines? What existing constraints of the EPI program must be considered?
- **Proposed recommendation**: What are the recommended sequencing scenarios?

We strongly encourage the NITAG to include ancillary recommendations beyond the sequencing scenarios in the same document. These recommendations could cover areas such as suggestions for complementary studies to address any data gaps, a review of the NITAG's composition, and improved access to global-level data.

Though it is generally recommended that recommendations sent to the MoH should not exceed 2-4 pages, the detailed consideration and prioritization of numerous vaccines will inherently require a greater length; as such, an executive summary describing the process and recommendations should be included.

Following the development of the recommendations, the NITAG should follow standard operating procedures to finalize the recommendations. A designated focal point – usually the NITAG Chair – should manage this process. Example of process could be:

1. Ensure that all recommendations are shared within the NITAG, allowing all members to provide comments and edits before finalization. Online sessions can facilitate efficient discussions and address any changes or feedback.
2. Share a draft version of the recommendations with the national immunization program and discuss them during a dedicated meeting. At this stage, address any conflicting priorities with other strategic documents, such as the National Immunization Strategy (NIS) and the Full Portfolio Planning (FPP).
3. Finalize the recommendations to be disseminated and presented to the Ministry of Health (MoH) for approval.

Per standard NITAG operating procedures, the recommendations must be **archived by the secretariat in a dedicated folder** or on the website along with the rest of the important NITAG meeting documents.

Conclusion and next steps

NITAG should ensure that recommendations from this exercise are presented to the Minister of Health (MoH) for endorsement and disseminated.

1. Endorsement by the Minister of Health

Ideally, alignment should have been reached with the national immunization program, allowing the NITAG to jointly present its recommendations alongside the immunization program.

The NITAG should then seek an opportunity to present the recommendations and their rationale to the Minister of Health, particularly if this process was initiated by the NITAG rather than at the MoH's request.

The NITAG should share its recommendation with the Minister of Health for endorsement before dissemination. In case the Minister of Health decides not to endorse the recommendations for some reasons (e.g. lack of funding, other priorities etc.), the NITAG shouldn’t alter its recommendations as they are the products of an evidence-based process.

2. Dissemination of recommendations

Final recommendations should be disseminated to all relevant stakeholders. The following steps should be taken:

1. Present the final recommendations to the partners during an Immunization Inter-agency Coordination (ICC) meeting
2. Record any edits or comments occurring during the ICC and incorporate them into the final recommendations document
3. Share the final recommendations widely with government and partner stakeholders
4. Propose next steps regarding ancillary recommendations that require action. For example, define actions to be taken to collect missing data on demand for specific vaccines (the first step usually being to seek funding for a complementary study)
5. Ensure recommendations are reflected in strategic planning documents such as the National Immunization Strategy (NIS) or the Full Portfolio Planning (FPP) process

Appendix A: Bibliography

The NVI Prioritization and Sequencing Tool framework is founded on a comprehensive list of criteria that were identified through an extensive literature review. The following sources were consulted to develop the criteria list and align the criteria with existing tools.

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11. GAVI. Vaccine Investment Strategy (VIS) process

Appendix B: Acknowledgments

The following experts contributed to the framework design and helped build a comprehensive criteria list:

NVI Prioritization tool development team

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Appendix C: Criteria List

The NVI Prioritization and Sequencing Tool framework includes 71 criteria, of which a subset are selected by countries to use for their prioritization exercise. The table below includes the comprehensive list of 71 criteria, including the pre-classification into essential, significant and other. These criteria were identified through an exhaustive literature scan and review of existing tools and resources to ensure consistency, including the CAPACITI Decision-Support Tool, Vaccine Investment Strategy (VIS), and the Evidence to Recommendations (EtR) Framework. Each of these 71 criteria have been categorized based on 11 topics. The classification of criteria (essential, significant, other) is reviewed in Phase 1 (Framework Adaptation) and 10-16 criteria are selected by the NITAG to use for the prioritization exercise, as appropriate to country context and priorities.

Category	Sub-category	Criteria	Pre-Classification
Acceptability of the vaccine	Demand generation	Availability of resources for marketing and communication	Other
	Perception of target population of the disease	Perception of the target population of the disease risk, severity, fear and demand for disease control	**Essential**
		Ethical, reputational or social issues that may affect acceptability of the vaccine to the target population (e.g. reputation of the country producer, halal)	**Significant**
		Level of use in HICs, thought-leader or neighbouring countries (e.g. related to safety)	Other
		Perception of the target population on the desirable and undesirable effects of the vaccine	Other
		Acceptability of schedule (e.g. multiple injections, additional visits)	**Essential**
Benefits of the vaccine	Direct impact	Coverage of active serogroups or serotypes in the country (for serogroup- or serotype-specific vaccines)	**Essential**
		Effectiveness of the vaccine including in different populations/age groups/cohorts	**Essential**
		Efficacy and immunogenicity of the vaccine in target population	**Significant**
		Duration of protection and waning of immunity	**Essential**
		Number needed to vaccinate to prevent a case	Other
	Indirect impact	Impact on resistance to antibiotics & antivirals	Other
		Herd immunity / protection	**Significant**
		Effect of the vaccine on transmission	Other
Burden & epidemiology of the disease	Alternatives	Absence of satisfactory alternatives to prevent/treat the disease (considering effectiveness, cost and practicality)	**Essential**
	Economic impact of the disease	Cost of the disease to the health system	**Significant**
		Direct & indirect costs to patient & families	**Significant**
		Short- and long-term use of health care (e.g. treatments, hospitalization)	Other
		Productivity losses e.g. linked to work & school absenteeism linked to the disease	Other
	Epidemiology	Burden inequity (highest prevalence in poorer / at risk populations / gender inequity)	**Significant**
		Incidence including in different sociodemographic and age groups	**Essential**
		Prevalence including in different sociodemographic and age groups	**Essential**

Category	Sub-category	Criteria	Pre-Classification
		Outbreak potential incl. past occurrence of outbreaks and potential for international spread, and epidemic and pandemic risk	**Significant**
	Health impact	Hospitalization rate	**Significant**
		Mortality and lethality including in different sociodemographic and age groups	**Essential**
	Social impact	Intensity of suffering/severity of disease symptoms	Other
		Long-term complications of disease (e.g. frequency of survivors with sequelae)	Other
		Disability-adjusted life years (DALYs)	**Significant**
		Loss of quality-adjusted life years (QALYs)	Other
Finances & economics	Benefits	Social and economic benefits including reduction in health care costs, improvement in life expectancy, in quality of life for individuals, families, caregivers and communities, productivity gains	Other
		Indirect benefits (i.e. reduced antimicrobial resistance, reduced emergency room overcrowding)	Other
	Cost	Direct costs (cost of vaccine, materials, vaccinators, delivery)	**Essential**
		Indirect costs (e.g. training of health-care workers, supply chain expenses)	Other
		Perspective on vaccine price	Other
		Availability and sustainability of funding to cover the total cost of the program (incl. GAVI eligibility)	**Essential**
	Ratio	Net present cost benefit ratios (from health care and societal perspectives) of vaccine vs. alternative strategies (per life saved, case prevented, life year gained, quality-adjusted life year gained)	Other
Legal & Ethical	Ethical	Accessibility and equity of vaccination for the target population	Other
		Ethical, market and diplomatic issues that may affect acceptability of the vaccine to stakeholders	Other
	Legal	Absence of legal constraints concerning use of vaccine (i.e. departure from manufacturers' recommendations/off license use of the vaccine, mandatory, recording, potential compensation for adverse events, incentives)	Other
		Licensing by foreign NRA	Other
		Prequalified by WHO	Other
		Licensing by national RA	Other
Logistics	Cold Chain	Ease of conservation (volume & cold chain requirements)	Other
		Shelf life of the vaccine	Other
		Availability of adequate cold chain equipment at all levels or ability to procure CCE required to store the vaccine	**Essential**
	Distribution	Readiness of the existing distribution channels in the country	**Significant**
	Product aspect	Compatibility of the presentation of the vaccines with the expected uses in the country (e.g. to population spread in the country)	Other
		Adequacy of the labels to the local language	Other
	Wastage	Indicative wastage rate	Other
		Ability to maintain wastage at expected levels	Other

Category	Sub-category	Criteria	Pre-Classification
		Ability to manage waste	Other
Market availability	Availability	Market availability of the vaccine and supplies over the selected time period	**Essential**
		Sustainability of the market availability of the vaccine and supplies in the longer term	**Significant**
	Procurement	Ease of procurement of the vaccine (e.g. ability to procure through UNICEF, procurement timeline, delivery speed)	Other
Service delivery	Human Resources	Ease of preparation, reconstitution & administration (open-vial policy, CTC)	**Significant**
		Expected impact of the introduction on the human resources (e.g. additional workload due to the schedule, complexity of the administration, flexibility of the schedule, level of training requirements for human resources)	**Essential**
		Impact on existing immunization services or other health sectors - risk of overload	**Significant**
	Systems	Availability of information systems to manage the vaccine supply chain and measure related performance metrics (i.e. coverage and vaccine utilization)	Other
Strategy	Administration	Administration strategy (single dose, routine primary series only, booster, campaigns)	Other
		Feasibility of the program delivery strategy (physicians, CHW, nurses, pharmacists, school-based)	Other
	Introduction	Ease of the considered immunization strategies - incl. geographic (stepwise or nationwide) and target populations (selective/stepwise or universal)	Other
	Opportunities	Interchangeability with alternative or future products/presentations	Other
		Contribution to national/regional/global goals (e.g., eradication, control, elimination, reduction)	**Significant**
		Opportunity to pair introduction with other planned program (e.g. other vaccine introduction or switch with same target population)	Other
		Existing recommendations / guidelines for use (e.g. SAGE, professional organizations)	Other
	Target	Accessibility of the target population (age, gender, special risk)	**Essential**
Vaccine safety	Safety	Safety issues related to the product being similar to an existing vaccines or drugs	Other
		Risk at population level (e.g. risk of displacement of average age of infection, potential impact of strain selection or emergence of non-vaccine serotypes)	Other
		Risk at individual level incl. Type, severity, consequences and frequency of AEFI, including reactogenicity profile & capacity to mitigate known adverse events	**Essential**
		Contraindications and precautions for vaccination (e.g. requirement to check background especially factoring risk groups or risk factors)	Other
		Interference with other vaccines regarding immunity/protection	Other