# **New Vaccines Introduction Prioritization and Sequencing Framework: Toolkit**

# Appendix X: Framework Adaptation Questionnaire

## Prioritization of new vaccine introductions

This questionnaire is part of the NITAG’s implementation of the New Vaccine Introduction Prioritization and Sequencing Framework. The NITAG is using this framework to produce realistic and feasible introduction sequencing recommendations for new vaccine introductions in the coming years. This comes against a backdrop of increasing external and internal pressure on the introduction of ever-increasing numbers of vaccines, potentially resulting in the national immunization program being overwhelmed and unable to deliver.

This questionnaire is a preliminary step in the framework methodology, in preparation for the first workshop that aims to adapt the framework to country context. As a member of the NITAG, you are asked to give your opinion on the timeframe to be considered for the prioritization and sequencing exercise, vaccines to be considered, and selection of prioritization criteria (essential, additional and other). This list will then be discussed in the first workshop for consensus.

Following this workshop, the NITAG will undertake a comprehensive evidence generation process and re-convene for a second workshop, in which the NITAG will assess the evidence, compare between vaccines and decide on sequencing.

**Identity of Respondent**

1. What is your name?
2. Are you a core member of the NITAG?
   1. Yes
   2. No

**Timeframe**

1. In your opinion, what time period should the NITAG consider for this prioritization exercise?
   1. 5 years (e.g., 2024 – 2029)
   2. 7 years (e.g., 2024 – 2031)
   3. 10 years (e.g., 2024 - 2034)
   4. A longer period

**Essential criteria**

1. The following criteria were classified as globally essential based on an assessment of perceived importance, ability to differentiate between vaccines, and availability of data. From this list of 16 criteria, please select 8 criteria that you believe are the most relevant for your country to be considered as essential criteria for this exercise.
   1. [Acceptability of the vaccine] Perception of the target population of the disease risk, severity, fear and demand for disease control
   2. [Acceptability of the vaccine] Acceptability of schedule (e.g. multiple injections, additional visits)
   3. [Benefits of the vaccine] Coverage of active serogroups or serotypes in the country (for serogroup- or serotype-specific vaccines)
   4. [Benefits of the vaccine] Effectiveness of the vaccine including in different populations/age groups/cohorts
   5. [Benefits of the vaccine] Duration of protection and waning of immunity
   6. [Burden & epidemiology of the disease] Incidence including in different sociodemographic and age groups
   7. [Burden & epidemiology of the disease] Prevalence including in different sociodemographic and age groups
   8. [Burden & epidemiology of the disease] Mortality and lethality including in different sociodemographic and age groups
   9. [Burden & epidemiology of the disease] Absence of satisfactory alternatives to prevent/treat the disease (considering effectiveness, cost and practicality)
   10. [Finances & economics] Direct costs (cost of vaccine, materials, vaccinators, delivery)
   11. [Finances & economics] Availability and sustainability of funding to cover the total cost of the program (incl. GAVI eligibility)
   12. [Logistics] Availability of adequate cold chain equipment at all levels or ability to procure CCE required to store the vaccine
   13. [Market availability] Market availability of the vaccine and supplies over the selected time period
   14. [Vaccine safety] Risk at individual level incl. Type, severity, consequences and frequency of AEFI, including reactogenicity profile & capacity to mitigate known adverse events
   15. [Service delivery] 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)
   16. [Strategy] Accessibility of the target population (age, gender, special risk)

**Important criteria**

1. Of the remaining 8 criteria from the previous question (those not chosen as essential) and the following 14 important criteria, please select 5 criteria that you believe are also relevant in this prioritization exercise; these will be considered important criteria for this exercise.
   1. [Acceptability of the vaccine] Perception of the target population of the disease risk, severity, fear and demand for disease control *(if not selected in previous question)*
   2. [Acceptability of the vaccine] Acceptability of schedule (e.g. multiple injections, additional visits) *(if not selected in previous question)*
   3. [Benefits of the vaccine] Coverage of active serogroups or serotypes in the country (for serogroup- or serotype-specific vaccines) *(if not selected in previous question)*
   4. [Benefits of the vaccine] Effectiveness of the vaccine including in different populations/age groups/cohorts *(if not selected in previous question)*
   5. [Benefits of the vaccine] Duration of protection and waning of immunity *(if not selected in previous question)*
   6. [Burden & epidemiology of the disease] Incidence including in different sociodemographic and age groups *(if not selected in previous question)*
   7. [Burden & epidemiology of the disease] Prevalence including in different sociodemographic and age groups *(if not selected in previous question)*
   8. [Burden & epidemiology of the disease] Mortality and lethality including in different sociodemographic and age groups *(if not selected in previous question)*
   9. [Burden & epidemiology of the disease] Absence of satisfactory alternatives to prevent/treat the disease (considering effectiveness, cost and practicality) *(if not selected in previous question)*
   10. [Finances & economics] Direct costs (cost of vaccine, materials, vaccinators, delivery) *(if not selected in previous question)*
   11. [Finances & economics] Availability and sustainability of funding to cover the total cost of the program (incl. GAVI eligibility) *(if not selected in previous question)*
   12. [Logistics] Availability of adequate cold chain equipment at all levels or ability to procure CCE required to store the vaccine *(if not selected in previous question)*
   13. [Market availability] Market availability of the vaccine and supplies over the selected time period *(if not selected in previous question)*
   14. [Vaccine safety] Risk at individual level incl. Type, severity, consequences and frequency of AEFI, including reactogenicity profile & capacity to mitigate known adverse events *(if not selected in previous question)*
   15. [Service delivery] 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) *(if not selected in previous question)*
   16. [Strategy] Accessibility of the target population (age, gender, special risk) *(if not selected in previous question)*
   17. [Benefits of the vaccine] Efficacy and immunogenicity of the vaccine in target population
   18. [Benefits of the vaccine] Herd immunity / protection
   19. [Burden & epidemiology of the disease] Cost of the disease to the health system
   20. [Burden & epidemiology of the disease] Direct & indirect costs to patient & families
   21. [Burden & epidemiology of the disease] Burden inequity (highest prevalence in poorer / at risk populations / gender inequity)
   22. [Burden & epidemiology of the disease] Outbreak potential incl. past occurrence of outbreaks and potential for international spread, and epidemic and pandemic risk
   23. [Burden & epidemiology of the disease] Hospitalization rate
   24. [Burden & epidemiology of the disease] Disability-adjusted life years (DALYs)
   25. [Logistics] Readiness of the existing distribution channels in the country
   26. [Market availability] Sustainability of the market availability of the vaccine and supplies in the longer term
   27. [Service delivery] Ease of preparation, reconstitution & administration (open-vial policy, CTC)
   28. [Service delivery] Impact on existing immunization services or other health sectors - risk of overload
   29. [Strategy] Contribution to national/regional/global goals (e.g., eradication, control, elimination, reduction)

**Other criteria**

1. The following criteria were considered less important; however may be more relevant in certain country contexts. Among the following other criteria, are there any that you would select to include for this prioritization exercise? Please select 5 maximum.
   1. [Acceptability of the vaccine] Perception of the target population on the desirable and undesirable effects of the vaccine
   2. [Acceptability of the vaccine] Availability of resources for marketing and communication
   3. [Benefits of the vaccine] Number needed to vaccinate to prevent a case
   4. [Benefits of the vaccine] Impact on resistance to antibiotics & antivirals
   5. [Benefits of the vaccine] Effect of the vaccine on transmission
   6. [Burden & epidemiology of the disease] Short- and long-term use of health care (e.g. treatments, hospitalization)
   7. [Burden & epidemiology of the disease] Productivity losses e.g. linked to work & school absenteeism linked to the disease
   8. [Burden & epidemiology of the disease] Intensity of suffering/severity of disease symptoms
   9. [Burden & epidemiology of the disease] Long-term complications of disease (e.g. frequency of survivors with sequelae)
   10. [Burden & epidemiology of the disease] Loss of quality-adjusted life years (QALYs)
   11. [Finances & economics] 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
   12. [Finances & economics] Indirect benefits (i.e. reduced antimicrobial resistance, reduced emergency room overcrowding)
   13. [Finances & economics] Indirect costs (e.g. training of health-care workers, supply chain expenses)
   14. [Finances & economics] Perspective on vaccine price
   15. [Finances & economics] 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)
   16. [Legal & Ethical] 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)
   17. [Legal & Ethical] Licensing by foreign NRA
   18. [Legal & Ethical] Prequalified by WHO
   19. [Legal & Ethical] Licensing by national RA
   20. [Legal & Ethical] Accessibility and equity of vaccination for the target population
   21. [Legal & Ethical] Ethical, market and diplomatic issues that may affect acceptability of the vaccine to stakeholders
   22. [Logistics] Compatibility of the presentation of the vaccines with the expected uses in the country (e.g. to population spread in the country)
   23. [Logistics] Ease of conservation (volume & cold chain requirements)
   24. [Logistics] Shelf life of the vaccine
   25. [Logistics] Indicative wastage rate
   26. [Logistics] Ability to maintain wastage at expected levels
   27. [Logistics] Ability to manage waste
   28. [Logistics] Adequacy of the labels to the local language
   29. [Market availability] Ease of procurement of the vaccine (e.g. ability to procure through UNICEF, procurement timeline, delivery speed)
   30. [Vaccine safety] Safety issues related to the product being similar to an existing vaccines or drugs
   31. [Vaccine safety] 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)
   32. [Vaccine safety] Contraindications and precautions for vaccination (e.g. requirement to check background especially factoring risk groups or risk factors)
   33. [Vaccine safety] Interference with other vaccines regarding immunity/protection
   34. [Service delivery] Availability of information systems to manage the vaccine supply chain and measure related performance metrics (i.e. coverage and vaccine utilization)
   35. [Strategy] Interchangeability with alternative or future products/presentations
   36. [Strategy] Opportunity to pair introduction with other planned program (e.g. other vaccine introduction or switch with same target population)
   37. [Strategy] Existing recommendations / guidelines for use (e.g. SAGE, professional organizations)
   38. [Strategy] Ease of the considered immunization strategies - incl. geographic (stepwise or nationwide) and target populations (selective/stepwise or universal)
   39. [Strategy] Administration strategy (single dose, routine primary series only, booster, campaigns)
   40. [Strategy] Feasibility of the program delivery strategy (physicians, CHW, nurses, pharmacists, school-based)

**Vaccine candidates**

1. Which vaccines do you recommend be included in this prioritization and sequencing exercise? Please select between 5 and 7 vaccines
   1. Malaria vaccine
   2. Human papillomavirus (HPV)
   3. Hexavalent
   4. Typhoid
   5. Measles-Rubella
   6. Cholera
   7. Hepatitis B at birth (HepB)
   8. Rotavirus
   9. Respiratory Syncytial Virus (RSV)
   10. Shigella
   11. Dengue
   12. Meningitis (Multivalent)
   13. Ebola
   14. Gonorrhea
   15. Chikungunya
   16. Mpox
   17. DTP booster
   18. Group B Streptococcus (GBS)
   19. Hepatitis E
   20. Tuberculosis (new vaccine)
   21. *Haemophilus influenzae* type b (Hib)