

ELEMENTS TO CONSIDER IN DEVELOPING A FRAMEWORK FOR ISSUING IMMUNIZATION RELATED POLICY RECOMMENDATIONS

National Immunization Technical Advisory Groups (NITAGs) provide evidence based recommendations for the development of immunisation policies. These recommendations are generated from a systematic, credible and transparent process of selecting, reviewing and synthesising evidence.

In generating evidence-based recommendations NITAG begins with defining a recommendation framework. This recommendation framework

outlines the elements on which evidence should be gathered. For each element, specific data required is identified. NITAG will then rank this data as critical (high priority), important (intermediate priority) or non-critical (low priority). Structured and comprehensive reviews of evidence are conducted for all critical and important data requirements.

The table provided lists key elements to be considered when developing an immunization recommendation. These elements may be related to the vaccine characteristics disease, economic or operational considerations, or health policy and programmatic issues.

ISSUE	ELEMENT	SPECIFIC DATA
1. VACCINE AND IMMUNIZATION CHARACTERISTICS	Safety	Type, consequences and frequency of short and long-term adverse events following vaccination
		Risk groups or risk factors for adverse events
		Contraindications
	Efficacy and Effectiveness	Type specific protection afforded
		Critical determinants of the immune response associated with protection
		Duration of protection and waning of immunity if any
	Vaccine indirect effects	Interference regarding protection or immunity with other vaccines
		Impact on resistance to antibiotics and antivirals
		Herd immunity Potential negative population impact through change in age of infection for unprotected individuals e.g. rubella or varicella vaccine or emergence of non-vaccine serotypes
	Vaccine characteristics	Vaccine presentation and formulation
		Dosage and route of administration
		Administration schedule and possibility of co-administration with other vaccines
Flexibility of vaccination schedules		
2. DISEASE	Burden of disease	Incidence of morbidity and mortality, age specific morbidity and mortality, risk groups, serotype/serogroup distribution, epidemic potential, disease occurrence over time, changes in epidemiology over time
	Clinical characteristics disease	Signs and symptoms of disease, severe forms of disease, long term complications of disease, medical management of disease
	Use and costs of health care	Primary/secondary/tertiary care implications, short and long term use of health care (e.g. treatments, hospitalization)
	Alternative preventive and control measures	Alternative preventive and control measures (e.g. health education, hygiene, vector control) and their effectiveness, costs and practicality
		Other existing vaccines against the same disease and their effectiveness, costs and practicality
Regional and international considerations	Existence of regional and global recommendations	
	Disease potential for international spread and pandemic potential	

ISSUE	ELEMENT	SPECIFIC DATA
3. ECONOMIC AND OPERATIONAL CONSIDERATIONS	Vaccine related costs and resource use	Direct and indirect costs to administer the vaccine as they compare to those of other existing vaccines or other prevention or control measures
	Vaccine availability	Availability of vaccine and long term supply Available suppliers and competition dynamic in the market
	Vaccine affordability	Availability of fiscal space to effectively implement and sustain the recommendation in the programme Prevailing prices for the vaccine in the market and price estimations for the specific country
	Socio-economic and social impact of disease	School and work absenteeism
		Indirect costs to patients and families
		Productivity losses Stigma around a disease
	Economic impact of intervention on immunization program as well as health sector	Reduction in health care costs
Health gain (years of life saved, QALY gained, etc)		
Cost effectiveness ratio of vaccination program		
4. HEALTH POLICY AND PROGRAMMATIC ISSUES	Interaction with other existing intervention and control strategies	Impacts of program (catch up) on safety and efficacy of other vaccines and other health care sectors
	Feasibility	Accessibility of target population
		Availability of the vaccine and long term supply in public and private sector including collaborations with insurance sector
	Vaccine registration and regulations	National regulatory authorities requirements for licensing the vaccine and/or its use in a different schedule as originally recommended
	Impact on resources	Availability of human, technical and financial resources for distribution (including cold chain sustainability); consider additional training needs of health workers
	Ability to evaluate	Availability of information systems to manage the vaccine supply chain and measure related performance metrics i.e. coverage and vaccine utilisation
		Existence and reliability of surveillance system
	Acceptability	Perception of the public and medical community about the disease and the vaccine
Equity	Universality, accessibility and gratuity of services for all the inhabitants in the country including vulnerable, hard to reach and immigrant populations	
Social considerations	Non health related effects of vaccination, ethical considerations, legal implications etc.	

NB: Vaccine safety data should always be selected as a component of a recommendation framework.