

Vaccine products and packaging

Tenet 1: Vaccine products and their packaging are designed with characteristics that best suit the needs and constraints of countries.

The visioning process

Over the course of 2010 and 2011, partners have joined forces to develop a shared, long-term vision for immunization supply and logistics systems and technologies. The goal of this vision is to guide key stakeholders at country, regional, and global levels in their work to strengthen supply and logistics systems. This process is being facilitated by project Optimize, a collaborative project of the World Health Organization and PATH.

Certain features of vaccine products can help to address constraints in under-resourced countries. Decreased product volumes can ameliorate cold chain capacity limitations. Clear labeling and minimal steps required for product preparation can facilitate ease of use for overburdened health workers and increase immunization safety. Increased product stability can help keep vaccines effective even in extreme climate conditions or areas where electricity to provide refrigeration is unreliable.

Landscape analysis

A landscape analysis was conducted to better understand the activities under way by all global stakeholders that currently influence the characteristics of vaccine products and packaging for developing countries.

Developing vaccine products with the desired attributes requires close collaboration between national immunization programs, the global health sector, and vaccine manufacturers. The landscape analysis reviewed ongoing work that is contributing to each of the following objectives:

- Ensure vaccine products meet internationally recognized standards of quality and safety.
- Institutionalize mechanisms for dialogue between the public sector and manufacturers to reach consensus about product attributes.
- Provide guidance on product attributes preferred by developing countries for vaccine and device manufacturers.



Landscape analysis focus areas

Quality and safety

Public- and private-sector dialogue

Guidance and specifications

Streamlined tools and processes

Innovation and facilitation

The vision

By 2020, state-of-the-art supply systems meet the changing needs of a changing world in order to enable the right vaccines to be in the right place, at the right time, in the right quantities, in the right condition, at the right cost.

For more information

PATH

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project-optimize.php](http://www.path.org/projects/project-optimize.php)

World Health Organization

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systems_policy/optimize](http://www.who.int/immunization_delivery/systems_policy/optimize)

- Make streamlined tools and processes available to assess trade-offs in product profiles and inform purchase decisions.
- Continue innovation in vaccine technologies and facilitate manufacturers' efforts to provide products with the desired attributes.

Preliminary gaps

The goal of the landscape analysis was to identify gaps that need to be addressed in order to realize the vision of future immunization supply systems. The gaps identified to date are as follows:

- Increased involvement by national immunization programs in research and feedback to inform vaccine product profiles.
- Availability of appropriate tools and information for countries to strengthen national decision-making to help ensure that the vaccine products purchased have attributes that meet country needs.
- Movement toward a situation where vaccine purchasers value innovation by basing purchase decisions on systems' costs rather than on price alone.
- Ways to encourage industry to continue to improve vaccine products and packaging.

Landscape analysis summary table

By 2012, the vision statement will reflect evidence found through the following landscape analysis and other analyses. For more information, please contact optimize.who@path.org.

Vision of future immunization supply and logistics systems: Core tenets

1. Vaccine products and their packaging are designed with characteristics that best suit the needs and constraints of countries.
2. Immunization supply systems are designed to maximize effectiveness, agility, and integration with other supply systems, and to support continuous system improvement through learning, innovation, and leveraging synergies with other sectors.
3. The environmental impact of energy, materials, and processes used in immunization supply systems from the international to local levels is assessed and minimized.
4. Immunization information systems help staff plan and manage immunization activities and resources while ensuring that adequate quantities of vaccines are always available to meet demand.
5. Human resources policies provide immunization supply systems with adequate numbers of competent, motivated, and empowered personnel at all levels of the health system to overcome existing and emerging immunization supply challenges.

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Vision of future immunization supply and logistics systems: Tenet 1 landscape analysis summary—Vaccine products and packaging

Focus area	Project/concept	Partners involved	Description	Locations	Keywords
Quality and safety	Internal industry quality and safety standards	Industry (vaccine producers/developers), product development partnerships	Vaccine producers and developers test vaccines for efficacy, quality, and safety using three testing phases—preclinical, clinical, and surveillance.	Global	good manufacturing practices
Quality and safety	NRA oversight www.ifpma.org www.gsk.com/policies/Technology-Transfer-Vaccines.pdf	NRAs, industry (vaccine producers)	All vaccines must be licensed by an NRA. Core NRA functions: issuing marketing authorizations, inspecting and licensing vaccine production and distribution facilities, ensuring post-marketing surveillance (and responding to adverse events), verifying consistency or safety/quality of vaccines, assessing national control laboratories that test vaccines, and authorizing/monitoring clinical trials with vaccines.	Global	clinical trials, NRAs
Quality and safety	WHO prequalification of vaccines and immunization equipment	WHO, NRAs, UNICEF, PAHO	WHO provides a service to UNICEF and other United Nations agencies that purchase vaccines and immunization equipment to determine the acceptability, in principle, of products from different sources for supply to these agencies. The prequalification process also ensures that the vaccine-producing country has a functioning WHO-accredited NRA.	WHO Headquarters (Geneva)	NRAs, prequalification
Quality and safety	WHO fast-track mechanisms for licensing of vaccines through United Nations agencies	WHO, NRAs	Registration and licensing procedures in countries that procure their vaccines mainly through United Nations agencies may follow a fast-track procedure. This procedure follows product evaluation steps undertaken in the WHO prequalification process.	WHO Headquarters (Geneva)	NRAs, prequalification
Quality and safety	Guidelines for regulatory oversight of cold chain	WHO, NRAs	Best practices have been compiled, as a gold standard, into guidelines for country oversight of the cold chain and vaccine distribution.	WHO Headquarters (Geneva)	cold chain
Quality and safety	African Vaccine Regulatory Forum	WHO, NRAs, Bill & Melinda Gates Foundation	This forum may be considered an ad hoc scientific advisory body of experts invited by WHO to make presentations and assist regulators. Information sessions and sessions only for regulators led by WHO staff and external experts provide a non-threatening environment for regulators to discuss concerns and ask questions of experts and colleagues.	WHO Headquarters (Geneva)	NRAs
Quality and safety	Global Health CEO Roundtable	Bill & Melinda Gates Foundation, Industry (vaccine producers) chief executive officers	Annual forum to bring together the world's leading pharmaceutical companies and the Bill & Melinda Gates Foundation to leverage respective areas of strength and expertise in the pursuit of global health priorities.	Bill & Melinda Gates Foundation	public/private sector
Quality and safety	Various activities supported by the Bill & Melinda Gates Foundation	Bill & Melinda Gates Foundation, WHO, PATH, Aeras Foundation, Agence de Médecine Préventive, PAHO	Support from the Bill & Melinda Gates Foundation is provided to SAGE, Expert Committee on Biological Standardization, Immunization Practice Advisory Committee, TechNet21, WHO Prequalification, various product development partnerships, the SIVAC Initiative, and the ProVac Initiative.	Bill & Melinda Gates Foundation	prequalification
Quality and safety	Developing Country Vaccine Regulators' Network	WHO and NRAs from Brazil, China, Cuba, India, Indonesia, Republic of Korea, Russia, South Africa, and Thailand	The network's mission is to promote and support the strengthening of the regulatory capacity of NRAs of participating and other developing countries for evaluation of clinical trial proposals (including preclinical data and product development processes) and clinical trial data through expertise and exchange of relevant information.	WHO Headquarters (Geneva)	clinical trials, NRAs
Public- and private-sector dialogue	Vaccine Presentation and Packaging Advisory Group	WHO, UNICEF, GAVI Alliance, PATH, CDC, IFPMA, DCVMN, JSI	The purpose of the VPPAG is to: 1) Provide a forum for industry and public-sector dialogue on vaccine product presentation and packaging and respond to industry requests for guidance as well as proactively engage industry where appropriate; 2) Continue to facilitate improvements in presentation and packaging of vaccine products that are available or near market readiness, to maximize their appropriateness for public-sector use in developing-country markets, through specification of preferred product profiles; 3) Continue generic work to establish optimal vaccine presentation and packaging guidelines in conjunction with different vaccination strategies in order to maximize the appropriateness of vaccine packaging and presentations for the settings in which products will be employed.	Global	product profiles, public/private sector

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Focus area	Project/concept	Partners involved	Description	Locations	Keywords
Public- and private-sector dialogue	GAVI Alliance Supply Strategy Task Team (time limited)	WHO, USAID, PAHO, Developing Countries, Bill & Melinda Gates Foundation, UNICEF, PATH/Accelerated Vaccine Initiative, GAVI Alliance, Médecins Sans Frontières	The team's purpose is to revise the GAVI Alliance's overarching supply and procurement strategy, where the supply strategy refers to the determination of: 1) how the market should evolve and the associated objectives that should be pursued to achieve that evolution and 2) short- versus long-term approaches and mechanisms for interacting with manufacturers to shape the market, while the procurement strategy refers to the approach used to buy vaccines within the context of the supply strategy.	Global	procurement, supply
Public- and private-sector dialogue	Roundtable discussions or bilateral consultations on specific products between individual manufacturers and public-sector stakeholders	Vaccine producers, UNICEF, WHO, VPPAG, PAHO	Roundtable discussions are hosted by vaccine producers or device manufacturers for exchange of information on appropriate attributes and presentations for specific products. Similarly, bilateral consultations with non-industry VPPAG members and a single vaccine producer can be arranged by the vaccine producer or device manufacturer to discuss a specific product.	Global	product profiles, public/private sector
Public- and private-sector dialogue	Dialogue between the private sector and countries	Industry (vaccine producers and developers)	Dialogue with decision-makers in countries on the appropriate attributes for vaccines and packaging.	Global	product profiles, public/private sector
Public- and private-sector dialogue	Research for development study on new vaccine adoptions in low- and middle-income countries	Research for Development, Bill & Melinda Gates Foundation, GAVI Alliance, WHO, UNICEF, IFPMA, DCVMN, WHO Regional Office for the Eastern Mediterranean, PAHO, CDC, Netherlands Vaccine Institute	This study aimed to identify factors that play an important role in the decision-making process and outcomes for adoption of new and under-used vaccines in low- and middle-income countries. The goal was to identify practical interventions to address issues to positively impact new vaccine adoption in low- and middle-income countries. The study's finding that price and pricing are one of the top factors influencing vaccine decision-making led to the Vaccine Price and Pricing Information Meeting, convened by WHO.	Global	pricing, procurement
Guidance and specifications	Generic Preferred Product Profile	VPPAG—WHO, UNICEF, GAVI Alliance, PATH, CDC, IFPMA, DCVMN, JSI	This document provides guidance to vaccine developers on preferred presentations and packaging for vaccines intended for public-sector use in developing countries.	Global	product profiles
Guidance and specifications	Specific product profiles	NGOs	Development of specific vaccine product profiles for developing-country markets early in the product development process can help to ensure that developing-country requirements and preferences are taken into consideration.	Global	product profiles
Guidance and specifications	Programmatic Suitability of Vaccine Candidates for WHO Prequalification	WHO and PSPQ Standing Committee	The characteristics that determine programmatic suitability for WHO prequalification of vaccines are defined, as well as the process for assessing compliance with these characteristics.	WHO Headquarters (Geneva)	prequalification
Guidance and specifications	Immunization Practices Advisory Committee	Advisory committee members—academia, NRAs, USAID, NGOs	The Immunization Practices Advisory Committee supports and advises the Director of the Department of Immunization at WHO, Vaccines and Biologicals with the review and/or formulation of immunization practices, operational standards, tools, and technologies to strengthen and improve the delivery of immunization programs at the country level in order to realize the Global Immunization Vision and Strategies goals. Some recommendations may influence PSPQ requirements.	WHO Headquarters (Geneva)	policies
Streamlined tools and processes	Vaccine Presentation Assessment Tool	Malaria Vaccine Initiative (PATH), Optimize project (WHO/PATH)	The Vaccine Presentation Assessment Tool is designed to model the logistical and financial impact of adding a new vaccine to an immunization schedule. The tool output will provide an analytical basis to support collaborative evidence-based discussions on these impacts internally within the public sector and externally with vaccine manufacturers and target countries.	Global	cold chain volume, pricing, tool, vaccine wastage

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Focus area	Project/concept	Partners involved	Description	Locations	Keywords
Streamlined tools and processes	National Immunization Technical Advisory Groups	National academia, technical institutes, research institutes, Ministry of Health and Medical Education, vaccine manufacturers, national Expanded Programme on Immunization staff	National Immunization Technical Advisory Groups are expert advisory committees that provide recommendations to guide a country's national immunization programs and policies. They consist of independent experts with the technical capacity to evaluate new and existing immunization interventions. The group's premise is to facilitate a systematic, transparent process for developing immunization policies by making evidence-based technical recommendations to the national government. NITAGs can play a critical role in ensuring that evidence is generated to support decisions about ideal product attributes and packaging to meet country-specific demand.	National	policies, process, public/private sector
Streamlined tools and processes	WHO regional offices Technical Advisory Groups on Immunization	WHO regional offices	Advise WHO regional offices on immunization/vaccines at the regional level (like SAGE for the global level), review the technical and programmatic strategies adopted by WHO member states in the region, review the progress made toward disease control targets, and make technical and programmatic recommendations for introduction of new vaccines in national immunization systems.	WHO regions	policies, process
Streamlined tools and processes	Interagency Coordinating Committees	National ministries of health, ministries of finance, WHO, UNICEF, NGOs, bilaterals	The Interagency Coordinating Committees are a partnership between United Nations agencies, embassies, and NGOs that include a subcommittee for immunization. The immunization subcommittee serves as a partnership between the ministry of health, WHO, UNICEF, foreign government donor partners (e.g., USAID, Government of Japan, European Union), their technical subcontractors, NGOs/private voluntary organizations (e.g., BASICS, SANRU), and missionary groups (e.g., Rotary, Catholic Relief Services, Médecins Sans Frontières). The existing infrastructure could play a greater role in recommendations about vaccine product attributes.	National	process
Streamlined tools and processes	ProVac cost-effectiveness tool	PAHO, Latin American countries	ProVac's basic cost-effectiveness tool allows countries to calculate the incremental costs of new vaccine introductions. New functionality includes new program costing tool (to cost full program) and budget impact analysis.	Latin America	tool
Streamlined tools and processes	WHO/UNICEF cMYP Tool	WHO, UNICEF, GAVI Alliance countries	The comprehensive multiyear plans for immunization costing tool allows countries to cost programs and quantify resource needs for specific vaccines.	GAVI Alliance-eligible countries	tool
Streamlined tools and processes	List of United Nations prequalified vaccines www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en	WHO/UNICEF	The online list provides specifications to countries on product attributes including product price, vaccine vial monitors, and size of container.	Global	cold chain volumes, pricing, tool
Streamlined tools and processes	Logistics forecasting tool www.technet21.org/index.php/tools/view-document-details/1139-immunization-supply-chain-planning-tool.html	TechNet21 and countries	Excel spreadsheet tool designed to guide the process of forecasting the needs for vaccines and safe injection equipment as well as cold chain and ambient storage capacities for national immunization programs.	Technet21	cold chain volumes, tool
Streamlined tools and processes	New Vaccine Post-Introduction Evaluation Tool	WHO/Countries	Provides a systematic method for evaluating the impact of the introduction of a vaccine on the existing immunization system in a country.	WHO Headquarters (Geneva)	tool
Streamlined tools and processes	Vaccine Introduction Guidelines www.who.int/vaccines-documents/DocsPDF05/777_screen.pdf	WHO	These decision and implementation guidelines for introducing a new vaccine include information on product format selection.	WHO Headquarters (Geneva)	tool

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Streamlined tools and processes	Vaccine Volume Calculator www.who.int/immunization_delivery/systems_policy/logistics/en/index4.html	WHO	Allows countries to compare vaccine storage requirements between vaccine types and brands.	WHO Headquarters (Geneva)	cold chain volumes, tool
Streamlined tools and processes	Vaccine Store Volume Calculator www.technet21.org/index.php/tools/view-document-details/1116-vaccine-store-volume-calculator-vsvc-program-files.html	WHO/TechNet21	This tool is designed to calculate the required storage volume for specific vaccines.	TechNet21	cold chain volumes, tool
Streamlined tools and processes	Large Store Analysis Tool www.technet21.org/index.php/tools/view-document-details/1101-the-large-store-analysis-tool-lsat-program-files.html	WHO/TechNet21	This tool assists with the preliminary sizing of larger vaccine freezer rooms, cold rooms, and controlled ambient stores. The tool can also be used to size the associated dry stores used for storing bundled syringes and safety boxes.	TechNet21	cold chain volumes, tool
Innovation and facilitation	Advanced Market Commitments	Donor governments/ industry (vaccine producers)	A fund of US\$1.5 billion, donated by five donor governments and the Bill & Melinda Gates Foundation, is intended to guarantee purchase of pneumococcal conjugate vaccine, in a co-payment arrangement with GAVI Alliance. This involves purchasing at a high (US\$7.00) price for a limited period of time against a binding commitment of the manufacturer to subsequently supply at a low price (US\$3.50) indefinitely.	Global	procurement, pull mechanism, supply
Innovation and facilitation	Meningitis Vaccine Project	PATH, Bill & Melinda Gates Foundation, WHO, Serum Institute of India, Syncho Bio Partners BV, US Food and Drug Administration Center for Biologics Evaluation and Research, National Institute for Biological Standards and Control	Partnership for development, testing, introduction, and widespread use of conjugate meningococcal vaccines through a ToT to a developing-country manufacturer for large-scale production and low-price sale of vaccine.	Global	pricing, push mechanism, supply
Innovation and facilitation	Statens Serum Institute Transfer of Technology Division	Statens Serum Institute	For over a decade the Statens Serum Institute provided ToTs to developing-country manufacturers and the ToT unit was prized by researchers. But ToTs were conducted without generating any revenue for the institute and the program is now, for all intents and purposes, close to bankrupt.	Denmark/ Global	push mechanism, technology transfer
Innovation and facilitation	Branded ACTs for sale in the private market	The Global Fund to Fight AIDS, Tuberculosis and Malaria; Drugs for Neglected Diseases Initiative	ACTs for malaria have been developed in two forms: un-branded for sale at a low cost to public markets in poor countries and branded for sale into private markets. This model could be replicated for vaccines.	Global	pricing, supply
Innovation and facilitation	Push funding—product development partnerships	Bill & Melinda Gates Foundation, PATH, Aeras Foundation, and others	Three product development partnerships are ongoing with push funding.	Global	product development partnerships, pricing, push mechanism
Innovation and facilitation	Pull funding	Bill & Melinda Gates Foundation	Advanced Purchase Commitments to be funded for the GAVI Alliance.	Global	pricing, pull funding

Abbreviations used: ACT, artemisinin combination therapies; CDC, US Centers for Disease Control and Prevention; DCVMN, Developing Countries Vaccine Manufacturers Network; IFPMA, International Federation of Pharmaceutical Manufacturers & Associations; JSI, John Snow, Inc.; NGO, nongovernmental organization; NRA, national regulatory authority; PAHO, Pan American Health Organization; PSPQ, Programmatic Suitability of Vaccine Candidates for WHO Prequalification; SAGE, Strategic Advisory Group of Experts; SIVAC, Supporting National Independent Immunization and Vaccine Advisory Committees; ToT, transfer of technology; UNICEF, United Nations Children's Fund; USAID, US Agency for International Development; VPPAG, Vaccine Presentation and Packaging Advisory Group; WHO, World Health Organization.