

Vaccine Innovation Lexicon



October 2016



VACCINE INNOVATION LEXICON

Abbreviations

ACIP	Advisory Committee on Immunization Practices
BFS	blow-fill-seal
CDC	US Centers for Disease Control and Prevention
cPAD	compact pre-filled autodisable device
CTC	controlled temperature chain
gPPP	generic preferred product profile
GTIN	global trade item number
GVAP	Global Vaccine Action Plan
IPAC	Immunization Practices Advisory Committee
LMICs	low- and middle-income countries
MAP	microarray patch
MDVP	multi-dose vial policy
PDVAC	Product Development for Vaccines Advisory Committee
PPC	preferred product characteristics
PSPQ	Programmatic Suitability of Vaccine Candidates for Prequalification
RUP	reuse prevention
SAGE	Strategic Advisory Group of Experts on Immunization
SIP	sharps injury protection
TPP	target product profile
UNICEF	United Nations Children's Fund
VVM	vaccine vial monitor
WHO	World Health Organization

INTRODUCTION

[Gavi, the Vaccine Alliance](#), is placing an increased focus on the development of innovative vaccine products to overcome barriers to coverage and equity, as evidenced in the Alliance's 2016–2020 strategy. As a ready reference for partners, this lexicon aims to establish a common vaccine innovation vocabulary to help ensure clarity in our communications. While there are alternative ways to define certain terms, the main purpose of this document is to align understanding of how these terms are used across the Alliance.

The lexicon deals specifically with innovations applied to vaccine products to increase their programmatic suitability, reduce overall costs, bolster supply security and/or positively impact health outcomes. This includes means to improve vaccine thermostability, presentation and packaging, route and method of administration, combinations and schedules and/or effectiveness and safety. Some innovations have applicability beyond vaccines, but, for the purpose of this document, definitions focus solely on vaccine applications.

Terms are grouped by category and listed alphabetically within their category. Each term is accompanied by a definition, description of relevance and photo or illustration. Each category is represented by a visual icon from the following list.



Delivery device: a stand-alone technology used to administer a vaccine by a specific vaccine administration route.



Primary container: the immediate receptacle in direct contact with the vaccine as distributed for sale. Delivery devices that are combined with vaccines or contain vaccines are considered primary containers.



Formulation: the combination of chemical and biological substances used to produce a final vaccine product. Formulation is also used to describe the dosage form of the vaccine.



Standards, policies and recommendations: guidance, established norms or requirements regarding vaccines or immunisation.



Group: a committee, advisory group or association involved in vaccine innovation.



Technology value assessment: terms used to define the importance of specific vaccine product attributes.



Labelling: text, symbols, data or other visual cues provided on the primary, secondary or tertiary packaging of a vaccine or on documents included within the packaging.



Vaccine administration route: the point of contact (for example, oral, nasal, intramuscular, subdermal) where the vaccine is delivered to the recipient to ensure the correct immune response.



Packaging: the containers that enclose or protect vaccine products for distribution, storage, sale and use.



CATEGORY

DELIVERY DEVICE

PATH/Glenn Austin



AUTODISABLE SYRINGE

A delivery device designed to prevent reuse, this type of syringe automatically (passively) disables after a single, fixed-dose injection.

Autodisable syringes prevent disease transmission caused by reuse of conventional syringes. Only autodisable syringes are procured by UNICEF for immunisations.

PATH/Joel Little



BIODEGRADABLE IMPLANT INJECTOR

An injection device that propels and inserts a solid dose of vaccine into the body that dissolves over time to slowly release the vaccine.

Delivery of vaccines as biodegradable implants could decrease the risk of needle-stick injury and reduce the burden of sharps waste disposal.

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DISPOSABLE-SYRINGE JET INJECTOR

A needle-free injection system that uses a disposable syringe to deliver vaccines. The device generates a pressurised liquid stream to penetrate the skin and deliver vaccine to the intradermal, subcutaneous or intramuscular tissue.

Delivery of vaccines with jet injectors can reduce the risk of needle-stick injury and decrease the burden of sharps waste disposal.

PATH/Patrick McKern



DRY POWDER INHALER

A device that delivers the vaccine to the lungs in the form of a dry powder. Inhalers can be either mechanically activated or breath powered.

These inhalers could be used to deliver dry powder vaccine via the respiratory tract, which increases safety by removing the risks typically associated with delivery by injection.

Aerogen



NEBULISER

A delivery device that aerosolises a liquid vaccine to generate a mist for pulmonary delivery.

The vaccine mist created by this device is inhaled to enable pulmonary delivery, which targets the lungs and induces mucosal immunity.

PATH



REUSE PREVENTION (RUP) SYRINGE

A single-use, disposable syringe that can deliver variable doses and has a mechanism to prevent reuse. The mechanism can either be activated automatically after a single injection, or manually by the healthcare worker after the injection has taken place.

RUP syringes are recommended for reconstituting vaccines as well as for delivery of curative injections.

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SAFETY SYRINGE

A syringe that incorporates a sharps injury protection, reuse prevention and/or autodisable feature.

Safety syringes are recommended by WHO for administering all injections, including vaccines.

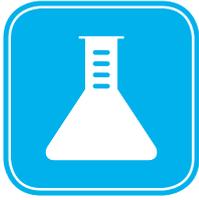
PATH



SHARPS INJURY PROTECTION (SIP) SYRINGE

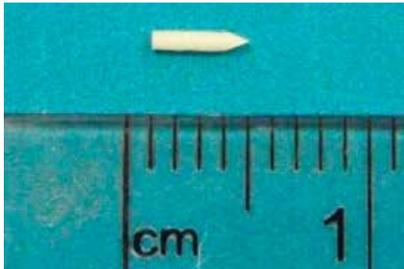
A single-use, disposable syringe with a mechanism that covers the needle after use to reduce the risk of accidental needle-stick injury. Mechanisms include retraction of the needle into the barrel after injection or a needle shield.

SIP syringes have an additional feature that helps prevent needle-stick injury and can increase the safety of immunisation delivery and disposal.



CATEGORY FORMULATION

Glide Pharmaceutical Technologies



BIODEGRADABLE IMPLANT

A solid dose of vaccine that is inserted into the body and dissolves over time to slowly release the vaccine.

When successfully formulated, solid implants can increase a vaccine's thermostability (in comparison to liquid presentations) as well as reducing the risk of needle-stick injury and the burden of sharps waste disposal.

PATH/Tina Lorenson

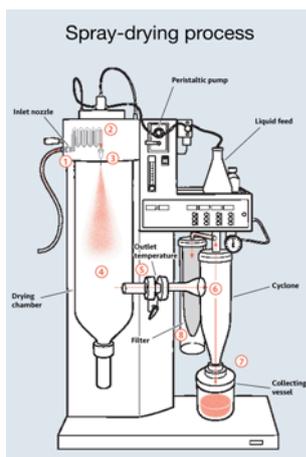


DILUENT (FOR VACCINES)

A liquid mixed with a lyophilised (freeze-dried) vaccine to reconstitute the lyophilised vaccine and provide the final vaccine ready for administration.

The correct diluents must be supplied and used for vaccines that require reconstitution. Use of incorrect diluents has resulted in adverse events.

PATH/Cornelius Brudi



DRY POWDER (VACCINE)

A vaccine formulation typically produced by a spray-drying process resulting in a free-flowing powder.

Dry powder vaccines are typically inhaled for intranasal or pulmonary delivery and have the potential for increased thermostability (compared with liquid formulations) and enhanced mucosal immunity. Dry powders can be administered by active (mechanically activated) or passive (breath-powered) inhaler devices.



FAST-DISSOLVING TABLET

A tablet form of a vaccine that disintegrates quickly in a small amount of saliva or liquid.

Fast-dissolving tablets target the mucosal immunisation route and have the potential to improve mucosal immunity. When placed in the mouth, the tablets quickly dissolve in saliva. They can also be reconstituted in a diluent or a buffer for oral administration with a liquid dropper.



FREEZE-SENSITIVE (LIQUID VACCINE)

A vaccine that may be damaged by exposure to freezing temperatures.

Proper cold-chain equipment and practices must be used to prevent freeze-sensitive vaccines from being damaged by exposure to freezing temperatures during storage, transport and delivery.



FREEZE-STABLE FORMULATION (VACCINE)

A vaccine formulation that uses excipients to protect vaccines from freeze damage.

Some vaccines, such as those containing aluminium adjuvant, are sensitive to freezing. Formulation methods have been developed that reduce the risk of damage when these vaccines are exposed to freezing temperatures. Incorporating the formulation methods into new or existing liquid vaccine products could reduce vaccine wastage and the delivery of less potent vaccines.



HEAT-SENSITIVE (VACCINE)

A vaccine that may be damaged by exposure to high temperatures.

Vaccines are generally heat sensitive and therefore must be stored in a cold chain for most or all of their shelf life. The heat sensitivity of vaccines varies. The degree to which a vaccine is heat sensitive determines the likelihood of damage occurring when exposed to high temperatures.



LIQUID (VACCINE)

A vaccine formulation that flows freely like water.

Most currently licensed vaccines are administered as liquids. A vaccine that is provided as a liquid in its primary container can be more easily prepared for administration and avoids the risks associated with reconstitution.



LYOPHILISED (VACCINE)

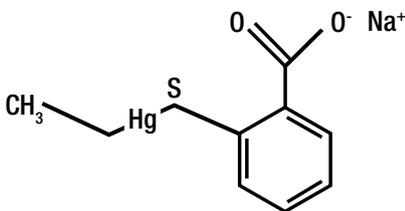
A dry vaccine that is produced by rapid freezing and dehydration of the frozen product under high vacuum. Also known as a “freeze-dried vaccine.”

Some vaccines are susceptible to loss of potency at elevated temperatures and lyophilisation can be used to improve their thermostability. However, a lyophilised vaccine must be reconstituted to be administered as a liquid. This adds further complexity and creates opportunity for error (see “Reconstitution” below for further details).

PRESERVATIVE

An excipient to prevent microbial growth in vaccine primary containers. Preservatives commonly used in vaccines include thiomersal and 2-phenoxyethanol.

Preservatives prevent microbial growth if the vaccine is contaminated. Multi-dose presentations of liquid vaccines commonly include preservatives, which enable open containers of the vaccines to be safely stored for use beyond one immunisation session.



THIOMERSAL



PRESERVATIVE-FREE (VACCINE)

A vaccine formulation that does not contain a preservative. Preservatives may be added to multi-dose liquid vaccines, for example, or to the diluent of lyophilised vaccines, to prevent microbial growth and allow safe use of opened containers.

To ensure safety, multi-dose presentations of vaccines that do not contain preservatives must be used within a single immunisation session. The need to discard unused doses (those that remain in an opened multi-dose container of a preservative-free vaccine) at the end of a session can lead to vaccine wastage and missed vaccination opportunities.



RECONSTITUTION

The process by which a lyophilised (freeze-dried) vaccine is mixed with a diluent and transformed into a liquid prior to administration.

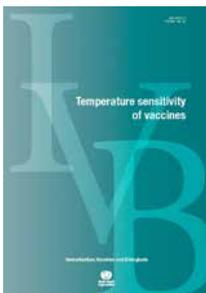
Reconstitution of lyophilised vaccines typically requires a reconstitution syringe and needle. This adds time as well as the potential for user error to the vaccine delivery process.



THERMORESPONSIVE GEL

A mucosal immunisation technology platform that starts as a liquid solution at room temperature and transforms into a gel upon contact with the oral mucosa. Its gel matrix enables it to adhere to mucosal surfaces.

Mucosal delivery of vaccines has the potential to improve mucosal immunity.



THERMOSTABILITY (OF VACCINES)

The level of resistance of a vaccine to damage or loss in potency caused by exposure to freezing temperatures or excessive heat.

The thermostability of a vaccine determines its temperature storage requirements and can impact its suitability for use in different settings.



CATEGORY GROUP

ACIP

The Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts that develop recommendations on use of vaccines in the civilian population of the United States...

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Established by the US Centers for Disease Control and Prevention (CDC), ACIP is a group of medical and public health experts that meets to review vaccine safety, efficacy and effectiveness data to generate public health guidelines on the use of vaccines among citizens of the United States of America. The ACIP panel advises the CDC and provides recommendations to guide decisions regarding immunisation practices, including dosing schedules, route of administration and any potential contraindications.

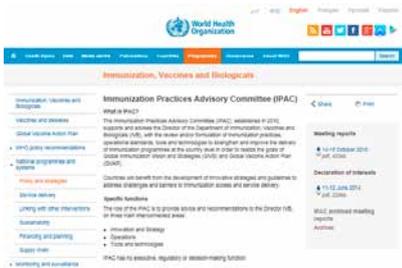
ACIP's recommendations serve as public health advice intended to lead to a reduction in the incidence of vaccine-preventable diseases and an increase in the safe use of vaccines and related biological products.



GS1

A neutral not-for-profit international organisation that facilitates the development and maintenance of standards for supply and demand chains across multiple sectors. The GS1 General Specifications system is designed to standardise supply chain data to identify, capture and share uniform, accurate data. It includes standards that define unique identification codes, which may be used by an information system to refer to a real-world entity, such as a logistics unit.

Use of GS1 standards for barcodes facilitates the international supply chain management of vaccines.



IMMUNIZATION PRACTICES ADVISORY COMMITTEE (IPAC)

A WHO committee that supports and advises the Director of the Department of Immunization, Vaccines and Biologicals on the review and/or generation of immunisation practices, operational standards, tools and technologies. These strengthen and improve immunisation programmes at the country level.

IPAC's recommendations to WHO encompass vaccine innovation topics such as new delivery and packaging technologies, new vaccine management practices and characteristics that improve the suitability of vaccine products for the health systems in which they will be used.



PRODUCT DEVELOPMENT FOR VACCINES ADVISORY COMMITTEE (PDVAC)

A committee that provides WHO with strategic advice and recommendations on vaccines at the Phase 2 stage of clinical evaluation or earlier. The PDVAC reports to and is guided by the Strategic Advisory Group of Experts on Immunization.

The PDVAC aims to guide the development of important, new vaccines for low- and middle-income countries (LMICs) focusing on vaccines that address substantial disease burdens. This includes disease areas in which vaccine research innovation is occurring but no vaccines currently exist. Second-generation vaccines may also be a focus of the PDVAC. WHO guidance to vaccine developers is a key objective of this committee.



STRATEGIC ADVISORY GROUP OF EXPERTS (SAGE) ON IMMUNIZATION

The principal advisory group to WHO for vaccines and immunisation.

SAGE is charged with advising WHO on overall global policies and strategies for immunisation, ranging from vaccine and technology research and development to the delivery of immunisations and linkages with other health interventions. SAGE is concerned not just with childhood vaccines and immunisation but with all vaccine-preventable diseases.



CATEGORY LABELLING



PATH

BARCODE

A label containing symbols which can be scanned electronically using laser- or camera-based systems. Barcodes are used to encode information such as product numbers, serial numbers and batch numbers.

Barcodes can facilitate automated data capture to improve vaccine distribution and inventory management.



PATH/Joel Little

GLOBAL TRADE ITEM NUMBER (GTIN)

A number used by a company to uniquely identify each of its trade items around the world. GS1 defines trade items as products or services that are priced, ordered or invoiced at any point in the supply chain.

GTINs are encoded in barcodes and facilitate the procurement and inventory management of vaccines.

ROTARIX (Rotavirus Vaccines, Live, Oral)
Oral Suspension
Initial U.S. Approval: 2008

INDICATIONS AND USAGE
ROTARIX is a vaccine indicated for the prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9). ROTARIX is approved for use in infants 6 weeks to 24 weeks of age. (1)

INDICATION (FOR USE)

Instructions specifying the vaccine's intended use among a specified age group to prevent a disease.

The indication informs the healthcare worker about the disease which the vaccine is intended to prevent and the target population to whom the vaccine should or should not be given. A vaccine's indication is considered part of the vaccine's labelling and must be reviewed and approved by regulatory authorities.



PACKAGE INSERT

A document containing detailed information about a vaccine (for example, clinical pharmacology, indications for use, contraindications). It is generally placed inside the vaccine product's secondary packaging.

Any change to a vaccine must be reflected in its package insert. Package inserts are a regulatory requirement for vaccines and provide instructions to healthcare providers on vaccine use and other key product information.



SHELF LIFE

The length of time for which a vaccine can be considered suitable for use when kept under recommended handling and storage conditions.

A longer shelf life can simplify vaccine product distribution and inventory logistics. For WHO prequalification, a vaccine should have a shelf life of at least six months at 2°C to 8°C.



VACCINE VIAL MONITOR (VVM)

A chemical-indicator label placed on vaccine vials, ampoules, tubes or other primary containers by the vaccine manufacturer. A VVM shows the cumulative heat exposure that an individual container of vaccine has received through a gradual and irreversible colour change.

VVMs indicate when vaccines have potentially been damaged by heat and must be discarded, helping to prevent both delivery of less potent vaccines and unnecessary vaccine wastage. VVMs are required on WHO-prequalified vaccines. There are four different types of VVMs for vaccines of differing heat stability. VVM types (2, 7, 14 and 30) are identified by the number of days they take to reach their endpoint at 37°C.



CATEGORY PACKAGING

Serge Garnivet



INSULATED SHIPPING CONTAINER

A single-use, insulated, passive container that holds coolant-packs, typically used for the international shipment of vaccines from the manufacturer.

Insulated shipping containers help keep vaccines at appropriately cool temperatures during shipment. However, they can be a challenge for countries to dispose of after use.

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MULTI-MONO-DOSE

Multiple, single-dose containers of vaccine packaged together and connected by a single label. In this configuration, each container remains physically connected until it is opened and used.

Multi-mono-dose packaging presentations combine the benefits of single-dose and multi-dose packaging into one container format to improve ease of use, reduce wastage and lower costs as well as storage volume.

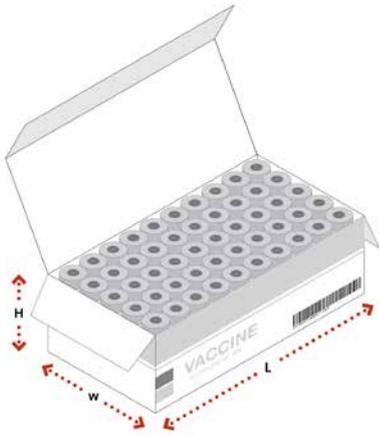
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MULTICOMPONENT VACCINE

A vaccine presentation that requires the mixing of components prior to use. The presentation differs from a single-component vaccine which is provided in a "ready-to-use" presentation that does not require mixing.

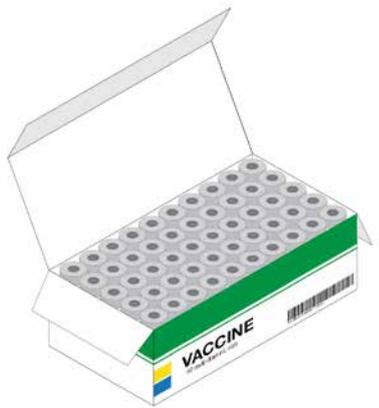
Multicomponent vaccines, such as lyophilised vaccines requiring reconstitution, add time to prepare a dose and increase the risk of errors.



PACKED VOLUME

The amount of space required (typically calculated as cm^3) to store or transport each dose of vaccine or diluent in the cold chain. Calculations include the vaccine or diluent primary container and packaging material.

The packed volume of a vaccine presentation is used to calculate the cold-chain impact and storage costs for the vaccine or diluent. In general, smaller packed volumes are preferable to reduce transport and cold-chain storage costs. They also facilitate vaccine availability in countries with limited cold-chain capacities.



SECONDARY PACKAGING

The vaccine or diluent packaging that holds the primary container(s) (for example, cartons containing one or more vials or pre-filled syringes).

Secondary packaging volumes are used to calculate vaccine storage requirements. Harmonising dimensions and minimising the volume of vaccines in secondary packaging is important for efficient use of cold-chain storage capacity.



TERTIARY PACKAGING

The pack or carton that contains multiple secondary packages. This type of packaging, also known as the third level of packaging, typically is an outer box or the shipping box.

Tertiary packaging is used for shipping vaccines. Vaccines are typically removed from tertiary packaging prior to storage.



VIAL CLIP

A plastic connector that physically joins together two primary containers (for example, a vial of lyophilised vaccine and a corresponding vial of diluent).

Vial clips can help prevent reconstitution errors, such as using an incorrect diluent. However, since diluents do not normally need to be stored in the cold chain, bundling vaccine components with a vial clip can increase cold-chain storage volume requirements.



CATEGORY

PRIMARY CONTAINER



PATH/Patrick McKern

COMPACT PRE-FILLED AUTODISABLE DEVICE (cPAD)

A pre-filled syringe with design features that prevent its reuse and minimise the space required for storage and shipping.

cPADs, such as the Uniject® injection system, are designed to facilitate the delivery of injections in low-resource settings. They include autodisable features, an attached needle and a low packed volume. These features can increase the ease of delivery of injections.



PATH/Patrick McKern

BLOW-FILL-SEAL (BFS) CONTAINER

Plastic containers that are extruded, blown, filled and sealed in a single, continual process.

BFS is an aseptic-filling process that is widely used in the pharmaceutical industry. BFS containers can be produced in large volumes at a low cost.



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DUAL-CHAMBER TECHNOLOGY

Primary containers, which include dual-chamber vials and dual-chamber syringes, with two separate compartments. These are used for storing the dry vaccine and the diluent respectively.

Dual-chamber technologies can simplify the reconstitution process for lyophilised vaccines and prevent errors such as using an incorrect diluent for reconstitution.



MICROARRAY PATCH (MAP)

A device, also known as a microneedle patch, uses coated or dissolving projections to deliver a vaccine to the epidermis and/or dermis layer of the skin.

MAPs increase the efficacy and thermostability of vaccine delivery compared with less-stable liquid vaccine presentations. They are also easy to use and to dispose.



MULTI-DOSE

Any primary container which contains more than a single dose of vaccine. For example, 10 or 20 doses of vaccine may be contained in a multi-dose vial.

Multi-dose presentations are commonly used in LMIC immunisation programmes, as they are typically less expensive and require less storage volume per dose. However, multi-dose presentations also increase the rate of vaccine wastage.



PRE-FILLED SYRINGE

A syringe that is pre-filled by the pharmaceutical manufacturer, serving as both the primary drug container and the delivery device.

Pre-filled syringes reduce the number of steps required to deliver an injection—making the process easier and faster for the user, and reducing the potential for dosing errors. Standard glass pre-filled syringes are commonly used in high-income countries but some are not suitable for use globally because of their high storage volume, lack of autodisable features and disposal challenges.



PRESENTATION (VACCINE)

The method by which the product is packaged in its primary container. For example, whether a vaccine is contained in a single-dose or multi-dose format, is provided as a liquid or lyophilised formulation, or is contained in a pre-filled syringe or vial.

Presentation determines a vaccine's impact on immunisation supply chains, affecting cold-chain storage volume, wastage rates and ease of delivery.



SINGLE-DOSE (VACCINE)

One dose of vaccine provided in a primary container.

Single-dose presentations are more expensive and often require more storage volume per dose than multi-dose presentations. However, single-dose presentations reduce vaccine wastage and the potential for contamination.



CATEGORY

STANDARDS, POLICIES AND RECOMMENDATIONS

PATH/Simona Zibursky



CONTROLLED TEMPERATURE CHAIN (CTC)

An innovative approach to vaccine management which allows vaccines to be kept at temperatures outside the traditional cold chain range of 2°C to 8°C for a limited period under monitored and controlled conditions. A CTC typically involves a single excursion of the vaccine into ambient temperatures not exceeding 40°C for a set number of days before administration.

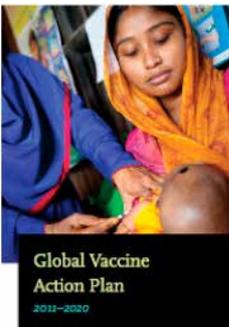
Approval of a vaccine for CTC storage can facilitate delivery in campaigns and outreach settings. The MenAfriVac® vaccine was the first to be approved for CTC use.



GENERIC PREFERRED PRODUCT PROFILE (gPPP)

Recommendations to vaccine developers and producers regarding the formulation, presentation, labelling and packaging of new vaccines intended for use in developing countries.

[The Vaccine Presentation and Packaging Advisory Group](#) published a gPPP to help vaccine manufacturers develop products appropriate for use in developing countries.



GLOBAL VACCINE ACTION PLAN (GVAP)

A framework for preventing millions of deaths by 2020 that is centered on achieving more equitable access to existing vaccines for people in all communities.

One of the six strategic objectives in the GVAP is for research and development innovations to maximise the benefits of immunisation—including innovations in vaccine formulation, packaging and delivery.

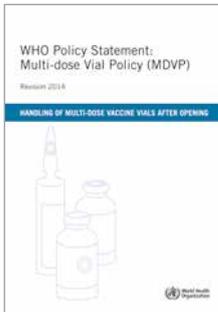
MINISTRY OF HEALTH / GHANA HEALTH SERVICE
EXPANDED PROGRAMME ON IMMUNIZATION
NATIONAL IMMUNIZATION AND VITAMIN A SCHEDULE FOR CHILDREN

AGE	VACCINE	VOLUME	ROUTE	ROUTE AND SITE OF ADMINISTRATION
At birth	BCG	0.05ml	Intra-dermal	right upper arm
	OPV 0	2 drops	Oral	
6 weeks	OPV 1	2 drops	Oral	
	DPT Hept-Inf 1	0.5ml	Intra-muscular	left thigh
	Poliovaccinal 1	0.5ml	Intra-muscular	right thigh
10 weeks	Poliovaccinal 2	0.5ml	Oral	
	OPV 2	2 drops	Oral	
	DPT Hept-Inf 2	0.5ml	Intra-muscular	left thigh
14 weeks	Poliovaccinal 3	0.5ml	Intra-muscular	right thigh
	Poliovaccinal 4	0.5ml	Oral	
	OPV 3	2 drops	Oral	
18 weeks	DPT Hept-Inf 3	0.5ml	Intra-muscular	left thigh
	Poliovaccinal 5	0.5ml	Intra-muscular	right thigh

IMMUNISATION SCHEDULE

A series of recommended or compulsory vaccinations, which also includes the timing of all doses.

WHO provides guidance on recommended immunisation schedules, while each country sets its own schedule. The introduction of new vaccines can be simpler if they are delivered according to the same schedule as vaccines already in use.



MULTI-DOSE VIAL POLICY (MDVP)

The MDVP provides guidance on how to handle all opened multi-dose vials of WHO-prequalified vaccines.

Proper application of the MDVP can reduce vaccine wastage while helping to ensure safety. This lowers costs and eases storage and transport constraints.

Vaccine Presentation and Packaging Advisory Group - Delivery Technology Working Group
Preferred Product Characteristics: Measles-Rubella Monovaccines
Version: 17 December, 2009 - Page 3

1. General considerations for a MR vaccine on MAPs

Issue	Key
Product	<p>Propaganda vaccination against measles (M) and R (rubella) at 12-18 months, followed by a combined M-R vaccine at 15-24 months.</p>
Manufacture	<p>Effective manufacturing process and appropriate temperature and handling 'best practice' (temperature, light, and humidity) and national response capabilities.</p>
Product quality	<p>MR vaccine (M/RV) should be stable at 2-8°C for at least 18 months. The vaccine should be stable at 2-8°C for at least 18 months. The vaccine should be stable at 2-8°C for at least 18 months. The vaccine should be stable at 2-8°C for at least 18 months.</p>

PREFERRED PRODUCT CHARACTERISTICS (PPC)

This strategic document aims to drive early-stage research to develop new products or improve existing ones to meet public health needs.

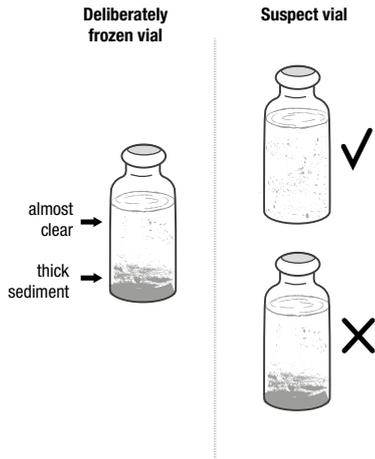
Developing and gathering stakeholder input on a PPC is a critical early step to inform the development of new or improved vaccines. It helps ensure that new products are appropriate for use in LMICs.



PROGRAMMATIC SUITABILITY OF VACCINE CANDIDATES FOR PREQUALIFICATION (PSPQ)

A set of criteria (mandatory, critical and preferred) that are used to assess the suitability of new vaccines for use in developing countries. They are a critical part of the WHO prequalification process.

The PSPQ governs how vaccines submitted for WHO prequalification are assessed for programmatic suitability. It provides guidance to vaccine manufacturers on required and desirable characteristics of vaccine presentations.



SHAKE TEST

A method to determine whether vaccines containing aluminium adjuvant have been damaged by freezing. To perform the test, the vaccine container is vigorously shaken along with a control—a vaccine vial from the same manufacturer and lot number that has been frozen overnight at -20°C and then thawed. The contents are examined for physical changes and the extent of sedimentation is compared with the control vial. A vaccine with a sedimentation rate that is as fast as or faster than that of the control has been frozen.

Correct use of the shake test helps determine whether a freeze-sensitive vaccine that may have been exposed to freezing temperatures can still be used or must be discarded.

PATH Technology Solutions Target Product Profile - Input Sheet

Description: Multi-dose liquid live attenuated rotavirus vaccine

Scope: The purpose of this target product profile is to provide guidance to rotavirus vaccine manufacturers on desirable product characteristics of a multi-dose, liquid live attenuated rotavirus vaccine intended for use in low and middle income country immunization programs. The overarching goal is to reduce the per-child vaccination cost through more efficient stabilization, packaging and delivery of existing and future vaccine formulations.

TPP Summary Attribute	Desired Target	Minimally Acceptable Target
Indication	For the active immunization of infants from the age of 6 weeks for prevention of paediatric rotavirus gastroenteritis ("rotavirus").	Same
Target Population(s)	Infants <6 weeks and <24 months of age.	Same
Route of Administration	Oral	Same
Dose Volume	1.2 ml	Same
Stability Formulation	Liquid (buffer and vaccine components)	Lyophilized (buffer and vaccine separate)
Doses per Container	9 or 10 doses per container (1.80)	2 doses per container
Preservative	Preservative free	With preservative
Dosage Schedule	2 doses at 6 and 10 weeks to be completed by 24 months	3 doses at 6, 10 and 14 weeks to be completed by 24 months
Efficacy	> 80% efficacy against any grade of rotavirus severity	Same
Safety Profile	The vaccine shall have a comparable safety profile to existing rotavirus vaccines.	Same
Co-administration	The vaccine shall have no interference or interactions with concurrently administered vaccines per the EPI immunization schedule.	Same
Product Presentation (primary container / delivery technology)	Delivery device integrated into primary container	Multi-dose vial with separate delivery device
Multiple Dose Format	Multi-dose container	Multi-dose dose (partitioned single dose containers)
Delivery Device	All consumables (including vial adapters) shall be packaged sterile with multiple syringes per pouch.	All consumables (including vial adapters) shall be packaged sterile in individual pouches.
Cold Chain Volume (in secondary packaging)	130 cm ³ per dose	*20 cm ³ per dose
Co-packaging	Only vaccine stored in cold chain	Vaccine and delivery devices bundled together for storage in cold chain.
Compatibility with Low Connection	The delivery device shall not be compatible with a low connection.	Same

TARGET PRODUCT PROFILE (TPP)

A summary of desired product attributes that includes performance and product requirements (such as safety, efficacy, presentation and programmatic requirements).

Developing and gathering stakeholder input on a TPP is a critical early step to inform the development of new or improved vaccine products or delivery devices. It helps ensure that the products are appropriate for use in their intended markets. A TPP is also an important summary document used as a communication tool with regulatory bodies such as the US Food and Drug Administration.



VACCINE WASTAGE

The quantity of vaccine that is not administered due to loss from both opened and unopened primary containers.

Many factors can lead to vaccine wastage, including vaccine presentation (for example, doses per container and presence of preservatives) and programmatic practices (for example, session size or application of the MDVP). Vaccine wastage rates must be factored into procurement and cost per delivered dose calculations.



CATEGORY TECHNOLOGY VALUE ASSESSMENT



APPROPRIATE (VACCINE PRODUCTS)

Vaccine products designed with characteristics that best suit the needs and constraints of the countries in which they will be used.

Certain vaccine product attributes can help to increase product appropriateness. For example, clear labelling and the minimisation of steps required for product preparation can facilitate ease of use for overburdened health workers and increase immunisation safety.



INNOVATIVE

Novel improvements that are more beneficial than the status quo.

Innovative vaccines and vaccine technologies are under development by a variety of organisations. The evaluation, prioritisation and advancement of these innovations will be important to achieving their public health benefits.

PREQUALIFIED

Describes a product that has successfully completed the WHO prequalification process, which aims to ensure that vaccines and immunisation-related devices for high-burden diseases meet global standards of quality, safety, efficacy and programmatic suitability in order to optimise use of health resources and improve health outcomes.

When vaccines and devices are WHO prequalified, they meet global standards for quality and appropriateness and can be procured by United Nations agencies.





QUALITY (VACCINE)

Reliance on WHO's definition for vaccines of assured quality. WHO considers a vaccine to be of known good quality provided that the national regulatory authority that independently controls the quality of the vaccine acts in accordance with six specified functions defined by WHO and that there are no unresolved reports of quality issues.

Compliance with regulatory requirements for vaccine quality helps to ensure the safety and efficacy of vaccines.



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READY-TO-USE (VACCINE)

A vaccine that does not require mixing of components before use.

Ready-to-use vaccines are generally preferred due to their ease of use and reduced potential for errors in vaccine preparation.



CATEGORY

VACCINE ADMINISTRATION ROUTE

CDC/Gabrielle Benenson

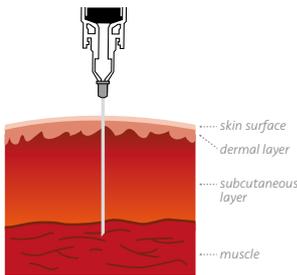


INTRADERMAL DELIVERY

Delivery of vaccines into the dermis layer of the skin, located just underneath the epidermis. Intradermal delivery can be achieved using a needle and syringe and the Mantoux technique (insertion of the needle at a 5 to 15 degree angle to inject just below the surface of the skin) or using a variety of intradermal delivery-capable devices.

Intradermal delivery is currently used for bacillus Calmette–Guérin, rabies and influenza vaccines. The technique can enhance immunogenicity and enable dose-sparing.

PATH/Shawn Kayon



INTRAMUSCULAR DELIVERY

Vaccines delivered intramuscularly are injected directly into the deltoid muscle or anterolateral thigh muscle.

Many vaccines are delivered by intramuscular injection using a needle and syringe, including most inactivated vaccines.

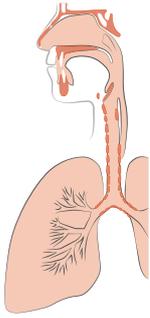
PATH/Patrick McKern



INTRANASAL DELIVERY

Intranasal vaccines are intended for absorption by the nasal mucosa for local action in the nasal cavity. They can be delivered as either liquid drops, liquid sprays or dry powder.

Currently available live attenuated influenza vaccines are delivered intranasally.



LIQUID RESPIRATORY DELIVERY

Liquid respiratory delivery of vaccines includes intranasal delivery, which targets the nasal cavity, and pulmonary delivery, which targets the lungs.

Respiratory delivery has been explored for some vaccines, such as measles vaccine, because it eliminates the sharps hazards typically associated with administration by injection.



SUBCUTANEOUS DELIVERY

Vaccines delivered subcutaneously are administered into the fatty tissue over the triceps or the anterolateral thigh by parenteral injection.

Many vaccines are delivered by subcutaneous injection using a needle and syringe, including many live attenuated vaccines.



SUBLINGUAL DELIVERY

Vaccines delivered to the oral mucosa under the tongue.

Sublingual delivery of vaccines can be achieved through formulation as thermoresponsive gels, fast-dissolving tablets and thin films. This route offers a potential alternative to parenteral delivery that is easy to deliver and can enhance mucosal immunity.

This lexicon was developed
by Gavi and PATH.





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