



Introducing the Measles and Measles-Rubella (MR) Vaccine Five-dose vial Presentations

Facts Sheet, Feb 2019

This Facts Sheet informs of the availability of a measles vaccines and combined measles-rubella (MR) vaccines in both a 10-dose vial and a 5-dose vial presentation through (or via) UNICEF procurement. The 5-dose vial presentation has the potential of reducing open vial wastage in some country settings compared to the 10-dose vial presentation.

Background

Expanded programmes on immunization (EPI) managers and health workers have expressed interest to access a presentation containing less than 10-doses per measles/measles-rubella vaccine vial, for use in the immunization programmes. In many countries, one of the cited reasons for failure to vaccinate has been the reluctance of healthcare providers to open a 10-dose vial in situations when immunization sessions have less than six to eight (6-8) infants in attendance. This is due to fear of a high wastage rate, an indicator often used to measure job performance, and fear of stock out for future sessions. For instance, in a 2011 United States Centres for Disease Control and Prevention (US-CDC)-led study of vaccine wastage-related knowledge and practices in Nigeria¹, healthcare providers stated they only open measles vials when 6 or more children are present and only on certain days of the week. While this practice aims to reduce vaccine wastage, it contributes to missed opportunities to vaccinate.

In contrast to the observed practices of waiting for more children or turning away children eligible for measles vaccinations, World Health Organization (WHO) policy² states that a vaccine vial should be opened anytime, even if only one eligible child presents for vaccinations, irrespective of the number of doses in the vaccine vial. This policy exists to increase coverage, nevertheless, health workers may often feel obliged to balance the immediate concern of vaccinating a single child with the potential of having measles vaccine stock out if available stocks are used-up faster than anticipated - e.g., when vaccine usage forecasts assume lower wastage rates in their estimations. Based on forecasts submitted by countries procuring measles/measles-rubella vaccine through UNICEF, the national wastage rate reported in 2017 has been ranging between 10 per cent and 60 per cent for measles/MR vaccines administered through routine immunization.

Five-dose measles vaccine has been prequalified since 1993 and 5-dose MR vaccine since 2000. Yet, nearly all low- and middle-income countries use a 10-dose measles/MR vial. Availing a vial with less doses is envisaged to encourage health workers to open a measles or MR vaccine vial more frequently, maintain low wastage rates and contribute to improving coverage. UNICEF is therefore working with manufacturers

¹ Vaccine wastage in Nigeria: An assessment of wastage rates and related vaccinator knowledge, attitudes and practices. 2017. Available from: https://stacks.cdc.gov/view/cdc/51027/cdc_51027_DS1.pdf

² WHO. Immunization in Practice: A practical guide for health staff. 2015 update. WHO 2015. ISBN 978 92 4 154909 7

to ensure access to measles/MR vaccine in 5-dose vial. Any country that procures measles/MR vaccines through UNICEF can have access to 5-dose vial presentation. Until sufficient demand is generated/secured, UNICEF will operate with longer lead times than standard for the initial support.³

Table 1- Characteristics of the Currently Available Measles/MR Vaccine Presentations

Vaccine	Measles vaccine (M)			Measles-Rubella Vaccine (MR)	
	10-dose vial	10-dose vial	5-dose vial	10-dose vial	5-dose vial
Presentation	10-dose vial	10-dose vial	5-dose vial	10-dose vial	5-dose vial
Manufacturer(s)	PT Bio Farma (Persero)	Serum Institute of India Pvt. Ltd.			
Commercial name	Measles vaccine	Measles Vaccine, Live, Attenuated		Measles and Rubella Vaccine, Live, Attenuated	
Shelf life at 2^o-8^o C	36 months	30 months			
Serotypes covered	CAM 70	Edmonston-Zagreb		Edmonston-Zagreb Wistar RA 27/3	
Preservative	None				
WHO prequalified	Yes				
Schedule	2 doses				
Primary packaging	Vial+Ampoule				
Pharmaceutical form	Lyophilized active component to be reconstituted with excipient diluent before use				
Storage temperature	2 ^o -8 ^o C				
Vaccine Vial Monitor	VVM14				
Handling of open multi-dose vials⁴	Reconstituted vial must be discarded after 6 hours or after the end of the session whichever comes first.				

The main differences between the 10-dose vial presentations and the 5-dose vial presentations of the measles and measles-rubella vaccines

Cold chain requirements. There will be an increase in cold chain space requirements if the 10 dose-vial presentation is replaced with the 5-dose vial presentation for both measles and combined MR products. The volume per dose for the different MR vaccine presentations are indicated in the table below:

Table 2- Cold chain requirements

Cold chain Volume (CM ³ /dose)		
Vaccine/Presentation	Vaccine	Diluent
Measles 10-dose vial	2.109-3.3	2.53-3.1424
Measles 5-dose vial	4.218	5.481
MR 10-dose vial	2.109	3.1424
MR 5-dose vial	4.218	5.481

³Standard lead times for delivery of Measles/MR vaccine in 10-dose vial presentations procured through UNICEF Supply Division for forecasted routine immunization needs is 6-8 weeks. The estimated lead time for Measles/MR vaccine in 5-dose vial presentation would be 4-6 months, depending on volumes required.

⁴http://apps.who.int/iris/bitstream/handle/10665/135972/WHO_IVB_14.07_eng.pdf;jsessionid=631922BD419122102457F35CA4CA03E2?sequence=1

Example below depicts a comparison of fully immunized child (FIC) volume requirements at the service delivery level when MR in 10-dose vial is used, and when MR in 5-dose vial is used:

Volume of antigen for Fully immunized child in country X with MR-10

Vaccine	No of doses	Presentation	Packed Volume	Total packed Volume
	Per schedule	Doses/vial	cm3	cm3
BCG + diluent	1	20	1.9	1.9
OPV	4	10	1	4
DPT-HepB-Hib	3	10	2.9	8.7
PCV-10	3	2	4.8	14.4
MR + diluent	2	10	5.3	10.6
TT/Td	3	10	3	9
Rotavirus	2	1	46.3	92.6
IPV	1	10	2.5	2.5
Total for FIC				143.7

Volume of antigen for Fully immunized child in country X with MR-5

Vaccine	No of doses	Presentation	Packed Volume	Total packed Volume
	Per schedule	Doses/vial	cm3	cm3
BCG + diluent	1	20	1.9	1.9
OPV	4	10	1	4
DPT-HepB-Hib	3	10	2.9	8.7
PCV-10	3	2	4.8	14.4
MR + diluent	2	5	9.7	19.4
TT	3	10	3	9
Rotavirus	2	1	46.3	92.6
IPV	1	10	2.5	2.5
Total for FIC				152.5

Please refer to UNICEF's cold chain weight and volume calculator⁵ for comparison of the space required for in-country deliveries and cold chain storage requirements. However, when calculating the increase in the cold chain requirements, the projected reduction in wastage needs to be considered.

Wastage Rate. The average wastage rate for the 10-dose vial presentation for both the measles and MR vaccines for routine immunization is estimated to be 40 per cent, while the same for the 5-dose vial is estimated at 30 per cent. However, national wastage estimates for both presentations will need to consider size of the target population per service point and vaccination session, frequency of sessions etc. Wastage rates will vary for urban and rural settings.

Table 3- Estimated Wastage rates

Estimated Wastage Rate (%)		
Vaccine/Presentation	Routine Immunization	Supplemental Immunization Activities
Measles 10-dose vial	40	10
Measles 5-dose vial	30 (TBC)	10 (TBC)
MR 10-dose vial	40	10
MR 5-dose vial	30 (TBC)	10 (TBC)

Price Per dose⁶. For measles vaccine in a 10-dose presentation accessible through UNICEF, the maximum price is US\$ 0.318 per dose, whereas in the 5-dose presentation, the price is US\$ 0.396 per dose. For MR vaccine in the 10-dose presentation the maximum price is US\$ 0.656 whereas in the 5-dose presentation, it is US\$ 0.82 per dose. There is no doubt that the overall cost implication of each presentation will depend

⁵ https://www.unicef.org/supply/index_51098.html.

⁶ Information valid until December 2020. Prices per manufacturer, year and presentation:

https://www.unicef.org/supply/files/2018_04_04_Measles.pdf and

https://www.unicef.org/supply/files/2018_04_17_MR.pdf for pricing information.

on the vaccine wastage. The table below provides the indicative maximum price for each presentation without considering the wastage rate.

Table 4- Price/dose (valid until December 2020)

Vaccine/Presentation	Price/dose
Measles 10-dose vial	US\$ 0.318
Measles 5-dose vial	US\$ 0.396
MR 10-dose vial	US\$ 0.656
MR 5-dose vial	US\$ 0.820

At the current maximum prices of measles and MR vaccine accessible through UNICEF, the price per administered dose from a 5-dose vial of MR, will be equal to the price per administered dose from a 10-dose vial MR, if the 5 dose vial ends up with an actual wastage rate of 26 per cent when compared to 40 per cent wastage when using the 10 dose vial.

Visual differentiation between 5 and 10 dose vial

The vaccine manufacturer is currently revising the visual appearance of the 5-dose vial presentation to ensure that the different vial and diluent containers are easily distinguished. This will include different color of flip-off seals for 5 and 10-dose vial presentation. Information regarding the physical appearance of the 5-dose vial presentation (vial and diluent containers) will be shared with countries as soon as the regulatory changes incorporating revised artwork have been finalized.

Action to be considered for the Replacement

- Present the justification for the replacement to ICC or equivalent forum.
- Hold advocacy and consensus meetings at national and sub-national levels.
- Assess cold chain and cold store capacity requirements.
- Secure funding for preparations for the replacement.
- Determine and address programmatic implications and challenges in the use of different presentations “side by side” for routine immunization and campaigns.

Preparatory activities for switching M/MR vaccine 10-dose to 5-dose vial

- Assess and calculate the cold chain and storage capacity at all levels based on the new requirements.
- Carry out a vaccine inventory review – to identify the stock level of the M/MR 10-dose vial.
- Revise/develop vaccine shipment and distribution plans at all levels.
- Revise, print, and distribute all vaccine monitoring, reporting and registration tools/forms.
- Amend immunization guides, plans, comprehensive multi-year plans (cMYP) etc. to reflect the changes.
- Conduct orientation/ training of health workers on the changes on the vaccine vial presentations and implications.
- Develop, print and distribute a simple guide for health workers for the 5-dose vial, possibly in the major local languages.

Resources

- **Monitoring vaccine wastage at country level**
http://apps.who.int/iris/bitstream/handle/10665/68463/WHO_VB_03.18.Rev.1_eng.pdf;jsessionid=4BDAC570B8C78C604B00A1B15406DD6C?sequence=1

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- **Immunization Tools to help the dose per container decision**
https://www.jsi.com/JSIInternet/Inc/Common/_download_pub.cfm?id=19420&lid=3
- **WHO Vaccine Management and logistics support**
EPI logistics forecasting tool, Cold chain equipment inventory and gap analysis tool, Immunization supply chain sizing tool.
http://www.who.int/immunization/programmes_systems/supply_chain/resources/tools/en/index4.html
- **UNICEF Cold Chain Weight and Volume Calculator**
www.unicef.org/supply/index_51098.html



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Contributors: Dr. Katrina Kretsinger (WHO); Dr. Yodit Sahlemariam (UNICEF); Ann Ottosen (UNICEF); Hans Christiansen (UNICEF); Dr. Imran Mirza (UNICEF); Dr. Robert Kezaala (UNICEF); Jean-pierre Amorij (UNICEF); Michelle Seidel (UNICEF); Ousmane Tamba Dia (UNICEF); Michaela Briedova (UNICEF).