



Information note for countries considering switching to a yellow fever 5-dose vial vaccine presentation



1. Purpose

The purpose of this document is to provide up-to-date information to support countries in making informed decisions around the appropriate yellow fever vaccine (YFV) vial presentations for routine immunization tailored to the country's context and needs.

2. Scope

The information note provides an update on YFV in 10-dose vial and 5-dose vial presentations available through the UNICEF procurement mechanism. It summarizes evidence and information gathered from studies on the advantages of using smaller vaccine vials/containers in reducing missed opportunities for vaccination by minimizing vaccine wastage rates in routine immunization. It also contains information on operational considerations that should be evaluated when planning for switching from 10-dose to 5-dose vial presentations (e.g. coverage, costs, wastage, and cold chain).

3. Audience

Immunization system stakeholders, including immunization managers, national and regional immunization technical advisory groups, and key partners including WHO, UNICEF, and Gavi, the Vaccine Alliance.

4. Background

Vaccines procured for low and middle-income countries are typically packaged in multi-dose vials to reduce program costs and cold chain capacity requirements^{1,2}. The performance of vaccinators is often measured using indicators such as vaccine wastage, which vaccinators may aim to limit for fear of vaccine stock-outs for future sessions and due to programme disincentives based on excessive wastage²⁻⁴, meaning vaccinators frequently refrain from opening a vaccine vial if one or few children are present at an immunization session. This practice is a missed opportunity for vaccination which impacts the timeliness of vaccination, immunization coverage and maintains population susceptibility to disease.

Lowering the number of doses in a vaccine vial aims to encourage health workers to open vials more frequently when one or few children are present, which can address wastage concerns and reduce missed opportunities for vaccination. In this note, we collate evidence on the effects of switching from 10- to 5-dose vial presentations on cost implications, the impact on wastage, and cold chain requirements. Most of this evidence is drawn from studies documenting the switch from 10 to 5 dose vial presentations for measles-containing vaccines (MCV) due to the limited studies done on YFV. However, both MCV and YFV are lyophilized vaccines that require reconstituting before use and are discarded at the end of the session, and have similar cold chain storage requirements, indicating the evidence gathered for MCV may also apply to YFV.

5. Current evidence

5.1 Coverage

Research in Zambia found that when health workers had access to measles rubella (MR) 5-dose rather than 10-dose vials, there was a 4.9% increase in the first dose vaccine (MR1) coverage and a 3.5% increase in the second dose (MR2) coverage⁵. While further research on the effects of switching vaccine presentation on YFV coverage will be crucial, a complementary modelling study that used routine immunization supply chain data in Zambia suggests that fewer dose MR vials could feasibly increase the number of doses administered, a proxy for coverage, without placing burdens on cold chain or immunization program costs⁶. The impact of switching to fewer vaccine vials on vaccination coverage can

also be inferred from a three-country study in Senegal, Vietnam, and Zambia. The study found that healthcare workers (HCWs) using 10-dose vaccines for BCG and MCV reported turning caregivers and children away if insufficient children were present in a session without plans in place to call back children to get vaccinated². In the southwest State of Nigeria, missed opportunities to vaccinate were more frequent for routine immunization vaccines with higher doses per vial compared to antigens with fewer doses per vial.

5.2 Healthcare worker preferences

A qualitative study examining HCW preferences and perspectives on doses per container found that HCWs in Zambia, Vietnam and Senegal preferred fewer doses per container for BCG and MCV². All HCWs interviewed, except those in districts that already used 5-dose vials for MCV, expressed interest in switching to fewer dose vials which they reported would alleviate the stress associated with avoiding excessive wastage.

5.3 Cold Chain

Recent studies from Zambia demonstrated that with recent efforts to increase cold chain capacity, facilities have sufficient space for smaller vial sizes for measles vaccines^{5,8}. A modelling study examining effects of re-designed supply chain components on supply chain performance in Madagascar, Guinea and Niger showed that more than 75% of the cold chain equipment at the facility level was using less than 20% of the available space⁹, suggesting increases in cold chain capacities can be accommodated. This runs counter to previous modelling data from Niger that suggest a switch from 10-dose measles vaccine to fewer vial sizes could exceed the capacities of many storage facilities and transport vehicles¹⁰. Further, because of the lower wastage, a facility does not need to double the number of YFV vials when switching to 5-dose. Evidence from a modelling study in Zambia found that switching from 10- to 5-dose vials for measles vaccines increased cold chain utilization and led to a 1% decrease in availability of other vaccines; however this did not impact the availability of the measles vaccine⁶. The findings from the Zambia study also suggest that tailoring the 5-dose measles vials to rural health facilities or by average session size yielded higher availability of vaccines without increasing cold chain utilization.

5.4 Wastage

Operational and modelling research studies examining the effects of switching to smaller dose vials have shown that using vaccine vials with fewer doses reduces open vial wastage rates. A study conducted in Zambia found that the open vial wastage rate was 47% lower in facilities using 5-dose MR vials compared to 10-dose MR vials⁵. The wastage rate in facilities using 5-dose vials was 16.2% versus 30.5% in facilities using 10-dose vials. The switch saved 573,892 doses and improved MR availability by 1%⁶. The Zambia modeling study found that switching to 5-dose vials would reduce the wastage rate by 21% if implemented across all vaccination sites⁶. In Brazil, an evaluation of the vaccine wastage in 4 states in 2008 found wastage to be higher for 10-dose vials like the measles-mumps-rubella (MMR) vaccine (65.7%) compared to single-dose vials like the oral rotavirus vaccine (3.2%)¹¹.

5.5 Cost

In Zambia, tailoring 5-dose MR vials to rural health facilities based on average session size reduced cold chain transport constraints, increased total vaccine availability (+1%) and reduced total cost per dose administered (-\$0.01) compared to baseline⁶. Previously, modelling of Niger data suggested a switch from the 10-dose measles vaccines to smaller vial sizes could increase the cost per vaccinated child¹². However, the effects on costs, wastage, cold chain, and coverage are challenging to compartmentalize because of inter-related trade-offs, i.e. while the direct costs of the vaccine may be more expensive, an immunization program can reach more children by alleviating wastage rates.

6. Characteristics of WHO-prequalified YFV presentations

Four WHO prequalified vaccine manufacturers produce YFVs in 5- and 10-dose presentations, some of which are available through the UNICEF procurement mechanism (Table 1).

Table 1: Characteristics of WHO-prequalified YFV in 10-dose and 5-dose vials available through the UNICEF procurement mechanism¹³

	Yellow Fever Vaccine				
Presentation	5-dose vial, lyophilized		10-dose vial, lyophilized		
Manufacturer	FSASI Chumakov FSC R&D IBP RAS1	Bio-Manguinhos/Fiocruz	Institut Pasteur, Dakar	FSASI Chumakov FSC R&D IBP RAS	Sanofi Pasteur
Commercial Name	Yellow Fever Vaccine Live Freeze-Dried	Yellow Fever Vaccine	Stabilized Yellow Fever Vaccine	Yellow Fever Vaccine Live Freeze-Dried	Stamaril
Shelf life at 2°- 8°C	24 months	36 months	36 months	24 months	36 months
Serotypes Covered	17-D				
Preservative	None				
WHO-Prequalified*	Yes				
Schedule	Single Dose				
Secondary Packaging	Ampoule	Vial	Ampoule	Ampoule	Vial
Storage Temperature	2°- 8°C				
Vaccine Vial Monitor	VVM 14				
Handling Open Vials	Opened vials should be discarded 6 hours after opening or at the end of the immunization session, whichever comes first.				

* [WHO List of Prequalified Vaccines](#)¹⁴

7. Main differences between YFV 10-dose vial and 5-dose vial presentations available through the UNICEF procurement mechanism

7.1 Cold chain requirements

Data from the Zambia study showed that the wastage-adjusted difference between 5- and 10-dose vials in net cold chain per immunized child was minimal. Despite the higher cold chain volume per dose for 5-dose vials, the reduced total required supply (TRS) helps to offset cold chain requirements such that the 5-dose vials had a minimal impact on the cold chain requirements in practice. All health facilities were able to accommodate 5-dose vials within existing cold chain capacity.

Table 2 below presents the per-dose volume for each product.

Table 2: Cold chain space requirements by YFV presentation

Cold Chain Volume	
Vaccine / Presentation	Vaccine cm ³ /dose
YFV 5-dose vial	6 cm ³
YFV 10-dose vial	1.4 cm ³ – 3.6 cm ³

7.2 Wastage rate

Based on Gavi Detailed Product Profiles¹⁵, the estimated average wastage rate in routine immunization activities when using the 10-dose vial is 40%, compared to 10% for the 5-dose vial. However, national wastage rate estimates for both presentations need to consider the size of the target population and vaccination sessions per service point, frequency of sessions, etc. Wastage rates will vary for urban and rural settings and between service points.

7.3 Price per dose¹⁶

In contrast to fewer dose vials for other antigens which are typically at a lower cost than higher dose vials, the YFV procured through UNICEF are at a maximum price of US\$1.67 per dose in a 10-dose vial whereas the 5-dose vial costs US\$0.97 per dose. The total cost implications of each presentation depend on the reduction in wastage rate that can be achieved in country-specific contexts; in addition to the trade-offs of potentially higher coverage rates and greater healthcare worker willingness to open a smaller sized vial.

Table 3 below provides the price range for each presentation, without considering the wastage rate and excluding freight, supplies and bulk costs.

Table 3: Price per dose by YFV vial (as of January 2022)

Vaccine/Presentation	Price/dose
YFV 10-dose vial	US \$0.97- \$1.67
YFV 5-dose vial	US \$0.97

7.4 Other considerations

The above impact on cold chain, wastage and price does not include indirect effects that would also need to be considered when switching to fewer dose vials. For example, the increased number of fewer dose vials will subsequently lead to increases in the requirement for safe injection equipment (such as syringes for vaccine reconstitution and preventable syringes (RUPs) and safety boxes) and, therefore, may have effects on increased costs, transportation frequency and storage facility requirements. In addition to increased costs due to syringes, the increased frequency of vaccine distribution to health facilities would also contribute to higher cost implications. Countries will need to conduct an assessment that incorporates the direct and indirect impact on cold chain, transport, and storage capacity, wastage,

and costs. A [Decision Support Resource](#)¹⁷ is available for countries that are considering different vaccine presentations (see additional resources section below).

8. Planning consideration when proposing a switch from 10-dose to 5-dose vials

Some of the areas that countries need to consider when planning to switch from the YFV 10-dose vial presentation to the 5-dose vial presentation are listed below.

- **Evidence-based decisions:** The effects of switching on MCV1 coverage are of great relevance for countries vaccinating against YF through their routine immunization programme, as similar impacts may be envisaged given that both vaccines are typically administered at the same age. **This should be strongly considered among a suite of tools to increase YF vaccination coverage.**
- **Socialization:** Present the justification for the change to national immunization technical advisory group or equivalent forum and hold advocacy and consensus meetings at national and sub-national levels.
- **Co-administration:** MCV and YFV are co-administered in African and in most Latin American countries. Hence, these countries should align their MCV and YFV vial presentations whenever possible. Countries co-administering YFV with MCV and considering or already implementing 5-dose vial presentations for MCV should concurrently consider 5-dose vial presentations for YFV, and vice versa.
- **Assessment:** Prior to deciding on vial size, countries should comprehensively assess the potential benefits of switching from 10-dose to 5-dose YFV vials, taking into consideration their specific context. Assessments should address policies and practices, vaccination coverage targets, stakeholder perceptions, healthcare worker willingness to open a vial, cold chain and storage capacity requirements, transportation capacity, and logistics management systems.
- **Cost and funding:** Assess the total cost implications and ensure sustainable funding as per other vaccines.
- **Logistics management information system:** The complexity of managing different vial sizes for the same vaccine (e.g. for routine immunization and campaigns) should be considered. It requires a well-functioning logistics management information system that provides accurate data and relies on good stock management to prevent delivery of the wrong vial sizes to immunization sites. Errors in management of stock records have been experienced in countries where campaign stock (with different vial sizes) is integrated with routine stock without accurate recording of doses and vial sizes. Each vaccination site should use only one presentation, 5-dose, or 10-dose, as to avoid programmatic errors and confusion.
- **Capacity-building:** Training of health workers and supervisors is crucial to understand which vial presentation will be delivered, what it means in practical terms (e.g., planning outreach, including cold-chain capacity and thermos weight), what to expect regarding wastage rates, and the continued need to put reaching high and equitable childhood vaccination rates as the priority over wastage.

9. Activities in preparation for implementing a switch from 10-dose to 5-dose vial

- Assess cold chain and storage capacity at all levels of the health system based on the new requirements.
- Carry out a vaccine inventory review to identify the current stock level of the YFV 10-dose vials.

- 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 and standard operating procedures, information systems, annual plans, National Immunization Strategies [e.g. comprehensive multi-year plans, etc.] to reflect the changes.
- Conduct orientation/ training of health workers on the changes in vaccine vial presentations and their implications.
- Develop, print, and distribute a simple guide or job-aid for health workers for the 5-dose vial, ideally in all major local languages, along with training of health care provider.

10. Countries supported by Gavi

Gavi-eligible countries may request support to switch from a 10-dose vial presentation to a 5-dose vial presentation for their routine YFV through [Gavi’s Country Portal](#)¹⁸ as part of their vaccine renewal request.

As part of the operationalization of Gavi’s 2021-2025 strategy (“Gavi 5.0”), Gavi is transitioning from an annual cycle of vaccine renewals to a multi-year renewal and approval approach (multiyear approval, MYA). A country can request a switch throughout the multi-year approval period by submitting a switch request form to Gavi’s Secretariat through the country’s Senior Country Manager.

The switch request form is vaccine-specific and is used to collect essential information for the implementation of the switch. Gavi, the Vaccine Alliance, may provide support in the form of a “switch grant” to facilitate the safe and effective transition to a new product, presentation, or use. This intends to cover a portion of the one-time investments associated with a switch (e.g. training, document production and printing, procurement of cold boxes and related equipment, safety boxes and other supplies to manage increased volume of open vials and reconstitution syringes, stock monitoring, and retrieval of stock). Please refer to the [Guidelines on Reporting and Renewal of Gavi Support](#)¹⁹ for additional information on Gavi processes and requirements.

11. Data source

Information in this note comes from several sources: 1) UNICEF supply division data on WHO prequalified YFV presentations and costs, and 2) a literature review on the immunization system impacts associated with switching from larger to smaller vaccine vial sizes for routine immunization.

12. Country guidance documents

[Immunization dose per container decision support resource](#)¹⁷

[Monitoring vaccine wastage at country level](#)²⁰

[Immunization tools to help the dose per dose container decision](#)²¹

[Planning Guide to Reduce Missed Opportunities for Vaccination](#)²²

[Intervention guidebook for implementing and monitoring activities to reduce missed opportunities for vaccination](#)²³ – See page 15 “Concerns about vaccine wastage” for solutions.



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14. Appendix 1

14.1 Visual differentiation between the 5-dose and the 10-dose vials

Vaccine manufacturers have developed different visual appearances for the 5-dose and 10-dose vials to ensure that the two are easily distinguished in size. The current artwork for each product is presented below and can also be found on [WHO's list of prequalified vaccines](#)¹⁴.

Yellow Fever vaccine 5-dose ampule and diluent, FSASI Chumakov FSC R&D IBP RAS



Source: WHO list of prequalified vaccines

Yellow Fever vaccine 10-dose ampule and diluent, FSASI Chumakov FSC R&D IBP RAS



Source: WHO list of prequalified vaccines

Yellow Fever vaccine 10-dose vial and diluent, Bio-Manguinhos/Fiocruz



Source: WHO list of prequalified vaccines

Yellow Fever vaccine 10-dose ampule and diluent, Institute Pasteur, Dakar



Source: WHO list of prequalified vaccines

Yellow Fever vaccine 10-dose vial and diluent, Sanofi Pasteur



Source: WHO list of prequalified vaccines

15. Appendix 2

15.1 Cold chain capacity requirements

The packed volume per dose for YFV 10-dose vial varies from 1.3 to 2.3 cm³ depending on the manufacturer. The only YFV 5-dose presentation has a packed volume of 4.2 cm³ per dose, 2.2 times the average packed volume for the 10-dose presentation. Despite the increase in packed volumes with the YFV 5-dose vial presentation, the cold chain volume may not significantly change for the 5-dose compared to the 10-dose vial presentation²⁴.

Table 4 below provides an estimation of vaccine storage volume for each presentation, with consideration of the anticipated wastage rates. Translating the Zambia evidence to facility level²⁴, switching to a 5-dose presentation required a 4% increase in capacity. For a facility with a target population of 646 children based on the full Expanded Programme on Immunization (EPI) schedule, the monthly cold chain requirement is about 7 liters, while facility level cold chain is typically a minimum of 16 liters and larger. Therefore, there is generally sufficient space at the facility level. District level cold chain may be more constrained; however this can be managed by variable delivery frequency.

Table 4: Estimated packed volumes for different measles vaccine presentations with anticipated wastage rates at a given health facility with 335 surviving infants

Vial size	Vaccine storage volume estimation (cm ³ per dose)	Frequency of sessions			
		cc/dose	1 days/week	2 days/week	3 days/week
1-dose vial	21.1	21.1	21.5	21.5	21.5
2-doses vial	10.5	10.5	11.2	12.2	13.1
5-doses vial	4.2	4.2	5.0	6.3	8.3
10-doses vial	1.9	1.9	2.6	4.6	7.1

15.2 Waste rate modelling

A WHO wastage rate modelling exercise conducted for the different vaccine presentations anticipates a significant reduction in opened vial wastage as the number of doses of the primary container increases. For instance, the anticipated wastage rates will increase on an average of 42% from 5-dose to 10-dose vial presentations.

Table 5 below provides anticipated wastage rates for different vaccine presentations from WHO prequalified manufacturers.

Table 5: Example: Anticipated opened vial wastage (No reuse) rates for different session frequencies at a given health facility with 335 surviving infants

Vial size	Frequency of service point sessions			
	1 days/week	2 days/week	3 days/week	5 days/week
1-dose vial	0%	0%	0%	0%
2-doses vial	4%	8%	12%	18%
5-doses vial	14%	23%	32%	48%
10-doses vial	25%	40%	57%	72%