IMMUNIZATION DOSE PER CONTAINER DECISION SUPPORT RESOURCE

This resource has been developed by the Dose Per Container Partnership to assist in identifying trade-offs around vaccine dose per container to help support decision making among immunization stakeholders.

March 2019

DPCP
DOSE PER CONTAINER PARTNERSHIP

CONTENTS

ACRONYMS

AEFI	adverse events following immunization
AMP	Agence de Médecine Préventive
BMGF	Bill & Melinda Gates Foundation
CCE	cold chain equipment
CHAI	Clinton Health Access Initiative
cMYP	comprehensive multi-year plan
CSO	civil society organization
DPC	dose per container or doses per container
DPCP	Dose Per Container Partnership
EPI	Expanded Program on Immunization
EVMA	Effective Vaccine Management Assessment
Gavi	Gavi, the Vaccine Alliance
HCW	health care worker
HERMES	Highly Extensible Resource for Modeling Event-Driven Supply Chains
HF	health facility
ICC	Inter-agency Coordination Committee for Immunization
IVAC	International Vaccine Access Center
IVS	Institute for Vaccine Safety
JE	Japanese encephalitis
JSI	JSI Research & Training Institute, Inc.
KAP	knowledge, attitudes, and practices
LMIC	low- and middle-income countries
MDV	multi-dose vial
MDVP	multi-dose vial policy
M&E	monitoring and evaluation
MOH	Ministry of Health
MOV	missed opportunities for vaccination
NGO	non-governmental organization
NITAG	National Immunization Technical Advisory Group
PCV	Pneumococcal conjugate vaccine
TCO	total cost of ownership
UNICEF	United Nations Children's Fund
WHO	World Health Organization

ABOUT THE DOSE PER CONTAINER PARTNERSHIP

The Dose Per Container Partnership (DPCP) came together to support vaccine product and program decision making, with a focus on assessing the trade-offs between cost and immunization systems impact when choosing dose per container (DPC).

Funded by the Bill & Melinda Gates Foundation (BMGF) and implemented by JSI Research and Training Institute, Inc. — in partnership with the Clinton Health Access Initiative (CHAI); PATH; the International Vaccine Access Center (IVAC) and Institute for Vaccine Safety (IVS) through Johns Hopkins University's Bloomberg School; Agence de Médecine Préventive (AMP); and the Highly Extensible Resource for Modeling Event-Driven Supply Chains (HERMES) Logistics Modeling Team — DPCP builds upon existing evidence to assess how DPC choices affect cost/immunization system tradeoffs.

DPCP has implemented country-level research in several countries to generate new evidence on the impact of DPC decisions on an immunization system, to explore current decision making on DPC options, and to inform country and global decisions on vaccine procurement. Full details of research, results, and evidence can be found at JSI.com/DPCP.

ACKNOWLEDGEMENTS

The Dose Per Container Partnership is very grateful to all those who gave up their time to participate in interviews, design surveys, give technical strategic advice, support the analysis of data, develop communications plans, and support recommendations. These include:

- Members of the Ministry of Health, WHO, UNICEF, and key partner agencies in Benin, Côte d'Ivoire, Democratic Republic of Congo, Ghana, Philippines, Senegal, Vietnam, and Zambia
- Technical Advisory Group members, representing Gavi secretariat (Steve Sosler and Lauren Franzel), WHO (Souleymane Kone), UNICEF Supply Division (Ann Ottosen), and the vaccine industry (Sy Gebrekidan), as well as independent experts (Robin Beillik, Elsie Le Franc, Boubacar Dieng, and K.O. Antwei Agyei)

INTRODUCTION

The global effort to protect all people from vaccine-preventable diseases has historically leveraged multi-dose vials (MDVs) in low- and middle-income countries (LMIC) to offer lower prices and reduce the constraints on cold chain space. As newer, more expensive vaccines are introduced in multi-dose formats, however, the burden of cost efficiency potentially moves from the national-level Ministry of Health (MOH) to the health care worker (HCW).

To achieve maximum utilization of every dose in a vial and depending on the country's policies, health care workers (HCWs) need to be strategic when deciding to open a vial or not, diligent about how they care for open vials, and potentially more active with community outreach and communication to ensure optimal attendance and timely immunization.

For this reason, the number of doses per container (DPC) can impact the ability to efficiently achieve a country's goals for timely and equitable coverage — including the ability to reach specific communities, such as urban poor or rural remote — and also has implications for safety, costs, supply chain, and wastage.

Given the complexity associated with trade-offs, or the balance, between price and immunization coverage and other system components — particularly in LMICs, where resources are even more limited — it is important that immunization stakeholders understand the evidence to support the DPC decision and the potential market-shaping influence on manufacturers with demonstrated demand for a specific vaccine presentation.

Once the advantages and disadvantages are assessed, trade-off decisions can be made within the health system's context and with consideration of how DPC links to immunization coverage and equity goals, as well as overall health sector goals. **This resource is a culmination of DPCP research results to provide decision makers with evidence that can be generalized to other countries when considering vaccine presentation.**

ABOUT THIS RESOURCE

The Purpose of This Resourse

This resource can help guide the DPC decision-making process through:

- Structuring data analysis; guiding discussions
- Providing a basis for decisions, policies, and proposals; and
- Identifying appropriate implementation guidance for any changes made.

Also, this resource can also be used to stimulate meetings and dialogue among groups engaged in supply chain efforts with program designers and budgeters to ensure a connection is made between product selection and program outcomes.

It is important to note that DPC is only one consideration of many within an immunization program. During the DPC discussion, stakeholders should also consider other options, such as supply chain optimization or different immunization delivery strategies, to achieve program goals.

Who Should Use This Resource and When

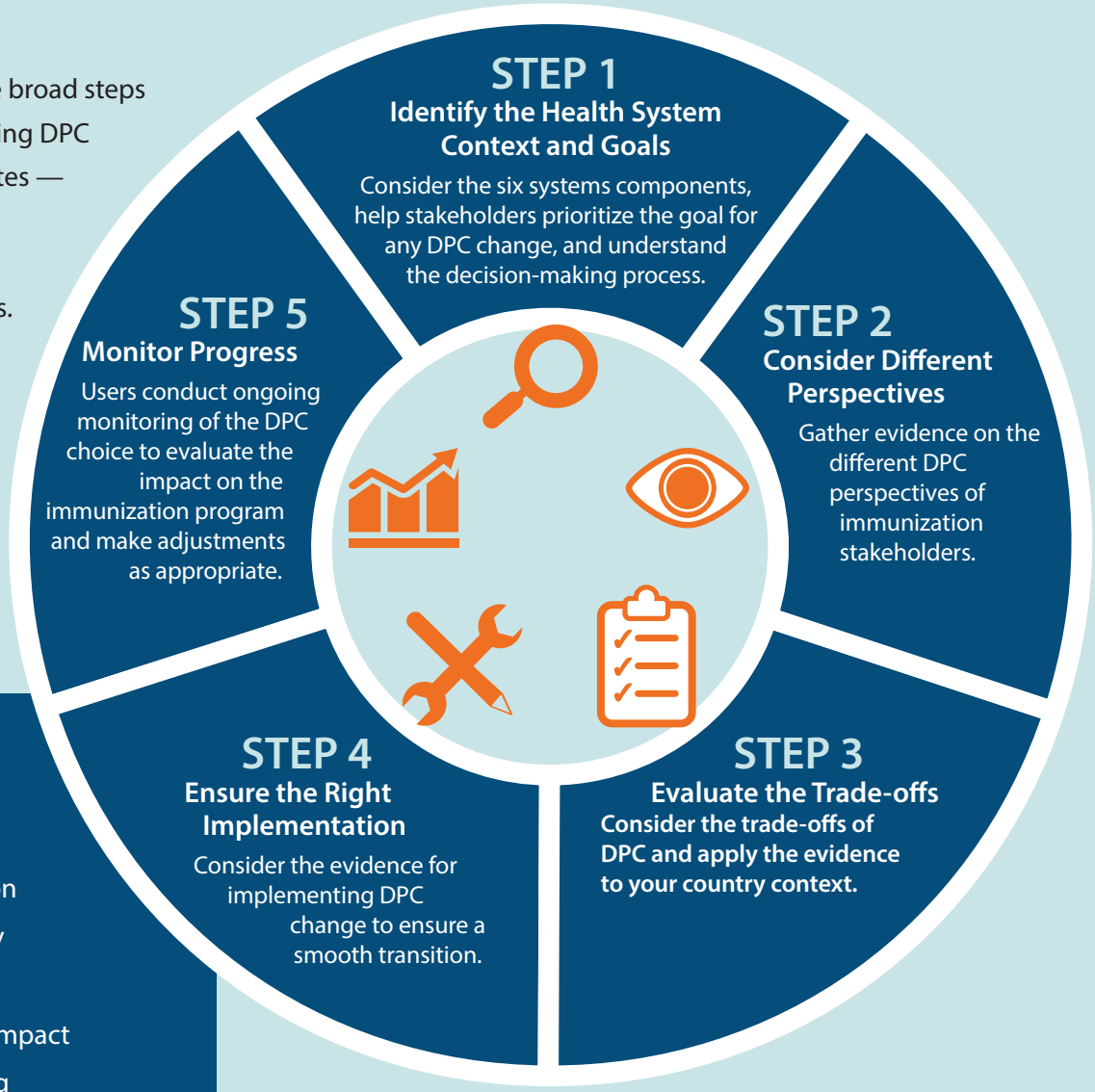
Country- and global-level stakeholders — such as Expanded Program on Immunization (EPI) managers, logisticians, Ministries of Health (MOHs), Ministries of Finance (MOFs), donors, procurement agencies, manufacturers, global partners, and other stakeholders — can use this resource to better understand the potential trade-offs of various DPC choices and to select the best vaccine presentations for their program. The discussion will typically be led by the EPI manager or one of his/her delegates. The National Immunization Technical Advisory Group (NITAG) and/or the Inter-agency Coordinating Committee for Immunization (ICC) are usually engaged and will need to approve these decisions. Civil society, particularly organizations working on behalf of vulnerable populations, should also understand the tradeoffs to advocate for the right presentations for their populations.

Logical times to consider the DPC decision include:

- When a new vaccine application is being made to Gavi or another organization;
- When the country is preparing its annual forecast and vaccine order to UNICEF or another supplier;
- During program reviews, such as Joint Appraisals or EPI reviews; and
- During planning cycles when developing the comprehensive multi-year strategic plans (cMYPs) for immunization.

How This Resource Is Organized

This decision support resource is organized by five broad steps taken when an immunization program is considering DPC for a specific vaccine (considering all other attributes — such as effectiveness, preservative inclusion, or stability — are the same or at least comparable). These steps are described in the following sections.



Additional Resources to Support DPC Decision Making

In making decisions on dose per container, immunization stakeholders can also consider a quantitative analysis by using the UNICEF Immunization Forecast Tool or the WHO EPI Logistics Forecasting Tool, and can assess the impact of DPC change on the cold chain capacity required using WHO's Cold Chain Equipment Inventory Tool. All tools assessed for DPCP can be found in Annex 1.

STEP 1: Identify the Immunization System Context and Goals

As the vaccine market continues to grow, product specifications continue to adapt, and country contexts continue to change, EPI managers have the opportunity to assess changes to the immunization program and different vaccine presentations to help meet country-specific priorities.

New DPC are becoming available for different vaccines; countries have the option of vaccines with and without preservatives; and the controlled-temperature chain, in which vaccines can be kept out of the traditional cold chain for a limited period of time, is now available for use in certain situations with certain vaccines.

To support immunization stakeholders in assessing the immunization system context and goals in their countries, DPCP has focused on six immunization system components and the trade-offs among them related to DPC (see also graphic on page 10):

1 **COVERAGE RATES**, and particularly timely and equitable coverage rates, contribute to the overall goal of eliminating vaccine-preventable diseases.

2 **WASTAGE RATES** are an important consideration, particularly as new vaccines are becoming available and are often more expensive. The pressure to reduce wastage can strongly influence HCW behavior.

3 **SAFETY** is a heightened concern with MDV, as there is a risk of contamination once the vial is opened. This risk may be greater for vaccines without a preservative that must be discarded at the end of a session. All vaccines require proper storage and handling procedures; not following these for MDVs can lead to adverse events following immunization (AEFI).

4 **COSTS** are related to the per-dose cost of the vaccine — typically less for MDVs — as well as the cost per child immunized, which is influenced by immunization system characteristics, such as session size and frequency, wastage rate, and human resource need and level of effort.

5 **SUPPLY CHAIN** management is a significant investment, and the potential need for new cold chain equipment is an important consideration when assessing DPC options.

6 **HEALTH CARE WORKER BEHAVIOR** is the last-mile influential factor on whether a vaccine vial is opened or not, whether missed opportunities for vaccination (MOV) are reduced, and whether a child is vaccinated or not. Multiple inputs affect this component, such as size of the immunization session, HCW understanding and willingness to open a vial for every child, and the availability of vaccines for an immunization session.

BY TAKING STEP 1
You Should Be Able to

- Identify priorities for your immunization program based on your current country context; and
- Identify key stakeholders who should be involved in the decision.

Figure 1 These Immunization System Components Will Influence and Be Influenced by DPC Choices

Complex Relationships Among the Six System Components

When country programs are considering a different DPC, the priorities often cited are linked to coverage, cost, and cold chain capacity. But a different vaccine DPC may have surprising implications for trade-offs among the six system components. For example, an increase in vaccine and system costs due to a different DPC may also increase coverage by improving vaccine availability and increasing the HCW's willingness to open a vial; or a different presentation may require less cold chain capacity than expected.

Assessing trade-offs associated with changing DPC and these six system components can provide a better understanding of the complex relationships within the immunization program and help support decisions that improve positive health impacts. See figure 1.

Immunization Program Decision Making at Different Levels

Each country has different processes for making immunization program decisions, such as DPC, but some generalizations on roles and challenges have become clear through DPCP research, even in decentralized contexts:

GLOBAL LEVEL

Manufacturers, Donors, and Procurement Agencies

ROLE: Manufacturers, donors, and procurement agencies coordinate to develop different vaccine presentations based on the demand and type of delivery (routine immunization, campaign, outreach, etc.).

POTENTIAL CHALLENGE: For different vaccine presentations, demand from country-level decision makers may be unknown to manufacturers and procurement agencies.

NATIONAL LEVEL

NITAG, EPI managers, Logisticians, Ministries of Finance, ICC, UNICEF Country Office, and CSOs/NGOs

ROLE: At the national level, stakeholders support the introduction of a new vaccine or change the presentation of a current vaccine.

POTENTIAL CHALLENGES: These stakeholders may not choose a new vaccine or presentation due to inaccurate assumptions about increased cost or increased need for cold chain capacity, or they may not be aware of different presentations.

SUB-NATIONAL LEVEL

EPI managers, logisticians, sub-national health directorates, CSOs/NGOs, and monitoring and evaluation (M&E) experts

ROLE: Stakeholders at the sub-national level contribute to the proposed change in vaccine or presentation.

POTENTIAL CHALLENGES: These stakeholders may not be consulted during the decision-making process. They may also express concern about cold chain capacity, wastage, or safety concerns of open vials.

HEALTH FACILITY LEVEL

Health care workers

ROLE: Health care workers' role is to ensure that all children are immunized.

POTENTIAL CHALLENGES: HCWs are often faced with the decision of whether to open a vial if only a few children are present, as a way of reducing wastage. They are also often not consulted for DPC decisions made at the national level.

MYTH BUSTERS:

For the Six System Components, Did You Know…?

- Having presentations with fewer DPC may increase **timely coverage**, as HCW will be more willing to open a vial. This can also reduce the burden on HCWs, who often develop strategies and "workarounds," such as mobilization and outreach, to ensure children arrive on vaccine-specific days to help keep wastage low.
- Having presentations with fewer DPC will typically decrease open-vial **wastage** rates, which should be considered when measuring trade-offs for supply chain and cost as well.
- Inherent with multi-dose vials is a **safety** risk of contamination once opened. This risk can be mitigated through using vaccines with preservatives, adhering to the multi-dose vial policy, using auto-disable syringes, not reusing reconstitution syringes, using presentations with fewer DPC, and improving HCW safe practices, as examples. Yet the extent of safety risks is unknown, as AEFI following immunization (e.g., abscesses) often go unreported.
- The purchase **cost per dose** of a vaccine often slightly increases for presentations with fewer DPC; however, because of reduced wastage, the overall vaccine need also decreases, which may counter some of the increased purchase cost.
- In a **supply chain** that has few constraints, changing to a presentation with fewer DPC for measles vaccine, as an example, has little impact on the cold chain requirements due to the trade-offs with reducing wastage and the vial size compared to other vaccines in the system.
- **Health care workers** are often driven to reduce wastage, particularly of vaccines without preservatives that need to be discarded at the end of a session. Presentations with fewer DPC may reduce the burden on the HCW to decide to open a vial or not, while also increasing timely coverage and reducing wastage.

As part of identifying the immunization system context and goals in Step 1, immunization stakeholders should take a close look at who is involved in the decision-making process at each level — especially at the sub-national and health facility levels, which are often not consulted — and how coordination and communication can be improved to ensure that each decision maker has the information needed to contribute to sound decisions and come to consensus on priorities for considering DPC.

Questions to Ask Stakeholders in Step 1

- What are the goals for your immunization program and the different antigens?
- Does the country have plans for any new vaccine introductions that need to be considered for long-term planning? How will that impact a change on DPC?
- What challenges do you face to reach these goals?
- What do recent assessments and planning — Joint Appraisals, EPI Review, Effective Vaccine Management Assessment (EVMA), cMYP, etc. — indicate as priority areas for your immunization program?
- Beyond the immunization program leaders, who else needs to be involved in the decision around DPC (Ministry of Finance, civil society, sub-national stakeholders, ICC, etc.)?
- Are stakeholders interested in considering a different DPC and assessing trade-offs among system components?

STEP 2: Consider Different Perspectives

As with any decision, different stakeholders will have different perspectives as to benefits and challenges of different DPC (see figure 2 at right).

Different Perspectives Globally

Dose per container of any vaccine is initially determined during the design, manufacturing, and production process. For manufacturers, changing the DPC is a lengthy process involving many cost implications related to the production fill line, production rate, country-level product registration requirements, and product packaging, to name a few.

Knowing the demand for different DPC is also an important factor in whether manufacturers will invest in production. As a result, procurement agents — such as UNICEF's Vaccine Procurement Services, which works with most LMICs — face the challenge of estimating demand for a product or vial size that may not yet exist in order to secure supply first.

Sometimes market forces (supply) drive an immunization program's product decisions. For example, Ghana made the decision to change the vial sizes of yellow fever and pentavalent vaccines in 2012 and again in 2014 largely due to market availability of specific DPC presentations. In that case, country-level decision makers responded to the market and identified the best approach to implement the resulting changes with minimum disruption.

By contrast, sometimes program decisions (demand) drive the vaccine market, as in the example from Vietnam in the box on page 14.

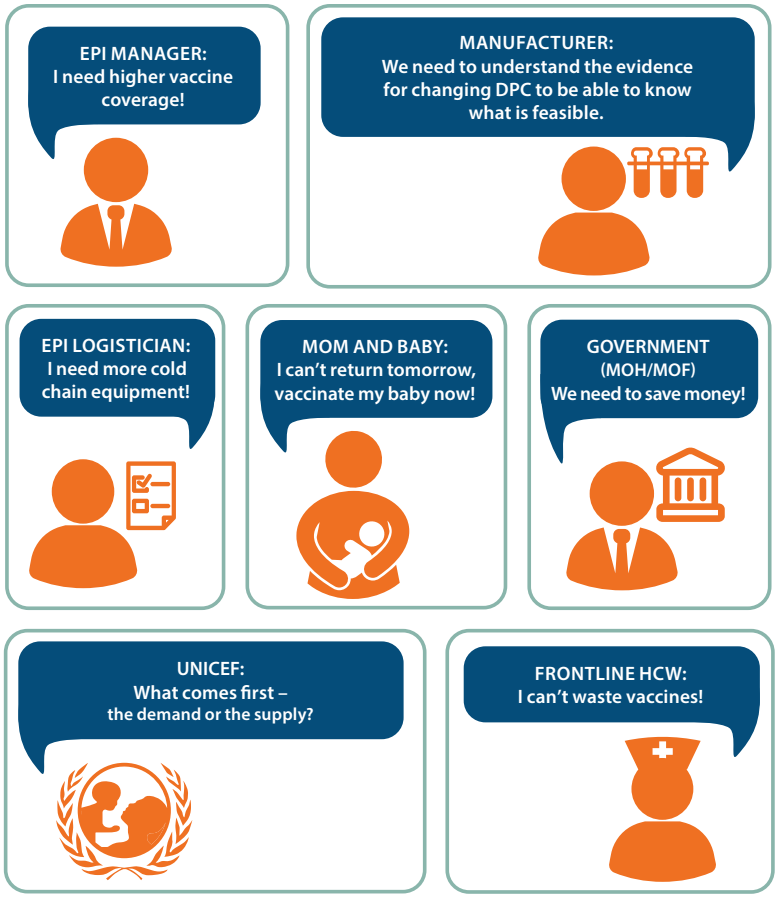


Figure 2 Immunization stakeholders may have different perspectives in relation to DPC.

BY TAKING STEP 2
You Should Be Able to

- Better understand the country context and influential factors around DPC; and
- Incorporate different perspectives from each level of the health system into considerations of the DPC choice.

Stories From the Field: The Manufacturer Perspective and Changing DPC

Different vaccine presentations may not always be available. For manufacturers, the decision to change DPC of any vaccine is based on perceived demand for a different vial presentation, costs, and feasibility related to the specific vaccine, and is often closely coordinated with procurement agencies, such as UNICEF. Changing the production line of a vaccine for a different vial size can be a lengthy process and requires a significant amount of investment and planning.

Vietnam provides an interesting case study of government-owned local manufacturers changing the DPC of two vaccines at the request of the National Expanded Programme on Immunization (NEPI) and through an extensive consultative process. In this case, the Institute of Vaccine and Medical Biologicals changed BCG (a vaccine that protects against tuberculosis) from 20-dose to 10-dose vials at the request of NEPI to reduce vaccine wastage; and Vabiotech changed the hepatitis B vaccine from 2-dose to 1-dose vials, also at the request of NEPI, since it is used only for the birth dose.

In both cases, the decision to change DPC was based on a request from NEPI to help reduce wastage of these vaccines and, in the case of hepatitis B, to decrease safety risks related to multi-dose vials. Both manufacturers noted that changing DPC presentations is a long process involving regulatory steps and takes several years to complete. The decision process included many stakeholders and considered the trade-offs from the manufacturers' perspectives in terms of ease of administration, cost per dose, and the impact on production, as well as the perspectives of the EPI and health care workers on reducing wastage and improving timely coverage.

In this case, the collaborative decision making was not surprising, given that all parties (manufacturer, purchaser, and program administrator) were at least partly controlled by the government of Vietnam. It has been more difficult to change DPC of vaccines from other manufacturers, as the demand has been unknown. An additional complication is the registration process in countries often required for different presentations.

As of 2018, measles and measles-rubella vaccines are now available in both 5-dose and 10-dose vials for countries procuring through UNICEF. A stronger feedback loop between countries, procurement agents, and manufacturers could improve the availability of preferred vaccine presentations, particularly for new vaccines under development. To this end, UNICEF's annual forecasting tool asks for DPC preference beyond what is currently available to help inform long-term planning and coordination with manufacturers.

Differing Perspectives in Country

At the country level, different stakeholders also have different perspectives. When considering changing DPC, national stakeholders often consider the impact on coverage, wastage, and cold chain requirements. However, the perspectives of health care workers and sub-national managers and the realities of managing immunization activities at the facility level are often not taken into consideration when making this decision.

As mentioned in Step 1, HCWs — in an effort to minimize wastage — are often reluctant to open a multi-dose vial, especially for vaccines without preservatives, until enough children are present at immunization sessions, and some HCWs have created workarounds, such as waiting for five or more children to arrive before opening a 10-dose vial of measles vaccine, or engaging community activists in mobilization efforts to ensure optimal attendance at an immunization session to reduce wastage. Implementing these workarounds places an extra burden on HCWs, influencing timely coverage, overall costs, and planning for the immunization program, and increasing MOVs. For vaccines without preservatives, evidence shows that HCWs' preference would be presentations with fewer DPC to aid in reducing wastage and increasing coverage. An additional factor is the MOH multi-dose vial policy (MDVP), which explains whether an opened multi-dose vial can or cannot be kept for subsequent sessions or days based on WHO criteria for that vaccine. Different perspectives lead to varying degrees of adherence to these policies.

An additional challenge is that the current planning tools are not designed to consider different DPC or multiple vial sizes within the same immunization program. UNICEF's Immunization Forecast Tool can be used to plan for a different vial size, but it falls short of incorporating HCW behavior or the impact of that vial size on coverage. WHO's Cold Chain Inventory Gap Analysis tool can be used to estimate the cold chain required for a different vial size, yet it falls short of factoring in the varied approaches to immunization session frequency and size.

Questions to Ask Stakeholders in Step 2

Below are general questions to ask of stakeholders from each level of the immunization system; additional questions are tailored to specific groups, as identified below, to help understand all perspectives.

GENERAL (FOR ALL):

- What benefits and challenges do you see with the current DPC?
- What is the current cold chain capacity at all levels, including transport? Where are the constraints, if any?
- Could a different presentation of any vaccine have an effect on coverage, timely coverage, wastage, cost, distribution of vaccines, space in the cold chain equipment, or transport?

STEP 2

- Would you prefer a different vial size of a vaccine that currently is not available?
- What policies or guidelines exist for when to open a vaccine vial? Do current practices differ from the policy?
- Do you think it would be beneficial and feasible to have multiple presentations of the same vaccine to allow for tailoring sessions in the country (i.e., both 5-dose and 10-dose vials of the measles vaccine)? What would need to change to manage that system?

NATIONAL LEVEL:

- What new vaccine introductions are planned for the next five years?
- Regarding safety, is the MDV policy followed or not, and have there been issues with AEFI at the hospital level?
- Are there different vial presentations available to consider?

SUB-NATIONAL LEVEL:

- How could distribution practices change to accommodate any constraints?

HEALTH CARE WORKERS:

- Do you have planned days when vaccination sessions (fixed, outreach, or mobile) are held each month?
- Do you give all vaccines at every vaccination session?
- Do you have enough vaccine to open a vial for every planned session?
- What do you do if a child comes for vaccination on a day when a session is not being held?
- Do you have a minimum number of children who must be present before opening a vial of certain vaccines?
- Do you have enough cold chain space for all vaccines required to meet your target coverage, including for outreach?
- Do you think a different presentation of any vaccine would affect the time health workers take to vaccinate people?

Step 3: Evaluate the Trade-offs

As discussed in Steps 1 and 2, changing the DPC will affect the immunization system components and their influence on each other. A different vial size may reduce wastage yet increase some procurement costs; it may improve timely coverage but increase constraints on supply chain capacity. Having multiple presentations of the same vaccine may allow HCWs to tailor the vial size to the immunization session size to reduce wastage and increase coverage, yet it may increase the effort to manage multiple DPC or introduce additional safety risks. All of these considerations must be weighed in the country context.

Six Key Considerations for the DPC Decision

Based on DPCP evidence, six key considerations for the DPC decision have been developed to provide insight into weighing the trade-offs and enable stakeholders to apply these considerations to their own country context. The considerations are not intended to provide definitive answers, but they can help structure and guide the decision-making process.

See also Annex 1 for a worksheet to use to apply these key considerations to your country context. The worksheet also provides references to quantitative tools that can be used to assess certain aspects of the DPC decision.

Key Consideration #1: Coverage and Session Size and Frequency

Different DPC presentations can enable closer alignment with immunization session sizes for both fixed and outreach sessions to optimize timely coverage and reduce wastage. Presentations with fewer DPC may facilitate an increase in the frequency of the scheduled sessions or facilitate opportunistic use between scheduled sessions.

Questions related to session size and frequency were posed in the HERMES computational model, with analysis conducted to tailor vial size to the district or facility level. For district-level tailoring, the model looked at distributing 5-dose MR to rural districts and 10-dose MR to urban districts, to be used by health facilities within those districts. For facility-level tailoring, 5-dose was provided to rural facilities and 10-dose to urban facilities. Additional analysis looked at using 5-dose MR at all locations. All of these options were compared with the current situation of 10-dose MR everywhere.

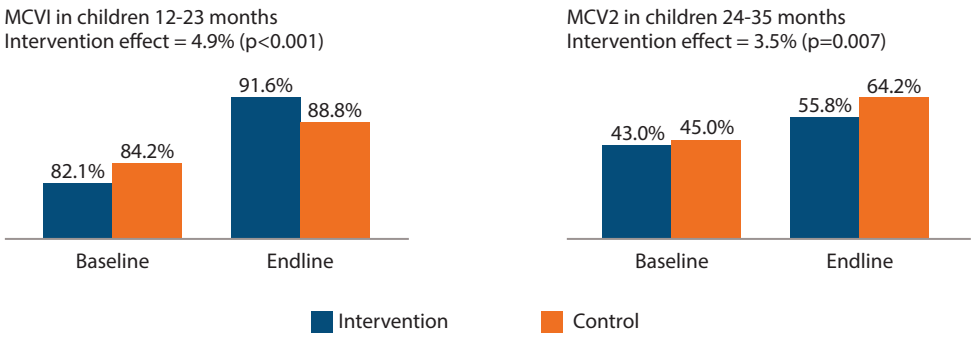
The modeling results showed that distributing 5-dose MR to all locations is the simplest method with the highest increase in vaccine availability and the largest decrease in open vial wastage, yet with some minimal constraints in transportation for vaccine distribution. Tailoring vial size to rural health facilities or by average session size can lead to an increase in total doses administered, reduction in open vial wastage, minimal impact on the cold chain, and reduction in or maintaining of costs.

BY TAKING STEP 3
You Should Be Able to

- Understand the evidence around DPC choices; and
- Apply the evidence to your country context.

DPCP Study Findings: The Positive Impact of Lower DPC on Coverage, Wastage Rates, and Supply Chain in Zambia

The results of the implementation study in Zambia show a five-percentage-point increase in the coverage of first dose of MR among children in districts using 5-dose MR vials compared to those using 10-dose vials (based on vaccination card plus caregiver recall), and a 3.5-percentage-point increase in the coverage of second dose of MR. The coverage rate results validate the HCW-reported behavior that they are more willing to open a 5-dose MR vial for any number of children. Wastage rate decreased from 31% to 16% for districts using 10-dose and 5-dose MR, respectively. Also, cold chain equipment at facilities could easily accommodate the switch to 5-dose MR with no constraints. The results of the implementation study in Zambia were inconclusive as to changes in session size and frequency, although the key informant interviews found that HCWs would prefer presentations with fewer DPC, especially for vaccines without preservatives, as HCWs believe they would be able to open a vial more frequently. When asked about having multiple vial sizes available, a majority of HCWs in Zambia felt that this would bring additional challenges and risks.



What cannot be truly captured in a model, however, is the burden on HCWs, logisticians, and managers to manage multiple presentations in an immunization system, as well as the level of effort required for a change in any presentation. Much of that decision rests on the country context and the next key consideration.

Stories From the Field

Everyone is concerned on reducing the vaccine wastage. It is a reason why mothers are sent back and asked to come a different day when there are enough children to open the vial."

— Zambian HCW referring to 10-dose MR

"Experience has been good so far. The use of MR 5-dose is helping us reach out to more children."

— Zambian HCW using 5-dose MR

Key Consideration #2: Health Care Worker Behavior

To prevent stockouts and reduce or limit wastage, health care workers may hesitate to open a multi-dose vial if fewer than half the number of doses will be used, based on the number of eligible children present at an immunization session. Vials with fewer DPC can reduce such hesitancy and enable the HCW to improve timely coverage and reduce MOVs, while also limiting wastage. This is especially true for vaccines that must be discarded at the end of an immunization session. This can make it easier to vaccinate hard-to-reach people, such as those in remote, rural, or conflict areas.

Research shows that HCWs often wait until a minimum number of children are present before opening a vial of vaccines without preservatives to reduce wastage, despite MOH guidance to vaccinate every child regardless of the number present at the vaccination session.

HCWs across all DPCP studies described workarounds, such as specific immunization days and community mobilization efforts, to increase the number of children who present at a session. This may reduce wastage but also increases the HCW's level of effort and increases MOV if vaccinations are not given to all children who present.

An additional consideration is the safety component with an inherent risk of contamination of MDVs once they are opened, and resulting AEFI may occur with the use of MDVs. However, these events could be unrecognized or underreported,

DPCP Study Findings: The Positive Impact of Lower DPC on Health Care Worker Behavior in Zambia

During DPCP's study in Zambia, key informants pointed out that facility performance is based on coverage, not wastage, but concerns about wastage clearly dominate decision making. District supervisors and HCWs both stressed the importance of limiting wastage, and the majority of HCWs said that concerns about wastage influenced their decision to open a 10-dose MR vial. Half of HCWs said that they had turned children away during outreach if there were not enough (usually at least five) to justify opening a 10-dose vial of MR vaccine.

After the introduction of 5-dose MR in 7 districts in Zambia, HCWs reported that they were more willing to open a vial for any number of children and also felt less restricted to offer the vaccine during other services, such as family planning, antenatal care, and other maternal care. Interviews with HCWs showed that 40 out of 42 who were using 5-dose vials had not turned children away during the past month, as they could open a 5-dose vial with less concern about wastage.

While the study looked specifically at MR, many HCWs indicated their preference is a vial size with fewer DPC for vaccines without preservatives to reduce wastage and ensure all people receive timely immunization. HCWs specifically mentioned BCG, stating that the BCG 20-dose vial is even more difficult to use than the MR 10-dose vial.

and the true prevalence of violations to such policies and the rates of AEFI are unknown. Under pressure of a low supply of syringes or lack of training or awareness, for example, HCWs may inadvertently introduce viral or bacterial contamination into MDVs.

The inherent risk in MDVs can be mitigated by:

- Using vaccines with preservatives;
- Adhering to the multi-dose vial policy;
- Using auto-disabled syringes;
- Providing presentations with fewer DPC; and
- Improving HCWs' safe injection practices.

A lower number of DPC can help change the behavior of health care workers, alleviating their hesitancy to open vials and boosting timely immunization coverage. An example from Zambia, in the box on page 19, illustrates this.

Key consideration #3: Cold Chain Requirements

Increases in cold chain requirements after changing to vials with fewer doses per container are often less significant than expected, especially when considering the cold chain requirements for all vaccines in the immunization schedule, as well as the reduction in wastage.

With the reduced wastage rate of 16% for 5-dose MR, the cold chain capacity needed at the facility level for the switch is an additional 4.88% of cold chain space per fully immunized child (the equivalent of 1.2 liters annually for a facility with a target population of 250), which was easily available at all facilities.

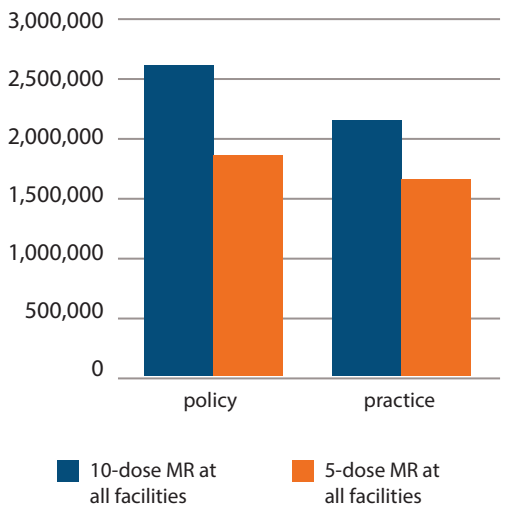
As another evidence point, the HERMES modeling results also show minimum impact on cold chain capacity when switching to 5-dose MR, and no constraints in the cold chain at the facility level. Interestingly, the model did identify constraints in the transportation system for vaccines, even with 10-dose MR, and these constraints slightly worsened when 5-dose MR was introduced into the model. However, these transportation constraints were not borne out during the implementation study; different delivery intervals and strategies may have balanced out this constraint in practice.

Key Consideration #4: Annual Forecasting Practices

When switching to a different DPC presentation for a particular vaccine, annual forecasting and monthly estimation should adjust the overall quantities based on different wastage rates, overall volume requirements, and potential changes in vaccine use associated with different DPC.

The main opportunity for countries to make decisions on DPC occurs during the annual vaccine procurement process in September, often through UNICEF Supply Division. However, to consider all trade-offs for changing DPC, the planning process should begin earlier and involve a wide variety of stakeholders.

Figure 3 MR Doses Procured Annually



Results of the HERMES modeling for Zambia show fewer MR doses are required for yearly procurement needs when shifting to 5-dose MR. This, however, must be considered in the context of whether HCWs follow the policy of opening a vial for every child or if they follow the more common practice of waiting for more children to present before opening a vial.

The goal of vaccine forecasting is to estimate the quantity of goods and financial needs necessary to conduct immunization programs. The process takes into consideration the type of vaccine, vial size, and quantity and timing of delivery, and is calculated based on target population, coverage rate expectation, expected wastage rate, cold chain availability, and — importantly and often not considered — health care worker behavior (i.e., the willingness to open a vial for every child).

The HERMES modeling compared two approaches to immunization activities:

1. The MOH policy is followed, with HCWs opening a vial for every child; and

2. HCWs open an MR vial when at least half the vial would be used, based on the number of children at the immunization session — often the practical reality.

These two different scenarios have implications for overall vaccine forecasting (see figure 3 at left).

DPCP research shows that DPC decisions often involve high-level decision makers, with little input from HCWs and little understanding of HCWs' views or practices. An inclusive decision-making process and stronger support for immunization systems could help countries achieve their programmatic targets.

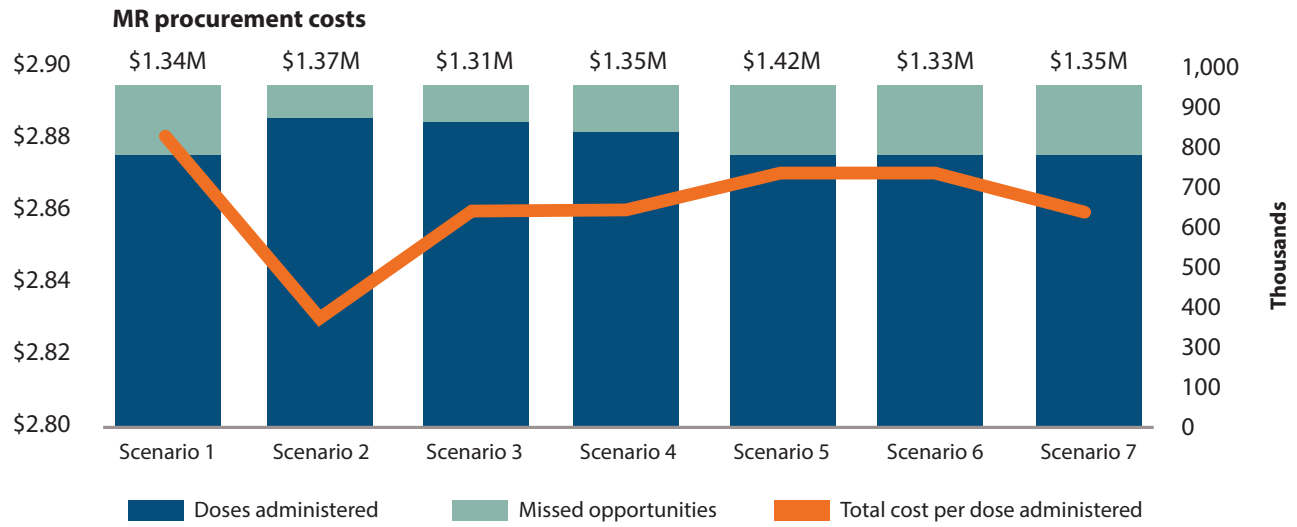
Key Consideration #5: Wastage Rate and Costs

Using vials with fewer DPC can reduce vaccine wastage. The savings from this reduced wastage can sometimes offset the higher price per dose, resulting in fewer vaccines needing to be procured. This may be particularly true for more expensive vaccines and vaccines that must be discarded at the end of a session.

A vial size presentation with fewer DPC will typically have a higher cost per dose of the vaccine, which is often a prohibitive factor when considering changing vial size. However, the cost per dose must be considered together with the impact of

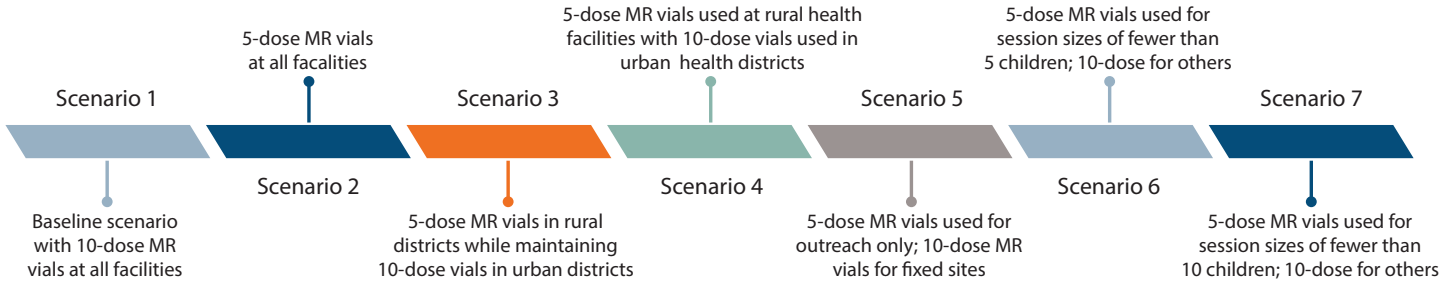
STEP 3

Figure 4 Results of the HERMES modeling analysis for seven scenarios in Zambia (see below for seven scenarios)



Results of the modeling analysis for the common practice context in Zambia of HCWs waiting until a minimum number of children arrive to administer vaccines. The total cost per dose administered of all vaccines is tracked against the number of MR doses administered and missed opportunities. The cost of MR vaccines procured (provided across the top of the chart) must be weighed against fewer missed opportunities and doses administered.

Figure 5 The seven scenarios included in the model



the different vial size on the other system components.

As previously mentioned, the wastage rate in the Zambia study decreased with 5-dose MR vials. This has implications for the amount of vaccines needed through procurement.

The modeling for Zambia showed, however, that the higher purchase cost for the 5-dose vial was not completely offset by lower wastage. With the model that reflects the common practice of waiting until more children are present to open a vial, with 10-dose vials at all facilities, 2.14 million MR doses are needed for a year of routine service delivery; with 5-dose vials everywhere, only 1.67 million doses are needed, yet these cost $32,890 (USD) more (2.45% more) than the 10-dose scenario — although this also reflects more doses administered and fewer missed opportunities to vaccinate.

The DPCP research in Senegal and Vietnam analyzed the break-even point of a different vial size presentation for different vaccines. Read the box on the left for a summary of findings.

DPCP Study Findings: Lowering DPC Saves Costs Due to Reduced Wastage... Up to a Point

Generally, for more expensive vaccines, there is a higher likelihood that when switching to a presentation with fewer DPC, a reduction in costs due to reduced wastage would outweigh the increase in costs due to the higher price per dose. But there is a threshold: with very cheap vaccines (like BCG), fewer DPC will cost more, therefore it would not be worth switching.

For example, for MR vaccine in Vietnam, if a lower DPC costing $0.78 per dose could result in a reduction in the wastage rate from 39 percent to 25 percent, then the value of vaccines used at the average facility would remain the same as the current value. Naturally, less reduction in cost is seen for less expensive vaccines.

In Senegal, if the average health facility were to switch to a 10-dose BCG vial with a cost per dose of $0.10, the value of vaccines used would increase even if wastage rates fell by as much as 20 percent, compared to current use of 20-dose vials. For BCG, because the vaccine is so inexpensive, the savings from the reduction in wastage with a presentation with fewer DPC would not outweigh the increase in procurement costs due to the higher price per dose.

Key Consideration #6: Trade-offs of All Components

When selecting a vaccine product presentation, decision makers must weigh trade-offs, which may include impact on high and timely coverage, equity, safety, wastage, supply chain capacity, costs (of the vaccines as well as logistics and service delivery costs), and health care worker behavior.

When considering changing DPC, the most notable decision drivers for high-level decision makers are coverage rates and

costs, with the ultimate goal of preventing disease. The higher price of a smaller vial size, though, should not deter stakeholders from considering a different DPC, as there may be other advantages.

A smaller DPC may relieve the burden on the HCW of deciding between a lower wastage rate or immunizing a child; as noted, more HCW willingness to open a vial can have a positive impact on coverage rates, timely coverage, and ultimately disease prevention. It may also increase access to vaccines for vulnerable populations that require special strategies to reach. Lower wastage rates can also lead to reducing the overall vaccine need (although this may not translate into savings of procurement costs).

When HCWs are clear on the policy to open a vial and are more willing to open vials for any number of children at an immunization session, this, in turn, has implications for national-level forecasting and sub-national-level needs estimation. Facility-level needs estimation would need to be adjusted to reflect the change and the willingness of HCWs to open vials with fewer DPC.

Figure 6 on page 25 visually summarizes the results of the HERMES modeling and provides a framework to weigh the trade-offs of the system components among the scenarios that were modeled. The components are ranked based on the percentage differences compared to the baseline scenario (Scenario 1) of 10-dose MR vial everywhere for each of the components. The size of the dot represents the degree of the impact compared to all scenarios. Blue represents a positive impact; orange represents a negative impact. The results of the modeling are the basis for the first four components in the figure (coverage, wastage, logistics cost per dose, and supply chain). The final two components — HCW behavior and safety — are more subjective.

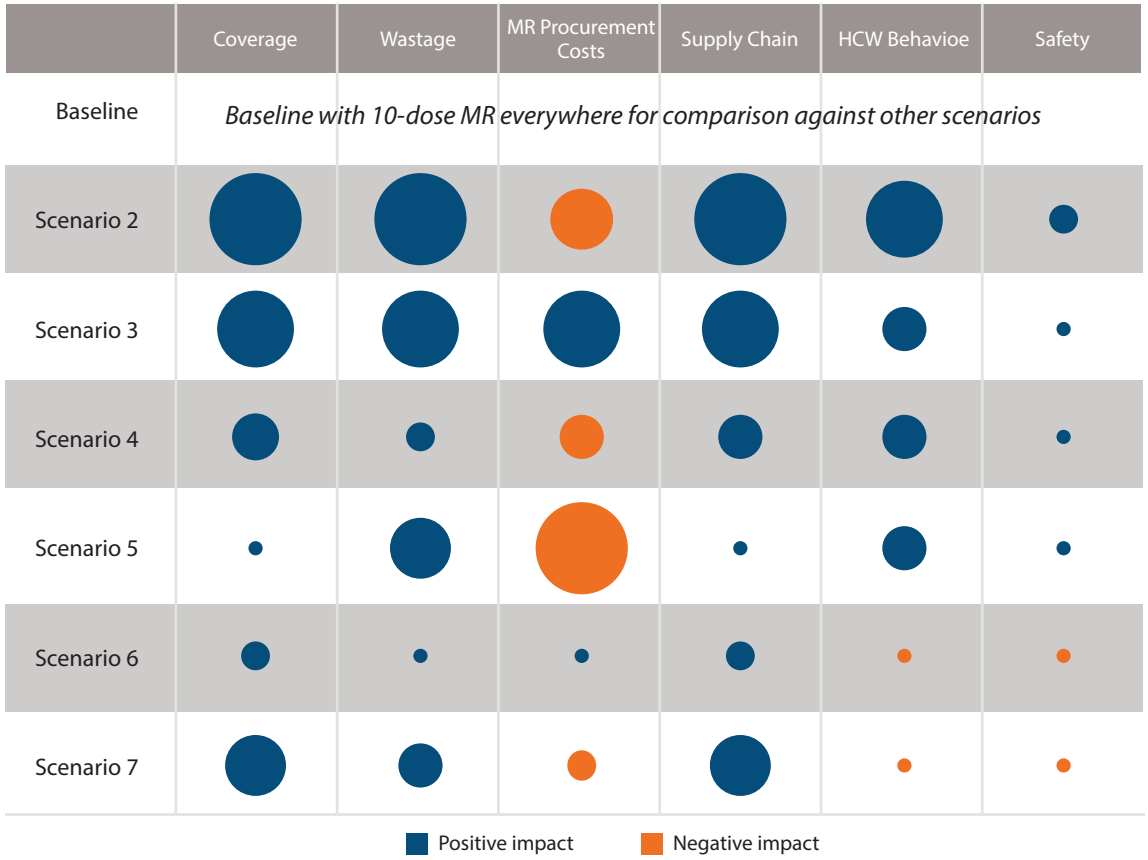
For the assumptions around HCW behavior, there is a positive impact for a presentation with fewer DPC, assuming HCWs will be more willing to open a vial. However, there

DPCP Study Findings: Anecdotal Evidence That AEFI and Unsafe Immunization Practices Were Minimal

In DPCP's studies in Vietnam, Senegal, and Zambia, only a small number of respondents at health facilities mentioned having witnessed AEFI over the last year.

Similarly, during observation of immunization sessions in Senegal to check for safe vaccine management and injection practices, immunization teams largely complied with safe practices; however, the research team noted 14 safety exceptions out of 752 observed injections, including reusing reconstitution syringes, depositing used syringes in the safety box only at the end of the session instead of immediately after use, and not keeping vaccine vials that were being used during the session in cold boxes or refrigerators.

Figure 6 Positive/negative impact map based on results of the HERMES modeling to provide a framework for considering trade-offs



Note: Scenarios are ranked in ascending order based on percent differences compared to baseline. The size of impact is not reflective of the actual percentage difference between the scenario and baseline. The size of impact is based on how a scenario ranks compared to all scenarios.

is a negative impact when both 5-dose and 10-dose vials are available at the facility level, as this still places the burden on the HCW to decide whether to open a vial or not; it also introduces a complexity into managing the supply chain (noted by the red dot for Scenarios 6 and 7). In some situations, this option may be the best choice and may simply require good management practices to mitigate the risks.

For the safety component, there is an inherent risk of contamination of multi-dose vials, although many can be mitigated by HCW behavior (highlighted in the box to the side). As such, there is a positive impact when vials with fewer DPC are included in the model (i.e., a reduced safety risk); yet there is a negative impact when both 5-dose and 10-dose vials are available at the facility level, as there is an assumption of a higher risk of confusing the two vials. Again, these risks can be mitigated through training, supervision, and good management practices.

Questions to Ask Stakeholders in Step 3

- How does this evidence apply to your country context?
- Is there a difference between policy and practice regarding MDV policy, supply distribution plans, session frequency, etc.?
- How does the realistic practice of the immunization program at the facility level affect national-level program planning?
- Are there regional or sub-national differences of the immunization program that must be considered for this decision?
- How do these considerations support your country's priorities for your immunization program as identified in Step 1?
- What vaccine are you considering for different DPC?
- Are different vial presentations available for vaccines in your schedule?
- What aspects of these considerations can be quantified (cold chain capacity, procurement costs with assumed different wastage rates, etc.) using existing tools?
- What does the quantitative analysis indicate in terms of cold chain capacity needed with any DPC change? And for vaccine need and procurement costs? What insight does your qualitative analysis provide for these trade-offs?
- What is your final preference or decision regarding DPC for this vaccine?
- What is the best way to communicate this preference to other stakeholders for support (i.e., ICC, NITAG, Ministry of Finance, etc.)?

Step 4: Ensure the Right Implementation Arrangements

Decision makers must consider the delivery system context to understand where the challenges are and where a different DPC or multiple DPC options may provide the most benefit. This entails considering the difference between policy and practice; rural and urban areas and associated challenges; and even how vaccines are delivered, if mostly through routine immunization, outreach, or campaigns.

Planning for any change must include budgeting for training on the DPC change and any potential implications on activities with the change, such as reduced wastage or more frequent immunization sessions. WHO and UNICEF have developed many resources for new vaccine introduction for planning and implementing that change. Many of the same principles for the decision making and for best approaches to implementation can be applied to DPC.

DPCP has documented a change of DPC in Ghana with yellow fever and pentavalent, and in Zambia through the implementation study with 5-dose MR vaccine, as well as switching from 2-dose to 4-dose pneumococcal conjugate vaccine (PCV). Through implementing these changes, both Ministries of Health identified key learnings that can help ensure a successful transition with minimum disruption (of course, these key learnings and any DPC choice must be considered in broader planning for the immunization program):

Develop a Strong and Clear Communication Strategy

A strong and clear communication strategy is important to ensure a clear understanding of the rationale for the switch and the impact on standard operating procedures at all levels of the health system. The changes in DPC in Ghana and Zambia were communicated through various EPI and immunization system meetings, letters and email, and cascade training. People reported they felt well informed of the change in presentation.

Implement Effective Cascade Training

The Ghana MOH implemented a cascade training program that was reportedly very successful, using prepared training documents adapted to each level of the immunization system and building on other ongoing trainings and meetings to find cost savings. Another success factor was implementing the training closely timed with the arrival and distribution of the new vaccine presentation.

The Zambia MOH emphasized the need for refresher training for all HCWs before switching DPC. This could be combined with other trainings, such as for a new vaccine introduction, and ongoing supportive supervision.

BY TAKING STEP 4
You Should Be Able to

- Apply lessons learned about DPC from other countries to your country context for any DPC.

Clarify the Policy on Number of Children Required to Open a Vial, Considering the Realistic Context of Current Practices and Workarounds

Health care workers have created coping strategies with multi-dose vials to help reduce wastage, particularly for vaccines without preservatives that must be discarded at the end of a session. It is unclear what these coping strategies add in terms of level of effort for an already overburdened HCW or how they may impact MOVs. The policy on the number of children required to open a vaccine vial should be very clearly explained to health workers and should be reflected in stock available.

In Ghana, despite efforts cited at the national level to normalize higher wastage rates to ensure high coverage rates, there was a pervasive sense from HCWs at health facilities that wastage was still something that was judged negatively and seen as HCWs' responsibility to minimize. Zambian HCWs also said that although coverage was a more important performance measurement than wastage, they frequently discussed strategies for minimizing wastage with their supervisors and colleagues.

Clarify Best Practices for Vaccine Handling

Changing DPC provides an opportunity to reinforce best practices for safe vaccine handling, particularly for multi-dose vials. MDVs that do not contain a preservative have the potential for bacterial or viral contamination if proper storage and handling procedures are not followed. Although the frequency of improper vaccine handling practices has not been studied thoroughly, anecdotal evidence implies it occurs. This safety risk can be mitigated by improving HCW knowledge, understanding, and adherence to the MDV policy and best practices.

Strengthen Supply Chain

Improving supply chain performance to reduce stockouts could alleviate an HCW's concern about opening a vial for fear of running out of a vaccine. This would need to be tied to better forecasting at the national and sub-national levels, and using more accurate wastage rates based on reality and more accurate session size and frequency information.

Additionally, different vaccine distribution strategies can be considered to address DPC changes, such as different vaccine delivery frequencies to accommodate for cold chain constraints or shifting responsibilities for vaccine distribution levels of the health care system that have greater capacity (human,

Resources for Planning the DPC change:

- WHO: Principles and considerations for adding a vaccine to a national immunization programme
- PAHO: Introduction and Implementation of New Vaccines Field Guide

cold chain, transportation resources, etc.) to manage the change. Additional information should be gathered around missed opportunities, as well as vaccine management and distribution practices, to better determine vaccine quantities required at service delivery points.

Questions to Ask Stakeholders in Step 4

- What is the timeline for the new vaccine introduction or the change in DPC?
- If considering multiple presentations of the same vaccine, what are special considerations for implementation?
- What funding is available to roll out the new vaccine or change in DPC?
- What trainings are scheduled for the upcoming year that could be combined with distributing information on DPC switch?
- What other established processes could be used to ensure a successful implementation of DPC change (i.e., microplanning, outreach activities, annual planning, etc.)?
- What supply chain gaps need to be addressed to ensure full availability of vaccines? How will these be addressed?
- If your priority is to reduce the burden on HCWs related to workarounds and deciding to open a vial or not, how will you communicate this to HCWs and its relation to the policy to open a vial or not?
- What can be improved to better assess AEFI and improve HCW adherence to safe practices?
- Who will develop a communications strategy for the change?

Step 5: Monitor Progress

According to WHO's "Training for mid-level managers," monitoring is the systematic and continuous process of examining data, procedures, and practices. It is used to measure progress, identify problems, develop solutions, and guide policies and interventions. Monitoring can help improve the quality of the immunization program by ensuring:

- All children, young people, and pregnant women are immunized.
- Vaccines and safe injection equipment are available in correct quantities and on time.
- Staff are well trained and adequately supervised.
- Information on disease incidence and AEFIs are collected and analyzed.
- The community has confidence in the vaccines delivered and the immunization services they receive.

In the DPC context, it is important to monitor and document any changes to key indicators after a switch in vial presentation to update forecasting and supply planning and to clarify practices related to multi-dose vial policy. This can involve regular review of sub-national data to look at coverage trends, drop-out rates, and wastage rates following the switch and should be done within the overall health planning process and assessments. Supply chain indicators should be monitored to track availability of vaccines related to cold chain and transport capacity and to track any change in distribution practices to respond to emergency stockouts.

The annual forecast and procurement plan provided to UNICEF can also be updated during the year to reflect more accurate wastage rates and expected coverage based on the DPC switch; this update should also then be applied at the sub-national level for more accurate vaccine distribution.

Knowledge, attitudes, and practices (KAP) studies or other research can provide additional insight into the effects of the switch on all system components.

Questions to Ask Stakeholders in Step 5

- Since changing DPC, have you seen any changes in coverage, timely coverage, wastage, cost, distribution of vaccines, space in the cold chain equipment, or transport?
- Have you tracked adherence to the multi-dose vial policy and HCW safety practices? Have there been any changes? Do these policies need to be reinforced through additional training or dissemination?
- Six months after annual forecasting and procurement, are there any updates to make to your order with your supplier based on different wastage rates, consumption, or coverage expectations?

BY TAKING STEP 5
You Should Be Able to

- Effectively monitor performance of your immunization program and assess any changes related to DPC.

Annex 1: Worksheet for Dose Per Container Decision Making

Qualitative Assessment

The EPI manager can initiate this discussion or can delegate the responsibility to someone to start collecting the information and opinions required for a DPC decision. Complete this worksheet with perspectives, preferences, and the country context from the discussions with stakeholders around each of the steps, using the questions on the following pages as guidance:

Step 1: Identify the immunization system context and goals

- What are the priorities of the immunization program based on the current context?
- Who are the key stakeholders who should be involved in the decision?

Step 2: Consider different perspectives

- What are the country context and influential factors around DPC?
- Describe the different perspectives from each level of the immunization system on considerations of the DPC choice.

Step 3: Evaluate the trade-offs

- What was surprising about the evidence around DPC?
- How does the evidence apply to your country context?

Step 4: Ensure the right implementation arrangements

- How will you apply lessons learned about DPC from other countries to your country context for any DPC choice?

Step 5: Monitor progress

- How will you incorporate DPC considerations into the ongoing monitoring of your immunization program and assess any changes related to DPC?

Use these questions to facilitate discussions among stakeholders and partners around the DPC decision. Complete the worksheet on the previous page with a high-level summary of perspectives, preferences, and the country context.

Step 1: Identify the Immunization System Context and Goals

- What are the goals for your immunization program and the different antigens?
- Does the country have plans for any new vaccine introductions that need to be considered for long-term planning? How will that impact a change on DPC?
- What challenges do you face to reach these goals?
- What do recent assessments and planning (Joint Appraisals, EPI Review, EVMA, cMYP, etc.) indicate as priority areas for your immunization program?
- Beyond the immunization program leaders, who else needs to be involved in the decision around DPC (Ministry of Finance, civil society, sub-national stakeholders, ICC, etc.)
- Are stakeholders interested in considering a different DPC and assessing trade-offs among system components?

Step 2: Consider Different Perspectives

Below are general questions to ask of stakeholders from each level of the health system; additional questions are tailored to a specific group, as identified below, to help understand all perspectives.

GENERAL (FOR ALL):

- What benefits and challenges do you see with the current DPC?
- What is the current cold chain capacity at all levels, including transport? Where are the constraints, if any?
- Could a different presentation of any vaccine have an effect on coverage, timely coverage, wastage, cost, distribution of vaccines, space in the cold chain equipment, or transport?
- Would you prefer a different vial size of a vaccine that currently is not available?
- What policies or guidelines exist for when to open a vaccine vial? Do current practices differ from the policy?
- Do you think it would be beneficial and feasible to have multiple presentations of the same vaccine in order to tailor sessions within the country (i.e., both 5-dose and 10-dose vials of the measles vaccine)? What would need to change to manage that system?

NATIONAL LEVEL:

- What new vaccine introductions are planned for the next five years?
- Regarding safety, is the MDV policy followed or not, and have there been issues with AEFI at the hospital level?

- Are there different vial presentations available to consider?

SUB-NATIONAL LEVEL:

- How could distribution practices change to accommodate any constraints?

HCW:

- Do you have planned days on which vaccination sessions (fixed, outreach, or mobile) are held each month)?
- Do you give all vaccines at every vaccination session?
- Do you have enough vaccine to open a vial for every planned session?
- What do you do if a child comes for vaccination on a day that a session is not being held?
- Do you have a minimum number of children who must be present before opening a vial of certain vaccines?
- Do you have enough cold chain space for all vaccines required to meet your target coverage, including for outreach?
- Do you think a different presentation of any vaccine would affect the time health workers take to vaccinate people? Please explain.

Step 3: Evaluate the Trade-offs

- How does this evidence apply to your country context?
- Is there a difference between policy and practice regarding MDV policy, supply distribution plans, session frequency, etc.?
- How does the realistic practice of the immunization program at the facility level affect national-level program planning?
- Are there regional or sub-national differences of the immunization program that must be considered for this decision?
- How do these considerations support your country's priorities for your immunization program as identified in Step 1?
- What vaccine are you considering for different DPC?
- Are different vial presentations available for vaccines in your schedule?
- What aspects of these considerations can be quantified (cold chain capacity, procurement costs with assumed different wastage rates, etc.) using existing tools?
- What does the quantitative analysis indicate in terms of cold chain capacity need with any DPC change? And for vaccine need and procurement costs? What insight does your qualitative analysis provide for these trade-offs?
- What is your final preference or decision regarding DPC for this vaccine?
- What is the best way to communicate this preference to other stakeholders for support (i.e., ICC, NITAG, Ministry of Finance, etc.)?

Step 4: Ensure the Right Implementation Arrangements

- What is the timeline for the new vaccine introduction or the change in DPC?
- If considering multiple presentations of the same vaccine, what are special considerations for implementation?
- What funding is available to roll out the new vaccine or change in DPC?
- What trainings are scheduled for the upcoming year that could be combined with distributing information on DPC switch?
- What other established processes could be used to ensure a successful implementation of DPC change (i.e., microplanning, outreach activities, annual planning, etc.)?
- What supply chain gaps need to be addressed to ensure full availability of vaccines? How will these be addressed?
- If your priority is to reduce the burden on HCWs related to workarounds and deciding to open a vial or not, how will you communicate this to HCWs and its relation to multi-dose vial policy?
- What can be improved to better assess AEFI and improve HCW adherence to safe practices?
- Who will develop a communications strategy for the change?

Step 5: Monitor Progress

- Since changing DPC, have you seen any changes in coverage, timely coverage, wastage, cost, distribution of vaccines, space in the cold chain equipment, or transport?
- Have you tracked adherence to the multi-dose vial policy and HCW safety practices? Have there been any changes? Do these policies need to be reinforced through additional training or dissemination?
- Six months after annual forecasting and procurement, are there any updates to make in your order with your supplier based on different wastage rates, consumption, or coverage expectations?

Quantitative Assessment

A high-level quantitative assessment can be done using some UNICEF or WHO tools, although the tools fall short of being able to weigh the trade-offs and impact of DPC change across all system components and determine how they relate to and influence each other. The tools also cannot assess the impact of multiple DPC for the same vaccine — for example, targeting 5-dose measles vials for rural facilities and 10-dose measles vials for urban facilities. However, they can provide some quantitative insight that must be considered together with the qualitative assessment.

All tools assessed by DPCP are shown in the table on page 36. Of these, a few can be used to partially understand the DPC choice:

- EPI Logistics Forecasting Tool
- Immunization Supply Chain Sizing Tool
- Vaccine Volume Calculator
- Vaccine Presentation Assessment Tool
- Cold Chain Equipment Total Cost of Ownership Tool

ANNEX 1

Tools Inventoried for the DPC Decision

	Tools	Description
1	Cold Chain Equipment Inventory and Gap Analysis Tool (Inventory Tool)	Analyzes existing cold chain equipment and gaps at service delivery points, district and provincial stores.
2	Expanded Program on Immunization (EPI) Logistics Forecasting Tool (Forecasting Tool)	Forecasts needs for vaccines, safe injection equipment, cold chain, and ambient storage capacities.
3	Immunization Supply Chain Sizing Tool (Sizing Tool)	Estimates required cold chain capacity at each level while planning for expected significant EPI changes.
4	Vaccine Volume Calculator (VVC)	Estimates net storage volume required and wastage expected per fully immunized child; can test the effect of new vaccine introductions.
5	District Vaccination Data Management Tool (DVD-MT)	Facilitates data processing from district vaccination monthly reports to summarize vaccine coverage rates.
6	Comprehensive Multi-Year Plan (cMYP)	Estimates costs, resource requirements, and financing needs for EPI; analyzes corresponding financing gaps.
7	Vaccine Forecasting and Cold Chain Tool	Uses country forecast with manufacturing availability and timing to determine shipment schedules, timing, and required funding.
8	Cold Chain Weight and Volume Calculator (CC W&V)	Determines shipping volume for in-country deliveries and cold chain storage.
9	Vaccine Presentation Assessment Tool (VPAT)	Models logistical and financial impact of adding a new vaccine to an immunization schedule.
10	Cold Chain Equipment (CCE) Total Cost of Ownership (TCO) Tool	Evaluates CCE and operating costs to budget and plan for new CCE across models and technologies.

Annex 2: DPCP Research and Key Findings

Snapshot Countries: Overview of DPCP Research

	Type of research	Stakeholders interviewed	Considerations in DPC decisions: Procurement Considerations in DPC decisions: Program	Stakeholders consulted in DPC decisions
Ghana	Retrospective mixed-method documentation of DPC changes for yellow fever and pentavalent	13 entities, including national-level MOH Health Services; MOH Procurement and Supply Unit; EPI team; focal points from UNICEF, WHO, and Gavi; sub-national managers; and HCWs	Global supply, per-dose price, cold chain N/A	MOH, EPI, UNICEF, Gavi, WHO
Philippines	Key informant interviews	One national manager and one WHO focal point	Supply (local and international, cost analysis, manufacturer costs) Views of stakeholders, HCW feedback on multidose vials	National and logistics, donors, HCW organizations; HCW feedback on DPC changes
Senegal	Formative mixed-method research on DPC trade-offs, cost analysis, and HCWs knowledge and preferences	69 immunization staff: 1 coordinator at the national level, 2 regional focal points for EPI and disease surveillance, 6 district-level EPI managers and logisticians, and 60 health facility staff	Program needs, costs, cold chain HCWs knowledge, preference, and behavior	EPI
Three-Country Francophone (Benin, Côte d'Ivoire, Democratic Republic of Congo)	Mixed-method study on the process of DPC decisions	13 officials in regulation and procurement, including Immunization Focal Point at WHO, Supply Officer at UNICEF and others, and 20 frontline HCWs	Global supply; donors strongly influence decisions N/A	EPI, NITAG, UNICEF, WHO
Vietnam	Formative mixed-method research on DPC trade-offs, costs, and HCWs' knowledge and preferences	One national manager, 2 regional focal persons, 4 provincial managers, 7 district managers, 30 frontline HCWs, 3 manufacturers	Program needs, costs, cold chain HCWs' knowledge, preference, and behavior	N/A
Zambia (baseline)	Household coverage survey, key informant interviews, routine immunization observation, administrative data review, costing survey	28 district managers, 32 frontline HCWs	Program needs, costs, cold chain HCW concern of wastage when opening a vial and decisions on managing 10-dose presentation	N/A
Zambia (midline)	Qualitative research	4 district managers, 4 district pharmacists, 16 frontline HCWs	N/A HCW willingness to open 5-dose MR vial for every child	N/A
Zambia (endline)	Household coverage survey, key informant interviews, routine immunization observation, administrative data review, costing survey	6 national level, 7 district managers, 42 frontline HCWs	Program needs, costs, cold chain; views of stakeholders, HCW concern of wastage when opening a vial and decisions on managing 5-dose presentation	MOH, EPI, NITAG, ICC, UNICEF, WHO
Tools' assessment	Assessment of 10 commonly used tools for relevance to decisions on DPC	3 countries and 4 individuals	Examination of each tools effectiveness in predicting DPC-related changes to immunization system N/A	N/A
HERMES computer simulation modeling	Computer model comparing impact of 5-dose and 10-dose MR on the Zambian supply chain	Data collected included health facilities, target population, supply chain costs, cold chain equipment, transport modes, HCW behavior related to DPC	N/A HCW behavior related to DPC; tailoring DPC to session size, rural/urban	HCW

Ghana: Retrospective mixed-method documentation of DPC changes for yellow fever and pentavalent

FINDINGS

- Decisions are based on what products are available on the global market and on easily quantifiable factors, such as cold chain capacity and per-dose purchase price. Decision makers prefer options that reduce cold chain storage requirements.
- Stakeholders at the highest levels generally make decisions on DPC with little input from those working at lower levels, such as frontline HCWs.
- National- and facility-level stakeholders have different perceptions of how well the immunization system might manage multiple DPC presentations of the same vaccine.

Tools assessment: Assessment of 10 commonly used tools for relevance to decisions on DPC

FINDINGS

- Users reported that populating the tools required significant effort and generally required technical support.
- No tool addressed DPC considerations comprehensively or the impacts of changing DPC across the immunization system; however, users also stressed the importance of not adding new tools.
- Three of the tools assessed could be adapted to examine the effect of DPC changes on some system elements. However, no individual tool could weigh these trade-offs across the whole immunization system.

Three-country Francophone: Mixed-method study on the process of DPC decisions

FINDINGS

- Decisions on changes in vaccine presentations are heavily influenced by market availability and procurement agencies, with limited input from the MOH or other country-level actors.
- Procedures for deciding on changes in DPC are insufficiently defined, and in-country program leaders lack the information and evidence they need to examine these changes comprehensively.
- Actors across all three countries had similar views of the potential advantages of a change to a lower-DPC presentation: decreased wastage and increased coverage (weighed against the potential disadvantages of increased management complexity and cold chain capacity requirements).

Senegal: Formative mixed-method research on DPC trade-offs, cost analysis, and HCW knowledge and preferences

FINDINGS

- HCWs and managers took DPC into account when planning and implementing the immunization program, and HCWs employed a range of workaround strategies with multi-dose presentations to reduce wastage and increase coverage.
- High DPC vaccines — such as 5, 10, or 20 doses that could be kept for up to 28 days after opening — had similar wastage rates to single-dose presentations in countries that use the multi-dose vial policy; thus, higher DPC does not necessarily translate to more wastage, possibly due to the workarounds.
- Reducing DPC of more expensive vaccines may reduce overall costs. An economic analysis of three multi-dose vaccines with six-hour viability after opening showed that for two vaccines, switching to a lower DPC may not yield economic benefits because savings from reduced wastage may not outweigh the higher price per dose.

Vietnam: Formative mixed-method research on DPC trade-offs, costs, and HCW knowledge and preferences

FINDINGS

- Except for a few regional variations, HCWs adhere to the national policy of opening a vial for every child, as immunization sessions are often held only monthly; this is coupled with many mobilization strategies to ensure coverage targets are reached, yet wastage is still high, especially in higher-dose presentations.
- Respondents at all levels of the immunization program expressed a preference for lower-dose presentations to reduce wastage. However, DPCP's cost analysis suggested that such changes would only be cost effective for higher-priced vaccines — pentavalent, Japanese encephalitis (JE), and MR.
- In the past, domestic government manufacturers in Vietnam have changed DPC in response to a request by the national immunization program and through a consultative process considering program needs, cost, and cold chain constraints.

Zambia baseline: Household coverage survey, key informant interviews, routine immunization observation, administrative data review, costing survey

BASELINE FINDINGS

- 62% of children in the baseline coverage survey had received their first measles vaccination, and only 29% had received their second. Fewer than half had received either of their doses on time.
- HCWs reported frequently turning children away rather than waste vaccine from the 10-dose vial, despite MOH guidance to vaccinate every child regardless of the number present at the vaccination session.
- HCWs reported that they would favor lower-dose vials to prevent children from being turned away.

Zambia midline: Qualitative research

FINDINGS

- When comparing a 10-dose vial to a 5-dose vial at midline, district staff and HCWs felt that the 5-dose vial could help to reduce missed opportunities, as they would be more likely to open the vial when only a few eligible children were present.
- Many HCWs at midline said that the 5-dose vial increased efficiency by reducing time spent waiting for the minimum number of children to arrive, giving them time to attend to other duties; but some said that reconstituting and transporting the lower-dose vials presented challenges.
- Some HCWs at midline reported that they are now vaccinating daily with the lower-dose presentation, while others retained scheduled vaccination sessions.

ANNEX 2

Zambia endline: Household coverage survey, key informant interviews, routine immunization observation, administrative data review, costing survey

FINDINGS

- Wastage rates are much lower in HFs using 5-dose vials than in those using 10-dose vials (16% compared to 31%).
- Most respondents using 5-dose vials believed wastage had reduced through the use of the 5-dose vial.
- All except one respondent using the 5-dose vial reported opening vials regardless of the number of children at a session.
- Coverage of first dose of MR with 5-dose MR vials saw a five-percentage-point increase compared to those using 10-dose vials; coverage of second dose of MR saw a 3.5-percentage-point increase.

Zambia modeling: HERMES computer simulation modeling of the Zambian immunization supply chain and change to MR 5-dose container

FINDINGS

- Tailoring 5-dose vials to be used only at rural health facilities or for session sizes with fewer than an expected five or 10 children is the most beneficial in terms of providing a balance between reducing MR wastage, improving availability of MR at the health facility from a supply chain perspective, and slightly improving availability of all vaccines by reducing cold chain equipment utilization.
- Shifting to 5-dose MR vials can increase the number of MR doses administered (as a proxy of coverage), especially in the context of HCWs waiting to open a vial. While this shift marginally increases the constraint of cold chain requirements during transport, there was minimal impact on cold chain space at the district and facility level. This transport constraint could be mitigated by different approaches, such as altering delivery intervals or transport routes, or using different vaccine carriers.
- Shifting to 5-dose MR vials requires procuring fewer MR doses and introduces cost savings for vaccine procurement in the policy-following context, in which HCWs open a vial for every child.
- Replacing 10-dose MR with 5-dose MR at all health facilities led to the largest reduction in open vial wastage, particularly when HCWs follow the policy to open a vial for every child compared to when they wait until more children are present.

Annex 3: Resources and References

Zambia Endline report

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Note: *A list of the full literature review from Phase 1 can be found in the annex of the report from the stakeholder meeting in 2015.*

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