



DPCP SNAPSHOT

FINDINGS IN DECIDING DPC

Providing vaccines in multidose presentations entails balancing trade-offs among timely coverage, wastage, safety, costs per dose, supply chain, and healthcare worker (HCW) behavior, weighing the advantages and disadvantages of lower versus higher dose per container (DPC). Beginning in 2016, the Dose Per Container Partnership (DPCP) conducted a series of activities to document how governments make decisions about DPC for vaccines in their national programs and to document these DPC trade-offs at different levels of the health system—national, province, district, health facility, and community/outreach (see **Table 1**). The results of the research in eight countries are summarized in a series of case studies, or “snapshots,” that provide a broad picture of common elements, gaps in evidence, and examples of good practices that can inform future research and program guidance related to DPC. The results of the studies suggested several findings:

- Decisions about DPC consider numerous factors, including global vaccine availability, per-dose price, and cold chain requirements. Even with an increased focus on coverage and equity, these two are rarely considered in DPC decisions. In many countries, input from government officials and service delivery partners is limited; donor decisions or market availability dominate decision-making.
- The decision-making process is generally top down and driven by supply, with little input from sub-national decision-makers or from frontline HCWs, and little understanding of HCWs’ views or practices.
- Recognition that different products may have different benefits in different delivery strategies (urban/rural or mobile/outreach/fixed site) or different communities (such as the displaced, mobile, urban poor, and ethnic minorities) is often absent.
- Use of tools and quantification techniques for considering different DPC is limited in most settings, and poor data quality limits the country’s ability to plan or evaluate the effects of DPC decisions.
- Both sub-national managers and frontline HCWs may favor lower-dose presentations to reduce wastage, but the relationship between DPC and wastage is not straightforward.
- The main opportunity for countries to order or make decisions about DPC occurs during the annual vaccine ordering process, often

DPCP: EXAMINING THE EFFECTS OF MULTIDOSE VACCINE PRESENTATIONS

The widespread use of multidose vaccine containers in low- and middle-income countries’ immunization programs is assumed to offer benefits and efficiencies for health systems, such as reducing the purchase price per vaccine dose and easing cold chain requirements.

Yet the broader impacts on immunization coverage, costs, and safety are not well understood. It is also unclear what processes governments typically go through to determine their choices about DPC, and what information decision-makers have or use when determining DPC.

To add to the limited evidence base on this topic, the Dose Per Container Partnership, or DPCP, is undertaking a series of activities to explore current decision-making on DPC options and better understand the relationship between DPC and immunization systems, including operational costs, timely coverage, safety, product costs/wastage, and policy/correct use.

through UNICEF Supply Division (SD), when a new DPC is available and when introducing a new vaccine. It may also require new registration with national regulatory authorities.

- Changing DPC at the manufacturer level requires a long lead time to be pre-qualified or fill lines re-purposed for different size containers.

TAKEAWAY

Decisions on DPC are complex, often based on supply and previous practices more than country priorities, and entail input from a broad range of stakeholders, with little input from the sub-national level. Countries should gather and analyze additional data to better understand the trade-offs of the DPC decision on the components of the immunization system to best support full and timely coverage. An inclusive decision-making process and stronger support for immunization systems that target communities and contexts most in need of vaccines and health care could help countries achieve their programmatic targets (see **Figure 1**).

THE RESEARCH

Between 2016 and 2018, DPCP conducted research in eight countries (see **Table 1**) to investigate the factors that affect decision-making on vaccine presentations—including stakeholders consulted, tools and analytics used, system factors, HCWs’ views, and other considerations. The research was packaged into a suite of case studies

that looked at the factors that went into decision-makers’ choices on DPC. As the table shows, the research used mixed methods and varied in focus areas. Despite these variations, as a whole the findings suggest common trends and major issues affecting decisions about DPC.

THE FINDINGS

Stakeholders involved in decisions on DPC: The country-level process for program planning, decisions on DPC, and vaccine procurement generally includes staff from the Extended Program on Immunization (EPI), other units within the Ministry of Health (MOH), partners, and donors, as well as engagement or approval by the NITAG or ICC. All countries but the Philippines and Vietnam depend on donors for their vaccine supplies.

Participants in the three-country study in Benin, Côte d’Ivoire, and Democratic Republic of Congo (DRC) reported that donors strongly influence national decisions on vaccine presentation. In Vietnam, where most vaccines are locally manufactured, the EPI program is the principal stakeholder, with the Administration of Preventive Medicine, other MOH leaders, and manufacturers providing major input. In the Philippines (see **Box 1**), the stakeholder pool is wider: it includes the government, professional organizations, partners, and government staff concerned with finance, procurement, logistics, and disease prevention.

Factors affecting national decisions on DPC: National-level respondents said that when making decisions on DPC

FIGURE 1: DECISION-MAKING PROCESS FOR DPC PROGRAMMING

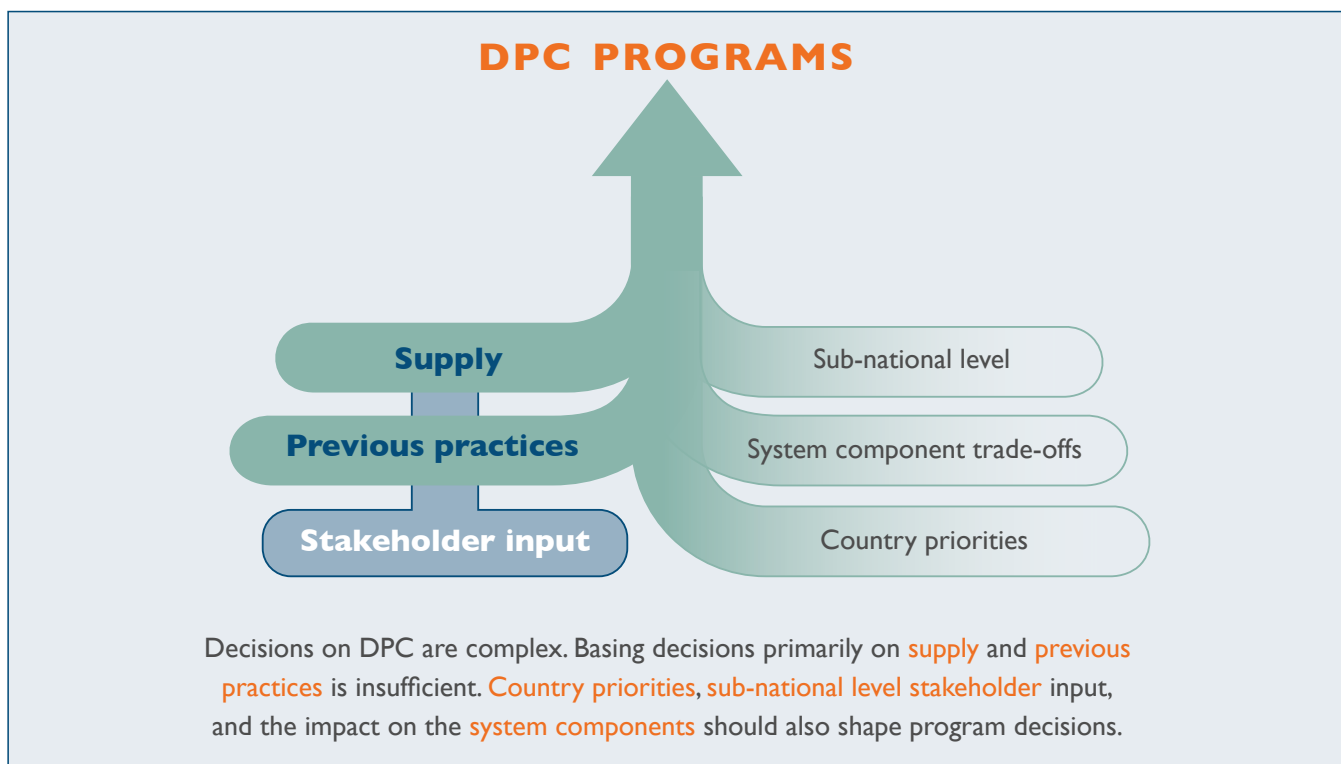


TABLE 1: SNAPSHOT COUNTRIES: OVERVIEW OF DPC RESEARCH

	Type of research	Stakeholders interviewed	Considerations in DPC decisions: Procurement	Stakeholders consulted in DPC decisions
			Considerations in DPC decisions: Program	
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 from health facilities	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	
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 N/A	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

presentation or changes, they mainly consider availability on the global market (through UNICEF SD or directly from manufacturers), costs (vaccines and supplies account for the second-highest program costs behind human resources), and cold chain requirements. Cold chain requirements are often cited as a reason not to consider smaller doses because of the assumption that they will necessitate more storage and transport means. In reality, smaller doses have minimum impact on the cold chain unless it is already constrained.

Rationale for DPC changes: Research participants said

that they see DPC changes as a way of improving the performance of the immunization program. In the three-country study, the majority of both immunization managers and decision makers in procurement and regulation believe that changing DPC could reduce wastage and improve coverage. A trend across all studies suggests that both national-level decision-makers and HCWs believe that reducing DPC (especially for lyophilized vaccines without preservatives¹) will reduce wastage.

Use of tools and analysis: Use of tools and analytical

¹ WHO's multi-dose vial policy recommendation is to discard vaccines without preservatives at the end of the session or 6 hours after opening the vial, whichever comes first.

methods to forecast program needs and identify DPC options varies widely among countries. Decision-makers in Ghana said they did not use any analysis or tools to decide on different presentations of yellow fever and pentavalent. Their decision was based on what was available in the market that required a change.

Some respondents in the Francophone countries and the Philippines reported using several tools and datasets for program decision-making and planning. However, a DPCP study of the 10 most common tools showed that no single tool would enable a comprehensive assessment of the effects of DPC changes. In some cases, limited data availability hinders quantification of major indicators, such as wastage, coverage, and stockouts. Such a basis for decision-making may highlight a potential need for a tool or increased effort to support countries to make DPC decisions.

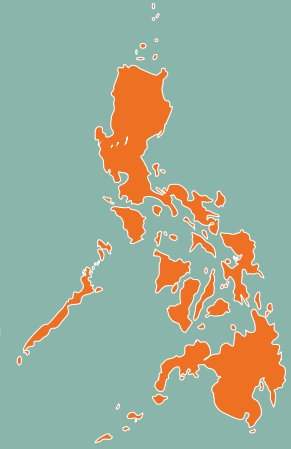
Challenges in improving coverage rates: Coverage varies widely between countries, within different regions in the same country, and depending on the data source (i.e., administrative vs. survey). Vietnam reports high coverage in the national vaccine program, with over 90 percent of children fully immunized, according to administrative data. There are large regional variations, with a low of 29 percent in one rural area in 2017, and variations in timeliness (see **Box 2**). Reported coverage for the measles vaccine (based on vaccination cards viewed during household surveys) in Zambia is 62 percent for the first doses and 29 percent for the second doses.

Respondents in all countries cited similar barriers to achieving immunization coverage targets. The factors included lifestyles (migration, work pressure, difficult access to remote areas) and lack of knowledge among clients. Infrastructure challenges, such as poor roads and power outages, fuel availability and costs, and stockouts of vaccines or immunization supplies present additional barriers. Communities are not always aware that children need vaccination. In some cases, respondents said that people of certain ethnic or religious affiliations tend to decline vaccination services. Additionally, data limitations in some countries (Ghana and Zambia, for instance)

BOX 1. PHILIPPINES: COMPREHENSIVE VACCINE PROGRAM

The Philippines offers one example of an immunization program in which:

- The immunization program is country-funded.
- DPC decisions are based on multisectoral input and cost analysis.
- Cold chain requirements are a major consideration in DPC decisions.
- The Effective Vaccine Management tool is used to monitor and assess the immunization supply chain.
- Funding is based on a 5-year forecasting with annual reviews.
- National budgeting includes vaccines and supplies.
- Only one presentation of multi-dose vials is maintained for all public-sector vaccines; private-sector providers prefer single-dose vials.
- HCWs fear wastage for several multidose vaccines, and are likely to wait for enough patients to present before opening a vial.



prevented ascertainment of the extent of missed opportunities to vaccinate, which could also affect coverage.

Policymakers' views versus HCWs' experiences:

Interviews showed a difference in perspectives and knowledge between high-level government stakeholders and HCWs, who are generally not consulted about DPC choices or changes. For example, although policymakers and supervisors in Zambia and Senegal reported that facilities are assessed based on their achievement of coverage targets rather than on wastage, HCWs said that

BOX 2. TIMELINESS

Not all of the research addressed timeliness, but DPCP's activities showed that the timeliness of coverage varied. Timely provision of pentavalent, measles-rubella, and yellow fever (all available in 10-dose vials) was similar among these vaccines in Senegal (51%, 64%, and 53%); baseline findings in Zambia showed that fewer than half of children received their measles vaccination on time. In Vietnam, reported timeliness was high for the hepatitis B birth dose (90%) but lower for bacillus Calmette-Guérin (42%), which should also be given at birth but is in a 10-dose vial compared to hepatitis B which is in a single dose vial and so may be less likely to be opened due to concern of wastage.



wastage rates affect facility performance assessments. Interviews with HCWs indicated that their reluctance to waste vaccines strongly influences their decisions about opening a multidose vial (especially for vaccines without preservative). They frequently ask caregivers to return another day if a minimum number is not present, which possibly affects national vaccination target rates. On the other hand, in one region of the Vietnam study, facilities provide immunization sessions only monthly, yet they strictly adhere to the policy of opening a vial for every child.

Policymakers had little understanding of HCWs' experiences or behavior on the ground. They felt that introducing multiple presentations of a specific vaccine would create excessive complexity to HCWs' vaccine administration. Multiple presentations may also introduce safety risks with different size diluent ampoules for different vaccine presentations. Interviews in Ghana and the three Francophone African countries, however, showed that HCWs favored the concept as a way of addressing wastage, and felt that multiple presentations would not cause problems. Moreover, HCWs use multiple strategies to cope with local conditions and programmatic requirements: for example, scheduling specific immunization days, going door to door, or using community mobilization to ensure that children in their catchment areas receive their vaccinations.

Effects of DPC changes: Many policymakers and most HCWs preferred lower-dose vials to reduce vaccine wastage. However, cost analyses in Senegal and Vietnam showed that the relationship between DPC and wastage is complex and affected by several factors, including the

frequency of sessions, wastage, and the lower per-dose cost of high-DPC presentations versus the higher per-dose cost with lower DPC. In Vietnam, an analysis of six vaccines² showed that for more expensive vaccines (Japanese encephalitis and measles-rubella), switching to a lower DPC could yield a reduction in wastage that outweighs the increased per-dose cost induced by the switch.

In Zambia, HCWs said that they saw significant benefits in coverage and wastage with a switch from a 10-dose to a 5-dose presentation for MCV during the 12 months of implementation (see **Box 3**). The study showed a three percentage point increase in coverage rate in facilities with 5-dose MCV compared to facilities with 10-dose MCV. The wastage rate was significantly less in facilities with 5-dose MCV (16% compared to 31%).

SAFETY CONSIDERATIONS

In Vietnam, Senegal and Zambia, only a small number of respondents at health facilities mentioned having witnessed adverse events related to immunization over the last year. These events could be underreported. The events that respondents mentioned were minor and DPC was not indicated as a cause. During observation of immunization sessions in Senegal to check for safe vaccine management and injection practices, immunization teams complied with safe practices for the most part. There is an inherent risk of contamination of multi-dose vials of vaccines without preservatives once they are opened. This risk can be mitigated by preservatives in the vaccine, adhering to the multi-dose vial policy, smaller DPC, auto-disabled syringes, and improving HCW safe practices. Still, risk is

BOX 3. HCWS AND LOWER-DOSE MEASLES VACCINE IN ZAMBIA

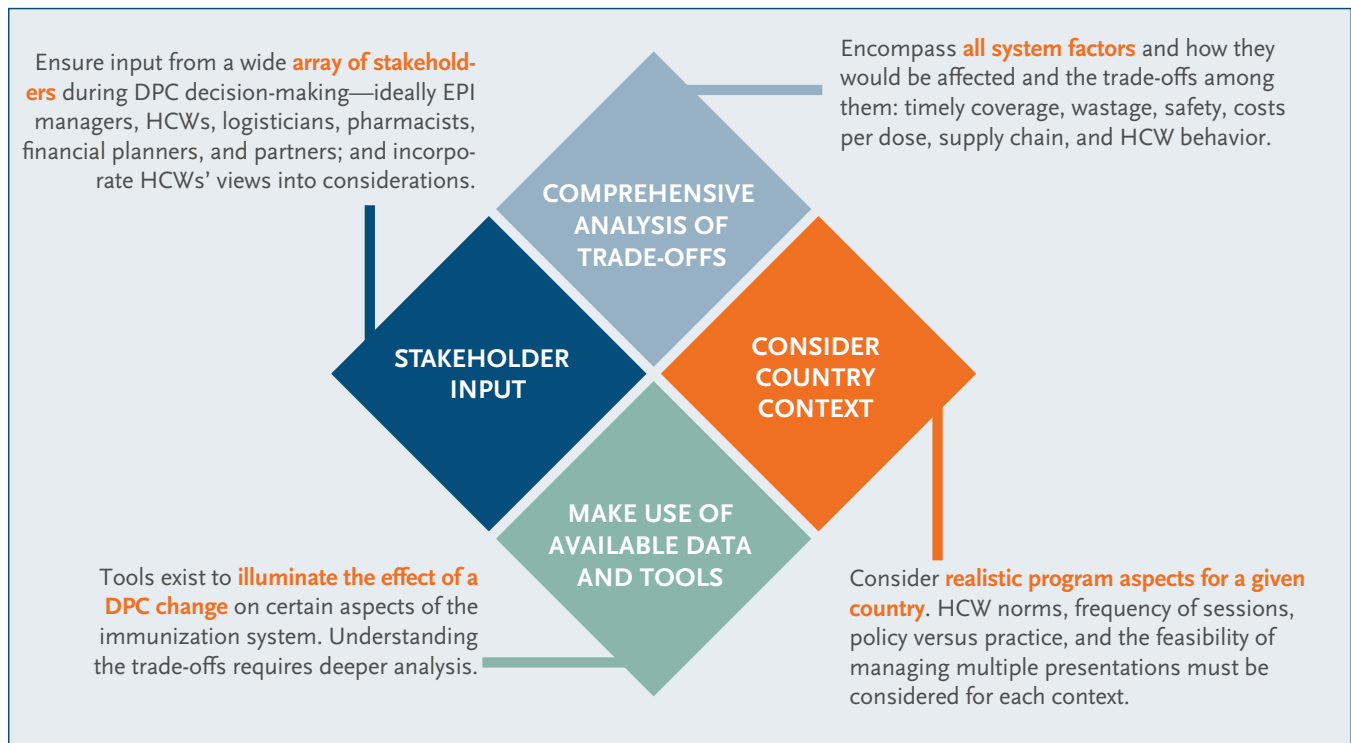
In May 2017, DPCP began research to assess HCWs' experiences with switching from a 10-dose to 5-dose vial of measles-containing vaccine (MCV) in 7 health districts. Twenty-four of the intervention participants interviewed at midline (HCWs, supervisors, and district pharmacists) saw many advantages in the lower-dose presentation. HCWs believed that the 5-dose vial reduced missed opportunities, because with the lower-dose vial they less frequently have to turn children away out of fear of wasting vaccine. They reported that the lower dose saved time because the HCWs did not need to wait for enough children to justify opening a vial (which freed them for other duties). The HCWs also reported telling mothers that they could have their child vaccinated on the "usual" day, or during visits for other services; and said that mothers, knowing they would not need to wait, were now bringing their children more often. One HCW describes this well: "It [5-dose vial] has made it easy with wastage; we don't waste a lot of vaccines doses. For example, with the 5-dose vial, we open the vial when we have 3 children and we waste just 2 doses. When we had 10-dose vials in the same scenario, we would have lost 7 doses. It's easier to administer and clear children quickly."

However, some HCWs and managers said that the lower-dose vial presented challenges, since diluting the additional vials took more time, and that there was insufficient cold chain space for transporting the increased number of vials in some locations.



² BCG (bacillus Calmette-Guérain), bOPV (bivalent oral poliovirus), measles, JE (Japanese encephalitis), DTP (diphtheria-tetanus-pertussis), and MR (measles-rubella).

FIGURE 2. HOW TO CHOOSE OR CHANGE DPC



not completely eliminated. From the country studies, safety or contamination was not a prominent concern for DPC decisions.

RECOMMENDATIONS ON CHOOSING OR CHANGING DPC

When considering a DPC choice or change, **conduct comprehensive analysis** to encompass all system factors and how they would be affected: timely coverage, wastage, safety, costs per dose, supply chain, and HCW behavior. When deciding on vaccine products, different product DPC may have positive or negative impacts on the performance of different system components; understanding these trade-offs can contribute to more engaged decision making.

Consider the context and whether mixed DPC presentations may be preferred and/or feasible to manage by different stakeholders such as national level or HCW. Additional research on the effects of multiple presentations is needed to make informed decisions.

Improve data-gathering to provide a comprehensive picture

of the immunization situation at all system levels. Factors to consider include session size and frequency, equity, application of the multi-dose vial policy, and demand, among others.

To the extent possible, **ensure input from a wide array of stakeholders** during DPC decision-making—ideally EPI managers, HCWs, logisticians, pharmacists, financial planners, and partners; and incorporate HCWs' views into considerations.

There is an emerging need for National Immunization Technical Advisory Groups, Inter-Agency Coordinating Committees and other decision making bodies to be more aware of the effect of DPC on program aspects and an existing tool or ordering process could be adapted to include DPC issues. ■



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