DPCP
DOSE PER CONTAINER PARTNERSHIP

Implementing 5-dose Measles-Rubella Vaccine Vials in Zambia

Research Findings

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JSI

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This document was developed with input from colleagues at the AMP Services; Clinton Health Access Initiative; the HERMES Logistics Modeling Team and the International Vaccine Access Center (IVAC) through Johns Hopkins University, Bloomberg School of Public Health; and PATH and was coordinated by JSI Research & Training Institute, Inc., through the Dose Per Container Partnership (DPCP). This material is intended to provide partners and stakeholders with evidence to guide informed, sustainable decisions on DPC when considering vaccine products and designing programs. It may be used freely by all partners.

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Acronyms

AEFI	adverse events following immunization
BCG	bacille Calmette-Guerin vaccine
CHAI	Clinton Health Access Initiative
CIDRZ	Centers for Infectious Disease Research in Zambia
diff-in-diff	difference-in-difference analysis
DPC	doses per container
DPCP	Dose Per Container Partnership
DPT	diphtheria-tetanus-pertussis vaccine
EA	enumeration area
EPI	Expanded Programme on Immunization
FRF	Facility Returns Form (for Vaccines and Supplies Stock)
FIC	fully immunized child
HCW	health care worker
HERMES	Highly Extensible Resource for Modeling Event-Driven Supply Chains
HF	health facility
HIA2	Health Service Delivery Aggregation Form
Hib	Haemophilus influenzae type b vaccine
ICC	Inter-agency Coordinating Committee
IPV	inactivated polio vaccine
IRB	institutional review board
JSI	JSI Research & Training Institute, Inc.
JRF	WHO/UNICEF Joint Reporting Form
KII	key informant interview
MCH	maternal and child health
MCV	measles-containing vaccine
MOH	Ministry of Health
MOV	missed opportunities for vaccination
MR	measles rubella
OPV	oral poliovirus vaccine
PCV	pneumococcal conjugate vaccine
Penta	pentavalent vaccine (DPT, Hepatitis B, Haemophilus influenzae type b)
RI	routine immunization
Rota	rotavirus vaccine
SII	Serum Institute of India
SSAM	local data collection partner in Zambia
tOPV	trivalent oral polio vaccine
TWG	technical working group
UNICEF	United Nations Children's Fund
UNZA	University of Zambia
WHO	World Health Organization
ZITAG	Zambia Immunization Technical Advisory Group

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- The Serum Institute of India (SII), which donated the vaccine used in this research
- The Bill & Melinda Gates Foundation
- The DPCP Technical Advisory Group
- DPCP partners

01 | Background

DPCP History

The Dose Per Container Partnership (DPCP) is a project funded by the Bill & Melinda Gates Foundation (BMGF), led by JSI Research & Training Institute, Inc. (JSI), and jointly implemented in partnership with PATH, the Clinton Health Access Initiative (CHAI), the Highly Extensible Resource for Modeling Event-Driven Supply Chains (HERMES) modeling team, and the International Vaccine Access Center (IVAC). DPCP supports better-informed decision making on doses per container (DPC). The project examines specific immunization program issues, including:

- Timely and equitable coverage rates
- Wastage rates
- Cold chain and supply chain footprint
- Total systems costs
- Safety
- Health care worker (HCW) behavior
- Perceptions and preferences of HCWs, district supervisors, and pharmacists related to the management and delivery of vaccine services.

See the six system components that may be impacted by a change in DPC in Figure 1 below.

Figure 1. The six system components

Additional project resources can be found at www.jsi.com/dpcp.

Implementing 5-dose MR vials in Zambia: Background

From January 2017 through July 2018, the DPCP conducted implementation research using quantitative and qualitative methods in Central and Luapula provinces in Zambia. The country was selected to carry out this work because of Ministry of Health (MOH) interest and commitment to engaging in the implementation research; a functional supply chain; minimal regulatory barriers to introducing a new presentation; and support from in-country and regional partners. The DPCP introduced 5-dose vials of measles-rubella (MR) vaccine to a select group of health facilities (HFs) in May 2017 to assess the effects on the immunization system of reducing the number of DPC from the 10-dose vials in use.

Research Objectives

The primary objectives of this implementation research were to:

- Examine the relative effects of 5-dose compared to 10-dose vials of measles-containing vaccine (MCV) on first- and second-dose coverage; open vial wastage; dropouts; session size and frequency; storage and distribution capacity; and logistics, service delivery, and total systems costs for routine immunization (RI)
- Understand how vial presentation may have an influence on missed opportunities for vaccination (MOV), timely coverage, equitable coverage, and safety
- Understand HCW preferences and examine HCW behavior for various vial presentations
- Identify the factors that enable and hinder the proper use of each of the two presentations

Zambian Context

The Zambian Expanded Programme on Immunization (EPI) has been providing measles vaccine to children since the late 1970s. In July 2013, a second dose of measles vaccine was introduced. With this update to the schedule, MCV is now given at nine months and 18 months of age. Following an MR campaign in September 2016, Zambia switched from 10-dose measles to 10-dose MR vaccine in June 2017. Districts participating in this DPCP research switched in May 2017 to ensure all facilities were using MR vaccine throughout the entire implementation period.

Routine childhood immunizations in Zambia are given during fixed and outreach sessions. Health facilities conduct sessions that are held anywhere from daily to monthly depending on the catchment population, size of the facility, availability of staff to conduct outreach, and other factors.

Reported measles first-dose coverage (MCV1) by 12 months of age has fluctuated over the past 10 years, from 89% in 2008 to 80% in 2013 to 96% in 2017, according to official administrative data from the WHO/UNICEF Joint Reporting Form (JRF). The 2013–2014 Zambia Demographic and Health Survey (DHS) estimated first-dose measles coverage for surveyed children 12 months to 23 months of age at 70% (through review of vaccination cards only), and 85% (through review of cards plus recall of caregivers). Only 73% of the overall population had been vaccinated by 12 months of age (card plus recall). While reported routine coverage for MCV1 was 96% in 2017, reported second-dose (MCV2) coverage was only 64%, according to the JRF. There were also considerable disparities in performance between regions and districts and difficulties in estimating population denominators, so that MCV1 reported coverage in districts ranged from 64% to 256% in 2017.

To attain the regional measles elimination goal, both MCV1 and MCV2 coverage of greater than 95% must be achieved and sustained.

02 | Implementation Research Design

Site selection

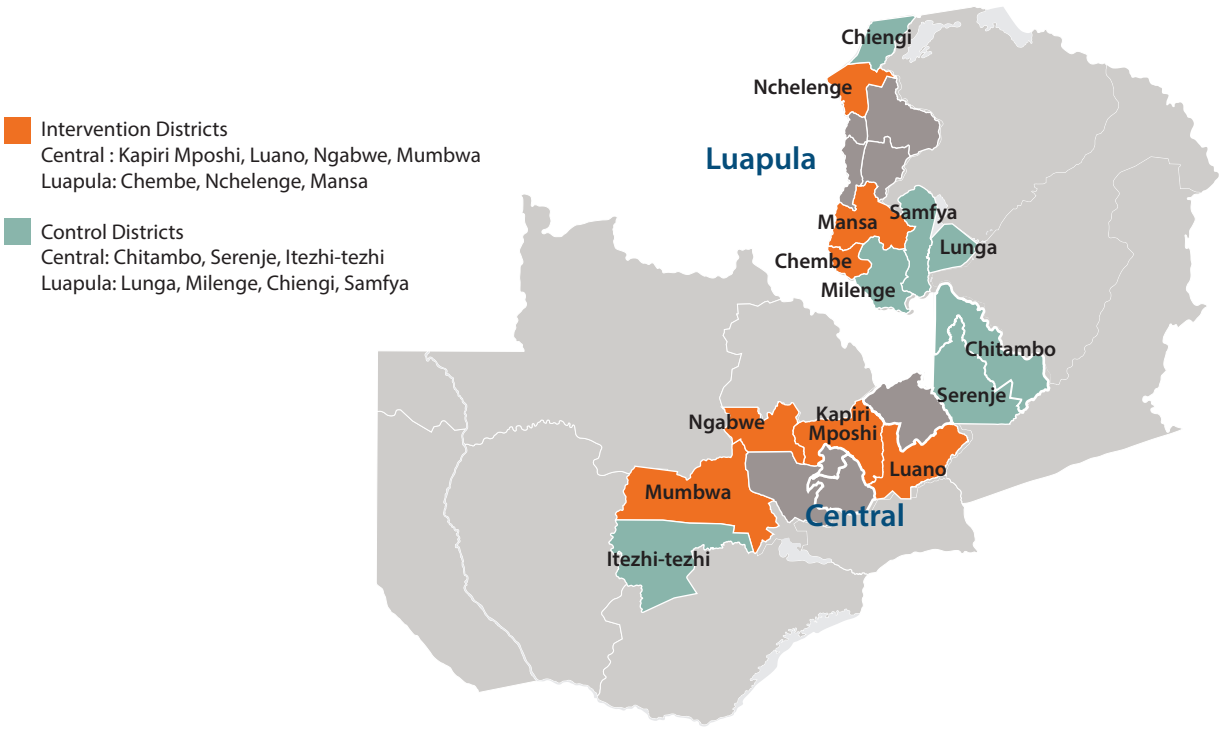
The desired setting for this activity was a combination of rural and urban districts, as classified by the country. The DPCP, with support from the MOH, selected two provinces (Central and Luapula, see Figure 2 below) using the following considerations:

- Low Diphtheria-Tetanus-Pertussis 3 (DPT3), MCV, and fully immunized child (FIC) coverage, as reported in the 2013–2014 DHS
- Low timely MCV coverage (coverage for under 12 months old) as reported in the 2013–2014 DHS
- Equity indicators — including socio-economic status, antenatal care visits, and maternal education — as reported in the 2013–2014 DHS
- Logistical feasibility to implement in selected provinces

The MOH then selected 14 districts from within the two selected provinces. Criteria considered for district selection included indicators used for provincial selection, as well as:

- Number of measles outbreaks
- Average catchment population per health facility (mix of smaller and larger)
- Number of outreach sessions and number of fixed sessions (preference for areas with more outreach sessions) scheduled per month
- Mix of urban and rural areas
- Accessible and reliable data currently collected at district level

Figure 2: Map of Central and Luapula provinces, Zambia



Protocol Development and Ethical Approvals

The protocol for this research was developed in collaboration with DPCP partners, the DPCP Technical Advisory Group, the Bill & Melinda Gates Foundation, and the Zambian MOH. The study was approved by the Biomedical Research Ethics Committee of the University of Zambia, as well as by JSI's Institutional Review Board (IRB).

Materials

Prior to this research, Zambia used lyophilized measles vaccine in 10-dose vials manufactured by the Serum Institute of India (SII) and procured through the UNICEF Supply Division. Following the country-wide switch from measles to MR vaccine in May and June 2017, the country continued to use lyophilized vaccine manufactured by SII.

To support this research, SII donated 90,000 doses of MR vaccine in 5-dose vials and bundled diluent, which were shipped according to the WHO/UNICEF guidelines for international packaging and shipping of vaccines. Vaccination syringes, reconstitution syringes, and safety boxes were procured from BD International, the manufacturer who currently provides supplies to the Zambian MOH to ensure the standardization of immunization supplies within the existing immunization program.

Orientation of Facility, District, and Provincial Staff to the Implementation Research

The DPCP held orientation meetings in the two provincial capitals, with separate sessions for intervention and control districts. A half-day session for facility-based HCWs and district supervisors was held in the morning, and additional information was provided to the district supervisors in the afternoon. All orientations were opened by the Provincial Health Office to show the support and involvement of the MOH in this research.

Topics covered during the orientation included:

- Background of the project
- Brief review of the MR vaccine
- Key indicators for the research
- Review of DPCP's form to collect monitoring data at HFs and how to submit form

Facility-based HCWs were trained to capture routine logistics and immunization session data on a daily and monthly basis on paper forms, which were submitted to the district monthly. An Excel tool was provided to district staff to enter the data and submit it to the DPCP team every month, starting from June 2016.

In addition, HCWs in intervention districts were informed that they would be using 5-dose vials of MR vaccine for the next year. The orientation emphasized that the vaccine was produced by the same manufacturer and was reconstituted and administered in the same way as the 10-dose vial. During the orientation, facility-level HCWs were requested to continue ordering vaccine as they have done in the past. Since HCWs order in doses and not in vials, they did not need to recalculate required quantities based on the change in vial size.

District pharmacists in the intervention districts were requested to distribute the 5-dose vials, diluents, and ancillary supplies in the same way as they had done with 10-dose vials, which was based on order requests from HFs. They were informed that twice as many reconstitution syringes were needed with the 5-dose vials to ensure one syringe for each smaller vial. All district staff were requested to document any challenges experienced with the 5-dose vials to share with the DPCP team.

Distribution of Vaccines

At the MOH's request, the DPCP facilitated the delivery of the 5-dose MR vaccine to the seven districts in the intervention arm prior to implementation. All 10-dose vials were removed on the same day (May 22, 2017) as HFs were supplied with 5-dose vials.

Six of the seven districts had adequate cold storage space to store a year's supply of MR vaccine. The last district was newly created and did not have cold storage, so vaccines were kept in a neighboring district's cold storage, along with other vaccines used in this district.

Quantities for distribution were calculated using estimated target populations for each district, which is the same method used for distribution of vaccine in 10-dose vials. A small buffer stock of 500 doses was maintained in each of the provincial cold stores in Kabwe and Mansa. Districts in the control arm continued to be restocked through the regular quarterly distribution system.

Health facilities in Zambia follow a pull system for vaccine resupply (i.e., the HF staff estimate quantity required) and are required to order vaccines on a monthly basis. All orders are reported in the number of doses requested. Most HFs collect vaccines from the district store and transport them to the facility in vaccine carriers or cold boxes. A few HFs in our sample did not have refrigerators, usually because they were recently opened, so they stored vaccines at a neighboring HF. Additionally, a few remote or hard-to-reach HFs received direct delivery of vaccines from the district instead of collecting them.

As described above, facility-level HCWs were informed to continue ordering vaccines as they had done in the past. District pharmacists that distribute vaccines to HCWs were also instructed to resupply as they had done in the past.

03 | Methods

For the DPCP study, a stratified-pair, cluster-randomized field design was implemented in the study districts. The districts were paired according to similar average population size per HF and number of HFs within each district; from each pair, the intervention district was randomly picked, while the other district served as the comparison district. During the implementation period, HFs in the intervention group received 5-dose vials of MCV, while HFs in the control group continued with the standard 10-dose vials.

The DPCP implementation research team collected data at baseline, during project implementation, and at endline. Baseline data collection was completed between March and April 2017. Implementation took place in May 2017 through April 2018. Endline data collection was completed in May 2018 for all data except for the household survey, which was completed in August 2018.

Data collection methods included:

- Household surveys
- Key informant interviews (KIIs) at facility, district, and national levels
- Observations of routine immunization (RI) sessions
- Administrative data review
- Costing surveys

Table 1 below lists each question and the methods that were used to collect data. Each method is also described in detail.

Table 1: Research questions by method

Research Question	Method
What are the effects of 5-dose MR vaccine on first and second dose coverage?	• Household Survey
Does introduction of the 5-dose MR vaccine affect the timeliness of coverage?	
What is the influence of DPC on equitable coverage and dropout rates?	
What is the influence of the 5-dose MR vaccine on open vial wastage, storage and distribution capacity, and logistics?	• Administrative data review • Key informant interviews (KIIs) at facility, district, and national levels • Costing surveys
What is the influence of the 5-dose MR vaccine on the total systems costs for RI?	• Costing surveys
How does vial presentation influence missed opportunities, session size and frequency, and safety?	• Administrative data review • KIIs at facility and district levels • Costing surveys • Session observations
What are the factors that influence MCV1 and MCV2 coverage, equity, and timeliness?	• KIIs at facility, district, and national levels
What are HCW preferences regarding DPC, and how does their behavior change for different presentations?	• KIIs at facility, district, and national levels
How does the national level make decisions about DPC? What trade-offs do they consider?	• KIIs at the national level

Household Coverage Survey

The household survey used a two-stage cluster design. The survey questionnaire, adapted from the World Health Organization's (WHO's) Vaccination Coverage Cluster Survey[1], was implemented to obtain childhood vaccination information from the caretakers of two cohorts of children — those aged 12 months to 23 months for estimating MCV1 coverage, and those aged 24 months to 35 months for estimating MCV2 coverage. In addition, timeliness of MCV1 and MCV2 were collected and analyzed based on vaccination cards. All antigens were included in the survey, although the focus was on MCV.

Sample size and survey design

The sample size for the household survey was estimated to detect a 7 percentage-point higher increase in MCV1 and MCV2 rates between baseline survey and endline survey in the intervention group, as compared to the control group (i.e., difference-in-difference), with 80% power, one-sided alpha error set at 0.05, and cluster survey design effect set at 1.5. The design effect was estimated using the intra-class correlation coefficient obtained from the Zambia DHS 2013–2014 and assuming four respondents per cohort, per cluster. The assumption was that the coverage increased from 50% to 57% in the intervention area but remained unchanged at 50% in the control area. The sample size estimation was done using the methods and tools described by McConnell and Vera-Hernandez.[2]

Based on this, the sample size was estimated to be 1,952 children from 488 clusters per each cohort and each study arm during each survey period. The survey design is given in Box 1.

BOX 1: SURVEY DESIGN

Stage 1 (cluster selection):

Enumeration areas (EAs), as defined by the 2010 Zambia Census of Population and House, were selected as the primary sampling units (clusters), with the probability proportional to its population size, stratified by study arm.

Stage II (household selection):

Four households per cohort, per EA, were selected randomly using the following method:

- Each EA was divided into four approximately equal segments based on household distribution derived from Census Bureau housing maps.
- From the middle of each segment and working outward, one household was randomly selected.

EAs selected at baseline were revisited at endline.

Data collection

DPCP's local research partner, SSAM, managed data collection and field logistics. SSAM conducted data collection between March 20 and April 19, 2017, at baseline, and from August 1 through 24, 2018, at endline. A five-day field data collection training for survey teams was held in Lusaka, followed by a pilot test in Chongwe district, prior to data collection at baseline and endline. Six five-person teams, consisting of four data collectors and one supervisor each, were deployed to assigned district areas to conduct household surveys. Data collection took approximately 25 minutes per household. Data were collected electronically through the mobile data platform SurveyCTO[3] using smartphones and tablets.

1 World Health Organization. World Health Organization Vaccination Coverage Cluster Surveys: Reference Manual. Version 3. Working Draft. Updated July 2015. https://www.who.int/immunization/monitoring_surveillance/Vaccination_coverage_cluster_survey_with_annexes.pdf?ua=1

2 McConnell B, Vera-Hernandez M. Going beyond simple sample size calculations: a practitioner's guide. Institute for Fiscal Studies. Working Paper W15/17; 2015. https://doi.org/10.1920/wp.ifs.2015.1517

3 SurveyCTO. https://www.surveycto.com/

Data were checked and validated routinely throughout survey implementation. Before departing from an enumeration area (EA), data teams checked interview records to ensure that all data were captured properly. Data were also validated each evening by the team supervisor before uploading to the SurveyCTO cloud server. Data in the server were further validated and cleaned in Lusaka by SSAM.

Final sample distribution for baseline and endline

The final sample numbers for the household coverage survey at baseline and endline are presented in Table 2 below. The discrepancies in total observations for the final sample between baseline and endline are due to issues found during data cleaning. Approximately 150 observations were dropped at baseline, and 10 at endline, due to incomplete data or ineligibility.

Table 2: Distribution of final sample by cohort and study arm

	Children aged 12–23 months (n)	Children aged 24–35 months (n)	Total
Baseline			
Intervention	1,907	1,920	3,827
Control	1,960	1,867	3,827
Total	3,867	3,787	7,654
Endline			
Intervention	1,962	1,931	3,893
Control	1,965	1,937	3,902
Total	3,927	3,868	7,795

Data analysis

The indicators of interest in this survey were:

- Percentage of children aged 12 months to 23 months who received at least one dose of MCV
- Percentage of children aged 24 months to 35 months who received at least two doses of MCV
- Percentage of children aged 12 months to 23 months who received a timely[4] dose of MCV1
- Percentage of children aged 24 months to 35 months who received a timely dose of MCV2

To estimate the adjusted intervention effect, the study arms were balanced by matching intervention area EAs with control area EAs using baseline attributes. The propensity scores[5] were first estimated for each EA using a logit model[6] predicting the probability of an EA to be in the intervention area at baseline. The covariates of the logit model were province, urban or rural, EA-level baseline averages of household wealth, sex, age, education and occupation of the caregiver, and outcome variables of interest. Intervention and control EAs with similar propensity scores at baseline were coded so that they could be identified as similar. To assess the adequacy of the matching, t-tests were performed to ensure that the covariates of the final logit model were not statistically significantly different ($p > 0.1$) between the intervention and the control EAs, after accounting for the matched EAs.

4 Timely vaccination is defined as receiving a vaccination within three days before or four weeks after the recommended vaccination date in accordance with the national immunization schedule.

5 Propensity score matching is a statistical procedure for reducing bias by assembling a sample in which confounding factors are balanced between treatment and control groups.

6 Logit (or logistic) model is a widely used statistical method to model binary dependent variables.

Intervention effects were estimated from logit models predicting the outcome of interest with indicator variables for study arm, survey period, the interaction between study arm and survey period, and for the EAs that matched between the intervention and control areas (dummy variables) as the predictors. The models were adjusted for survey design using Stata's survey estimators. Stata's post estimation 'margins' command was used to obtain adjusted estimates of the outcomes of interest according to study arm and survey period and the intervention effects (i.e. difference-in-difference) with 95% confidence interval.

The intervention effect was estimated using difference-in-difference (diff-in-diff) analysis — that is, the difference in the change of an indicator of interest between baseline survey and endline survey in the intervention group and that change, if any, in the control group. The fixed effect regression models produced the baseline and endline adjusted values for each indicator, and adjusted intervention effects, which were analyzed. Data were analyzed using Stata 14.[7]

Limitations

There were several limitations in this survey:

- The sampling frame and demarcation of EAs was based on the EAs created for the 2010 Zambia Census of Population and House. Using an outdated sampling frame can introduce sampling bias, as it may not accurately reflect population changes or migratory shifts in the area.
- Thirty-one selected EAs (out of a total of 976) were not reachable at baseline due to inclement weather, inaccessible roads, and/or flooded conditions. While replacement EAs with similar location and population characteristics were selected, it is important to consider that these inaccessible EAs may have had lower coverage due to recurrent inaccessibility during rainy seasons.
- During the second stage of the household survey, the selection of households and respondents was not based on probability but a quasi-random process.
- The intervention effects were based on intention to treat analysis. Thus, the treatment effects could be underestimated due to contamination (if some of the children in intervention districts attended immunization sessions in teh adjacent district where 10-dose MR vial were used, or vice versa).

These limitations may affect the external generalizability of survey point estimates but are unlikely to impact the internal validity of the intervention effect estimates of this study because the biases are expected to be similar across study arms. Additionally, data from the same clusters visited at baseline were collected during endline; as such, the biases have been differenced out (expunged) from the diff-in-diff analysis used to estimate the intervention effect.

Although the analysis accounted for unobserved time-invariant cluster-level confounders by using fixed-effects regression and propensity-matching methods, the intervention effects could still be biased due to time-variant cluster-level confounders. However, for this to happen, the time-variant confounders would have to be systematically associated with the intervention area but not the control area.

Key informant interviews

Key informant interviews (KIIs) were conducted at baseline, midline, and endline. At baseline, qualitative data were collected through KIIs that were conducted at a subset of health facilities and district

7 StataCorp. Stata: Release 14. Statistical Software. College Station, TX: StataCorp LLC; 2015.

offices across all 14 districts to examine factors associated with missed opportunities to vaccinate, safety, equitable coverage, and health care worker preferences for vial sizes.

During KIIs, respondents were asked whether there were any reports from communities concerning adverse events following immunization (AEFI) or injection abscesses; they were also asked to list the causes of AEFI and abscesses. Key informants included HCWs providing immunizations, district maternal child health (MCH) coordinators, and pharmacists.

At midline, KIIs with HCWs, district-level MCH coordinators, and district pharmacists were conducted only in the intervention districts. At endline, KIIs were conducted at a subset of HFs and district offices in the seven implementing districts in order to focus on the experience of the 5-dose vial districts. We did not anticipate any significant change in the 10-dose districts since there were no major policy changes or budget updates during the one year of implementation; we therefore focused on the 5-dose vial districts at endline.

Additionally, KIIs were conducted with national-level decision makers at endline to understand the decision-making process around switching vial size. Data were collected by interview with EPI Manager, EPI National Logistician, Ministry of Finance Deputy Director of Budgeting, WHO and UNICEF immunization focal points, and in-country PATH staff. The questions focused on the processes for ordering and forecasting vaccines, which influenced decisions regarding introduction of new vaccines or any change in the vial size of any vaccine. Questions also probed the possibility of introducing multiple presentations of the same vaccine for use with different strategies and settings in Zambia, such as urban/rural, large/small HFs, or fixed/outreach.

Sample selection

At the national level, the DPCP conducted six interviews (with the EPI Manager, EPI Logistician, Ministry of Finance, WHO, UNICEF, and PATH). At the district level, the project conducted 28 interviews across all 14 districts at baseline, while 14 interviews were conducted at endline. At midline, the DPCP conducted eight interviews at the district level. Respondents were MCH coordinators and district pharmacists or logisticians. These two roles were purposefully chosen to enable interviewers to ask questions about immunization service delivery from a district perspective around logistics and supply chain, as well as around HCW supervision, which was the role of MCH coordinators. At baseline, 32 interviews were conducted at the HF level; at midline, 16 interviews; and at endline, 42 interviews. The HFs were chosen to represent different population sizes and varying distances from the district.

Data collection

All interviews were conducted in English. The DPCP contracted local partners — University of Zambia (UNZA) at baseline and a team of independent consultants for midline and endline — to conduct the KIIs. Local partners were chosen based on their experience and training in qualitative research methods.

DPCP conducted a five-day training at baseline and at endline with the consultants to orient them to the research objectives and data collection methods and tools to ensure a common understanding of research goals and establish collective agreement around the expected standards and quality from the data.

The tools were pilot tested in Chongwe district to ensure the questions were clearly phrased and easily understood by interviewers and respondents.

For baseline and endline, four two-person teams, consisting of one interviewer and one notetaker, were deployed to selected HFs to conduct interviews. Two field supervisors oversaw the data collection. Since the midline was a smaller study, one two-person team conducted all the interviews. National-level interviews were conducted by one two-person team. The notetaker was responsible for transcribing the interviews. The field supervisors reviewed all transcripts before they were shared with the DPCP team.

Data analysis

All transcripts were uploaded into NVivo 11[8], a qualitative data management software. NVivo was populated with an initial list of codes derived from the research questions. The qualitative team generated an initial set of codes derived from the research questions to analyze the data. All codes were accompanied by code definitions that described the codes and the appropriate application to the transcript.

The initial set of codes comprised major thematic categories, which were refined through analysis; sub-categories (i.e., sub-codes) were developed through iterative analysis. The research team used thematic analysis methods as defined by Richard Boyatzis (1998), which state that a useful, meaningful code includes:

- A label
- A definition of what the theme concerns
- A description of how to know when the theme occurs
- A description of any qualifications or exclusions to the identification of the theme
- Examples, both positive and negative
- Select quotes that illustrate major themes were highlighted as well.

Limitations

In KIIs, respondents may alter their responses to meet what they believe to be researcher expectations. The DPCP tried to address this by training data collection teams to maintain neutral expressions and body language so as not to indicate preferred response to the respondent. The data collection team was also trained not to ask leading questions that would allude to a "correct" answer.

Routine Immunization Session Observation

At baseline, the qualitative data collection teams conducted 20 systematic observations of vaccine handling and vaccination practices at HFs. This included inspecting refrigerators for functionality and temperature and observing vaccine storage; handling and stock-keeping practices; transportation; vial discard; safe injection; and vaccination sessions at facilities to observe HCWs' attitude, behavior, and practices.

Site selection and data collection

The data collection team used checklists to observe vaccination sessions. Convenience sampling was used because Zambia conducts a limited number of static and outreach sessions per month, and the data collection team had to align its KII or costing data collection schedule with observations at facilities whenever convenient.

8 NVivo. https://www.qsrinternational.com/nvivo/what-is-nvivo

Data analysis

Observations at HFs were summarized quantitatively to HCW practices before, during, and after the immunization session that was observed. Responses to each of the 20 questions were tallied by *yes* or *no.*

Limitations

The numbers of observations were limited mainly due to low frequency of vaccination sessions conducted during the time of data collection. Also, some vaccination sessions had already started when data collectors arrived, so they were not able to observe prepartions for the session. Data collectors attempted to overcome this limitation by collecting data on the same themes through KIIs to triangulate findings.

For observations, respondents sometimes alter their behavior to meet researcher expectations. As with the KIIs, data collection teams were specifically trained to maintain neutral expressions and body language so as not to influence the respondent's immunization session practices.

The data collection teams were trained researchers, not health professionals. The DPCP team trained the data collectors in how to properly conduct observations and oriented them to the relevant data on RI to enable them to focus on key practices at RI sessions.

However, DPCP decided not to conduct HF observations at endline due to the low frequency of sessions, which would have resulted in a sample size too small to draw valid conclusions about safe injection practices. The project decided instead to learn more about safety through targeted questions during the KIIs.

Facility-level retrospective administrative data review

At baseline, the team aimed to collect retrospective administrative data from all HFs in the implementation and control districts for a period of 12 months (January through December 2016). The team used these data to calculate vaccination coverage, wastage, and stock-related indicators in the year prior to implementation. However, due to the poor availability and quality of data, these findings are not presented as part of the end of research analysis.

Sampling design

Data were collected from all HFs in the 14 districts through the standard MOH forms submitted by facilities to districts. Program and supply data collected by HFs were submitted to districts monthly using the MOH Facility Returns Form for Vaccines and Supplies Stock (FRF) and the MOH Health Service Delivery Aggregation Form (HIA2). The FRF records logistics data, including the beginning vaccine balance, total received, total used, doses wasted, and ending balance. The HIA2 records the number of doses administered of each vaccine in fixed and outreach sessions. Stock control cards were maintained in each district store and recorded the number of MCV doses distributed to each HF.

Data collection and analysis

The data collection team at UNZA was trained on research objectives, methods, and tools over a two-day period to ensure that data collection met a high standard of accuracy. The team also implemented a pre-test in Chongwe district to gain familiarity with the FRF, HIA2, and district stock control cards and to assess data availability by facility on the required indicators. Data collectors took photographs of all forms and transferred the data into Excel workbooks. The supervisors and the DPCP team cross-checked the photographs with the Excel sheets to ensure the accuracy of data entry. All data were cleaned and analyzed in Excel.

Limitations

Data collectors found that staff rotation in many districts over the year prior to implementation limited the quality and availability of data collected during visits, as new staff sometimes could not locate the archives or were unsure if data had been collected previously. Stock cards were not completely filled in for the full 12 months, and since many HFs were only restocked a few times in the year, it was difficult to determine if data were missing. When stock data were compared to number of doses administered, we were able to estimate that most data were available in a majority of the HFs.

The availability of FRF forms was severely limited, with many districts not using this form at all during 2016. Of districts that did use the form, many HFs did not regularly submit them to the district. We were able to calculate wastage rates only for a small subset of HFs. Some HFs included doses administered in the September 2016 MR campaign on their forms, while others appeared to have not done this or did not report at all during that month. HIA2 and FRF forms are submitted to different units in the district office, and during analysis, it was discovered that data that should have been identical on both forms (namely, the number of children vaccinated) did not always match.

Target population estimates, which were used to calculate coverage rates, appeared often to be inaccurate, resulting in inaccurate coverage rates for many HFs (for example, over 100%).

Additional data were collected during monitoring to ensure more accurate data to compare between intervention and control facilities, since the DPCP team decided that it could not adequately quantify changes in key indicators from baseline to endline using administrative data.

Administrative Data Collection During Implementation

Due to the poor quality and incompleteness of HF administrative data from baseline, and to collect additional data (such as session size) that were not available through MOH forms, the DPCP developed a data collection system for the period of implementation to ensure that wastage, average session size, frequency of RI sessions, frequency of sessions in which MR vaccine was administered, stockouts, and resupply data would be available to compare between study arms. The DPCP collected 11 months of HF data covering a number of indicators that were not available through the regular administrative data.

The DPCP team collected monitoring data from 240 HFs. Four HFs submitted no reports during the implementation period and are not included in the total sample. Of the 240 HFs, 135 were in the intervention districts, and 105 in control districts. Along with having more HFs in the intervention arm, the total catchment population covered by those HFs was also larger, at 38,041, compared to 30,574 in the control arm.

Table 3 below summarizes the selected HFs by residence, HF size, and distance to the district capital.

Table 3: Distribution of final sample by study arm*

		Intervention		Control	
		Number of HFs	%	Number of HFs	%
Total		135		105	
Residence*	Urban	4.4	3	9	2.9
	Rural	88.9	100	120	94.3
Health Facility Catchment Population	Large: 500+ Target Pop	16.3	13	22	12.4
	Medium: 200 to 499 Target Pop	45.9	47	62	44.8
	Small: 0 to 199 Target Pop	37.8	45	51	42.9
Distance from Health Facility to District Capital	0-39 km	50.4	40	68	38.1
	40-99 km	31.1	46	42	43.8
	100 km	18.5	19	25	18.1
Total Catchment Population		38,041		30,574	

*Descriptive data not available for all HFs, so groups may not equal 100%.

Data collection

Health care workers from all facilities in both intervention and control arms received an orientation on using the DPCP form before implementation began. HCWs documented on a daily basis whether a fixed or outreach session was held, if MR vaccine was included in that session, the number of MR vaccine vials opened, and the number of doses of MR vaccine (first and second dose) and Pentavalent (Penta) vaccine (DPT-Hep B-Hib) (first, second, and third dose) administered.

At the end of each month, HCWs documented the MR vaccine stock balance from the previous month, MR vaccine stock received, MR vaccine stock issued, and current MR vaccine balance, as well as the number of days, if any, in which MR vaccine was out of stock and the number of unopened MR vaccine vials wasted.

These forms were submitted on a monthly basis to the district MCH coordinator, who entered the data into a macro-enabled Excel file and sent the completed forms to an email account that DPCP created for data collection. An in-country DPCP team member reviewed and cleaned data and contacted districts and health facilities to clarify any incomplete or inconsistent entries.

One hundred and three immunization sessions were excluded from the analysis due to negative wastage rates, suggesting data quality issues. For 76 sessions, the negative wastage was adjusted to zero since some HCWs were able to extract one extra dose from a vial (e.g., 11 children vaccinated with a 10-dose vial). A total of 13,043 immunization sessions were reported during implementation, with more sessions in the intervention arm compared to the control arm (7,518 in intervention districts and 5,525 sessions in control districts). Reporting rates were also higher in the intervention arm (see Table 4).

Table 4: Reporting rate by study arm

	10-dose vials	5-dose vials
Reporting rate	80.2%	91.2%

Data analysis

The unit of analysis was the HF. The distribution of data by session type (outreach/fixed), distance of HF from district capital, province, location of facility, reporting rate, and facility size were compared between the two study arms using Wald's statistics adjusted for repeated observations within a facility. The mean of the facility-level average monthly open vial wastage rate over the observation period (i.e., 11 months) was then compared between the two study arms, stratified by session type and facility size. The analyses were adjusted for the time series nature of the data (i.e., health facility level monthly measures over the observation period), province, distance of the health facility from the district, catchment population size of the health facility, and reporting rates. To account for possible dependencies between one month's report with the next or with the previous, an autoregressive conditional heteroskedasticity (ARCH) model was used with 3 month moving averages of monthly reports from each health facility. Predicted wastage rates by study arm and the differences between the two (i.e., the intervention effect) with 95% confidence interval were calculated using Stata's post estimation 'margins' command. Similarly, the average frequency of MR sessions per month and average number of children vaccinated with MR per session were analyzed. The adjusted analyses are presented in this report.

Limitations

The major limitation of the administrative data analysis was the lack of appropriate pre-intervention data. However, the analysis partly accounted for the issue by adjusting for the known differences between the intervention and control area facilities, with the assumption that doing so would indicate that they had a similar health system performance before the intervention.

Reporting rates were 11 percentage points higher in the intervention arm; therefore, if the HFs that reported less frequently were systematically associated with poor health systems performance, then the intervention effect estimates would be overestimated or vice versa.

Costing Study

DPCP examined the additional costs or savings associated with switching from 10-dose to 5-dose MR vials. We sought estimates on whether and how the costs included in this analysis are affected by the DPC switch. Areas examined for cost impact included costs for procuring vaccine and injection equipment, storage, and transport; and human resource time for conducting fixed and outreach vaccination sessions, stock management and reporting, and sharps waste disposal.

Data were collected using a structured questionnaire to gather information on the resources used for logistics system and immunization service delivery in order to to estimate costs. The survey documented the types and quantities of resources used for vaccine storage and distribution, the time spent on routine service delivery, and types and quantities of resources used for sharps waste management. Endline questionnaires followed the same format as those used in the baseline analysis, with additional questions on how resource requirements for routine service delivery had changed following the switch to 5-dose MR vials.

Sampling design

There were eight urban HFs in the 14 study districts, and all eight were included in the costing study. Stratified sampling was used to select the rural HFs included in the sample. The rural facilities were

stratified into four groups based on the distance from the HF to the district vaccine store and HF catchment population, resulting in a total of 16 survey strata. The number of HFs selected in each stratum was proportional to the number of HFs falling into the stratum.

In addition, the number of HFs included in the costing sample from each district was proportional to size of the district where the size was based on the number of HFs in the district.

The final costing sample at baseline included 44 HFs in the control arm and 57 HFs in the intervention arm. The endline costing data collection was conducted at the 57 HFs located in the intervention districts where the baseline costing survey had been conducted and in the seven districts where they were located.

Data elements collected

HCWs at HFs and districts were interviewed using structured questionnaires, which documented the following:

- Types and quantities of resources used for the storage and distribution of vaccines
- Resources used for immunization service delivery (only for HFs)
- Resources used for sharps waste management
- Whether the listed resources and time spent on routine service delivery had changed following the change to 5-dose MR vials (endline only)
- If changes, whether the change in resource use was specifically attributable to the change in MR vial size and not to other factors related to the immunization program (endline only)

For example, at endline, we gathered information on the additional cold chain equipment, if any, that was provided for storing the 5-dose MR vaccines and other routine EPI vaccines at each HF. This information was used to estimate the incremental cold chain costs associated with switching from 10-dose to 5-dose MR vials.

In addition, we gathered information on the frequency of vaccine resupply to HFs, the number of staff traveling for these trips, modes of transport, the types of vehicles used, and the frequency of disposing sharps waste.

For HCW time use, we asked staff to self-report the frequency of administering vaccines, time devoted to administering vaccines, and/or the number of staff conducting immunization activities — such as providing fixed or outreach services, forecasting quantities of vaccines needed, conducting stock management, and doing program reporting. In the endline survey, if the frequency, time spent, or number of staff had changed, we asked the HCWs to provide additional details regarding these changes.

Since we only collected data for costs that were potentially subject to change because of the intervention, surveillance and management costs were not collected. The team focused on costs for the EPI at district and facility levels, not on out-of-pocket costs to households for receiving services.

In addition to collecting costing data, the project collected information on the quantity of MR vaccines received, administered, and wasted at each facility as part of the project's monitoring activities (described earlier). These reports were collected for the 11-month intervention period when available. Similar data were also collected from the control HFs for the same time period. This information was

used to estimate the value of vaccines received by each facility, the value of those administered, and the value of those wasted, and also to conduct a break-even analysis to explore the trade-off between reductions in wastage rates due to the DPC reduction for MR vaccines and the increase in the price per dose for the vaccine as a result. At baseline, we used FRFs and stock control cards, when available, to examine the quantities of vaccines and immunization supplies at each facility.

Identical unit costs for salaries, vehicles, fuel, and electricity were used in both the baseline and end-line analyses. These data were obtained from in-country sources. Other unit prices, such as those of cold chain equipment and vaccines, were obtained from online sources[9] and are shown in Annex 1.

Some data used for this analysis were collected previously by the Centers for Infectious Disease Research in Zambia (CIDRZ) and shared with DPCP through a data-sharing agreement.

Data analysis

Data were analyzed using Excel software. For the costing data, we used a micro-costing method for analysis, in which the quantity of resources (Q) was multiplied by their unit prices (P) to estimate the total cost — i.e., Q x P = total cost.

Similar to the baseline analysis, the resource use data were collected from the perspective of the health system. Hence no patient or household-level costs, such as transport costs to travel to receive services, were collected. Also, the actual prices of the vaccine and other resources were used in the analysis, even though the vaccines were donated to the Zambian government regardless of their funding source.

Also similar to the baseline, capital equipment costs (such as for cold chain equipment and vehicles) for items with a useful life over one year were annualized over their assumed useful life using a straight-line depreciation method (i.e., annual depreciation is equal to the price to buy the same capital equipment in 2016 divided by years of useful life). Assumptions on useful life were obtained from the country's most recent immunization comprehensive multi-year plan. Costs for shared resources were allocated to the immunization program based on the reported estimate of the share of the resource that was used by the immunization program, as described in Table 5 below.

We asked staff at each HF to provide estimates of these shares — for example, they provided the estimates of the share of cold chain space used by the immunization program if other products were stored in the refrigerators; for vehicles, we used the distance driven and the number of days per month dedicated to the immunization program to allocate costs; for staff, we used the percentage of time reported as devoted to immunization program activities.

Incremental costs or savings associated with the switch to using 5-dose MR vials were estimated for each cost component (transport, storage, waste disposal, human resources, vaccines, and immunization supplies), as shown in Table 5 below. All costs were reported in 2016 in US dollars (USD). Annual incremental costs or savings were estimated and reported.

9 World Health Organization. PQS catalogue, prequalified devices and equipment, product list. Available at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=17. Vaccine price data. Available at: https://www.unicef.org/supply/index_57476.html

Table 5: Cost components included if these costs changed because of the switch to using 5-dose MR vaccine vials

Cold chain costs	Transport costs for vaccine collection	Outreach costs (excluding human resource costs)	Waste disposal costs	Human resource costs	Vaccines and supplies costs
Depreciation cost for refrigerators, freezers, cold boxes, and vaccine carriers used for storing vaccines	Public transport costs and costs of hiring private vehicles for collecting vaccines	Depreciation of vehicles owned by the MOH that are used during outreach sessions	Depreciation costs for incinerators	Cost of staff time for providing fixed immunization services	Cost of vaccines used
Energy costs for running the refrigerators used for storing vaccines or freezers used for making ice packs	Depreciation of vehicles owned by the MOH that are used for collecting vaccines	Fuel costs for outreach sessions	Cost for fuel used for burning sharps waste	Cost of staff time for providing outreach immunization services	Cost of syringes used
	Fuel costs for the vehicles owned by the MOH that are used for collecting vaccines	Costs of hiring private vehicles for outreach		Cost of staff time for collecting vaccines	Cost of safety boxes used
	Per diems paid for trips to collect vaccines	Per diems paid for outreach sessions		Cost of staff time for forecasting vaccine demand, managing immunization stock, and reporting	

All changes in costs were estimated for each HF and then averaged for all HFs. We present the average costs per HF, including data from HFs with non-zero estimates only (i.e., average costs for HFs where costs had changed) and also the average costs for all HFs.

Additional total costs or savings per HF in the intervention districts, which excluded the value of vaccines and injection equipment, were calculated as:

Incremental annual total costs or savings per facility =

Incremental cold chain costs + incremental costs or savings for transport for vaccine collection + incremental costs or savings for outreach + incremental costs or savings for waste disposal + incremental costs or savings for human resources

The baseline resource use, as reported in the baseline costing surveys conducted in May 2017, were compared with the endline resource use reported in the surveys conducted in May 2018, and were used to determine the incremental change in resource use. These incremental costs of savings attributable to the switch to 5-dose MR vials were estimated as:

Incremental costs for cold chain =

Annualized capital cost of any new refrigerator or vaccine carrier provided specifically due to the additional capacity requirements associated with the switch to using 5-dose MR vials + annual energy costs to run the refrigerator

Incremental costs or savings for transport =

[(Number of trips at endline – number of trips at baseline) x cost per vaccine collection trip at baseline, excluding human resource and per diem costs] +

[(Number of staff traveling together to collect vaccines at endline – number of staff traveling together to collect vaccines at baseline) x per diem rate per trip x (number of trips at endline – number of trips at baseline)]

Incremental costs for immunization waste disposal =

(Number of times per month waste was disposed at endline – number of times per month waste was disposed of at baseline) x baseline waste disposal cost per occurrence

Incremental costs or savings for outreach =

(Number of staff traveling for outreach sessions at endline – number of staff traveling for outreach at baseline) x per diem costs per person at baseline for staff attending outreach sessions x number of outreach sessions held at baseline

Incremental costs or savings for human resources =

*Salary rate * ∑ [(frequency of conducting an immunization activity at endline – frequency of conducting this same immunization activity at baseline) x time spent on this activity at baseline +*

(Time spent conducting an immunization activity at endline – time spent conducting this same immunization activity at baseline) x frequency of conducting this same activity at baseline +

(Number of staff conducting an activity at endline – number of staff conducting this same activity at baseline) x baseline frequency of conducting this activity x baseline time spent on this activity

The changes in human resource costs for each immunization activity listed in Table 5 (where the change was specifically attributable to the switch to 5-dose MR vials) were summed to estimate the total change in human resources costs per facility.

The key metrics for the endline costing study were the incremental cost or savings per MR vaccine dose used when using the 5-dose vials. This metric was estimated for each facility as:

Incremental cost per MR vaccine dose used =

Incremental annual total costs for the facility / number of MR vaccine doses used by the facility

Note that because of a lack of good baseline administrative data on the number of children vaccinated and the number of 10-dose MR vaccine vials used, and because of the challenge of attributing changes in doses used or the number of children vaccinated solely to the change in the vial size for MR vaccine, the number of additional children vaccinated following the change to 5-dose MR vials could not be directly estimated. Hence the incremental costs estimated above are based on total number of doses and children vaccinated, rather than incremental number of doses administered or children vaccinated.

We used the vaccine stock data collected by the project as described in the section above on administrative data collection. Using the available data for each HF, we calculated the monthly average quantity of vaccines used and wasted, and multiplied this by 12 to calculate annual estimates. Forty of the 57 intervention HFs had stock data for the 11-month period, while the remaining 17 HFs had between five and 10 months of data.

Limitations

This analysis has several limitations. First, the data collected through the interviews is self-reported by staff based on their best knowledge. Some of the self-reported data were validated by observation, such as cold chain equipment available at the health facility, while other data were harder to validate through observation.

Specifically, human resource time use was self-reported and could not be validated, yet this is also the largest cost driver of all the incremental costs reported, excluding vaccine costs. Some of the values reported on either the frequency of conducting immunization sessions or the time spent on these activities at endline appeared to be incorrect but could not be validated or corrected, hence they were accepted as reported. Therefore, these values represent some of the outliers in our data that may overestimate the additional costs attributable to the switch to 5-dose MR vials.

In addition, the costing questionnaire was designed so that each staff member would self-report his or her own time use, but during data collection visits, data collectors reported that they often found only one staff available at the health facilities and other staff were not available. So the available staff member had to report time use data for all staff, creating further challenges with the data. However, the finding that human resource costs are the largest share of costs is consistent with findings from previous costing studies.

Furthermore, some of the increase in time use for some activities reported by staff, such as completing reports, may have been due to some study-related data reporting, which was necessary because of the inadequacy of the routine program data, especially on vaccine stock data. Therefore, the increase in human resource time use may be overestimated.

For the stock data, not all facilities in the costing sample had complete data for the 11 months of the study. The available data were used to estimate the average quantities of vaccines used and administered, extrapolated up to an annual estimate. Seventeen out of the 57 health facilities had less than 11 months of data, hence the extrapolation to annual estimates may over- or underestimate these quantities, depending on how representative the months with data were of monthly vaccine usage levels.

04 | Findings

Coverage

Coverage, timeliness, and dropout rates were calculated through the household survey.

Administrative data collected throughout implementation were used to calculate administrative coverage, session size, frequency of immunization sessions, and frequency of MCV included in sessions.

Factors that influence MCV1 and MCV2 coverage, equity, and timeliness were analyzed based on the key informant interview data with health care workers.

Data have been triangulated to inform a holistic understanding of the factors that contribute to the coverage rates, equity, and timeliness of vaccination.

Household survey sample description

In Table 6 and Table 7 (pages 21 and 22), the samples are presented by key background characteristics to illustrate any variation between the intervention and control groups at baseline and endline. There are notable differences in background characteristics between the intervention and control study arms at both survey periods for both cohorts.

For Cohort 1 (12 months to 23 months of age), the results indicate statistically significant differences ($p<.05$) in wealth, location (urban/rural), caregiver's education and occupation, and distance from the closet HF or vaccination site between the intervention and control groups during both survey periods (Table 6). The intervention group respondents were more likely to be urban, educated, from households with higher wealth quintile, and located further from a health facility or a vaccination site during both the surveys. Similar differences in the background characteristics of the sample between intervention and control areas was observed for Cohort 2 (24 months to 35 months of age) during both survey periods (Table 7).

Among Cohort 1 in both the intervention and control groups, between baseline and endline surveys, there was a statistically significant ($p<.05$) increase in wealth, decrease in the household's distance to the nearest health facility, and change in the occupation of the caregiver (the p-values shown in Table 6). In the control group, the education of the caregiver also increased statistically significantly ($p<.05$) among Cohort 1.

A similar change in the background characteristics between baseline and endline surveys were observed in Cohort 2.

Table 6: Demographic characteristics of children aged 12–23 months included in each study arm

	Baseline			Endline		
	Intervention (N=1907)	Control (N=1960)	p-value*	Intervention (N=1962)	Control (N=1965)	p-value*
Background characteristic	%	%		%	%	
Sex of child						
Male	49.3%	49.4%	0.953	49.2%	49.5%	0.885
Female	50.7%	50.6%		50.8%	50.5%	
Wealth						
Lowest	18.4%	24.4%	<0.001	12.4%	27.9%	<0.001
Second	18.4%	24.5%		17.6%	20.8%	
Middle	19.7%	21.9%		17.1%	19.1%	
Fourth	20.3%	14.3%		25.1%	19.9%	
Highest	23.3%	14.9%		27.8%	12.4%	
Residence						
Rural	79.7%	91.0%	<0.001	79.9%	90.5%	<0.001
Urban	20.4%	9.0%		20.1%	9.5%	
Caregiver's education						
No education	8.7%	13.7%	<0.001	10.8%	19.2%	<0.001
Some primary	44.5%	49.6%		40.8%	48.5%	
Completed primary	15.2%	13.2%		14.8%	9.9%	
Some secondary	22.6%	19.2%		24.4%	17.8%	
Completed secondary	7.2%	3.3%		6.7%	3.7%	
More than secondary	1.8%	1.0%		2.6%	0.9%	
Mother's occupation						
Professional (private/ public sector)	2.7%	1.4%	<0.001	3.7%	1.3%	<0.001
Agriculture	52.4%	58.9%		42.8%	48.8%	
Self-employed/business owner	11.5%	8.2%		10.5%	4.7%	
Casual work/petty trade	5.4%	5.9%		10.6%	12.7%	
Unemployed	28.0%	25.0%		32.3%	32.5%	
Distance from closest health facility or vaccination site						
Less than 10 minutes	15.4%	16.1%	<0.001	14.2%	26.7%	<0.001
Less than 30 minutes	25.8%	29.4%		29.9%	29.1%	
Less than 1 hour	21.6%	29.8%		31.6%	29.5%	
1-2 hours	31.5%	20.5%		20.2%	12.8%	
More than 2 hours	5.7%	4.2%		4.2%	1.9%	

**p-values are from Wald's statistics testing the difference between intervention and control groups.*

Table 7: Demographic characteristics of children aged 24–35 months included in each study arm

	Baseline			Endline		
	Intervention (N=1920)	Control (N=1867)	p-value*	Intervention (N=1931)	Control (N=1937)	p-value*
Background characteristic	%	%		%	%	
Sex of child						
Male	48.2%	47.5%	0.634	45.9%	49.6%	0.022
Female	51.8%	52.5%		54.1%	50.4%	
Wealth						
Lowest	15.0%	24.8%	<.001	11.1%	26.1%	<.001
Second	19.2%	22.6%		16.3%	20.9%	
Middle	20.2%	22.8%		19.8%	19.3%	
Fourth	20.0%	14.5%		26.0%	19.9%	
Highest	25.6%	15.4%		26.9%	13.8%	
Residence						
Rural	79.6%	91.1%	<.001	79.5%	90.9%	<.001
Urban	20.4%	8.9%		20.5%	9.1%	
Caregiver's education						
No education	9.3%	14.0%	<.001	11.0%	18.9%	<.001
Some primary	46.9%	49.2%		43.7%	46.4%	
Completed primary	16.6%	14.5%		14.8%	12.2%	
Some secondary	20.6%	16.9%		22.6%	17.9%	
Completed secondary	8.2%	4.3%		5.7%	3.1%	
More than secondary	1.4%	1.0%		2.2%	1.6%	
Mother's occupation						
Professional (private/public sector)	3.2%	2.0%	<.001	3.2%	1.6%	<.001
Agriculture	53.3%	58.9%		46.0%	49.5%	
Self-employed/business owner	13.7%	10.0%		9.6%	6.5%	
Casual work/petty trade	5.3%	7.7%		9.7%	13.0%	
Unemployed	24.5%	21.4%		31.5%	29.6%	
Distance from closest health facility or vaccination site						
Less than 10 minutes	15.2%	16.0%	<.001	14.5%	27.5%	<.001
Less than 30 minutes	27.0%	30.7%		29.5%	28.8%	
Less than one hour	21.1%	29.0%		29.5%	29.7%	
1-2 hours	30.8%	20.5%		21.5%	12.2%	
More than 2 hours	6.0%	3.9%		5.0%	1.8%	

**p-values are from Wald's statistics testing the difference between intervention and control groups.*

Vaccination card availability

In the household coverage survey, the retention of home-based record (vaccination cards) was assessed pre- and post-intervention. Respondents were asked whether they had ever received a vaccination card for their child and if that card was available on the day of the interview. Table 8 and Table 9 below show the unadjusted point estimates for card availability for each cohort. Card prevalence was relatively high among children aged 12 months to 23 months and those aged 24 months to 35 months at both survey periods and in both study arms.

Card availability on the day of the interview increased in both cohorts at endline. In Cohort 1 (children aged 12 months to 23 months), card availability increased statistically significantly from 73% at baseline to 85% at endline among those in the intervention arm ($p<0.001$). Similarly, card availability in the control arm statistically significantly increased from 72% at baseline to 85% at endline ($p<0.001$).

Cohort 2 had similar increases in card availability on the day of the interview, increasing statistically significantly from 63% at baseline to 76% at endline for children in the intervention arm ($p<0.001$); in the control arm, card availability increased from 63% to 75% between the two survey periods ($p<0.001$).

Table 8: Card availability for children aged 12–23 months

	Baseline			Endline		
	Intervention (n=1907)	Control (n=1960)	p-value	Intervention (n=1962)	Control (n=1965)	p-value
Card available today	73.2%	71.5%	0.32	84.6%	84.8%	0.86

Table 9: Card availability for children aged 24–35 months

	Baseline			Endline		
	Intervention (n=1920)	Control (n=1867)	p-value	Intervention (n=1931)	Control (n=1937)	p-value
Card available today	63.4%	63.3%	0.97	76.4%	75.3%	0.49

Coverage among children aged 12 months to 23 months

Coverage of MCV1 and MCV2 was assessed among children aged 12 months to 23 months and 24 months to 35 months, respectively. Coverage of bacille Calmette-Guerin (BCG) vaccine, oral poliovirus vaccine (OPV) 1-3, Penta vaccine 1-3, pneumococcal conjugate vaccine (PCV) 1-3, and Rotavirus (Rota) vaccine 1 and 2 was also assessed in children aged 12 months to 23 months and those aged 24 months to 35 months. For more information on coverage of these vaccinations, the unadjusted point estimates are presented in Annex 3 and Annex 4.

Vaccination data were obtained via two sources: card review and caregiver's recall. If a vaccination card was not available at the time of the interview or there was no information on the card indicating a vaccination was given, the caregiver was then asked to recall whether or not the child received that vaccination.

Table 10 below shows the unadjusted coverage rates for Penta1 and MCV1 pre- and post-intervention in children aged 12 months to 23 months within the sample. As the table indicates, there was a sta-

tistically significant increase in unadjusted Penta1 coverage at endline based on card review for both those in the intervention arm (71% to 83%, p<0.001) and in the control arm (70% to 82%, p<0.001). However, there was no statistically significant change in overall Penta1 coverage based on card review and caregiver recall in either study arm (p=.057 and p=.730, respectively).

Overall MCV1 coverage based on both card review and caregiver's recall increased statistically significantly from 83% at baseline to 91% at endline in the intervention arm (p<0.001). Similarly, MCV1 coverage based on both sources increased statistically significantly in the control arm from 83% at baseline to 88% at endline (p<0.001).

Table 10: Unadjusted coverage of Penta1 and MCV1 in children aged 12–23 months

	Intervention			Control		
	Baseline (N=1907)	Endline (N=1962)	p-value	Baseline (N=1960)	Endline (N=1965)	p-value
Penta1						
Vaccination card	71.3%	83.0%	p<.001	69.8%	82.3%	p<.001
Caregiver's recall	27.2%	16.2%	p<.001	29.5%	17.0%	p<.001
Both sources	98.5%	99.2%	p=.057	99.3%	99.2%	p=.730
MCV1						
Vaccination card	61.7%	77.1%	p<.001	61.6%	77.7%	p<.001
Caregiver's recall	21.6%	13.9%	p<.001	21.4%	10.7%	p<.001
Both sources	83.3%	91.0%	p<.001	83.1%	88.4%	p<.001

Table 11 below shows the adjusted MCV1 coverage rates pre- and post-intervention among children aged 12 months to 23 months by the two sources — card and caregiver's recall — and by both sources combined.

Adjusted coverage rates for MCV1 based on vaccination card review increased statistically significantly from baseline to endline in both study arms. In the intervention arm, MCV1 adjusted coverage rates significantly increased by 14 percentage points from baseline (62%) to endline (76%) (p<.001). Similarly, in the control arm, MCV1 coverage increased from 63% to 77% (p<.001) across the two survey periods. However, the difference in the changes in the coverage rates between the two study arms (i.e., the intervention effect or diff-in-diff) were not statistically significant (p=.869).

MCV1 coverage based on card review and caregiver's recall increased statistically significantly between baseline and endline. In the intervention arm, MCV1 coverage increased statistically significantly from 82% pre-intervention to 92% post-intervention. In the control arm, there was also a statistically significant, but smaller, change in MCV1 coverage from 84% pre-intervention to 89% post-intervention. A difference of 4.9% in adjusted MCV1 coverage between the intervention and control arms at endline was statistically significant (p<.001) when considering both sources to estimate MCV1 coverage..

Table 11: Adjusted MCV1 coverage in children aged 12–23 months

Source of data	Study arm	Baseline	Endline	Difference between baseline and endline (absolute change)			Intervention effect			
				diff	95% CI		diff-in-diff	95% CI		p-value
Vaccination card	Intervention	61.8%	75.6%	13.8%	11.8%	15.8%	0.2%	-2.3%	2.7%	.869
	Control	63.1%	76.7%	13.6%	11.8%	15.4%				
Vaccination card and caregiver's recall	Intervention	82.1%	91.6%	9.6%	8.1%	11.0%	4.9%	0.3%	6.6%	<.001
	Control	84.2%	88.8%	4.7%	3.4%	6.0%				

Coverage among children aged 24 months to 35 months

Unadjusted coverage of MCV2 among children 24 months to 35 months are presented in Table 12. There was a statistically significant increase in unadjusted MCV2 coverage rates, based on both card review and caregiver's recall, from baseline to endline in both study arms. In the intervention arm, the unadjusted MCV2 coverage rates increased from 52% at baseline to 70% at endline (p<.001). Similarly, in the control arm, the unadjusted MCV2 coverage rates increased from 58% to 67% at endline (p<.001).

Table 12: Unadjusted MCV2 coverage in children aged 24–35 months

	Intervention			Control		
	Baseline (N=1920)	Endline (N=1931)	p-value	Baseline (N=1867)	Endline (N=1937)	p-value
Vaccination card	29.2%	47.5%	<.001	28.2%	45.5%	<.001
Caregiver's recall	22.3%	22.8%	.742	29.8%	21.6%	<.001
Both sources	51.5%	70.3%	<.001	58.0%	67.1%	<.001

Based on card review, the adjusted coverage rates of MCV2 among children aged 24 months to 35 months increased during the survey period across both study arms (Table 13). In the intervention arm, there was a statistically significant increase in adjusted MCV2 coverage (based on card review) pre- and post-intervention, increasing from 24% to 39% (p<.001). The control arm saw a similar statistically significant increase (26% to 41%) during the study period (p<.001). However, the intervention effect was not statistically significant for the adjusted MCV2 coverage from card review (p=.777).

Adjusted coverage of MCV2 based on both card review and caregiver's recall increased significantly between pre- and post-intervention in both study arms. In the intervention arm, there was a statistically significant increase in the adjusted MCV2 coverage, increasing from 43% pre-intervention to 56% post-intervention (p<.001). In the control arm, the adjusted MCV2 coverage also demonstrated a statistically significant increase from 45% pre-intervention to 64% post-intervention (p<.001). A difference of 3.5% in adjusted MCV2 coverage between the intervention and control arms at the endline was weakly stasticially significant (p=.007).

Table 13: Adjusted MCV2 coverage in children aged 24–35 months

Source of data	Study arm	Baseline	Endline	Difference between baseline and endline (absolute change)			Intervention effect			
				diff	95% CI		diff-in-diff	95% CI		p-value
Vaccination card	Intervention	24.3%	39.4%	15.1%	13.1%	17.2%	-0.4%	-3.0%	2.2%	.777
	Control	25.8%	41.4%	15.5%	13.4%	17.6%				
Vaccination card and caregiver's recall	Intervention	43.0%	55.8%	12.8%	10.7%	14.9%	3.5%	1.0%	6.1%	.007
	Control	45.0%	64.2%	19.3%	7.2%	11.3%				

Coverage by travel time

There was no evidence to conclude that there was a differential effect of the intervention due to travel time from the child's home to the HF (Table 14 and Table 15).

Table 14: MCV1 coverage in children aged 12–23 months by distance to facility

		Baseline	Endline	Difference between baseline and endline (absolute change)				Intervention effect			
				diff	95% CI		p	diff-in-diff	95% CI		p-value
Close to facility (30 minutes or less)	Intervention	55.6%	81.1%	25.5%	9.5%	41.5%	.002	-0.69%	-5.5%	4.1%	.779
	Control	55.7%	81.8%	26.2%	10.2%	42.2%	.001				
Far from facility (more than 30 minutes)	Intervention	54.8%	81.0%	26.1%	10.0%	42.2%	.001	-0.13%	-4.9%	4.7%	.957
	Control	56.1%	82.3%	26.2%	10.6%	41.8%	.001				
Differential effect due to travel time								0.56%	-5.4%	6.5%	.854

Table 15: MCV2 coverage in children aged 24–35 months by distance to facility

		Baseline	Endline	Difference between baseline and endline (absolute change)				Intervention effect			
				diff	95% CI		p	diff-in-diff	95% CI		p-value
Close to facility (30 minutes or less)	Intervention	56.9%	75.9%	19.0%	0.37%	37.6%	.046	2.1%	-3.5%	7.7%	.470
	Control	57.1%	74.0%	16.9%	-3.0%	7.7%	.093				
Far from facility (more than 30 minutes)	Intervention	56.8%	71.6%	14.7%	-5.5%	35.0%	.115	-2.2%	-7.8%	3.5%	.454
	Control	57.6%	74.0%	16.4%	-3.1%	35.9%	.098				
Differential effect due to distances								-3.8%	-10.7%	3.1%	.281

Timely coverage

Timeliness of vaccine receipt was defined as having received MCV1 and/or MCV2 vaccination within three days before or four weeks after the optimal due date (9 months and 18 months of age, respectively) and was calculated in days from birth date to reception of vaccination. The timeliness analysis only includes children who have a vaccination card with dates documented for given vaccinations.

As Table 16 indicates, adjusted timely coverage of MCV1 among children aged 12 months to 23 months increased between pre- and post-intervention across both study arms. The adjusted timely coverage of MCV1 increased statistically significantly from 47% to 73% (p=.005) in the intervention arm. Similarly, in the control arm, the adjusted timely coverage of MCV1 increased statistically significantly from 48% to 76% (p=.001) post-intervention. While there was a statistically significant increase in adjusted timeliness, there was no evidence of an intervention effect among this group (p=.273).

Table 16: Timeliness (by 9 months plus 4 weeks) of MCV1 administration in children aged 12–23 months

		Baseline	Endline	Difference between baseline and endline (absolute change)				Intervention effect			
				diff	95% CI		p-value	diff-in-diff	95% CI		p-value
Timeliness of MCV1 in children with cards and an MCV1 vaccination date recorded only	Intervention	47.4%	72.6%	25.2%	7.6%	42.8%	.005	-2.5%	-7.1%	2.0%	.273
	Control	48.1%	75.9%	27.8%	10.9%	44.7%	.001				

The proportion of children aged 12 months to 23 months who received MCV1 by 12 months of age increased between survey periods in the intervention and control arms (Table 17). In the intervention arm, adjusted MCV1 reception by age 12 months increased from 49% pre-intervention to 78% post-intervention. In the control arm, similar increases pre- and post-intervention can be noted at 50% and 80%, respectively. These increases between survey periods are statistically significant changes (p=.001 and p<.001, respectively). However, there was no statistically significant intervention effect for this indicator (p=.652).

Table 17: Percentage of children aged 12–23 months who received MCV1 by 12 months

	Baseline	Endline	Difference between baseline and endline (absolute change)				Intervention effect			
			diff	95% CI		p-value	diff-in-diff	95% CI		p-value
Intervention	48.5%	77.7%	29.1%	12.4%	46.0%	.001	-0.9%	-5.0%	3.1%	.652
Control	49.9%	80.0%	30.1%	13.8%	46.5%	<.001				

Timely coverage of MCV2 is defined as children 24 months to 35 months who received timely MCV1 and MCV2 vaccinations. As Table 18 shows, there was no statistically significant change in the adjusted timely coverage rates of MCV2 among children 24 months to 35 months pre- and post-intervention in either study arm. Additionally, there was no statistically significant intervention effect (p=.421).

Table 18: Timeliness (by 18 months plus 4 weeks) of MCV2 administered in children aged 24–35 months

		Baseline	Endline	Difference between baseline and endline (absolute change)				Intervention effect			
				diff	95% CI		p-value	diff-in-diff	95% CI		p-value
Timeliness of MCV2 in children with cards and an MCV2 vaccination date recorded only	Intervention	57.1%	55.6%	-1.5%	-2.8%	2.5%	.910	3.2%	-4.6%	1.1%	.421
	Control	57.6%	52.9%	-4.7%	-3.2%	2.2%	.731				

There was no statistically significant change in the adjusted proportion of children 24 months to 35 months of age who received MCV1 by 12 months and MCV2 by 24 months between baseline and endline in either study arm (Table 19).

Table 19: Percentage of children aged 24–35 months who received MCV1 by 12 months and MCV2 by 24 months

	Baseline	Endline	Difference between baseline and endline (absolute change)				Intervention effect			
			diff	95% CI		p-value	diff-in-diff	95% CI		p-value
Intervention	52.5%	67.5%	14.9%	-6.8%	36.7%	.179	1.4%	-3.8%	6.7%	.591
Control	53.6%	67.1%	13.5%	-8.5%	35.5%	.230				

Dropout rates

Adjusted dropout rates between Penta1 and MCV1 vaccines among children aged 12 months to 23 months decreased from baseline to endline in both study arms. There was a statistically significant decrease in adjusted dropout rates, based on children with cards, from 13% pre-intervention to 7% post-intervention in the intervention study arm (p<.001). For those in the control study arm, the adjusted dropout rates among children with cards also decreased statistically significantly from 12% to 7% (p<.001). Adjusted dropout rates based on cards and caregiver recall also decreased statistically significantly post-intervention, decreasing from 15% to 8% in the intervention arm (p<.001) and from 14% to 9% in the control arm (p<.001). However, there was no statistically significant intervention effect on dropout rates between Penta1 and MCV1 (based on cards) (p=.992). A 2.6 percentage-point reduction in the adjusted drop-out rate from Penta1 to MCV1 in the intervention area is attributable to the intervention (p=.010). See Table 20.

Table 20: Dropout rates between receipt of Penta1 and MCV1 vaccines among children aged 12–23 months

Source of data	Study arm	Baseline	Endline	Difference between baseline and endline			Intervention effect			
				diff	95% CI		diff-in-diff	95% CI		p-value
Vaccination card	Intervention	13.0%	7.2%	-5.8%	-7.5%	-4.1%	.01%	-1.9%	2.0%	.992
	Control	12.4%	6.6%	-5.8%	-7.4%	-4.1%				
Vaccination card and Caregiver's recall	Intervention	15.3%	7.9%	-7.3%	-9.1%	-5.6%	-2.6%	-4.7%	-0.6%	.010
	Control	14.0%	9.3%	-4.7%	-6.3%	-3.1%				

Similarly, there was a decrease in the adjusted dropout rates of MCV1 to MCV2 among children aged 24–35 months pre- and post-intervention in both study arms. In both the intervention and control arms, the adjusted dropout rates of MCV1 to MCV2, based on cards, decreased by 15 percentage points (p<.001).

The intervention effect on dropout rates between receiving MCV1 and MCV2 was statistically significant when both cards and caregiver recall were combined (p=.038). A 3.6-percentage-point greater reduction in the dropout rate was observed in the intervention area compared to the control area. See Table 21.

Table 21: Dropout rates between MCV1 and MCV2 receipt in children aged 24–35 months

Source of data	Study arm	Baseline	Endline	Difference between baseline and endline			Intervention effect			
				diff	95% CI		diff-in-diff	95% CI		p-value
Vaccination card	Intervention	44.9%	30.1%	-14.8%	-18.1%	-11.5%	0.3%	-3.7%	4.2%	.900
	Control	43.3%	28.2%	-15.1%	-18.2%	-12.0%				
Vaccination card and Caregiver's recall	Intervention	36.4%	21.9%	-14.5%	-17.2%	-11.8%	-3.6%	-6.9%	-0.2%	.038
	Control	33.8%	22.8%	-11.0%	-13.6%	-8.4%				

In addition to the household coverage survey, other data collected through key informant interviews and DPCP monitoring forms allowed the project to analyze administrative coverage rates and other indicators related to coverage, including session frequency and size.

Administrative coverage

Administrative coverage rates were calculated using the DPCP monitoring data, although there are known discrepancies in the target populations (Table 22). There was no statistically significant difference between study arms for any of the doses measured.

Table 22: Adjusted administrative coverage rates for Penta and MR vaccines

	Intervention	Control	Difference between intervention and control
Penta1	105.8%	92.1%	13.7%
Penta2	102.9%	90.2%	12.6%
Penta3	96.0%	84.0%	11.9%
MCV1	103.3%	92.9%	10.4%
MCV2	73. 6%	71.7%	1.9%

Session frequency

Based on KIIs, 38 of 42 HCWs using 5-dose MR vials reported offering MR vaccines at every fixed session regardless of the number of children. By contrast, over 50% of respondents using 10-dose vials indicated that they waited for a minimum of five children before offering the MR vaccine and a minimum of 10 children before offering the BCG vaccine.

All 42 HCWs using 5-dose MR vials reported offering MR vaccines at every outreach session.

All HCWs, whether they used 10-dose or 5-dose vials of MR vaccine, stated that BCG was not given at every fixed and outreach session. It was given on specific days, such as post-natal sessions at health facilities or on a designated day per month, to ensure there were enough children to limit wastage.

> **"Actually, the issue of referring mothers to another session is not there anymore; it has reduced. Mothers are not worried about them being able to get the vaccines because of the number of children available."**
>
> — HCW using 5-dose MR vaccines

When asked whether their practices had changed since the introduction of the 5-dose vial, HCWs replied that they were less concerned about MR vaccine wastage and felt more comfortable opening vials to vaccinate children.

By contrast to responses collected in KIIs, project monitoring data collected by HCWs showed that MR vaccine was administered at a same similar average frequency in fixed and outreach sessions regardless of vial size (see Table 23).

Sessions where Penta and/or MR vaccines were given were used as a proxy for a vaccination session being held, as data were not collected on all vaccines administered on the DPCP form. The average number of sessions where Penta and/or MR were administered was statistically significantly higher in HFs using 10-dose vials (p=.03). On average, both intervention and control facilities conducted more outreach sessions (with or without MR vaccine) than fixed sessions.

Table 23: Average number of sessions per month per HF

		Intervention	Control	Difference between intervention and control
Average number of times per month MR vaccines administered	Fixed	1.86	1.67	0.19
	Outreach	2.64	2.86	-0.23
	Total	4.50	4.54	-0.04
Average number of times per month Penta and/or MR vaccines administered	Fixed	2.48	2.59	-0.12
	Outreach	3.02	3.49	-0.47
	Total	5.50	6.09	-0.59*

* $p<0.05$

There were no statistically significant differences in average session frequency between the study arms depending on residence, distance to the district capital, or HF size (Table 24).

Table 24: Average number of sessions per month where MR vaccine was given, by type of HF

		Intervention	Control	Difference between intervention and control
Residence	Urban	5.30	4.13	1.17
	Rural	4.52	4.67	-0.14
	Difference in rural vs urban effect			-1.31
Distance to district	Near: 0-39 km	4.47	4.36	0.11
	Mid: 40-99 km	4.34	4.38	-0.05
	Far: 100+ km	4.81	5.14	-0.33
	Difference in mid vs near effect			-0.16
	Difference in far vs near effect			-0.44
	Difference between far and mid effect			-0.28
Health facility size	Large: 500+ target pop	5.46	4.51	0.95
	Medium: 200 to 499 target pop	4.76	4.83	-0.07
	Small: 0 to 199 target pop	3.83	4.17	-0.34
	Difference between medium vs large effect			-1.02
	Difference between small vs large effect			-1.29
	Difference between small vs medium effect			-0.27

Session size

There was no significant difference in the average number of children vaccinated with MR vaccine per session between the control and intervention HFs (Table 25). By contrast, the number of children immunized with Penta1, Penta2, and Penta3 was larger in the intervention arm compared to the control (p=.047). Fixed MR sessions were larger than outreach sessions in both arms.

Table 25: Average number of children vaccinated per session by vaccine received

		Intervention	Control	Difference between intervention and control
MR	Fixed	10.73	10.47	0.26
	Outreach	8.69	9.96	-1.27*
	Total	9.86	10.32	-0.46
Penta	Fixed	21.24	14.57	6.67***
	Outreach	14.87	15.75	-0.88
	Total	18.29	15.65	2.64*

* p<0.05, ** p<0.01, *** p<0.001

There was little difference in average MR or Penta session size by residence, distance to the district capital, or health facility size (Table 26 and Table 27).

Table 26: Average number of children immunized with MCV1 and MCV2 per session by type of HF

		Intervention	Control	Difference between intervention and control
Residence	Urban	11.91	13.94	-2.03
	Rural	9.86	10.19	-0.32
	Difference in rural vs urban effect			1.70
Distance to district	Near: 0-39 km	9.72	10.23	-0.51
	Mid: 40-99 km	10.89	11.18	-0.28
	Far: 100+ km	8.54	9.22	-0.68
	Difference in mid vs near effect			0.22
	Difference in far vs near effect			-0.17
	Difference between far and mid effect			-0.40
Health facility size	Large: 500+ Target Pop	8.90	8.79	0.11
	Medium: 200 to 499 Target Pop	9.76	11.17	-1.40
	Small: 0 to 199 Target Pop	10.37	9.99	0.38
	Difference between medium vs large effect			-1.52
	Difference between small vs large effect			0.27
	Difference between small vs medium effect			1.79

Table 27: Average number of children immunized with Penta1, Penta2, or Penta3 per session by type of HF

		Intervention	Control	Difference between intervention and control
Residence	Urban	20.72	7.73	12.99
	Rural	18.46	16.21	2.25
	Difference in rural vs urban effect			-10.74
Distance to district	Near: 0-39 km	18.61	13.71	4.89*
	Mid: 40-99 km	18.49	19.44	-0.95
	Far: 100+ km	17.06	12.14	4.91
	Difference in mid vs near effect			-5.84*
	Difference in far vs near effect			0.02
	Difference between far and mid effect			5.87
Health facility size	Large: 500+ Target Pop	16.73	10.82	5.91
	Medium: 200 to 499 Target Pop	17.61	17.06	0.55
	Small: 0 to 199 Target Pop	19.73	15.90	3.83
	Difference between medium vs large effect			-5.36
	Difference between small vs large effect			-2.09
	Difference between small vs medium effect			3.28*

* p<0.05, ** p<0.01, *** p<0.001

Wastage

As noted in the methods section, retrospective data to calculate wastage prior to implementation were either missing or suggested high levels of inaccuracy, so wastage rates could not be calculated at baseline. Throughout implementation, data on the number of vials opened and number of children immunized with MCV1 and MCV2 per session were collected on the DPCP form to calculate open vial wastage rates. Using the same form at the end of each month, HCWs reported on closed vial wastage. We also explored HCW perceptions and concerns about wastage as documented through key informant interviews.

"Coverage rates are more important [than wastage], as coverage confirms how many children you have vaccinated and it assures us that we may not have a disease outbreak."

— HCW using 5-dose MR vaccine

Open vial vaccine wastage

The KIIs indicate that HCWs using either 10-dose or 5-dose MR vials stated that HF performance was measured by coverage and not wastage. All respondents using 10-dose or 5-dose MR vials at district and HF levels confirmed the importance of limiting wastage.

"The wastage is not much with MR 5-dose vial compared to the time we were using 10-dose vial. The wastage was high and this made us have high missed opportunities."

— HCW using 5-dose MR vaccine

Most HCWs using 5-dose MR vials mentioned that they discussed wastage with colleagues and supervisors and that their supervisors monitored wastage, and if wastage rates were higher than expected, they offered suggestions and strategies to mitigate wastage. None of the respondents reported having obligatory vaccine wastage targets.

"Yes, wastage rate has reduced this time we can open the vial. Even when we have two children, we only lose three doses, as compared to the time we were using 10-dose vial, which would make us lose eight doses."

— HCW using 5-dose MR vaccine

Most respondents using 5-dose MR vials believed wastage had declined through use of 5-dose vials. Respondents at the district level explained that districts did not have target wastage rates set for any vaccines but that HF staff used their judgement to determine the right amount of wastage. MCH coordinators and pharmacists stated that they cautioned HF staff when wastage was high.

When asked about what they do if HFs report high wastage rates, respondents explained that to avoid this trend of high wastage, particularly with BCG, district health officials advised HF staff to administer BCG vaccine only on a fixed day at a fixed session or give BCG when they go out for outreach sessions to help capture every child and avoid MOVs. Though wastage rates were still high at outreach sessions, MCH coordinators said that staff at HFs with small catchment populations preferred to give appointment dates for BCG to help ensure assembling sufficient children to minimize wastage.

"Yes, wastage has been reduced with the use of 5-dose vial compared to when we are using the 10-dose vial. Even when we have a low turnout of children, we can't waste a lot of dosages like it was when we were using the 10-dose vial."

— HCW using 5-dose MR vaccine

The analysis of the monitoring data indicated that MR vaccine wastage rates were similar during both fixed and outreach sessions. However, wastage for 10-dose MR vials was significantly higher at 30.53%, compared to 16.18% for 5-dose vials ($p<0.001$, Table 28).

Table 28: MR vaccine wastage rates by vaccination session type

		Intervention	Control	Difference between intervention and control
MR	Fixed	16.68	30.45	-13.77***
	Outreach	17.51	31.19	-13.68***
	Total	16.18	30.53	-14.35***

* p<0.05, ** p<0.01, *** p<0.001

As seen in Table 29, the difference in wastage rates between the intervention and control HFs varied by the size of the HF's target population. The reduction in wastage rates observed in the intervention HFs was greater in the large- and medium-sized HFs compared to the small HFs.

Table 29: MR vaccine wastage rates by type of HF

		Intervention	Control	Difference between intervention and control
Residence	Urban	19.23	24.14	-4.91
	Rural	15.78	30.60	-14.82***
	Difference in rural vs urban effect			-9.91
Distance to district capital	Near: 0-39 km	15.03	30.77	-15.75***
	Mid: 40-99 km	16.70	28.02	-11.32***
	Far: 100+ km	18.07	35.19	-17.12***
	Difference in mid vs near effect			4.43
	Difference in far vs near effect			-1.37
	Difference between far and mid effect			-5.80
Health facility size	Large: 500+ Target Pop	18.86	28.18	-9.32***
	Medium: 200 to 499 Target Pop	17.51	29.36	-11.85***
	Small: 0 to 199 Target Pop	13.44	32.36	-18.92***
	Difference between medium vs large effect			-2.53
	Difference between small vs large effect			-9.59*
	Difference between small vs medium effect			-7.06*

* p<0.05, ** p<0.01, *** p<0.001

Costing

The endline costing sample included 57 HFs located in the seven intervention districts where baseline data were collected. The tables below show the responses of the staff at each facility on whether any of these cost components had changed because of the switch to using 5-dose MR vials.

Table 30 shows that staff in 55 of the 57 HFs in the costing sample responded that their existing refrigerators had adequate capacity to store 5-dose MR vials and other vaccines, while staff in two HFs

said they did not; of these two HFs, staff in one reported that they received an additional refrigerator. However, discussions with the EPI logistician revealed that this additional refrigerator was provided for other reasons not related to the switch to 5-dose MR vials. Therefore, the costs for this refrigerator were excluded in this costing analysis.

In addition, staff in four out of the 57 HFs said that because of the switch to 5-dose MR vials, they did not have adequate capacity in the vaccine carriers used to transport vaccines from the district vaccine store, and staff in one out of the 57 said they did not have adequate capacity in the vaccine carriers or cold boxes when taking MR and other vaccines on outreach sessions. However, none of the staff reported that they had received additional vaccine carriers or cold boxes.

Table 30: Impact on the cold chain of switching from 10-dose to 5-dose MR vaccine vials — responses from staff in 57 intervention HFs in the endline costing sample

Question asked	Number of HFs responding	
	No	Yes
Since the 5-dose MR vials were introduced, has this facility had adequate refrigerator space required to store the 5-dose MR vials and other vaccines?	2	55
Did this facility receive any additional refrigerator(s) because you needed more refrigerator space to store the 5-dose MR vials and other vaccines?*	1**	1a
Since the 5-dose MR vials were introduced, has this facility had adequate space in the vaccine carriers or cold boxes to use when collecting the 5-dose MR vials and other vaccines from the district vaccine store?	4	53
Since the 5-dose MR vials were introduced, has this facility had adequate space in the vaccine carriers or cold boxes to use when taking the 5-dose MR vials and other vaccines for outreach?	1	56
Did this facility receive any additional vaccine carriers or cold boxes because they needed more of them to use to transport the 5-dose MR vials and other vaccines from the district or when going for outreach sessions?	5	0

* This question was only asked if the respondent answered "no" to the previous question.

** As noted above, discussions with the EPI logistician revealed that this refrigerator was not provided because of the switch to using 5-dose MR vaccine vials and hence is not included in the costing analysis.

Table 31 shows that of the 49 HFs that collected vaccines from the district vaccine store, staff in five of them reported that they either changed the frequency and/or number of trips made to collect vaccines, while staff of one HF said they had changed the number of staff traveling together on these trips. Two of these responses were outliers and seemed incorrect when comparing the baseline to the endline response, and hence were excluded from the analysis. In addition, staff in one HF said they had changed the mode of transport used: when 10-dose vials were used, they had used a government vehicle, but now they were using a hired vehicle. This change in mode of transport was excluded from the endline analysis.

Table 31: Impact on transport of switching from 10-dose to 5-dose MR vaccine vials — responses from staff in 49 intervention HFs in the endline costing sample that collected vaccines from the district vaccine stores

Question asked	Number of health facilities responding		Most common direction of change reported
	No	Yes	
Because of the switch to using 5-dose MR vials, did this health facility have to change the frequency at which it collects vaccines or the number of trips made to the district vaccine store?	44	5	Increase in frequency or number of trips to collect vaccines
Because of the switch to using 5-dose MR vials, did the health facility have to change the number of staff who travel together to collect vaccines?	48	1	Increase in number of staff traveling
Because of the switch to using 5-dose MR vials, did this health facility have to change the mode of transport that it uses on trips to collect vaccines?	48	1	Change from using government vehicle to using hired vehicle

Table 32 shows that because of the switch to using 5-dose MR vaccine vials, staff in five of the 57 HFs reported that they had changed the number of outreach sessions at which MR vaccines were offered, and staff in four had changed the number of staff who travel together to conduct outreach sessions. Staff in six of the 57 HFs reported that they had changed the frequency of either burning, incinerating, or burying sharps waste because of the change in the volume of immunization supplies, which was attributable to the switch to using 5-dose MR vaccine vials.

Table 32: Impact on outreach and sharps waste disposal of switching from 10-dose to 5-dose MR vaccine vials — responses from 57 intervention HFs in the endline costing sample.

Question asked	Number of HFs responding		Most common direction of change reported
	No	Yes	
Impact on outreach			
Because of the switch to using 5-dose MR vials, have you changed the number of outreach sessions per month where the MR vaccine is offered?	52	5	Increase in number of sessions where MR vaccine is offered
Now that you are using 5-dose MR vials, have you changed the number of staff who travel together to conduct outreach services?	53	4	Increase in number of staff traveling together to conduct outreach
Impact on wastage disposal			
Did the frequency of waste disposal change because of the change to using 5-dose MR vials?	51	6	Increase in frequency of disposing immunization waste

Table 33 shows the impact on human resource time use of the switch from 10-dose to 5-dose MR vials. Compared to the other cost categories reported above, human resource time use was the cost category that relatively more respondents mentioned had been impacted by the switch to 5-dose MR vials.

The human resource activities that were most impacted by the DPC switch were the time conducting fixed immunization sessions, conducting stock management, and reporting. Specifically, more staff reported that they dedicated more time for data reporting post-intervention. Increase in time use that was incurred due to the additional time for project-related reporting was excluded in the cost estimates below.

Table 33: Impact on human resource time use of switching from 10-dose to 5-dose MR vaccine vials — responses from 57 intervention HFs in the endline costing sample*

	Main respondent (interviewee)		Other respondent (other HCWs who interviewee reported on)		Most common direction of change reported by the facilities at which staff reported change in time use (excluding zero values) and impact on time use per health facility
	No	Yes	No	Yes	
Because of the change to using 5-dose MR vials, would you say the amount of time spent on providing fixed immunization services has changed?	42	15	55	1	An average decrease per facility in time spent of 17.6 hours per month**
Because of the change to using 5-dose MR vials, would you say the amount of time spent on conducting or assisting with outreach sessions has changed?	45	12	45	4	An average increase per facility of 4.5 hours per month
Because of the change to using 5-dose MR vials, would you say the frequency of forecasting and estimating the vaccine stock and immunization supply needs for the facility has changed?	44	8	44	6	Increase in frequency and time spent: net change is an additional 7.6 hours, on average, per month per health facility
Because of the change to using 5-dose MR vials, would you say the amount of time spent on forecasting and estimating the vaccine stock and immunization supply needs for the facility has changed?	47	5	42	8	
Because of the change to using 5-dose MR vials, would you say the frequency for completing or checking the paperwork for ordering vaccines and immunization supplies has changed?	41	11	44	6	
Because of the change to using 5-dose MR vials, would you say the frequency of traveling to the district to collect vaccines has changed?	35	5	42	8	Increase in frequency of travel: net change is an additional 3.7 hours, on average, per month spent on travel per health facility
Because of the change to using 5-dose MR vials, would you say the frequency of conducting stock management activities has changed?	48	8	48	5	Increase in frequency and time spent: net change is an additional 2.6 hours, on average, per month per health facility
Because of the change to using 5-dose MR vials, would you say the amount of time you spend on stock management activities has changed?	47	9	44	9	
Because of the change to using 5-dose MR vials, would you say the frequency of conducting the stock count has changed?	46	10	45	8	Increase in frequency and time spent: net change is an additional 1.4 hours, on average, per month per health facility
Because of the change to using 5-dose MR vials, would you say the amount of time you have spent on stock counting has changed?	46	10	44	9	
Because of the change to using 5-dose MR vials, would you say the frequency of conducting data reporting for immunization services has changed?	50	5	48	3	Increase in frequency and time spent: net change is an additional 3.5 hours, on average, per month per health facility
Because of the change to using 5-dose MR vials, would you say the amount of time you spend on data reporting for immunization services has changed?	35	21*	43	8***	

* Totals may not add to 57 because not all respondents were engaged in all the activities asked about.

** There were several seemingly incorrect responses that could not be verified. For example, one facility reported only spending 10 minutes per session for a fixed immunization session, compared to six hours per session at baseline, and another facility reported that they changed from holding sessions three times a week to only having one session a month.

*** We do not include this increase in time use in the costing estimates because this is all most likely due to time spent on study-related reporting.

Incremental costs or savings

For each of the 57 intervention HFs, we estimated the annual incremental costs or savings for cold chain, transport for vaccine collection, outreach (excluding human resource costs), sharps waste disposal, and human resource costs, as mentioned in the Methods section. Changes in those costs that HCWs attributed directly to the switch from 10-dose to 5-dose MR vials were included in the calcuations, taking into account the adjustments noted above for the cold chain equipment and human resource time devoted to reporting.

These costs were then aggregated in order to estimate the annual incremental total costs or savings per facility. These facility-level costs were then averaged for the HFs reporting a change in costs. The average incremental costs or savings for all 57 HFs in the sample were also estimated, and first and third quartile costs were calculated. Costs disaggregated by characteristics, such as location (rural/urban) or target EPI population served, were not calculated because of the low number of HFs reporting changes in these cost categories (other than for human resources).

Table 34 shows the estimated incremental annuals costs attributable to the switch from 10-dose to 5-dose MR vials and the number of HFs reporting a change in each of the cost categories. There was no change in cold chain costs attributable to the switch to using 5-dose MR vials. For the three HFs that reported a change in transport costs due to the DPC switch, the average annual incremental costs were estimated at $267, and these were mainly driven by the reported increase in the number of trips to collect vaccines from the district vaccine stores. These annual incremental costs are estimated at $14.04 per HF per year when averaged across all 57 HFs.

For all cost categories, because the majority of the HFs reported no change in the resource use for the activity, the first and third quartile values of costs are both zero. Twenty-eight of the 57 HFs reported a change in time dedicated to immunization-related activities due to the switch to using 5-dose MR vaccine vials, and this was estimated to result in average annual incremental costs of $28.62 per HF per year when only including the HFs reporting a change in any human resource activity, and $13.57 per HF per year when averaged across all 57 HFs.

The average of the total incremental costs was estimated at $87.18 per HF per year when including only the 30 HFs that had reported a change in any one of the cost categories included in the analysis. When including all 57 HFs, the average of the total annual incremental costs was estimated at $45.88 per HF. Twenty-five percent of the HFs that had the lowest annual incremental costs actually reported no change in costs attributable to switching to the 5-dose MR vials. The top 25% of costs reported by HFs attributable to the switch had total incremental costs of $29.93 per HF per year and above.

Table 34: Estimated annual incremental costs and savings attributable to the switch to using 5-dose MR vials — estimates from the 57 intervention HFs in the endline costing sample*

	Cold chain	Transport	Outreach	Waste disposal	Human resources	Total incremental costs or savings
Number of health facilities with a change in costs	0	3	4	5	28	30
Average costs for these health facilities with a change in costs	$0	$267	$179	$66	$27.62	$87.18
Average per health facility (n=57)						
Average incremental costs or savings	$0	$14.04	$12.53	$5.75	$13.57	$45.88
First quartile of incremental costs or savings	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Third quartile of incremental costs or savings	$0.00	$0.00	$0.00	$0.00	$0.00	$29.93

* Note that the total is calculated for each HF and then averaged. Therefore, this total is not based on the averages reported for each cost category but is an average of the total costs for each HF.

Value of vaccines used and wasted

We estimated the annual value of vaccines administered and wasted at each HF included in the costing sample. Each of these facilities used an average of 722 doses (interquartile range 415–897) of MR vaccine over a one-year period, which includes an average of 98 doses (interquartile range 50–144) that were wasted at each facility.

We estimated the incremental annual cost per MR vaccine dose administered (excluding the value of vaccines) for each facility at $0.11 (interquartile range $0.00–$0.05) when including all HFs in the costing intervention sample. This means that the switch to using 5-dose MR vaccine vials resulted in an increase in average costs for storage, transport, human resources, outreach, and wastage disposal costs of $0.11 per dose of MR vaccine used.

We also used the study data from all HFs to calculate the value of vaccines used and wasted by health facilities using 5-dose vials (intervention) and by those using 10-dose vials (control) during the 11-month study period. As shown in Table 35, on average, a HF using 5-dose vials administered 416 doses during the 11-month study period and wasted 80 doses, while an HF using 10-dose vials administered an average of 432 doses and wasted 190 doses.

Holding the quantity of vaccines administered at the level for facilities using 10-dose vials but applying the respective wastage rate based on vial size used, Table 35 shows that the average health facility that was using 5-dose vials would have used (administered and wasted doses) $423 worth of vaccines, compared to $408 worth of vaccines used by health facilities using 10-dose vials.

With wastage rates for 5-dose and 10-dose vials at 16.18% and 30.53%, respectively, and with the MR vaccine price per dose at $0.82 and $0.656, respectively, the wastage-adjusted MR vaccine price per dose is $0.98 and $0.94 for 5-dose and 10-dose vials, respectively. The reduction in wastage rates with 5-dose vials did not outweigh the increase in the vaccine costs per dose administered associated with the smaller vial size, hence the total value of vaccines used was greater in the HFs using 5-dose vials compared to 10-dose vials.

Table 35 also shows these calculations when the HFs are stratified by size of catchment population served. Facilities that served fewer than 200 children per year and were using 10-dose vials had the highest wastage rates, while those using 5-dose vials had the lowest wastage rates. For these facilities, when considering the trade-off between lowering the wastage rate and increasing the vaccine price per dose associated with smaller vial sizes, the value of lowering the wastage rate becomes even more important. The results show that for facilities that served fewer than 200 children per year, the value of vaccines used by HFs using 5-dose vials was lower than that for facilities using 10-dose vials ($241 vs. $246). Therefore, the savings from lowering wastage rates outweighed the higher price increase with the smaller-dose vial for these small HFs. The wastage-adjusted price per dose for MR vaccine at these wastage rates for HFs serving fewer than 200 children was $0.95 and $0.97 for 5-dose and 10 dose vials, respectively.

Table 35: Quantities of MR vaccines used, wastage rates, and value of vaccine used per health facility during the 11-month study period

	Average number of doses administered per health facility		Average number of doses wasted per health facility		Wastage rate per health facility		Average value of vaccines used per health facility (holding the doses administered at the level for control facilities)	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
All facilities	416	432	80	190	16.18%	30.53%	$423	$408
Stratified by size of EPI target population served								
Large: 500+ target pop	780	796	181	312	18.86%	28.18%	$804	$727
Medium: 200 to 499 target pop	456	473	97	196	17.51%	29.36%	$470	$439
Small: 1 to 199 target pop	238	254	37	121	13.44%	32.36%	$241	$246

In summary, the incremental economic costs for supply chain and service delivery of switching from 10-dose to 5-dose MR vaccine vials was estimated to be $0.11 (interquartile range $0.00–$0.05) per HF. At the wastage rates reported in the study, the incremental vaccine price per dose would be $0.04 (because the wastage-adjusted vaccine price per dose would be $0.98 with 5-dose vials and $0.94 with 10-dose vials). Therefore, incremental costs for vaccine purchase, supply chain, and service delivery would be approximately $0.15 per dose when using the average costs, and $0.09 per dose when using the upper end of the interquartile range for supply chain and service delivery costs (given that our estimates may be overestimates due to project impact). This estimate would be lower for HF serving fewer than 200 children, for which there is a savings in vaccine purchase costs from swtitching to 5-dose MR vials because the reduction in wastage outweighs the increase in vaccine price.

District costing

The district endline costing sample included the seven intervention districts from which baseline data were also collected. The three tables below show the responses of the staff from each district on whether any of the cost components had changed due to the switch to using 5-dose MR vials. The cost components for the district included cold chain, transport, and human resources; districts did not have outreach or waste disposal costs.

As shown in Table 36, staff in only one district noted they did not have adequate cold chain storage capacity and they did not receive additional refrigerators. All districts reported they had sufficient cold boxes and vaccine carriers for collecting vaccines from the provincial vaccine store.

Table 36: Impact on cold chain when switching to 5-dose MR vaccine vials among the seven intervention districts

Question asked	Number of districts responding	
	No	Yes
Since the 5-dose MR vials were introduced, has this district vaccine store had adequate refrigerator or cold room space required to store the 5-dose MR vials and other vaccines?	1	6
Did this district vaccine store receive any additional refrigerator(s) because you needed more refrigerator space to store the 5-dose MR vials and other vaccines?*	1	0
Since the 5-dose MR vials were introduced, has this district vaccine store had adequate space in the cold boxes or vaccine carriers to use when collecting the 5-dose MR vials and other vaccines from the provincial vaccine store?	0	7
Since the 5-dose MR vials were introduced, has this district vaccine store had adequate space in the cold boxes or vaccine carriers to use when distributing vaccines to the health facilities?	0	7

* This question was only answered if the respondent answered "no" to the previous question.

The impact on collecting vaccines from the provincial store was minimal. Staff in only one district reported that the frequency to collect changed (Table 37). None reported changing the number of staff required for collecting vaccines.

The district that changed the frequency in collecting vaccines from the provincial store increased from four trips per year to once per month. Since switching to 5-dose MR vials, only one district reported needing to make an emergency trip to collect vaccines from the province. Since the 5-dose MR vaccine was delivered to the districts prior to implementation, these changes were not considered in the analysis.

None of the districts needed to change the mode of transport to collect vaccines. The one district that delivers vaccines to the health facility did not make any changes to frequency, number of staff, or mode of transportation after the DPC switch.

Table 37: Impact on transport requirements following the switch from 10-dose to 5-dose MR vaccine vials among the seven intervention districts

Question asked	Number of districts responding	
	No	Yes
Because of the switch to using 5-dose MR vials, did this district vaccine store have to change the frequency at which it collects vaccines from the provincial vaccine store or the number of trips made?	6	1
Because of the switch to using 5-dose MR vials, did this district vaccine store have to change the number of staff who travel together to collect vaccines from the provincial vaccine store?	7	0
Since you started using 5-dose MR vials, have there been any emergency trips to the provincial vaccine store made to replenish MR vaccine stocks because MR vaccine stock levels were low or stocked out?	6	1
Because of the switch to using 5-dose MR vials, did this district vaccine store have to change the mode of transport that it uses on trips to collect vaccines from the provincial vaccine store?	7	0
Because of the switch to using 5-dose MR vials, did the district vaccine store have to change either the frequency of delivering vaccines, the number of staff traveling, or the mode of transport used to deliver vaccines to the health facilities on any of the delivery routes?	1	0

Table 38 summarizes the responses from districts on the impact on human resource time use of the switch to 5-dose MR vials. Of the main respondents interviewed at the seven districts, five noted they were involved in forecasting and estimating vaccine stock and immunization supply needs for the district. Staff in one district reported a change in frequency and time spent on forecasting and counting vaccine stock. In that district, the frequency increased from once every three months to once per month, and the time devoted to the activity declined from two hours to one.

Staff in two districts had changes in frequency for completing and checking paperwork after changing to 5-dose MR vials. One district increased frequency from monthly to twice a month, while another increased from every three months to monthly. The time spent on paperwork increased for two districts.

Staff in one district saw a change in frequency for forecasting and estimating vaccine stock and immunization supply for the health facility, and staff in another saw a change in the amount of time. Two districts reported a change in the frequency of completing or checking paperwork for ordering vaccines.

No district reported a change in the time spent on checking paperwork for ordering vaccines. None reported any change in frequency or time on stock management activities, stock count, or data reporting. Staff in one HF reported a change in the amount of time devoted to stock counting.

Among the other respondents, six were involved in forecasting and counting vaccine stock. The impact was similar to the main respondent in terms of very little change in frequency and time spent on forecasting and counting stock and supply needs for the district; completing or checking paperwork for ordering vaccines for the district; frequency of conducting stock management activities or time spent on stock counts; and frequency of data reporting. There was no impact on forecasting or counting vaccine stock and supply needs for HFs, frequency of checking paperwork for HFs, frequency of traveling to collect vaccines from the province, time spent on stock management activities, or time spent on data reporting.

Table 38: Impact on human resource time use when switching to 5-dose MR vaccine vials among the seven intervention districts

Question asked	Main respondent		Other respondent	
	No	Yes	No	Yes
Because of the change to using 5-dose MR vials, would you say the frequency at which you forecast and estimate the vaccine stock and immunization supply needs for the district has changed?	4	1	5	1
Because of the change to using 5-dose MR vials, would you say the time you spend on forecasting and estimating the vaccine stock and immunization supply needs for the district has changed?	4	1	5	1
Because of the change to using 5-dose MR vials, would you say the frequency for completing or checking the paperwork for ordering vaccines and immunization supplies has changed?	3	2	4	2
Because of the change to using 5-dose MR vials, would you say the amount of time you spend completing or checking the paperwork for ordering vaccines and immunization supplies has changed?	3	2	5	1
Because of the change to using 5-dose MR vials, would you say the frequency at which you forecast and estimate the vaccine stock and immunization supply needs for the health facilities in this district has changed?	4	1	3	1
Because of the change to using 5-dose MR vials, would you say the time you spend on forecasting and estimating the vaccine stock and immunization supply needs for the health facilities in this district has changed?	4	1	4	0
Because of the change to using 5-dose MR vials, would you say the frequency for completing or checking the paperwork for ordering vaccines and immunization supplies for health facilities in this district has changed?	3	2	2	2
Because of the change to using 5-dose MR vials, would you say the amount of time you spend completing or checking the paperwork for ordering vaccines and immunization supplies for health facilities in this district has changed?	5	0	4	0
Because of the change to using 5-dose MR vials, would you say the frequency of traveling to the provincial vaccine store to collect vaccines or supplies has changed?	5	0	4	0
Because of the change to using 5-dose MR vials, would you say the frequency of conducting stock management activities has changed?	6	0	5	1
Because of the change to using 5-dose MR vials, would you say the amount of time you spend on stock management activities has changed?	5	0	6	0
Because of the change to using 5-dose MR vials, would you say the frequency of conducting the stock count has changed?	5	0	6	1
Because of the change to using 5-dose MR vials, would you say the amount of time you have spent on stock counting has changed?	4	1	6	1
Because of the change to using 5-dose MR vials, would you say the frequency of conducting data reporting for immunization services has changed?	4	0	6	1
Because of the change to using 5-dose MR vials, would you say the amount of time you spend on data reporting for immunization services has changed?	4	0	6	0

Incremental costs or savings at district

For the seven intervention districts, the annual incremental costs or savings for cold chain, transport, and human resource costs were estimated. The same approach used for HFs was also applied to the districts.

There were no incremental costs or savings for cold chain or transport. The one district that noted there was not adequate space did not receive an additional refrigerator.

Similar to the HFs, staff in three districts reported a change in time use for human resources. The average annual incremental cost was $3,139 for districts reporting a change in any human resource activity and $1,345 per district when averaged across the seven districts. The average of the total annual incremental costs was estimated at $3,583 among the three districts that had reported a change in any of the cost categories. When all seven districts were included, the average of the total annual incremental costs was $1,345 per district. See Table 39.

Table 39: Estimated annual incremental costs and savings per district per year attributable to the switch from 10-dose to 5-dose MR vials for the seven districts

	Cold chain	Transport	Human resources	Total incremental costs or savings*
Number of districts with a change in costs	0	0	3	3
Average costs for these districts with a change in costs	$0.00	$0.00	$3,139	$3,139
Averages across all districts (n=7)				
Average incremental costs or savings	$0.00	$0.000	$1,345.15	$1,345.15
First quartile of incremental costs or savings	$0.00	$0.00	$0.00	$0.00
Third quartile of incremental costs or savings	$0.00	$0.00	$234.49	$234.49

* Note that the total is calculated for each district and then averaged. Therefore, this total is not based on the averages reported for each cost category but is an average of the total costs for each district.

When switching to 5-dose MR vials, there was no impact on the cold chain and very minimal impact on transport. There was an increase in human resource time spent on performing vaccine stock management activities in three out of seven districts. Overall, the switch from 10-dose to 5-dose MR vaccine vials did not have a significant impact on transport or cold chain costs in the districts.

Summary of costing findings

For cold chain, transport, outreach, and immunization waste disposal, five or fewer of the HFs reported that costs in these categories had changed because of the switch to 5-dose MR vials. Therefore, a sizable number of HFs reported no change in these cost categories due to the DPC switch.

Human resource costs were the cost category for which more staff at the HFs reported that there were changes in costs because of the switch to 5-dose MR vials. In fact, 34 of the 57 HFs included in the endline costing sample reported a change in either the frequency of or time spent conducting at least one task for the immunization program. Specifically, most of the health staff reported either an increase in the frequency of conducting activities for the immunization program or an increase in time spent on the activities. Hence, there was a net increase in average human resource costs at the health facility level because of the switch to 5-dose MR vaccine vials.

Average annual incremental total costs per health facility were estimated at $45.88 (interquartile range from $0–$29.93), when excluding the value of vaccines. The lower value of the interquartile range shows that even though costs did increase on average, some HFs had no change in costs due to the switch to 5-dose MR vials, but overall there were additional costs for cold chain, transport, waste disposal, and human resources that were attributable to the DPC switch.

For the district vaccine stores, human resource costs were most impacted by the change to 5-dose MR vials. Overall, there was an increase in human resource time spent on vaccine stock management for three of the seven districts in our sample.

Each HF used an average of 416 MR vaccine doses in 5-dose vials, valued at $427, of which 85 doses were wasted each year, compared to HFs using 10-dose vials, which used an average of 432 MR vaccine doses, valued at $393, of which 167 doses were wasted.

The incremental annual costs (excluding the value of vaccines) was $0.11 per HF. This means that the switch to 5-dose MR vials resulted in an increase in costs for storage, transport, human resources, outreach, and wastage disposal costs of $0.11 per dose of MR vaccine used.

Note that this analysis does not factor in the other potential benefits of smaller vial sizes, such as increasing routine and timely immunization coverage and the resulting reduced morbidity, disability, and mortality; less reliance on expensive periodic campaigns; and economical savings in parents' time to get their children vaccinated.

SAFETY

DPCP examined vaccine safety through direct observations at baseline and key informant interviews at baseline and endline. Data collectors observed HCWs administering vaccines, but due to the low frequency of sessions, no conclusions could be drawn from the observations. During KIIs, respondents were asked whether there were any reports from communities on adverse events following immunization (AEFIs) or abscesses, and respondents were also asked to list the causes of AEFI and abscesses.

All 2016 AEFI reports from HFs submitted to districts were requested from all 14 districts, but the districts had no reports to share. In addition, Zambia reported no AEFIs in 2017 on the JRF, which suggests that reporting is unreliable. Therefore, the DPCP was unable to study the impact of the intervention on the frequency of AEFIs.

"Maybe wrong dilution, administering expired vaccines, and also if you don't use the correct vaccine administration route; hygiene is also key — if you don't follow the infection prevention rules, you can introduce some infections."

— HCW

None of the respondents at HFs mentioned any reports from communities regarding AEFIs or abscesses. At the district level, respondents mentioned that while no AEFIs were reported, they wanted to re-train HF staff because they suspected these staff did not recognize and report AEFIs. One district respondent gave the example of vaccine vials not being diluted properly and vials not being discarded after six hours.

At endline:

- Thirty-three of the 36 HCWs interviewed listed errors in vaccine preparation, handling, storage, or administration as the key determinants of AEFI or abscesses.
- Four of the 33 also mentioned that the genetics of the child increased their propensity for an AEFI.
- Two of the 33 stated that the steel material of the syringes could cause AEFI.
- Three of the 33 mentioned that mothers were responsible for AEFI or abscesses because they applied herbs to the vaccination site or did not wash hands when handling the vaccination site.
- Two of the 33 said that administering a vaccine to a sick child also caused AEFI or abscesses.

All seven district MCH coordinators correctly listed errors in vaccine preparation, handling, storage, or administration as the key determinants of AEFI or abscesses.

Cold chain, supply chain, and distribution capacity

Information on cold chain, supply chain, and distribution capacity was collected through the baseline and endline costing surveys at facilities, key informant interviews with logisticians at district offices, the administrative implementation data, and data shared with DPCP from CIDRZ. The key themes we explored included cold chain capacity, months of stock, vaccine distribution, stockouts, and challenges faced by districts and facilities in delivering vaccines.

Cold chain space

The costing survey and the administrative data collection also gathered quantitative information on cold chain equipment, vaccine distribution, and stockouts at facilities. Data were triangulated to provide a comprehensive perspective on the magnitude of the challenges and the factors that contribute to them.

Most HCWs and district respondents using 5-dose vials reported sufficient space in cold boxes, vaccine carriers, and refrigerators. A few expressed concerns about not having big enough cooler boxes to collect vaccines from the district and vaccine carriers to carry vaccines to sessions.

The total net storage requirement per fully immunized child, including the use of 10-dose vials of MR vaccine, was 88.46 cm^3, while the total requirement, including use of 5-dose vials, was 93.66 cm^3.

When considering wastage rates found during this research, the overall increase in cold chain requirements for 5-dose vials of MR vaccine (compared to 10-dose vials) was 4.88%, which has a minimal impact on available capacity.

An analysis was completed using information on Zambia's national immunization schedule, current vaccine presentations, wastage rates, cold chain equipment, and the target population of each health facility. All HFs in the intervention arm had sufficient cold chain space for the increase in volume required for introducing 5-dose MR vials.

Resupply of vaccines

Most of the district pharmacists and MCH coordinators from both the intervention and control districts reported ordering vaccines every quarter or as the need arose, and they supplied HFs on a monthly basis. The district pharmacies said they were able to stock up to three months of vaccine without any major challenges, with the exception of two districts that reported not having enough storage capacity for three months of stock.

Pharmacists reported collaborating with the MCH coordinators to ensure that the vaccines were available for health facilities. The MCH coordinators and pharmacists both could place orders for vaccines and collect from them the province. The two departments coordinate around the vaccine supply chain and the pick-up and delivery of vaccine from the province to the district and from the district to the facilities.

DPCP monitoring data showed that in reality, most HFs were restocked every two to three months and not on a monthly basis as reported by district staff. Intervention facilities were restocked more frequently ($p<.001$) than control facilities but received fewer doses per restock ($p<.001$, Table 40).

Table 40: Average frequency and quantity of MR vaccine restocked

	Intervention	Control	Difference between intervention and control
Average number of MR doses received per restock	103.45	166.99	-63.54***
Average number of times HFs were restocked with MR during 11-month study period	4.47	3.43	1.04***

* p<0.05, ** p<0.01, *** p<0.001

Stockouts

KIIs revealed that more than half of the HCWs using the 5-dose vials mentioned having had stockouts of vaccines in the intervention period. Vaccines included OPV, BCG, PCV, and in one case the MR 5-dose vial. The duration of the stockouts ranged from four days to 31 days.

"We get from our nearby facility whilst waiting for the supply, or our district pharmacist takes up to find out which facility has more vaccine."

— HCW

In the event of a stockout, HCWs stated that they requested more from districts or collected vaccines from HFs close in proximity.

HCWs said that they explained to their communities when they had stockouts and requested them to come to the next session for that particular vaccine.

According to DPCP monitoring data, on average, 9% of HFs were out of stock of MR vaccine in any given month, with no difference between the study arms. A slightly higher number of control facilities were never stocked out during the implementation period (see Table 41).

Table 41: Proportion of HFs reporting MR vaccine stockouts during 11-month study period

	Intervention	Control
Never stocked out	46%	52%
One stockout	29%	28%
Two stockouts	15%	13%
Three or more stockouts	10%	8%

There was not a significant difference in the average duration of stockouts of MR vaccine between study arms, with intervention facilities stocked out an average of 12 days and control facilities stocked out an average of 11.3 days.

Health care worker perceptions, behaviors, and preferences

Health care worker behavior during vaccine administration was assessed through the costing survey, key informant interviews, and observations. HCWs were interviewed to explore their experience providing immunization services, perspectives on the challenges they faced, and understanding and application of the policy of when to open a vial.

Missed opportunities

KII respondents using 5-dose and 10-dose MR vials reported asking mothers to return with their child on a day when sessions were being held. If families were coming from a great distance, HCWs reported opening a vial and vaccinating the child regardless of the potential impact on vaccine wastage.

Only a couple of HCWs using 5-dose MR vials stated that at fixed sessions in the last month, they had asked children to return because the number of children was too small to justify opening a vaccine vial. For outreach sessions, a couple of HCWs using 5-dose MR vials stated that, in the last month, they had asked children to return because the number of children was too small for them to open the MR vial.

By contrast, 15 of 32 HCWs using 10-dose MR vials stated that, at fixed sessions in the last month, they had asked children to return because they did not want to open a vial for a small number of children. Similarly, for outreach sessions, 50% of the respondents stated they had asked children to return.

HCWs using 5-dose vials stated that smaller vial sizes had positively influenced their ability to vaccinate more children and reduced their concern about wastage.

Vial size preference

None of the respondents at HF or district level using 5-dose MR vials wanted to return to using 10-dose vials. The majority of HCWs in the intervention arm preferred 5-dose, and the remainder even stated a preference for vials with fewer than 5 doses. Some named 3 doses, others said 2 or even 1. When broken down by HF size, 10 of 11 respondents from small facilities preferred 5 dose; 13 of 17 respondents from medium-sized facilities preferred 5 dose; 8 of 13 respondents from large facilities preferred 5-dose vials. Ten of 14 district respondents preferred 5-dose vials.

This perspective was echoed by HCWs from facilities using 10-dose vials as well. They believed the change in vial size would raise coverage because children would not be turned away during fixed and outreach sessions and wastage would be reduced.

"Yes, we had some children who came on wrong days; we had to open the vial because the children were enough and they came from hard-to-reach areas."

— HCW using 5-dose MR vaccine

"We have no restrictions when to open the 5-dose vial compared to when we had the 10-dose vial; we were required to have a specific number of the children to allow us to open the vial."

— HCW using 5-dose MR vaccine

"Actually, the issue of referring mothers to another session is not there anymore, it has reduced; mothers are not worried about them being able to get the vaccines because of the number of children available."

— HCW using 5-dose MR vaccine

"Yes, because 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. This is so because everyone wants to reduce the wastage."

— HCW using 5-dose MR vaccine

"It has made things easier for us in that you do not have to worry about babies not being immunized, it's rare that we miss out any child. It has made our work easier, our minds are free that we are doing our job (Immunizing) unlike the BCG."

— HCW using 5-dose MR vaccine

"The children have benefited a lot, for measles rubella, we have never turned them away because in the past most of the children would be told to go back and come when they are enough. Coverage has improved compared to when we had the 10 dose."

— HCW using 5-dose MR vac

Mixed presentations (multiple vial sizes of the same vaccine)

Out of 34 respondents from HFs using 5-dose vials, 19 respondents (56%) said they did not want multiple presentations of the same vaccine in the same facilitiy, while 15 respondents (44%) said they would prefer a mix of presentations.

When broken down by facility size, out of 10 HFs with small catchment populations using 5-dose vials, staff in three HFs said they did not want mixed presentations; out of 14 medium-sized facilities using 5-dose vials, 10 respondents said they did not want mixed presentations; out of 10 large facilities using 5-dose vials, six respondents said they did not want mixed presentations. At the facility level, the main concern expressed by HCWs was that they would get confused by having more than one presentation.

> **"Like the static, would prefer to use 10 and 5 at the outreach because outreach we do usually have less children."**
>
> — HCW using 5-dose MR vaccine

At the district level, nine respondents out of 14 total expressed concerns about mixed presentations, including:

- HCWs would get confused by having more than one presentation.
- HCWs may mix up the diluents.
- The burden of reporting for two different vials will increase.
- The confusion would cause more wastage.

Views similar to those expressed by respondents at the district level were echoed by stakeholders at the national level too.

National-level decision making around DPC selection

Decision-making process and factors determining and changing DPC presentation

Historically, there have been few discussions within Zambia regarding potential changes to the presentations of vaccines used in the country. Previous changes were based on market availability and global and regional partner agency recommendations. While changing the presentation of existing vaccines is uncommon, vial size options are routinely discussed when a new vaccine is being introduced and the appropriate presentation must be selected.

Based on experience, national-level stakeholders described the process for changing DPC. Three groups collectively decide on switching an existing DPC presentation and introducing a new vaccine: the Zambia Immunization Technical Advisory Group (ZITAG), Inter-agency Coordinating Committee (ICC), and EPI Technical Working Group (TWG). The MOH EPI is the secretariat for all three groups.

The EPI team initiates a discussion around a DPC change or introducing a new vaccine at the TWG. If the TWG is in agreement with the change or the introduction, the proposal is then submitted to the ZITAG, which reviews the evidence around the disease burden, benefits, coverage, and cost effectiveness. Once ZITAG approves the concept, the ICC is presented with the plan, reviews the recommendations, and makes a decision. The MOH's Permanent Secretary for Health Services is aware of discussions throughout each stage and issues the final approval.

At the global and country levels, WHO sets standards and provides guidelines for new vaccine introduction. UNICEF works closely with the MOH throughout the process of procuring vaccines. The country's Ministry of Finance (MOF) releases funds for vaccines whenever the request is submitted and if it is within the budget threshold. The MOF does not participate in meetings at the MOH, as this is not part of its job duties, although the EPI team invites the MOF to participate in TWG discussions.

The MOF provides a budget envelope to the MOH for all programs, and the MOH decides how to allocate funds for each of the programs, including EPI. If the budget envelope is insufficient to cover all budget requests, it is up to the MOH to determine where to cut.

As those interviewed indicated, decisions around the change in DPC or introducing a new vaccine require coordination and consultation between the global, regional, and country levels. According to respondents, the key criteria that influenced decisions were market availability, cold chain requirements, coverage, and cost. In addition, the team also considers other factors that may offset costs, such as cold chain requirements (either increase or decrease) and vaccine wastage. There has been insufficient data on wastage, which makes it challenging to consider when making decisions, so historically this has played less importance in decision making.

Respondents felt that the EPI also needs more evidence on cold chain storage availability and requirements at all levels in the system, as decisions such as whether to stagger shipments are made if there are concerns about insufficient storage capacity. As a recent example of changing DPC, the country switched from 2-dose vials of PCV to 4-dose vials. A major factor in the decision-making process was to free up space for new vaccines entering the system in the next year or two (such as HPV).

Costs for developing or revising documents and tools are small, so this is not considered during decision making. Global and regional priorities and market availability often influence DPC decisions, as was the case with the introduction of inactivated polio vaccine (IPV) and change in presentation for PCV.

Process for switching DPC once the decision has been made

After the decision is made, stakeholders reported that planning for a switch takes a minimum of six to 12 months. Quantification and forecasting of required amounts of vaccine will need to account for changes in vial size, as well as change in wastage and cold chain requirements. The new product also needs to be registered, which can take up to 18 months, although sometimes registration is waived.

Staff at all levels will need to be trained on the new presentation to ensure its proper use. Some stakeholders felt that the practice of examining vials before vaccination is not strong, and that a switch could result in incorrect dosage, which makes it critical to plan for and conduct orientations and refresher trainings.

One suggestion was to use existing platforms/events to interact with HCWs. This could include pre-Child Health Week Orientation, the MR campaign planned for 2020, or training for new vaccine introduction. If there is no opportunity for training, the EPI would instead send a memo to sub-national levels.

Orientation should also include information on how to forecast and order the new presentation (considering wastage or cold chain changes). Consistent supportive supervision and mentorship is also needed, which is currently lacking but would be important for a switch.

When Zambia switched PCV from a 2-dose to 4-dose presentaiton, WHO provided manuals and guidelines to train health care workers on handling the new vaccine presentation, information on the new packaging, and general capacity strengthening for HCWs. However, due to limited resources for training, the EPI combined this activity with training for IPV introduction. The country adapted the trivalent oral polio vaccine (tOPV) counting document and carefully monitored PCV stock levels to track when to switch to 4-dose vials.

Multiple DPC presentation

Respondents stated that even though there might be benefits to having multiple presentations of the same vaccine in the system at the same time, the risks outweighed the benefits, and overall they were not in favor of multiple presentations. Two national-level stakeholders stated that it may work to have multiple presentations in the country but not at the HF level. They suggested that urban districts could benefit from using 10-dose MR vials, while rural districts could benefit from using only 5-dose vials. In addition to MR, other vaccines — such as BCG, IPV, and tetanus toxoid-containing vaccines — could be considered for multiple presentations to reduce wastage.

There is interest in generating evidence on the advantages and disadavantages of managing multiple presentations of different vaccines before considering nationwide rollout, as this has not been done previously.

05 | Conclusion

Through this implementation research in Zambia, the DPCP team has generated deep insights through multiple methods and sources of data into the many programmatic dimensions that must be reviewed when considering a change in DPC.

While this level of data collection and analysis is not necessarily required by individual countries considering a DPC switch, it has been important to examine the potential impact on as many programmatic components and operational contexts as possible in order to generate evidence of the benefits and drawbacks assocated with switching from 10-dose to 5-dose MR vaccine vials.

Findings from the research described in this report show that in the balance between achieving high coverage and avoiding vaccine wastage, HCWs must decide when to open a vial, and this can affect timely and equitable coverage, wastage, and costs.

The household coverage survey found a statistically significant increase in coverage for both doses (a 5-percentage-point increase in MCV1 coverage and 3.5-percentage-point increase in MCV2 coverage) among children in districts using 5-dose vials, compared to those using 10-dose vials (based on vaccination card plus caregiver recall). In addition, dropout rates between MCV1 and MCV2 receipt was reduced by 3.6 percentage points following the switch from 10-dose to 5-dose vials.

When using 5-dose vials, HCWs reported frequently that they believe they can reach more children, since opening a smaller vaccine vial, even when only one eligible child is present, results in reduced vaccine wastage. The practice of turning children away where vaccination sessions are small can be discontinued, which may explain the significant improvement in vaccination coverage in the intervention arm. These findings suggest that a reduction in missed opportunities for vaccination (MOV) is an important benefit of switching to 5-dose MR vials.

HCWs also showed a strong preference for smaller-dose vials, with no HCW saying that they wanted to return to using 10-dose vials at the end of the intervention.

Wastage also decreased statistically significantly (47% lower) in HFs where 5-dose MR vials were used, even while coverage increased. As observed in many other countries, HCWs in Zambia are concerned about wastage and tailor their behavior to achieve low wastage rates.

One frequent concern about switching to a smaller vial size is the potential impact on cold chain capacity requirements. An analysis of cold chain equipment in intervention HFs showed that there was sufficient space to accommodate the small increase in volume that occurred when switching from 10-dose to 5-dose MR vaccine vials. In addition, the reduction in wastage also contributed to alleviating additional cold chain capacity requirements.

Considering wastage rates documented in this research, wastage-adjusted vaccine price per dose is only $0.04 higher with 5-dose vials then with 10-dose vials and in small HFs, vaccine purchase costs are lower using 5-dose vials because the reduction in wastage outweighs the increase in vaccine price. The only cost category that increased was the cost of human resources and of those that reported an increase, most HCWs reported either an increase in the frequency of conducting activities for the immunization program or an increase in time spent on the activities. The incremental annual costs for switching to 5-dose vials (excluding the value of vaccines) was $0.11 per HF.

This research was conducted over a limited time period, so the full impact of switching vial sizes may not be represented here. It also was carried out in a relatively small number of districts in a single African country, so the impact of switching vial sizes may be different in other settings. Further research

may be needed to better understand all the effects on vaccination coverage and other programmatic indicators following a presentation switch. Research on the effects of maintaing multiple presentations of the same vaccine within a single country is also needed. Every country considering a switch in vaccine presentation must balance the trade-offs to determine the right set of options for their program.

06 | References

1. NVivo qualitative data analysis software. Available at: https://www.qsrinternational.com/nvivo/what-is-nvivo
2. SurveyCTO mobile data collection program. Available at: https://www.surveycto.com/
3. UNICEF. Vaccine price data. Available at: https://www.unicef.org/supply/index_57476.html
4. World Health Organization/UNICEF. Joint Reporting Form. Available at: https://www.who.int/immunization/monitoring_surveillance/routine/reporting/reporting/en/
5. World Health Organization. PQS catalogue, prequalified devices and equipment, product list. Available at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=17
6. World Health Organization. World Health Organization Vaccination Coverage Cluster Surveys: Reference Manual. Version 3. Working Draft. Updated July 2015. Available at: https://www.who.int/immunization/monitoring_surveillance/Vaccination_coverage_cluster_survey_with_annexes.pdf?ua=1
7. The 2013–2014 Zambia Demographic and Health Survey (DHS). Available at: https://dhsprogram.com/publications/publication-fr304-dhs-final-reports.cfm

07 | Annexes

Annex 1: Selected unit prices used in the baseline and endline costing analysis

Resource unit price	Amount or range for unit price (US$)
Price of an electric refrigerator (range — which depends on the model/make)	$500–$2,200
Price of a solar refrigerator (range — which depends on the model/make)	$3,019–$5,900
Price of a vaccine carrier	$11.50
Annual salary of an enrolled nurse, midwife, or environmental health technician	$6,384
Per diem paid per person per day	$8.50
Petrol price per liter	$1.30
Paraffin price per liter	$0.80
Electricity price per kilowatt hour	$0.05
Price of a new 4WD vehicle	$45,000
Price of a new motorcycle	$4,300
Cost of an incinerator	$11,000

Annex 2: Final sample distribution of baseline and endline by district

	Baseline				Endline				Total number of EAs
	Children aged 12–23 months		Children aged 24–35 months		Children aged 12–23 months		Children aged 24–35 months		
	%	n	%	n	%	n	%	n	
Central Province									
Chitambo	8.7	164	7.24	132	8.22	158	8.24	154	40
Itezhi-tezhi	12.09	228	11.64	212	12.18	234	11.88	222	57
Kapiri Mposhi	27.31	515	27.39	499	26.7	513	27.13	507	128
Luano	2.76	52	3.02	55	2.92	56	3	56	14
Mumbwa	25.72	485	27.06	493	26.39	507	26.22	490	125
Ngabwe	2.28	43	2.03	37	2.24	43	2.35	44	11
Serenje	21.16	399	21.62	394	21.34	410	21.19	396	97
Luapula Province									
Chembe	2.52	50	2.6	51	2.59	52	2.6	52	13
Chiengi	18.73	371	19.29	379	18.59	373	18.96	379	94
Lunga	3.79	75	3.87	76	3.74	75	3.85	77	20
Mansa	22.11	438	23.05	453	22.58	453	22.41	448	113
Milenge	7.17	142	7.33	144	7.08	142	7.3	146	36
Nchelenge	16.36	324	16.9	332	16.85	338	16.71	334	84
Samfya	29.33	581	26.97	530	28.56	573	28.16	563	144
TOTAL	100	1981	100	1965	100	2006	100	1999	976

Annex 3: Unadjusted coverage rates in children aged 12–23 months at baseline and endline

Vaccine	5-dose vials			10-dose vials		
	Baseline (N=1907)	Endline (N=1962)	p-values	Baseline (N=1960)	Endline (N=1965)	p-values
BCG						
Vaccination card	68.8%	80.4%	p<.001	67.7%	80.7%	p<.001
Caregiver's recall	29.2%	18.9%	p<.001	30.5%	17.4%	p<.001
Both sources	98.0%	99.2%	p<.001	98.2%	98.1%	p=.831
OPV 1						
Vaccination card	71.5%	83.0%	p<.001	69.1%	81.5%	p<.001
Caregiver's recall	27.3%	16.0%	p<.001	30.4%	17.2%	p<.001
Both sources	98.9%	99.0%	p=.689	99.4%	98.7%	p=.014
OPV 2						
Vaccination card	70.9%	81.3%	p<.001	68.3%	81.7%	p<.001
Caregiver's recall	24.7%	16.6%	p<.001	28.5%	14.8%	p<.001
Both sources	95.5%	97.9%	p<.001	96.8%	96.5%	p=.630
OPV 3						
Vaccination card	66.8%	78.5%	p<.001	65.4%	79.0%	p<.001
Caregiver's recall	16.7%	14.8%	p=.121	17.7%	10.6%	p<.001
Both sources	83.5%	93.3%	p<.001	83.0%	89.7%	p<.001
Penta1						
Vaccination card	71.3%	83.0%	p<.001	69.8%	82.3%	p<.001
Caregiver's recall	27.2%	16.2%	p<.001	29.5%	17.0%	p<.001
Both sources	98.5%	99.2%	p=.057	99.3%	99.2%	p=.730
Penta2						
Vaccination card	70.7%	81.7%	p<.001	69.2%	82.1%	p<.001
Caregiver's recall	25.4%	16.1%	p<.001	27.7%	15.1%	p<.001
Both sources	96.1%	97.8%	P=.003	96.9%	97.2%	P=.597
Penta3						
Vaccination card	67.8%	79.2%	p<.001	66.6%	80.9%	p<.001
Caregiver's recall	19.8%	15.1%	p<.001	16.2%	9.9%	p<.001
Both sources	87.6%	94.3%	p<.001	82.8%	90.8%	p<.001
PCV1						
Vaccination card	68.8%	82.1%	p<.001	67.8%	80.8%	p<.001
Caregiver's recall	28.3%	17.0%	p<.001	30.7%	18.1%	p<.001
Both sources	97.1%	99.0%	p<.001	98.5%	98.9%	p=.284
PCV2						
Vaccination card	66.7%	80.1%	p<.001	66.2%	80.3%	p<.001
Caregiver's recall	27.1%	17.6%	p<.001	28.9%	16.4%	p<.001
Both sources	93.8%	97.7%	p<.001	95.2%	96.7%	p=.024

PCV3						
Vaccination card	61.8%	77.2%	p<.001	61.9%	76.7%	p<.001
Caregiver's recall	22.7%	16.9%	p<.001	18.3%	12.6%	p<.001
Both sources	84.5%	94.1%	p<.001	80.2%	89.3%	p<.001
MCV1						
Vaccination card	61.7%	77.1%	p<.001	61.6%	77.7%	p<.001
Caregiver's recall	21.6%	13.9%	p<.001	21.4%	10.7%	p<.001
Both sources	83.3%	91.0%	p<.001	83.1%	88.4%	p<.001
Rota1						
Vaccination card	67.9%	81.4%	p<.001	65.5%	80.6%	p<.001
Caregiver's recall	20.5%	15.5%	p<.001	31.0%	17.3%	p<.001
Both sources	88.4%	96.9%	p<.001	96.5%	97.8%	p=.019
Rota2						
Vaccination card	63.0%	79.4%	p<.001	62.1%	78.2%	p<.001
Caregiver's recall	16.8%	13.7%	p=.014	28.2%	13.3%	p<.001
Both sources	79.8%	93.0%	p<.001	90.4%	91.5%	p=.262

Annex 4: Unadjusted coverage rates in children 24 months–35 months at baseline and endline

	5-dose vials			10-dose vials		
	Baseline (N=1920)	Endline (N=1931)	p-values	Baseline (N=1867)	Endline (N=1937)	p-values
BCG						
Vaccination card	60.1%	71.6%	p<.001	59.1%	69.2%	p<.001
Caregiver's recall	37.8%	26.9%	p<.001	38.9%	29.0%	p<.001
Both sources	97.9%	98.5%	p=.220	98.0%	98.2%	p=.714
OPV 1						
Vaccination card	61.2%	73.8%	p<.001	60.4%	70.8%	p<.001
Caregiver's recall	37.2%	25.0%	p<.001	38.3%	27.3%	p<.001
Both sources	98.4%	98.8%	p=.333	98.7%	98.1%	p=.206
OPV 2						
Vaccination card	60.8%	73.6%	p<.001	60.0%	70.3%	p<.001
Caregiver's recall	34.3%	24.1%	p<.001	37.1%	25.4%	p<.001
Both sources	95.1%	97.7%	p<.001	97.2%	95.7%	p=.019
OPV 3						
Vaccination card	57.8%	70.5%	p<.001	57.6%	67.8%	p<.001
Caregiver's recall	26.8%	22.7%	p=.007	27.8%	21.7%	p<.001
Both sources	84.6%	93.2%	p<.001	85.4%	89.5%	p<.001
Penta1						
Vaccination card	61.8%	74.5%	p<.001	60.6%	71.3%	p<.001
Caregiver's recall	37.0%	24.8%	p<.001	37.7%	27.5%	p<.001
Both sources	98.9%	99.2%	p=.251	98.3%	98.8%	p=.256
Penta2						
Vaccination card	61.0%	74.0%	p<.001	60.1%	70.3%	p<.001
Caregiver's recall	34.5%	24.3%	p<.001	36.0%	25.9%	p<.001
Both sources	95.5%	98.3%	p<.001	96.1%	96.2%	p=.895
Penta3						
Vaccination card	58.6%	72.6%	p<.001	58.3%	68.6%	p<.001
Caregiver's recall	27.6%	22.7%	p=.002	25.0%	19.3%	p=.001
Both sources	86.2%	95.3%	p<.001	82.3%	87.9%	p<.001
PCV1						
Vaccination card	56.7%	73.0%	p<.001	57.5%	69.4%	p<.001
Caregiver's recall	40.3%	26.0%	p<.001	40.1%	28.7%	p<.001
Both sources	97.0%	98.9%	p<.001	97.6%	98.1%	p=.313
PCV2						
Vaccination card	54.4%	71.8%	p<.001	56.3%	67.9%	p<.001
Caregiver's recall	38.9%	25.6%	p<.001	38.4%	26.6%	p<.001
Both sources	93.3%	97.4%	p<.001	94.6%	94.5%	p=.887
PCV3						
Vaccination card	49.6%	67.8%	p<.001	51.0%	64.8%	p<.001
Caregiver's recall	31.6%	25.0%	p<.001	26.4%	21.3%	p<.001
Both sources	81.2%	92.8%	p<.001	77.4%	86.2%	p<.001

MCV1						
Vaccination card	55.8%	70.4%	p<.001	55.7%	67.8%	p<.001
Caregiver's recall	21.3%	20.4%	p=.564	26.0%	17.8%	p<.001
Both sources	77.0%	90.8%	p<.001	81.7%	85.6%	p<.001
MCV2						
Vaccination card	29.2%	47.5%	p<.001	28.2%	45.5%	p<.001
Caregiver's recall	22.3%	22.8%	p=.742	29.8%	21.6%	p<.001
Both sources	51.5%	70.3%	p<.001	58.0%	67.1%	p<.001
Rota1						
Vaccination card	49.6%	72.0%	p<.001	50.7%	68.8%	p<.001
Caregiver's recall	31.6%	24.2%	p<.001	42.7%	27.9%	p<.001
Both sources	81.2%	96.2%	p<.001	93.4%	96.7%	p<.001
Rota2						
Vaccination card	40.0%	70.5%	p<.001	42.6%	66.0%	p<.001
Caregiver's recall	29.5%	20.7%	p<.001	41.1%	23.3%	p<.001
Both sources	69.5%	91.1%	p<.001	83.7%	89.3%	p<.001


DPCP
DOSE PER CONTAINER PARTNERSHIP