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Maternal and Child Survival Program

Experiences in New Vaccine Introduction


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Background

In support of the US Agency for International Development (USAID)'s efforts to help increase the equitable coverage of vaccines, strengthen routine immunization (RI) systems, and leverage the US Government's large global contribution to Gavi, the Vaccine Alliance,[1] the Maternal and Child Survival Program (MCSP, 2013–2019) has provided technical assistance to support countries in planning for, preparing for, and introducing new vaccines and in following up post-introduction. Since 2014, MCSP has supported 25 new vaccine introductions (NVIs) in 11 Gavi-eligible countries. This work has built on lessons from MCSP's predecessor program, the Maternal and Child Health Integrated Program (MCHIP, 2009–2013).

NVI under MCHIP and MCSP

MCHIP provided in-depth technical assistance for 15 NVIs in 10 Gavi-eligible countries in coordination with key partners, including the World Health Organization (WHO), UNICEF, and Gavi. Building on this experience, MCSP's influence on introductions has varied depending on in-country human and other resource capacity, but for all introductions, the program was an active technical partner at the national level, participating in planning and drafting training, monitoring, and other tools. In MCSP focus districts, program staff and local collaborators trained government staff to use those tools and provided monitoring, supervision, and logistical support during the transition to the new vaccines. Project vehicles contributed to delivery of vaccines, and, in the case of the switch from tOPV to bOPV, the removal of vaccines. The types of vaccines introduced shifted between MCHIP and MCSP, and MCSP supported several countries in the historic global shift from tOPV to bOPV.[2] Under MCSP there was much less focus on PCV and RV introductions and much more on IPV and measles-containing vaccine, including the second-year-of-life dose as part of expansion to life course vaccination. Global supply was a more prominent limiting factor for introductions under MCSP. Although the project planned to support introductions of IPV in 11 countries, this was not possible in Tanzania, Malawi, and Zimbabwe due to delays caused by the global IPV shortage. A table detailing MCSP's role, challenges, and successes in IPV introductions and country switches from tOPV to bOPV can be found in Annex I.

VACCINE ACRONYMS

bOPV bivalent oral polio vaccine
HPV human papillomavirus vaccine
IPV inactivated polio vaccine
MCV1 measles-containing vaccine, first-dose
MCV2 measles-containing vaccine, second-dose
MR measles-rubella vaccine
MSD measles vaccine, second dose
PCV pneumococcal conjugate vaccine
RV rotavirus vaccine
tOPV trivalent oral polio vaccine

1 Gavi, the Vaccine Alliance is an international organization that brings together public and private sectors to improve access to new and underused vaccines for children living in the world's poorest countries. Countries are eligible for Gavi support when their Gross National Income per capita is below or equal to US $1,580 on average over the past three years. The U.S. Government is a longstanding donor to Gavi.

2 For more information, please see Report on MCSP Support for the Polio Switch in April 2016, https://www.mcsprogram.org/resource/report-mcsp-support-polio-switch-april-2016/.

Lessons and Recommendations for NVI

The introduction of new vaccines presents an opportunity to protect against major causes of mortality and disability, and to strengthen RI and other health programs. However, to achieve these goals, deliberate planning is critical, as without careful preparation, NVI can instead stress immunization programs, especially during the first 6–12 months post-introduction. The ease of introduction and its effects on the RI system are significantly influenced by the vaccine and its formulation, presentation, and packaging; country capacity and experience; and the duration and quality of NVI planning and preparation.

Over the last decade, MCHIP and MCSP have documented challenges and successes from supporting countries to introduce new vaccines and engaged in global working groups to share lessons learned and develop guidance for future introductions. While ministries of health (MOHs) and in-country partners often understand how to effectively plan, prepare, and introduce new vaccines, too often, plans are not fully implemented before the vaccine launch. For example, updated data collection forms may not be ready, training may be incomplete, or communication materials may not be printed and in use. Incomplete plans can occur due to:

- **Other priorities:** Many Expanded Programme on Immunization (EPI) units have too few staff to adequately handle EPI reviews, multiyear plans, Gavi Joint Appraisals, multiple NVIs and/or post-introduction evaluations, and polio or other disease outbreak responses while simultaneously planning, managing, reporting on, and implementing RI services.
- **Political imperatives:** High-level political interest is sometimes prioritized over operational readiness for a successful launch. This means attention is sometimes focused on highly visible components of the introduction, such as launch ceremonies, rather than on timely logistical preparations, such as ensuring that all relevant health staff are trained, cold chain improvements are completed, and data collection tools are updated before the launch.
- **Funding issues:** Funding for NVI typically comes from the national government, Gavi, and other donors. In some cases, promised funds are insufficient for thorough preparations, and sometimes funding is not available on time, especially at subnational levels.

NVI partners should be aware of these common barriers and try to anticipate and address them by providing ample time and/or resources for the NVI preparation process. Additional challenges that should be considered include adequately addressing:

- High vaccine costs, often in the medium to long term
- Strengthening weak components of the RI program
- The increased complexity of data collection due to additional vaccines, which can change the definition and utility of the "fully immunized child" concept and reduce the reliability of mother's recall in coverage surveys
- Needed revisions to paper records and electronic information systems on time for the launch
- New service delivery and communication channels required to reach new target and age groups
- Staff's lack of skills and knowledge needed to handle and administer many vaccines with differing characteristics
- Increased requirements for cold chain storage and transportation capacity for new, bulkier vaccines
- Concern from health workers and parents about the increasing number of injections offered on the same day and confusion over eligibility for new vaccines
- Inadequate surveillance and tracking of adverse events following immunization
- Cold chain preventive maintenance and repair

Some MCSP country staff specifically identified several of these challenges, including:

- Inadequate time for preparation activities (especially at subnational levels), training, and sensitization
- Competing demands and lack of funding when and where needed, which negatively affected preparations for NVI
- Global supply problems, which delayed IPV introductions and pressured some countries to accept presentations of PCV and RV that were not their first choices

A table noting challenges that each MCSP-supported country faced with NVI can be found in Annex II.

In addition, it is important to acknowledge that coverage of a new vaccine during the year of introduction is often lower than that of other vaccines targeting the same age group, typically increasing gradually over the following year or two post-introduction. In MCSP-supported countries, this was consistently observed with IPV (see Annex III). This trend may be due to many factors besides the quality of NVI, including global vaccine shortages, national and subnational stock-outs, strikes, and disease outbreaks and responses.

For introduction of MCV2, many countries have found it difficult to achieve high coverage compared to MCV1, a trend also observed in MSCP-supported countries (see Annex IV). This most likely occurs because of the long interval between doses and the need to adjust to the new vaccination contacts in the second year of life, including the shift away from the concept that full immunization ends by a child's first birthday. This challenge highlights the needs for strong communication with families and for health workers to change their perception that immunization is only for infants and therefore ends at a child's first birthday. To address these potential challenges, important actions for introductions include:

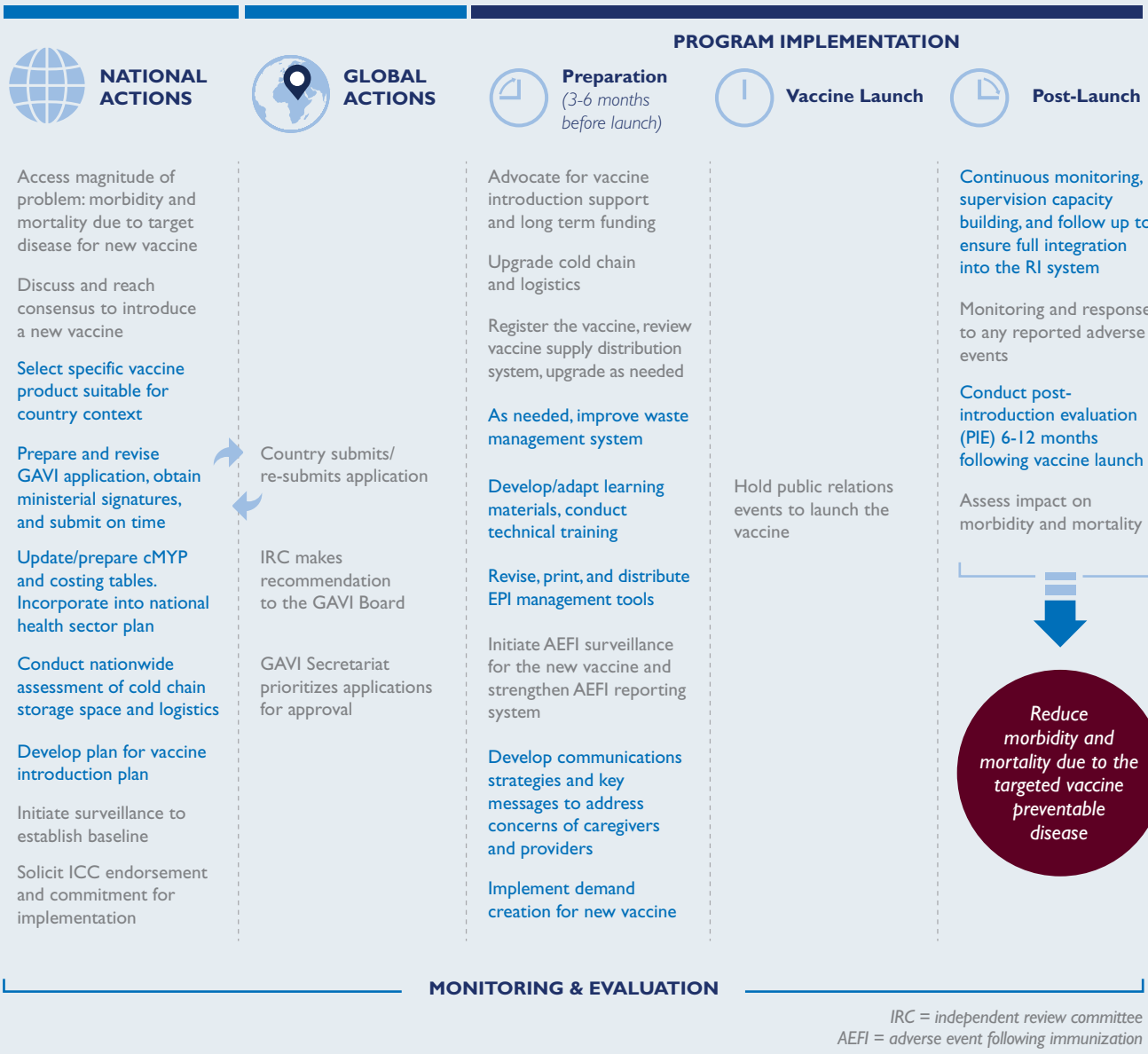
- Establishing or strengthening steering and other committees to advise the MOH on policy considerations, monitoring NVI preparations and implementation, and strengthening the RI system more broadly
- Reinvigorating partnerships, including with civil society, to mobilize popular demand
- Making and implementing NVI preparations that will help revitalize weak components of the RI program
- Completing the process of revising and disseminating the new immunization schedule, recording and reporting forms, job aids, and management tools

- Updating/preparing microplans at various levels, including implementation budgets
- Assessing requirements for cold chain procurement, vaccine distribution, storage, supply management, and waste disposal
- Building workforce capacity through training and supportive supervision
- Orienting/involving key public- and private-sector collaborators; providing public information and strengthening health staff and civic leaders' abilities to counsel and respond to questions and concerns on the new vaccine and vaccination in general
- Monitoring NVI planning and implementation closely to rapidly remedy any issues
- Taking advantage of the NVI process to build coordination for integrated approaches to prevent pneumonia, diarrhea, and some types of cancer

NVI provided an opportunity for health workers to receive refresher training on vaccine and data management for RI and to develop partnerships across sectors. This suggests that successful introductions can also benefit the health system when planning and implementation are effective.

To support countries introducing new vaccines, MCHIP created the Scale Up Map for New Vaccine Introduction in GAVI Supported Countries (Figure 1) and a monograph, Bottlenecks and

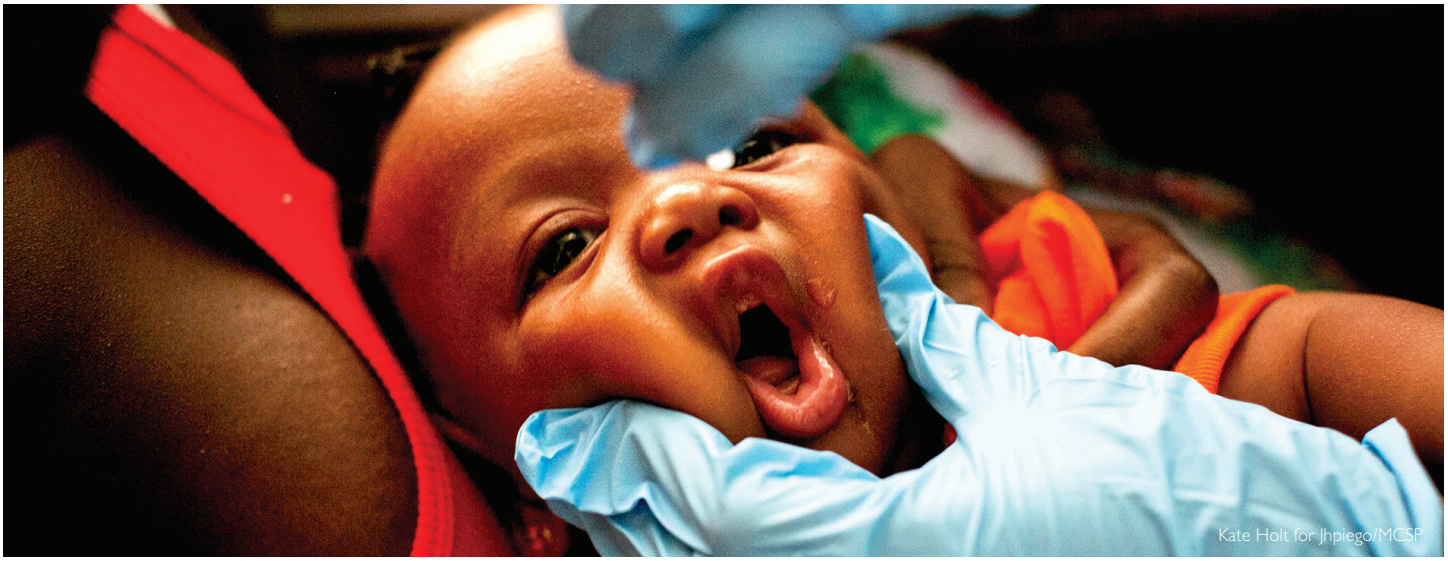
Figure 1. Steps involved in introducing a new vaccine in Gavi-supported countries[3]



IRC = independent review committee
AEFI = adverse event following immunization

Source: MCHIP | Note: The map is also available in French

3 Blue text indicates steps where MCHIP and MCSP provide technical support



Breakthroughs: Lessons Learned from New Vaccine Introductions in Low-resource Countries, 2008 to 2013.[4] A French version is also available. These resources were used to improve introductions supported by MCSP.

Using Lessons from the Past to Inform NVI: Country Examples

Although there were some challenges during MCSP-assisted introductions, they were less common than during MCHIP introductions and were typically resolved quickly. There is evidence that MCSP and national immunization programs learned from experiences under MCHIP.

TANZANIA

In 2012, MCHIP supported Tanzania to introduce PCV13 and RV. Stakeholders noted logistical challenges during preparation for the introduction specifically involving distribution of vaccines and related supplies, training materials, and revised data collection tools. Based on this experience, when Tanzania moved to introduce MSD and MR with support from MCSP, stakeholders emphasized the importance of effective microplanning. In addition, stakeholders highlighted the need to ensure that ample preparation time was provided for health workers and community leaders to be adequately trained on vaccine eligibility and for all levels of the health system to be effectively prepared for the introduction. Stakeholders referred to the NVI monograph as guidance for the NVI process and noted that while there were still challenges with the introduction of MSD and MR, the process did improve based on lessons learned from the MCHIP-supported introductions. As Tanzania moves forward to introduce HPV and IPV, preparation efforts have further improved, particularly sensitization at all levels through radio, TV, and newspapers, with even journalists being briefed on clear communication in order to avoid spreading misinformation or rumors.

KENYA

In Kenya, NVI was initiated by the National Vaccine and Immunization Project at the national level, but the national health system was responsible for actual implementation and rollout. During preparation for the launch of MR and IPV, stakeholders provided feedback to technical working groups and technical support at the national and subnational levels to share lessons learned from MCHIP NVI experiences. Despite highlighting the MCHIP-identified need for adequate NVI preparation time to ensure health workers are adequately trained, and that vaccines and revised data collection tools are distributed, inadequate country health system capacity, competing demands, and late release of funds led to similar challenges under MCSP. Although appropriate planning took place for NVI, steps under the responsibility of the country health system, including rollout of training and preparation and dissemination of communication materials, were not carried out as scheduled. In addition, country stakeholders experienced unanticipated disruptions to RI vaccine distribution and service delivery during the first year of introduction due to frequent nurse strikes and inadequate planning and commitment of funds.

Conclusions

In summary, national governments and partners, including MCHIP and MCSP, have learned and endeavored to implement many lessons so that NVIs can be smoother, avoid stressing vaccination services and ideally strengthen services, and reap the benefits of the new vaccines as rapidly as possible. While MCSP has noted some positive trends, challenges clearly remain. Governments and partners should continue the ongoing processes of identifying problems and best practices, and honestly assessing and continuing to improve performance based on those findings.

4 For more information please see Bottlenecks and Breakthroughs: Lessons Learned from New Vaccine Introductions in Low-resource Countries, 2008 to 2013, https://www.mchip.net/technical-resource/bottlenecks-and-breakthroughs-lessons-learned-from-new-vaccine-introductions-in-low-resource-countries-2008-to-2013/.

Annex

Annex 1. MCSP Roles and Overall Experiences of tOPV to bOPV Switch and IPV Introductions

Country	MCSP Role	Overall Successes	Overall Challenges	Supply/Distribution Problems
Haiti	Provided general technical and logistic support	• Training session with nurses at district level about bOPV • Strategies for switch well-defined and communicated to districts and partners	• Insufficient time allotted to carry out the switch • Defining clear procedures for destroying tOPV stock • Problems picking up tOPV in remote areas	• IPV: transportation, stock-out at national level, storage • Switch: no issues reported
Kenya	Provided general technical and logistic support	• Good use of the polio campaign logisticians to collect remaining tOPV vaccines in facilities • Timely distribution of bOPV to facilities • Universal availability of IPV during the switch period • Involvement of national polio committees • Early switch in facilities that vaccinate on weekends	• Adding extra topics to the switch training reduced the attention the switch deserved • Most facilities lacked incineration facilities, which delayed disposing the tOPV waste • tOPV was distributed as bOPV in some subcounties • Trainings did not emphasize the disposal of used vials that could have been stored in the facilities	• IPV: national stock-out • Switch: Short-term stock-outs at some health facilities
Liberia	• Provided general technical support • Planned and coordinated meetings for the switch	No information	• Competing priorities: polio national immunization days, introduction of RV, HPV pilot • Development of immunization improvement plan	No issues reported
Madagascar	• Provided training and general technical support, including logistic support and switch supervision • Participated in planning and coordinating meetings	No information	• Delay in collection and destruction of tOPV samples for 1–2 weeks	No issues reported
Malawi	• Supported technical training • Participated in planning and coordinating meetings	• Preparatory activities were implemented on time • Country able to switch when originally planned	Lack of funds for completion of some activities	No issues reported
Mozambique	Provided switch supervision in focus provinces and districts	• Vaccine arrived in all health facilities • No stock-outs until introduction date • Population acceptance • Materials in place in a timely manner	IPV stock-outs at some facilities (post-introduction)	IPV stock-outs at some facilities (post-introduction)
Nigeria	• Provided general technical support • Participated in planning and coordinated meetings on the switch	• Switch committees formed at all levels • States ready for switch • Weekly updates on dashboard of transfer of tOPV stock from all local government authorities (LGAs) to national level • Partner collaboration with government led to synchronized training • All RI providers, both public and private, sensitized on switch	• Template revisions without notice • Delays in reports from LGAs on the formation of switch committees • Timeframe for switch not long enough for proper completion • Inadequate funding • Destruction method for tOPV was unclear	IPV stock-outs at national and subnational levels

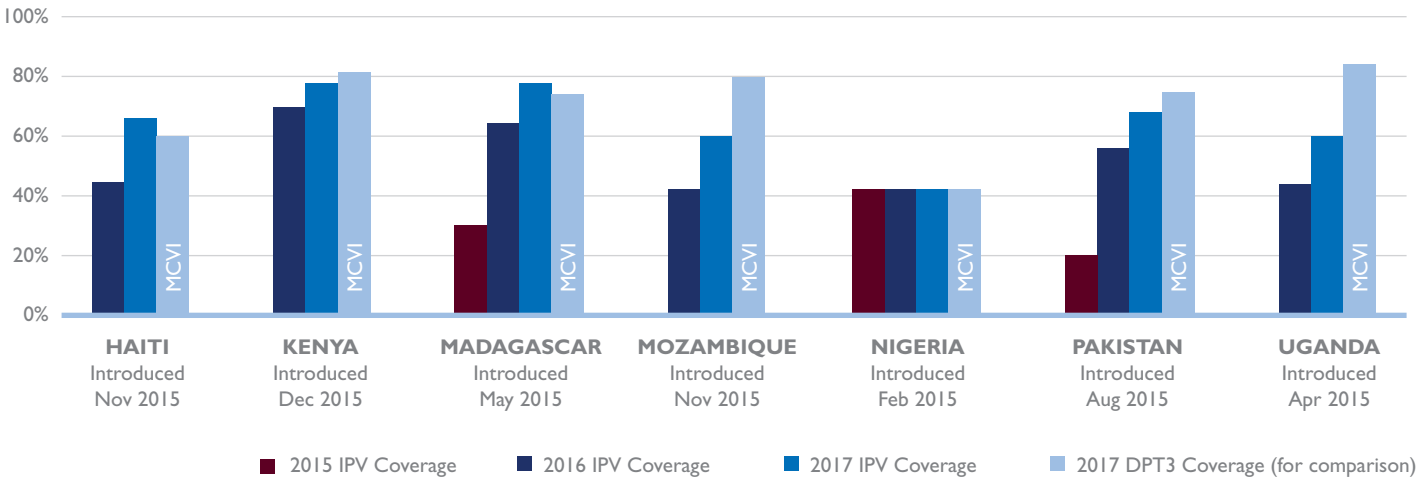
Country	MCSP Role	Overall Successes	Overall Challenges	Supply/Distribution Problems
Pakistan	Assisted switch supervision and general technical support in Sindh Province	National and provincial switch plans prepared and followed	• At initial stages, issue getting physical inventories from the provinces/districts • Availability of the budgeted funds	No issues reported
Tanzania	Provided technical support at national and subnational levels (in planning, coordination, and training)	• All tOPV collected for disposal before switch date • All health facilities received bOPV 1 day before switch date	No major challenges noted	No issues reported
Uganda	• Provided switch supervision, general and training technical support, and general logistical support • Participated in planning and coordination of meetings	• All scheduled trainings successfully conducted • IPV introduction was given maximum attention and clear activities and timelines • Supportive supervision during IPV introduction provided opportunity to reinforce RI	• Delay in the release of funds from the MOH to districts • Reference training materials and other communications came in separate pieces • Health workers needed clarification on whether multiple-dose vial policy applied to IPV	No issues reported
Zimbabwe	• Provided training technical support, general technical support, and switch supervision • Participated in planning and coordinating meetings	• Independent monitoring training organized and completed • Motivation of all stakeholders involved in the switch, including District Health Teams • Timely development of switch guidelines, job aids, and training packages • Timely training of all health workers involved in the switch	• Inadequate funding for the switch processes, including adequate transport • Inaccurate data on the status of tOPV stocks in the health facilities and cold stores to facilitate monitoring of over-stocking or stock-outs before the switch • Finding "independent" independent monitors	No issues reported

Annex II. NVI in MCSP-Supported Countries

Country	Vaccine	Launch Date	MCSP Role	Benefits	Challenges
Haiti	IPV	November 2015	• Assisted in immunizing children in four selected districts • Provided technical assistance to conduct RI rapid assessment before launch	No benefits reported	• Little launch preparation • Poor distribution from the national level and insufficient cold chain storage capacity • Issues with stock-outs
Kenya	MR IPV	November 2015 December 2015	• Developed training materials • Oversaw introduction at subnational level • Developed communication and monitoring and evaluation plans • Participated in post-introduction evaluations	• Health worker refresher trainings on RI • Partnerships with new stakeholders	• Insufficient time for planning • Delayed dissemination of documentation and communication tools • Inadequate training of health workers and communication officers • Delayed arrival of vaccines • Introduction delayed
Malawi	MSD MR	July 2015 August 2017	Supported pre-introduction activities, including: • Training health workers and EPI coordinators in all districts • Developing social mobilization materials • Co-facilitated preparatory meetings	• Health worker refresher training on vaccine and data management • Community sensitization on second-year vaccinations • Collaboration between immunization and education stakeholders	• High dropout rate from MCV1 to MCV2 high • MR second-dose coverage low due to difficulties mobilizing families to return to facility at 15 months
Mozambique	MCV2 IPV PCV switch (10 to 13) MR	November 2015 November 2015 December 2017 May 2018	• Facilitated national- and provincial-level trainings • Participated in technical working groups • Assessed readiness of provincial teams • Provided post-introduction supervision • Participated in post-introduction evaluations • Supported distribution of vaccines at subnational level	• Collaboration among immunization partners for successful introduction/switch	• Lack of timely funding for subnational logistics • Campaigns and trainings not held according to established schedule • Quality of district trainings negatively impacted because national and provincial trainers did not participate
Nigeria	IPV PCV	February 2015 December 2014	• Participated in planning at national level • Contributed to training facilitation, supervision, and monitoring during rollout in Bauchi and Sokoto states	• Health worker refresher trainings • High-risk states given priority for IPV and PCV introductions (phased introductions), which allowed for better supervision and monitoring	No issues reported
Tanzania	MSD MR	May 2014 October 2014	Advised country stakeholders on key steps, including: • Assessing cold chain needs • Revising data collection tools • Developing microplans • Building capacity of health workers • Engaging in communication and social mobilization activities • Implementing supportive supervision		• Delayed distribution of revised data tools • Health workers unclear about eligibility • Caregivers and community leaders in hard-to-reach areas not sufficiently sensitized • Low initial coverage of MCV2
Uganda	RV	June 2018	• Provided support for supervision and training, and general technical and logistical support • Participated in planning and coordination of meetings	• All scheduled trainings successfully conducted • Introduction was given maximum attention and clear activities and timelines • Supportive supervision provided opportunity to reinforce RI	• Delayed release of funds from MOH to districts • Reference training materials and other communications came in separate pieces • Health workers needed clarification on whether multiple-dose vial policy applied

Annex III. Coverage of IPV Over Time

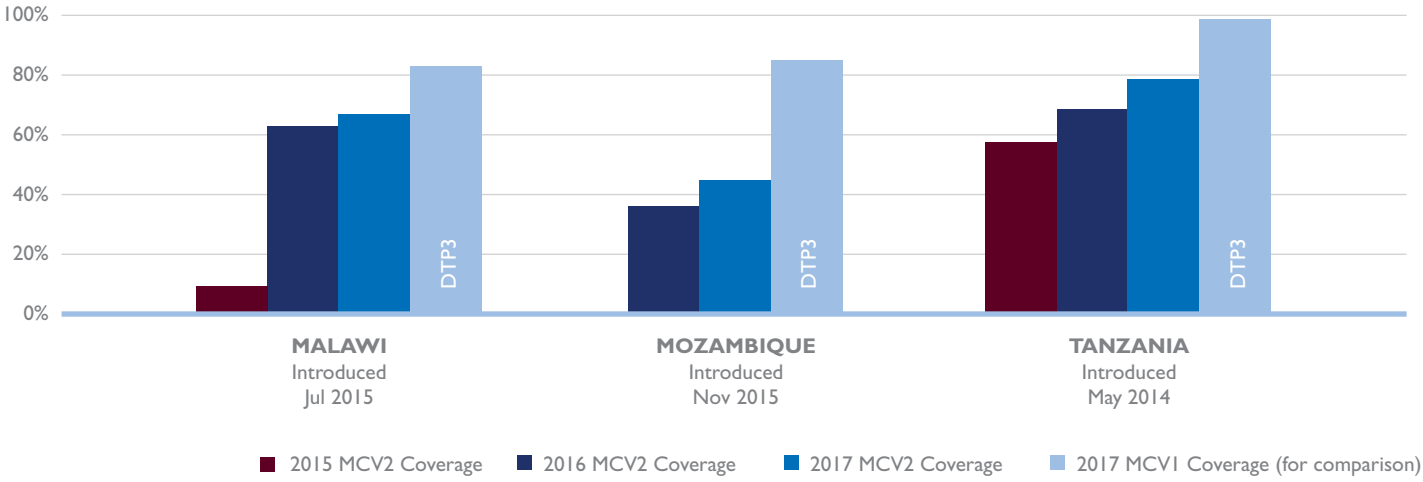
Coverage of IPV over time (year of introduction–2017) compared to diphtheria-tetanus-pertussis (DTP3) coverage (2017)



Data source: WHO/UNICEF
Coverage of IPV (based on WHO/UNICEF data) is displayed from the year of introduction through 2017, with DPT3 coverage in 2017 shown for comparison.

Annex IV. Coverage of MCV2 Over Time

Coverage of MCV2 over time (2015–2017) compared to MCV1 coverage (2017)



Data source: WHO/UNICEF
Coverage of MCV2 (based on WHO/UNICEF data) is displayed from the year of introduction through 2017, with MCV1 coverage in 2017 shown for comparison.

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