Bottlenecks and Breakthroughs:

Lessons Learned from New Vaccine Introductions in Low-resource Countries, 2008 to 2013

Prepared by
Maternal Child Health Integrated Program (MCHIP)
U.S. Agency for International Development

The Maternal and Child Health Integrated Program (MCHIP) is the USAID Bureau for Global Health's flagship maternal, neonatal, and child health (MNCH) program. MCHIP supports programming in maternal, newborn, and child health, immunization, family planning, malaria, nutrition, and HIV/AIDS, and strongly encourages opportunities for integration. Cross-cutting technical areas include water, sanitation, hygiene, urban health and health systems strengthening.

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Abbreviations and Acronyms

AEFI	adverse events following immunization
cMYP	comprehensive multi-year plan
DTP	diphtheria, tetanus, pertussis vaccine
EPI	Expanded Program on Immunization
GAVI	Global Alliance for Vaccines and Immunization
Hib	*Haemophilus influenzae* type b
HMIS	health management information system
ICC	Inter-Agency Coordinating Committee
IEC	information, education, and communication
KAP	knowledge, attitudes, and practices
PCV	pneumococcal conjugate vaccine
PIE	post-introduction evaluation
MCHIP	Maternal and Child Health Integrated Program
MOH	ministry of health
NGO	nongovernmental organization
OPV	oral polio vaccine
PMTCT	prevention of mother-to-child transmission
RV	rotavirus vaccine
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VIG	vaccine introduction grants (from GAVI)
VVM	vaccine vial monitor
WHO	World Health Organization

Executive Summary

Over the past several years, the development of new vaccines, along with global efforts to make them more available and affordable, has resulted in the introduction of lifesaving vaccines in low-resource countries around the world. From 2008 to 2013, the Maternal and Child Health Integrated Program (MCHIP), funded by the United States Agency for International Development (USAID), provided in-depth technical assistance on the operational aspects of the introduction of 15 new vaccines in 10 GAVI-eligible countries; this represented 14% of all GAVI-supported introductions during this time period of vaccines used in routine immunization. The lessons learned from these experiences are shared in this document with the hope that they will be useful in supporting smooth and successful introductions of vaccines today and in the future.

Although many of these new vaccine introductions encountered some temporary "bumps in the road" and missed opportunities to strengthen the countries' immunization and health programs, all were successful in that the new vaccine was introduced into the vaccination schedule, protecting more children against serious diseases, and overall coverage did not decline. Popular demand for and acceptance of these new vaccines (primarily pentavalent, pneumococcal conjugate, and rotavirus vaccines) was relatively high due to knowledge and fear of the target diseases for the new vaccines and to successful communication activities. Some vaccine introductions did lead to improvements in various aspects of the routine immunization program, especially when there were concerted efforts to use the opportunity of the vaccine introduction and accompanying partner funding to make such improvements. Zimbabwe improved its schedule for maternal and child health interventions—stimulated first by the introduction of pneumococcal conjugate vaccine (PCV) and taken further with the introduction of rotavirus vaccine (RV)—with the aim of increasing early access to critical services such as prevention of maternal-to-child transmission (PMTCT) of HIV/AIDS. Similarly, other countries used the training for new vaccine introduction as an opportunity to address other immunization topics, so as to improve health worker skills and knowledge.

There is clearly room for improvement, however. Many of the countries that introduced new vaccines encountered implementation problems, particularly in the year following the vaccine launch. Common problems included stock-outs due to unclear eligibility policies; poor vaccine management and insufficient funding for transport and fuel for cold chain equipment; health management information system (HMIS) forms not updated in a timely fashion; and insufficient numbers of health workers trained on the new vaccine. The concept of making vaccine introductions contingent on a country's readiness was not translated to common practice because of pressure, both from within countries and from donors and the international health community, to introduce a given vaccine.

The vaccine introductions highlighted and sometimes exacerbated existing flaws in health and immunization systems. These neglected areas included weak or nonexistent surveillance for adverse events following immunization (AEFI), inadequate systems to manage the increasing volume of waste generated by each new vaccine, and poor vaccine management and distribution.

Concerns Based on MCHIP Experiences

- High-level **political interest** at the global and national level to launch new vaccines sometimes outweighed programmatic and operational readiness for a successful introduction that strengthened routine immunization. Instead, attention was focused on the development, supply, and finance of the vaccines. In the absence of careful planning and preparation, the introduction of new vaccines stressed the immunization programs that delivered them.
- New vaccine introductions posed particular challenges to **supply chain management**. Additional capacity was needed to handle the cold chain and logistics burdens presented by the new, bulkier vaccines. Even as new equipment was purchased, cold chain repair and maintenance facilities were often neglected. Insufficient attention was given to the need to manage and dispose of the increased volume of medical sharps waste generated by the additional injectable vaccines.
- The vaccines introduced during this period were well accepted, and they generated high demand–both for the particular vaccine and, in some instances, for immunization overall. At the same time, they posed **communication challenges**. Pneumococcal conjugate and rotavirus vaccines prevent some but not all types of pneumonia and diarrhea, respectively, and this information had to be communicated clearly in order to manage expectations. Health worker training did not always build vaccinators' ability to address parental (and health worker) concerns about the new and unfamiliar vaccines. In some instances, the eligibility criteria regarding who could and could not receive the popular vaccines were not clearly conveyed to the public, resulting in confusion and rapid depletion of vaccines. In some countries, health workers and parents expressed concerns about the increased number of injections to be given to an infant on the same day.
- **Data and information needs and procedures** became more complex with the addition of more vaccines. Thorough, systematic changes to paper records and electronic information systems were needed but not always accomplished by the time of the vaccine introduction or even months afterward. With so many vaccines now administered to children, coverage surveys can no longer rely on parental recall to help inform coverage estimates; yet the availability of family-held vaccination cards or other individual records remains low. AEFI and surveillance systems have been inadequate in many countries, as has been the monitoring of immunization performance.

Needs-based technical assistance across multiple domains has helped to protect the investment in expensive new vaccines. MCHIP supported countries in addressing a range of issues, including developing service delivery and communication approaches to reach new target and age groups, strengthening health workers' skills to handle and administer the growing number of vaccines with differing characteristics, managing detailed considerations regarding eligibility criteria, recording and reporting of data, managing the cold chain and logistics, and updating policies and guidelines.

The Way Forward

New vaccine introductions are also a good opportunity to reinvigorate partnerships with civil society and mobilize popular demand. On a technical basis, steering and other committees can be established to advise the MOH on policy considerations, monitor preparations and implementation of the introduction process, and strengthen the routine immunization system more broadly.

Future introductions can benefit from past experience if the following measures are taken:

- Update and introduce the revised immunization schedule, recording and reporting forms, job aids, and other management tools before the introduction.
- Request that all levels of the health system prepare micro-plans that include implementation budgets.
- Assess requirements for cold chain, logistics (including transport and fuel for an expanded cold chain), and vaccine supply management and take appropriate action based on the assessment findings.
- Build the capacity of the workforce through the use of effective methods for training and supportive supervision.
- Conduct strategic, targeted communications and provide public information.
- Closely monitor the vaccine introduction to rapidly remedy any problems in order to enhance the positive effect on routine immunization, avoid any negative effects, and reap the full benefits of all vaccines.

On a larger scale, countries can channel the high-level interest in new vaccines against some of the major causes of mortality and disability to secure support for routine immunization. The routine immunization system must be strong enough to achieve high and equitable coverage with all vaccines on a sustainable basis.

Introduction, Background and Methods

The number of new vaccine introductions in national immunization programs in developing countries has grown exponentially in the past decade due to the development and commercialization of new vaccines and support from the GAVI Alliance.[1] As of late 2013, nearly all low- and middle-income countries had introduced vaccines against hepatitis B and *Haemophilus influenzae* type b (Hib), usually in the form of pentavalent vaccine, which also provides protections against diphtheria, tetanus, and pertussis (DTP). Some 49 developing countries, including 30 GAVI-eligible countries, had introduced pneumococcal conjugate vaccine (PCV), which protects against pneumonia, meningitis, sepsis, and other conditions caused by *Streptococcus pneumoniae*. In addition, 35 low- or middle-income countries, including 13 GAVI-supported countries, had introduced rotavirus vaccine (RV) to protect against a virus that can cause severe diarrhea in infants and is responsible for much of the diarrheal-related hospitalizations and deaths of young children worldwide. Many more countries plan to introduce PCV and/or RV in the next few years.

Over the next several years, several additional vaccines are expected to be introduced in low-resource countries. These include human papillomavirus vaccine to protect against cervical cancer, for which pilot projects were under way in 2013 in 10 GAVI-eligible countries[2]; rubella vaccine, in the form of a combined measles-rubella vaccine; and meningitis A vaccines in countries in the African meningitis belt. In addition, the "endgame strategy" of the global polio eradication initiative calls for all countries to add one dose of inactivated polio vaccine (IPV) to their existing schedule of oral polio vaccine (OPV). Eventually, it is anticipated that new vaccines that protect against malaria, dengue, and typhoid will be produced, prequalified by WHO, and introduced into countries, possibly with support from the GAVI Alliance.

This document analyzes MCHIP's experience and lessons learned in assisting many countries with the introduction of new vaccines, in the hope that they may be instructive for future vaccine introductions.

MCHIP'S TECHNICAL SUPPORT FOR NEW VACCINE INTRODUCTION

Between 2008 and 2013, the Maternal and Child Health Integrated Program (MCHIP), with support from the United States Agency for International Development (USAID), provided in-depth technical assistance for the introduction of 15 vaccines in 10 GAVI-eligible countries, as shown in **Table 1.**

Table 1. Vaccine introductions assisted by MCHIP

COUNTRY	VACCINE INTRODUCED	DATE OF LAUNCH
Democratic Republic of Congo (DRC)	PCV-13[a]	2011
India (Kerala and Tamil Nadu)[b]	Pentavalent[c]	December 2011
Kenya	PCV-10	February 2011

[1] Formerly known as the Global Alliance for Vaccines and Immunization
[2] MCHIP did not provide assistance for the introduction of human papilloma virus vaccines.

COUNTRY	VACCINE INTRODUCED	DATE OF LAUNCH
Malawi	PCV-13	November 2011
	RV (RotaRix®)[d]	October 2012
Rwanda	PCV-7	April-July 2009
	Transition to PCV-13	2011
	RV (RotaTeq®)	May 2012
	Measles-Rubella	March 2013
Senegal	Meningitis A	November 2012 (mass campaign)
	PCV-13	October 2013
	Measles-Rubella	November 2013
Tanzania	PCV-13	January 2013
	RV (Rotarix®)	January 2013
Timor-Leste	Pentavalent	October 2012
Uganda	PCV-10	April 2013
Zimbabwe	PCV-13	August 2012

[a] PCV-13 protects against 13 strains of *Streptococcus pneumoniae,* while PCV-10 protects against 10 strains and PCV-7 against seven strains.
[b] MCHIP played a limited role in new vaccine introduction in these two states.
[c] Pentavalent vaccine contains antigens that protect against five diseases: diphtheria, pertussis, tetanus, hepatitis B, and *Haemophilus influenzae* type b.
[d] Rotarix® and Rotateq® are the brand names of the two rotavirus vaccines provided through GAVI. Table 2 provides information on the features of these two products.

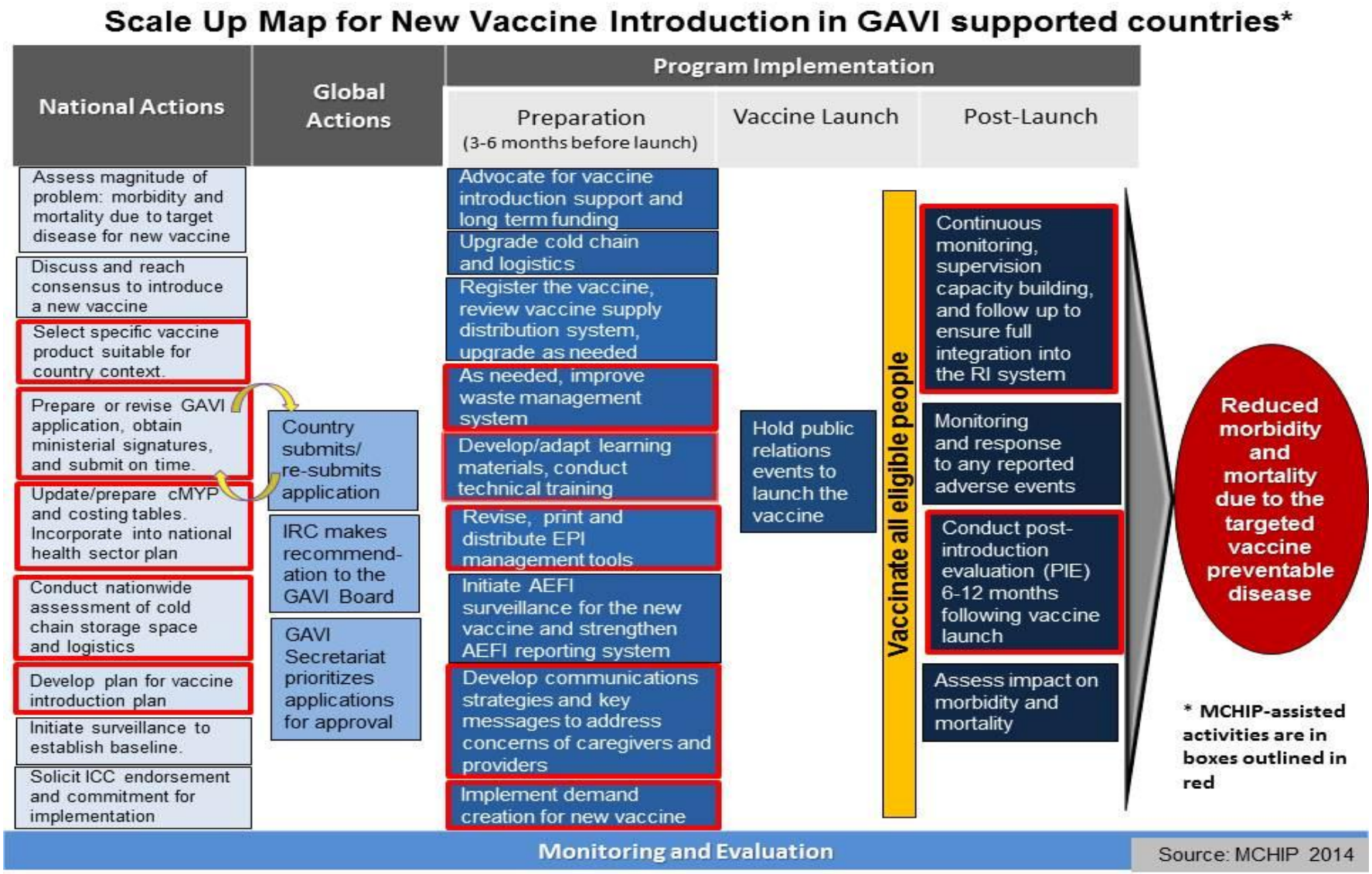
OVERVIEW OF STEPS IN INTRODUCING A NEW VACCINE

The introduction of a new vaccine is a complex, multistage process, as shown in **Figure 1**. It starts with a determination of the epidemiologic need for the vaccine and progresses to preparing an application to GAVI for new vaccine support. Once GAVI approves the application and indicates that sufficient vaccine is available, countries carry out several preparatory activities, from upgrading cold chain and waste management systems to revising data management forms, updating and improving surveillance systems, training health workers, and communicating with the public about the vaccine.

After the initial launch of the vaccine, the introduction process continues with post-introduction monitoring to identify and rectify problems. Immunization programs, with support from WHO and other partners, usually conduct a post-introduction evaluation (PIE) six to 12 months after the launch, and in some countries they later conduct an analysis of the vaccine's impact on disease incidence.

This monograph focuses on lessons learned in the programmatic areas for which MCHIP provided technical assistance to countries' national immunization programs. MCHIP typically did not advise countries on whether to introduce a vaccine, or on disease surveillance or monitoring the vaccine's impact on disease incidence. Usually, MCHIP was requested to assist countries with technical and operational aspects of the introduction. MCHIP helped countries decide which particular vaccine product to select by examining the programmatic suitability and cost implications of each product. MCHIP also assisted with the preparation of the GAVI application and required supporting documents, as well as in a range of programmatic areas, indicated in boxes with red outlines in **Figure 1**. These experiences, lessons learned, and practical implications for action are presented in this paper.

Figure 1. Steps Involved in Introducing a New Vaccine in GAVI-supported countries [MCHIP, 2014]



METHODS FOR REVIEWING MCHIP EXPERIENCE

The information presented in this monograph is based on a review of planning documents, introduction plans, comprehensive multiyear plans (cMYPs), training guides, internal project reports, quarterly and trip reports by MCHIP staff, and PIEs in which MCHIP participated. Document review was augmented through telephone interviews that an external consultant conducted with MCHIP technical staff, including seven headquarters staff and 11 field-based program officers in eight countries where MCHIP assisted with new vaccine introductions.[3] Follow-up information was obtained through e-mail communications with MCHIP headquarters and field staff. Findings were entered into a matrix organized by country and programmatic category (e.g., training, cold chain) and analyzed to identify common themes, instructive disparities, common problems, enabling factors, promising practices, and lessons learned.

[3] Interviews were conducted with field staff in all countries where MCHIP assisted with vaccine introductions, except Rwanda and Timor-Leste.

Pre-Introduction Decisions

This section focuses on the decisions to be made once a country has decided to introduce a vaccine, such as the selection of the specific vaccine product, the ages and populations eligible for the vaccine, whether catch-up immunization for older age groups will take place, and the appropriate vaccination schedule. All of these decisions must be included in the GAVI application and accompanying documents, including the introduction plan, budget, and the cMYP.

SELECTING THE VACCINE PRODUCT

A country's decision to introduce a vaccine against a particular disease ideally is based on a systematic review of data on the magnitude and cost of the disease and the vaccine's safety, efficacy, cost-effectiveness, and programmatic feasibility within the country context. The country must also consider the specific attributes of products available through GAVI from different manufacturers and select the one best suited to country circumstances. Vaccine products for a given vaccine such as PCV or RV may vary substantially by manufacturer in the following ways:

Vaccine formulation

- How completely the vaccine addresses the disease strains prevalent in the country

Vaccine cost

- Price per dose
- Number of doses required to be fully immunized

Vaccine handling and management

- Heat stability and freeze sensitivity
- Cold storage volume requirements
- Number of doses per vial
- Whether multi-dose vials contain a preservative and can be used on subsequent days
- Whether vials contain vaccine vial monitors (VVMs) to indicate heat exposure
- Whether the vaccine comes in liquid form or is lyophilized and thus requires reconstitution
- Route of administration and delivery device (e.g., a squeeze tube vs. oral syringe for orally administered vaccines)
- Whether age eligibility is compatible with groups targeted for other vaccines
- Whether the recommended schedule for the new vaccine corresponds to the country's existing schedule

These variables have practical implications for ease of use under field conditions as well as long-term cost implications. Thus, some products are better suited than others for use in GAVI-eligible countries. **Table 2** summarizes some key characteristics of the vaccine products currently available through GAVI.

Table 2. Comparison of Key Characteristics of PCV and RV Vaccines Available With GAVI Support
(based on MCHIP materials and interviews with MCHIP staff, October 2013)

CHARACTERISTIC	PNEUMOCOCCAL CONJUGATE VACCINES		LIVE, ORAL ROTAVIRUS VACCINES	
	PCV-13	PCV-10	Monovalent	Pentavalent
Brand name	Prevnar-13	Synflorix®	RotaRix®	RotaTeq®
Manufacturer	Pfizer	GlaxoSmithKline	GlaxoSmithKline	Merck
Composition	13 serotypes of *S. pneumoniae* conjugated to diphtheria carrier protein	10 serotypes of *S. pneumoniae* conjugated to various carrier proteins	Single strain (RIX4414)	5 human-bovine reassortant strains
Number of doses per series	3	3	2	3
Vaccine formulation	Liquid	Liquid	Liquid	Liquid
Presentation	1-dose vial	2-dose vials without preservative	Single-dose squeeze tube	Dispensing tip with single-dose vaccine attached to plastic tube into which vaccine is emptied
Dose	0.5 ml	0.5 ml	1.5 ml	2.0 ml
Storage volume per series (packed volume per dose) X (# doses) X (wastage factor)	43.48 cm^3 (13.8 volume/dose X 3 doses X 1.05 wastage factor)	15.98 cm^3	35.9 cm^3	144.6 cm^3

The successful introduction and use of a vaccine requires that planners consider the characteristics of available products. For example, PCV-10 occupies considerably less storage space in the cold chain than PCV-13, but its presentation in two-dose vials without preservative may pose a safety challenge, particularly in countries with weaker health infrastructure, because vials with unused doses must be discarded within six hours of opening to avoid the risk of contamination. This differs from typical handling practices for liquid vaccines, and as an issue of safety it must be stressed during the training of health workers and in supervision and on-the-job training. For this reason, WHO attached certain conditions to the introduction of PCV-10 in Kenya, the first African country to use the vaccine. These included providing extra support from the manufacturer for training, a two-year post-introduction study in selected districts to examine health workers' handling of the vaccine, and intensive post-monitoring surveillance at three points following the introduction.

Similarly, there are important differences between the two available rotavirus vaccines, including a two-dose versus three-dose schedule, a VVM on one product but not the other, a substantial difference in the total storage volume per dose in the cold chain required for one vaccine product compared to the other, and a difference in cost per dose and per complete series.

Main Findings

With high global demand for PCV and RV and only a single producer for each formulation of them, there was a global shortage of these vaccines in 2008-2013. Some MCHIP-assisted countries had to choose between taking a vaccine product that was not their preference and waiting an unknown period of time to obtain the vaccine product they viewed as most compatible with their circumstances.

Countries reacted in different ways to this situation. Of the seven MCHIP-supported countries presented with a choice between PCV-10 and PCV-13, all preferred PCV-13. However, Kenya, Tanzania, and Uganda accepted PCV-10 rather than wait. In Tanzania, PCV-13 became available before the scheduled launch date. By contrast, the Senegal Ministry of Health (MOH) stood by the decision of its technical committee to select PCV-13, even though this action resulted in a delay of more than a year and notwithstanding the considerable pressure from the medical community to introduce PCV as soon as possible.

Shortages of the two available rotavirus vaccines caused similar dilemmas for countries. Some, like Kenya, opted to wait for their top choice of rotavirus vaccine. Another (Rwanda) preferred a different rotavirus vaccine, but did not learn for certain until a few days prior to the start of national-level training which product they would receive. Consequently, two sets of training materials had to be prepared, one for each type of vaccine.

Accepting a vaccine presentation that is not optimal makes training, vaccine handling, and supply chain and logistics management more challenging, potentially giving rise to problems in implementation. Some national immunization programs are able to handle such challenges better than others.

Lessons Learned and Implications for Action

- Even when countries make careful product decisions based on the advice of a technical advisory committee, there are both external pressures (e.g., from development partners) and internal pressures (e.g., from the medical community) to accept a different product to avoid delaying the introduction. Therefore, policymakers need to hear the views of technical immunization experts, in addition to those of the medical community, regarding the selection of vaccine products. Accepting a product that the national immunization program and the MOH cannot adequately manage should be avoided.
- GAVI-supported countries and their partners need to be kept informed well ahead of launch dates about which specific vaccine products are available and will be sent to the country. This is key information that affects many aspects of preparation for the vaccine introduction, including the content of the training materials, supply chain management, and communication messages and materials.

DECIDING WHO IS ELIGIBLE FOR THE NEW VACCINE

Countries need to decide well in advance of a vaccine introduction which children are eligible for the new vaccine, particularly for the period immediately following introduction. This policy should be clearly stated in actionable terms in field guides, because it affects training, communication to the public, and vaccine forecasting and management.

For example, for an infant vaccine such as PCV, health officials must decide whether only the new birth cohort (e.g., children six weeks old who have not yet received any vaccines beyond birth doses of OPV or hepatitis B) is eligible, or if all children under a certain threshold age (e.g., 12 months) can receive the new vaccine, even if they have already started another vaccination series (such as pentavalent vaccine). The backlog of unvaccinated infants already alive at the time of the introduction plus those born in the following 12 months constitutes the

equivalent of two birth cohorts in the first 12 months of vaccine introduction. Immunization programs must also decide whether children who have reached a cutoff age (e.g., 12 months) before receiving some or all doses of the new vaccine can complete the series.

These decisions affect both the amount of vaccine needed and the required funding as GAVI normally provides vaccine only for a single birth cohort. They also affect the content and complexity of the training and communication messages to the public. Once the decisions are made, they need to be clearly stated—to policymakers, health workers, and parents—to avoid parents demanding the vaccine for non-eligible children, health workers not complying with the policy, and vaccine shortages if a larger-than-planned cohort of children is given the vaccine. Health workers, in particular, need support from the program to enable them to refuse the vaccine to ineligible children. The factors that policymakers should consider in establishing eligibility criteria should include how to respond to the population's demand for the vaccine, how to prevent vaccine shortages while staying within budget, and how to make the policy as simple as possible to avoid confusion. While the issue of eligibility criteria is a short-term problem during the first several months after the vaccine is introduced, if not handled well it can cause the introduction to get off to a poor start and affect longer-term community attitudes toward the immunization program.

Main Findings

Table 3 shows the policy decisions regarding vaccination eligibility for PCV and experiences in MCHIP-assisted countries.

Table 3. Vaccination Eligibility Policies for PCV in MCHIP-Assisted Countries

COUNTRY	ELIGIBILITY POLICY	RESULTS
DR Congo	All children under one year of age, regardless of pentavalent vaccination status, were eligible. Once children reached 12 months, they could not finish the PCV series, even if they had started it at an older age.	Health workers did not follow the policy and gave the rest of the PCV series to children older than 12 months, even if they started late. A new directive for the first two provinces was sent out to address this.
Kenya	All children < 1 year old as of January 1, 2011, were eligible. The training guide did not clarify what to do with children mid-cycle for other vaccines or who had not finished PCV by 12 months of age.	An estimated 1.5 birth cohorts were vaccinated in six months, including some older children. This resulted in a national PCV stock-out for several months as well as local stock-outs of other vaccines in some areas, as the high demand for PCV attracted large numbers of defaulters for other vaccines.
Malawi	All children ≤ 11 months old, regardless of pentavalent status, were eligible. Children > 11 months could finish the series if they started late.	National stock-outs were averted because UNICEF sent a larger upfront vaccine supply in anticipation of high demand plus buffer stock was used.

COUNTRY	ELIGIBILITY POLICY	RESULTS
Rwanda	All children < 1 year old, regardless of pentavalent status, were eligible.	Children who started late finished the series after 12 months. No national vaccine stock-outs occurred because the amount of vaccine received from the producer covered more than the target population and the introduction was phased in.
Uganda	All children ≤ 11 months old, regardless of pentavalent status, were eligible. Children could finish the series after they turned 11 months if they started late. The field guide also said that children > 1 and 2-5 years old could get a single catch-up dose, although health workers weren't trained to provide this.	The catch-up among children ≤ 11 months old might have contributed to stock-outs in the initial district where PCV was introduced, as vaccine forecasts were not based on the larger cohort. Health workers reportedly were not giving single catch-up doses to older children.
Zimbabwe	All children < 1 year old who had not started pentavalent vaccine were eligible. The policy was not explained in detail in the training materials.	Information/education/communication (IEC) activities created demand for the vaccine. Health workers did not comply with the policy in some districts and administered new vaccine to children who had already started the pentavalent series. 85% of clinics surveyed in the PIE had stock-outs, including of PCV. After depleting the reserve stock, a national stock-out was avoided by having the next quarter's shipment sent early and obtaining additional vaccine from GAVI.

Of the eight MCHIP countries that introduced PCV, five (DR Congo, Kenya, Malawi, Rwanda, and Uganda) opened up eligibility to all infants up to 11 or 12 months of age, regardless of their vaccination status for pentavalent or other vaccines. In some cases, training materials were unclear or barely mentioned the policy or the potential scenarios that health workers would face with children who were delayed with their vaccinations or who aged out before completing the PCV series. The problem was most acute in Kenya, one of the first African countries to introduce PCV: It vaccinated an estimated 1.5 birth cohorts in six months and consequently experienced a national stock-out of PCV for several months. Local stock-outs of other Expanded Program on Immunization (EPI) vaccines also occurred in Kenya because the high demand for PCV attracted children who had not completed their immunizations or were unvaccinated (see Section 3.7). The other four countries managed to avoid national stock-outs during the first year of introduction by using their buffer stock, receiving a larger upfront supply of vaccine in anticipation of the high demand (Malawi), or rapidly addressing the problem in the first provinces to introduce the vaccine (DR Congo).

Zimbabwe's policy called for not vaccinating children with PCV if they had already started the pentavalent vaccine series. But due to the large demand for PCV and health worker reluctance to refuse parents, the policy was not strictly followed in many districts and children mid-cycle for pentavalent were given PCV anyway. Some mothers reportedly delayed bringing their infants until PCV was introduced because they wanted their infants to receive the new vaccine and knew that prior doses of pentavalent would disqualify them from receiving PCV. A national stock-out of PCV was averted by drawing down on the buffer stock, having the supplier send its shipment for the following quarter early, and obtaining additional vaccine from GAVI.

Senegal and Tanzania reviewed their experience with earlier vaccine introductions when planning their introductions in 2013. Their new policies stipulated that only children in the new birth cohort (those six weeks old after a cutoff date in the year of introduction) were eligible for the new vaccine and no catch-up doses were allowed. Tanzania proactively managed the

situation: Health workers were alerted that stock-outs would result if the policies were not followed, and informational materials for parents emphasized that tiny infants were most at risk and in need of the vaccines. Some parents reportedly complained, but health workers followed the policy and did not report major problems with backlash.

Lessons Learned and Implications for Action

- Immunization programs should take into account the specific cultural, political, and practical realities of their country in developing policies about eligibility for new vaccines. For example, narrowing the target population to the birth cohort born shortly before and after the vaccine is introduced is easier for health workers to follow and reduces confusion as well as the likelihood of vaccine shortages. However, the political and cultural acceptability of this policy may be low in some countries, particularly for a vaccine in such high demand as PCV. This may well be the case for future vaccines against malaria or other high-burden diseases that are well known by the population.
- The vaccine eligibility policy must be made clear to both health workers and the public. If the policy allows any type of catch-up vaccination, program managers need to identify all possible scenarios and present them in charts or tables in the training materials and job aids to assist frontline workers. Countries that expand eligibility for a new vaccine to children beyond the new birth cohort (e.g., to all children under 12 months at the time of introduction) must base their vaccine forecasts on this larger cohort for the year in which the vaccine is introduced.
- GAVI and other international partners should provide guidance to countries concerning eligibility policies for the new vaccines and ensure that the vaccine forecast for the first year corresponds to the selected policy. The GAVI application could be revised to require countries to analyze all possible options and scenarios and to estimate vaccine needs accordingly.

REVISING THE IMMUNIZATION SCHEDULE

WHO's standard schedule for OPV and pentavalent or DTP vaccines calls for three doses to be given at six, 10, and 14 weeks. WHO recommends also providing doses of PCV and RV at these same vaccination contacts to optimize health system efficiency and improve convenience for caregivers. However, some countries that introduced PCV and RV between 2008 and 2013 had been using alternative schedules, (e.g., two, three, and four months) for decades.

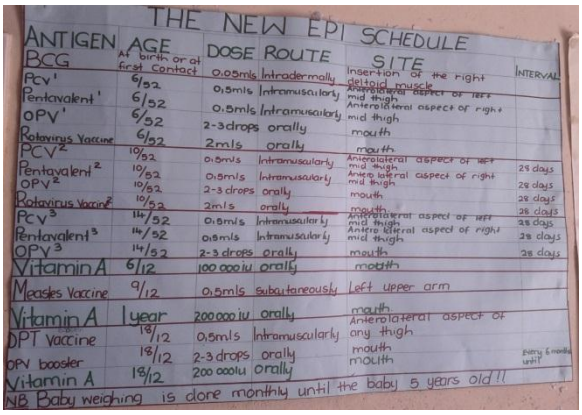
A later vaccination schedule poses a problem if countries adhere to the age restrictions for RV that WHO had recommended for minimizing the risk of intussusception. These restrictions called for the first dose of RV to be given by age 15 weeks and the last dose by 32 weeks. Starting the vaccination schedule at two or three months (i.e., eight or 12 weeks) of age considerably reduces the opportunity for infants to receive the first dose of RV by the age of 15 weeks. In 2012 the WHO Strategic Advisory Group of Experts recommended lifting the age restrictions, and in 2013 WHO officially revised its policy and position paper to reflect this.[4] However, WHO still recommends that RV be given as early as possible.

Main Findings

Changing immunization schedules. Two of the 10 countries that MCHIP assisted had immunization schedules that did not follow the WHO recommended schedule for age of administration of pentavalent or OPV vaccines. Both countries used the new vaccine introduction as an opportunity to change their schedules, handling this change in creative and instructive ways.

[4] World Health Organization. 2013. Rotavirus vaccines. WHO position paper. *Weekly Epidemiological Record* 5; 88, 49-64.

In planning for the simultaneous introduction of PCV and RV in January 2013, Tanzania realized the need to revise the infant immunization schedule from four, eight, and 12 weeks to the WHO-recommended schedule of six, 10, and 14 weeks. The MOH decided to enact the schedule change several months prior to the introduction and announced it nationally in April 2012 during African Vaccination Week. The rationale for this timing was to give health workers plenty of time to get accustomed to the new schedule so that they would not be faced with two major changes (new vaccines and new schedule) at the same time.


THE NEW EPI SCHEDULE

ANTIGEN	AGE	DOSE	ROUTE	SITE	INTERVAL
BCG	At birth or at first contact	0.05mls	Intradermally	Insertion of the right deltoid muscle	
Pcv¹	6/52	0.5mls	Intramuscularly	Anterolateral aspect of left mid thigh	
Pentavalent¹	6/52	0.5mls	Intramuscularly	Anterolateral aspect of right mid thigh	
OPV¹	6/52	2-3 drops	orally	mouth	
Rotavirus Vaccine	6/52	2mls	orally	mouth	
PCV²	10/52	0.5mls	Intramuscularly	Anterolateral aspect of left mid thigh	28 days
Pentavalent²	10/52	0.5mls	Intramuscularly	Anterolateral aspect of right mid thigh	28 days
OPV²	10/52	2-3 drops	orally	mouth	28 days
Rotavirus Vaccine²	10/52	2mls	orally	mouth	28 days
Pcv³	14/52	0.5mls	Intramuscularly	Anterolateral aspect of left mid thigh	28 days
Pentavalent³	14/52	0.5mls	Intramuscularly	Anterolateral aspect of right mid thigh	28 days
OPV³	14/52	2-3 drops	orally	mouth	28 days
Vitamin A	6/12	100 000 iu	orally	mouth	
Measles Vaccine	9/12	0.5mls	subcutaneously	Left upper arm	
Vitamin A	1 year	200 000 iu	orally	mouth	
DPT vaccine	18/12	0.5mls	Intramuscularly	Anterolateral aspect of any thigh	
OPV booster	18/12	2-3 drops	orally	mouth	
Vitamin A	18/12	200 000iu	orally	mouth	Every 6 months until 5

NB Baby weighing is done monthly until the baby 5 years old!!

In Zimbabwe, the National Immunisation Technical Advisory Group also used the introduction of PCV and RV as an opportunity to revise the infant immunization schedule from three, four, and five months (approximately 12, 16, and 20 weeks) for most vaccines to six, 10, and 14 weeks. This decision was based on data presented by the EPI Technical Working Group showing the limited opportunities for children to receive RV under the current schedule, given that the first dose of RV should be given by 15 weeks. The Ministry of Health and Community Welfare decided to take this opportunity to revise and streamline the entire schedule of MCH interventions recorded on the child health card, including screening and treatment for prevention of mother-to-child transmission (PMTCT) of HIV, growth monitoring, vitamin A supplementation, postnatal care visits, and immunization. The aim was to bring mothers and infants in earlier for critical health interventions and reduce the number of clinic visits, thus increasing the likelihood of adherence. The child health cards were redesigned to emphasize the schedule change, which was also heavily advertised through various communications channels.

Handling age restrictions for rotavirus vaccines. Even after WHO loosened its recommended age restrictions for RV, all MCHIP-supported countries introducing the vaccine opted to retain the lower and upper age limits. The Zimbabwe Ministry of Health and Community Welfare, which will introduce rotavirus vaccine in 2014, made this decision based partly on a small retrospective study of vaccine registries that showed that the vast majority of children were on time for their first two doses of pentavalent vaccine and that coverage rates for the second pentavalent dose were high. They therefore concluded that the age restrictions would not significantly affect coverage for RV.

Immunization programs face the challenge of communicating the age restrictions clearly to the public— so that parents don't demand RV for ineligible children—without scaring the parents away from getting their children vaccinated. Some countries, including Tanzania, tried to strike this balance by stressing in their communication and health worker training the need for all infants to get screened for and receive missed doses of other vaccines so that children beyond the age of the new cohort would not be left out entirely. In general, the issue of age restrictions and intussusception risk is not addressed directly in information for the public.

Lessons Learned and Implications for Action

- The introduction of new vaccines provides the opportunity for countries to revisit and improve their immunization schedules to maximize protection of children as early as possible and promote adherence to the schedule. This is also an opportunity to better integrate immunization with other maternal and child health interventions, especially when integrated forms, such as child health cards, are used.
- When introducing a new vaccine, one way to make the transition to a new immunization schedule smoother is to systematically enact the schedule change well in advance of the vaccine introduction to provide time for both health workers and the public to get accustomed to the new schedule before the new vaccine is introduced.

Preparing for the Vaccine Introduction

As noted earlier, the introduction of a new vaccine is a complex process with many steps, including the following:

- Updating the country's cMYP and accompanying costing tables
- Preparing a detailed vaccine introduction plan
- Assessing and upgrading cold chain and logistics systems to meet the storage requirements of the new vaccine
- Strengthening vaccine management practices to prevent stock-outs and vaccine spoilage due to freezing or heat exposure
- Improving medical waste management systems so they can dispose of and destroy the increased volume of used needles and syringes associated with the new vaccine
- Training and capacity-building of health workers at all levels on handling, administering, and managing the new vaccine (this requires a strong training plan and training materials)
- Revising, producing, disseminating, and introducing health management information forms and tools for immunization
- Preparing a communication and advocacy plan and developing messages to create demand for the vaccine
- Planning a well-publicized launch or series of launches
- Developing surveillance plans for the disease in question as well as surveillance for adverse events following immunization (AEFI) with the new vaccine
- Preparing for and implementing a schedule of intensive supportive supervision and monitoring visits shortly after the new vaccine launch to identify and resolve problems

Managing this process well requires strong leadership and coordination among the various activities, adequate and timely funding, and sufficient time to carry out all activities well and in proper order.

ESTABLISHING ORGANIZATIONAL STRUCTURES TO PREPARE FOR NEW VACCINE INTRODUCTION

Main Findings

In most MCHIP-assisted countries, an Inter-Agency Coordinating Committee (ICC)—a national group consisting of representatives from the immunization program, the MOH, and various international partners—oversaw the planning of the vaccine introductions. In some other countries, the government established a separate national task force, national steering committee, or similar group to oversee the process. As shown in **Table 4**, in most countries, the ICCs or other national committees then set up three or four subcommittees or working groups with responsibility for various aspects of the introduction. These subcommittees, which prepared and monitored specific work plans for their technical areas, reported to the ICC or equivalent group. In Kenya and Tanzania, a technical working group was set up to coordinate the work of the subcommittees, thus creating an additional layer of oversight.

Most countries did not, however, establish subcommittees at the subnational level, nor did they develop regional or district-level introduction plans, according to the PIEs. One exception was in Kerala and Tamil Nadu in India, where district officials helped prepare introduction plans for the pentavalent vaccine down to the level of the health facility.

Table 4. Organizational Structures to Support New Vaccine Introductions in MCHIP Countries

COUNTRY AND VACCINE	PRINCIPAL OVERSIGHT GROUP	SUBCOMMITTEES ESTABLISHED
DR Congo (Bas Congo and Kinshasa) (PCV-13)	Provincial ICCs	▪ Technical ▪ Logistics ▪ Communications
Timor-Leste (pentavalent)	ICC	▪ Technical/training ▪ Communications ▪ Launch event
Kenya (PCV-10)	National steering committee and technical working group	▪ Logistics ▪ Training ▪ Monitoring and evaluation ▪ Advocacy
Malawi (RV)	National Task Force (technical working group reconstituted by the MOH)	▪ Protocol (for logistics and planning) ▪ Transport (later merged with protocol group) ▪ Social mobilization
Rwanda (PCV-7 and RV)	ICC	▪ Technical ▪ Logistics ▪ Waste management and disposal ▪ Social mobilization
Senegal (PCV-13)	National Steering Committee (made up of ICC members and others)	▪ Technical ▪ Logistics ▪ Communications ▪ Disease and AEFI surveillance
Tanzania (PCV-13 and RV)	ICC and technical working group	▪ New vaccine coordinating committee (oversaw other subcommittees) ▪ Logistics ▪ Communications
Uganda (PCV-10)	National coordinating committee	▪ Resource mobilization ▪ Micro-planning, training, administration ▪ Cold chain, transport, and logistics ▪ Surveillance ▪ Advocacy/social mobilization
Zimbabwe (PCV-13)	ICC	▪ National EPI technical team with MOH/EPI officers and representatives from UNICEF, WHO, and MCHIP

Lessons Learned and Implications for Action

- To help ensure that all critical steps are taken, all relevant MOH departments and even other ministries, as appropriate, should be represented on the technical committees preparing the vaccine introduction. In one country, no one from the MOH's health management information system (HMIS) department, which was responsible for maternal and child health cards and various immunization monitoring and tracking forms, was asked to sit on the logistics subcommittee. It was just assumed that the forms would be revised in time for the new vaccine introduction. In fact, most forms were not revised, printed, or distributed to health facilities until well after the vaccine launch. Health workers were instructed to add space for the new vaccines on child health cards and other forms until the revised forms were distributed. Ten months after the launch, one form that was solely the responsibility of the HMIS was still not updated.

BUDGETING AND SECURING FUNDING FOR NEW VACCINE INTRODUCTION AND THE LONG TERM

Main Findings

The many steps involved in vaccine introduction incur costs above and beyond those in the usual annual immunization program budget. GAVI provides vaccine introduction grants (VIGs) to help cover those costs. In several MCHIP-assisted countries, the funding from VIGs was considerably less than the actual costs estimated by countries. For instance, a budget prepared for the introduction of RV in one country totaled $481,000, while GAVI provided a grant of $230,000—less than half the projected need.

Some MCHIP-assisted countries succeeded in raising additional funds from partners and national or provincial governments to supplement the VIGs. For example, by preparing plans and budgets for the introduction of RV on a timely basis and sharing these with all partners, Malawi's immunization program secured funds for training and other key activities from several partners (see **Box 1**). In Rwanda, MCHIP advocacy was instrumental in getting the USAID Mission to support the purchase of cold chain equipment for PCV introduction. When Zimbabwe's economic crisis in 2012 led to a delay in the transfer of GAVI funds for training from the Ministry of Finance to the Ministry of Health and Child Care (MOHCC), two actions were taken. First, the country made optimal use of available funding by combining the training for PCV with that for measles/polio vaccination campaigns, thereby using some measles and polio funds to cover some training costs for PCV introduction. Second, the MOHCC temporarily transferred internal funds to help cover the training and was subsequently reimbursed by the Ministry of Finance with GAVI funds.

Box 1: How Malawi Improved Planning and Coordination for the Introduction of Rotavirus Vaccine

Malawi's immunization program committed to learning from its experience with PCV introduction in 2011 to improve its planning and coordination for RV introduction in 2013. First, a national task force for RV introduction was established that included several partners as well as MOH officials. The EPI then prepared introduction plans and budgets and shared them openly with all partners, allowing ample time for them to fill in financial gaps.

With this improved planning and financing, the EPI was able to train all health workers who provide vaccinations (more than 14,000 health workers for RV compared to 2,000 for PCV), increase the training from one half-day (for PCV) to two full days, reproduce and distribute sufficient training materials on time, hold a well-publicized national launch, and conduct post-launch monitoring visits to districts to identify and address problems.

Other countries also obtained substantial government contributions for vaccine introduction. Kenya's immunization program accessed one-time funding from an economic stimulus program to help co-finance PCV for two years, pay for operational costs and traditional vaccine purchases, and employ additional nurses. In several second-tier provinces that introduced PCV in DR Congo, the EPI team, using data from a pre-introduction assessment showing the funding requirements and previous gaps for PCV introduction, raised funds from the provincial government to cover operational costs such as vaccine transport and fuel for cold chain equipment. In some countries, the introduction of a new vaccine with GAVI support led the government to increase its long-term contribution to immunization financing. In one country, successful advocacy from partners, using support for PCV introduction as leverage, resulted in the government agreeing to pay for the procurement of traditional EPI vaccines for the first time ever. Overall, however, immunization programs in MCHIP-assisted countries relied heavily on financial support from GAVI and other partners to cover the cost of introducing new vaccines.

The availability of flexible funding (i.e., funds that can be moved from one activity or account to another or funds that are extra-budgetary) was critical for solving problems as they arose during the preparation and implementation of vaccine introductions. In one country, government funds for district-level training were not released in time to provide training before the launch. It was only due to USAID/MCHIP funds (not pooled with those of the MOH and therefore possible to provide directly to the districts) that the training for PCV introduction was able to take place—although on a very limited basis.

In some instances, the funding available was insufficient to cover all projected costs for some introductions, and some activities had to be dropped or curtailed. In several countries, training was limited to only one nurse per facility or to vaccinators from health centers but not health posts. Post-introduction supervisory visits were also often dropped because of a lack of funds.

A common bottleneck in vaccine introduction was shortage of funds for critical operational costs such as fuel for refrigerators and petrol for transportation to distribute vaccines. These costs are not always captured in cMYPs and immunization program budgets. This problem was especially acute in countries with decentralized health systems, where funds for operational costs come from local governments (not the immunization program) or are shared with other health activities. This was observed in countries adopting the health system funding platform mechanism to integrate the planning, funding, and delivery of multiple health services and programs.

In one decentralized country, a shortage of kerosene for refrigerators coupled with insufficient fuel for transport resulted in some health centers not being able to store vaccines and having to collect them—at their own, unbudgeted expense—from district cold storage facilities. In countries with decentralized governments or devolved funding, immunization programs and district health teams must advocate to local government authorities for funds to cover these operational costs which, while sometimes overlooked, determine if immunization services will be provided.

Lessons Learned and Implications for Action

- Sufficient, timely funding to finance all activities for introducing a vaccine is essential to its success. Budgets must be prepared well ahead of time and must include expenses that are sometimes overlooked in introduction budgets or cMYPs. Examples include the additional costs of fuel for transport and cold chain equipment, the costs of pre-introduction visits to monitor and determine the readiness of districts to introduce the new vaccine, and intensive post-introduction supervision to address problems before they negatively affect the immunization program.
- Funding for new vaccine introduction has often been insufficient. Given the great dependence of countries on GAVI and others for financial support, immunization programs and their partners need to increase their efforts to advocate for and mobilize increased funding from both external partners and national governments for the vaccine introductions and the long-term financing of the immunization program.

- It is also critical to clarify which operational costs are funded by sources outside the immunization program, such as provincial or district governments, and to develop advocacy plans to secure sufficient funding from those sources. One possible approach is to establish subnational committees to stimulate and assist local governments in mobilizing funds locally (e.g., from district assemblies) and partners operating at the district level.
- EPI managers should advocate to partners as well as to the MOH for more flexibility in funding so that funds can be available when and where they are most needed to ensure a smooth vaccine introduction.

DETERMINING COUNTRY READINESS AND APPROPRIATE TIMING FOR VACCINE INTRODUCTION

Main Findings

In the eight MCHIP-assisted countries for which data were available, the length of time that countries had to prepare for a vaccine introduction—as measured by the time between the date that GAVI approved an application or indicated that a vaccine was now available (if there had been a supply issue) and the date of the vaccine launch—ranged from eight months to 2.5 years. In several instances, countries were not adequately prepared to introduce the new vaccine by the planned launch date as many of the necessary steps were taken either just before the launch date or after the launch.

Factors beyond the control of the immunization program sometimes influenced the timing of the introduction. In some cases, the launch of a new vaccine was set by government leaders or development partners for political reasons—for example, to coincide with global events such as African Vaccination Week or a high-visibility international immunization conference. Once a launch date was officially announced by the government and plans were made for high-level officials from government and partner organizations to attend, it was often politically impossible to change the date, even if the country clearly was not ready to introduce the vaccine.

Insufficient preparation before the introduction of new vaccines had tangible program consequences. In some countries, inadequate cold storage space at the central or regional level to accommodate the new vaccine led to an increase in vaccine deliveries to the districts, thereby increasing transport costs. In other countries, training was too brief to build the needed skills, or too few health workers were trained, or training took place immediately before the vaccine arrived at health facilities. In one extreme case, the vaccine could only be introduced in a single district following the official launch because health workers elsewhere had not been trained. **Boxes 2, 3, and 4** describe the diverse experience of three African countries.

Box 2: Introducing a Vaccine in the Midst of Major Health System Changes

One African country announced that it would introduce PCV during African Vaccination Week – five months away—but two major health system changes that had recently been enacted led to serious unresolved problems. First, a new, more rigorous process had been adopted for approving disbursements of funds from the MOH to the districts for operational costs (e.g., training of health workers). No districts could fulfill the requirements and obtain funding in time for the PCV training. Training took place before the scheduled launch date only in the five districts where MCHIP operated and only because the project was able to transfer funds directly to districts for training.

The second major change was the transfer of national-level responsibility for vaccine management and distribution from the immunization program to the National Medical Stores in an effort to integrate the vaccine and drug supply chain systems. Because the National Medical Stores lacked the needed expertise in vaccine management, however, the change resulted in frequent vaccine stock-outs at the district level up to the date of PCV introduction.

These supply chain problems meant that PCV could be introduced following the official launch in only one of the five districts where training had taken place, and this situation continued for several months. Even in that one district, frequent stock-outs of PCV were observed, in part because children from other districts were coming to obtain the vaccine and because the need for vaccination of the backlog of older cohorts.

Box 3: Organizing and Determining Readiness for PCV-7 Introduction in Rwanda

For the introduction of PCV-7 in Rwanda in 2009, the country's ICC established four subcommittees: technical, logistics, waste management and disposal, and social mobilization. Each subcommittee met weekly and developed detailed, three-month work plans that included key activities for each week, their timing, and the persons or organizations responsible. The various EPI partners also developed a joint checklist of key activities and milestones that was updated and modified during the monthly ICC meetings held to assess progress with preparations.

The checklist identified key milestones and key issues to resolve before the introduction. Subcommittees and partners met shortly before the planned launch date to assess whether preparations were sufficiently advanced to move forward with nationwide introduction. Because many activities had not yet taken place two weeks before the launch—including training 800 health workers and community leaders and deciding how to dispose of the vaccine's prefilled glass syringes—the MOH decided to phase in introduction on a province-by-province basis over the course of four months.

Box 4: Introducing Two Vaccines Simultaneously: The Experience of Tanzania

Tanzania introduced the PCV-13 and rotavirus vaccines in January 2013. The dual introduction posed major challenges. Health workers had to be sufficiently trained in the use of two very different vaccines, one injectable and the other administered orally using an unfamiliar squeeze tube. The program also had to educate the public about two vaccines at the same time, with the added complication that both prevent only a portion of a syndrome (diarrhea or pneumonia) so that other preventive measures are also essential. The simultaneous introductions also required a substantial, rapid expansion of cold chain and logistics systems.

To meet these challenges, the immunization program allotted a year to prepare. Health workers—even those at the lowest level of the health system—attended a four-day training covering the new vaccines as well as a refresher on selected aspects of immunization. An extensive communication campaign included media and stakeholder seminars and TV and radio spots that were broadcast 300 times. The cold chain system was expanded at all levels, including new walk-in cold rooms in all 27 regions. Although these extensive activities created a large workload and considerable challenges, they did result in costs savings—for example, in travel and per diem costs during training and in activities such as the media and stakeholder seminars.

The dual introduction was made easier by the fact that just one of the vaccines—rotavirus—had an unusual presentation and a method of administration that was unfamiliar to health workers. Thus the rotavirus vaccine became the main focus of the training. Countries should consider the complexity of the new vaccines and the training required before deciding to introduce more than one vaccine at the same time.

Some countries have adopted a phased approach for introducing a new vaccine over time. While Rwanda phased in PCV-7 vaccine over a four-month period, India is phasing in pentavalent vaccine on a state-by-state basis over several years. In some cases—for example, PCV in the DR Congo and pentavalent vaccine in India—the phased introduction was planned from the beginning. In others, the decision to use a phased approach was made during the preparation period, when it became clear that the immunization program would not be ready for a nationwide rollout. This approach would not be politically feasible in some countries, as the public and press would question why the vaccine was available in some locations but not in others. To avoid such repercussions, Kenya phased in PCV-10 introduction in all districts over the course of a single month—as soon as health workers were trained and the vaccine was delivered locally.

One promising practice observed in several countries has been the use of a detailed pre-introduction checklist (see **Box 3**). These checklists have been used to conduct readiness assessments and proactively manage and monitor progress so that all outstanding issues could be addressed and key actions taken before new vaccine introductions. In Rwanda, this checklist was used to determine the level of readiness of each district to introduce PCV-7 vaccine. In the DR Congo, starting with the fifth province to introduce PCV-13, a checklist was used to determine whether each province was ready to introduce the vaccine. The checklist applied certain criteria, including the adequacy of cold storage capacity, existence of a provincial ICC and subcommittees to oversee the introduction, development of a provincial introduction plan, and successful mobilization of funds from the provincial government for recurrent costs such as transport of vaccine to health zones and fuel and maintenance costs for cold chain equipment. In Zimbabwe, a checklist was used to conduct pre-introduction visits to districts to assess their readiness to introduce pentavalent and later PCV vaccines.

Lessons Learned and Implications for Action

- Countries and partners should start preparing for the introduction of a new vaccine at least six to 12 months before its launch. Communications must be strong between the technical units covering immunization and the higher-level MOH officials and agencies that establish the date of the launch.
- Countries should evaluate their readiness to introduce a new vaccine in a systematic way (such as by using a pre-introduction checklist) and either delay or phase in the introduction if it is determined that the vaccine cannot be introduced on the planned date without serious problems.
- Immunization programs should allow time for major health system changes, such as in the management and distribution of vaccines, so that issues and bottlenecks are worked out before introducing a new vaccine.

ASSESSING, UPGRADING AND EXPANDING COLD CHAIN, LOGISTICS, AND WASTE MANAGEMENT SYSTEMS TO ACCOMMODATE NEW VACCINES

Main Findings

The expansion and upgrading of cold chain and logistics systems is one of the most visible and common improvements to immunization and health systems associated with new vaccine introduction. These systems upgrades are especially necessary for RV and PCV, which currently are available only in single- or two-dose presentations.

Cold chain capacity. Among the 10 vaccine introductions that occurred by September 2013 in MCHIP-supported countries, cold chain inventories indicated that cold storage space was adequate in five cases; thus no expansion took place before the vaccines were introduced. In two of these cases, the vaccine being introduced was pentavalent in 10-dose vials, which has a relatively low storage volume. In the other three cases, the country switched from single-dose to 10-dose vials of pentavalent vaccine when the latter became available. This freed up sufficient space to accommodate the new PCV vaccine that was to be introduced.

In the remaining five countries, refrigerators were purchased and/or cold rooms built or expanded to accommodate the new vaccine, with additional funding from UNICEF, WHO, and USAID in addition to GAVI. In Tanzania, the expansion and upgrading of cold chain systems required for introducing PCV and RV was extensive. Eight new cold rooms were built at the central level and an entire new system of 27 regional cold rooms was created.

In part because cold chain expansion focused mostly on a single level, some gaps in cold chain capacity remained at certain levels in most countries at the time of introduction. In two countries, storage capacity increased sufficiently at the central and regional cold rooms but remained inadequate in the districts and health centers due to a lack of new or functional refrigerators or kerosene to run them. In one country, this led to a delay in introducing RV in some locations. In another, central cold room capacity was inadequate despite an expansion of storage capacity at the local level. Countries generally dealt with the issue of insufficient storage capacity at subnational levels by increasing the frequency of vaccine deliveries to the lower levels, thus incurring additional costs that were usually not budgeted. With the introduction of PCV in the DR Congo, for example, vaccine deliveries to some health zones doubled from once to twice a month. Such cold chain problems delayed PCV introduction in two countries and RV introduction in another.

Temperature monitoring. PIEs and monitoring visits in several countries revealed problems with temperature monitoring of cold chain equipment and freezing of vaccines. This is a critical issue because many new vaccines, including PCV, pentavalent, hepatitis B, and IPV, are damaged by freezing. Fridge-tags®, which monitor and record temperatures and set off alarms if refrigerator temperatures fall below or exceed the acceptable temperature range, were not used consistently in several countries. Even in some countries where tags were installed in all refrigerators, health workers took little or no action when temperatures fell outside the accepted range. A PIE following PCV introduction in one country found that 24% of the health facilities visited were using vaccines with VVMs at stage 3 or 4. This issue highlights the need for greater attention to vaccine handling during health worker training.

Waste management. In most countries, insufficient attention was devoted to planning for the increased volume of waste (i.e., syringes, needles, and containers of used, unusable, or expired vaccine) generated by new vaccines. Various PIE reports note that in the face of insufficient funding to construct incinerators, vaccine-related wastes are often buried in open pits (sometimes burned first), and disposal sites are often not fenced in, leaving communities exposed to needles and syringes. Some countries have begun to develop plans to build additional incinerators using external project financing (e.g., from World Bank projects). The southern Indian states that introduced pentavalent vaccine outsourced waste management in urban health facilities to a private agency, reportedly with good results.

Lessons Learned and Implications for Action

- Potential bottlenecks in the cold chain system, such as a lack of vehicles for delivering vaccines to the local level and a lack of recurrent funding for fuel for refrigerators and transport, should be examined during pre-introduction assessments and addressed during the preparation period.
- If cold chain capacity is inadequate, immunization programs should plan, budget, and seek funding for the additional costs associated with temporary measures, such as increasing the frequency of vaccine deliveries.
- The need for increased funding for fuel to operate the expanded cold chain should be anticipated and addressed before the vaccine introduction. In countries in which local budgets for fuel for kerosene or liquid propane gas-powered refrigerators are often inadequate, immunization programs and their partners may wish to consider the programmatic suitability of purchasing solar-powered cold chain equipment. However, in places where outreach services are widely used, solar fridges may be less appropriate because they produce little or no ice.
- To address the issue of additional waste management, immunization programs and partners can use the new vaccine introduction as an opportunity to improve current systems and practices.
- GAVI should strengthen its operations to ensure that the plans that countries have prepared, and that the GAVI Independent Review Committee has studied and commented on, are reviewed again by the GAVI staff who support the countries before vaccines are shipped to countries.

REVISING VACCINE MANAGEMENT SYSTEMS TO ACCOMMODATE NEW VACCINES

Main Findings

The addition of new vaccines to the immunization program presented additional challenges to vaccine management at all levels. Approximately midway through the time period under review, GAVI instituted a requirement that countries submit a report of a recent Effective Vaccine Management (EVM) assessment as part of the application process for new vaccines. The assessments were to be followed up with an EVM improvement plan. Despite submitting these documents, countries did not implement the recommended actions in a uniform way and problems with stock-outs were widespread.

In five out of the six MCHIP-supported countries where PIEs were conducted, stock-outs of new or traditional vaccines at health facilities had occurred in the previous six months. In four of these countries, more than 60% of health facilities had experienced stock-outs (**Table 2**). In only one case was this due to a national stock-out; in all others it was attributed to managerial issues, including poor vaccine management and lack of transport or fuel to deliver the vaccines from the districts stores to health facilities.

Table 5. Vaccine Stock-Outs Reported in the Past Six Months: Results From PIEs in Six Countries

COUNTRY	HEALTH FACILITIES REPORTING STOCK-OUTS IN PAST SIX MONTHS (%)	REASONS AND COMMENTS
A	91%	Mainly stock-outs of new vaccine due to a national stock-out
B	85%	Poor stock management at supplying and receiving units and unavailability of transport
C	61%	Poor vaccine management or distribution problems at district and facility levels
D	No statistics available	Some stock-outs of OPV, pentavalent, and other vaccines (not the newly-introduced vaccine)
E	100%	Poor vaccine management and lack of funding for transport
F	0%	NA

To avoid stock-outs that occurred with its previous vaccine introduction, one country provided each district with a 2.5-month stock of the new vaccine, rather than the usual one-month supply. Despite this precaution, 23% of health facilities visited by the national EPI team had still not received the new vaccine two weeks after the launch, reportedly due to local transportation problems. Another action that can help avoid stock-outs and ensure potent vaccine is correct implementation of open vial policies, as in India (see **Box 5**).

Box 5: Using the Introduction of Pentavalent Vaccine to Extend the Multi-Dose Vial Policy in India

In May 2011, the Government of India issued guidelines for the multi-dose vial policy, which allows multi-dose vials of OPV and monovalent hepatitis B with unused doses of vaccines that contain preservatives to be stored for later use at fixed health centers. With the introduction of pentavalent vaccine in 10-dose vials (to replace DTP) in Kerala and Tamil Nadu in December 2011, the government extended this policy to pentavalent vaccine at both fixed and outreach sites. Considerable attention was given to the policy during the training for the new vaccine, and the PIE found adherence by health workers to be strong. Consequently, the vaccine wastage rate in one state declined from 16% for DTP in the four-month period before the introduction to 8% for pentavalent over the same period the following year and to 7.5% in the other state.

Issues with customs policies and procedures have also arisen in some countries. In one, vaccines were held for customs clearance for two weeks at the airport, where cold storage facilities were less than optimal, although not damaging to vaccines. To address this problem, the MOH subcontracted with a firm to ensure speedy clearance of vaccines through customs and installed temperature data loggers in the airport cold rooms. In another country, the government initially imposed a 25% customs clearance charge for all imported vaccines but later dropped it to a nominal fee.

Lessons Learned and Implications for Action

- The introduction of new vaccines has highlighted and even amplified deficiencies with vaccine management, including the frequent stock-outs that persist in many countries. Opportunities to improve vaccine management through EVM assessments and training of health workers have often been missed and need to be taken in conjunction with new vaccine introduction.
- More and better advocacy, especially at subnational levels, is needed to ensure sufficient and timely release of operational budgets to cover recurrent expenses.
- Introduction of a new vaccine can be used to shine a light on and remedy long-standing, suboptimal practices, such as delayed or costly customs clearance policies and procedures.

BUILDING HEALTH WORKER CAPACITY FOR SAFE AND EFFECTIVE USE OF VACCINES

Capable health workers are critical to the effective and safe use of any vaccine, whether new or old. With the addition of new vaccines comes greater complexity in vaccine handling, administration, interpersonal communication, and recording and reporting data on their use. In all countries where MCHIP supported new vaccine introduction, training of health workers was a major activity.

Main Findings

Training on new vaccine introduction. Table 6 provides an overview of the length of training and training topics in MCHIP-assisted countries.

Table 6. Training of Frontline Workers on New Vaccines in MCHIP-Assisted Countries

COUNTRY AND VACCINE	NO. OF LEVELS TRAINED	LENGTH OF TRAINING	COMMENTS
DR Congo (PCV)	3	1 day	Some refresher training on vaccine management, injection safety, and waste disposal, but focus was on PCV
Timor-Leste (Penta)	2	1 day	Vaccine management and Immunization in Practice training conducted apart from training on vaccine introduction
India - Kerala and Tamil Nadu (Penta)	3	½ day	Training started at state level and extended to *angwanwadi* (child care) workers and volunteers
Kenya (PCV)	3	1 day	Focus on PCV, with refresher training on good vaccine management practices (VVMs, multi-dose vial policy, etc.); included facility-based training of workers who did not attend district-level training
Malawi (PCV and RV)	3	2 days	Included refresher training on selected topics to address gaps in health worker skills and knowledge identified during supervisory visits
Rwanda (PCV-7)	2	3 days	Topics included vaccine and cold chain management, vaccine waste calculations, multi-dose vial policy, and other technical skill areas
Rwanda (RV)	2	3 days	Content of refresher training based on weaknesses observed from the PCV PIE, including AEFI reporting
Senegal (PCV)	3	1 day	Minimal refresher training, but separate immunization and surveillance training took place in some districts
Tanzania (PCV + RV)	4	4 days	In addition to PCV and RV, two full days spent on skills and knowledge for vaccine management and other aspects of immunization
Uganda (PCV)	4	3 days	Refresher training interspersed throughout the course on a range of topics and skills; included facility-based training of workers who did not attend district-level training
Zimbabwe (PCV-13)	3	1½ days on PCV + ½ day on polio/ measles campaign	Included refresher training in injection safety, AEFI reporting and management, and general drug administration principles; also addressed integrated polio/measles campaign; facility-based training provided to workers who did not attend district-level training

Length and scope of training. The training of frontline workers ranged from one half-day with no refresher training on other aspects of immunization to four days covering the dual introduction of RV and PCV plus extensive refresher training. Trainings of one day or less focused primarily on the new vaccine, whereas trainings of two days or more included refresher training. In Tanzania, the two days of refresher training (addressing vaccine management, cold chain maintenance, and the use of VVM) was included because a lack of immunization training in recent years, coupled with high staff turnover, had resulted in many health workers having never received formal training in immunization. In one country refresher training was deemed unnecessary because health worker skill levels were assumed to be high, but gaps in skills and knowledge in standard areas such as calculating coverage rates, disease surveillance, and vaccine wastage monitoring were observed after the introduction. These gaps demonstrate the wisdom of a needs assessment, followed by refresher training as needed, even in places with high-performing programs.

As a best practice, the content and design of the refresher training in some countries—notably Malawi, Rwanda, and Senegal—were based on data from supervisory visits, PIEs, and other assessments.

Scale of training. The proportion of frontline health workers trained on the new vaccine varied across countries. In some, there was an effort to formally train all health workers involved in immunization, while in others budgetary and logistical constraints limited the number and type of health workers trained. In one country, vaccinators from all health centers were trained, but resource constraints prohibited the training of vaccinators from health posts. In another country, only one person per health facility received training, resulting in just half of the health workers involved in immunization being formally trained on the new vaccine. In these countries, the untrained health workers were to receive training from those in their health facility who had been formally trained; however, the extent to which this occurred and the quality of this on-the-job training are unclear. The PIEs from several countries identified a lack of formal training in the new vaccine for a large proportion of health workers as a major gap in new vaccine introduction.

Training strategies and quality. Nearly all countries used a cascade training approach to carry out large-scale, countrywide training of health workers on new vaccines. In this approach a national team is trained to serve as trainers of regional or provincial personnel, who then train district-level officials and so on, down to the frontline workers. The number of levels of training was typically three or four (see **Table 6**).

While a cascade training strategy enables training to be implemented quickly and on a large scale, it is notorious for quality issues because the content is often diluted across levels, and many health officials may have expertise in technical content but not training methods or vice versa. Different countries addressed the issue of quality in different ways. In Uganda, only those national trainers who passed the post-test during the national training of trainers went on to become trainers. The result was the creation of a new pool of national immunization trainers. In several countries, national trainers attended local-level training to monitor the training quality, supervise the local trainers, and serve as resource persons. Most countries employed pre- and post-tests to assess the quality of the training.

Rwanda was the one country where cascade training was modified to help address concerns about quality. The country used a national training team that moved across provinces to train district personnel who in turn trained local health workers, essentially cutting out one or two levels of training (see **Box 6**).

Box 6: Ensuring the Quality of Training in Rwanda through a Phased Training Strategy

With the introduction of PCV-7, the Rwanda EPI trained a team of 25 health professionals from different MOH departments (e.g., EPI, MCH, communications) and district hospitals to serve as national trainers. These trainers then traveled together to the country's five provinces and divided into teams of five to train all the district health personnel in the province before moving on to the next province. The trained district officers then trained frontline health workers in their respective districts. This strategy helps to ensure high-quality training but requires more time than traditional cascade training.

It is not surprising that problems and challenges were observed across countries. In one country, personnel shortages meant that national facilitators had little knowledge of immunization, and staff of partner organizations filled in as trainers in some zones to help ensure quality. In another country, vaccinators and volunteers were trained together for a vaccine introduction that required a mass campaign involving many volunteers; however, there was reported dissatisfaction with the training because these two groups required very different skills and knowledge.

Training methods and materials. While training in some countries relied on lectures and slides, other countries employed hands-on, practical, participatory methods that are known to be effective with adult learners. These included practice in handling the new vaccine (e.g., using dummy vaccine containers [see **Box 7**], role playing in communicating with parents, and question-and-answer periods).

High-quality job aids and other training and reference materials to supplement field guides were produced in some countries. In one country where not enough health workers had been trained, there was such a high demand for the training materials, especially among those not formally trained, that the supply was quickly depleted. The materials were then posted and made available online.

Box 7: Use of Dummy Vaccines for Hands-On Training

Countries introducing new vaccines in recent years have been faced with this dilemma: they want health workers to learn how to handle and administer the new vaccine during training; but because manufacturers want to avoid problems with untrained workers administering the vaccine incorrectly, they will often not ship any vaccine to the country until training has taken place. The need to practice using the vaccine in training is especially important when a presentation or delivery mechanism that is new to health workers is involved, as is the case with one type of RV, which is available in single-dose squeeze tubes. If the tube is not opened carefully, the tip can drop into the tube and potentially enter the infant's mouth. As a solution, both the National Task Force in Malawi and the immunization program in Tanzania asked the manufacturer to provide enough dummy vaccines to allow all trainees to practice using them. The dummies have the same squeeze tube and label as the actual vaccine, but contain water instead of vaccine.

In one country, the IEC/advocacy committee produced a training video for PCV that was financed by manufacturers and partners. The video featured the president of the country's pediatric association and was interactive, asking questions to check participants' comprehension after each of five segments. It was well received when used at provincial and district-level trainings. However, follow-up surveys indicated that health workers who had received only on-the-job training had not seen the video and that it was no longer available in most health facilities.

Timing of the training. Immunization programs must time the training for the new vaccine so that it is not so early before the vaccine introduction that health workers will forget what they learned, yet not so late that it bumps up against or even goes beyond the launch date. An ideal interval between the training of frontline workers and the vaccine launch is two to four weeks. Uncertainty concerning the expected arrival date of the vaccine affected the training schedule and the interval between training and introduction in some countries. In one country, the training of health workers occurred in some areas just days before the vaccine was introduced, leaving no time for health workers to conduct the planned social mobilization activities that had been introduced in the training. Thus, radio messages became the main means by which the communities served by these health workers learned about the new vaccine.

Lessons Learned and Implications for Action

- Training for new vaccines provides an excellent opportunity to refresh the immunization skills of health workers, which is needed in most countries. MCHIP's country experience suggests that if the frontline training for the new vaccine includes refresher training on other basic immunization areas, at least two days are needed. The selection of topics to cover should be based on an assessment of health workers' skills and knowledge.
- A large proportion of health workers received only on-the-job training, which was of short duration and uncertain quality. To ensure the safe and effective use of any vaccine, new or traditional, all health workers who handle vaccines or provide immunization (or supervise vaccinators) should receive formal, competency-based training provided by qualified trainers.
- The quality of training is a continuing concern, especially in light of resource constraints that favor convenience and speed over quality. Countries have used a variety of methods to address quality concerns and must continue doing so. Practical, active, and participatory training methods reflect the principles of adult learning and are more effective than a heavy reliance on didactic methods such as lectures and slides. Post-training supervision and other methods of follow-up, such as providing health workers with job aids or posting reference materials online, can help reinforce and maintain the skills needed to handle vaccines safely and effectively.
- The timing of training throughout the country needs to be carefully planned to ensure sufficient time to train all health workers adequately, while not allowing too much time to lapse before the vaccine is introduced. Time is also needed to design, develop, test, and revise job aids.

COMMUNICATING AND CREATING DEMAND FOR NEW VACCINES AND IMMUNIZATION

Main Findings

Demand for new vaccines. MCHIP's experience suggests that most introductions of new vaccines, and particularly PCV, achieved high population awareness and acceptance and, consequently, substantial demand. The demand for PCV was high because it targets pneumonia and meningitis, diseases that are well known and frightening to the population. Several countries reported PCV coverage rates well over 100% for the first several months or year after introduction. (Data quality issues are a concern and are described in section 3.8.)

In one country where PCV was available in only one district for the first several months, mothers from surrounding districts reportedly brought their children to the district to receive the vaccine, thus contributing to the stock-outs. In another country, PCV attracted a backlog of children from an earlier birth cohort, since all children under one year of age were eligible, as well as older children who were behind on their other vaccinations ("defaulters"). The high demand led to a

national stock-out of PCV for several months as well as local shortages of pentavalent, polio, and measles vaccines in areas with high numbers of defaulters who were given missed doses of other vaccines when they came for PCV. The ensuing vaccine shortages essentially thwarted the high demand for immunization that had been stimulated by PCV introduction.

Communication strategies. High demand also resulted from the extensive and comprehensive communication campaigns conducted in many countries. Key information was distributed through multiple channels: distribution of leaflets, posters, and other print materials; broadcasting of radio and TV messages; and high visibility vaccine launches, media seminars, and stakeholder advocacy meetings.

National launches were well-publicized, high-profile events that in several instances were attended by the country's president or first lady. Because they attract considerable media attention, launches provide an excellent opportunity to educate the public about the new vaccine and the disease that it prevents and to raise awareness about its availability in the public sector. Several countries, including Kenya, Tanzania, and Zimbabwe, also conducted launches in each province or even each district. In Kerala and Tamil Nadu states in India, launch ceremonies for pentavalent vaccine were held in most health facilities. Local launches were viewed as critical to successful uptake of the new vaccine because they were conducted in local languages, covered by local media, and involved local political and community leaders. In some countries, these local leaders can facilitate or block the local population's acceptance of a new intervention.

Involving the media. Several countries, including India, Kenya, Malawi, Tanzania, and Zimbabwe, held seminars or press briefings for the media to enlist their help in informing and providing accurate information to the public. These activities encouraged the media to broadcast TV and radio spots promoting the vaccine, and preempted possible rumors and misinformation about the vaccine's safety. Media representatives often received information packets during the events and were encouraged to follow up by providing coverage of the vaccine introduction. For Tanzania's simultaneous introduction of PCV and RV—a particularly high visibility event that drew international attention as well as support from GAVI—a national media seminar was attended by 60 members of the press and other stakeholders and was then followed by zonal-level seminars. These events led to articles being published in local newspapers in various provinces and cities, interviews with Regional Medical Officers on local radio stations, and the airing of promotional spots on local radio and TV stations.

Strategic engagement of stakeholders. To increase awareness and acceptance of the new vaccine, several countries convened advocacy meetings with stakeholders, especially those in the medical community. In Kenya, such meetings were held for PCV-10 introduction at the national, district, and sub district levels, with participants including representatives from the MOH, other government offices, nongovernmental organizations (NGOs), and the community. In Tanzania, the stakeholder meetings for PCV and RV—one each on the Mainland and Zanzibar—were well-publicized events attended by the representatives of professional medical associations, NGOs, partner organizations, government ministries, and the media.

In the Indian state of Kerala the introduction of Hib vaccine (as a component of pentavalent vaccine) was accompanied by controversy because the Indian press had reported an association between the vaccine and deaths in neighboring countries. Some medical professionals had campaigned against introducing the vaccine. To address these concerns, the State government established a technical review committee, composed of pediatricians and public health experts and NGOs nongovernmental organizations, to review the data and provide independent advice to the State immunization program. Following an in-depth review of all relevant data, the committee supported the decision of India's National Technical Advisory Group on

Immunization to introduce the vaccine. Popular acceptance of the vaccine has reportedly been strong in Kerala since the vaccine's introduction.

Developing a basis for key messages and content. Some MCHIP-assisted countries conducted special studies to gain an understanding of common beliefs and attitudes toward the target disease, the new vaccine, immunization, barriers to vaccine uptake, and effective channels of communications. In Kenya, a nationwide knowledge, attitude, and practice (KAP) household survey was conducted both with households and with health workers, community leaders, and journalists. Such surveys can be costly and take considerable time to conduct and analyze. In one country, the KAP survey could not be completed in time for the development of communication materials. A different approach was used in Rwanda: a small-scale rapid assessment was conducted and analyzed in two weeks. The assessment consisted of focus group discussions with a relatively small number of mothers and health workers (**Box 8**). Information gleaned from socio-behavioral studies has been used to inform IEC materials and health worker training to effectively address parents' concerns—for example, about side effects and how to respond to them as well as concerns about their children getting two injections at the same time (e.g., PCV and pentavalent vaccine).

Box 8: How Rapid Assessments Can Improve Communication about a New Vaccine

Rwanda was the first GAVI-supported country in Africa to introduce PCV. Very little was known about the attitudes of not just mothers but also health workers regarding pneumococcal disease or PCV. There were also concerns about whether mothers and health workers would find it acceptable for infants to receive two injections (for pentavalent and PCV) during the same clinic visit. An understanding of these points was needed to develop job aids and training materials to foster trust and strong communication between health workers and caregivers.

A small rapid assessment was carried out consisting of focus group discussions with 48 mothers of infants in urban and rural areas and interviews with 16 health workers. The findings indicated that mothers had grave concerns about pneumonia and great enthusiasm for PCV vaccine, even though they recognized that it would not prevent all forms of pneumonia. The fact that their children would now receive two injections on the same day was of minor concern—in fact, it was much less a concern than the health workers had anticipated. The mothers clarified the specific types of information they wanted health workers to give them about both the vaccine and how to handle side effects. These findings were incorporated into the job aid and health worker training. This experience highlights the value of basing IEC messages and training content on data about community and health worker attitudes, as well as the fact that gathering such data can be done relatively quickly and inexpensively.

Challenges with communication campaigns. In several countries, PIEs and monitoring visits found that immunization programs were unable to print and distribute sufficient IEC materials, including materials translated into the appropriate local language, in time for the vaccine introduction. Because of inadequate funding, some IEC materials were still not printed two months after the vaccine introduction in one country and 11 months after the introduction in another.

Another problem was that high-level government officials and political leaders speaking at public events sometimes gave out incorrect information. In two countries, speakers at national events said that all children under five years of age should receive PCV. These remarks were picked up by the mass media and may have contributed to out-of-age children receiving the vaccine. This experience points out the wide reach and power of well-known figures to create demand for immunization, but it also underscores the need for speeches to be written or reviewed by the immunization program or technical partners to ensure that they are accurate and "on message."

Lessons Learned and Implications for Action

- GAVI-eligible countries have demonstrated their ability, with financial and technical assistance from partners, to conduct comprehensive communications activities targeting

parents, the media, the medical community, and political leaders, and to reach the national level, districts, and local communities to create demand for a new vaccine.

- Immunization programs should anticipate a surge in demand generated by communication activities around the time of a new vaccine introduction, especially for vaccines against well-known diseases such as pneumonia. They should prepare by stocking extra supplies of the new vaccine (if possible), and in areas with large numbers of unvaccinated children, they should increase supplies of other infant vaccines as well. This will enable the program to "catch up" these children and will improve overall immunization coverage rates.
- Conducting special activities to engage the media and elicit their support can be critical, both to create demand for the new vaccine and to preempt potential crises by dispelling rumors or misinformation spread by less responsible elements of the popular press.
- Efforts ranging from nationwide KAP surveys to small, rapid qualitative assessments can be invaluable for developing effective, relevant communication messages that are responsive to people's real needs and concerns. It is critical that these assessments capture the views not just of parents but also of frontline health workers.
- Engaging national and local-level political leaders in vaccine launches and media seminars can be an effective way to generate demand for a new vaccine. However, their messages should be vetted with immunization or public health officials to ensure accuracy and consistency.
- The establishment of an independent committee of well-respected experts to guide the immunization program in introducing a new vaccine can help reassure the public and the media about the vaccine's safety and ensure acceptance of the vaccine.

REVISING HEALTH AND IMMUNIZATION MANAGEMENT AND REPORTING FORMS AND MATERIALS TO INCLUDE THE NEW VACCINE

Although sometimes overlooked, the process of updating and actively disseminating tally sheets, monthly summary forms, facility monitoring charts, home-based records, and other data management instruments is vital to managing the vaccine introduction process and fully integrating the new vaccine into the immunization program.

Main Findings

In most MCHIP-assisted vaccine introductions, the forms for recording and reporting immunization data—including child health or vaccination cards, tally sheets, vaccination registries, and monthly reporting forms—were revised to add the new vaccine before it was introduced. To save future costs, some countries also added vaccines to these materials that they planned to introduce in the future (e.g., RV).

In other countries, however, the forms were revised too late to be produced and distributed before the vaccine introduction. Consequently, several PIEs and monitoring visits found that some or all of the revised forms were absent in some of the health facilities visited. The main reason given in multiple countries was that a separate MOH department, not under the control of the immunization program, was responsible for updating, printing, and distributing health management information tools. In some countries, updating the electronic database to include the new vaccine was also neglected.

Health workers often said that they improvised by recording the doses of the new vaccine by hand on the old forms; elsewhere doses were simply not recorded. In one country in which the revised forms were in use but the electronic database had not been updated, the immunization program created a separate database for the new vaccine. Such problems resulted in incomplete and poor-quality reporting for the new vaccine.

In Kenya, where children under one year of age who had started other vaccinations were eligible for PCV, a sticker was added to the children's child health card to record PCV vaccinations. Only infants who were just starting the immunization schedule received a new, revised card that included PCV.

Some countries took advantage of the need to update the HMIS forms for the new vaccine to review and make overall improvements in their forms. In Uganda, for instance, the various HMIS tools were revised not only to add PCV, but also to align with the information needs (e.g., data disaggregated by gender) of the National Development Plan, the Millennium Development Goals, and other policy documents.

Lessons Learned and Implications for Action

- Because the HMIS system is outside the control of the immunization program, extra time may be needed in the vaccine introduction plans to ensure that the various immunization-related forms are revised, printed, and distributed to all health facilities and that electronic databases are updated before the introduction of the vaccine.
- The updated forms should also be available for training so that health workers are introduced to them ahead of time. One way to facilitate the forms being available on time is to involve representatives from the MOH's HMIS department on the relevant subcommittee that is preparing for the vaccine introduction.
- Given the costs involved in reprinting and distributing various health and immunization information tools, health ministries can reduce the need for repeated revisions by adding vaccines that they plan to introduce in the near future and by making overall improvements to the forms that are consistent with the data requirements of national health and social development goals and policies.

Monitoring and Evaluating the Vaccine Introduction

COVERAGE MONITORING FOR THE NEW VACCINE

Main Findings

Monitoring coverage of the new vaccine is a standard way of measuring the success of the vaccine introduction and identifying low-performance areas and bottlenecks. However, in MCHIP's experience, obtaining high-quality, credible coverage data for the first year after a new vaccine has been introduced can be extremely challenging for several reasons:

- The phasing in of the new vaccine in different parts of the country over the course of one or more years complicates the ability to assess national coverage with the new vaccine. Assessment is further complicated if the launch date for the vaccine is not at the beginning of the reporting year.
- There may be uncertainties or inaccuracies in the denominator used to calculate coverage in the first year of vaccine introduction. In the countries that targeted all infants under 11 or 12 months to receive PCV during the year of introduction, as well as babies born during the 12 months following introduction, two cohorts were represented in the numerator without being factored into the denominator. The result was that coverage rates in several of these countries were well over 100% during the first year (and over 200% in the early months). The issue was usually resolved after the first year.
- The late or uneven distribution of revised EPI reporting forms that include the new vaccine may affect the quality of coverage estimates.
- Health workers' knowledge of how to calculate coverage and dropout rates has been weak in several countries (although adequate in others).

In some countries, a population census had not been taken in many years; thus estimates of the size of the birth cohort were considered inaccurate or varied substantially by data source. In one MCHIP-assisted country, the estimate of the population under one year of age was adjusted upward by 15%, while in another it was revised downward by 37% based on a rapid household survey in selected districts (**Box 9**).

Box 9: The Effect of Declining Birth Rates on Immunization Coverage in Rwanda

Immunization coverage rates in Rwanda increased steadily from 2002 to 2008 for all vaccines. However, a substantial decline began in 2009 and continued into 2010. At the same time, disease surveillance indicators showed no increase in disease incidence, with the exception of measles. To investigate this situation, a joint team from WHO and the MOH conducted a household survey in four districts in a low-coverage province. The survey found that third-dose coverage of pentavalent vaccine was nearly universal in the province, although administrative data showed a coverage rate of 66%. The survey also estimated that the proportion of children under the age of one year in the selected districts was not 4.1%, the figure used by the HMIS, but 2.6%—a difference of 37%. The team concluded that the discrepancy in the estimated size of the infant population was attributable to a family planning program that resulted in a 10-fold increase in contraceptive use between 2002 (the date of the last census) and 2010. Annual estimates of the birth cohort were revised based on the survey results, and these new estimates were used in planning the introduction of RV in 2012.

In response to the overall issues of poor and uneven quality of vaccination data, including inflated coverage rates, some countries conducted Data Quality Self-Assessments (DQS). However, it is possible that improving the quality of data would lead to a downward revision of coverage rates, which would in turn be a disincentive for countries, local health authorities, and/or health workers to conduct a DQS in the future. Another means of improving immunization coverage data, as practiced in the southern Indian states, is to have health workers conduct community immunization coverage surveys on a regular basis.

Lessons Learned and Implications for Action

- When analyzing coverage rates for a newly introduced vaccine, immunization programs should keep in mind that the reliability of the coverage rates can be affected by such factors as whether catch-up of infants is involved during the first year, whether children who reach 12 months of age can complete their PCV series, the timing of the introduction within the calendar year, the geographic scope of introduction, and the accuracy of the population data. It might take a year for the program and coverage rates to reach a steady state.

POST-INTRODUCTION PROGRAM MONITORING AND SUPERVISION

Supportive supervision is an important means by which countries can monitor performance of the immunization program on a regular basis and identify key issues to address. Supervisory visits should take place at all levels and can cover other health interventions besides immunization.

The establishment of disease surveillance for the diseases targeted by the new vaccine is an important step but one in which MCHIP was not directly involved. Similarly, the introduction of a new vaccine brings with it the need to address surveillance and management of AEFI for the vaccine in question. It is an opportunity to strengthen AEFI management overall as it remains a neglected area in many GAVI-supported countries, even those with relatively strong immunization programs. MCHIP's input in this area, however, was relatively limited.

Main Findings

The regularity and quality of supportive supervision varied considerably from country to country and were often neglected due to budget constraints. In some MCHIP-assisted countries, including Kenya, Malawi, Rwanda, and Tanzania, national immunization programs, often with participation and funding from partners, conducted intensive monitoring visits or "sweeps" to the districts shortly after a vaccine was introduced. These visits served to assess the quality of new vaccine introduction processes, identify and investigate problems, and make onsite corrections when possible.

In Malawi, monitoring visits that began two weeks after RV introduction examined whether clinics had received the new vaccine, health workers had completed training, social mobilization activities had taken place, health workers were administering and handling the vaccine correctly, and communities were accepting the new vaccine. The most intensive monitoring of a vaccine introduction took place in Kenya, where monitoring surveys were conducted six weeks, six months, and 12 months after the introduction of PCV-10. These surveys, which were funded by partners, were a special case in that they were required as one of the conditions established by WHO for the first use of non-preserved, two-dose vials of PCV-10 in an African country.

Multi-agency PIEs were conducted after new vaccine introductions in all of the countries that MCHIP supported. Provincial-level PIEs were required by GAVI when it resumed its support to the DR Congo. MCHIP staff participated in a total of 10 PIEs over the life of the project. MCHIP drew on its in-depth experience when contributing to the global revision of the PIE instruments. The extent to which the findings from PIEs were put to active use varied. Malawi made strategic use of the results of its PIE following PCV introduction to inform its subsequent planning for RV introduction.

Lessons Learned and Implications for Action

- Because PIEs do not take place until several months after a vaccine introduction, intensive supportive supervision or monitoring visits by the immunization program soon after a vaccine is introduced can be critical for identifying and resolving problems and bottlenecks early on. Such intensive monitoring should be budgeted for up to six months following the introduction.
- Funding for new vaccine introduction (from GAVI or elsewhere) can be used to support a supervision schedule that is more intensive than usual. This should have a beneficial effect on routine immunization performance in general.
- PIE results provide useful programmatic information and should be made available to other countries on a regular basis to help guide their vaccine introductions. Currently, countries do not actively share their findings and experience with other countries.

Conclusions

MCHIP's experience in supporting the introduction of new vaccines indicates that there are some relatively common challenges that can be anticipated and largely addressed through proactive planning, management, and implementation. Beyond smoothly adding a new vaccine in a non-disruptive manner, the well-planned introduction of new vaccines has the potential to strengthen the routine immunization systems that deliver them.

PREVENTING PROBLEMS AND ADDRESSING CHALLENGES IN INTRODUCING NEW VACCINES

In MCHIP's experience, many introductions of new vaccines encountered some challenging but temporary "bumps in the road." On the one hand, the introduction process highlighted and even exacerbated existing flaws in health and immunization systems, including weak or non-existent AEFI surveillance and reporting, poor vaccine management, and inadequate waste management systems. On the other hand, vaccine introductions were used in many countries to provide training not just on the vaccine itself but on other aspects of immunization as well.

Proactive, thorough planning and management that involves all parties affected (directly or indirectly) by new vaccine introduction is needed to both identify and address challenges. A planning horizon of several months is essential. MCHIP's experience suggests that there are also specific steps countries can take to address common challenges, as outlined in **Table 7**.

Despite the challenges encountered, and by using the approaches in **Table 7**, all MCHIP-supported vaccine introductions were successful: the new vaccines were introduced into the vaccination schedule, immunization programs were adapted to integrate the vaccines into their systems, popular demand and acceptance for the vaccines were high, and more children were protected against serious diseases.

USING NEW VACCINE INTRODUCTIONS TO STRENGTHEN ROUTINE IMMUNIZATION SYSTEMS

The introduction of new vaccines presents an opportunity to strengthen routine immunization and other health programs more broadly. But this does not happen automatically; it must be deliberately planned.

This can be done in various ways. For example, new steering committees and other advisory groups can be formed to provide guidance on policy considerations, monitor the implementation of the new vaccine introduction, and advise more broadly on strengthening of the routine immunization system. After all, new vaccines do not deliver themselves; their reach and impact depend on the underlying strength of the routine immunization system.

New vaccines against pneumonia, diarrheal disease, and human papillomavirus are important tools in comprehensive strategies to prevent and control diseases. The occasion of the new vaccine introduction can be used to draw attention to the need for and utility of integrated approaches to address different aspects of disease control.

The introduction of new, powerful, lifesaving vaccines against some of the major causes of mortality, morbidity, and disability, such as pneumonia and diarrhea, attracts high-level political and popular interest. Because a new vaccine becomes an old vaccine the day after it is introduced, forward-looking ministries of health can channel this high-level interest toward strengthening routine immunization to achieve maximum vaccination coverage and public health benefit.

Table 7. Common Challenges in Introducing New Vaccines and Possible Actions to Prevent and Address Them

CHALLENGES	POSSIBLE CAUSES	POSSIBLE ACTIONS TO PREVENT OR ADDRESS CHALLENGES
Introduction before country is ready	The launch date is determined months in advance and/or based on high-level political interests.	▪ Use a detailed checklist to systematically and actively manage the introduction process. ▪ Postpone introduction until entire country is ready. ▪ Conduct the launch as scheduled but delay nationwide introduction and introduce vaccine in phased manner throughout the country. If the introduction is phased, then communication, training, and logistical preparations must clearly reflect this.
Outdated or inappropriate vaccination schedule	The schedule has been in use for many years.	▪ Use the new vaccine introduction as an opportunity to update the schedule for vaccination and possibly for other child health services.
Large increase in cold chain capacity needs	The packed volume per dose of some new vaccines is much larger than that of traditional vaccines.	▪ Select a form of the vaccine product and a vial size that are appropriate for the context of the immunization program and health system. ▪ Conduct an EVM assessment at least six months before the introduction to identify needs and potential bottlenecks in the cold chain. ▪ Use the EVM findings as a basis for procuring additional equipment and repairing and/or redistributing existing equipment. ▪ Estimate recurrent costs for additional fuel needed to run cold chain equipment, and identify sources of funding.
Vaccine stock-outs	The new vaccine is bulky and may require more frequent deliveries, resulting in an increase in transport costs. The new vaccine is given to children who do not meet the eligibility criteria.	▪ Select a form of the vaccine product and a vial size that are appropriate for the context of the immunization program and health system. ▪ Use a bottom-up approach to estimate additional capital and recurrent transport costs needed to distribute vaccines, and identify funding sources or seek new sources. ▪ Clarify the programmatic consequences and health worker actions needed to operationalize the eligibility criteria, particularly in the first year after introduction. ▪ Adapt training materials, communication materials, and supervision instruments to clearly reinforce the eligibility criteria and give guidance on practical situations (e.g., whether to open a vial if only a few children attend a vaccination session).

CHALLENGES	POSSIBLE CAUSES	POSSIBLE ACTIONS TO PREVENT OR ADDRESS CHALLENGES
Incorrect handling and administration of vaccine	The new vaccine requires unfamiliar or complicated procedures for appropriate use. Training is inadequate, of low quality, does not reach the right personnel, and/or is not reinforced.	▪ Select a vaccine product whose presentation, formulation, and handling needs are consistent with immunization program conditions. If that product is not available right away, consider delaying introduction until a more appropriate form of the vaccine product is available. ▪ During training and supervision, devote extra attention to the features of the vaccine that may be different, such as sensitivity to freezing, use (or non-use) of the multi-dose vial policy, and the importance of timely immunization. ▪ In training, apply active learning methods to build practical skills (e.g., practice in vaccine handling, recording doses, and communicating with mothers). ▪ Prepare job aids to reinforce proper vaccine handling and systematically distribute them to all health facilities. ▪ Revise supportive supervision tools to address the new vaccine and intensify supervision for the first few months post-introduction.
Demand for the new vaccine is higher or lower than expected	Vaccine benefits, attributes, and/or eligibility criteria are not clearly or accurately communicated.	▪ Provide technical review for accuracy of messages used in social mobilization activities. ▪ Engage with media, provide briefings and orientations, and offer them materials that provide clear and accurate information. ▪ As part of health worker training, build skills in communicating with mothers about the vaccine, the disease it prevents, and immunization. ▪ Conduct rapid formative research to identify the most effective ways to describe the vaccine, the disease against which it protects, and the nature of the protection it provides.
Difficulty in monitoring coverage and performance of the new vaccine	HMIS forms and vaccination cards are not updated. Lack of participation of appropriate government units involved in HMIS or involvement at too late a stage.	▪ Engage all units associated with statistics and data management in planning meetings for new vaccine introduction. ▪ Revise all forms and information systems to accommodate the new vaccine. ▪ Print and distribute revised recording and reporting forms before the vaccine is put into use. ▪ Revise and distribute new vaccination cards and provide guidance to health workers on how to record doses of new vaccine on existing vaccination cards that mothers bring.
Weak AEFI surveillance for new vaccine	May be an area that receives little attention for routine immunization.	▪ Build guidance on AEFI management for the new vaccine into training materials, job aids, and supervision checklists. ▪ Develop a communication plan for addressing any AEFI reports that may arise for the new vaccine.
Waste is not managed well	The additional waste generated by the new vaccine is not adequately recognized.	▪ As part of planning, clarify procedures for addressing additional waste. ▪ Develop revised budget estimates for recurrent operational costs, and identify source of funding.