Post-Introduction Evaluation of 7-valent Conjugate Pneumococcal Vaccine (PCV-7) in Rwanda

29 March – 9 April 2010

Contents

EXECUTIVE SUMMARY

1. BACKGROUND

Given the extent and seriousness of pneumococcal infections in the country and the WHO recommendation encouraging all poor countries with an under-five mortality linked to these infections of 50 deaths per 1000 livebirths to introduce the pneumococcal vaccine (PCV-7) , the government of Rwanda took the decision to introduce this vaccine in its national Expanded Programme on Immunization (EPI).

In February 2008, Rwanda EPI submitted a proposal to the GAVI Alliance to support pneumococcal vaccine. In May 2008, the GAVI Alliance approved Rwanda's proposal, making Rwanda the first country in sub-Saharan Africa to obtain approval for this vaccine. From then, preparations began, with introduction of the vaccine on 25 April 2009, with a province by province approach. This introduction, starting in April 2009, was completed in August 2009.

Before this introduction, an evaluation of the cold chain, vaccine management and EPI logistics was organized. Following this evaluation, the country obtained new cold chain equipment, revised the management tools used by EPI, developed training modules, trained the trainers and health personnel working at the operational level, developed key messages for mothers, and strengthened sentinel surveillance for pneumococcal infections. During the same process, the country set in place a system for management of the PCV-7 prefilled glass syringes.

2. POST-INTRODUCTION EVALUATION OF PCV-7

WHO recommends a post-introduction evaluation of new vaccines 6 to 12 months after introduction in order to assess their impact on the different components of the vaccination programme. For this reason, a group of external evaluators made up of representatives from the intercountry support team for central Africa, UNICEF HQ, the Centers for Disease Control and Prevention (CDC), the American Red Cross, and USAID/MCHIP jointed local evaluators to organize this evaluation

Eastern Province, Kigali Province and Western Province were chosen ; 7 district hospitals and 18 health centers were chosen based on the data of introduction (early or late), on population density, on vaccination performance, and on geographic considerations. This evaluation consisted essentially of a review of documents, interviews with health professionals, interviews with mothers of children who came for vaccination, and direct observation of vaccination sessions, vaccine depots, and vaccination materials.

3. OBJECTIVES

The objectives of this evaluation were as follows:

- Evaluate the process of introduction of the pneumococcal vaccine through the collection of qualitative and quantitative data from the central, district and health center levels;
- Summarize the strong points and the areas for improvement during the three phases (before, during and after implementation) ;
- Present the observations to the Ministry of Health and to partners ;
- Formulate recommendations for strengthening of the programme and for improving future new vaccine introductions.

4. SYNTHESIS OF OBSERVATIONS

Observations are groups into three phases:

- Pre-introduction : planning, training, cold chain, waste management, and key message for mothers
- Introductory phase : Acceptance of the new vaccine, injection safety and waste management, vaccination coverage and dropout rates, data quality, management of vaccines and cold chain equipment, monitoring and supervision, knowledge of health professionals
- Post-introduction phase : Surveillance and monitoring of AEFI

Overall, the introduction was found to go well and Rwanda did a good job in preparing for and introducing PCV7. Most health care workers (HCW) at the district hospital and health centers reported that the introduction of PCV7 helped to improve their overall immunization programme by reinforcement of cold chain systems and supplies and the provision of training on PCV7. Pre-implementation planning, training of health staff , overall knowledge of health workers, cold chain management, vaccine management and storage, waste management, communication and new vaccine acceptance were found to be good.

Identified areas for improvement included the use of inaccurate and inconsistent target population data (denominator) which resulted in coverage rates well over 100% in many districts. Skills for monitoring and calculating drop-out rates, vaccine stock and wastage rates were inconsistent and could be strengthened. Improvements are needed to increase frequency and quality of monitoring and supervision and to ensure established systems and protocols for AEFI are in place. Improved interpersonal communication is needed at immunization table to ensure all identified key messages are communicated to mothers.

The boxes below display the strengths and areas for improvement in each of the three phases of PCV7 introduction.

I. Pre-introduction phase ; Planning, Training, Cold Chain, Waste Management, and Key messages for mothers

Strengths

- Revised introduction plan available
- Most health personnel trained by provinces before vaccine introduction;
- Reference documents for training available
- Cold chain equipment obtained and distributed to health facilities before introduction
- Installation of a high temperature incinerator for the destruction of glass containing syringes before introduction of PCV-7
- Key messages developed and tested to address the concerns of mothers

Areas for Improvement

- Absence of activity timelines for introduction of PCV-7 in certain health facilities
- Feedback from certain staffers showed that training was of short duration and that certain practical aspects were not included in the training.
- In one health center visited, personnel did not get training.

II. Introductory phase : Acceptance of the new vaccine, injection safety and waste management, vaccination coverage and dropout rates, data quality, management of vaccines and cold chain equipment, monitoring and supervision, knowledge of health professionals

Strengths

- Most staff interviewed found the introduction of PCV-7 to be a smooth process with good preparation.
- Vaccine well accepted by parents because of key messages developed to address mothers' concerns
- The process of collection and elimination of PCV-7 prefilled, glass containing syringes was well understood by health personnel.
- In 35% of the health centers visited, the coverage for PCV-7 was higher than Penta coverage (one year before), and in 41 % of the centers, the first to third dose dropout rate for PCV-7 was lower than that for Penta 1 – 3.
- Supervisory visits were organized in December 2009 and March 2010 in the framework of preparation for the evaluation. Feedback was given to health centers (each health center was visited at least once in the last six months).
- No vaccine stockouts, no VVM at Stage 3 or 4, and no vaccines expired in the last six months

Areas for Improvement

- The EPI director mentioned that communications between the international community and the country on new vaccines could be improved. In particular, notification of the first delivery of PCV-7 was suboptimal preventing sufficient planning by the EPI staff.
- Weak quality of vaccination data (coverage above 100% and negative dropout rates).
- Poor knowledge of the target population (use of different sources of demographic data).
- In most health centers, data are not analyzed
- Interpersonal communication at the immunization session between vaccinators and mothers id not take place in all facilities.
- Feedback not documented in some health centers
- Moreover, recommendations not implemented because the written feedback was in a language unknown to those supervised
- Vaccine wastage not calculated in some health centers
- Absence of vaccine wastage reports and/or incomplete reports
- Placement of vaccines which cannot be frozen (PCV-7, Pentavalent, TT) at the bottom of top opening refrigerators
- Use of frozen icepacks for vaccine transport
- For lack of training, not all health professionals are familiar with this tool.
- A few unsafe injections were observed during

III. Post-introduction phase : Surveillance and monitoring of AEFI

Strengths

- AEFI surveillance protocol described in the *fiches techniques* of EPI.
- Investigation report forms available at the health center level.

Areas for Improvement

- No case of AEFI reported. There is no system of zero reporting if no AEFI cases are seen during a reporting period.
- Weak syndromic surveillance system in place for pneumococcal related sicknesses with standard case definitions

5. RECOMMENDATIONS

To address the areas for improvement identified during the evaluation, the evaluators elaborated recommendations and suggested responsible parties, timeframes, expected outcomes, and indicators.

Recommendation	Responsible	Timeframe	Expected outcome	Indicator
Vaccine coverage and management				
Provide updated vaccine coverage wall charts	EPI District supervisors	By June 1, 2010	Each facility has updated coverage chart on which coverage for PCV7 and Penta are monitored; data are used appropriately.	Supervision shows wall charts with coverage data and trend line; health care workers (HCW) correctly explain how they developed trend line and how they will use results.
Explore ways to provide a more accurate target population for coverage calculation	EPI, partners	By August 31, 2010	Accurate denominators for vaccination coverage data based on available data (family planning; migration; birth, death registries)	Collaboration established between EPI and partners to study ways to obtain more accurate target population figures
Analyze data for vaccine coverage, drop-out rates, wastage; implement self-evaluation of data quality	EPI District supervisors	By August 31, 2010	Accurate calculation of vaccine administration, drop-out rates, and wastage for decision-making.	Supervision shows self-evaluations done, problems identified, and a plan for addressing problems.
Assess proper documentation for PCV receipt				Supervision shows evidence of proper documentation of PCV receipt.
Training, supervision				
Provide supportive supervision or retraining on AEFI procedures and forms, safe practices for mixing vaccine components, use of Fridge Tags®, vaccine wastage reporting, use of vaccine management tools, shake test, open vial policy, conditioning of ice packs for vaccine transport, data management, and interpersonal communication of key messages at immunization table	EPI District supervisors	By August 31, 2010	HCW has knowledge and skills to address gaps found during PIE	Supervision visits are documented with written summary Visits show vaccine management tools are complete and accurate and communication between HCW and mother is taking place at the immunization table. Evidence that vaccine wastage reports are included on monthly vaccine orders.
Communication				
For communication, explore opportunities to incorporate corresponding messages on disease prevention, recognition of warning signs, improved care-seeking and home treatment into vaccination activities and tools	MoH EPI, MCH, WASH, nutrition National Health Communication Center partners	By September 31 2010	MoH and partners identify key interventions and corresponding strategies to scale-up communication for child survival with focus on pneumonia and diarrhea.	--Collaboration established between MoH and partners on coordinated behavior change communication for child survival. --Strategic plan developed to take communication for child survival to scale with focus on engagement of communities and households in key family practices.
Surveillance				
Conduct an assessment of surveillance for vaccine preventable diseases including pneumonia, meningitis, and diarrhea in preparation for new vaccine introduction.	EPI, Comm. Ds Surv. and Resp., Epidemiology Unit, MOH, HMIS, partners	By December 31, 2010	Information on the availability and quality of surveillance data for pneumonia, meningitis, and diarrhea.	Report available on strengths, weaknesses and recommendations* of surveillance for pneumonia, meningitis, and diarrhea (include responsible, timeframe, outcomes, and indicators)
Consider impact study of PCV7 or next generation PCV to document	EPI, Partners	By August 31, 2010	Proposal for evaluating the impact of PCV7 or next generation PCV.	Collaboration established between EPI and partners to develop an

the effect on the vaccine on disease for decision making for vaccine sustainability.				approach to measure impact
Cold chain				
Conduct a cold chain assessment to determine current capacity and plan for introduction of rotavirus (RV) vaccine and higher valency PCV formulation in multi-dose vial	EPI, partners	Pending timeframe for new vaccine introduction	Information for decision making on how to prepare the cold chain capacity vis à vis needs for RV and other PCV presentations.	Plan developed for cold chain enhancements in preparation for introduction of RV vaccine and other PCV presentations.

REPORT

I. BACKGROUND

1.1. Justification for introduction of PCV-7

Created in 1978, the Expanded Programme on Immunization (EPI/Rwanda) developed rapidly, and, in 1980, became operational with six routine disease vaccinations: BCG, OPV, DPT, TT and measles. Since 1999, DPT 3 coverage has reached and exceeded 80%, until the present day. Since 2003, the proportion of health districts with a DPT3 coverage of at least 80% has only increased. The DPT1-DPT3 dropout rates are always below 10 percent. The country eliminated neonatal tetanus by 2004[1]. In 2002, the programme introduced the pentavalent vaccine, including DPT, hep B and Hib, thanks to GAVI Alliance support.

Pneumococcal infections are an important cause of morbidity and mortality in all regions of the world. In Rwanda, a review of the fragmentary studies done at the university sites in Kigali and Butare showed that pneumococcal conditions are frequent in the country. Among children under five years of age suspected of meningitis, examination of cerebrospinal fluid showed more *Streptococcus pneumoniae* than *N. meningitidis* or *Salmonella*, as the following table shows.

Table 1: Pneumococcal surveillance data, Rwanda, 2004-2007

#sites	Period	Test done	Number of suspected cases < 5 years	Sentinel sites
1	Jan-Nov. 2004	Suspected cases and lab results (CSF)	144 suspected cases : 9 pneumococcus 2 *N. meningitidis* 1 *Salmonella*	CHU/Kigali Positive lab test
2	Jan-Oct 2005	Suspected cases and lab results (CSF)	97 cases suspects : 4 pneumococcus Others: negative	CHU Kigali CHU Butare
1	Jan-Oct 2006	Suspected cases and lab results (CSF)	19 cases suspects : 8 pneumococcus 4 *N. meningitidis* 7 *Salmonella* *0 H. influenzae*	CHU/ Kigali
2	Jan-Oct 2007	Suspected cases and lab results (CSF)	128 cases suspects : 3 pneumococcus 1 *N. meningitidis* 4 *Salmonella* 0 Remaining	CHU/Kigali CHU/Butare

Source : University Hospital Centers, Kigali & Butare

[1] NNT incidence rate of < 1 per 1000 livebirths

Faced with this situation, Rwanda decided to adopt the WHO recommendation for introduction of pneumococcal vaccine in its routine vaccination programme from 2009 / 2010.

1.2. Description of the introduction

The conjugate pneumococcal vaccine (PCV-7) was introduced in Rwanda in 2009 using a province by province approach. Starting in April 2009 in Eastern province, introduction was completed in August in Western province.

This vaccine was added to other antigens already included in the existing vaccine schedule. It presented the following challenges: a prefilled syringe with glass enclosed, without VVM, without attached needle, and requiring a great storage capacity (1 dose at 55.9 cm^3). The glass containing syringes need high temperatures (>1200°C) for their total destruction after use. Since the vaccine is administered at the same time as pentavalent vaccine, a second injection is required for each child during the same vaccination session.

A cold chain evaluation was conducted in 2007 as part of the preparation for introduction. This identified additional cold chain equipment needs.

As respects waste elimination, a second system for collection and destruction of glass containing syringes was set in place. It consists in making red security boxes available to health facilities (different from the white and yellow ones used for A-Ds), for use in the high temperature incinerator.

Based on formative research, key messages were developed and included in the PCV7 job aid and training materials to address the concerns of parents and health professionals about the administration of two child injections on the same day during the same session. Messages were also included to inform parents about the importance of PCV7, the administration schedule, the diseases PCV7 will help to prevent, what to do if mild side effects occur, and when to bring the child back for their next appointment.

All the vaccination management tools were revised with information on PCV-7.

An official launching of the introduction was organized in Nyamata, Eastern Province. The ceremony included participation by national authorities from the Ministry of Health and ICC members, as well as representatives of international organizations such as delegates from the GAVI Alliance, Wyeth (the manufacturer), UNICEF, and WHO. National and international media covered this event (radio, television, print media, with pamphlets and stickers).
Supervisions were done from the start to ensure the high quality of services linked to the introduction of the new vaccine.

II. METHODS USED

2.1. Selection of facilities to visit

The guide used for the evaluation proposes selection of at least three provinces, with two health districts per province (six in total) and three health centers in each district (18 health centers) in addition to the central level, which corresponds to the EPI coordination. The selection criteria also took into account the chronology of introduction (early or late), urban/rural locations, population size, EPI performance and the geographic location of the sites.

Table 2 : Evaluation sites

Province	District	Health Facility	Justification
East	Bugesera	Nzangwa Ruhuha Nyamata	Province where the vaccine was first introduced
	Nyagatare	Nyagatare h.c. Matimba Nyarurema	Largest district with a high rural population, bordering on Uganda and Tanzania, presence of nomads
Kigali	Gasabo	Kacyiru Kayanga Kimironko	Urban and Semi-urban areas Large population Low vaccination coverage
	Kicukiro	Busanza Gikondo Masaka	Site of the high temperature incinerator
West	Rusizi	Mushaka Bugarama Rusizi h.c.	Last province to introduce the vaccine Center most distant from Kigali Borders with DRC and Burundi Weak vaccination coverage Movement of refugee populations
	Rubavu	Gisenyi h.c. Gacuba II Byahi	Large population Border with the DRC Movements of refugee populations High vaccination coverage

2.2. Data collection tools and methodology

A generic tool from the evaluation guide was adapted to the context of Rwanda and the conjugate pneumococcal vaccine in prefilled glass containing syringes (PCV-7), before the visits to the facilities selected. Thus, in addition to documentary review at all levels, the following tools have been used in the evaluation in Rwanda:

- Standardized questionnaires have been used for interviews of health personnel at central, district hospital and health center levels;

- Checklists for observation of vaccination practices and practices of vaccine storage;
- Another questionnaire served for interviews of mothers after vaccination sessions in the health centers evaluated.

2.3. Areas covered by the evaluation

All EPI components were reviewed in the course of the evaluation. These are :

- Planning and the process of introduction
- Vaccination coverage and reports
- Cold chain management
- Vaccine management, storage and logistics
- Waste management and injection safety
- Monitoring and supervision
- Training and knowledge of health personnel
- Vaccine wastage
- Adverse events following immunization (AEFI)
- Advocacy, communication and acceptance
- Sustainability
- Surveillance

2.4. Members of the evaluation team

This evaluation was done by six teams, each made up of two evaluators. Among the evaluators, six were external and belonged to the following organizations : WHO / Intercountry Support Team for Central Africa (OMS/IST), UNICEF / New York, Centers for Disease Control and Prevention (CDC), American Red Cross, and USAID / Maternal and Child Health Integrated Program (USAID / MCHIP). These external evaluators were paired off with seven national evaluators from the Ministry of Health and EPI partners.

The members of this team were as follows:

International team, consisting of the following persons:

- Dr Pierre Kandolo Wenye, OMS / IST Central, Coordinator of the evaluation
- Dr Michel Othepa, USAID / MCHIP, Member
- Mr Robert Davis, American Red Cross, Health Delegate, Member
- Ms. Kathy Cavallaro, CDC-Atlanta, Member
- Dr. Laura Conklin, CDC- Atlanta, Member
- Ms. Shalu Rozario, UNICEF / New York, Member

The local team was made up of the following persons:

- Mrs. Jeanine Uwimana
- Mr. Anicet Rwasangabo
- Mr. Eugène Kanyamanza
- Mr. Eugène Rukagengwa

- Mr. Eliphaz Nzajybwanu
- Ms. Françoise Kanyiranwa
- Mr. Alexis Mucumbitsi

Each team was made up of one international and one national evaluator.

III. OBJECTIVES OF THE EVALUATION

The main objective of this evaluation was to assess the programmatic impact on EPI of the introduction of pneumococcal vaccine.

Specifically, we sought :

- To collect data on training, knowledge of health professionals, communication and vaccine acceptance, vaccination coverage and reporting, AEFI, monitoring and supervision, cold chain capacity and management, injection safety, and management of waste generated by the vaccines ;
- To analyze the data collected to identify the strong and weak points linked to this introduction; and
- To propose recommendations to strengthen the programme and improve the process of introduction of additional new vaccines, such as rotavirus, which the country plans to introduce in the near future.

IV. RESULTS OF THE EVALUATION

This section presents the main results of the evaluation. We describe the strengths and weaknesses observed for each of the programme components mentioned above.

4.1. Pre-introduction planning, training, and revision of EPI management tools

Vaccine introduction requires rigorous planning, integrating different areas such as personnel training, cold chain evaluation to assure that current capacity is sufficient to accommodate the new vaccine, and the revision of management tools used in EPI in order to integrate information related to the new vaccine.

We describe in the following section the situation observed in Rwanda.

4.1.1. Strong points

A PCV-7 introduction plan was developed by Rwanda and submitted to the GAVI Alliance in the framework of a request for vaccine introduction. The evidence of cascade training was noted. Training of trainers in Kigali and training of health professionals in district hospitals and health centers were organized. Before introduction, an evaluation of storage capacity was made. Following up on gaps identified in certain hospitals and health centers, cold chain equipment was acquired with support from partners and from the government. Guidelines (EPI guide, *fiches techniques*) and management tools (tally sheets, vaccination registers, forms for vaccination reports, etc.) were revised, including information on PCV-7. These were reproduced and disseminated to the districts and the health centers. Key messages, adapted to local conditions, were developed to address the concerns of mothers and health personnel on the opportunity of giving two injections to the child on the same day and provided mothers key information about the benefits of the PCV7 vaccine, administration schedule, and caring for potential side effects.

4.1.2. Areas for improvement

At this stage, the following areas needing improvement were noted: although we observed in some health centers the timeline of activities linked to PCV-7 introduction, this document was not developed in other health centers. In the Kacyiru health center, personnel trained did not, in turn, train other vaccination staff. We recommend that training should take place no more than 2 weeks before the launch of the introduction, so as to avoid staffers' forgetting details of the information received. Unfortunately, we observed in some facilities visited that the interval between training and introduction varied from 1 to 2 months. The wall charts for monitoring of vaccination coverage were not revised to include pentavalent and PCV 7.

4.1.3. Essential recommendations

- Develop and distribute a national directive on the obligation of every hospital and health center to develop a timeline of activities linked to new vaccine introduction.
- Set in place a training strategy to reach all vaccination personnel in the health centers.
- Implement trainings no longer than 2 weeks before the start of introduction.

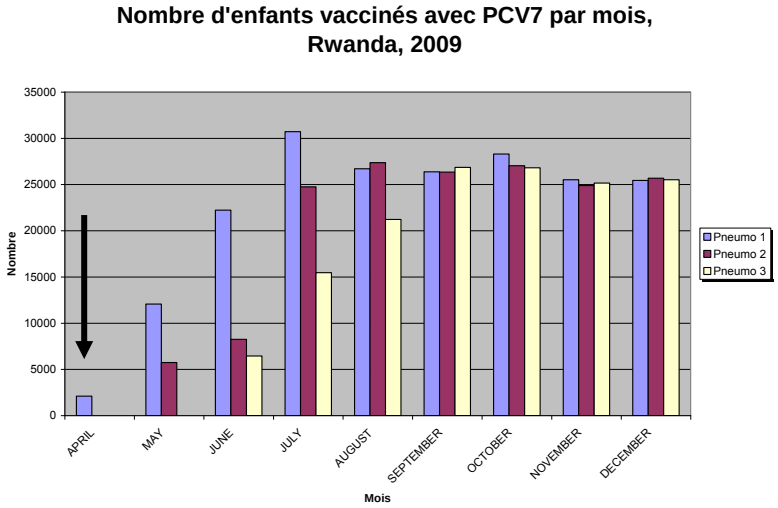
4.2. Vaccination coverage and reporting

In general, vaccination coverage has reached and exceeded 80 percent from 1999 until today. Since 2003, the proportion of health districts with a DPT3 coverage of at least 80 percent has only increased. The dropout rates between DPT1 and DPT 3 have always been under 10 percent.

PCV-7 introduction started in April 2009 in Eastern Province, gradually spreading to cover the whole country by August 2009. The number of children vaccinated has also progressively increased. During the first months, from June to August 2009, the number of dropouts between first and third dose of PCV-7 was important; from September 2009 onwards, this number has decreased, as shown in the Graphic 1, below.

Coverage data on PCV-7 have varied from center to center. In most health centers visited, the coverage for third dose of PCV-7 was above 100 percent. In others, the coverage was below 65 percent. This situation suggests a problem of poor knowledge of the target population, but also the possible existence of pockets of undervaccination.

Graphic 1: Evolution in the number of children vaccinated with PCV-7 between April and December 2009



4.2.1. Strong Points

Trends in coverage with the third dose of PCV-7 show, at the national level, good performance, over 80%. In a high proportion of the health centers visited, third dose coverage of PCV 7 was higher than 80 percent. Teams were able to confirm the availability of coverage data in most of the facilities visited. Comparing third dose of PCV-7 for the period October 2009-February 2010 with that of third dose pentavalent for October 2008-February 2009, it was observed that third dose PCV-7 coverage was higher than that for third dose of pentavalent in 35 percent of the cases.

4.2.2. Areas for improvement

The following areas require a special attention on the part of the national authorities. There is the question of the denominator: several sources of demographic data are being used; moreover, it was observed that some health centers used the same target population over several years. The fact of having, in many health centers, coverage figures higher than 100 percent, sometimes 200 percent, and the existence of negative dropout rates both denote

weak quality of data. We also observed in certain hospitals and health centers the absence of reports because of failure to file them.

4.2.3. Essential recommendations

- Harmonize the population data sources at all levels
- Proceed to file reports at all levels
- Set in place the practice of self-evaluation of data quality at all levels (DQS)

4.3. Cold chain management

The Rwanda cold chain is made up at the central level of four positive cold rooms with a total capacity of 116 m^3, a negative cold room, four refrigerators and three freezers. There are no vaccine depots at the provincial and district levels. District hospitals are equipped with refrigerators and freezers. Health centers have refrigerators. After identification of gaps by pre-introduction evaluation of storage capacity, cold chain equipment was purchased and supplied to these facilities.

4.3.1. Strong Points

We found proper functioning of cold chain equipment since PCV-7 introduction in most facilities visited. Mechanisms exist to cope with failures in energy sources. Most cold chain equipment has twice daily temperature recording. Fridge-Tags® were found in all the refrigerators visited.

4.3.2. Weaknesses

One of the cold rooms at the central level had a temperature below 2°C the day of our visit. Similarly, the readings on the Fridge-Tag® showed a temperature of 0°C without corrective action being taken.

The team noted that the refrigerators at the Gasabo Hospital and the Kacyiru health center had no temperature recording. At the Kayanga health center, frozen icepacks surrounded the vaccines inside the refrigerator. Health center staffers did not use the Fridge-Tag® because they were unfamiliar with this quality control tool.

4.3.3. Recommendations

- The managers of the positive cold rooms and the refrigerators must make sure that the temperature is between +2°C and +8°C ;
- Every piece of cold chain equipment must have temperature recorded correctly and systematically twice per day sheet, including weekends and public holidays.
- Train health center personnel to use the Fridge-Tag®.

4.4. Management and storage of vaccines; vaccine wastage

Vaccine is the main input of the vaccination programme. Correct forecasting is essential; vaccine orders and deliveries need to be done in a timely way to avoid stockouts. The vaccines need to be correctly placed in the refrigerator so as to retain their efficacy. At every level, the wastage rates need to be calculated and monitored, with the reports sent up through the reporting channels.

4.4.1. Strong Points

The team observed no stockouts, nor did we see expired vaccines or vaccines with the VVM at Stage III or IV for the period October 2009 to March 2010. The EPI Guide, with guidelines on vaccine management, was available in all the facilities visited. Vaccine wastage reports were seen in some health centers visited.

4.4.2. Weaknesses

Although the formula for calculation of vaccine needs is known, estimations for vaccine orders are made empirically by most health center personnel. Stocks at different levels are unknown. Stock orders and deliveries are not done systematically based on the bundling principle. Vaccines which cannot be frozen (PCV-7, pentavalent, TT) are placed at the bottom of top opening refrigerators in most facilities visited. For vaccine transport, most personnel use frozen icepacks, risking freezing the vaccines and rendering them inactive. Many centers have vaccine freeze indicators, the Fridge-tags ®, but personnel do not know how to use them correctly. In many health centers, personnel do not know how to calculate vaccine wastage. In others, vaccine wastage reports are incomplete.

4.4.3. Recommendations

- Strengthen staffers' capacity in vaccine management through retraining in the following areas : estimation of vaccine needs for preparing orders, appropriate placement of vaccines in each kind of refrigerator (front opening and top opening), use of freezing indicators, calculation of vaccine wastage…);
- Strengthen formative supervision at different levels.

4.5. Monitoring and supervision

The system of monitoring is essential for programme development. It allows monitoring of progress and of questions needing special attention. Monitoring at the health center level, through use of vaccination coverage wall charts and meetings with the community, is an essential tool for taking corrective actions to improve EPI performance. Supervisory visiting,

with written feedback in a language familiar to personnel, is an effective way of motivating personnel.

4.5.1. Strong points

Reporting of vaccination data is done through the monthly report of all health center activities (curative, preventive). Wastage figures are reported in a specific report. In all the facilities visited, teams found vaccination data. Documented supervisory visits were organized in December 2009 and March 2010 to follow up on the implementation of PCV-7 introduction.

4.5.2. Weaknesses

Written feedback was only seen in some health centers during the evaluation. In others, supervisors' recommendations could not be implemented because the feedback was in English.

4.5.3. Recommendations

- Feedback written in a language familiar to those supervised must be made at the end of each supervisory visit.

4.6. Knowledge of health personnel

The evaluation planned to assess the training given to health personnel, notably their knowledge of the diseases prevented by PCV-7 and vaccine contraindications.

4.6.1. Strong points

Most health personnel know at least 3 of the main sicknesses preventible by PCV-7 ; the same applies to knowledge of contraindications.

4.7. Safety of injections and waste management

Good vaccination practices are an effective way of protecting health professionals and vaccinees from accidental injuries. The destruction of prefilled glass containing syringes requires the use of a very high temperature incinerator.

Figure 2 : Red safety boxes with PCV-7 prefilled glass containing syringes used in the Kacyiru health center.

4.7.1. Strong Points

The facilities visited use A-D syringes for administration of other vaccines (pentavalent, measles, TT, and BCG). Personnel applied the correct injection techniques in most cases.

Yellow or white safety boxes are used to collect these sharps for destruction, once the boxes are full. Standard incinerators are used for this purpose at the health center level. The prefilled syringes of PCV-7 are collected in red safety boxes and stored at the health center level. Once per month, the filled boxes are taken by health center nurses to the district, where they are stored for bimonthly or quarterly dispatch by hospital staff to the country's only high temperature incinerator at the Kanombe Military Hospital, Kigali, for complete destruction (See figure 3).

The team had no chance to observe transportation of the boxes or how the glass was incinerated. Neither could the team, for lack of time, visit the very high temperature incinerator. However, guidelines related to this activity are well set out in the EPI Guide.

Figure* 3: *High temperature incinerator in Kanombe

4.7.2. Weaknesses

We observed recapping by some health workers at the time of reconstituting freeze dried vaccines. In some health centers, personnel reconstitute several vaccine vials which stay on the foam several hours before the vaccination session.

4.7.3. Recommendation

- Improve vaccination practices by retraining and by formative supervision of personnel

4.8. Monitoring of Adverse Events Following Immunization (AEFI)

4.8.1. Strengths

AEFI guidelines included in the EPI Guide were not updated with PCV-7 introduction. The team found investigation notification forms for AEFI in most health centers visited.

4.8.2. Weaknesses

Unfortunately, the system of AEFI monitoring is not operational. Personnel do not understand the guidelines relating to AEFI in the EPI Guide, and no AEFI reports were seen in the health centers visited.

4.8.3. Recommendations

- Establish and implement a functioning national system for AEFI through training and sensitization of personnel
- Implement a system of zero reporting for AEFI cases where no AEFI were found during a given reporting period.

4.9. Advocacy, communication and acceptance

4.9.1. Strong points

Since, with PCV-7 introduction, the child must receive an extra injection on the same day, the MoH conducted focus group discussions with mothers and health professionals before

introducing the vaccine, in order to obtain data for developing key messages on sensitization. During this evaluation, a good acceptance of PCV-7 was noted on the part of mothers who were questioned after their children were vaccinated; some of the mothers were able to name some of the diseases that PCV7 helps to prevent and knew the data for next visit. Health workers were generally well-informed of key messages to communicate to mothers and engaged in some form of interpersonal communication during the registration in addition to conducted group health education sessions prior to the start of immunization session.

4.9.2. Weaknesses

Interpersonal communication between health staffers and mothers during vaccination sessions is not systematic. Mothers reflected gap in knowledge regarding causes and prevention of pneumonia.

Although not included in the formal scope of the PIE, communication by vaccinators with mothers about preventative and care-seeking behaviours was not observed by the evaluators. Vaccination sessions and immunization activities may provide an opportunity to support current strategies for communication of pneumonia prevention with care-givers and community health workers.

4.9.3. Recommendation

- Systematize interpersonal communication between health personnel and mothers during vaccination sessions.
- Strengthen coordinated communication strategies to engage health care workers, communities and households in improved preventative and care-seeking behaviours for pneumonia control.

V. LESSONS LEARNED

5.1. New vaccine introduction requires a lead time of at least 12 months, a decentralized system of primary health care, and staff trained and responsible at the operational level.

5.2. New vaccine introduction can require an increase in vaccine storage capacity. To do this, it is indispensable to organize an evaluation of the cold chain storage capacity, to identify the real needs and to determine the gaps which must be closed to accommodate the new vaccine.

5.3. New vaccine introduction requires prior training of all personnel participating in vaccination activities, not only for the vaccine in question but also for all technical areas of vaccination to insure quality services.

5.4. To assure parental acceptance, new vaccine introduction requires the development of key message which take into account parental concerns.

5.6. Taking account of the high costs of new vaccines, advocacy with the political authorities is indispensable to securing new vaccines (co financing).

VIII. ANNEXES

1. **Work schedule for PIE**
2. **Members of the evaluation team and their provincial assignments**
3. **Tools for data collection (questionnaires for health facilities)**
4. **Tools for data collection (questionnaires for mother or care-giver)**
5. **Presentation to the Interagency Coordination Committee**

1. Work schedule for Post Introduction Evaluation (29th March – 9th April 2010) - Responsibilities

PHASE	DAYS	ACTIVITIES	Responsible
March 29, 2010	29th March, 2010	Designation of 6 national evaluators from Kigali	MOH- Rwanda
		To select 3 provinces, 6 Districts 18 facilities to be visited	Evaluators
		To prepare transport for the ground teams and the per diem for the team	MOH- Rwanda
		To notify the provinces, districts and Heath facilities to be visited	MOH- Rwanda
		To obtain approval from ICC and briefing meeting on April 9, 2010	MOH- Rwanda
		To adapt the questionnaires to the context of Rwanda	Evaluators
		To reproduce the questionnaires	MOH- Rwanda
From March 29, 2010	29- 31st April, 2010	To meet the EPI team, MOH officials and Key partners	Evaluators
		To finalize the selection of 3 provinces, 6 Districts and 18 facilities to be visited	Evaluators
		To finalize the adaptation of the questionnaires to the context of Rwanda	Evaluators
		To constitute the evaluation teams	Evaluators
	April 1-2, 2010	To train the evaluators	Evaluators / MOH
		To finalize the administrative aspects for the field visits	MOH- Rwanda
	April 3-4, 2010	Departure of teams to the ground	MOH- Rwanda
	April 05-07, 2010	Data collection in the provinces, districts and facilities	Evaluators
	April 07, 2010	Return of the teams to Kigali	MOH- Rwanda
	April 08, 2010	To compile and analyze the collected data	Evaluators
		To prepare presentation, recommendations for ICC de-briefing	Evaluators
		Compilation of evaluation report	Evaluators
	April 09, 2010	De-briefing meeting for ICC	Evaluators / MOH
After April 9, 2010	April 16, 2010	To finalize the report and submission to MOH Rwanda and partners	Evaluators

MOH- Ministry of Health, Rwanda
ICC – Inter-agency Coordinating Committee

2. Questionnaire - Central/ /District (Hospital)

Pneumococcal Vaccine (PCV-7)

Post Introduction Evaluation (PIE) in Rwanda

Date of interview _____ Name of interviewer _____

This questionnaire was conducted at: (insert name of country, region or district)
☐ Central level: _____

☐ District level (District hospital): _

Name (s) and title (s) of person(s) interviewed (please list all persons that you interviewed):
EPI Manager/person responsible for vaccinations (or their deputy) should be interviewed

*Name*_____ *Title* _____

*Name*_____ *Title* _____

*Name*_____ *Title* _____

Contact details of most senior person:
Telephone _____ *E-mail address* _____

Name of new vaccine(s) being evaluated: ____PCV-7 _____

New vaccine preparation: Liquid_____

New vaccine presentation: (e.g., prefilled syringe,): glass prefilled syringes - 1 dose
Documents to request at beginning of interview:

Document / data	**Document received**	**Document reported to exist but not available at time of interview**	**Document unavailable**
Copy of national immunization schedule (central level only)			
Introduction plan for new vaccine			
Training materials/reference documents utilized at new vaccine training			
Vaccine management guidelines			
Media campaign/social mobilization/education materials (e.g., brochures, posters, pamphlets)			
Vaccine stock records			
Supervisor's book/site visit reports (regional and district level only)			
Injection safety/waste management policy document			
Wastage reports			
AEFI protocol/reporting form			
AEFI logbook/registry			
Surveillance data/bulletin on disease targeted by new vaccine			
National coverage and dropout rates (central level)			

Abbreviation	BACKGROUND INFORMATION	Central / District Questionnaire
GEN	1. Date **PCV-7 vaccine** introduced nationally/ regionally/ district **Note**: *if interviewing region or district, put date for appropriate area.*	(DD/MM/YYYY) _____ / _____/ _____
GEN	2. Was the **PCV-7 vaccine** introduced nationally or phased?	☐ National introduction (all regions and districts at once) ☐ Phased introduction (explain) _____
GEN	3. What is the population of children less than 1 year of age in this country/ district hospital ? **Note**: *If not available for <1 year, get for <2 or <5 years*	Number of children <1 year of age _____ Source/Year_____
CENT	4. What factors influenced the decision for introduction of the **PCV-7 vaccine**?	**Check all that apply** ☐ Strong political will ☐ Strong pediatrics association ☐ Introduction by neighbouring countries ☐ Hib data available nationally ☐ Visit by international advisor ☐ Other influences (specify)
CENT	5. Was the national immunization ICC supportive of the decision to introduce the new vaccine?	☐ Yes ☐ No ☐ Don't know If no, what were their reasons: _____
CENT	6. What is the national immunization schedule? **Note**: *Ask for a copy of the schedule for all EPI vaccines (central level only)*	Copy of schedule received ☐ Yes ☐ No
CENT	7. Was the immunization schedule changed when the new vaccine was introduced? If yes, why?	☐ Yes ☐ No ☐ Don't know If yes, reason
CENT	8. What is the schedule for the **PCV-7 vaccine**? **Note**: *See WHO schedule recommendation for the **PCV-7 vaccine** in PIE manual and note if there are any differences*	**Insert age that dose is given** Schedule: Dose 1 _____ Dose 2_____ Dose 3_____ Dose 4_____
GEN	9. What disease(s) does the **PCV-7 vaccine** prevent? **Note**: *For penta ask about all 5 antigens.* *Hib and pneumococcal vaccines prevents some, not all, meningitis and pneumonia. Rotavirus vaccine prevents some, not all, mild and severe diarrhea*	☐Yes ☐ No If yes, which disease(s) do they prevent? ☐ Does not know ☐ Pneumonia ☐ Meningitis ☐ Otitis ☐ Septicemia
	PRE-IMPLEMENTATION PLANNING AND VACCINE INTRODUCTION PROCESS	Central / District Questionnaire
GEN	10. Do you have a central / district **PCV-7 vaccine** introduction plan or timeline (chronogram for district) for introduction activities?	☐ Yes national plan/timeline ☐ ☐ Yes, district hospital plan/timeline

	Note: *For example, if someone from the district only has a national plan, just check national plan. If they have a national and a district plan check both.*	**Interviewer please ask for a copy at time of interview. Review later to ensure essential components are included.** ☐ No. If no why not?
CENT	**Ask only if response to question 10 was "yes"** 11. Did you receive support or use guidelines to develop your introduction plan/timeline?	☐ Yes. If yes specify support? _____ ☐ No. If no why not? _____ ☐ Don't know
	TRAINING	Central / District Questionnaire
GEN	12. Please describe staff training for the **PCV-7 vaccine** introduction, if any	Type of training ☐ Cascade ☐ province by province ☐ Other (specify) Was training conducted before vaccine introduction ☐ Yes ☐ No If yes, how long before _____ Was training conducted after vaccine introduction ☐ Yes ☐ No If yes, how long after _____ ☐ How long was the training? _____ Who conducted the training at each level? Regions / provinces_____ District _____ Health facilities _____ Other comments on training _____
GEN	13. How were the trainings financed?	
GEN	14. What specific training was given on the administration of PCV-7 vaccine?	☐ Correct collection of used glass PFS ☐ Correct final disposal for used glass PFS ☐ Key messages to mothers before and immediately after immunization of children related to multiple injection to a child the same day ☐ Other, specify ☐ Don't know
GEN	15. Were there any problems with the training?	☐ Yes ☐ No ☐ Don't know If yes, please describe _____
GEN	16. What educational and reference materials were provided to participants at time of training? **Ask for samples**	
GEN	17. Is there a clear policy for immunization schedule of children previously unimmunized with penta and of children who have started with Penta (how many doses of PCV-7 to give to children who have received Penta-1, penta 2 or Penta 3?)	☐Yes ☐ No ☐ Not applicable If yes, verify if health workers know it and are correctly implementing it
	VACCINE COVERAGE	Central / District Questionnaire
GEN	18. What formula do you use to calculate vaccine coverage? Include the source of the numerator (doses administered) and denominator (target population)	Formula Numerator source _____ Denominator source_____ Correct formula used ☐ Yes ☐ No

GEN	19. What was Penta-1 and Penta-3 vaccine coverage in comparable for the period of Oct. 2008 to Feb 2009?	Penta-1 coverage _____ year _____ Penta-3 coverage _____ year _____ Calculate dropout rate: (*Penta1 - Penta3)/Penta1 x 100* = _____%
GEN	20. What is the coverage of the first and last dose of the PCV-7 vaccine for the period of Oct. 2009 to Feb 2010 Note: If coverage is unknown for PCV-7 vaccine because PIE is done before administrative data are available, record anecdotal reports or look at number of doses of PCV-7 vaccine used *versus number of doses of Pentavalent used.*	**PCV-7 vaccine** first dose (PCV-7-1) coverage _____ **PCV-7 vaccine** last dose (PCV-3) coverage _____ Calculate drop out rate: (*PCV-11 – PCV-3)/PCV-1 x 100* = _____%
GEN	21. Is coverage of the **PCV-7 vaccine** higher or lower than Pentavalent? **Note**: *Use OPV for rotavirus vaccine evaluation*	**PCV-7 vaccine** first dose vs. Penta-1 ____% Higher ____% Lower ☐ No change **PCV-7 vaccine** last dose vs. Penta-3 ____% Higher ____% Lower ☐ No change
GEN	22. Is the dropout rate for the **PCV-7 vaccine** higher or lower than the Pentavalent dropout rate?	**PCV-7 vaccine** dropout rate versus Penta dropout rate ____% Higher ____% Lower ☐ No change
GEN	23. In the last year, what proportion of districts/health facilities sent all monthly immunization summary forms completed and submitted on time?	% of districts/health facilities submitting reports on time every month _____ % Reports complete _____ (of reports received, how many have all key information completed for every month)
	COLD CHAIN MANAGEMENT	Central / District Questionnaire
GEN	*24.* Discuss any changes you had to make in the cold chain before introduction of the **PCV-7 vaccine** **Note:** *Try to distinguish cold chain expansion/replacement of equipment that is part of normal cold chain rehabilitation from changes specifically for the new vaccine.*	
GEN	25. Were any problems with the cold chain recognized after the introduction of the **PCV-7 vaccine**? If yes, what were the problems and how have the problems been addressed?	☐ No problems ☐ *Frozen vaccine,* ☐ M*alfunctioning refrigerators,* ☐ *Power supply/fuel shortage* ☐ Other (specify) If problem, what measures were taken?
GEN	26. Do you use freeze watch monitors during vaccine transportation?	☐ Yes ☐ No ☐ Don't know Freeze watch
	VACCINE MANAGEMENT, STORAGE & LOGISTICS	Central / District Questionnaire
GEN	27. Do you have immunization policy guidelines for vaccine management? If yes, have they been updated to include the PCV-7? **Please provide a copy at time of interview**	☐ Yes ☐ No
GEN		

	28. How do you forecast vaccine need?	
GEN	29. Did the estimated needs for other vaccines change with introduction of the **PCV-7 vaccine**?	☐ Yes ☐ No ☐ Don't know If yes, why? _____
GEN	30. How are PCV-7 and other vaccines ordered?	
	31. When preparing vaccines for transport, do you use frozen icepacks?	☐ Yes ☐ No
GEN	32. Please describe how vaccines are transported to the districts/health facilities, and is there enough space in the trucks.	
GEN	33. How and how often are the vaccines and supplies distributed from your level to the next level?	
GEN	34. Did the frequency of deliveries change with introduction of the **PCV-7 vaccine**? If yes, by how much?	☐ Yes ☐ No ☐ don't know If yes, Frequency of delivery before introduction _____ times/year Frequency of delivery after introduction _____ times/year Reason for change?
GEN	35. What effect did the **PCV-7 vaccine** have on cold storage space requirements?	
GEN	36. What were the costs associated with increased transport or cold chain requirements?	Please state how many of the following were required: Extra trucks/cars rental or purchase _____ Extra logistic staff _____ Extra petrol _____ Extra cold chain space _____ Other costs (specify) _____
GEN	37. Who paid for these extra costs?	
GEN	38. Did you run out of any vaccines including the PCV-7 vaccine, or vaccines supplies in the past 6 months(Oct 2009 to March 2010)?	☐ Yes vaccines (specify) _____ ☐ Yes vaccine supplies (specify) _____ ☐ No If yes, how many weeks _____ If yes, reason for stock out _____
GEN	39. Have you had any vaccine expirations at your level in the last 6 months Oct 2009 to March 2010)? (? If yes, what did you do with the expired stock?	☐ Yes ☐ No If yes, action taken
GEN	40. Have you had any vaccine with the vaccine vial monitor (VVM) in stage III or IV in the last 6 months (Oct 2009 to March 2010)? If yes, what did you do with these vaccines?	☐ Yes ☐ No If yes, action taken: _____
GEN	41. Are vaccine orders/deliveries tied to injection supplies (i.e., bundling)? **Note**: *Look at stock records to get this information.*	☐ Yes ☐ No Verified by checking stock records ☐ Yes ☐ No

	WASTE MANAGEMENT & INJECTION SAFETY	Central / District Questionnaire
CENT	42. Describe the waste disposal policy/plan at each level.	
GEN	43. Do health facilities generally follow these guidelines?	☐ Yes ☐ No ☐ Don't know
GEN	44. Did you have to make changes to your waste disposal system for introduction of the **PCV-7 vaccine**?	☐ Yes ☐ No ☐ Don't know If yes explain.
	VACCINE WASTAGE	Central / District Questionnaire
GEN	45. What formula is used to calculate vaccine wastage and what is the source of the data. **Ask for wastage report**	☐ Vaccine wastage not calculated Formula: Data source, numerator: _____ Data source, denominator: _____ Is provided formula correct**?** ☐ Yes ☐ No Source of data: ☐ Stock books ☐ Summary sheets ☐ Other
GEN	46. What is the vaccine wastage rate of the PCV-7 vaccine (Oct 2009 to Feb 2010)?	**PCV-7 vaccine** wastage rate _____%
GEN	47. Has the PCV-7 vaccine wastage rate changed when compared to Pentavalent vaccine wastage rate (Oct 2009 to Feb 2010)?	**PCV-7 vaccine** wastage rate versus Pentavalent wastage rate ____% Higher ____% Lower ☐ No change
GEN	48. Did you change anything about the way you administer vaccines, to reduce wastage of the PCV-7 vaccine?	
	MONITORING AND SUPERVISION	Central / District Questionnaire
GEN	49. How often do you think supervisory visits should be made to the district/health facility level?	District level _____ Health facility level _____
GEN	50. Have you or a member of your staff or a partner organization made supervisory visits, to the districts/health facilities since **PCV-7 vaccine** introduction? If so, how often and by whom?	☐ Yes ☐ No If yes, how often: _____ By whom: _____(job title) If no, why not? _____

GEN	51. How do supervisors give feedback to sites visited?	☐ Written ☐ Supervisory log book ☐ Supervisory checklist ☐ Send site visit report ☐ Other (specify) _____ ☐ Oral ☐ Discussion with staff ☐ Other (specify) _____
GEN	52. Are follow-up visits conducted at sites with inadequate performance?	☐ Yes ☐ No
HOP DIST	**53.** Have you received a supervisory visit (from October 2009)? If yes, when and by whom?	☐ Yes ☐ No When: _____ By whom: _____ Ask to see a copy of the visit report.
	ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)	Central / District Questionnaire
GEN	54. Do you have a system and written protocol for monitoring and reporting AEFIs for all vaccines? Please describe the procedure. **Ask for a copy of the AEFI protocol and reporting form**	☐ Yes ☐ No If no, why not: _____ .
GEN	55. Do you have a emergence response plan in place to manage AEFIs? Please describe.	
GEN	56. Did you make any changes to the AEFI protocol specifically for the **PCV-7 vaccine**?	☐ Yes ☐ No ☐ Don't know
GEN	57. Have you had any reported AEFIs for the **PCV-7 vaccine** or another vaccine since the **PCV-7vaccine** was introduced? **Note**: *Verify using AEFI log book/registry if available*	☐ Yes ☐ No ☐ Don't know If yes, How many for the **PCV-7 vaccine** _____ How many for a traditional vaccine (specify) _____ What were the AEFIs_____ How were they handled? _____
	ADVOCACY & COMMUNICATION	Central / District Questionnaire
CENT	58. Did you have an official launch ceremony at the time of the **PCV-7** introduction? **Prompt:** *If yes, what did it involve, was it successful, did it get much media coverage?*	☐ Yes ☐ No ☐ Don't know If yes, describe _____ If no, why not? _____
GEN	59. Whom or what did you use to promote the **PCV-7 vaccine** and inform/educate the community about the vaccine? **Note***: Please ask for copies of any materials*	**Check all that apply** ☐ Radio ☐ Television ☐ Community Groups /Community leaders ☐ Community health workers ☐ Town crier ☐ Celebrity ☐ Government Officials ☐ Other (specify) Main messages _____
GEN	60. Did you prepare or distribute any health education material for the community on the **PCV-7 vaccine**? If yes what, and	**Check all that apply** ☐ Posters ☐ Brochures

	when? **Note:** *Please ask for copies of any materials*	☐ Flyers ☐ Clothing (t-shirts, hats etc.) ☐ Other (specify) Main messages _____
	SUSTAINABILITY	Central / District Questionnaire
CENT	61. Is there a budget line for vaccine purchases in the national budget?	☐ Yes ☐ No ☐ Don't know
CENT	62. How are the traditional vaccines financed? **Note**: *List all sources that pay for the vaccine*	
CENT	63. How is the **PCV-7 vaccine** paid for? **Note**: *List all sources that pay for the vaccine*	
CENT	64. Do you plan to introduce any more new vaccines in the future? If yes which one(s) and when? **Note**: *If they say no, this is an opportunity to mention new vaccines, such as pneumococcal vaccine, rotavirus vaccine and HPV, that probably will be available in the future*.	
	Surveillance	Central / District Questionnaire
GEN	65. Do you have surveillance for the diseases which the PCV-7 vaccine will prevent? Please describe. **Note***: include the number of sites, date started* **Ask for a copy of the surveillance data/bulletin**	
GEN	66. Have there been any problems with the surveillance?	☐ Yes ☐ No ☐ Don't know If yes, describe
	IMPACT ASSESSMENT	Central / District Questionnaire
CENT	67. Are you or do you plan to conduct a vaccine impact assessment, i.e., a study to determine if the **PCV-7 vaccine** is reducing disease burden.	☐ Yes ☐ No ☐ Don't know If yes, give details _____ If no, why not? _____
	GENERAL IMPRESSIONS	Central / District Questionnaire
GEN	68. How well was the **PCV-7 vaccine** accepted? If there were any problems, please comment for each group. **Prompts:** *Was considered to be a safe and effective and needed vaccine*	**New vaccine well accepted** Healthcare workers ☐Y ☐ N Professional societies ☐Y ☐ N Community/public ☐Y ☐ N Government ☐Y ☐ N Media ☐Y ☐ N Discuss any problems _____
GEN	69. Were there financial implications of introducing the **PCV-7 vaccine** for each of the following areas?	**Ask about the financial implications of each of the following:** Cold chain ☐Y ☐ N, If yes, specify:_____ Vaccine transport ☐Y ☐ N, If yes, specify:_____ Wastage ☐Y ☐ N, If yes, specify:_____ Communication materials/media ☐Y ☐ N If yes, specify:_____

		Training ☐Y ☐ N, If yes, specify:_____ Other costs? ☐Y ☐ N, If yes, specify:_____
GEN	70. What effect has the introduction of the **PCV-7 vaccine** had on your EPI program?	**Please check one that best describes the introduction:** ☐ Improved the EPI program. Please explain _____ ☐ Made the EPI program worse. Please explain _____ ☐ No effect. Please explain _____
GEN	71. In your opinion, was the introduction of the PCV-7 vaccine a smooth process or problematic? Please explain	**Please check one that best describes the introduction:** ☐ Very smooth. No problems ☐ Smooth, minor problems. Please explain _____ ☐ Somewhat smooth, some major problems. Please explain _____ ☐ Not smooth at all, some major problems. Please explain _____
GEN	72. Many other countries will be introducing this and other new vaccines soon. What have you learned from this experience, and what advice do you have for other countries to ensure a smooth introduction?	
	OBSERVATION OF VACCINE STORAGE AREA AT THE CENTRAL/ DISTRICT LEVELS	Central/ District Questionnaire
GEN	73. Are all freezers and refrigerators clean and properly functioning?	☐ Y ☐ N
GEN	74. Is there a thermometer outside the freezers and refrigerators?	☐ Y ☐ N ☐ Some
GEN	75. Is there a thermometer inside the freezers and refrigerators?	☐ Y ☐ N ☐ Some
GEN	76. Is the temperature inside the refrigerators currently between +2° and +8° C?	☐ Y ☐ N ☐ Some
GEN	77. Is there a log of freezer and refrigerator temperatures?	☐ Y ☐ N ☐ Some If yes, has temperature consistently been between +2° and +8° C for refrigerators in the last 2 months? ☐ Y ☐ N ☐ Some
GEN	78. How often are temperatures recorded?	☐ Twice daily ☐ Daily ☐ No records ☐ Other (specify) _____
GEN	79. Are temperatures monitored and recorded on weekends and holidays? **Note**: *Check specifically for holidays in __April 2nd 2010*	☐ Y ☐ N ☐ Sometimes
GEN	80. Are all vaccines arranged as "First expiry, First out"?	☐ Y ☐ N If no, why not? _____ ☐ Not applicable, why _____
GEN	81. Did you observe any expired vaccines?	☐ Y ☐ N

		If yes, which vaccine, and how many _____
GEN	**For vaccines with a VVM** 82. Did the VVMs that you observed indicate that vaccine is usable, i.e., stage 1 or 2	☐ Yes, all vaccines usable ☐ No some vaccines stage 3 or 4 (unusable) Specify vaccine and proportion unusable _____
GEN	**For vaccines with a VVM** 83. Are vaccines with VVM in stage 2 arranged so that they are used first?	☐ Y ☐ N ☐ Not applicable, no stage 2
GEN	84. Are there spaces between the vaccine boxes/trays to allow air circulation?	☐ Y ☐ N
GEN	85. Is injection equipment stored in good condition	Adequate space ☐ Y ☐ N Clean and dry conditions ☐ Y ☐ N Well organized (i.e., easily accessible) ☐ Y ☐ N ☐ Other observation (specify) _____
	NOTES AND COMMENTS	
GEN	If you were unable to visit the cold store or dry store area, please mention reason. Record any interesting positive or negative anecdotes or comments by immunization staff.	

3. Questionnaire- Health Facility

Pneumococcal Vaccine (PCV-7)

Post Introduction Evaluation (PIE) in Rwanda

Date of interview _____ Name of interviewer _____

This questionnaire was conducted at
Province_____
District hospital: _____
Health facility name: _____

Type of health facility (check one):
☐Health Center/Clinic ☐Health Post/Outpost ☐ Other (specify) _____

Name (s) and title (s) of person(s) interviewed (please list all the persons that you interviewed): EPI Senior Nurse/Healthcare Worker responsible for vaccinations (or their deputy) should be interviewed

*Name*_____ *Title* _____

*Name*_____ *Title* _____

*Name*_____ *Title* _____

Contact details of most senior person:
Telephone _____ *e-mail address* _____

★ Denotes – Suggested Key Finding (see appendix 3)

Documents to ask for at beginning of interview: (check appropriate boxes)

Document / data	**Document received**	**Document reported to exist but not available at time of interview**	**Document unavailable**
Chronogram of activities for PCV-7 vaccine			
Training materials/reference documents utilized at PCV-7 vaccine training			
Vaccine management guidelines			
Media campaign/social mobilization/education materials (brochures, posters, pamphlets, etc)			
Vaccine stock records			
Supervisor's book/site visit reports			
Injection safety/waste management policy document			
Wastage reports			
AEFI protocol/reporting form			
AEFI logbook/registry			
Sample child health card/immunization card			
Immunization logbooks, monitoring forms, tally sheets, vaccine register,s			

Abbreviation		PRE-IMPLEMENTATATION PLANNING	Health Facility Questionnaire
GEN	1.	Were you (interviewee) working at this health facility at the time of the **PCV-7 vaccine** introduction	☐ Yes ☐ No Interviewer, if no, try to get a staff member who was present when the new vaccine was introduced to participate. If not, continue with interview but it may not be possible to answer all questions.
GEN	2.	When was the **PCV-7 vaccine** first administered at this health facility?	(MM/YYYY) _____/ _____ ☐ Don't know
		TRAINING	Health Facility Questionnaire
GEN	*3.*	Please describe health facility staff training for the **PCV-7 vaccine** introduction if any	How many people from this health facility were trained? _____ How long was the training for health facility staff? _____ Did the person from this health facility who was trained train others in the health facility? ☐ Yes ☐ No ☐ Don't know Was training conducted before vaccine introduction ☐ Yes ☐ No If yes, how long before _____ Was training conducted after vaccine introduction ☐ Yes ☐ No If yes, how long after _____ Who conducted the training for health facility staff? _____ Other comments on training _____
PCV-7	4.	What specific training did you receive on the administration of PCV-7 vaccine?	**Check all mentioned** ☐ Correct transportation and storage of PFS (Vaccine without VVM, store between +2°C and +8°C, can't be frozen) ☐ Correct administration (injection in intra muscular, site) ☐ How to collect used PFS in "red safety boxes" storage at health center before their transport to high temperature incinators for final disposal ☐ Specific messages to mothers before and immediately after immunization of children ☐ Other, specify ☐ Don't know
GEN	5.	Were there any problems with the training?	☐ Yes ☐ No. ☐ Don't know If yes, please describe
GEN	6.	Are **PCV-7 vaccine** introduction guidelines or educational and reference materials from the training available? **Ask to see samples**	☐Yes ☐ No ☐ Don't know ★ Key Finding: Guidelines/training materials provided?
GEN	7.	Overall, were you satisfied with the training provided?	☐Yes ☐ No ☐ Not applicable ★ Key Finding: Satisfaction with training?
		VACCINE COVERAGE	Health Facility Questionnaire
GEN	8.	What is the size of the target population for infant immunizations in this health facility? What is the source of this figure?	<1 year of age:_____ Source of data _____

	Note: *If not available for <1 year, get information for <2 or <5 years*	
GEN	9. What formula do you use to calculate vaccine coverage? Include the source of the numerator (doses administered) and denominator (target population)	Formula Numerator source _____ Denominator source_____ Correct formula used ☐ Yes ☐ No
GEN	10. What was Penta-1 and Penta-3 vaccine coverage in the period of October 2008 to Feb 2009 before the PCV-7 vaccine introduction?	Penta-1 _____ year _____ Penta-3 _____ year _____ Calculate drop out rate: (*Penta-1 - Penta-3)/Penta1 x 100* = _____%
GEN	11. What is the coverage of the first and last dose of the PCV-7 vaccine for the period of October 2009 to February 2010? *Note: If coverage is unknown for PCV-7 vaccine because PIE is done before administrative data are available, record anecdotal reports or look at number of doses of PCV-7 vaccine used versus number of doses of Penta used.*	**PCV-7 vaccine** first dose (PCV-7-1) coverage _____ **PCV-7 vaccine** last dose (PCV-7-3) coverage _____ Drop out rate: *(PCV-7-1 – PCV-7-3)/PCV-7-1 x 100* = _____%
GEN	12. Is coverage of the **PCV-7 vaccine** higher or lower than Penta?	**PCV-7 vaccine** first dose vs. Penta-1 coverage rates ____% Higher ____% Lower ☐ No change **PCV-7 vaccine** last dose vs. Penta-3 coverage rates ____% Higher ____% Lower ☐ No change ★ **Key** Finding**: % change in coverage rate**
GEN	13. Is the dropout rate for the **PCV-7 vaccine** higher or lower than the Penta dropout rate?	**PCV-7 vaccine** dropout rate versus Penta drop out rate ____% Higher ____% Lower ☐ No change ★ **Key** Finding**: % change in dropout rate**
GEN	14. How often do you report immunization data to the district hospital? **Ask to see a report**	Frequency of reports_____ Report seen and matched___
GEN	15. Have immunization registries/child health cards, etc. been updated to include the **PCV-7 vaccine**? **If yes, indicate date each updated item was received at your level.**	**Check box if updated and indicate date updated** ☐ Vaccine registry/logbook _____ ☐ Child health card _____ ☐ Tally sheets/district reporting forms ____ ☐ Vaccine stock forms _____ ☐ Other (specify) _____
GEN	16. How many days a week does your site perform immunization fixed strategy, i.e. immunization session at health facility?	_____ times per week ☐ fixed strategy not performed
GEN	17. How many days a week does your site perform outreach immunization sessions, i.e. immunization sessions not conducted at the health facility?	_____ times per week ☐ Outreach not performed
GEN	18. Are outreach data collected separately?	☐ Yes ☐ No
GEN	19. Do you include the PCV-7 vaccine in the outreach immunization sessions?	☐ Yes ☐ No. If no, reason

GEN	20. What changes, if any, did you have to make to outreach sessions when you introduced the **PCV-7 vaccine?**	☐ No changes required ☐ More vaccine carriers required ☐ Increased number of outreach sessions ☐ Other changes (specify)
	COLD CHAIN MANAGEMENT	Health Facility Questionnaire
GEN	21. What is the source of cold storage?	**Check all that apply** ☐ Cold box ☐ Refrigerator kerosene ☐ Refrigerator electricity ☐ Refrigerator solar ☐ Refrigerator mixed power source ☐ Other (specify) _____
GEN	22. If there is an interruption in your power supply, what do you do? *(includes lack of kerosene)*	
GEN	*23.* Discuss any changes you had to make in the cold chain (such as changes in frequency of vaccine distribution) before introduction of the PCV-7 **vaccine.** **Note:** *Try to distinguish cold chain expansion/replacement of equipment that is part of normal cold chain rehabilitation from changes specifically for the new vaccine.*	
GEN	24. Were there any problems with the cold chain recognized after the introduction of the **PCV-7 vaccine**? If yes, what were the problems and how have the problems been addressed?	☐ No problems ☐ Frozen vaccine, ☐ Malfunctioning refrigerators, ☐ Power supply/fuel shortage ☐ Other (specify) ★**Key** Finding**: % health facilities observed or reported problems with the cold chain**
	VACCINE MANAGEMENT, STORAGE, & LOGISTICS	Health Facility Questionnaire
GEN	25. Do you have immunization policy guidelines for vaccine management? If yes, have they been updated to include the PCV-7? **Please provide a copy at time of interview**	☐ Yes ☐ No Copy received ____
GEN	26. How do you forecast vaccine need?	
GEN	27. Did estimated vaccine needs change following introduction of the **PCV-7 vaccine**?	☐ Yes ☐ No ☐ Don't know If yes, why? _____
GEN	28. Please describe how vaccines are ordered and delivered to the health facility	Who orders _____ How often are vaccines delivered? _____ Any problems with this? _____
GEN	29. Have you had any vaccine expirations in the last 6 months (from October 2009)? If yes, what did you do with the expired stock?	☐ Yes ☐ No If yes, action taken_____
GEN	30. Have you had any vaccine with VVM in stage III or IV in the last 6 months (from October 2009)? If yes, what did you do with these vaccines?	☐ Yes ☐ No If yes, action taken
GEN	31. Did you run out of any vaccines, including the **PCV-7 vaccine** or vaccines supplies in	☐ Yes ☐ No ☐ Yes vaccines (specify)

	the past 6 months (from October 2009)?	☐ Yes vaccine supplies (specify) ☐ No If yes, how many weeks _____ If yes, reason for stock out _____ ★**Key** Finding**: % of health facilities reporting vaccine or supply stock-out in last 6 months**
GEN	32. Are vaccine orders/deliveries tied to injection supplies (i.e., bundling)? **Note**: *Look at stock records to get this information.*	☐ Yes ☐ No Verified by checking stock records ☐ Yes ☐ No
	WASTE MANAGEMENT AND INJECTION SAFETY	Health Facility Questionnaire
GEN	33. Did you have to make any changes to your waste disposal system for introduction of the **PCV-7 vaccine**? If yes, explain	☐ Yes ☐ No If yes, explain _____ ★**Key Finding: Centers with changes in waste disposal?**
GEN	34. Have you experienced any problems with your waste disposal system? **Observe site**	
	VACCINE WASTAGE	Health Facility Questionnaire
GEN	35. What formula is used to calculate vaccine wastage and what is the source of the data. **Ask for wastage report**	☐ Vaccine wastage not calculated Formula: Data source, numerator: _____ Data source, denominator: _____ Source of data: ☐ Stock books ☐ Summary sheets ☐ Other ★**Key** Finding**: wastage report on site? ☐Yes ☐ No**
GEN	36. What is the vaccine wastage rate of the **PCV-7 vaccine** for the period of October 2009 to February 2010? **Note:** *If vaccine wastage rate is unknown for new vaccine because PIE is done before administrative data are available, record anecdotal reports or attempt part-year calculation*	**PCV-7 vaccine** wastage (October 2009 to February 2010) _____%
PCV-7	37. What was the Penta wastage rate? **Note**: *Use year before new vaccine introduction or closest administrative period.*	Penta wastage (October 2008 – February 2009) _____%
PCV-7	38. Has the PCV-7 vaccine wastage rate changed when compared to Pentavalent wastage rate (for the above periods)?	**PCV-7 vaccine** wastage rate versus Penta wastage rate ____% Higher ____% Lower ☐ No change
GEN	39. Did you change anything about the way you administer vaccines, to reduce wastage of the **PCV-7 vaccine**?	

	MONITORING AND SUPERVISION	Health Facility Questionnaire
GEN	40. How many times in the past 6 months (from October 2009) have you received a supervisory visit from district level or from a partner agency? Was the visit documented? **Ask to see the supervisory book, copy of last report.**	Number of visits _____ Is there a written report of the visit? ☐Yes ☐ No ★**Key** Finding**: At least one documented visit ☐Yes ☐ No**
GEN	41. If yes, who visited, and what were the problems identified?	Who visited _____ (job title) Problems identified _____
	ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)	Health Facility Questionnaire
GEN	42. Do you have a system and written protocol for monitoring and reporting AEFIs for all vaccines? Please describe the procedure. **Ask for a copy of the AEFI protocol and reporting form**	☐Yes ☐ No If no, why not _____ ★**Key** Finding**: AEFI system/protocol in place?**
GEN	43. Did you make any changes to the AEFI protocol specifically for the **PCV-7 vaccine**?	☐Yes ☐ No **If yes, what changes _____**
GEN	44. Have you had any reported AEFIs for the **PCV-7 vaccine** or another vaccine since the **PCV-7 vaccine** was introduced? **Note**: *Verify using AEFI log book/registry if one*	☐ Yes ☐ No ☐ Don't know If yes, How many for the **PCV-7 vaccine? _____** How many for a traditional vaccine? (specify) _____ What were the AEFIs? _____ How were they handled? _____
	ADVOCACY, COMMUNICATION & ACCEPTANCE	Health Facility Questionnaire
GEN	45. Did your health facility provide any materials to the community about the **PCV-7 vaccine** at the time of introduction? **Ask to see copies of materials**	**Check all that apply** ☐ None provided ☐ Posters ☐ Brochures ☐ Other (specify)
	46. Did your health facility provide any health education messages to the community about the PCV-7 at the time of introduction?	☐ Health education sessions ☐ Public meetings ☐ Other (specify)
GEN	47. Did you experience any resistance from the community regarding the **PCV-7 vaccine**?	☐ Yes ☐ No ☐ Don't know **If yes, describe**
GEN	48. Do you remember any media focus (e.g., on radio or television or newspapers) on the **PCV-7 vaccine**?	☐ Yes ☐ No If yes, describe _____
	HEALTHCARE WORKER KNOWLEDGE: (ask HCW, not head of health facility)	Health Facility Questionnaire
GEN	49. What is the immunization schedule for the **PCV-7 vaccine**?	

PCV-7	50. Are there infants who should not receive the vaccine? Prompt: age restrictions: max age for first dose, max age for last dose and contra indications	☐ Yes ☐ No ☐ Don't know If yes, who _____
PCV-7	51. Has your staff experienced any problems with administering PCV-7 vaccine?	**Record any problems mentioned**
GEN	52. What disease(s) does the **PCV-7 vaccine** prevent?	**Interviewer : Write exact response given** ★**Key** Finding**: % HCW that knew what disease(s) the new vaccine prevents?**
GEN	53. For what vaccines do you use the shake test and why?	
GEN	54. What is the opened vial policy and which vaccines does it cover?	
GEN	55. What information do you provide to parents before and immediately after vaccination with the **PCV-7 vaccine**?	**Check if mentioned—don't prompt but can tell afterwards** ☐ *Vaccine schedule/when to return* ☐ *Child will receive two injections the same day* ☐ *Normal side effects? What to do in case of side effect?* ☐ *What side effects they should return for* ☐ *Bring vaccination card* ☐ *Other health messages (specify)* Two or more mentioned? ☐Yes ☐ No ★**Key** Finding**: % HCW providing two or more accurate pieces of information to parents?** ☐Yes ☐ No
	GENERAL IMPRESSIONS	Health Facility Questionnaire
GEN	56. Were there any financial implications for the health facility involved in introduction of the **PCV-7 vaccine**?	**Ask about the financial implications of each of the following:** ☐ Don't know Cold chain ☐Y ☐ N, If yes, specify:_____ Vaccine transport ☐Y ☐ N, If yes, specify:_____ Wastage ☐Y ☐ N, If yes, specify:_____ Communication materials/media ☐Y ☐ N If yes, specify:_____ Training ☐Y ☐ N, If yes, specify:_____ Other costs? ☐Y ☐ N, If yes, specify:_____
GEN	57. What effect has the introduction of the **PCV-7 vaccine** had on your EPI program?	**Please check one that best describes the introduction:** ☐ Improved the EPI program, Please explain:_____ ☐ Made the EPI program worse, Please explain:_____ ☐ No effect. Please explain :_____ ★**Key** Finding**: % sites reporting that PCV-7 vaccine improved the EPI program?**
GEN	58. In your opinion, was the introduction of the **PCV-7 vaccine** a smooth process or problematic? Please explain	**Please check one that best describes the introduction:** ☐ Very smooth. No problems

		☐ Smooth, minor problems. Please explain:_____ ☐ Somewhat smooth, some major problems. Please explain _____ ☐ Not smooth at all, Some major problems. Please explain _____ ★**Key** Finding**: % sites reporting a smooth or very smooth introduction**
GEN	59. Many other countries will be introducing this and other new vaccines soon. What have you learned from this experience and what advice do you have for other health facilities to ensure a smooth introduction?	
	OBSERVATIONS AT VACCINATION SESSION	Health Facility Questionnaire
GEN	60. Are (all) vaccines reconstituted correctly including use of chilled diluents? (e.g., measles, BCG, pentavalent)	☐ Y ☐ N ☐ Unknown (N=unsafe practice)
GEN	61. Are vaccines stored/handled properly during the session? e.g. clean, organized, vaccine vials outside carrier are in foam pad	☐ Y ☐ N ☐ Unknown (N=unsafe practice)
GEN	62. Are appropriate administration techniques observed (e.g., PCV-7 and pentavalent intramuscular injection, different thighs,)	☐ Y ☐ N ☐ Not observed (N=unsafe practice)
GEN	63. Are AD syringes used?	☐ Y ☐ N (N=unsafe practice)
GEN	64. Are needles recapped? (look in safety box for capped needles)	☐ Y ☐ N ☐ Unknown (Y=unsafe practice)
GEN	65. Are AD syringes and glass pre-filled syringes (PFS) disposed of in two different safety boxes?	☐ Y ☐ N ☐ Unknown (N=unsafe practice)
GEN	66. Is the policy on use of the open multi-dose vial observed for OPV and TT?	Date opened marked on vial ☐ Y ☐ N ☐ Open vial discarded at end of immunization session ☐ Y ☐ N ☐ Other observation (specify) _____ ☐ Unknown (N=unsafe practice)
GEN	67. **Summary** How many unsafe practices, based on questions above, were observed	Number of unsafe practices _____ ★**Key** Finding**: % of sites with 2 or more unsafe practices observed**
GEN	68. Did you observe inter personal communication between health worker and mother?	☐ Y ☐ N
	OBSERVATION OF VACCINE STORAGE AREA	Health Facility Questionnaire
GEN	69. Are all refrigerators clean and properly functioning?	☐ Y ☐ N
GEN	70. Is there a thermometer outside the refrigerator?	☐ Y ☐ N
GEN	71. Is there a thermometer inside the refrigerator?	☐ Y ☐ N
GEN	72. Is the temperature inside the refrigerator	☐ Y ☐ N What is the temperature: _____

	currently between +2° and +8° C	
GEN	73. Is there a written log of refrigerator temperatures?	☐ Y ☐ N
GEN	74. How often are temperatures recorded?	☐ Twice daily ☐ Daily, seven days a week ☐ No records ☐ Other (specify)
GEN	75. Are temperatures monitored and recorded on weekends and holidays? **Note:** Friday, April 2nd (holiday)	☐ Y ☐ N ☐ Sometimes
GEN	76. Are vaccines arranged as "First expiry, First out"?	☐ Y ☐ N If no, why not? _____ ☐ Not applicable, why _____
GEN	77. Did you observe any expired vaccines?	☐ Y ☐ N If yes, which vaccine and how many doses? _____
GEN	**For vaccines with a VVM** 78. Did the VVMs that you observed indicate that vaccine is usable, i.e. stage 1 or 2	☐ Yes, all vaccines usable ☐ No, some vaccines stage 3 or 4 (unusable) Specify vaccine and proportion unusable _____ ★**Key** Finding**: % of health facilities reporting with any VVM in stage 3 or 4.**
GEN	**For vaccines with a VVM** 79. Are vaccines with VVM in stage 2 arranged so that they are used first?	☐ Y ☐ N ☐ Not applicable, no stage 2
GEN	80. Are there spaces between the vaccine boxes/trays to allow air circulation?	☐ Y ☐ N
GEN	81. Describe any other cold chain monitoring devices used at this level	
	HEALTH COMMUNICATION	Health Facility Questionnaire
GEN	82. Are any posters or other literature about the PCV-7 noted in the health facility?	☐ Y ☐ N If yes, what materials and what language?
	STOCK ROOM	Health Facility Questionnaire
GEN	83. Is injection equipment stored in good condition?	Adequate space ☐ Y ☐ N Clean and dry conditions ☐ Y ☐ N Well organized (i.e., easily accessible) ☐ Y ☐ N ☐ Other observation (specify)
	WASTE DISPOSAL	Health Facility Questionnaire
GEN	84. How are used AD syringes being disposed of? (If not observed, ask how boxes are disposed)	☐ Safety box (which color?) ☐ Open bucket ☐ Other ☐ Other observations
GEN	85. How are used glass PFS being disposed of? (If not observed, ask how boxes are disposed)	☐ Safety box (which color?) ☐ Open bucket
GEN	86. How are the used "red" safety boxes being disposed of? (If not observed, ask how boxes are disposed of) **Note:** *Specify whether box is emptied and reused*	☐ Standard incinerator on site ☐ High temperature incinerator in Kigali ☐ Pit-burned ☐ Pit-exposed ☐ Pit-buried

	or destroyed with contents inside.	☐ Above ground area ☐ Box reused ☐ Other observation
GEN	87. How are the used "yellow" safety boxes being disposed of? (If not observed, ask how boxes are disposed) **Note:** *Specify whether box is emptied and reused or destroyed with contents inside.*	☐ Standard incinerator on site ☐ High temperature incinerator in Kigali ☐ Pit-burned ☐ Pit-exposed ☐ Pit-buried ☐ Above ground area ☐ Box reused ☐ Other observation
GEN	88. Were discarded needles and syringes observed on the ground outside the facility?	☐ Y ☐ N
GEN	89. Is waste disposal site closed off?	☐ Y ☐ N ★ **Key** Finding**: % of health facilities with clean, closed off disposal sites**
GEN	90. Describe any other observation of the disposal site	
	NOTES AND COMMENTS	
	If you were unable to visit the cold store or dry store area, please mention reason. Record any interesting positive or negative anecdotes or comments by health care workers.	

4. Questionnaire – Mother or Care-giver

Pneumococcal Vaccine (PCV-7)

Post Introduction Evaluation (PIE) in Rwanda

Date of interview _____ Name of interviewer _____

Province: _____District: _____Health facility name: _____
Interview mothers/caregivers whose child has just received the new vaccine (can also talk to a group of mothers waiting to be vaccinated to get their impressions)**.** Please modify questions as appropriate for the type of new vaccine introduced. Begin the interview by saying the following *"I would like to ask you a few questions about the vaccines your child received today. The answers you give will help us learn more about new vaccines being used."*

1. Do you have your child's immunization card with you today? If yes*:* May I please see it? **Note**: *If pentavalent vaccine is not used, ask for Hib, Hep B, and DTP separately*	**Use card to answer the following** Card present ☐ Yes ☐ No **Vaccines received today** ☐ Pentavalent ☐ OPV ☐ Pneumo ☐ BCG ☐ Measles ☐Other *(specify)*_____ **Card updated?** ☐ Old card (not updated to include new vaccine) ☐ Old card (with new vaccine written in by hand) ☐ New card (updated to include new vaccine)
2. What vaccine(s) did your child receive today? ***Note****: Check if answers correct by looking at vaccination card or, if card not available, verifying with clinic record.*	**Check one box** ☐ Names all vaccines (answer correct) ☐ Names some vaccines (partially correct) ☐ Does not know ☐ Mentions specific health benefit of vaccine (e.g., for Hib vaccine says, 'got vaccine to prevent meningitis or pneumonia') ☐ Mentions general beneficial effects of vaccines, e.g.. 'my child got vaccines to keep him healthy' ☐ Other – specify _____
3. Do you know about the **PCV-7 vaccine** for infants? **Note***: Be country specific; give the time when the vaccine was introduced.*	☐Yes ☐ No If yes, which disease(s) do they prevent? ☐ Does not know ☐ Pneumonia ☐ Meningitis ☐Otite ☐Septicemia
4. If yes to #3: How did you receive the message about the PCV-7 vaccine? **Prompt***: radio, newspaper, television, healthcare worker, friend, public meeting, community health workers*	
5. Do you know when to bring your child for his/her next vaccination? **Note: *If answer is no or yes but incorrect, please advise mother of when next vaccination is due***	☐ Yes (answer correct) ☐ Yes (answer incorrect) ☐ No
6. Do you know any reaction that your child may get following his/her vaccination today? **Note***: This question is not trying to differentiae between baseline knowledge and knowledge received at current vaccination session.*	☐ Yes (answer correct) ☐ Yes (answer incorrect) ☐ No **Interviewer: *If answer is no or yes but incorrect, please advise mother of potential side effects, e.g. mild redness, pain, mild swelling at injection site, mild fever, drowsiness and irritability***.
7. Other comments or observations. Record any interesting positive or negative anecdotes or comments by mothers.	

5. Presentation to the Interagency Coordination Committee

Post-Introduction Evaluation of PCV-7 Vaccine

WHO, MCHIP, CDC, UNICEF,
AMERICAN RED CROSS

Rwanda

29 March – 9 April, 2010

Plan of Presentation

- Background and rationale
- Objectives
- Methodology
- Key findings
  - Pre-introduction activities
  - Introduction/implementation activities
  - Post-introduction activities
- Recommendations

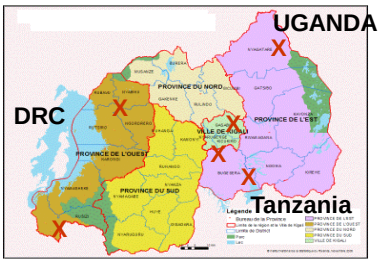
Background and rationale

- **Rwanda introduced PCV-7 vaccine in 2009 using a phased approach:**
  - **Vaccine was introduced first in Eastern province (April, 2009).**
  - **Western province was the last province to introduce the vaccine in August, 2009.**
- **WHO recommends formal post-introduction evaluation (PIE)**
  - **To identify strengths and weaknesses associated with new vaccine introduction,**
  - **To correct identified problems,**
  - **To improve planning for introduction of additional vaccines in the future.**
  - **To document lessons learned.**

Objectives

- **Evaluate introduction process of PCV-7 vaccine**
  - **Qualitative and quantitative data from central, district and health facility levels**
- **Summarize strengths and areas for improvement during:**
  - **Pre-implementation**
  - **Implementation**
  - **Post-implementation**
- **Present findings to MOH & to ICC partners**
- **Make recommendations for program strengthening related to additional new vaccine introduction**
- **Other observations on the immunization program in general**

Methodology



- Documentation Review
- Review and update PIE tools
- Training of evaluators
- Site visits and data collection at:
  - Central level
  - 7 district hospitals in 6 administrative districts
  - 3 health centers in each district (18 in total)
- Staff interviews using standardized updated questionnaires
- Post-immunization interviews of mothers whose children have just received vaccines
- Field observation:
  - Immunization session
  - Cold chain and dry stores, vaccine management
  - Management tools, etc.

Site fields for visit

Provinces	Districts	District hospitals	Health centers
East	Bugesera	Nyamata	1. NYAMATA
			2. RUHUHA
			3. NZANGWA
	Nyagatare	Nyagatare	1. NYAGATARE
			2. MATIMBA
			3. NYARUREMA
MVK	Gasabo	Gibagabaga	1. KACYIRU
			2. KIMIRONKO
			3. KAYANGA

Site fields for visit

Provinces	Districts	District hospitals	Health centers
MVK	Kicukiro	Kanombe	1. BUSANZA
			2. GIKONDO
			3. MASAKA
West	Rusizi	Mibilizi	1. MUSHAKA 2. BUGARAMA
		Guhundwe	3. RUSIZI
	Rubavu	Gisenyi	1. GISENYI
			2. GACUBA II
			3. BYAHI

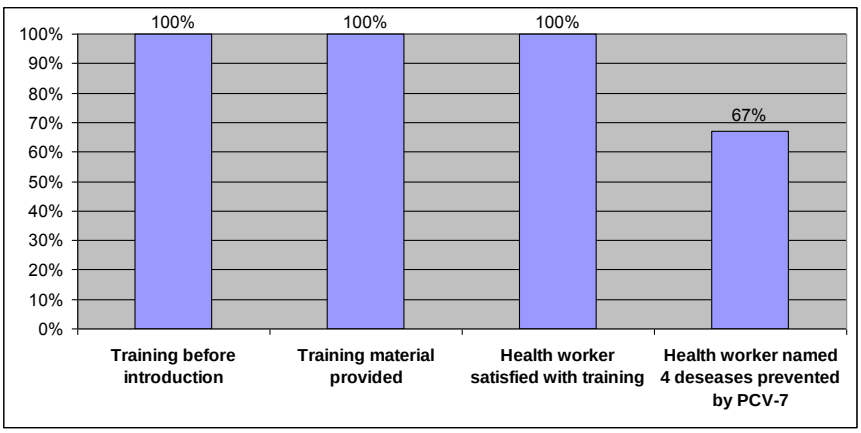
A. Pre-Implementation:

Key Findings

Pre-implementation - Strengths

- PCV7 Introduction Plan and revised cMYP for the period 2008-2012 available
- Phased training conducted at all levels before PCV7 vaccine introduction:
  - TOT at national level
  - Training of staff at operational level
  - Reference documents for training available at all levels
- All reporting forms updated with PCV7 information before introduction
- Additional cold chain material procured and distributed to districts and health centers before introduction
- Development of key messages based on formative research

Key pre-introduction indicators at Health centers

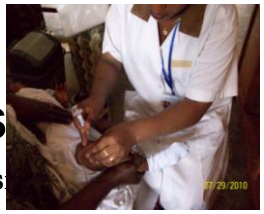


Pre-implementation Areas for Improvement

- Timeline of key PCV7 activities was not available in some health centers
- Absence of clear policy on the vaccination of children who arrive after the age of 6 weeks
- Long time between training and the introduction of new vaccine in most health centers (about 1 month)
- Wall charts with coverage data not always updated with Penta data

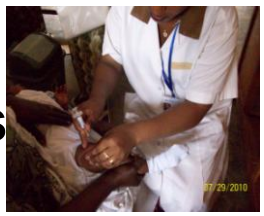
B. Implementation and Introduction: Key findings

Implementation & Introduction-Strengths



- Smooth introduction of PCV7 vaccine us approach,
- Good acceptance of PCV7 vaccine by parents with acceptance reinforced by radio and by health workers,
- PCV7 coverage increased in most of health facilities
- Supervisory visits to health centers by the staff from district hospitals and central levels conducted at least once during the last 6 months,
- New cold chain equipment distributed to all health facilities to accommodate new vaccine
- No stock-outs, no expired vaccine, no vaccine with VVM at stage 3 or 4 for the last 6 months

Implementation & Introduction-Strengths



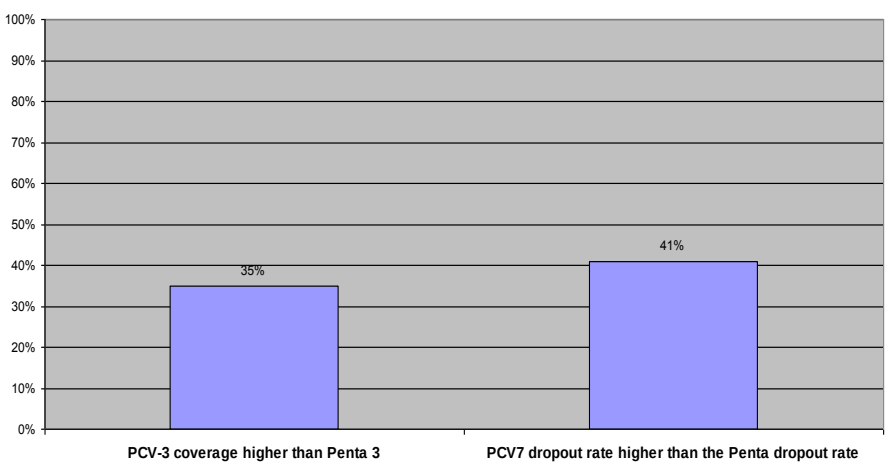
- Guideline for final disposal of AD and glass PFS syringes well implemented
- Standard incinerators on site clean and close off

Implementation & Introduction - Areas for improvement:

Monitoring for action

- Use of inconsistent sources of population data at national, district and health center levels (target population not well known),
- Poor data quality with reported coverage more than 100% and negative drop-outs in most health centers
- Weak surveillance for pneumococcal related diseases
- Lack of analysis and use of data for action at health center level:
  - Vaccine coverage
  - Vaccine needs (Mini- and Maxi-stocks)
  - Drop-out and wastage rates

Implementation indicators



Implementation & Introduction-Strengths

- Funding:
  - **Country pays for all traditional vaccines and co-finances new vaccines (pentavalent vaccine).**

Implementation & Introduction - Areas for improvement

- <u>Cold chain management:</u>
  - **Temperature, at national cold store, in one of positive cold rooms, was <2°C; Fridge-tag recorded, for about 2 days, temperature of about 0°C, and no action was taken**
  - **At most facilities, staff used frozen icepacks for vaccine transportation.**
  - **Fridge-tag ® available in most health centers but not used appropriately**

Implementation & Introduction - Areas for improvement:

- Vaccine management, storage and logistics:
  - **Vaccine management tools not current in most health centers**
  - **In most health centers, vaccine forecasting not well done**
  - **Incomplete or nonexistent wastage reports in some health centers**
  - **Some health centers do not calculate vaccine wastage rates**
  - **In several health centers, PCV7 vaccine was found at the bottom of the refrigerator.**

Implementation & Introduction Areas for improvement:
Supervision & monitoring

- **Frequency and quality of supervisory visits need to be improved:**
  - **In some health centers, there was no written feedback to assure follow-up on identified issues.**
  - **Some health centers did not implement the recommendations (written in a language health workers do not understand).**

Key Findings

Post-Introduction

Post Introduction - Strengths

- **AEFI reporting and investigation forms were found in all districts.**

Post Introduction – Areas for Improvement: Surveillance

- **No functional system for tracking AEFI in place**
  - **No comprehensive written protocol was available at health center level.**
  - **No AEFI case was reported.**
- **Weak syndromic surveillance in place for pneumococcal related diseases.**

Recommendations

Recommendations

- **Harmonize population estimates;**
  - **Apply consistently same demographics at all levels.**

- **Analyze and use data for action:**
  - **Vaccine coverage, drop-out and wastage rates should be calculated at all levels and should trigger appropriate actions at the field level.**
  - **Data Quality Self-Assessment**

Recommendations - II

- **Training (vaccine management, Fridge-tag, Shake test, multidose vial policy (opened vial policy), data quality**
- **Cold chain capacity should be expanded as required for new vaccines:**
  - **National level: reinforce monitoring and take appropriate action if needed**
- **Fridge-Tag® monitors to be used during vaccine transportation and in health facility cold chains, with training;**

Recommendations - III

- **Supervisory visits should be improved :**
  - **Written feedback to assure follow-up of identified issues in language health staffers understand**
- **Communication: interpersonal communication during the immunization session**
- **Communication: consider opportunities for integrated prevention messages**
- **Surveillance: strengthen surveillance at the district level for pneumonia/meningitis LRI using standardized case definitions**

Recommendations - IV

- **Bundling of vaccine, AD syringes and safety boxes needs to be consistently applied at all levels, with correct formulas, x Ads for x doses**
- **Establish and implement nation-wide AEFI monitoring system through training and sensitization at all levels,**

Partners involved

Ministry of Health

EPI

WHO

UNICEF

Thank You