

Lessons Learned: Rotavirus & PCV Vaccine Introduction in Niger

March 2016

Exhibit A-6

LESSONS LEARNED: ROTAVIRUS & PCV VACCINE INTRODUCTION IN NIGER

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JSI, Research & Training Institute, Inc.
Exhibit A-6

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The experiences, challenges and achievements captured in this report on introduction of rotavirus and PCV vaccines in Niger are to serve as a reference for the country for further roll-out of these vaccines in the routine immunization system and when introducing other vaccines in the near future. JSI sincerely appreciates the collaboration that the Ministry of Health and the Ministry of Health's Direction de Immunization have exhibited throughout the preparation and implementation of introduction activities.

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ACRONYMS

AAP	Annual Action Plan
AEFI	Adverse Events Following Immunization
BCH	Building Capacities for Better Health in Africa
CCL	Cold Chain Logistics
CERMES	Centre de Recherche Médicale et Sanitaire
cMYP	Comprehensive Multi-Year Plan
CHR	Centres Hospitaliers Régionaux
CRI	Coordonnateur Régional des Immunisations
CSI	Integrated Health Center (Centre de Santé Intégré)
CSO	Civil Society Organization
DI	Direction des Immunisations (Immunization Division)
DRSP	Direction Régionale de Santé Publique (Regional Division of Public Health)
DS	District Sanitaire (Health District)
EVM	Effective Vaccine Management
EPI	Expanded Program on Immunization
CF	Common Fund (Fond Commun)
Gavi	Global Alliance for Vaccine and Immunization
HPV	Human Papilloma Virus
ICC	Interagency Coordination Committee
IEC	Information, Education, and Communication
JSI	JSI Research & Training Institute, Inc.
MCD	Médecin Chef de District
MoH	Ministry of Health
PCV13	Pneumococcal Conjugate Vaccine-valent 13
PDS	Plan de Développement Sanitaire
PIE	Post-Introduction Evaluation
UNICEF	United Nations Children's Fund
TFP	Technical and Financial Partners
TOT	Training of Trainers
WHO	World Health Organization

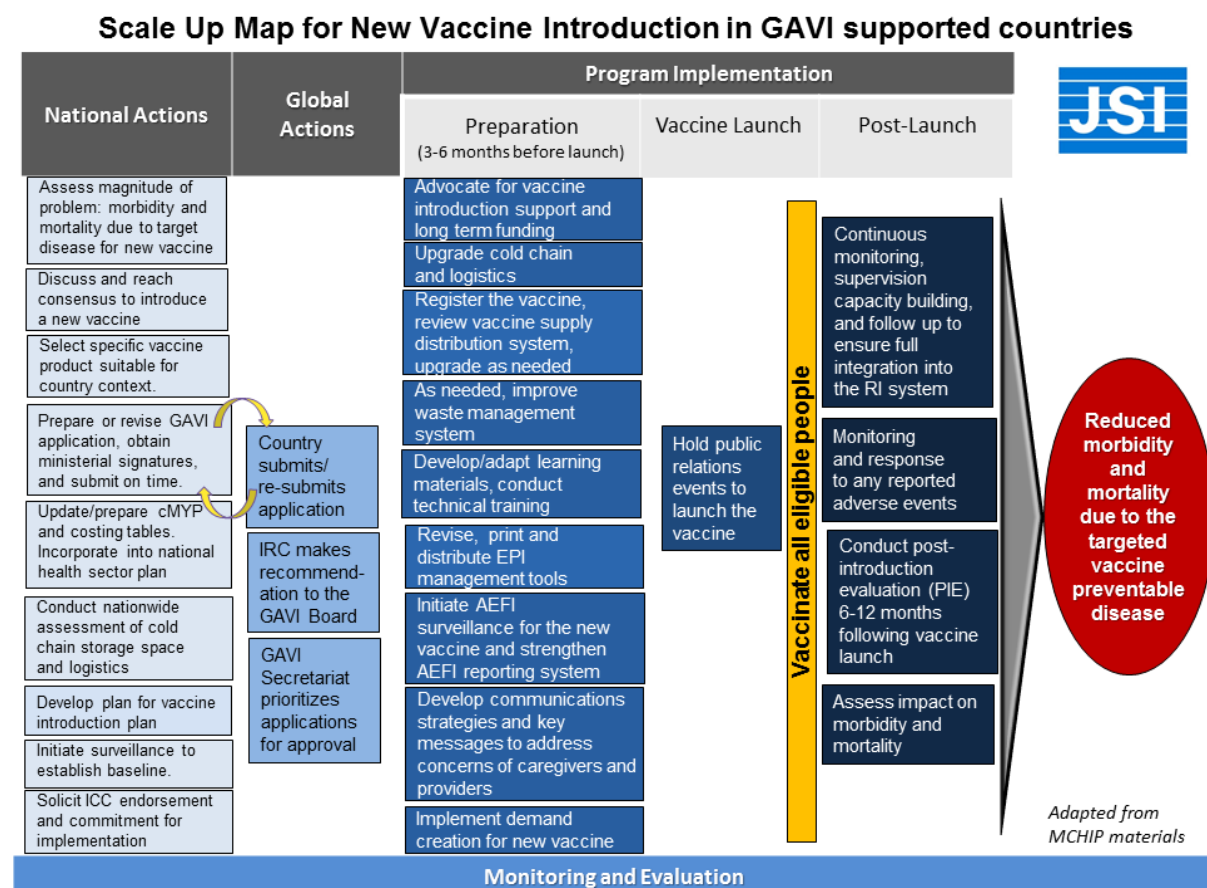
INTRODUCTION

The Republic of Niger's comprehensive multi-year plan 2011-2015 proposed adding three new vaccines into its routine immunization system – the nationwide introductions of pneumococcal conjugate vaccine (PCV13) and rotavirus vaccine, and a demonstration project of human papilloma virus vaccine (HPV) in two districts (urban and rural). Initially, PCV13 was to be integrated into the national routine immunization system (Niger's EPI) in 2012, with rotavirus vaccine to be introduced in 2013 and the HPV demonstration pilot to begin in 2013. For various reasons discussed in this document, HPV vaccine was introduced in April 2014 and PCV13 and Rotarix were launched simultaneously in August 2014.

Following the submission of its country plan to Gavi, the Vaccine Alliance (Gavi), Niger was approved and received funding for the introduction of these new vaccines. With the goal of better preparing the country for the introduction of these vaccines into the national routine immunization system, Gavi also responded to the country's request for additional technical support by enlisting JSI on an agreement that began in September 2013 and ended in February 2016. As part of this assistance, JSI worked with the MOH's Immunization Division (DI) and partners to rapidly assess the country's introduction readiness level and status of preparations for these introductions, including identifying areas in the field where more attention was required: technical assistance for updating and further outlining the DI's micro plan and timeline of activities for the rotavirus introduction (which then became linked with the delayed PCV introduction); training and management tools; logistics and cold chain preparedness; communication, advocacy and social mobilization strategies and plans/activities; monitoring and coordination at all levels; etc. A checklist used to monitor the PCV and rotavirus vaccine introduction readiness is available in Annex III of this report. Likewise, a table containing the principal activities conducted is available in Annex II.

The figure below, which summarizes JSI's approach for assistance in new vaccine introduction in Gavi-supported countries, was used to help guide the process in Niger:

Figure 1: Scale up Map for New Vaccine Introduction in Gavi-supported counties



See Annex I for illustrative indicators that were used to help monitor the introductions of these new vaccines in Niger.

The following report provides a summary of the introduction experience of rotavirus vaccine and pneumococcal conjugate vaccine (PCV) in Niger. It highlights the learning from the introduction, including the elements of planning, cold chain, social mobilization, partner and CSO engagement, financing and implementation. The report also includes observations and recommendations from the post introduction evaluation (PIE) that was conducted in July 2015, twelve months after the introduction of both vaccines. These lessons learned and recommendations may be useful for informing future vaccine introductions in Niger and other countries.

INTRODUCTION OF ROTAVIRUS AND PNEUMOCOCCAL VACCINES

Planning and Preparation

The PCV introduction was originally planned for 2012. Several preparatory steps were to have been completed by December 31, 2013 (with PCV13 introduction to have started earlier in 2013). A national workshop was held in Niamey July 26-27, 2013, with participation from the DRSP, Regional Immunization Coordinator (CRI), District Medical Head (MCD), pediatricians from Regional Hospital Centers (CHRs) and national hospital, representatives from CSOs, managers from the central level and representatives from UN organizations. Preparatory steps were identified, including updating the vaccination calendar to include the new vaccines; developing a communication plan and timeline for activities; developing training plans and updating of technical materials and guides (including reporting tools); and ensuring availability of vaccines and consumables.

Unfortunately, because of delays in financing and preparatory activities, difficulties in releasing Gavi introduction funds and other basket funds from the Common Fund (CF), needs for additional vaccine and syringe storage capacity at all levels, and numerous other competing priority immunization activities planned by the Ministry and partners in 2013, the PCV13 launch was delayed and linked with the Rotarix introduction, with simultaneous launch on August 5, 2014.

Calendar and Checklist

Although the PCV and rotavirus vaccine introductions had been approved by Gavi for introduction in 2013 and there was commitment by the Immunization Division (DI) and local partners (WHO and UNICEF) to introduce the vaccine, the startup of introduction preparation activities only began in earnest in September/October 2013.

With technical assistance from JSI, the technical team developed a dynamic monitoring checklist (see Annex III), to identify the level of preparation of the country for the introduction of the new vaccines. The checklist was organized according to areas of technical activities, logistics and cold chain, communication and social mobilization, and surveillance. As the DI manages several activities (not just the introduction of new vaccines), that team then incorporated the activities identified in the checklist into an integrated timeline with ongoing routine and annual activities. This timeline was updated once a week by the team of technical partners together with the DI and used to monitor implementation, according to each organization/focal point's defined responsibilities.

A significant challenge, however, was that the planned activities in the timeline were often postponed due to various priority health and immunization activities that took the time and focus of the limited number of DI and partner staff available to support the new vaccine preparations. This included evaluation and annual programming of activities in the health sector, vaccination campaigns for polio and other target diseases - including measles and neonatal tetanus – and the HPV pilot. In light of this, the proposed plans and dates for the vaccine introductions were postponed several times.

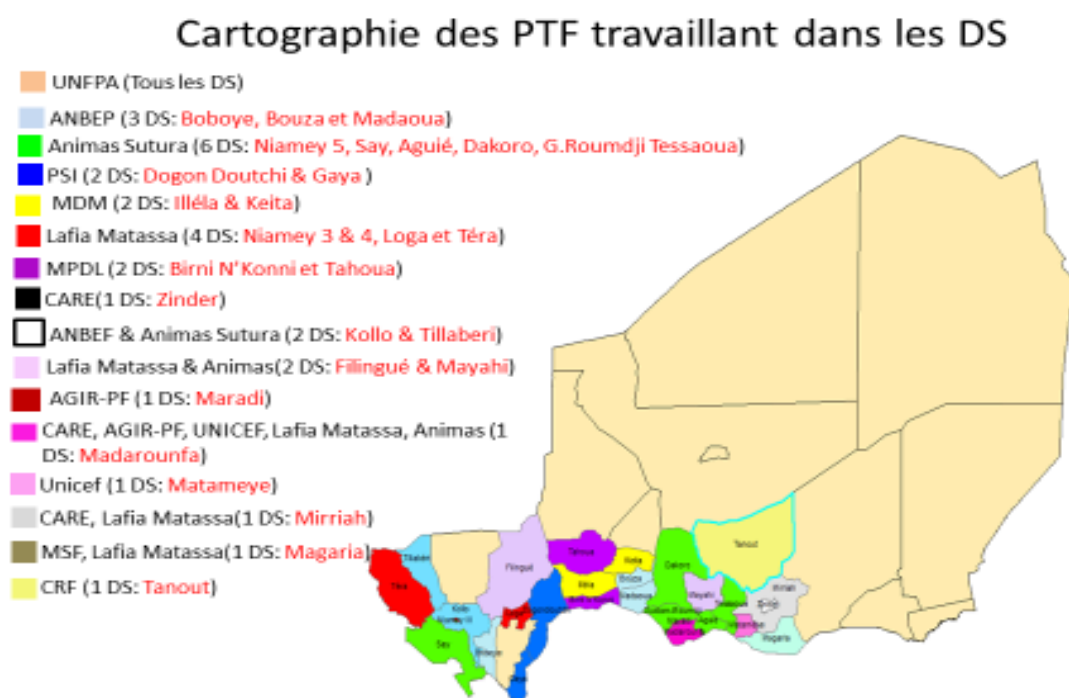
Mapping of partners by health districts and identification of target populations

Each health has a specific partner, and as part of its role, provides support to districts in monitoring key activities such as new vaccine introduction processes. A map of partners by each health districts was developed (see Figure 2 below).

Given an epidemiological profile similar to neighboring countries (and experiences of the CERMES lab which showed that 42% of serotypes in Niger are sensitive to Prevnar 13), the country selected PCV-13, a monovalent, liquid vaccine administered in three doses, on the same schedule as the pentavalent vaccine, at 6, 10 and 14 weeks.

Rotarix is a liquid, monodose vaccine requiring two doses to be administered at 6 and 10 weeks.

Figure 2: Map of partners working with the DI in different health districts



Key partners active in the PCV and rotavirus vaccine introductions are in Annex IV.

To identify the target populations for routine immunization, infants 0-11 months were used, with the target population estimated to be 902,681 in 2013; 937,480 in 2014; and 968,417 in 2015. Unfortunately, this population data, obtained from projections from a 2011 census, were likely to be underestimated and the forecasting of vaccine need using this population data led to stock-outs for PCV. Weaknesses in calculating the target population is an area that the National Institute of Statistics is helping the DI to improve in order to ensure the EPI has more accurate target population projections for the coming years.

Financing, the process of co-financing, and communication with Gavi

Gavi participated in the update of the Health Development Plan (PDS) for 2011-2015, in conjunction with the CF, and co-financed three years' of vaccine procurement. The financing mechanism of the CF is based on the Annual Action Plan (AAP), for which each center creates and submits a list of costs for validation on the National Health Council. Once the AAP is approved, it is not possible in the course of the year to finance an activity that was not planned, nor is it possible to increase the budget, even for planned activities. For the rotavirus vaccine, for example, the AAP 2014 approved 379,413,411 FCFA, of which 330,072,072 FCFA were expended, a consumption rate of 87%.

Traditional vaccines are provided by an agreement with the State and UNICEF, who assists with the purchasing of these vaccines. The procedure of financing from the State for the vaccines and immunization operational costs is based on the submitted and agreed budgeting within the government system. However, problems persist with the treasury and the timely release and dispensing of funds, and thus delays are common. The absence of an account or system to provide advance payments is a major problem under this financing mechanism risking stockouts of vaccines, including PCV/RV.

Capacity Strengthening

Within the frame of new vaccine introduction, the DI technical team, with the assistance of partners (WHO, UNICEF and JSI) updated the training modules to include content on both PCV and rotavirus vaccines, as these modules had been adapted from the generic English WHO modules and therefore needed to address the country context and be available in French. These modules were then used to train central and regional level trainers as well as health professionals at the operational level. In total, 30 trainers at the central level and 50 at the regional level were trained one month before the introduction of the two vaccines (July 2014). Through cascade training, these central and regional trainers then worked with district teams to train district health staff and CSIs. In total, approximately 850 health agents at the operational level were trained by regional trainers, an average of 20 health agents per district from the period of July 21 to August 9, 2014.

Table 1: Trained Health Workers in Each Region

REGIONS	Dosso	Maradi	Tahoua	Tillabéri	Zinder	Niamey
Number of trained health agents at operational level	204	132	204	167	109	35

Although the trainings were conducted before the launch, additional follow-up is needed to ensure quality and retention of information from those trainings. The JSI team, with the DI, initiated supervision visits in the districts of Niamey and Madarounfa to identify potential problems related to the new vaccines and to provide on-the-job training to address areas in need of strengthening. As part of these visits, some issues were raised, including the need to emphasize the optimal target ages for rotavirus vaccine as well as to address stock-outs of PCV13. The observations from these visits were also shared with the other partners to highlight the need to conduct training and supervision visits in more remote districts.

Additional follow-up is needed through supervision and refresher training/capacity building activities; however there has been a lack of human and financial resources to conduct these.

Logistics and Cold Chain

In order to prepare for the new vaccine introduction, a rapid assessment of vaccine storage capacity and logistics was conducted by a JSI logistics technical advisor in April 2014, with several weaknesses identified at the central and regional levels. The advisor called the attention of partners to the need to install the cold rooms that were already available in all regions, before proceeding with the distribution of vaccines at the regional level. He also provided recommendations on the need to plan for further expansion and modernization of the cold chain and strengthen human resource capacity for logistics management in advance of other new vaccines being added to the routine system in the coming years.

With the support of UNICEF, new cold rooms as well as emergency generators were paid for and installed at the central level and in six regions before the introduction of the new vaccines. However, the delay in the installation of these cold rooms also contributed to the delay in the new vaccine introduction. After the installation of these additional cold rooms, the logistics and cold chain subcommittee proceeded to distribute the vaccines to the regional and district levels. Following their training, representatives from CSIs came to collect the new vaccines from the district level.

A more detailed, multi-agency evaluation of effective vaccine management (EVM) was conducted from June 28 – July 16, 2014, with assistance from WHO. This evaluation was followed by the development of a vaccine and logistics improvement plan, which the DI used to request Gavi/ELMA funding of approximately USD \$1,000,000 to fill the gaps in cold chain storage and better accommodate new vaccines. This proposal was approved by Gavi, and over the course of the following year, the funds were used to purchase four cold rooms (three positive and one negative), two generators for the cold rooms, and one frog lift. Some of the funding was also used to contribute to the building of a new modern warehouse at central level and to support trainings for solar fridge installation.

An inventory of cold chain equipment was also conducted with technical assistance from WHO in late April/early May 2014. The data from this inventory were analyzed by a JSI consultant in May 2014, who also helped with developing the report and formulating recommendations to inform a distribution plan for cold chain equipment throughout the country.

Social Mobilization and Communication

UNICEF and JSI (with its partner, BCH Africa) contributed significantly to the development of an integrated communication plan for introduction of PCV and rotavirus vaccines within the broader diarrhea and pneumonia prevent-protect-treat approach. Community-based focus groups were conducted with parents to identify knowledge/awareness of - and any concerns with - the two vaccines (Rotarix and PCV13). The findings were used to assist in development of appropriate messages for the community and caregivers as well as to reinforce linkages within the broader pneumonia and diarrhea prevention and control strategy. Messages to announce the event, to sensitize the population, and to inform parents were created.

Pre-tested messages were used to sensitize the community through available media prior to and during the launch and as part of the new vaccine roll-out. These messages and materials had been developed through seminars organized with communication managers:

- The first seminar focused on pneumococcal vaccine introduction in 2013 and was financed by UNICEF, with the support of a UNICEF consultant. The terms of reference for the UNICEF consultant were to help the country develop a communication plan for the introduction of PCV vaccine, identify major concerns of parents and propose key messages. This seminar had been conducted before the decision had been made to delay PCV introduction and link this with rotavirus vaccine introduction.
- Given the decision to simultaneously introduce PCV and rotavirus vaccines, a second workshop was needed to ensure updating of the communication strategy and materials as well as for combining the messaging. This workshop was conducted with the technical assistance of JSI/BCH Africa and UNICEF, along with DI staff, in June 2014. It built on the pneumonia communication plan and created an integrated pneumonia and rotavirus vaccine introduction communication plan with the financial support of Gavi/FC, with a particular focus on integrated approaches to fight the two diseases. In the course of the workshop, key messages to prevent, protect, and treat diarrhea and pneumonia (for the new vaccines and more broadly) were developed and finalized.

In addition, IEC materials (targeting health workers, communities, the media, and the vaccine launch), posters, banners, pamphlets, caps, pagnes (fabric wraps), t-shirts, and flipcharts were developed with financial support from Gavi. GSK also manufactured banners, caps, etc. and had them shipped to the launch ceremony location.

Partner Engagement/ICC

Engaging managers of the MoH, EPI, and ICC partners

The ICC technical team (composed of technical staff from the DI, WHO, UNICEF and JSI), was closely engaged in the organization and technical preparation of the new vaccine introduction process. Weekly technical meetings were held to review the activity timeline (for planned and carried out activities as well as revision of plans for new activities). However, the lack of availability of certain technical partners at times, due to limited staffing and other priority immunization and health activities, somewhat compromised the effectiveness or follow-up implementation subsequent to these meetings.

The ICC strategic committee held meetings every three months under the facilitation of the Minister or Secretary General of the MoH and endorsed the decisions proposed by the ICC technical group for the PCV and rotavirus vaccine introductions. Three senior ICC meetings were organized, during which the members were informed of the state of new vaccine introduction preparations, particularly regarding the availability of financial resources from Gavi/FC, the installation of cold rooms at central and regional levels, the availability of vaccines, and of the launch of the new PCV and rotavirus vaccines.

CSO Engagement

There is a network of civil society organizations (CSOs) which works in the health sector and has representation at the national level. Unfortunately, CSOs had not been sufficiently engaged by the ICC in the vaccine introduction process for the two new vaccines. An attempt to map the CSOs was begun by the ICC partners, in collaboration with the director of ROASSN (a network for NGOs in Niger), with technical inputs from JSI/BCH-Africa. This network and CSO partners should be more actively involved in the future, particularly in the implementation of integrated approaches to fighting diarrhea and pneumonia and to assist with the integration and sustainability of these vaccine introductions within the routine immunization system. This should be followed-up by the ICC to ensure further CSO participation with the ICC and immunization support at sub-national levels.

Implementation

The MoH held meetings at national level and worked at various levels to sensitize the population on the benefits of the two new vaccines. To help guide the introduction process, pre- and post-introduction checklists developed with JSI technical assistance were used (see Annex III for an example) as well as a revised immunization supervision checklist.

After the launching ceremony in Mirrah on August 5, 2014, supervision visits in the health districts of Madarounfa and Zinder were carried out by JSI and the DI to follow-up on the implementation of the new vaccines. During that field visit, the team also met with representatives implementing a clinical efficacy and safety study of a new rotavirus vaccine - being carried out by Epicentre in selected health centers in the Madarounfa district. (This clinical trial is for a rotavirus vaccine being tested for approval that is different from the Rotarix vaccine described in this report, which has already been approved by WHO for use worldwide, including in Niger.) The DI and JSI team provided guidance on how to handle the PCV and Rotarix introductions in the district as well as in the specific study sites so as not to compromise the introduction of the pneumococcal and Rotarix vaccines nor taint the results of the Epicentre rotavirus vaccine study. Coordination between the ICC and Epicentre is ongoing to monitor and maintain the integrity of these two interventions. The information obtained during these visits was documented in order to inform Niger's planning for nationwide rotavirus introduction and to reinforce coordination to avoid confusion.

As noted previously, an intensification of supervision visits by the MOH/DI was planned to take place subsequent to the launch, especially for the rotavirus vaccine (for which timeliness of vaccination and stricter adherence to the vaccination schedule age ranges are important). Unfortunately, the supervision visits planned for the DI immediately after the vaccine introduction could not take place due to lack of funds. JSI's technical team, conscious of the need for the supervision, negotiated with the DI and began some supervision visits with immunization focal points in the Niamey districts. These supervision visits identified serious problems regarding the availability of vaccines at the district level. The JSI team shared these observations with the DI and other technical partners. With involvement from WHO and the DI, further supervision visits were conducted from November 2014.

Revised management tools from the EPI had been reproduced and distributed at all levels in 2013 to ensure that both PCV and rotavirus vaccine information was updated in the reporting and monitoring tools. These tools include:

- Guide for completing the monthly report,
- Form for reporting AEFI,
- The consensus document showing the target population for EPI routine immunization,
- Monthly EPI report form,
- Summary tally sheet for all antigens,
- Tally sheet for vaccination sessions,
- Daily cold chain temperature monitoring chart,
- Vaccine stock management tool,
- Vaccine order and delivery form,
- Vaccination register,
- Vaccination wall monitoring charts,
- A vaccination calendar and a vaccination card.

The JSI team worked with partners to review these tools and noted several errors, notably on the vaccination calendar and vaccination card. Since the vaccination cards had already been printed in large numbers, these errors had to be taken into account and explained at trainings and supervision visits to highlight the corrections with health agents.

Evaluation

For both vaccines, vaccine coverage and numbers of children vaccinated by antigen and dose are being monitored each month, along with other routine immunization reporting, to observe the trends for the new vaccines and compare them against the trends of other antigens administered during the same period. At the end of 2014, the cumulative vaccine coverage for each new vaccine was also evaluated and reported on in addition to the wastage rate for these vaccines. As of September 2015, cumulative vaccine coverage for the third dose of PCV was 70% and for Rota second dose was 67%. The cumulative wastage rate during this same period was 0% for PCV and 1% for Rota.

Post Introduction Evaluation (PIE)

The introduction of the PCV and RV vaccines in Niger was carried out smoothly. The great success of the introduction was facilitated by advocacy at the highest levels and through positive political will. Findings from the PIE, carried out in July 2015, identified strengths and weaknesses including:

- The introduction plan for both vaccines was successfully developed and implemented. This plan was revised and took into account the availability of both vaccines in the international market.
- The Effective Vaccine Management (EVM) assessment was conducted, and an improvement plan was developed and implemented. New cold chain equipment (cold rooms and solar refrigerators) was procured and the installment process and training of health workers were implemented.

- EPI management tools and the vaccination schedule were revised to integrate both PCV and RV into the routine immunization system. During the training of trainers, participants were trained on how to use the tools, and health services providers retained the information provided during their trainings when administering the new vaccines.
- AEFI surveillance was also fairly well established, with clear guidance and reporting forms which included specific information related to the new vaccines being introduced. No major AEFIs related to PCV or to Rota were reported.
- Training of trainers was conducted at central and regional levels. Trainers from the central and regional levels trained the health workers at the operational level. Some health workers reported that this training was too short to cover all the technical areas.
- Both PCV and Rota were accepted by the different stakeholders, including caregivers, health professionals, CSOs, and the media.
- The introduction of the new vaccines had a positive effect on the immunization program in the following areas:
 - Increased public support, notably with the anticipated reduction in cases of diarrhea,
 - Many health service providers intensified their efforts to encourage mothers to respect the date for bringing their children for follow-up vaccinations.

The evaluation reported that the introduction of PCV and Rota was done without major problems, despite insufficient funding allocated for reproduction and dissemination of communication materials at regional and district levels and conflicting information on the actual launch date of the vaccines. Even where communications materials were not available on the ground at the moment of introduction (to help promote the benefits of the additional vaccines), the report noted a general acceptance of the vaccines by mothers and service providers. They acknowledged that the benefits the children would receive from an additional life-saving vaccine (PCV) outweighed the pain they would experience from the additional injection.

Although experience from several countries has shown that completeness of reporting in the first 4-6 months subsequent to introduction can be delayed, the coverage for the two antigens as reported in the PIE showed coverage for PCV1 and PCV3 at 85% and 68%, respectively, and Rota 1 and Rota 2 at 75% and 65%, respectively.

The introduction of PCV and Rotarix is anticipated to contribute to strengthening the protection of children from deadly illness and to improve awareness of diarrhea and pneumonia prevention. However, certain weaknesses in availability of communications materials (noted above), data collection, and cold chain management were identified. In addition, self-monitoring charts of vaccine coverage and drop-out rates, as well as temperature monitoring charts posted on refrigerators, were not often up-to-date.

In terms of logistics, the PCV and Rota vaccines were received and distributed to CSIs in June 2014. EPI management tools integrating these two new vaccines were reproduced and distributed at least one month before the official launching ceremony, and TOT (training of trainers) workshops for regional and district introduction teams were conducted from June-July 2014. These regional and district teams held multiple trainings in each district for health

service providers and vaccinators. In the weeks before and following the official launch, radio and TV announcements were disseminated and sensitization activities were implemented by the Communications and Advocacy Division.

Some challenges with the vaccines' introduction included:

- Insufficient skilled human resources for program implementation in general
- Insufficient stock capacity at central level and in certain CSIs
- The financial impact of introducing the two new vaccines – it may be a strain for the country to meet its co-financing contribution of 400m FCFA, dispersed in less than two years
- Stock outs of the vaccines in a large proportion of CSIs in the regions visited (Dosso, Zinder, Niger), with the exception of the Niamey region

LESSONS LEARNED AND RECOMMENDATIONS FOR THE INTRODUCTION OF NEW VACCINES

Principal lessons learned

- The supplementary technical and coordination assistance, provided by JSI through the Gavi support, was a catalyst to move the process of new vaccine introduction forward (after a long period of delays).
- Advance coordination and frequent communication among responsible parties of the DI and those of the FC is critical to agree on financial needs and avoid disagreement or delays in the development of requests, the processing of those requests, and the process of releasing funds for the financing of introduction activities. This lack of understanding of and compliance with the overall process for request and release of Gavi funds with the FC caused delays in the new vaccine introduction process in Niger and must be avoided in the future.
- Development and use of a checklist for rapid monitoring of the preparations for new vaccine introduction helped to orient partners and update activities for the introduction process.
- Several competing priority activities for the Ministry in general - and the DI and partners in particular - compromised the implementation of certain preparatory activities and led to insufficient monitoring of some key activities. Lack of monitoring of the installation process for cold rooms and emergency generators in the regions (preceding the distribution of vaccines to the regions) contributed significantly to the introduction delay in June and July 2014, for example.
- Insufficient follow up on the recommendations of the different technical assistance missions by consultants and technical staff delayed the implementation of new vaccine introduction preparation. For example, supervision visits discovered pentavalent vaccines with stage 3-4 VVMs in the system, as well as a lack of post-introduction supervision visits in distant regions.
- Inadequate communication between the central, regional, and district levels and the lack of in-country initiative, coupled with a wait-and-see attitude from those in the field, contributed to delays and challenges with the introduction of the new vaccines.

Recommendations for future introductions

- Strengthen the coordination between different partners for new vaccine introduction and routine immunization through a stronger immunization technical ICC and more frequent communication and meetings; this should include timelines and focal points for activities at national and sub-national levels as well as clarity on the roles of multi-agency partners and further engagement of CSOs and other partners that are not currently active in the technical ICC;

- Identify management solutions to help support the DI and implement innovative approaches to distribution of labor/tasks (e.g. in cases of conflicting priorities) as well as to reinforce and supplement human resource needs in light of insufficient staffing;
- Establish sub-working groups by theme (e.g. communications, training and capacity building, logistics), and develop a checklist of introduction preparation activities in line with these themes, including closely monitoring and updating the completion of these activities on a systematic basis;
- Strengthen the competency of staff at all levels, including community volunteers, with sufficient lead-time before the introduction of new vaccines (i.e. several months prior to the launch and not reliant primarily on cascade training);
- Strengthen the monitoring and the supervision of training in vaccination centers in all CSIs in the country. Monitoring, review meetings, and supportive supervision must be intensified, especially after the introduction, to identify potential problems;
- Strengthen communication between different levels of the health system and the community to ensure that all parental and community concerns are addressed;
- Central level coordination between the DI and partners is needed to monitor rotavirus/PCV implementation and roll-out, with particular prioritization and attention to regions with high population density, as well as those with a high concentration of un-vaccinated/under-vaccinated children. It is necessary to identify districts with consistently weak performance (e.g. over the last 3 years) as well as districts that could be prioritized during African Vaccination Week.

ANNEX I: INDICATORS USED FOR NEW VACCINE INTRODUCTION OF ROTAVIRUS AND PCV VACCINES IN NIGER

As of August 2014

Illustrative Indicator	Definition/clarification	Data source /collection method	Frequency of data collection	Results To-Date
Workstream I: New vaccine introduction				
Vaccine pre-introduction plans finalized and implemented	# and % of plans prepared and implemented; ICC subcommittees established and meetings regularly held	Record review	Quarterly-	Each district has prepared a timeline of introduction activities, created in the training of trainers (PCV13 and rotavirus); All 3 HPV pilot districts have likewise prepared timelines of critical activities
Recording, reporting, and monitoring tools are updated, printed distributed	# and % of EPI management tools revised to reflect new vaccine information	Record review	Once, before vaccine introduction	All management tools revised, printed and distributed.
Health workers capable of using new vaccine properly	Minimum of one trained health worker per health facility providing immunizations (public and private); Minimum of one trained teacher per school providing immunizations for HPV	Record review	At least once before vaccine introduction	HPV: about 2 staff per CSI and one teacher per school trained; PCV13 and Rotavirus: 30 central level trainers, 50 regional/district

	(public and private)			trainers trained. At least one staff from each CSI trained
New vaccine fully integrated into routine immunization system	Technical guidelines revised to reflect new vaccine; reporting tools revised; new vaccines available and used regularly in most HFs; Quarterly (monthly if feasible) monitoring of coverage (for rota) reported post-introduction; Supervision	Record review and supervision visits	Once for record review; ongoing monitoring through supervision	Technical guide and management tools revised; New vaccines (HPV, PCV13, and Rotavirus) distributed and introduced.
Country co-financing process and communication with Gavi improved	Key advocacy meetings conducted; teleconference/meeting discussions held between country and Gavi; co-financing discussed on ICC agenda	Annual Progress Report to Gavi	Annual APR workshop	

ANNEX II: INTEGRATED TIMELINE OF DI ACTIVITIES

Activité	2014																												Respon sables				
	Avril				Mai				Juin				Juillet				Aout				Septembre				Octobre					Novembre			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4					
Mise en place du comité national de pilotage																																	
Mise en place du sous-comité (technique, communication et logistique)																																	
Enregistrer les vaccins contre les infections à Pneumocoque et à Rotavirus au niveau de l'Autorité Nationale de Régulation (ANR)																													DI / MSP				
Sensibiliser le comité d'éthique en vue de son adhésion à l'introduction des nouveaux vaccins																													DI / MSP				
Enquête CAP Pneumo																																	
Elaboration du plan de communication Pneumo en intégrant les résultats de l'enquête CAP																																	
Elaborer et transmettre toutes les requetés par Division																																	
Elaboration d'un plan de communication Rota intégré au Pneumo																																	
Plaidoyer auprès des acteurs (PTF, ONG/Associations, Etc.)																													DI / MSP				
Conception et vulgarisation des supports de communication, production et diffusion des messages																																	
Révision des outils de collecte des données																													DI / MSP				
Réactualiser l'inventaire de la chaine de froid au niveau de chaque district et faire une mise à jour permanente																																	

Activité	2014																												Respon sables				
	Avril				Mai				Juin				Juillet				Aout				Septembre				Octobre					Novembre			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4					
Effectuer une évaluation rapide de la capacité de stockage au niveau des districts, régions et niveau central																													DI / MSP				
Elaborer une feuille de route de suivi de mise en œuvre du chronogramme élaboré et des recommandations issues de l'évaluation de la CDF																													DI / MSP				
Conduire une évaluation GEV																																	
Augmenter la capacité de stockage des districts en accélérant le processus en cours d'acquisition du matériel chaine de froid																													Fonds Com/Avril 2015				
Prévoir les pièces de rechanges dans la commande du matériel en cours non programmées dans le PAA 2014																																	
accélérer le processus de réhabilitation et de mise en fonctionnalité des nouvelles chaines de froid																																	
Négocier un accord avec les Centres Mères et Enfants pour renforcer les capacités régionales de stockage en vaccins																																	
Effectuer les formalités administratives pour la réception des vaccins (Douane, transit)																																	
Réception des vaccins au niveau central																													Livraison tous les 3 mois				
Approvisionnement des 8 régions et 44 DS																													DI / MSP, Approvisionnement des régions				

Activité	2014																												Respon sables				
	Avril				Mai				Juin				Juillet				Aout				Septembre				Octobre					Novembre			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4					
																													tous les 2 mois				
Elaborer un projet de requête pour la construction d'un dépôt central moderne																													Recher che de financem ent pour 2015				
Tenir une réunion du CCIA pour la validation de la révision du chronogramme																													DI / MSP				
Réviser les modules et tenir les formations en cascade																													DI / MSP				
Effectuer un lancement officiel																																	
Administration des vaccins dans les centres de santé																													DI / MSP				
assurer la gestion des MAPI et la surveillance																																	
Tenir des supervisions intégrées de la mise en œuvre des activités du niveau central vers les régions et des régions vers les districts																													Une supervisi on par semestr e				
Tenir des supervisions intégrées de la mise en œuvre des activités du niveau district vers les CSI																													Une supervisi on par trimestre				
Réalisation d'une enquête de couverture																													DI / MSP				
effectuer une évaluation post introduction																																	
Restituer les résultats de l'évaluation																													DI / MSP				
	2014																												Respon				

Activité	Avril				Mai				Juin				Juillet				Aout				Septemb re				Octobre				Novemb re				sables
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4					
Mise en place du comité national de pilotage																																	
Mise en place du sous-comité (technique, communication et logistique)																																	
Enregistrer les vaccins contre les infections à Pneumocoque et à Rotavirus au niveau de l'Autorité Nationale de Régulation (ANR)																													DI / MSP				
Sensibiliser le comité d'éthique en vue de son adhésion à l'introduction des nouveaux vaccins																													DI / MSP				
Enquête CAP Pneumo																																	
Elaboration du plan de communication Pneumo en intégrant les résultats de l'enquête CAP																																	
Elaborer et transmettre toutes les requetés par Division																																	
Elaboration d'un plan de communication Rota intégré au Pneumo																																	
Plaidoyer auprès des acteurs (PTF, ONG/Associations, Etc.)																													DI / MSP				
Conception et vulgarisation des supports de communication, production et diffusion des messages																																	
Révision des outils de collecte des données																													DI / MSP				
Réactualiser l'inventaire de la chaine de froid au niveau de chaque district et faire une mise à jour permanente																																	
Effectuer une évaluation rapide de la capacité de stockage au niveau des districts, régions et niveau central																													DI / MSP				

Activité	2014																												Respon sables				
	Avril				Mai				Juin				Juillet				Aout				Septembre				Octobre					Novembre			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4					
Elaborer une feuille de route de suivi de mise en œuvre du chronogramme élaboré et des recommandations issues de l'évaluation de la CDF																													DI / MSP				
Conduire une évaluation GEV																																	
Augmenter la capacité de stockage des districts en accélérant le processus en cours d'acquisition du matériel chaine de froid																													Fonds Com/Avril 2015				
Prévoir les pièces de rechanges dans la commande du matériel en cours non programmées dans le PAA 2014																																	
accélérer le processus de réhabilitation et de mise en fonctionnalité des nouvelles chaines de froid																																	
Négocier un accord avec les Centres Mères et Enfants pour renforcer les capacités régionales de stockage en vaccins																																	
Effectuer les formalités administratives pour la réception des vaccins (Douane, transit)																																	
Réception des vaccins au niveau central																													Livraison tous les 3 mois				
Approvisionnement des 8 régions et 44 DS																													DI / MSP, Approvisionnement des régions tous les 2 mois				

Activité	2014																												Respon sables				
	Avril				Mai				Juin				Juillet				Aout				Septembre				Octobre					Novembre			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4					
Elaborer un projet de requête pour la construction d'un dépôt central moderne																													Recher che de financem ent pour 2015				
Tenir une réunion du CCIA pour la validation de la révision du chronogramme																													DI / MSP				
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effectuer une évaluation post introduction																																	
Restituer les résultats de l'évaluation																													DI / MSP				

ANNEX III. NEW VACCINE CHECKLIST FOR PCV 13 & ROTA INTRODUCTION

As of August 2014

N ^o	Issue	Status	Action(s) to be taken	Lead Agency / Focal point
I	Need for cold chain equipment			
A	National needs assessment with the cold chain team	Completed and the report is available. The analysis of inventory data was completed and shared with Gavi and other partners.	-	UNICEF, JSI/Gavi and WHO under the coordination of EPI / CCL
B	Effective Vaccine Management (EVM) Evaluation	Completed	Awaiting the report.	WHO consultant with the logistics sub-committee
C	Advocacy with new partners targeted at obtaining additional cold chain equipment	Ongoing. The inventory report has been created and analyzed by JSI and has been largely shared with Gavi partners. One special proposal has been submitted to Gavi for CC strengthening at the central level. We await their orders through the common fund/Gavi.	Await Gavi's decision	EPI / logistics sub-committee Communications sub-committee, under the coordination of the EPI manager.
D	Storage capacity insufficient at regional level	Five cold rooms have been installed before the introduction of PCV13 and rotavirus vaccines in all regions except for Niamey.	Install the new cold room in the Niamey region.	CCL & UNICEF
E	Distribution plan to districts for new equipment	Apart from the regional cold rooms, the new CC equipment has not yet been received.	Awaiting the arrival of new equipment to propose a plan for distribution of equipment in stock on the basis of inventories which have been completed.	CCL Department / EPI coordinated by the CCL subcommittee
F	Distribution and installation of new equipment at the health centers	Completed		UNICEF/DI

N°	Issue	Status	Action(s) to be taken	Lead Agency / Focal point
2	Revision of recording, reporting and of the monitoring EPI tools			
A	Review of technical orientation and other strategic EPI documents	Completed	These new EPI policies should be simplified and disseminated throughout the country.	DI and partners
B	Revision of all EPI management tools (tally sheets, vaccination cards, health cards, reporting forms, etc.)	Done. Management tools have been revised, printed and distributed before the decision on the type of vaccine that the country will use. Some errors exist in the revised tools.	Gradually correct these errors during supportive supervision visits.	Technical sub-committee under the coordination of DI
3	Training of health workers and logisticians			
A	Availability of adapted training materials (trainer's guide, training modules for health professionals at the peripheral level)	Training materials were adapted and translated into French. Copies have been printed and distributed to trainers, but not health staff.	Print training materials for operational-level health staff.	Technical sub-committee under coordination of the DI
B	Training of Trainers	In turn, these trainings have been completed for PCV13 and rotavirus using cascade approach.	Follow up on training through supportive supervision visits to districts.	Technical sub-committee
C	Training of health professionals at the operational level	Training for health professionals and community members has been completed for the new vaccines.	Additional refresher or monitoring may be needed, notably in poorer performing districts	Technical sub-committee
D	Logistics training (installation and maintenance of cold chain equipment)	Not yet	Organize training, plan specific next steps	Technical/ Communications/ CCL sub-committee
E	Training of community health educators and/or security officials	Not yet realized	Train educators and community security officials	Technical/ Communications/ CCL sub-committee
4	Advocacy, Communication & Social Mobilization			
A	Train and promote partners, mobilize necessary resources to buy additional CC	Training completed but there remains need for resources.	Continue with trainings	Communications sub-committee

N ^o	Issue	Status	Action(s) to be taken	Lead Agency / Focal point
	equipment.			
B	Develop key messages (to address concerns from the KAP and from parents regarding the vaccine)	Complete. Key, integrated messages have been developed and pretested for the two vaccines (PCV13 and rotavirus). Messages were diffused before the launch of the vaccines.	Continue to diffuse messages in the context of routine immunization, especially in places where there is resistance against vaccination.	Communications sub-committee
C	Identify and train media	The media are identified	Awareness programs were debuted before the vaccines' introduction.	Communications sub-committee
D	Communication in the community	Completed but ongoing work is necessary	Continue with awareness programs	Communications sub-committee with community volunteers
5	Vaccine and injection material supply			
A	Prepare to receive the PCV and rota vaccine and the injection material at the central and district levels	Quarterly needs arrived - 494,200 PCV13 and 355,500 rota doses were received 313 200 doses of PCV13 have arrived as of 09/08/2013	<ul style="list-style-type: none"> - Distribution plan was prepared - Storage capacity at the regional level was confirmed - Vaccines and commodities were distributed 	CCL/MoH
B	Register the vaccines with the National Regulatory Authority (ANR)	Complete		MoH
C	<ul style="list-style-type: none"> - Prepare a distribution plan - Ensure the storage capacity at the regional level - Distribute vaccines and commodities 	Complete Complete Complete	Regularly supply the districts with vaccines and injection materials, with special attention to stock management.	Logistics sub-committee and vaccine managers at all levels.
6	Injection safety, waste management and disposal			
A	Availability of vaccines and syringes, needles, safety boxes, etc. at	Vaccines and injection materials are already in the country.	Ensure that vaccines and injection materials are always distributed following	CCL/MoH

N°	Issue	Status	Action(s) to be taken	Lead Agency / Focal point
	national level	Distribution was done in the provinces and from provinces to districts.	the bundling strategy.	
B	Availability of functional incinerators in the health facilities	Current inventory shows there are 5 large modern incinerators (Maradi, Zinder (2), Tillabéri, Niamey), and nearly all CSIs are equipped with burners.	Create a circuit for the collection and transport of waste to incinerators where necessary. Decide on what will be done in health centers without incinerators?	CCL/MoH
C	Training on correct usage of incinerators	Not yet	Planning and conducting training (propose a date)	CCL/MoH
7	Surveillance system updated for VPDs and AEFIs related to new vaccines			
A	Monitoring for AEFI is not functional- what should be done?	Integrate AEFI into the system of routine monitoring.	Propose specific actions	
B	Training of supervision personnel	Building in IDSR-specific surveillance after the introduction of PCV and rotavirus were discussed during NVI personnel training.	Need for follow-up on this, with possible partner support for surveillance	MoH
C	Monitoring and reporting system up to date for the new vaccine	Complete. EPI disease reporting tools have been updated with pneumo- and rotavirus-specific information.	Sensitize and train clinicians in the case definition and reporting system of the diseases.	MoH
D	Other monitoring tasks?	Community-based surveillance of pneumonia & diarrhea cases is not yet in place.	Train Community Health Workers (CHWs)	Health District
8	Launching ceremony preparation			
A	Select introduction date	Dates were set. PCV and rotavirus vaccines were introduced on August 5 2014.	Intensify activity supervision and monitoring of results in all districts.	Technical sub-committee (JSI to also support)
B	Determine the site for	Completed for all vaccines. Launch		Technical sub-committee

N°	Issue	Status	Action(s) to be taken	Lead Agency / Focal point
	the launching ceremony	ceremony for PCV13 and rotavirus was organized by the MoH with the presence of key partners, as planned.		and partners
C	Prepare the sites with IEC materials and media	Complete	Follow-up needed to ensure that materials are available and in use	Technical and social mobilization sub-committees
9	Documentation			
B	Link between new vaccine introduction and strengthening routine immunization within the EPI	Needs to be strengthened	<p>Improvement of implementation plan;</p> <p>Strengthening of staff competency;</p> <p>Improvement of community use of vaccination services;</p> <p>Role of advanced vaccination services to reduce the number of unvaccinated children.</p>	All the ICC sub-committees and partners
C	Plans for PIE	6 to 12 months after introduction		

ANNEX IV: LIST OF KEY PARTNERS

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