

ANALYSIS OF POST LAUNCH ASSESSMENT OF PNEUMOCOCCAL CONJUGATED VACCINE DEMONSTRATION PROGRAM IN WEST LOMBOK AND EAST LOMBOK, WEST NUSA TENGGARA, 2018

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ABSTRACT

Background: Pneumonia is the major cause of mortality of under five children in the world, also in Indonesia. Considering high burden of the disease and good performance of immunization program in Lombok island, Ministry of Health introduced Pneumococcal Conjugated Vaccine (PCV) immunization in West and East Lombok districts since October 2017. This study aimed to evaluate and assess the implementation of PCV demonstration program in West Lombok and East Lombok. The aim of this article is to analyze the results of Post Launch Assessment of PCV demonstration program in East Lombok and West Lombok districts, West Nusa Tenggara province.

Subjects and Methods: Post Launch Assessment (PLA) was conducted using PLA tools which was developed together between Ministry of Health and CHAI. It was adapted from the instruments of Supportive Supervision, Post Introduction Evaluation WHO dan Effective Vaccine Management UNICEF. The assessment was carried out in all community health centre (*Puskesmas*) which implementing PCV demonstration program, 32 *Puskesmas* at East Lombok Districts and 19 *Puskesmas* at West Lombok Districts. The data were collected through interview to immunization officer, Head of *Puskesmas* and vaccinators and through observed immunization services at *Pos-yandus*, facilities and infrastructure at *Puskesmas* also register and logistic books. Ministry of Health assisted by Clinton Health Access Initiative (CHAI) conducted this activities in May - September 2018.

Results: Several components of assessment that need special attention were: (1) Cold chain, (2) Recording and reporting system, (3) Management of vaccine and logistics, (4) Monitoring and analysis of the program, and (5) Adverse Event Following Immunization (AEFI) surveillance.

Conclusion: PCV demonstration program in West Lombok and East Lombok are well implemented. But for better implementation in the future, the recommendations are: (1) Supplementary vaccine distribution system to cover limited vaccine storage capacity or alternative provision of vaccines with smaller volumes preparation, (2) Printing Immunization Recording and Reporting Books with additional columns for PCV especially for districts who conduct PCV demonstration program, (3) Strengthening management of vaccine and logistics, especially for vaccine requirements calculation, vaccine stock recording and temperature monitoring, and (4) Strengthening data analysis capability of immunization officer at *Puskesmas* level to do immediate follow up of the problem.

Keywords: pneumonia, Pneumococcal Conjugated Vaccine, immunization, demonstration program, post launch assessment

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BACKGROUND

Pneumonia is the major cause of mortality of under five children in the world. World Health Organization mentioned that Pneumonia is the single largest infectious cause

of death in children worldwide, Pneumonia killed 808.694 children under the age of five in 2017, accounting for 15% of all deaths of children under five years old. Pneumonia caused a big problem of mortality in children, so Pneumonia called as "The Forgotten

Pandemic”, but not much attention given to this disease.

Pneumonia also give a big problem in Indonesia. Riskesdas (2013) showed the prevalence of Pneumonia di Indonesia is about 4.5% with the highest incidence is in children aged 12-23 months, which is 21.7%.

The most common cause of Pneumonia are: a) *Streptococcus pneumoniae* – the most common cause of bacterial pneumonia in children; b) *Haemophilus influenzae type b* (Hib) – the second most common cause of bacterial pneumonia; and c) respiratory syncytial virus – the most common viral cause of pneumonia. In infants infected with HIV, *Pneumocystis jiroveci* is one of the most common causes of pneumonia, responsible for at least one quarter of all pneumonia deaths in HIV-infected infants (WHO, 2019).

A study conducted by Soewignyo et al. (1997) showed the prevalence of carriage *Streptococcus pneumoniae* bacteria reached 48% in Lombok. Another study conducted by Dunee et al. (2016) in Bandung, Central Lombok and Padang region showed that *Streptococcus pneumoniae* is the most prevalence carriage of children aged 12-24 month, which is 49.5%. *Streptococcus pneumoniae* can cause mild disease (non-invasive) and severe and invasive disease. Severe clinical manifestation could be bacteriemia, pneumonia dan meningitis. The CFR was 29.2% and 21.0% in infants aged 1–11 and 12–23 months, respectively, while the overall CFR attributable to IPD was 23.5% (Hadinegoro in Bravo, 2009).

In order to prevent Pneumonia caused by pneumococcus, WHO recommends the inclusion of PCVs in childhood immunization programmes worldwide especially to countries with high under five children mortality rate. Considering high burden of the disease and good performance of immu-

nization program in Lombok island, Ministry of Health introduced PCV immunization ini West and East Lombok districts as a demonstration program since October 2017. Further, to evaluate and assess the implementation of this program, Ministry of Health together with Clinton Health Access Initiative (CHAI) conducted Post Launch Assessment for PCV demostration program in May-September 2018.

The aim of this article is to analyze the results of Post Launch Assessment of PCV demonstration program in East Lombok and West Lombok districts, West Nusa Tenggara province.

SUBJECT AND METHOD

1. Study Design

This study was an analytic quantitative and qualitative using interview and observation.

2. Population and Sample

The assessment was carried out in 32 *Puskesmas* at East Lombok Districts and 19 *Puskesmas* at West Lombok Districts, from May to September 2018. Data collected through interview to immunization officer, Head of *Puskesmas* and vaccinators and observed immunization services at *Posyandus*, observed facilities and infrastructure at *Puskesmas* also register and logistic books.

3. Study Instrument

The interview was conducted using Post Launch Assessment tools wich developed together between Ministry of Health and CHAI adapted from the instruments of Supportive Supervision, Post Introduction Evaluation WHO dan Effective Vaccine Management UNICEF. There are 18 components in this questionnaires which are general data, supporting documents, facilities, equipments, planning, capacity building of *Puskesmas* staffs, recording and reporting, cold chain management, logistics, immuni-

zation services, safety injections, waste managements, program monitoring and follow up, adverse event following immunization, advocacy and communication, surveillance and knowledge of *Puskesmas* staffs about PCV Program.

About 16 out of 18 assessment components assessed quantitatively which needs to be cross checked with observation and documentation. Moreover, there are 2 qualitative questions to dig more deeper information from the health staffs.

4. Data Analysis

The data in this study were collected and descriptively described.

RESULTS

Table 1. The components of immunization system

Component	East Lombok	West Lombok
Observation of Cold Chain		
<i>Puskesmas</i> with low score (<80%)	78.1%	31.6%
Recording and Reporting System		
<i>Puskesmas</i> with low score (<80%)	53.1%	73.7%
Logistic		
<i>Puskesmas</i> with low score (<80%)	77.7%	57.8%
Monitoring and Analysis		
<i>Puskesmas</i> with low score (<80%)	100%	100%
AEFI Surveillance		
<i>Puskesmas</i> with low score (<80%)	100%	52.6%

DISCUSSION

1. Cold chain Observation

There is lack of cold chain capacity since introduction of PCV. PCV vaccine has the largest volume of all routine vaccines, which is 157.5 dm³ per dose. So it occupied 68% space of cold chain. Before the introduction of PCV, one of the *Puskesmas* in East Lombok needs storage capacity about 17.9 dm³ every month, but since PCV introduction, the required storage capacity reaches 71 dm³ every month and this means an increase of three times volume than usual. After the introduction of PCV immunization, 22

The results obtained from the two districts showed that PCV is well accepted, PCV1 and PCV2 coverages was quite high, which are 88% and 83% (total from the two districts), while PCV3 still ongoing at that time. However there is a difference between PCV1 and PCV2 with DPT-HB-Hib1 and DPT-HB-Hib2 coverages which should be given simultaneously (multiple injections). DPT-HB-Hib 1 coverage higher than PCV1 which is 105% and this happened also DPT-HB-Hib2 coverage which is 87%. The components of immunization system that should have attention in this demonstration program in the two districts are described in Table 1.

Puskesmas (68.8%) in East Lombok and 12 *Puskesmas* (63.2%) in West Lombok did not have sufficient storage capacity.

Before the introduction of PCV, distribution of routine vaccine enough to did once a month, but after the introduction the vaccine delivery must be done at two or three times a month. However, this increase cannot covered by district level, they only have budget to deliver vaccines once a month. Therefore, *Puskesmas* actively pick up the vaccine to district health office with their own budget. This cases also happened in other countries, who have a new vaccine introduction, like in South Africa while

introducing PCV and Rotavirus vaccine, cold chain capacity for the pneumococcal and rotavirus vaccine also increased demand by more than 450% (Scott et al., 2012).

Lee et al. (2011) also made a computational models of the Trang Province, Thailand vaccine supply chain to simulate introducing various PCV and Rotavirus vaccine, they said that all other presentations of new vaccine could overwhelm some district level storage capacities. Additional cold storage capacity needed at the provincial level and additional cold storage capacity required at the district level following various RV and PCV-7 introduction. The need for more storage is greater when shipping frequency decreases.

Other problems found during observation was in the cold chain management. As many as 25 immunization officers at *Puskesmas* (78%) in East Lombok and 10 immunization officer at *Puskesmas* (53%) in West Lombok has not monitored and recorded cold chain temperatures on the temperature chart book on weekends or holidays. The findings of Effective Vaccine Management (EVM) assessment Indonesia in 2015 conducted by Ministry of Health and UNICEF showed similar result, that temperature monitoring at *Puskesmas* level is around 67%. This is cause of concern because PCV is one of the freeze sensitive vaccine but shake test is not possible to do (UNICEF, 2015).

2. Recording and Reporting System

Recording and reporting system for PCV immunization needs more attention. There are 17 *Puskesmas* out of 32 (53.1%) in East Lombok district and 14 *Puskesmas* out of 19 (73.7%) in West Lombok district that have score <80%. There is no special PCV column available in the recording book for routine immunization, this is found at 12 *Puskesmas* (38%) in East Lombok and 16 *Puskesmas* (84%) in West Lombok. Recording system

were varies between *Puskesmas* and not in accordance with the PCV implementation guidelines. Immunization coverage reported was not accurate, even found the PCV2 coverage was higher than PCV1.

Beside the completeness and accuracy, timeliness also become a factor that need special attention. Late reporting results in lower coverage that is not in accordance with the actual conditions. Shen et al. (2014) mentioned that one key problem in routine immunization is the inaccuracy of denominator (population) data, which are often based on outdated census data or inaccurate projections that do not reflect recent growth or population movement. Other common problems include double-counting of doses given, the mixing of doses given to older children with doses given to infants, and the fabrication of reports in order to achieve targets.

Regarding recording and reporting coverage, PCV coverage is different from the DPT-HB-Hib coverage which should provided on the same schedule. Results of the assessment showed different coverage between DPT-HB-Hib and PCV because of several reasons:

- a. Concerns about multiple injections.
PCV should be injected at the left thigh simultaneously with the injection of DPT-HB-Hib at the right thigh. But, this multiple injections become concern of the mothers because of the worries of adverse reaction. This should not have happened because multiple injections is actually very safe (WHO, 2015).
- b. The age of the target less than 2 months.
Vaccinators did not want to take the risk of giving PCV to baby which is not yet 2 months old, but they gave DPT-HB-Hib vaccine. In this cases, both vaccine should not be given to the babies if they are less than 2 months old (Ministry of Health, 2017).

- c. There is a shortage of one of the two vaccines (DPT-HB-Hib or PCV) at the *Puskesmas* level.

Furthermore, Shen et al. (2014) also said that the growing complexity of immunization programs increases the need for a well-trained, capable health workforce. Technical skills must be adequate to administer an increasing number of vaccines to more children and expanded age groups.

In many places, vaccinators represent the lowest tiers of health workers authorized to provide injections. Despite the growing skill demands, the same basic approach to immunization training has been in use for more than 30 years. This usually takes the form of short, offsite, in-service training courses, often delivered through cascade training in which those providing the training may be experts in the subject matter but not in training techniques, or vice versa.

3. Logistic

Most of the *Puskesmas* in East Lombok (75%) and West Lombok (73.7%) calculate PCV requirements based on previous month usage amount, not based on number of the targets. This is not suitable with PCV Technical Guideline which suggested vaccine requirements calculation based on number of surviving infants in that year added with buffer stock, that is reserve needs for one week. Impact of the calculation without considering buffer stock seen when vaccine shortage occurred at district level since early June until 5th July 2018. At the *Puskesmas* level, stock out also occurred in 13 *Puskesmas* (81.3%) at East Lombok and 16 *Puskesmas* (84.2%) at West Lombok. Stock out causing delays in immunization services at *Posyandu*, that can cause missed opportunities and impact of coverage (WHO, 2017).

Logistical records are also did not meet the standard. There are 12 *Puskesmas* (37.5%) in East Lombok and 4 *Puskesmas*

(21%) in West Lombok who have not filled out the vaccine stock book regularly. Furthermore, there are 6 *Puskesmas* (18.75%) in East Lombok and 3 *Puskesmas* (15.8%) in West Lombok don't have vaccine stock book at all. Whereas vaccine stock book carries some important information that must also be recorded, like VVM condition, vaccine batch number and expiry date of the vaccine. VVM condition as indicator the quality of the vaccine, vaccine batch number is important for investigation if AEFI is happened. Expiry date also important to make sure that vaccine is still in a good time to use.

The thing that also needs attention is the placement of vaccine refrigerator in a tight spaces without good air circulation. In some *Puskesmas*, placement of vaccine refrigerators didn't meet the standard, which supposed to be 10-15 cm away from the wall and get good air circulation and lighting, this can influence to the quality of the vaccine (UNICEF, 2009).

Rahayu (2013) mentioned that the level of knowledge, cold chain facilities, supervision, and training affected the compliance of immunization managers to managing vaccines in Yogyakarta city. In this case, capacity building before PCV introduction has been done, but maybe the time allocated for training especially for logistics are not adequate, because logistic matters need more practice, on the job training and supervision.

4. Monitoring and Analysis

Monitoring of immunization system was not running well. All of *Puskesmas* in East Lombok and West Lombok have a low score of this component. 25 *Puskesmas* (78.1%) in East Lombok and 17 *Puskesmas* (89.5%) in West Lombok have printed the visualization of Local Area Monitoring chart and displayed it on the Data Board, but *Puskesmas* didn't have mapping of low coverage or hard to reach areas and strategies to give services

in that areas. Some of *Puskesmas* in the two districts didn't have the schedule of immunization services at *Puskesmas*. It means, if children missed the schedule at *Posyandu*, they will not get the immunization service at *Puskesmas* for that month (WHO, 2008).

Immunization officer also weak in making analysis and follow up of the immunization coverage with incidence of Vaccine Preventable Disease. Local Area Monitoring system has been made to facilitate *Puskesmas* to make analysis of coverage, so follow up and corrective action can be taken immediately (WHO, 2008). But most *Puskesmas* haven't utilized the system well.

A study conducted by Ronveaux O, et al (2005) about immunization data quality audit in 27 countries showed that the monitoring and evaluation of the data is the weakest at all level, monitoring charts with graphically display progress in reaching coverage targets throughout the year, were displayed in only 43% of health units. Fewer than 50% of health units monitored dropout rates (i.e. children who did not receive the full series of vaccination) and there was limited analysis and discussion of information. Administrative monitoring systems are needed to provide critical information on an ongoing basis to local staff in order to determine whether coverage is being met.

5. AEFI Surveillance

Until the PLA was done, there was no serious AEFI due to PCV reported. The common reaction after immunization was fever, but it was difficult to ensure whether from DPT-HB-Hib or PCV vaccine. But this non-serious AEFIs were not routinely reported by *Puskesmas* to the higher level, so the exact number of non-serious AEFIs after PCV vaccine were not calculated yet. All *Puskesmas* in East Lombok and 8 *Puskesmas* (42%) in West Lombok didn't report non-serious AEFI routinely, except if the serious cases happened. Based on the SOP, non-

serious AEFI should also be reported every month. This is part of vaccine safety surveillance. Referring to the literature, it is said that PCV is a very safe vaccine. The common reaction after PCV immunization is redness at the injection site, irritability, fever and swelling (Ministry of Health, 2017).

A study conducted by Ronveaux et al. (2005) also mentioned that the weakness of "storage and reporting practices" component were found in the failure of retain forms, to develop a procedure of handling late reports and procedures for reporting adverse events. Procedures of reporting adverse event had been established in only 19% (5/27) countries and 31% (21/67) districts.

Despite some limitations, PCV demonstration program in East and West Lombok districts seems to be well implemented. Both PCV1 and PCV2 coverages reached more than 80%. This was possible because of good planning at all levels. The Ministry of Health supported by CHAI planned and prepared this program since 2016, followed by provincial, district and *Puskesmas* level. All *Puskesmas* allocated operational budget to support immunization program, which can be used for socialization activities and printing of IEC material. PCV demonstration program does not cause an increase in costs specifically, because it's already include as a routine immunization activities.

Most of immunization officers at *Puskesmas* had developed a program plan internally by involving management and cross programs, followed by coordination with other sectors. After the launching PCV demonstration program, *Puskesmas* have conducted socialization in their areas by involving cross-program, cross-sectoral, and communities.

Capacity building for all health staff have been done at all level, so the knowledge

of health staff about PCV program is increased. Most of the *Puskesmas* also have SOP for Safety Injection and have a good waste management system. This is similar with the studies of “The Impact of new vaccine introduction from six low-middle-income countries” in Cameroon, Guatemala, Ethiopia, Kenya, Mali and Rwanda conducted by Burchett et al. (2014) mentioned that the new vaccine introduction give positive effect of staff training, disease surveillance and AEFI, financing and collaboration with cross sectorial.

However, in the beginning of PCV program still found parent’s hesitance regarding multiple injections. This indicates that health promotion activities for new vaccines should be done continuously and integrated with other routine immunization vaccines (WHO, 2008).

This assessment has limitations. The first is not all the interviewers in this study are people who understand immunization program, this can lead to improper interpretations of the results of the interview. The second is not all immunization officer interviewed are people who have attended PCV training due to the roll-over of *Puskesmas* staff, this affects mismatches between the components of the assessment.

PCV demonstration program in West Lombok and East Lombok are well implemented. The main challenge faced in the PCV immunization demonstration program is the limited vaccine storage capacity due to the large volume of PCV vaccine and *single dose*. In addition, the recording and reporting system, management of vaccine logistics, temperature monitoring of refrigerator, monitoring and analysis of the program also need attention. The monitoring and analysis is important because it relates to the steps must be taken immediately so that the program can run and give benefit to communities.

For better implementation in the future, the recommendations are: 1) Supplementary vaccine distribution system to cover limited vaccine storage capacity or alternative provision of vaccines with smaller volumes preparation; 2) Printing Immunization Recording and Reporting Books with additional columns for PCV especially for districts who conduct PCV demonstration program; 3) Strengthening management of vaccine and logistics, especially for vaccine requirements calculation, vaccine stock recording and temperature monitoring; 4) Strengthening data analysis capability of immunization officer at *Puskesmas* level to do immediate follow up of the problem.

ACKNOWLEDGEMENT

This study would like to acknowledge experts from Clinton Health Access Initiative, CHAI Foundation as well as national experts from Immunization Sub Directorate, Ministry of Health, West Nusa Tenggara Provincial Health Office, East Lombok District Health Office and West Lombok Health Office for contributing in data collection and data analysis of this evaluation.

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