

p-ISSN 0030-9311  
e-ISSN 2338-478x

Volume 54 • No. 4 (Supplement) • July 2014

# Paediatrica Indonesiana

(The Indonesian Journal of Pediatrics and Perinatal Medicine)

Abstract of the 16<sup>th</sup> Indonesian Congress of Pediatrics,  
Indonesian Pediatric Society,  
Palembang, Indonesia,  
August 25-28, 2014



Published by  
Indonesian Pediatric Society

**Paediatrica Indonesiana**  
*Indonesian Journal of Pediatrics and Perinatal Medicine*

167	P-HEM-048	Risk factors for mortality in children with Wilms tumor	183
168	P-HEM-049	The role of $\beta$ -thalassemia type c.-582 a>g promoter hamp gene polymorphism, serum hepcidin, and gdf15 level on iron status in newly diagnosed severe $\beta$ -thalassemia	184
168	P-HEM-050	The correlation between vivax malaria and iron deficiency in children in malaria endemic area	184
169	P-HEM-051	Imunophenotype findings and minimal residual disease in childhood acute lymphoblastic leukemia before and after induction chemotherapy	185
169	P-HEM-052	Ocular malignant fibrous histiocytoma: a rare case	185
170			
170			

**Poster: Indonesian College of Pediatrics**

71	P-COL-001	Vision, mission, and goals comprehension of pediatric residency training institution at Airlangga University/Dr. Soetomo Hospital Surabaya	186
71	P-COL-002	Decreased working memory capacity in sleep deprived pediatric residents	186
72	P-COL-003	The correlation between study duration with child's developmental concerning of pediatric residents in Soetomo Hospital	187
72	P-COL-004	Factors related to punctuality of scientific schedule among pediatric residents at Airlangga University/Dr. Soetomo Hospital Surabaya	187
73	P-COL-005	Suggestion to improve scientific scheduling system for pediatric residents at Airlangga University, Dr. Soetomo Hospital Surabaya	188
73	P-COL-006	National examination in pediatrics training program (Competencies assessment for new graduated pediatricians in Indonesia)	188
74	P-COL-007	Stakeholders appraisal to pediatricians as graduates from Airlangga University/Dr. Soetomo Hospital Surabaya: a tracer study (2012 – 2014)	189
74			
75			
75			
76			
76			

**Posters: Infection & Tropical Diseases**

7	P-INF-001	Dengue shock syndrome in infants	190
8	P-INF-002	Abdominal tuberculosis as an etiology of fever of unknown origin: a case report	190
8	P-INF-003	Clinical audit of dengue haemorrhagic fever grade III	191
9	P-INF-004	A case series of measles: a highly contagious, vaccine preventable disease	191
9	P-INF-005	Clinical profiles of patient with cytomegalovirus infection	192
0	P-INF-006	Growth and developmental status in children with human immunodeficiency virus exposed uninfected and infected	192
0	P-INF-007	Adverse events following immunization in East Java province: a 5 years experience	193
1	P-INF-008	Factors associated with developmental delay in children with cytomegalovirus infection	193
1	P-INF-009	Neonatal malaria	194
2	P-INF-010	Opportunistic infection presentations in children with HIV infection	194
2			
3			

P-INF-007

P-INF-008

### Adverse events following immunization in East Java province: a 5 years experience

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#### Abstract

**Background.** Beside the benefits, vaccine can cause some adverse events (adverse events following immunization = AEFI). These AEFI can become heavy obstacles for the whole vaccine campaigns. East Java is one of the leading provinces with good data of AEFI.

**Objective.** To describe AEFI in East Java from 2009 to 2013.

**Methods.** This descriptive study used secondary data from the population of children who have AEFI from all over the district and city in East Java province in the last 5 years, from 2009 to 2013. Data have been collected from AEFI Reporting form of the East Java provincial health office. We only recorded basic immunizations program (BCG, Hepatitis B, DPT, polio, and measles).

**Results.** During 5 years period, there were 153 reported AEFI cases. Most were from Bangkalan 57 (20.8%), Mojokerto 29 (10.58%), and Madiun 20 (7.3%) districts. The combined vaccines DPT-HB-Polio 49 (32%) are the most commonly reported cause. DPT vaccine was responsible for the highest systemic AEFI 132 (32.92%), which majority complained of fever 48 (27.59%). The highest local AEFI was due to Hepatitis B vaccine 48 (37.5%), and the majority was swelling in the injection site 43 (24.57%).

**Conclusion.** The total reported number of AEFI cases was not high and mostly dominated by DPT-HB vaccine.

*Keywords:* adverse events following immunization (AEFI), DPT, hepatitis B

### Factors associated with developmental delay in children with cytomegalovirus infection

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#### Abstract

**Background.** Cytomegalovirus (CMV) infection is a common neonatal infection affecting 1% of all live births and 10% of which are symptomatic. The challenge in children with congenital CMV is predicting the sequelae of neurological and developmental deficits.

**Objective.** To study the factors associated with developmental outcomes in children CMV infection.

**Methods.** A Cross sectional study was conducted at Soetomo Hospital from 2011 to 2013. Cytomegalovirus infection was assessed by CMV IgG or IgM antibodies detection. Subjects underwent head CT scan, ophthalmologic and audiology examination. Developmental delay was assessed using the Denver II test. The correlation between selected variables and developmental outcomes was analyzed using correlation test;  $P < 0.05$  was considered significant.

**Results.** Fifty children from a total of 63 children with CMV infection were included, male (54%) was predominant, most of the children were below 6 months of age (60.8%). Clinical presentation were fever 88%, jaundice 54%, anemia 44%, seizure 20%, microcephaly 69.7%, hepatomegaly 56% and splenomegaly 18%, chorioretinitis (2%) and sensorineuronal hearing loss (10%). The serology test revealed positive CMV IgG 22 (97%), IgM 2 (4%), both IgM and IgG 26 (52%). At the time of diagnosis, a state of developmental outcome was present in 52% of subjects. There were significant correlation between developmental delay status and abnormal CT scan ( $r=0.087$ ;  $P=0.000$ ), CMV IgM+ ( $r=0.439$ ;  $P=0.001$ ), as well as age at presentation ( $r=-0.348$ ;  $P=0.013$ ).

**Conclusion.** Developmental outcomes of children with CMV infection were associated with abnormality of CT scan, positive of CMV IgM, and age at presentation.

*Keywords:* cytomegalovirus infection, children, developmental delayed

# ADVERSE EVENTS FOLLOWING IMMUNIZATION IN EAST JAVA PROVINCE: A 5 YEARS EXPERIENCE

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East Java Provincial Health Office<sup>2</sup>

## Abstract

**Background:** Beside the benefits, vaccine can cause some adverse events (adverse events following immunization=AEFI). These AEFI can become heavy obstacles for the whole vaccine campaigns. East Java is one of the leading provinces with good data of AEFI.

**Objective:** To describe AEFI in East Java from 2009 to 2013.

**Methods:** This descriptive study used secondary data from the population of children who have AEFI from all over the district and city in East Java province in the last 5 years, from 2009 to 2013. Data have been collected from AEFI Reporting form of the East Java provincial health office. We only recorded basic immunizations program (BCG, Hepatitis B, DPT, polio, and measles).

**Result:** During 5 years period, there were 153 reported AEFI cases. Most were from Bangkalan 57 (20.8%), Mojokerto 29 (10.58%), and Madiun 20 (7.3%) districts. The combined vaccines DPT-HB-Polio 49 (32%) are the most commonly reported cause. DPT vaccine was responsible for the highest systemic AEFI 132 (32.92%), which majority complained of fever 48 (27.59%). The highest local AEFI was due to Hepatitis B vaccine, and the majority was swelling in the injection site 43 (89.58%).

**Conclusion:** The total reported number of AEFI cases was not high and mostly dominated by DPT-HB vaccine.

**Keywords:** *Adverse events following immunization (AEFI), DPT, hepatitis B.*

## Introduction

Vaccines have saved millions of lives, contributing to an important reduction of infectious diseases worldwide, and promise to further improve the control of infectious diseases.<sup>1,2</sup> Like any other medication or biological product, vaccines may sometimes cause adverse reactions. When serious or unexpected adverse events occur, health care providers and public health officials should carefully and thoroughly assess the evidence reported during the investigation of the event, trying to define the possible causal relationship with one or more vaccines that may have been administered.<sup>1</sup>

Since the safety demand at individual level is growing, particularly in areas where vaccine preventable diseases are uncommon, many countries are experiencing

different models of adverse events following immunization (AEFI) surveillance and prevention systems.<sup>3</sup> These AEFI can become heavy obstacles for the whole vaccine campaigns. East Java as one of the biggest province in Indonesia is one of the leading provinces with good data of AEFI.

This report summarizes the overall activity of a 5-year period, supplied by the East Java Provincial Health Office with the goal of this study was to describe AEFI in East Java from 2009 to 2013, which, to our experience has proved to be easily manageable and efficient.

## **Materials and Methods**

### **Study population**

The present study was a retrospective from surveillance report data in East Java Provincial Health Office during 5 years period from January 2009 to December 2013. All the subject criteria were children with basic immunization program (BCG, Hepatitis B, HiB, DPT, polio, and measles).

### **Statistical analysis**

This is a descriptive study analyze, showed with pie and/ or bar diagrams to easier interpretation.

### **Results**

During 5 years period, there were 153 reported AEFI cases. Most were from Bangkalan 57 (20.8%), Mojokerto 29 (10.58%), Madiun 20 (7.3%), and Pamekasan, Kediri, Malang (5%) districts.

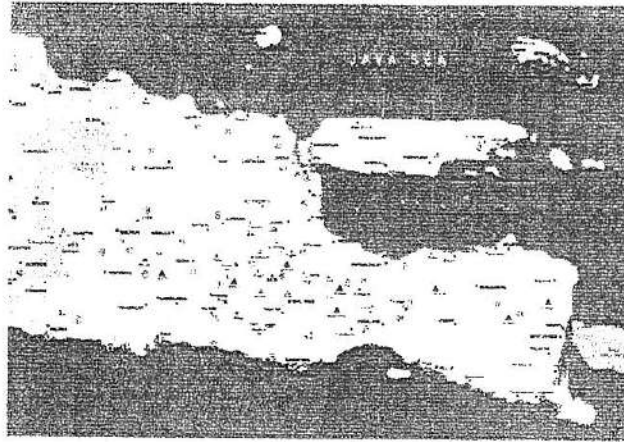


Figure 1. Region of reported AEFI, East Java 2009-2013

The combined vaccines DPT-HB-Polio 49 (32%) are the most commonly reported cause. Adverse events following immunization divided in 2 groups, there are systemic and local AEFI. The highest local AEFI was due to Hepatitis B, and the majority was swelling in the injection site 43 (24.57%).

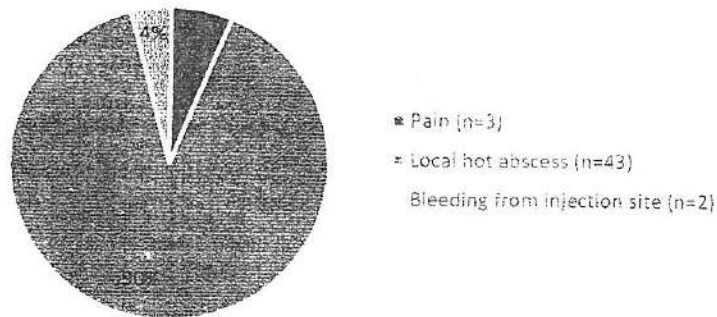
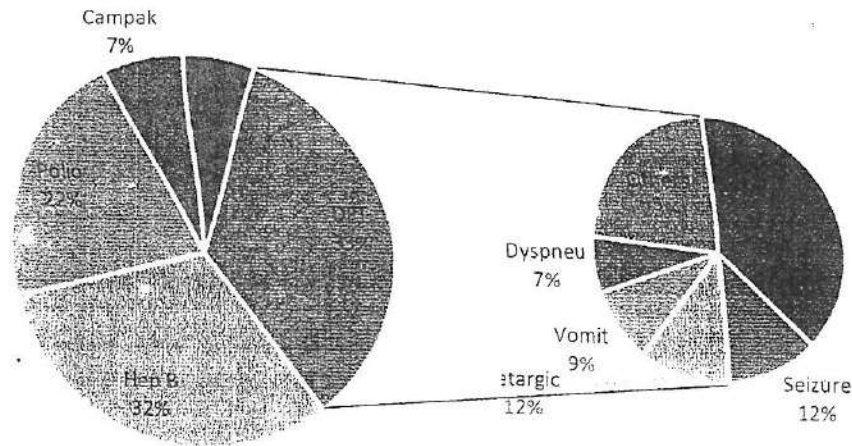


Figure 2. Local AEFI due to Hepatitis B vaccine

DPT vaccine was responsible for the highest systemic AEFI 132 of cases, which majority complained of fever 48 (36.36%). The others were seizure 16 (12.12%), letargic 15 (11.36%), vomit 12 (9.09%), dyspneu 11 (8.33%), and others 30 (22.73%).



**Figure 3. Systemic AEFI**

The most serious AEFI in children is anaphylactic reaction. Reported two fatal cases with anaphylactic shock soon after DPT vaccine (< 24 hours).

### Discussions

As vaccine-preventable infectious diseases continue to decline, people have become increasingly concerned about the risks associated with vaccines.<sup>5</sup> Furthermore, technological advances and continuously increased knowledge about vaccines have led to investigations focused on the safety of existing vaccines which have sometimes created a climate of concern. An AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease. If not rapidly and effectively dealt with, can undermine confidence in a vaccine and ultimately have dramatic consequences for immunization coverage and disease incidence.<sup>1,2,3</sup> No vaccine is completely risk-free and adverse events will occasionally result after an immunization.

AEFIs are grouped into five categories; vaccine product-related reaction, vaccine quality defect-related reaction, immunization error-related reaction, immunization anxiety-related reaction, and coincidental event.<sup>3,4</sup> During 5 years period, there were 153 reported AEFI cases reported in East Java Province. Most were

from Bangkalan 57 (20.8%), Mojokerto 29 (10.58%), Madiun 20 (7.3%), and Pamekasan, Kediri, Malang (5%) districts. The combined vaccines DPT-HB-Polio 49 (32%) are the most commonly reported cause. Adverse events following immunization divided in 2 groups, there are systemic and local AEFI. The highest local AEFI was due to Hepatitis B, and the majority was swelling in the injection site 43 (24.57%). DPT vaccine was responsible for the highest systemic AEFI 132 of cases, which majority complained of fever 48 (36.36%). The others were seizure 16 (12.12%), letargic 15 (11.36%), vomit 12 (9.09%), dyspneu 11 (8.33%), and others 30 (22.73%).

An AEFI will be considered serious if it results in death, life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/ incapacity, makes any congenital anomaly/ birth defect, or requires intervention to prevent permanent impairment or damage.<sup>2-5</sup> The most serious AEFI in children is anaphylactic reaction. Reported two fatal cases with anaphylactic shock soon after DPT vaccine (< 24 hours).

### Conclusion

The total reported number of AEFI cases was not high and mostly dominated by DPT-HB vaccine.

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## ADVERSE EVENTS FOLLOWING IMMUNIZATION IN EAST JAVA PROVINCE: A 5 YEARS EXPERIENCE

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East Java Provincial Health Office<sup>2</sup>

### BACKGROUND

Beside the benefits, vaccine can cause some adverse events (Adverse events following Immunization=AEFI).

These AEFI can become heavy obstacles for the whole vaccine campaigns. East Java is one of the leading provinces with good data of AEFI.

### OBJECTIVE

- To describe AEFI In East Java from 2009 to 2013.

### METHODS

Design	: Cross sectional study
Location	: East Java Province
Periode	: January 2009 - December 2013
Subject	: Children with basic immunization program ( BCG, Hepatitis B, DPT, polio, measles )
Data	: Age, sex, suspect vaccine(s), description of the AEFI, final outcome of AEFI.
Analysis	: Descriptive

### RESULTS

There were 153 reported AEFI cases from all 38 districts and city in East Java province.

DPT vaccine was responsible for the highest systemic AEFI (132 of cases).

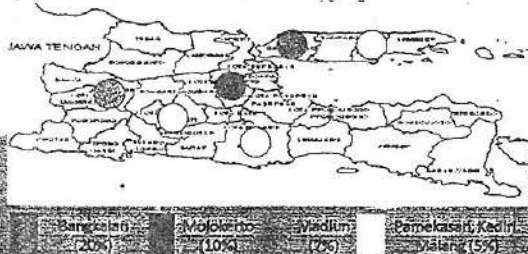


Figure 1. Region of Reported AEFI East Java 2009-2013

The highest local AEFI was due to Hepatitis B vaccine.



Figure 2. Local AEFI due to Hepatitis B vaccine

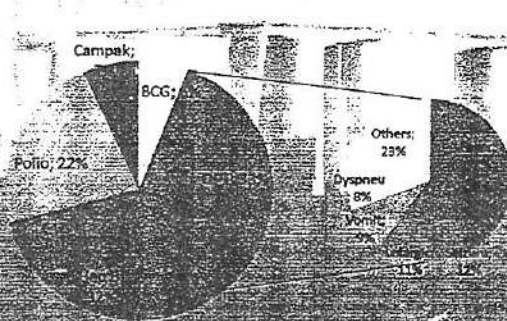


Figure 3. Systemic AEFI

The most serious AEFI in children is anaphylactic reaction. Reported 2 fatal cases with anaphylactic shock soon after DPT vaccine (< 24 hours)

### CONCLUSION

- The total reported number of AEFI cases was not high and mostly dominated by DPT-HB vaccine.

10  
Indonesian  
Congress of Pediatrics

Palembang - Indonesia, August 25-28, 2014

# Certificate of Attendance

This is to certify that

*Dominicus Husada*

has attended the 16<sup>th</sup> Indonesian Congress of Pediatrics (KONIKA XVI)

"Towards Global Equalities in Sustainable MDG's  
Achievements Through Comprehensive Health Care, for All Indonesian Children"

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of South Sumatera

M. Nazir, Dr., Sp.A(K)  
Chairman of the 16<sup>th</sup> KONIKA

This program has been accredited by Indonesian Medical Association (IMA/IDI) with maximal credit points of 30 (participant), 1 (speaker),  
and by Indonesian Pediatrics Society (IPS/IDAI) as category I and V CPD (No. 6754/CPD- I/Apl/2014 and 6755/CPD-V/Apl/2014)  
SK PB IDI No.1.223/PB/A.4/08/2014; participant 15, speaker 12, moderator 4, committee 3.