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Risk Factors of Adverse Events Following Immunization (AEFI) Measles Rubella (MR) in East Java Province, Indonesia

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Abstract

Measles and rubella (MR) can cause morbidity and mortality. The government's action to prevent the incidence of this disease is the MR immunization program. Decreased coverage of MR immunization can increase the incidence of measles and rubella. One of the barriers to the success of immunization is the public's concern about the occurrence of adverse events following immunization (AEFI). This study aims to identifying risk factors for serious adverse events following immunization after Measles Rubella. The data collected subsequently were analyzed using Chi-square Fisher Exact test for univariate and bivariate analysis. Logistic regression was used for multivariate analysis. Result show143 subjects, 43 subjects were obtained with serious MR AEFI. Ages range 1-5 years dominated the serious MR AEFI group, which was 88.3%. Male gender was found in 51.2% serious AEFI Group. Host factors and environmental factors were analyzed in this study. We found that from the overall risk factors analyzed, history of allergy and low maternal education had higher risk of 3.67 times (95% CI: 1.25-11.11) and 6.99 times (95% CI: 2.21-12.22) respectively for the onset of serious MR AEFI compared with subjects with no history of allergy and middle to high maternal education. Meanwhile, other risk factors did not have any significant association.

Keywords: MR AEFI, risk factors, children, East Java Province

Introduction

Global commitment to eliminate the incidence of measles and rubella is followed by all countries and has been campaigned by WHO since early 2000. One of the efforts made is by taking preventive measures through immunization [1]. The Indonesian government is also committed to achieve the elimination of measles and rubella by 2020, however the coverage of measles immunization in Indonesia has decreased from 2014 to 2015. As a result, the incidence of measles tends to increase. From 2010 to 2015, it was estimated that there were 23,164 measles cases in Indonesia. Adverse events following immunization (AEFI) is one of the barriers to successful immunization in the provision of measles and rubella (MR) immunization [2].

AEFI identifies all medical events that occur after immunization. AEFI may or may not be related to vaccines. AEFI can range from mild to severe or serious. A serious AEFI is an AEFI that causes a person to be hospitalized, die, become disabled, suffer a miscarriage, cause fetal defects, or cause a stir in the social, political, and cultural aspects. Serious AEFI will cause unrest in the community[3]. One of the efforts related to AEFI is to identify the risk factors for the occurrence of the unexpected Events after Immunization [4]. In some literatures, several factors can be a risk of AEFI such as reactions from the host and the environmental factors. The reaction of this host is influenced by gender, nutritional status, birth history, and history of allergy. Several environmental factors and agent factors are the type of vaccine used [5-7].

Therefore, this study was conducted with the aim of identifying the risk factors for serious AEFI in MR immunization. Identifying the risk factors is expected to minimize the occurrence of AEFI and increases the achievement of the immunization program.

Methods

This research is a case control study. This study is directed to identifying risks factors influence adverse events following immunization. This research was conducted in east java province from November 2020 to May 2021.

The population of case and control group in this study were children receiving MR immunization in the East Java region on the 2017 immunization program that meet the inclusion and the exclusion criteria. Sampling method use total sampling, with minimal sampling based on Rosner formula. The case group inclusion criteria in this research were aged less than or equal to 18 years, received Measles Rubella (MR) vaccination, had serious AEFI after administration of MR vaccine, and the data was recorded at the East Java Provincial Health Office. The control group inclusion criteria were aged less than or equal to 18 years, received Measles Rubella (MR) vaccination, but not experiencing AEFI. The case and control exclusion criteria were pediatrics who had chronic diseases, were not present at the time of data collection. The independent variables were sex, age, birth history, history of allergy, nutritional status, immunization workers, maternal knowledge, maternal education, economic status and occupancy density. The dependent variable was serious AEFI.

The instrument for data collection used in this study was in the form of a data collection sheet. Univariate analysis was conducted to describe the characteristics of pediatrics with serious and No AEFI and the frequency distribution of each variable, both independent and dependent variables

Univariate analysis in this study was conducted to describe each variable factor. Bivariate analysis using Chi-square test or Fisher's exact test, the test criteria are if the p-value < = 0.05 then the relationship is statistically significant, but if the p-value > = 0.05 then it is not statistically significant or not present. meaningful relationship. Data processing uses the Statistical Package for the Social Sciences (SPSS) program.

Results and Discussion

The number of samples that entered the inclusion and exclusion criteria were 143 children divided into serious AEFI group 43 children and no-AEFI group 100 children .

1. Basic Characteristics of Research Subject

The research subjects were presented based on basic characteristics, namely gender, age, nutritional status, history of allergy, birth history, gestational age, immunization workers, maternal education, maternal knowledge, economic status and occupancy density. The basic characteristics of research subjects are presented in Table 1.

Table 1. Basic Characteristics of Research Subjects

Variable	Total (%)	
	Serious MR AEFI	**No AEFI**
	N=43	**N=100**
Sex		
- Male	22 (51.2)	49 (49)
- Female	21 (48.8)	51 (51)
Age		
- < 1 year old	2 (4.7)	1 (1)
- 1-5 years old	38 (88.3)	77 (77)
- > 5 years old	3 (7)	22 (21)
Nutritional status		
- Good nutrition-more	31 (72.1)	86 (86)
- Malnutrition	12 (27.9)	14 (14)
History of allergy		
- Yes	8 (18.6)	6 (6)
- No	35 (81.4)	94(94)
Birth history		
- Spontaneous	35 (81.4)	88 (88)
- Caesarean section	8 (18.6)	12 (12)
Gestational age		
- Aterm or mature	38(88.4)	94 (94)
- Premature	5 (11.6)	6 (6)
Immunization workers		
- Midwife	42 (97.7)	97 (97)
- Nurse	1 (2.3)	3 (3)
Maternal education		
- Low (Elementary school)	15 (34.9)	13 (13)
- Intermediate (Junior-senior High school)	22 (51.1)	51 (51)
- High (Diploma/Bachelor)	6(14)	36 (36)
Maternal knowledge		
- Good	35 (81.4)	93 (93)
- Less	8 (18.6)	7 (7)
Economic status		
- Enough-more	16 (37.2)	53 (53)
- Less	27(62.8)	47 (47)
Occupancy density		
- One family	19 (44.2)	51 (51)
- > 1 family	24 (55.8)	49 (49)

In this study showed that male and female subjects between case and control groups did not show a significant difference in number. In both groups incidence of serious adverse event following immunization after measles rubella vaccine most was found at age 1-5 years old. Subjects with history of allergies was greater in the serious MR AEFI than in no AEFI group. In two groups case and control, the birth history was dominated by spontaneous labor and mature age of gestation.

2. Bivariate Analysis of The risk Factors That Affect Serious MR AEFI

Table 2. Bivariate analysis of the risk factors that affect serious MR AEFI

Variable	Total (%)		p	OR	95% CI	
	Serious MR AEFI	**No AEFI**			**min**	**max**
	N=43	**N=100**				
Sex			0.812	1.090	0.533	2.229
- Male	22 (51.2)	49 (49)				
- Female	21 (48.8)	51 (51)				
Age			0.047	3.57	1.21	11.05
- < 1 year old	2 (4.7)	1 (1)				
- 1-5 years old	38 (88.3)	77 (77)				
- > 5 years old	3 (7)	22 (21)				
Nutritional status			0.048	0.421	0.176	1.007
- Good nutrition-more	31 (72.1)	86 (86)				
- Malnutrition	12 (27.9)	14 (14)				
History of allergy			0.03	3.581	1.160	11.057
- Yes	8 (18.6)	6 (6)				
- No	35 (81.4)	94(94)				
Birth history			0.296	0.597	0.225	1.584
- Spontaneous	35 (81.4)	88 (88)				
- Caesarean section	8 (18.6)	12 (12)				
Gestational age			0.306	0.485	0.140	1.685
- Aterm or mature	38(88.4)	94 (94)				
- Premature	5 (11.6)	6 (6)				
Immunization workers			0.89	1.299	0.131	12.582
- Midwife	42 (97.7)	97 (97)				
- Nurse	1 (2.3)	3 (3)				
Maternal education			0.01	6.94	2.32	10.41
- Low (Elementary school)	15 (34.9)	13 (13)				
- Intermediate (Junior-senior High school)	22 (51.1)	51 (51)				
- High (Diploma/Bachelor)	6(14)	36 (36)				
Maternal knowledge			0.047	0.829	0.111	0.976
- Good	35 (81.4)	93 (93)				
- Less	8 (18.6)	7 (7)				
Economic status			0.083	0.526	0.253	1.093
- Enough-more	16 (37.2)	53 (53)				
- Less	27(62.8)	47 (47)				
Occupancy density			0.455	0.761	0.361	1.560
- One family	19 (44.2)	51 (51)				
- > 1 family	24 (55.8)	49 (49)				

In this study results of bivariate analysis showed that significant results were obtained with $p<0.05$ on the variables of the age of child, nutritional status, history of allergy, maternal education, and maternal knowledge with the largest odds ratio on the history of allergy variable. There are 6 variables with $p<0.25$ in the bivariate analysis and will be conducted multivariate logistic regression analysis, the age of child, nutritional status, history of allergy, maternal education, maternal knowledge, and economic status. Several factors can be a risk

of AEFI such as reactions from the host and environmental factors. The reaction of this host is influenced by gender, nutritional status, birth history, and history of allergy. Several environmental factors and agent factors are the types of vaccine used [5-7].

The results of statistical analysis showed that there was a significant relationship between the age of the child as a risk factor affecting the incidence of serious MR AEFI with p-value = 0.047 and odds ratio = 3.57 times. Age is one of the factors that influence vaccine response. A study in Brazil showed that the age group of less than one year has a risk for the onset of serious AEFI [8]. A different thing happened in a study in India where the incidence of AEFI was most common in the age group less than one year [9]. Neonates have lower levels of antibody production and it is well known that passively acquired maternal antibodies can interfere with the immune response to immunization. Immaturity of the immune system inhibits the formation of protective antibodies. The low number of B cells and inefficient antigen presentation and T-helper mechanisms [7]. The results of the bivariate analysis stated that nutritional status had a p-value = 0.048 and a risk of 0.421 times related to the occurrence of serious AEFI. AEFI after measles immunization in children with less nutrition compared to children with good nutrition did not state a significant difference [10].

A study in Australia showed that parents had a perspective on vaccine safety and post-immunization reactions. Reporting of an adverse event after immunization is not related to parental knowledge because parents in that study tend to seek medical advice from family doctors or other professional health workers, rather than making report about adverse events following immunization that was occurred [11]. In data processing on the economic status factor, a p-value of 0.083 was obtained so that the economic status was not significantly at risk for the emergence of serious AEFI. The economics status factor was included in multivariate data processing because it had a p-value of <0.25. Researches in Turkey and Nigeria states that economic status is related to the opportunity to obtain health services or consultation about immunization. From the research data, there are no significant differences in the AEFI reactions that occur in the socio-economic conditions of parents [12-13]

3. The Multivariate Analysis by Logistic Regression

Table 3. Logistic regression multivariate analysis

Variable	Odds Ratio	95% CI	p value
Age of child	3.64	1.841-3.865	0.064
Nutritional status	1.66	0.621-4.435	0.312
History of allergy	3.67	1.25-11.11	0.031*
Maternal education level	6.99	2.21-12.22	0.01*
Maternal knowledge	2.057	0.582-7.274	0.263
Economic status	1.914	0.876-4.182	0.104

Description: p value with * sign has a significant relationship

The results of the multivariate logistic regression analysis showed that the p value<0.05 was significant for the allergy history and mother's education variables. Subjects with a history of allergy had a risk of 3.67 times, while subjects with mothers with low education had a risk of 6.99 times having serious MR AEFI.

The results of data processing in this study illustrate that children with a history of allergy are more likely to experience serious AEFI compared to children without a history of allergy. A longitudinal study stated that children with a history of atopy had a higher risk of developing a rash after being given the measles-mumps-rubella combination vaccine than children who did not receive immunizations [14]. The Finland regional study stated that 41.7% of children who had received the Measles mumps rubella vaccine had a previous history of allergy. In that study, 10 children (27.8%) experienced an adverse reaction in the form of urticaria, shortness of breath, and 2 children with anaphylaxis. Blood samples of children who had a history of allergy were taken and examined by the CAP-RAST laboratory and then found that Ig-E antibodies were specific gelatine in the serum [15].

Low maternal education has a greater risk of having serious MR AEFI in this study. Low alertness of AEFI after immunization from the parents makes the response late so that it can aggravate the symptoms that arise [16]. A previous study in Poland reported incidence of AEFI is related to the educational level of parents. As many as 35% of parents reported AEFI was associated with attitudes or anxiety about vaccine reaction so that AEFI symptoms did not become worst [17]. Maternal education level makes it easier to understand information about immunization which will then affect behaviour. Low alertness from parents makes the response late when a follow-up event occurs after immunization so that it can aggravate the reactions that arise

[9].

Conclusion

In conclusion history of allergy as host factor and maternal education as an environmental factor significantly affect the risk of serious MR AEFI. These findings can be taken into consideration for increasing knowledge and reference purposes in Child Health Sciences. Further research on other factors is needed to improve the knowledge regarding the adverse event of MR AEFI.

This study has several limitations as vaccine components and the formation of specific antibodies were not studied. It is not known whether at the time of immunization it was already available and following the standard operating procedures

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