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Adverse Events Following Immunization: Management Preparedness Among Health Workers of Sunsari, Nepal

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ABSTRACT

Introduction: An Adverse Event Following Immunization (AEFI) refers to any unwanted medical condition that occurs after vaccination, whether or not it is caused by the vaccine. Maintaining and strengthening public confidence in the national immunization program requires health personnel to be aware of AEFI and adequately prepared to respond to public concerns. The objective of this study was to assess the management preparedness on AEFI among health workers of Sunsari, Nepal.

Methods: A descriptive cross-sectional study was carried out between March 2019 and March 2020 among 96 health workers selected by simple random sampling. Information was collected through interviews using a semi-structured questionnaire to assess knowledge and factors associated with AEFI management preparedness. Knowledge levels were classified as poor, fair, and good. Preparedness factors were analyzed descriptively and categorized as always, sometimes, and never, and supported by observation of the AEFI kit box. Mann–Whitney U and Kruskal–Wallis H tests were used to determine the association between socio-demographic variables and knowledge scores.

Results: 63% of the respondents had fair knowledge, 28% had good knowledge, and 9% of the respondents had poor knowledge of AEFI. All of the visited organisations had failed to make available the AEFI Kitbox for their routine immunization program.

Conclusion: The study concluded that health workers had proper management preparedness in Sunsari, Nepal. The knowledge regarding AEFI was found fair among them and the majority had followed the guidelines to conduct immunization program, but there was a failure of availability of the AEFI management Kitbox, including articles for the regular immunization program for immediate management if an adverse effect occurs. No significant association was found between socio-demographic characteristics and knowledge regarding AEFI ($p>0.05$).

Keywords: AEFI, AEFI Kitbox, Health workers, Knowledge, Management preparedness

INTRODUCTION

An adverse event following immunization (AEFI) refers to any untoward medical occurrence that follows immunization and does not necessarily have a causal relationship with the use of the vaccine. If such events are not managed promptly and effectively, they may undermine public confidence in vaccines and lead to serious consequences for immunization coverage and disease incidence[1].

AEFIs are classified into five categories: vaccine product–related reactions caused by the inherent properties of the vaccine; vaccine quality defect–related reactions resulting from defects in the vaccine or its administration device; immunization error–related reactions due to improper vaccine handling,

prescribing, or administration; immunization anxiety–related reactions arising from anxiety associated with vaccination; and coincidental events caused by factors unrelated to the vaccine or immunization process[2].

In Nepal, AEFI surveillance has been in place nationwide since 2004. Despite this, a monthly zero-reporting system has not yet been implemented in all 77 districts, and AEFI reporting is not integrated into the HMIS[3]. Immediate reporting and timely, thorough case investigations are not consistently conducted, partly due to inadequate resources and limited capacity to manage AEFI[3]. During the fiscal year 2070/71, 22 AEFI cases were reported from 14 districts, compared to 19 cases from 12 districts in the previous year. All reported cases were fully investigated, and causality assessments were conducted by the central AEFI committee. Of the total 22 cases, 18 were associated with the DPT HepB Hib vaccine and four with the oral polio vaccine. There were 12 deaths, all linked to the DPT HepB Hib vaccine[3].

In Province 1, Nepal 33 cases from BCG, 132 cases from DPT, 101 from OPV, 86 from PCV, 16 from IPV, 191 from Meseals/Rubella, 180 from Japanese Encephalitis had been recorded from fiscal year 2073/74 to 2075/76. (HMIS, Health Directorate)

WHO has developed Standard Operating Procedures for the investigation of AEFI and ensures the importance of its surveillance along with its effective management [4]. In Nepal, AEFI guide line developed in October 2003 and new AEFI committee established in December 2017[5].

To maintain and enhance public confidence in the national immunization program, health workers need to be knowledgeable about AEFI[2] and should always be prepared to address public concerns[1]. This study aimed to assess the level of knowledge among service providers regarding adverse events following immunization (AEFI), management practices, and factors associated with management preparedness, as well as to explore their needs, concerns, and challenges.

METHODOLOGY

A descriptive cross-sectional study design was adopted from different immunization centres which included District Hospital, Primary Health Care Center, Health Posts and Family Planning Association of Nepal of Sunsari district, Nepal. A total of 96 health workers were enrolled using simple random sampling technique to conduct the study using the lottery method from an established sampling frame, and data were collected using an interview technique.

A semi-structured questionnaire was adopted from a previous study [2] after permission was granted from the corresponding author. The questionnaire was modified based on the Standard Operating Procedures (SOP) given by the World Health Organization and guidelines on Immunization of Nepal. It was divided into 3 sections: Section A: questions related to socio-demographic characteristics: It consists of a total 6 items: age, sex, education, designation, work experiences and training on immunization, Section B: questions related to assessing knowledge on AEFI. It consists of 44 Yes/No questions which include meaning, types, signs and symptoms, serious AEFI and reporting method of AEFI, where 1 point for a correct answer and 0 points for a wrong answer were given during data entry; and section C: questions related to factors associated with AEFI management preparedness. It consists of 22 questions, including counselling to parents/guardians, perform ice conditioning, vaccine vial monitoring, check expiry date of vaccine, carry AEFIs kit box, perform shake test, etc. and were asked if they perform those activities always, sometimes or never. Also, it contained 1 observation checklist for availability of AEFI kit box containing all the articles including inj. adrenaline, inj. chlorpheniramine maleate, Normal Saline/Ringer Lactate, tab. Paracetamol, syringe, disposable syringe, scalp vein/butterfly cannula 24 guaze set, I/V drip set with cannula, cotton wool, adhesive tape and AEFI Reporting Forms.

Content validity of the instrument was obtained through review of literatures, consulted with guide, co-guides and other experts. The instrument was transmitted to Nepali language and back translation to English was done by respective subject experts. Before data collection, ethical clearance IRC board of BPKIHS (Ref. no. 067/076/077-IRC). Then,

permission from the Health Office, Sunsari was obtained (Ref. no. 389). Informed consent was taken from the participants and interview was conducted in private area in their working area. Instrument was pretested among 10% of study sample i.e. 9 samples before actual data collection. Necessary modifications such as sequence of the questions, modification in language were done. At first, descriptions of socio socio-demographic characteristics were done. Then, the score obtained on knowledge on AEFIs obtained by respondents were interpreted and grading was done of the overall score and converted into percentage. Knowledge was categorized as poor (<50%), fair (50-74%) and good (≥75%)[2]. Also, the factors associated with management preparedness were analyzed in descriptive aspect of always, sometimes and never and also interpreted from observation checklist of AEFIs Kit Box. The socio-demographic characteristics of the respondents included were age, gender, and professional education, designation, working experiences and training on immunization. The obtained data were edited, coded, and organized before entry into the computer software system. At first, master sheet was prepared and entered in MS Excel 2007. Data were transferred and analyzed by using SPSS version 11.5. Descriptive statistics like frequency, percentage, mean and standard deviation were used to describe the various socio-demographic variables, knowledge on AEFIs and analyze the factors associated with management preparedness. Mann-Whitney U Test and Kruskal-Wallis H Test were used to find the association between the socio-demographic data with knowledge score. The confidence interval was taken 95% at the level of significance 0.05.

RESULTS

Out of 96 respondents, 57.3% were of the age more than 36 years, and 59.40% were female. 100% of respondents had heard of Adverse Events Following Immunization (AEFI), and 63% of respondents had fair knowledge, 28% had good knowledge, and only 9% of the respondents had poor knowledge. Hundred percent of the respondents agreed that AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. Only 31.3% of the respondents recognised immunization surveillance events, and 44.7% wrongly acknowledged convulsion related reaction are not the types of AEFIs, and only 42.7% of the respondents recognised continuous bleeding from the injection site as a sign and symptom of AEFIs. 46.9% of the respondents always ask about any adverse event experienced after an immunization at the next immunization clinic visit. More than half (52.1%) of the respondents never take family history of any illness of parents before administration of vaccine to their child. 63.55% of the respondents never perform shake test of vaccine before immunization program. 16.7% of the respondents always and 11.5% sometimes use vaccine more than 3 days for outreach clinic. Out of forty health organizations visited, none of the immunization centre had AEFI kit Box for their regular immunization program. There was no significant association between any of the socio-demographic characteristics of respondent and knowledge on AEFI.

Knowledge on AEFIs

100% of respondents had heard of Adverse Events Following Immunization (AEFI). Regarding the sources of information, less than half (47.9%) got information from training, followed by 18.8% from a book.

Knowledge score on AEFIs

The majority (i.e., 63%) of respondents had fair knowledge (50-74% of total knowledge), and 28% had good knowledge (≥75% of total knowledge). Only 9% of the respondents had poor knowledge (<50% of total knowledge).

Table 1: Socio-demographic Characteristics of Respondents (n=96)

Demographic variables	Categories	Frequency(f)	Percent (%)
Age	≥36 yrs	55	57.3
	<36 yrs	41	42.7
Mean± SD =36.05± 9.87 (yrs)			
Sex	Female	57	59.4
	Male	39	40.6
Professional education	Upgraded ANM(MCHW)/Health education (VHW)	29	30.2
	ANM/CMA	40	41.7
	PCL. Nursing/HA	20	20.8
	BNS/B.Sc. Nursing/BPH	7	7.3
Designation	ANM/CMA	79	82.3
	SN/HA	17	17.7
Working Experiences			
Experience as health service provider	1 to 15 yrs	68	70.8
	16 to 30 yrs	28	29.2
Mean± SD=10.09 ± 7.56 (yrs)			
Experience on immunization	1 to 15 yrs	72	75
	16 to 30 yrs	24	25
Mean± SD =8.88± 7.63 (yrs)			
Training received			
Training on immunization	Yes	50	52.1
	No	46	47.9
No. of times of training (n= 50)	1 to 3 times	42	84.0
	4 to 6 times	8	16.0
Duration of training	1 to 3 days	16	32.0
	4 to 6 days	34	68.0
Organizer of training	Health Office	42	84.0
	Health Directorate	8	16.0

Table 2: Aspects of Knowledge related to Adverse Events Following Immunization (n=96)

Aspects of knowledge	Frequency(n)	Percent
Aware about definition of AEFI	96	100.0
Types of AEFIs		
Vaccine product-related reactions	78	81.3
Convulsion related reactions	40	41.7
Vaccine quality defect-related reactions	77	80.2
Program error-related reactions	76	79.2
Immunization anxiety-related reactions	61	63.5
Coincidental events	89	92.7
Immunization surveillance events	30	31.3
Sign and symptoms of AEFIs		
Fever	79	82.3
Redness	77	80.2

Swelling at injection site			67	69.8
Pain			63	65.6
Hypotonic- hyporesponsive Episodes (HHE)			46	47.9
Screaming/persistent crying			53	55.2
Local or generalized edema			61	63.5
Skin reactions such as urticaria			87	90.6
Convulsion/seizure			86	89.6
Encephalopathy/encephalitis			51	53.1
Severe vomiting and diarrhea			50	52.1
Disability			48	50.0
Continuous bleeding from injection site			41	42.7
Serious AEFIs				
All deaths			38	39.6
All cases requiring hospitalization			56	58.3
Fever less than 38^0C			78	81.3
Disability			52	54.2
Redness around injection site			39	40.6
Cluster of two or more cases			46	47.9
Life threatening events			83	86.5
Encephalitis/encephalopathy before 14 days			55	57.3
All AEFIs must be reported			80	83.3
Serious AEFIs must be reported after 24 hours			73	76.0
Methods of reporting AEFIs				
Filling an adverse event reporting form			73	76.0
Reporting via telephone calls			79	82.3
Reporting by fax			50	52.1
Reporting by electronic mail			70	72.9
Just talking about it with colleagues			54	56.3
Monthly reported AEFIs				
All deaths			52	54.2
All injection site abscesses			51	53.1
All cases of BCG lymphadenitis			32	33.3
Fever less than 38^0C			76	79.2
Redness around injection site			41	42.7
All cases resulting in prolongation of an already	hospitalized case		60	62.5
Seizures or convulsion			87	90.6
AEFI reporting system flows from				
Local health center	Health office	Family Welfare Division	76	79.2

Table 3: Factors associated with AEFI management preparedness (n=96)

Associated Factors	Always n (%)	Sometimes n (%)	Never n (%)
Counsel the parents/guardians before and after administration of vaccine to their child	96(100)	-	-
Take history of any illness of child before administration of vaccine	96(100)	-	-
Take family history of any illness of parents before administration of vaccine to their child	8(8.30)	38(39.6)	50 (52.1)
Ask about any adverse event experienced after an immunization at the next immunization clinic	45(46.9)	41(42.7)	10 (10.4)
Ask the immunized children and their parents/guardians to wait for 30 minutes after vaccination to observe for AEFI	74(77.0)	16(16.7)	6 (6.3)
Perform ice conditioning before running immunization program	96(100)	-	-
Check vaccine vial monitor before administration of vaccine to child	96(100)	-	-
Check expiry date of vaccine before administration of vaccine to child	96(100)	-	-
Carry AEFI kit box for immunization program	-	-	96 (100)
Discard vaccine after 6 hours after reconstitution	96(100)	-	-
Perform shake test of vaccine before immunization program	17(17.7)	18(18.75)	61 (63.55)
Write date and time after reconstituting vaccine: BCG, MR and JE	96(100)	-	-
Use vaccine immersed in water for administration	-	-	96(100)
Apply antiseptic solution at vaccination site before administration	-	-	96(100)
Use one vaccine dissolver to dissolve other vaccine	-	-	96(100)
Mix same type of vaccine from one vial to another	-	-	96(100)
Keep vaccine dissolver to refrigerator 1-day prior immunization day	96(100)	-	-
Prick needle continuously on vaccine vial to draw vaccine during immunization period	-	-	96(100)
Use vaccine more than 3 days for outreach clinic	16(16.7)	11(11.5)	69 (71.8)
Use clean vaccine carrier containing 4 ice packs	96(100)	-	-
Check expiry date, dryness, break, crack and tear of plastic cover of syringe before its use	96(100)	-	-

Table 4: Association between Socio-demographic Characteristics and Knowledge (n=96)

Variables	N	Mean±SD	Median	Range	Mean Rank	p-value
Age(years)						
<36	41	28.24±4.88	27	14-37	46.74	0.533*
≥36	55	29.10±4.84	29	20-40	49.81	
Total	96	28.73±4.85	28	14-40		
Sex						
Male	39	28.38±5.39	29	14-40	52.46	0.178*
Female	57	28.29±4.44	28	18-37	45.79	
Total	96	28.73±4.85	28	14-40		
Professional Education						
Upgraded ANM(MCHW)/Health education (VHW)	29	29.13±3.77	28	23-35	51.50	0.463**
ANM/CMA	40	27.90±5.80	27	14-40	45.43	
PCL Nursing/HA	20	30.20±4.27	30.50	22-37	53.00	
BNS/B.Sc. Nursing/BPH	7	27.71±4.02	28	21-34	40.79	
Total	96	28.73±4.85	28	14-40		
Designation						
ANM/CMA	79	28.97±4.83	28	14-40	49.66	0.305*
SN/HA	17	27.64±4.94	28	18-37	43.12	
Total	96	28.73±4.85		14-40		
Experience as Health Service Provider						
1-15 years	68	28.54±5.07	28	14-40	47.60	0.563*
16-30 years	28	29.21±4.33	29	18-36	50.70	
Total	96	28.73±4.85	28	14-40		
Experience on Immunization						
1-15	72	28.70±4.99	28	14-40	48.35	0. 917*
16-30	24	28.83±4.49	27	18-36	48.94	
Total	96	28.73±4.85	28	14-40		
Training on Immunization						
Yes	50	28.58±4.89	28	14-37	47.92	0.813*
No	46	28.91±4.86	29	20-40	49.13	
Total	96	28.73±4.85	28	14-40		
Number of times of Training						
1-3	42	28.66±4.93	28	14-37	26.42	0.220*
4-6	8	28.12±4.94	28	18-35	20.69	
Total	50	28.58±4.89	28	14-37		
Duration of Training						

1-3 days	16	29.56±4.61	27.50	22 -36	29.16	0.143*
4-6 days	34	28.11±5.01	28	14-37	23.78	
Total	50	28.58±4.89	28	14-37		
Organizer of training						
Health Office	42	28.59±5.05	28	14-37	25.43	0.924*
Health Directorate	8	28.50±4.20	27.50	24-35	25.88	
Total	50	28.58±4.89	28	14-37		

**Mann Whitney U Test, **Kruskal Wallis H Test*

DISCUSSION

The study revealed that more than half (i.e. 57.3%) of the respondents were more than 36 years where age ranges from 21 to 59 years, and more than half (i.e. 59.40%) were female. 41.7% had received professional education of ANM/CMA, and only 7.3% had received professional education of BNS/B. Sc. Nursing/BPH. The majority (i.e. 82.3%) of the respondents were designated to the post of ANM/CMA. Third by fourth (i.e. 75%) of the respondents had experience on immunization ranging from 1-15 years. Out of 50 of the respondents who had received training on immunization, the majority (i.e. 84%) had received training 1-3 times. Similarly, two-thirds (68%) of the respondents' training duration was about 4-6 days, and 84% of the respondents' training was organized by the Health Office.

This study revealed that more than half (i.e. 52.1%) of the respondents had received training on immunization, which was similar to the study done in Lagos, where 52.45% respondents had received training.[2] Similarly, the study done in Albania found inconsistent results, where most of the respondents (i.e. 68.6%) had not received training. In the current study, 100% of the respondents had heard about AEFI which was inconsistent with the study where majority (i.e. 47.9%) of respondent's source of information regarding AEFI was training which was higher than the study conducted in Albania[6] where only 17.7% of the respondents got the knowledge from training[6] whereas in similar study done in Ghana, Africa, 0.4% of the respondent had never heard about AEFI[7].

The finding of this current study revealed that 100% of respondent correctly acknowledged the meaning of AEFI which was considerably higher than findings from a study conducted in Kenya, where only 27.8% of participants recognized that AEFI is a medical condition not limited solely to vaccination[8], and a study from Ghana, Africa, which reported that about half (i.e. 50.1%) of respondent had similar awareness[7]. Furthermore, the current study revealed that the majority (i.e. 82.3%) identified the symptoms of AEFI as fever, which was consistent with the study done in Lagos, where the majority (i.e. 84.8%) identified fever as a symptom of AEFI[2]. Also, in this study, less than half (47.9%) of the respondents identified hypotonic hyporesponsive episode (HHE), while more than half (i.e. 53.1%) recognized encephalopathy/encephalitis. This proportion, which was higher compared to the Lagos study, was only 37.8% identified HHE and only 25.6% of the respondents identified encephalopathy/encephalitis as a sign and symptom of AEFI[2]. In this study, the majority (76%) of the respondents identified that serious AEFI must be reported within 24 hours seems similar to the study conducted in Kenya, where 74.5% of the participants answered that investigation of an AEFI should be reported [8]. This study revealed that one third (i.e. 33.3%)of the respondents correctly recognized all cases of BCG lymphadenitis as monthly reported AEFI, whereas the majority (i.e. 79.2%) incorrectly acknowledged fever less than 38^0C as the monthly reportable AEFI, which was higher in the Lagos study, where more than half (i.e. 53.3%) of the respondents recognised BCG lymphadenitis, whereas, similar to the present study, the majority (i.e. 76.2%) of the respondents acknowledged fever less than 38^0C as not reportable AEFI.[2] Furthermore, in the present study found that the majority (i.e. 79.2%) of the respondents acknowledged the correct reporting system, which was higher than the study conducted in Lagos, 29% of the respondents were unsure about the reporting system of AEFI[2].

This study revealed that nearly two-thirds (i.e. 63%) of the respondents had fair knowledge, 28% had good knowledge, and the least (i.e. 9%) had poor knowledge regarding AEFI. In contrast, a study from Albania reported poor knowledge, a much higher proportion (i.e. 52.9%) and fair knowledge was 34.3%[6]. Similarly, a study conducted in Kenya showed that only 29.2% of the respondents had good knowledge of AEFI[8]. Another study conducted in Ghana was inconsistent, that 42.2% of the participants had low knowledge of AEFI[7].

The present study revealed that all the respondents (i.e. 100%) always counsel the parents/guardians before and after administration of the vaccine to their child, perform ice conditioning, check vaccine vial monitor before administration of vaccine to child, never mix same type of vaccine from one vial to another and prick needle continuously on vaccine vial to draw vaccine during immunization period. Furthermore, none of the respondents carry AEFI kit box for immunization program, less than half (i.e. 46.9%) of the respondents always ask about any previous adverse events at the next immunization clinic visit, more than half (i.e. 52.1%) of the respondents never take family history of any illness of parents before administration of vaccine to child, 63.55% of the respondents never perform shake test of vaccine before immunization program. 16.7% of the respondents always and 11.5% sometimes use the vaccine more than 3 days for the outreach clinic. Moreover, the majority (i.e. 77%) of the respondents always ask the immunized children and their parents/ guardians to wait for 30 minutes after vaccination to observe for AEFI. The findings of the present study showed that all the respondents (i.e. 100%) recorded batch no, date and time after reconstituting the vaccine and also always checked the expiry date of vaccine before administration of vaccine to child which showed higher than the finding from Kenya study where 76.3% of the respondent had practiced recording the vaccine batch number and expiry date during vaccination[3]. This study revealed that 100% of the respondents always take history of any illness of child before administration of vaccine and only 8.30% of respondents always, 39.6% sometimes and more than half (i.e. 52.1%) never take family history of any illness of parents before administration of vaccine to their child which was dissimilar to study conducted in Pastoral Zone, Ethiopia revealed that majority (i.e. 83.5%) of respondent ruled out whether the child was contraindication or not to the vaccine before administration[9].

Furthermore, this study revealed that none of the visited organization had an AEFI Kitbox for their routine immunization services. However, during the period of data collection, the National Meseales-Rubella Campaign had been accomplished in Sunsari District from 16 February to 21 February and from that period Kitbox ware was provided to all the organization targeted to respective campaign, where it contained all the articles, including adrenaline, syringe, tab. Paracetamol, inj. Cefotaxime, Normal Saline/Ringer Lactate, disposable syringe, scalp vein/butterfly cannula 24 guaze set, I/V drip set with cannula, cotton wool and adhesive tape needed for management and reporting AEFI cases. Similarly, the study conducted in Kenya revealed that only 14.2% of the respondents had practice of having an anaphylactic pack containing adrenaline in the immunization room and 38.7% of respondents had available of AEFI reference guidelines materials at work station[8,] whereas another study in Pastoral Zone, Ethiopia, revealed that only 10.1% of the respondents had an anaphylactic pack at their service centre[9].

The present study revealed no significant association between age and knowledge score, which was found dissimilar to the study done in Alimosho Local Government Area, Lagos where younger age was significantly associated with a 0.029 p-value (i.e. <0.05)[2].

This study showed that there was no significant association between professional education and knowledge score, which was found dissimilar to the study conducted in Nairobi, Kenya, where the level of nursing education was significantly associated with knowledge score with a p-value of 0.022 (i.e. <0.05)[3].

This study showed that there was no significant association between training and knowledge score, which was found dissimilar to the study conducted in Nairobi, Kenya, where AEFI training was significantly associated with p-value <0.0001(i.e. <0.05)[6]. In another study done in Ghana, Africa, the number of AEFI trainings in past years was significantly associated with a p-value of 0.002(<0.05)[7].

This study showed that there was no significant association between the designation of the respondent and the knowledge score, which was found dissimilar to the study from Albania, which was statistically significant in total scoring between categories of health professionals with a p-value <0.001[6].

There were also no significant association between sex and experience of the respondents and knowledge score in the present study.

CONCLUSION

The study concludes that the health workers had proper management preparedness in Sunsari, Nepal. Almost two-thirds of the respondents had a fair knowledge score, and the majority had followed the guidelines to conduct the immunization program, but still lacked the availability of the AEFI management Kitbox, including articles for immediate management if an adverse effect occurs. No significant association was found between any demographic variables and knowledge score regarding AEFI, which may be attributed to the recent training held during the period of data collection for the National Meseales-Rubella Campaign. This study is cross-sectional in nature; thus, a further longitudinal study could be done in large scale, which would allow for more accurate observation of practices and support better planning and strengthening of AEFI preparedness and management.

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