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Original Research Article

Assessment of knowledge and experiences of adverse events following immunization among mothers of under-five children in a tertiary hospital of Arunachal Pradesh

Pepu Jini[1]*, Ngilyang Sunya[1], Rajon Jaishy[2], Mamum Kartek[1], Tilling Tani[1], Tam Tariang[1]

[1]Department of Pediatrics, Tomo Riba Institute of Health and Medical Sciences (TRIHMS), Naharlagun, Arunachal Pradesh, India
[2]Department of Psychiatry, Tomo Riba Institute of Health and Medical Sciences (TRIHMS), Naharlagun, Arunachal Pradesh, India

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***Correspondence:**
Dr. Pepu Jini,
E-mail: drpepujini@gmail.com

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ABSTRACT

Background: Since mothers are usually the primary decision-makers and caregivers for young children, their knowledge regarding immunization and AEFIs influence healthcare-seeking behaviour and completion of immunization schedules. In Arunachal Pradesh, the complete immunization rate is low and zero dose rate is high in under-five children. Hence, we aimed at assessing the knowledge and practices among mothers of under-five children about AEFIs.
Methods: Data was collected by interviewing the mothers of under-five children using a semi-structured questionnaire. Descriptive statistical analysis of the data was conducted and presented in frequencies and percentages.
Results: A total of 380 mothers were enrolled. Most of the mothers did not know what causes an AEFI but maximum of them were aware of atleast one form of AEFI. More than half of the mothers did not know that AEFI has to be reported. Mothers who were guided about AEFI by healthcare workers had the highest mean knowledge. There was no significant association between the socio-demographic characteristics with mother's knowledge about AEFI. Fever followed by pain/swelling was the commonest form of AEFI experienced. Vaccines given at 6, 10 and 14 weeks caused the maximum AEFI. Most of the mothers managed the AEFIs at home.
Conclusions: Understanding the knowledge and practices regarding AEFI among mothers helps to understand their health behaviour, especially preventive interventions like childhood vaccinations. This may help in training of healthcare workers and utilization of mass media for dissemination of AEFI information and clarification of misconceptions for better acceptance of vaccines among mothers.

Keywords: Adverse events, Arunachal Pradesh, Immunization, Under-five children

INTRODUCTION

Immunization is one of the most successful public health interventions, preventing an estimated 3.5-5 million deaths globally each year among children from vaccine-preventable diseases.[1] World Health Organization (WHO) defines an adverse event following immunization (AEFI) as "any untoward medical occurrence which follows immunization and does not necessarily have a causal relationship with the usage of the vaccine".[2] AEFIs may be minor, severe, serious, or coincidental and can result from vaccine reactions, immunization errors, anxiety-related responses, or unrelated health events.

Though AEFI surveillance has been in action in India since four decades, voluntary AEFI reporting is not robust due to parent unawareness, physician under training and cumbersome AEFI reporting procedure.[3] In Arunachal Pradesh, the proportion of fully immunized children aged 12 months to 23 months is 76.4% according to NFHS-5, which is much less than the national average.[4] Proportion of zero-dose children in Arunachal Pradesh is 13.4% according to WHO-UNICEF Estimates National Immunization Coverage (WUENIC), which is very high for a small state.[5]

Parental concerns like fear of potential adverse effects, concern for safety of new vaccines and misconceptions about vaccines can cause refusal of recommended vaccines.[6] Mothers are usually the primary decision-makers and caregivers for young children, particularly in low- and middle-income countries.[7,8] Their knowledge, attitudes, and practices (KAP) regarding AEFI strongly influence healthcare-seeking behaviour and completion of immunization schedules.

Arunachal Pradesh faces logistical challenges, difficult terrain, and limited access to tertiary care, which may contribute to underreporting. Data about nature of AEFI experienced, knowledge and perceptions of parents is lacking in the state. Also, keeping in view the high zero-dose children in the state and lower proportion of fully immunized children, we have attempted to probe the knowledge, experience and practices regarding adverse events following immunization among mothers of children up to five years of age.

The objectives of the study was to assess the existing knowledge, experiences and practices of mothers regarding AEFI, and also to determine their association with study participant characteristics.

METHODS

Study design and setting

This is a cross-sectional descriptive study based on pre-designed, semi-structured, interviewer administered questionnaire, performed in the Department of Pediatrics at Tomo Riba Institute of Health and Medical Sciences (TRIHMS), Naharlagun, Arunachal Pradesh, from January to June 2026. Ethical approval was obtained from the Institutional Ethics Committee.

Inclusion criteria

Study subjects were mothers of children upto 5 years of age visiting the Pediatric OPD during the study period.

Exclusion criteria

Mothers that consented to participate were included and those who did not consent were excluded.

Sample size calculation

As there was no study on the knowledge of AEFI in Arunachal, sample size was calculated using the Cochran's formula, $n=Z^2p(1-p)/e^2$, assuming a prevalence of 50% with an absolute allowable error of 5% at 95% confidence interval, to obtain the maximum sample size. This produced a sample size of about 380.

Data collection procedure

The objectives and nature of the study were explained to the mothers before enrolling them. Those who agreed and were willing to participate in the study were included and interviewed. Consent was obtained, and confidentiality of responses was assured at all stages. Participation was purely voluntary. Mothers were interviewed by sequential non-randomized technique until the desired sample size was reached. The information collected using the semi-structured tools were immediately entered into spreadsheet to ensure maximum response rate. The questionnaires included brief socio-demographic characteristics of the child and parents, knowledge questions like what is an AEFI, causes of AEFI, forms of AEFI, awareness on reporting of AEFI, perception regarding vaccination, experiences and action taken after AEFIs. The questionnaire included single response and multiple response questions. Scores were allotted with maximum total score of 12 and minimum score of zero.

Based on a similar study, the scores were then interpreted into ordinal categories as poor knowledge <50% (score of 0 to 5 out of 12), average knowledge 50-75% (score 6 to 8 out of 12), and good knowledge >75% (score >/=9 out of 12). On an average, it took 20-30 minutes to complete an interview, apply scores and enter into spreadsheet. The data was immediately checked for completeness and consistency.

Statistical analysis

Data obtained was entered into spreadsheet of Microsoft Excel and analyzed using SPSS version 22. Descriptive statistics were expressed as frequencies, percentages, mean with standard deviation and median with range. Associations between nonparametric categorical variables were explored using the Chi-square test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

There was a total of 380 participants (378 mothers and 2 fathers). two fathers were enrolled since the mothers of 2 study children were deceased.

Demographic characteristics

Most of the children were young infants up to 6 months of age (43.8%). There was almost equal number of boys and girls (1.11:1 ratio). Half (50.5%) of the participant

index children were first born and 97.5% were born institutionally.

Socio-demographic characteristics of mothers

Mean age of mothers were 29.56±5.48 years (SD); Median=29 years (range 18-47 years); n=378. Two participants whose mothers were deceased were excluded from mother-related analyses (Table 1).

Table 1: Socio-demographic characteristics of mothers.

Characteristics	Frequency, N (%)
Number of children	
1	173 (45.5)
2-3	171 (45)
≥4	36 (9.5)
Religion	
Christian	223 (58.7)
Hindu	67 (17.6)
Donyi Polo	64 (16.8)
Muslim	20 (5.3)
Buddhist	5 (1.3)
Sikh	1 (0.3)
Educational qualification of mother	
None	31 (8.2)
Primary	29 (7.7)
Middle	40 (10.6)
Secondary/Senior secondary	140 (37)
Graduate	96 (25.4)
Postgraduate/doctorate	42 (11.1)
Educational qualification of father	
None	29 (7.6)
Primary	20 (5.3)
Middle	35 (9.2)
Secondary/Senior secondary	117 (30.8)
Graduate	133 (35)
Postgraduate/doctorate	46 (12.1)
Parental Employment	
Mother employed	98 (26)
Father employed	239 (63.1)
Either parent employed	264 (70.2)
Both parents employed	71 (18.9)

Knowledge of AEFI

Total 97.1% of the mothers had only partial understanding of the concept of AEFI. 2.9% mothers had poor understanding of AEFI. None of the mothers had absolutely good understanding of AEFI. Awareness of specific causes of AEFI was limited: 68.7% of mothers could not correctly identify any cause (Table 2), and only 1.8% correctly identified more than one. Awareness of forms was better: 96.8% named at least one recognized form, though most (90.8%) could name only one or two (Table 3). 29.5% (n=112) mothers knew only 1 cause of AEFI, which was mostly being the chemicals in vaccine (20%). 6.1% mothers had idea about more than 2 AEFI forms or a serious AEFI. 3.2 % (n=12) mothers had no idea about any form of AEFI.

Table 2: Perceived causes of AEFI by mothers.

Causes of AEFI	Response, N (%)
Chemicals in vaccine	76 (20)
Inappropriate handling/infection (immunization error)	31 (8.2)
Fear/anxiety of vaccine	9 (2.4)
Coincidental	10 (2.6)
Can't say/don't know	261 (68.7)

Total response rate for causes of AEFI exceeds 100% since multiple responses were possible

Table 3: Knowledge of forms/manifestations of AEFI.

AEFI form identified	Frequency, N (%)
Fever	363 (95.5)
Pain/swelling	113 (29.7)
Weakness of limb/body	9 (2.4)
Continuous high pitch cry	9 (2.4)
Ulceration	5 (1.3)
Rash	4 (1.1)
Convulsions	4 (1.1)
Difficulty breathing	1 (0.3)
Sudden collapse	1 (0.3)

Percentages are of all 380 respondents; totals exceed 100% as respondents could select more than one form

Despite the poor understanding of the definition and causes of AEFI, the attitude towards immunization was positive in maximum respondents (99.5%). Two respondents (0.05%) had absolutely never gotten their child immunized for fear of "side effects" and discomfort to their children.

Total 12.6% (n=48) mothers had never been told about AEFI or ever received any guidance about AEFI. Healthcare workers (HCW) were the source of information about AEFI for 69.2%. Media or society (family, relatives, friends, neighbor) was the source of information about AEFI for 18.2% mothers. More than half of the mothers (51.8%) were not aware that AEFI has to be reported.

Total 79.2% mothers had average knowledge about AEFI. Knowledge score was poor in 18.7% mothers. Only 2.1% had good knowledge. Guidance source was the strongest correlate of overall knowledge (Table 4).

Source of AEFI guidance was strongly associated with knowledge score ($p<0.001$): mothers guided by healthcare workers had the highest mean knowledge score (6.89±0.82), followed by media/society (6.03±0.80), while those with no guidance scored lowest (2.04±1.09).

Awareness that AEFI should be reported was strongly associated with knowledge score (p<0.001): mothers aware of reporting had a higher mean score (6.95) than those unaware (5.36).

Table 4: Association between various socio-demographic characteristics with mother's knowledge of AEFI.

Participant characteristics	Poor, N (%)	Average, N (%)	Good, N (%)	P value (Chi-square)
Child's age group				
Up to 6 months	31 (18.7)	130 (78.3)	5 (3.0)	0.712
6-12 months	12 (18.2)	53 (80.3)	1 (1.5)	
>12 months-2 years	9 (13.4)	57 (85.1)	1 (1.5)	
2-5 years	19 (23.8)	60 (75.0)	1 (1.2)	
Child's gender				
Male	42 (21.0)	153 (76.5)	5 (2.5)	0.384
Female	29 (16.1)	148 (82.2)	3 (1.7)	
Religion				
Christian	47 (21.1)	172 (77.1)	4 (1.8)	0.148
Hindu	12 (17.9)	54 (80.6)	1 (1.5)	
Donyi Polo	8 (12.5)	55 (85.9)	1 (1.6)	
Muslim	2 (10.0)	17 (85.0)	1 (5.0)	
Buddhist	2 (40.0)	2 (40.0)	1 (20.0)	
Sikh	0 (0.0)	1 (100.0)	0 (0.0)	
Mother's age group (years)				
Upto 25	15 (18.1)	67 (80.7)	1 (1.2)	0.407
26-30	24 (15.7)	126 (82.4)	3 (2.0)	
31-35	20 (23.0)	66 (75.9)	1 (1.1)	
>35	12 (21.8)	40 (72.7)	3 (5.5)	
Mother's education				
None	10 (32.3)	21 (67.7)	0 (0.0)	0.090
Primary	9 (31.0)	20 (69.0)	0 (0.0)	
Middle	10 (25.0)	28 (70.0)	2 (5.0)	
Secondary/Senior secondary	25 (17.9)	112 (80.0)	3 (2.1)	
Graduate	11 (11.5)	84 (87.5)	1 (1.0)	
Postgraduate/doctorate	6 (14.3)	34 (81.0)	2 (4.8)	
Father's education				
None	6 (20.7)	22 (75.9)	1 (3.4)	0.549
Primary	7 (35.0)	13 (65)	0 (0.0)	
Middle	4 (11.4)	30 (85.7)	1 (2.9)	
Secondary/Senior secondary	26 (22.2)	88 (75.2)	3 (2.6)	
Graduate	23 (17.3)	108 (81.2)	2 (1.5)	
Postgraduate/doctorate	5 (10.9)	40 (87.0)	1 (2.2)	
Parental employment				
Mother employed	17 (17.3)	78 (79.6)	3 (3.1)	0.701
Father employed	39 (16.3)	193 (80.8)	7 (2.9)	0.118
Place of delivery				
Institutional	67 (18.1)	296 (79.8)	8 (2.2)	0.128
Home	4 (44.4)	5 (55.6)	0 (0.0)	
Source of information/guidance about AEFI				
None	48 (100.0)	0 (0.0)	0 (0.0)	<0.001
Media	1 (7.7)	12 (92.3)	0 (0.0)	
Society	19 (33.9)	37 (66.1)	0 (0.0)	
HCW	3 (1.1)	252 (95.8)	8 (3.0)	
Awareness about reporting of AEFI				
Yes	12 (6.6)	164 (89.6)	7 (3.8)	<0.001
No	59 (29.9)	137 (69.5)	1 (0.5)	

Experience of AEFI

AEFI was experienced at some point by 77.9% of index children Fever was the commonest (96.6%) AEFI experienced followed by pain and swelling at the injection site (18.9%) (Figure 1) and 20% reported more than one form. Only 4 mothers (1.4%) reported that they had experienced a serious AEFI.

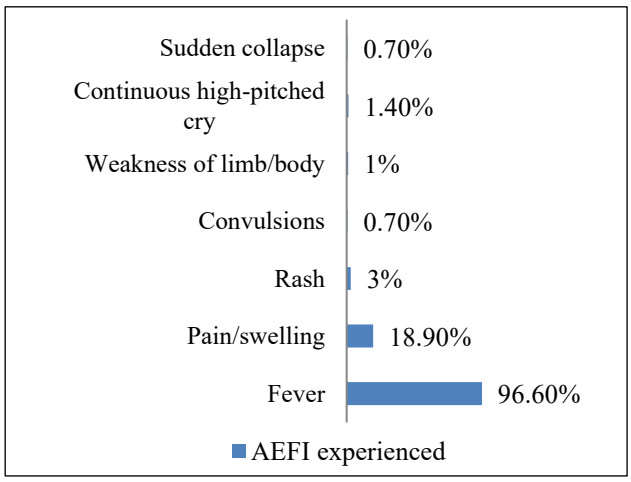

Figure 1: Forms of AEFI experienced.

34.7% mothers could not recount the vaccine schedule following which they had experienced AEFI (Figure 2). Vaccines received at 6 weeks, 10 weeks and 14 weeks were the commonest cause of AEFI.

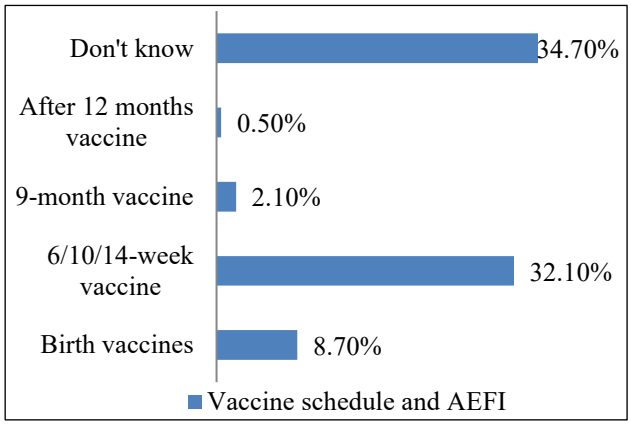

Figure 2: Vaccine schedule and AEFI experienced.

Most of the AEFI was experienced between 6 to 12 hours followed by within 6 hours of receipt of vaccine (Figure 3).

A statistically significant association was found between forms of AEFI experienced and onset of AEFI (Table 5).

Practice/action taken after AEFI

Among the mothers whose child experienced AEFI, the most common action was following the post vaccination instruction by HCW and managing the child at home (63.5%), followed by no action (23.3%) and hospital visit (9.8%). Visit to a private practitioner was practised by 3.4% mothers.

The form of AEFI experienced was significantly associated with the action taken ($p<0.001$): mothers whose child experienced pain/swelling most often consulted a healthcare worker and managed the child at home. All the serious AEFIs were managed at hospital.

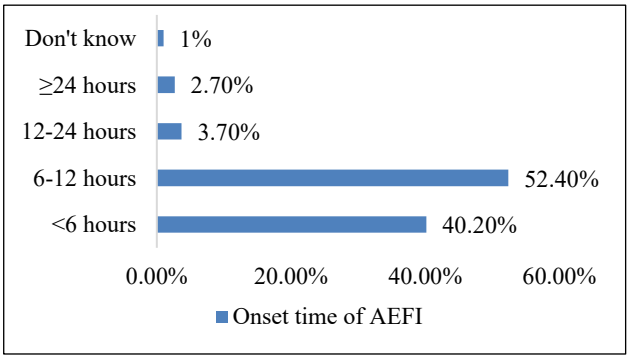

Figure 3: Onset time of AEFI.

Table 5: Associations within experience of AEFI.

Variable 1	Variable 2	Number	P value
Timing of causative vaccine (primary)	Form of AEFI experienced (primary)	296	0.952
Form of AEFI experienced (primary)	Onset time of AEFI	296	<0.001
Timing of causative vaccine (primary)	Onset time of AEFI	296	0.182

Associations are restricted to the primary (first-listed) form and timing code for respondents who reported experiencing AEFI (n=296), to allow valid cross-tabulation given the multiple-response nature of these items

DISCUSSION

Vaccines are given to individuals to protect against vaccine-preventable diseases, reduce the incidence and severity of diseases and save lives.[9,10] Vaccines are safe but not entirely free from adverse effects. Socio-cultural factors, poor knowledge and negative perception about childhood vaccines especially due to AEFIs experienced may have an impact on the attitude of mothers and immunization practices, who are usually the primary caregivers of young children. Hence, this study was conducted to assess this important component which affects childhood immunization keeping in view the low complete immunization and high zero dose rate of Arunachal Pradesh.

Nearly all the participants (99.5%) had their child immunized. This high number might be due to the fact that this was done on mothers visiting the OPD, which already indicate that they might have good health seeking behaviour. Maximum mothers had only partial understanding of the concept of AEFI, which is similar to that found in a community based study by Datta et al in Tripura, and much better than that found by Ngenna et al in South-east Nigeria.[11,6]

Total 96.8% mothers knew about atleast 2 forms of AEFI, which is much better as compared to the findings of Vanlalduhsaki et al in their study in Imphal, where only 40.3% respondents had heard about AEFI and knew about atleast one cause of AEFI.[12] Despite the poor understanding of the definition, causes and forms of AEFI, maximum mothers (99.5%) had a positive attitude about immunization, unlike the findings in a Nigerian study where majority (74%) nursing mothers had bad attitude towards immunization.[13] This indicates the success of immunization campaigns in India but contrasts the poor complete immunization among under-five children and high zero dose in Arunachal Pradesh.

Healthcare workers were the source of information about AEFI for 69.2% mothers which is similar to that found by Vanlalduhsaki et al, Joseph et al, and Angadi et al.[12,14,15] 87.4% mothers perceived that the information they had received was adequate. This is in contrast to the fact only 2.1% mothers had good knowledge about AEFI. Mothers guided by healthcare workers had the highest mean knowledge score (6.89±0.82), closely followed by media/society (6.03±0.80), while those with no guidance scored the lowest (2.04±1.09). This indicates the important role played by media and society in shaping the attitude towards immunization in mothers of young children.

AEFI was experienced by 77.9% of index children in our study which is very high as compared to the studies by Deoja et al and Sebastian et al.[16,17] But, only half of the mothers (51.8%) were aware that AEFIs were supposed to be reported. This indicates that though most of the mothers were informed and guided about AEFI by HCWs and maximum index children experienced an AEFI, there remained a gap between the impartation of AEFI information and the awareness for reporting. This might also indicate that even HCWs are poorly informed about the importance and procedures for AEFI reporting like that observed by Thomas et al.[3]

We found that fever (96.6%) was the commonest AEFI followed by pain and swelling at the injection site (18.9%) which is similar to that found in studies from different parts of India.[12,17-21] Many population-based surveillance studies from China consistently report that more than 90% of AEFIs are mild, with fever and injection-site reactions being the most frequent.[22-25] A Brazilian study by Camargos et al also found that most reported events were non-serious, with fever, local pain, and swelling being the predominant manifestations.[26]

Serious AEFIs, such as seizures and anaphylaxis, occur rarely and are often not causally related to vaccination.[1,2] Enhanced surveillance systems in Australia and Canada have demonstrated very low rates of serious AEFIs, generally below 1 per 10,000 doses.[27-31] Only 1.4% mothers experienced a serious AEFI in our study. All of them were managed in hospital and had complete recovery. This contrasts the finding by Pagar et al in Maharashtra, where most reported AEFI cases were convulsions (68.64%) followed by fever (58.47%).[32] This might be because Pagar et al analysed the reported AEFIs and most of the non serious AEFIs go unreported in India which was reiterated by Thomas et al.[3] Even Adubi et al found high rates of serious AEFIs like convulsions (32%), paralysis (32%) and even death (2%) in their study in Nigeria.[13] Simon et al also found very high rates of seizures (febrile - 51.16% and afebrile - 9.3%) and death (9.3%) in their study from a metropolitan city in Maharashtra among reported AEFIs.[33] More than one form of AEFI was experienced by 20% children in our study similar to findings in a Nigerian study.[13]

We did not find any association between child's gender/age, the number of children, birth order of the index child, religion, mother's age or education, parental employment, place of delivery, and the knowledge level of the mother about AEFI, or the action taken after AEFI. Even Angadi et al did not find any association between the educational status of mothers and their immunization knowledge.[15] Similarly, Adubi et al and Datta et al did not find a significant association between child's age, gender of the child, religion, literacy status of father and birth order of child with knowledge about immunization and AEFI.[13,11] But, Datta et al found that social caste, literacy status of mother, occupation of parents and place of delivery had a significant association with mothers' knowledge about immunization and AEFIs.[11] In contrast to our findings, Joseph et al and Vanlalduhsaki et al found that religion, educational status of mothers and employment status of mothers significantly influenced their knowledge about immunization and the immunization status of their children.[14,12] Joseph et al also found that boys were more likely to be fully immunized than girls and immunization status of children decreased with increasing birth order.[14]

In a Brazilian study, pentavalent and DTP-containing vaccines were associated with most AEFIs.[26] According to surveillance of AEFI in Australia, 13vPCV was the commonest cause of AEFI in children <7 year, followed by pentavalent vaccine.[37] Although we could not ascertain the exact causative vaccine for AEFIs, but the schedule of the vaccines in our study which caused the most AEFI was the vaccines given at 6, 10 and 14 weeks (32.1%) in the national immunization schedule (NIS) of India, which indicates that probably pentavalent vaccines and/or PCV

caused the most AEFI in childhood vaccines upto 5 years of age.

Most of the AEFIs were experienced between 6-12 hours (52.4%) followed by within 6 hours (40.2%) of receipt of vaccine which is similar to that found by Vanlalduhsaki et al and Ogundele et al, who found that majority AEFIs were experienced within 6 hours and also Pagar et al who found that most AEFIs happened within 12 hours of vaccine administration.[12,34,32]

Most mothers followed the instructions by healthcare workers at the immunization clinic and managed their children with paracetamol and tepid sponging, similar to that found by Ogundele et al (53.7%).[34] Ogundele et al also found that 46.3% mothers reported that they went to a hospital. We found that only 9.8 % of children visited a hospital after experiencing AEFI which resonates with the low awareness for reporting of AEFI. 23.3% mothers did not take any action for an AEFI, which resolved on their own. This further reiterates that most AEFIs are usually minor and self limiting.[1,2]

The form of AEFI experienced was significantly associated with the action taken ($p<0.001$) in our study, with mothers whose children experienced pain/swelling most often consulted a healthcare worker and managed the child at home. All the serious AEFIs (convulsions and sudden collapse), were managed at a hospital in our study which indicate the general awareness and good health seeking behaviour of the people.

This hospital-based study might not reflect the experiences, knowledge and practices of mothers regarding AEFI in the community setting. This is the limitations of this study.

CONCLUSION

Our study demonstrates that socio-demographic and cultural characteristics of mothers in this part of Arunachal Pradesh does not influence their knowledge and practices about immunization and AEFIs. Our study also reaffirms that adverse events following immunization among children up to five years of age are predominantly mild, short-lived, and manageable. Our study mirrors the WHO guidelines and global evidence that strongly support the safety of routine childhood vaccines. The role of society and media in influencing the health knowledge and attitudes of mothers should not be undermined. Healthcare providers should train about AEFIs, and practice to impart correct, complete and timely information to parents and caregivers during routine immunization.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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