### Challenges and solutions of immunization safety surveillance in Assosa Zone, Ethiopia: Mixed methods

Muluken Asres, Addis Ababa, Ethiopia, TMM Maja, UNISA, South Africa

#### **Abstract**

**Background**: Adverse Events Following Immunizations (AEFIs) reporting has increased over the past sixteen years worldwide, and requires strengthening in majority of Low Middle-Income Countries (LMICs) including Ethiopia. Additional efforts are needed to ensure and improve data quality, AEFI reporting and surveillance of immunisation safety in every country. Immunisation Safety Surveillance (ISS) is vital to identify AEFIs.

**Objective:** to assess challenges and solutions of immunisation safety surveillance in Assosa zone, Ethiopia,

**Methods**: Health facility based parallel convergent quantitative and qualitative data collected from 300 and nine respondents respectively.

**Result:** Only 14 (4.7%) respondents had ever reported AEFI case to a higher level and 69 (23%) ever treated it. All the zone and woreda level experts mentioned the performance related immunization safety surveillance is very minimal. The major challenges stated by respondents were; in-availability or denial of AEFI case presence (60%), no clarity on how to do immunisation safety surveillance (22%), no standard reporting forms (20.7%), thinking AEFI is mild problem which could resolve by itself or care takers could manage it at home (14.6%), there is no road and electricity access (9.3%), and health care providers has the ability to treat the case at health facility level (8.3%). Similarly, the in-depth interview participants mentioned that the performance related to immunisation safety surveillance was minimal due to poor infrastructure, lack of adequate information about AEFI, absence of proper AEFI reporting system; no training for AEFI, community members are not informed to report AEFI and experience of home treatment for mild cases. A total of 40 possible solutions to improve AEFI surveillance were proposed from one time to 185 times. The first five top solutions were; Providing training for health care workers (185), Sharing information or Create Awareness (129), Provide training for Health Development Armies or involve HDAs (100), Strengthening supervision (76), and Avail supplies (drugs, manpower, kits) for AEFI reporting (75)

**Conclusion**: the major obstacles for immunization safety surveillance were; lack of clarity on how to report, lack of attention from higher bodies, lack of ownership for the work and unavailability of reporting formats. The responsible bodies need to solve the existing challenges in line with the proposed solutions.

# **Background**

The population attention has been progressively shifted from the benefit of the vaccine to the safety of the vaccine following the dramatic progresses in immunisation coverage and the considerable drops in VPDs (Gattás, Braga, Koike, Lucchesi, Oliveira, Piorelli, Queiroz & Precioso 2018:2). As compared to the magnitude of the problems vaccines effectively protect, rare Adverse Events Following Immunisation (AEFIs) obtain unequal public and media focus because of the clear sequential probably coincidental occurrence of adverse events but often not due to vaccines (Singh et al 2017:1). AEFI refers to “any undesirable medical occurrence following vaccination and which does not essentially have a cause-and-effect association with the utilisation of the vaccine’’ (Sebastian, Gurumurthy, Ravi & Ramesh 2019:1).

According to Bok (2014:4), vaccines pre-licensure trials are often very small to trace rare occurrences and special populations may be insufficiently represented, thus immunisation safety surveillance (ISS) is vital to identify adverse events following immunisations (AEFIs). Masuka and Khoza (2019:2) refer to vaccine or immunisation safety surveillance as a strategy for safeguarding safety of immunisation through tracing, reporting, investigating and responding to AEFIs.

AEFI reporting has improved for the past 16 years globally, but needs reinforcing in most of Low-Middle-Income-countries (LMICs) including Ethiopia. Extra energies highlighted by Lei, Balakrishnan, Gidudu and Zuber (2018:1577) are needed to guarantee and enhance data quality, AEFI reporting and surveillance of immunisation care in each country. AEFIs are well known, however, health care providers do not know much about how to identify or report them. Reporting AEFIs is important in recognising the occurrence of rare events for new vaccines, which may not be known during clinical trials, or to monitor the rates of such events for well-established vaccines. Poor knowledge of AEFI among health care workers often results in many cases of AEFI going unreported and unaddressed, which may undermine confidence (Ogunyemi & Odusanya 2016:80).

A challenge refers to the condition of being confronted with something that requires excess mental or physical energy, in order to be conducted fruitfully and hence confronts an individual's capacity. Challenges in the context of this study, entail barriers or problems that impacted negatively on immunisation safety surveillance (Cambridge English Dictionary 2020).

Ogunyemi and Odusanya (2016:82) primary health care worker knowledge and reporting practices on AEFI in Alimosho, Lagos survey result clarifies the major common perceived challenges to not reporting AEFIs are not taking the event as connected to immunisation (56.1%) and inability to find AEFI reporting form (50.6%) whereas the least perceived barrier to reporting AEFIs was lack of time (48.2%).

The researcher has been working in the CORE Group Polio project for the last 10 years overseeing the polio campaign, routine immunisation and surveillance activities, and have observed the immunisation coverage in the country with large immunisation dropout rate which could be attributed to inadequate immunisation safety surveillance. Despite its significance, immunisation safety surveillance is very low in Ethiopia (FMoH Ethiopia 2015:48). In this relation, the Federal Ministry of Health of Ethiopia (FMoH) warned in a letter dated 5 February 2018 about the weak immunisation AEFI safety surveillance at ground level, and that it affected routine immunisation coverage (Worku 2018). It also became evident that there have been AEFI cases due to any of the five causes, since the immunisation programme was implemented (WHO 2016:13). Furthermore, no information or study was done which addressed the following problems; Why are AEFI cases not reported by the primary Health Care Providers (HCPs)? What seems to be the overall status of immunisation safety surveillance? What ground level challenges hinder health care providers to implementing AEFI surveillance in Assosa Zone? What will be the local level possible solutions to improve immunization safety surveillance/ AEFI surveillance?

Furthermore, in Ethiopia in 1980 the expanded programme on immunisation (EPI) was started with the aim of 10% coverage increment yearly. Although, the achievement in the first 20 years was extremely minimal but during the 1990s, encouraging achievements were obtained through universal child immunisation (FMOH Ethiopia 2015: viii). However, health care providers’ challenges related to immunisation safety surveillance was not assessed.

The outcome of this study could provide major insight on the challenges related to immunisation safety surveillance for decision makers. Based on this insight, the decision makers will take corrective action to strengthen immunisation safety surveillance. This in turn, will help to improve the weak immunisation performance and improve public trust on vaccines.

# **Purpose of the research**

The purpose of this research is to assess the challenges and solutions of immunisation safety surveillance in Assosa Zone, Ethiopia.

# **Methods**

Health facility based convergent parallel mixed method of quantitative and qualitative research design was employed for this study (Creswell 2018:12).

##  **Sample size for quantitative design**

The samples for the quantitative paradigm were Health Care providers (HCPs) working in hospitals and health centres as disease surveillance, immunisation, paediatric nurses and heads of facilities. In addition, randomly selected HEWs and out-patient department (OPD) nurses working in the health posts were included in the sample. Since the target population was small, Yamane 1967 formula, was used for the sample size calculation (Israel 2013:4), n=N/1+N (e) 2 where n is the sample size, N the population size, and e, level of precision. The total sample size for the quantitative approach was 300. In each health centre and hospital: there were four respondents (disease surveillance, immunisation and paediatric treatment focal persons and medical director) and in the health post level, 2 respondents (outpatient department nurse and health extension workers) all expected to have a mandate to contact for any AEFI related cases.

## **Sample size for qualitative design**

Purposive sampling was applied to select the research participants. The study focused on immunisation and safety surveillance, thus, HCPs working in the Zone and district health office serving as immunisation, safety surveillance and HMIS focal persons were purposely targeted. In Asosa Zone, all the districts were stratified in to two groups (near and distant), based on their distance from the zone town. One district was selected in each group. Two districts in the zone were part of the study. Therefore, the Asosa Zone and two districts were included and 3 participants from the zone and 6 (3 per district) from the districts were part of the study. In general, zone health departments and selected district health offices’ surveillance, immunisation and Health-Management-Information-System (HMIS) focal persons were included for the face-to-face interview. The sample size was decided based on the data saturation.

##  **Ethical considerations**

Ethical concerns were followed prior and during the process of this study to defend the rights of the participants. Written ethical approval was obtained from University of South Africa (UNISA) and Assosa Zone Health Department. These comprised the right to provide informed consent, dignity for the human being who has the right not to be harmed or abused, un-forced consent to take part in a specific portion of research, the right to privacy, and the right to confidentiality and/or anonymity usually summarised as the ethical principles of autonomy, justice, beneficence and non- maleficence (Saxena 2015:6-9).

# **Result and Discussion**

## **Socio demographic characteristics of quantitative study participants**

One hundred and seventy-three (57.7%) respondents were females and males were 127 (42.3%). The participants’ ages ranged from 19 years to 47 years. The mean age was 26.9 years with SD of 4.4 (95% CI: 22.5-31.3). The presence of two respondents with age 46 and 47 years influenced the data to be slightly positively skewed (skew: 1.019) and steep (Kurt: 2.281) as depicted in Figure 1. Most respondents, 206 (68.7%) had a diploma, 65 (21.7%) had a certificate and 29 (9.7%) had first degree in their level of education.

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**Figure 1 Age distribution of respondents (N=300)**

The largest study participants were from Asosa woreda with 97(32.3%) followed by Bambasi with 50 (16.7%) and Homosha with the least of 22 (7.3%). Refer to Figure 2.

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**Figure 2 Respondents’ distribution per assignment district (N=300)**

##  **Socio demographic characteristics of in-depth interview participants**

### Nine participants from two districts and Asosa Zone Health Department were included in this qualitative research design from a total of 19 HCPs. Three participants in each work discipline namely, Immunisation, Surveillance and HMIS were considered. The two districts were selected based on their distance from Asosa Zone town. The nearest district is Assosa town and Sherkole district, the furthest to the Zone town. In all the disciplines, the experts were permanently employed government staff. Refer to Table 1

**Table 1 Socio demographic characteristics of in-depth interview participants**

| **Respondent code**  | **Socio- demographic characteristics** |
| --- | --- |
| **Gender** | **Age** | **Education** | **Profession** | **Current position** | **Experience in years** |
| P1 | M | 30 | 2nd degree | MPH | Immunisation | 9 |
| P2 | F | 34 | 1st degree | Health Education | Surveillance | 15 |
| P3 | M | 28 | 1st degree | Statistics | HMIS | 6 |
| P4 | M | 36 | 1st degree | EHS | Immunisation | 11 |
| P5 | M | 34 | 1st degree | EHS | Surveillance | 14 |
| P6 | M | 24 | Diploma | IT | HMIS | 2.5 |
| P7 | M | 32 | 1st degree | Nurse | Immunisation | 13 |
| P8 | M | 27 | 1st degree | Health Education | Surveillance | 6 |
| P9 | F | 25 | Diploma | HIT | HMIS | 5 |

##  **Health Care Providers (HCPs) Knowledge, Perception and Practice (KPP) challenges to immunization safety surveillance**

In this study, 284 (94.7%) respondents had ever heard about AEFI but only 67 (22.3%) were able to define AEFI as per WHO standard definition. Furthermore, 137 (45.7%) were not informed that AEFI surveillance should be done in each health facility. Research in the USA comprised of 293 participants, physicians, pharmacists and nurses or nurse practitioners showed gaps to reporting comprised uncertain definitions of a reportable AEFI; lack of time due to other priorities than a report; and misunderstanding of whose responsibility it was to report. A study on gaps to HCPs’ reporting AEFI in four regions of Ghana found that the major usual hindrance was shortage of knowledge or training (25.2%) (Gidudu et al 2020:1).Reporting was associated with being advised to observe the exact events (87%); disregarding another reason for the event (81%); if the event was observed recurrently (71%) and if the events happened in susceptible patient groups such as infants, pregnant women or patients ≥ 65 years of age (44%) (Parrella 2014:26).

More than half the number of respondents, 157 (52.3%) strongly agreed and 18 (6%) agreed that to report AEFI will make vaccinator to develop guilt for causing injury. On the other hand, 22 (7.3%) respondents agreed with the perception that health care providers are not keen to report AEFI to the next higher level. A study on gaps to HCPs’ reporting AEFI in four regions of Ghana found that the major usual hindrances were fear of individual repercussions (44.1%) and not perceiving an AEFI was severely sufficient to report (22.2%) (Gidudu et al 2020:1). Another study done by Agarwal et al’s (2013:58) systematic reviews of 45 studies conducted in Europe, United Kingdom, Asia and USA identified most repeatedly attitudes that contributed to health care workers not reporting Adverse Drug Reactions (ADRs) were: negligence of what to report or negligence of a reporting system in 95% studies; fatigue in 77% studies; hesitancy in 72% studies; indifference and insecurity regarding causation in 67% studies; a perception that only harmless drugs are out into the market in 47% studies; and fear of likely involvement in lawsuits or scrutiny in 24%. AEFI surveillance system evaluation in Guruve district, Zimbabwe identified the major rationale for defaulting to report AEFIs comprised: HCPs’ fear of personal negative consequences and assuming that an adverse event was not severe enough to report (Constantine, Cremance, Juru, Gerald, Notion, Peter & Mufuta 2018:1).

The HCPs practice towards AEFI reporting showed that 219 (73%) had never observed sign or symptoms that resemble to AEFI (injection site swelling/ redness/ abscesses/ convulsion/ shock/ fever >38oC following immunisation, while 77 (25%) had observed. Only 14 (4.7%) respondents had ever reported to a higher level and 69 (23%) ever treated an AEFI case.

Furthermore, the majority of respondents; 269 (89.7%), 279 (93%) and 278 (92.3%) reported that they had no AEFI surveillance standard guidelines, no reporting forms and had never reported an AEFI case to a higher level, respectively. However, of the 15 respondents who had the standard guidelines, 9 (64.3%) described the guidelines as friendly, 4 (28.6%) somewhat friendly and 1 (7.1%) claimed not to know how to describe the guidelines. Almost all respondents agreed that there was neither non-governmental organisations nor partners who supported AEFI surveillance activities.

Other studies also identified that detecting, monitoring, responding and reporting AEFI remains of concern to manufacturers, regulators, health care providers, and the public (Graham et al 2012:4953). Unless the health system detected and reported it is not addressing the main objectives of immunization safety surveillance as stated Post-marketing Vaccine safety surveillance involves implementing specific pharmacovigilance plans that are “timely, efficient, sufficiently large and in place for the life of the vaccine” (Griffin et al 2009: s346).

##  **General challenges that hindered immunisation safety surveillance: quantitative section**

Both the quantitative and in-depth interview participants were asked an open-ended question as what challenges hindered immunization safety surveillance activities implementation. Of the total quantitative study participants 275 proposed 39 different challenges which further grouped in to 18. But 25 respondents said there was no challenge related to immunization safety surveillance. The major challenge was raised 180 times and the least was mentioned once. Some of the major raised challenges were; no AEFI case found 180 (60%), no clarity how to do immunization safety surveillance 66 (22%), no standard reporting form 62 (20.7%), the problem is mild which relieved by itself or care takers managed it at home 44 (14.6%), there was no road and electricity access 28 (9.3%) and health care provider able to treat the case at health facility level 22 (7.3%), as shown in Table 2.

Other similar study done by Gupta et al (2015:7) identified contributing variables for pharmacy vigilance underreporting in South India as: no payment, time shortage to report ADR, perception that ADR database will not be affected because of one unreported case, difficulty identifying whether an ADR occurred or not, lack of training, unfamiliarity with the ADR reporting form, unawareness of the rules and procedure for reporting.

**Table 2 Challenges that hindered immunisation safety surveillance (quantitative)**

| **Reasons/challenges** | **Freq**  | **%** | **Reasons/challenges** | **Freq**  | **%** |
| --- | --- | --- | --- | --- | --- |
| No case of AEFI | 180 | 60.0 | Lack of attention or follow up from responsible bodies  | 20 | 6.7 |
| No clear information or AEFI surveillance system | 66 | 22.0 | No training for AEFI separately or poor capacity to identify the problem | 17 | 5.7 |
| Absence of reporting format or other supplies | 62 | 20.7 | Community have no awareness of reporting AEFI | 10 | 3.3 |
| AEFI is a mild problem, it will resolve by itself or cases can be treated at home  | 44 | 14.6 | HWs not working properly at duty station | 4 | 1.3 |
| No road or electricity | 28 | 9.3 | Service provider’s fear of accountability | 4 | 1.3 |
| Indicated that there was no problem | 25 | 8.3 | No responsible person | 3 | 1 |
| Could not justify/raise issue or challenge | 25 | 8.3 | Work load | 3 | 1 |
| Able to treat the case easily at HF level | 22 | 7.3 | No documentation  | 3 | 1 |
| No network for telephone communication | 20 | 6.7 | Proper administration of the vaccine | 2 | 0.6 |

\*All are multiple responses

##  **Challenges of Immunization Safety Surveillance Implementation *(*qualitative section*)***

The ability of the participants to define AEFI as per the standard WHO definition was explored. Only three participants knew the concept and only one participant defining according to the standard AEFI definition. Participants responses are summarised as follows:

*“AEFI as unexpected medical occurrence following vaccination. It may be related to company, vaccine product related reaction and product quality. In addition to that AEFI is related to cold chain, professional safety or accidental complication following vaccine administration.” (P1)*

*“AEFI, I guess is the side effects after vaccination. Meaning fever, swelling, irritability, and there may be infection. The fever can be back and the infection may be because of error.” (P8)*

*“Adverse Events Following immunization is the English word when we changed it to Amharic; it is health problems happening in relation to immunization. There are five types, first it may be caused because of the vaccine, and second, it is not related to the vaccine but happens by chance what we call it coincidental and may occur because of fear of the injection.” (P7)*

Other similar study shows that inadequate knowledge level regarding vaccinations, and their inability to communicate effectively with mothers about immunization have been identified as some of the reason’s children are not vaccinated in Nigeria (Victoria et al 2017:2). A study by Michailova and Husted (2003) revealed that there are five reasons why employees are reluctant to share knowledge. The reasons include (i) the fear of decrease personal value, (ii) cost involved, (iii) uncertainty of how the receiver will use the shared knowledge, (iv) accepting and respecting a strong hierarchical and formal power, and (v) actual negative consequences of sharing knowledge with subordinates (Husted et al 2012:756). The general population receives conflicting information about the importance and safety of immunizations from a variety of sources including health care professionals and the media (Remple et al 2013: e516). The quality of healthcare services mainly depends on practitioners’ knowledge and technical skills (Ali 2014:81).

All the zone and woreda level experts mentioned the performance related immunization safety surveillance is very minimal. This could be because of challenges which hinder them. So, all the interviewees were asked to mention possible reasons or challenges which hinder them to manage AEFI surveillance. All the nine participants interviewed were mentioned different challenges however, lack of attention or follow up from higher levels, no training, absence of clear responsible department and unavailability of reporting formats were problems mentioned repeatedly. The in-depth interview participants response is summarized as follows;

R1 mentioned that *low awareness, low attention, unavailability of encouraging supports like guidelines and strategies, no routine requisition from higher levels other than during the new vaccine introduction* were the major challenges to conduct immunization safety surveillance.

R2 reported that the *first not to do the surveillance is the government did not give attention because largely, we are working on those cascaded from higher level. Based on that there is nothing reach to us related to AEFI surveillance. Poor health worker commitment because our professionals are negligence. There is training gaps. Lack of Information sharing since we had not the habit to share such problem has happened. There are no manuals, no standard checklist which show the component and used to monitor up to ground level.*

R3 reported that *in most of the time the tools what we had are not complete at the ground level to capture all the information related to AEFI. The other wide problem is related to data quality. No specific supervision is done because of resource shortage.*

R4 mentioned that *attention did no given to work on immunization safety surveillance, partner and government are not working with attention, reporting time bound has to be set, training is given but no wide awareness when to be reported and similarly the officer, the core process owner is not giving attention. Similar to others activities report whether the problem is available or not monthly or quarterly report has to be prepared.*

R5 said that *first there is no owner of the work which led it which is the first challenge, second capacity issue, there is no training, third the frontline workers had limited capacity to report it, fourth there is no guideline from top to bottom, fifth no reporting form and not known what able to receive and no clarity if case found for whom does it reported.*

While R6 reported *the Federal Ministry of Health of Ethiopia did not prepare separate format for AEFI surveillance like other District Health Information System (DHIS)*.

R7 mentioned that *HEWs do not took detailed training. They know the minor sign and symptoms which we gave them during on site orientation otherwise separate training was not given on it. No one asked regarding to AEFI such as those who come from Partner, Zone Health or Region Health no one asked and even not much included in the checklist. There is no partner working on this area. It seems an area which is ignored.*

Similarly, R8 reported that *the higher bodies (region, zone) did not ask related to AEFI surveillance. If they incorporate in their check list, I will do that. No sensitization given on it and there is lack of attention.*

##  **Solutions proposed to improve immunization safety surveillance**

The quantitative study respondents were asked to propose solutions to improve immunization safety surveillance in their respective areas. A total of 40 issues proposed as solution from one time to 185 times. The first ten top proposed solutions were; Providing training for HWs 185 (61.7%), Sharing information or Create Awareness 129 (43%), Provide training for Health Development Armies (HDAs) or involve HDAs 100 (33.3%), Strengthening supervision 76 (25.3%), Avail supplies (drugs, manpower, kits) for reporting 75 (25%), Avail separate formats 53 (17.7%), House to house surveillance or Strengthen the surveillance 44 (14.7%), Integration of the work with HEWs/HWs/ or Other stakeholders 35 (11.7%), Manual supported with training 33 (11%) and Give attention from top to bottom 25 (8.3%). Refer Table 3

On the other hand, the in-depth interview participants proposed solutionsfor better future achievement of immunization safety surveillance as follows;

* *A force full means or principle like AEFI surveillance to be done together with immunization, surveillance rather than connecting AEFI surveillance during only new vaccine introduction (R1).*
* *The PHEM has a weekly reporting system. It is done through telephone. But if they upgraded it in to online it may be more important to improve AEFI surveillance (R3).*
* *Avail an AEFI surveillance guideline in simple way which any one able understand (R5).*
* *It is possible to include one column for AEFI reporting in EPI or PHEM reporting template and remark it there (R2).*

These solutions are in line with other literatures such as, ‘’Human capacity development in low medium countries is an important priority in order to address multiple vaccine safety issues that can affect the performance of immunization programs. Improved capacity in terms of know-how should also be accompanied by the development of an infrastructure that supports ongoing monitoring of the safe use of vaccines (Calistus 2016:16; Patrick,Z et al 2009:705). The ability of organizations and individuals within them to share knowledge with each other, particularly organizational knowledge, is identified as one of the contributing factors to organizational competitiveness (Funmilola 2015:2). Sharing of knowledge helps individuals and organizations build up knowledge. This is because it allows them to discuss and deliberate on certain topics which can encourage the generation of new knowledge, Fernie, et al., 2003 (Faizuniah 2007:15). To reduce the occurrence of vaccine adverse events and maintain public confidence in vaccines, it is important to improve understanding of vaccine safety and thereby foster the development and use of safer vaccines (Lawal et al 2018:82). The importance of post-licensure vaccine safety monitoring cannot be understated as vaccines are given to mainly healthy individuals, most often children (Alberta et al 2016:6672). Job-related knowledge encompasses job related entities, such as operational thoughts, behaviors, standard operation procedures, organizational routines, and competitor and customer knowledge, as well as individuals’ insights and their past working experience which is relevant to the current job (Pangil 2012:351).

**Table 3 solutions to improve immunization safety surveillance**

| **Solution proposed**  | **Number** | **%** | **Solution proposed**  | **Number** | **%** |
| --- | --- | --- | --- | --- | --- |
| Provide training for HWs | 185 | 61.7 | Create Awareness | 129 | 43 |
| Provide training for HDAs or involve HDAs | 100 | 33.3 | Strengthening supervision | 76 | 25.3 |
| Avail supplies (drugs, manpower, kits) for reporting | 75 | 25 | Avail separate report format | 53 | 17.7 |
| House to House surveillance or strengthen the surveillance | 44 | 14.7 | Integration of the work with HEWs/HWs/ or other stakeholders | 35 | 11.7 |
| Manual supported training | 33 | 11 | Give attention from top to bottom | 25 | 8.3 |
| Create community Mobilization | 22 | 7.3 | Involve religious leaders and influential | 21 | 7 |
| Proper vaccine handling or keep cold chain | 18 | 6 | Incorporate AEFI surveillance with weekly reporting system | 17 | 5.7 |
| Follow up for those vaccinated children | 15 | 5 | Organize discussion forum among HEW and HW | 13 | 4.3 |
| Assign FP focal at Woreda level | 13 | 4.3 | Partner support | 13 | 4.3 |
| Avail motorcycle or means of transportation | 12 | 4 | Maintain functional refrigerator | 11 | 3.7 |
| Frequent evaluation and feedback | 11 | 3.7 | Organize committee for AEFI at the HC level | 11 | 3.7 |
| Enhance HWs/ HEWs commitment through motivation | 11 | 3.7 | Mechanism to motivate mothers | 10 | 3.3 |
| Give direction to do AEFI surveillance | 8 | 2.7 | Incorporate in the HF annual plan | 8 | 2.7 |
| Strengthen referral linkage | 6 | 2 | Give free service for AEFI case | 4 | 1.3 |
| Proper documentation | 4 |  | Allocate budget | 4 | 1.3 |
| Enhance HWs skill competency | 4 | 1.3 | Prepare comfortable job aid and leaf lets | 3 | 1 |
| Proper site and dose administration of the vaccine | 3 | 1 | Solar power | 3 | 1 |
| Establish accountability | 3 | 1 | Increase number of HEWs | 2 | 0.6 |
| Check VVM to avoid expired drug | 2 | 0.6 | Use local language for health education | 2 | 0.6 |
| Assess defaulters | 2 | 0.6 | Continuous assessment and experiment | 2 | 0.6 |
| Integration of EPI and PHEM for AEFI surveillance | 2 | 0.6 | Update for new vaccine when it arrives | 1 | 0.3 |
| Providing medication for the side effects | 1 | 0.3 | Properly identify the vaccine which cause AEFI | 1 | 0.3 |
| Use proper infection prevention | 1 | 0.3 | Water supply per HP | 1 | 0.3 |

##  **Integration of quantitative and qualitative data**

Both the quantitative and qualitative participants were asked what challenges hindered them from conducting immunisation safety surveillance activities. The major challenge was raised 180 times and the least was mentioned once. The major challenges proposed by the quantitative study groups were: no AEFI case was found, no clarity on how to do immunisation safety surveillance, no standard reporting form, the problem was mild which could resolve by itself or care takers managed it at home, there was no transportation access and respondents were able to treat the case at health facility level were the major issues raised. Similarly, all the nine participants interviewed mentioned almost similar challenges such as lack of awareness on AEFI, lack of attention, no follow up or guidance given from higher level, no supplies such as reporting format and guideline, poor commitment of health workers, lack of information sharing, immunisation safety surveillance has no specific and clear ownership at different levels (Zone, Woreda and Lower level) and no partner provided support on AEFI surveillance. Therefore, the challenges mentioned in both study groups synergized one with the other. Lack of clarity on how to report AEFI surveillance, lack of attention from higher bodies, lack of ownership for the work and no reporting format were mentioned by both groups as huge obstacles.

Parrela (2014:29) states that in Malaysia a qualitative study involving 16 community pharmacists the gaps identified on ADR reporting: not able to get an ADR, poor understanding for procedure of reporting, reporting procedure difficulty and absence of feedback from leadership. According to Tew et al’s (2016:1) study though under-reporting of AEFI may happen because of inability to identify an ADR, it has been known that doctors were not reporting AEFI even when they encountered and identified it in Kuala Lumpur Malaysia because of the participants were unclear for the presence of the countrywide reporting system in Malaysia (40%).

# **Conclusion and Recommendation**

The major challenges to do immunization safety surveillance were; no clarity how to do immunization safety surveillance, lack of attention from higher bodies, lack of ownership for the work, no standard reporting form. To combat these challenges; Providing training for HWs, involving the community, strengthening supervision, avail supplies for reporting, avail separate formats, house to house surveillance or strengthen the surveillance, integration of the work with HEWs/HWs/ or other stakeholders, manual supported training and due attention from top to bottom, were proposed. In general, all responsible government structures and partners need to plan, implement and evaluate for the implementation of these solutions.

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