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Adverse Events Following Immunization (AEFI) Surveillance System Evaluation, 2016-2020 Kumasi Metropolis

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Abstract: Even though the process of vaccine licensure is rigorous, vaccines meant to protect individuals and populations may result in Adverse Events Following Immunization (AEFIs). An AEFI, is any untoward medical occurrence that follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The AEFIs have the potential to derail a vaccination programme if not handled professionally. The WHO makes it mandatory for the Expanded Programme on Immunization to work with the Food and Drugs Authority to implement a robust AEFI surveillance system. This is to detect, correct, and prevent AEFIs caused by errors in vaccine preparation, handling, storage, or administration and to allay fears due to false alarms. This study aimed to evaluate the AEFI surveillance system of the Kumasi Metropolis to determine whether it was meeting its objective, describe its attributes, and assess its usefulness from 2016 to 2020. A descriptive cross-sectional design was used, based on the updated CDC guidelines for evaluating public health surveillance systems. A semi-structured questionnaire was used to collect data from health workers and caregivers within the Kumasi metropolis. Purposive sampling was adopted. Records were also reviewed. Excel pivot tables were used for analysis. In all, 21 health staff and 16 caregivers were interviewed. Knowledge among health workers and willingness to contribute to the system was high. All staff interviewed knew AEFI. The AEFI reporting forms were available. Between 2016 and 2020, 15 AEFI cases had been reported with no feedback officially received from the Technical Advisory Committee. More than 93% (15/16) of caregivers confirmed experiencing non-serious AEFIs in their children but never reported them. Knowledge among health workers was high, though the system was not meeting most of its objectives. The system was acceptable among health workers, unlike among caregivers. It was not sensitive enough, though stable, flexible, and representative. Since the system

failed to meet its objectives, it was not fully useful. We recommend that the Technical Advisory Committee sends prompt feedback on AEFIs. The case definition could also be reviewed to target AEFIs that may be of concern to caregivers only. Caregivers should be continuously educated on AEFIs.

Keywords: Adverse Events, Immunization, Kumasi, Surveillance System, Evaluation

1. INTRODUCTION

On a global scale, substantial advancements have been achieved in the realm of vaccine-preventable disease control. These milestones represent a testament to the effectiveness and dedication of vaccination programs around the world. Yet, it is imperative to acknowledge that the issue of immunization safety continues to be a topic of concern in numerous countries, with Ghana being no exception. The stringent procedures involved in vaccine licensure are designed to ensure the highest standards of safety and efficacy. However, it's important to recognize that even after licensure and widespread deployment, unforeseen reactions may still occur, as elucidated by the Epidemiology Unit and the Ministry of Health in Sri Lanka back in 2012. This underscores the ongoing need for vigilant monitoring and research to maintain and enhance the safety of vaccination programs worldwide.

According to the WHO, Adverse Events following Immunization (AEFI) “is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine”. Vaccines are meant to protect individuals and populations by preventing diseases. However, there has always been the likelihood of these vaccines resulting in AEFIs. The WHO classifies AEFIs into four broad categories; these categories are vaccine related, programmatic errors, coincidental and unknown (WHO, 2018). Thus, AEFIs could result from intrinsic vaccine components factors, errors that may be committed by programme staff or faulty equipment, or may be just a mere coincidence which could have occurred even in the absence of the vaccination, or one with unknown cause after investigation.

AEFIs take different forms to manifest, from mild to life threatening events (FDA & Ghana Health Service / Expanded Programme on Immunisation, 2014). The mild ones could be pain at site of injections, swelling or redness. Systemic AEFIs can include fever, anaphylactic shock, bleeding, convulsions, urticarial reactions, thrombocytopenia. Serious AEFIs are those that result in life threatening conditions, hospitalization, death or incapacitation (Malande et al., 2021). In general, AEFIs could occur immediately after vaccine administration, or later up to about 30 days after the administration of the vaccine (FDA & Ghana Health Service / Expanded Programme on Immunisation, 2014). These AEFIs, no doubt could be sources of serious concerns for vaccine recipients or their caretakers if not responded to. It has a potential of derailing efforts the vaccination programs.

Globally, 549 AEFI cases per 100,000 surviving infants are reported (Lei et al., 2018). It was reported in 2015 that 81 countries exceeded the threshold of 10 per 100,000 surviving infants. In the WHO Afro region, the reporting rate in 2015 was a 74 per 100,000 surviving infants, with only 10 countries (21%) crossing the threshold of 10 per 100,000 surviving infants (Lei et al., 2018). However, in Ghana, it is estimated that only 55% of AEFIs are reported, of which only 31.7% are actually reported formally, using the appropriate form. Ghana, according to a study in 2020, had a reporting rate of 1.56 per 100,000 surviving infants, lower than the WHO target of 10 (Gidudduaa et al., 2020).

For quality assurance purposes, WHO makes it mandatory for national Expanded Programme on Immunizations office to work in close collaboration with a regulatory agency to develop a surveillance system for AEFIs (WHO, 2021). Ghana has an existing surveillance system, which is a collaborative effort between EPI and Food and Drugs Authority (FDA), that seeks

to rapidly detect and report incidences of AEFI for investigations and further actions in order to safeguard the health of the population (FDA & Ghana Health Service / Expanded Programme on Immunisation, 2014).

According to Guidelines for AEFI surveillance in Ghana, BCG vaccine can produce mild AEFIs of pain, swelling or redness in up to 95% of recipients. Fever could also occur among 50% of recipients of pentavalent vaccines, whiles 5% of Measles vaccine recipients could experience rash as an AEFI (FDA & Ghana Health Service / Expanded Programme on Immunisation, 2014). The Kumasi Metropolitan Health Directorate expects to vaccinate 4% (Children under 1) of its population annually with routine vaccines. (Kumasi Metro Health Directorate, 2020). With this, and based on the AEFI guidelines, AEFIs could be occurring in huge numbers. The AEFI Surveillance would therefore be very beneficial to detect these and respond to them.

Timely reporting of safety information post vaccination is essential for the success of any vaccination program. In Ghana, AEFI reports start with the vaccine, or the caregiver if a child. Such reports are expected to be relayed to a health worker or volunteer in the community, then to the nearest health facility up the national level. At every level, feedback is given to the lower level and decisions are taken as to whether to do further investigations or not. In any circumstance, the report must be forwarded to the next level. A final decision on causality is taken by the Technical Advisory Committee, which is made up of experts. Feedback is then given to all stakeholders for further action to be taken, including suspension of a vaccine, changes in the dosages and route, or further training for staff (FDA & Ghana Health Service / Expanded Programme on Immunisation, 2014).

The stakeholders in the AEFI surveillance system includes the following: Caregivers of children receiving vaccines, Healthcare workers conducting or supervising vaccinations and reporting, AEFI focal persons at the facility, Metropolis and regional level, Clinicians who would be managing AEFI cases and the Food and Drugs Authority (FDA & Ghana Health Service / Expanded Programme on Immunisation, 2014). Though vaccines used in Ghana's Expanded Programme on Immunization are safe and certified, there are no such things as *perfect vaccines*. Vaccinations programmes are complex and may result in some AEFIs no matter how careful staff handle the programme. Safety data from clinical trials are mostly obtained from a smaller sample size (Singh & Metha, 2016). In recent times, *antivax* campaigners are doing so much to discredit vaccines and its safety (Armitage, 2021; Benoit & Mauldin, 2021)

In order to properly estimate the magnitude of AEFIs and also assure vaccine takers of the safety of vaccines, it is imperative to have a robust AEFI surveillance system to continuously detect any AEFI for management, and to take decisions with regard to changes in dosage, eligibility criteria and production. The AEFI surveillance system, in the Kumasi Metropolis has not undergone any evaluation since its inception, hence, this project in order to make informed decisions for policy makers.

AEFIs are common with vaccines and other biological agents. Though they are mostly mild and transient, they have the potential of derailing a vaccination programme if not handled professionally. For the success of vaccination programmes, every AEFI must be reported and investigated and feedback given to all stakeholders to allay their fears. To the extent that AEFI (fever for example) can occur among up to 50% of pertussis vaccine (FDA & Ghana Health Service / Expanded Programme on Immunisation, 2014) recipients means that AEFI surveillance should be of utmost importance in our public health discourse.

It is estimated that about 70% of AEFIs are unreported in Ghana (Gidudu et al., 2020). This means the reporting rate is far less than the WHO target of 10 per 100,000 surviving infants. The huge estimated proportion of unreported cases of AEFIs could be a source of misinformation for anti-vaccination campaigners. Since Ghana ranks low on AEFI reporting, it would be very important to evaluate the AEFI surveillance system with the view of offering recommendations for improvements.

The objectives of an Adverse Events Following Immunization (AEFI) surveillance system, as outlined by the World Health Organization (WHO) in 2021, encompass a multifaceted approach aimed at ensuring the safety and efficacy of vaccines. These objectives are as follows:

Firstly, the system's primary aim is to meticulously identify any issues related to vaccines that could potentially result in adverse reactions in recipients. This proactive approach seeks to preemptively address vaccine-related problems.

Secondly, the system strives to detect, rectify, and prevent errors in the immunization process caused by inaccuracies in vaccine preparation, handling, storage, or administration. This emphasis on accuracy is essential for maintaining the integrity of vaccination programs.

Furthermore, the surveillance system works to prevent the misattribution of coincidental adverse events following immunization, recognizing that some adverse events may have causes unrelated to the immunization itself. This helps to dispel unwarranted blame and maintain public confidence in immunization.

Additionally, the system is designed to promptly respond to concerns from parents and the community, thereby fostering trust and transparency in the immunization process.

Moreover, it aims to generate new hypotheses specific to vaccine reactions in the context of Ghana, contributing to a deeper understanding of vaccine safety in the local setting.

Finally, the system seeks to estimate the incidence of AEFIs within the local population, making comparisons to clinical trials and contributing to a more comprehensive evaluation of vaccine safety.

In the context of an evaluation, the objectives encompass a range of goals:

Firstly, the evaluation aims to determine whether the AEFI surveillance system in Kumasi effectively fulfills its stated objectives, thereby assessing its overall performance and impact.

Secondly, it seeks to provide a detailed description of the attributes of the AEFI surveillance system in the Kumasi Metropolis, shedding light on its specific characteristics and functioning.

Lastly, the evaluation assesses the practical utility of the AEFI surveillance system in Kumasi, gauging how well it serves its intended purpose and whether it aligns with the broader objectives of vaccine safety and public health.

2. MATERIALS AND METHODS

2.1 Study Area

Kumasi Metropolis is the capital of Ashanti region of Ghana, and the second largest city in Ghana. It lies about 300km from the national capital, Accra. It lies in the central part of Ghana with an estimated population of 1,069,876 which is estimated to be 18% of the entire Ashanti regional population. It shares boundaries with Suame, Tafo, Kwadaso, Oforikrom, Askowa Municipalities and Atwima Kwanwoma District. Kumasi has 70 health facilities, including four main government owned hospitals: Komfo Anokye Teaching Hospital, Manhyia District Hospital, Suntreso Government Hospital and Maternal and Child Health Hospital.

Vaccinations under the Expanded Programme on Immunization take place at the main facilities and at outreach sites in the 48 demarcated CHPS zones within the Metropolis. There are 10 sub metropolitan areas with the Metropolis. It is estimated that more than 42,795 children under one year would be vaccinated each year with various antigen doses**.**

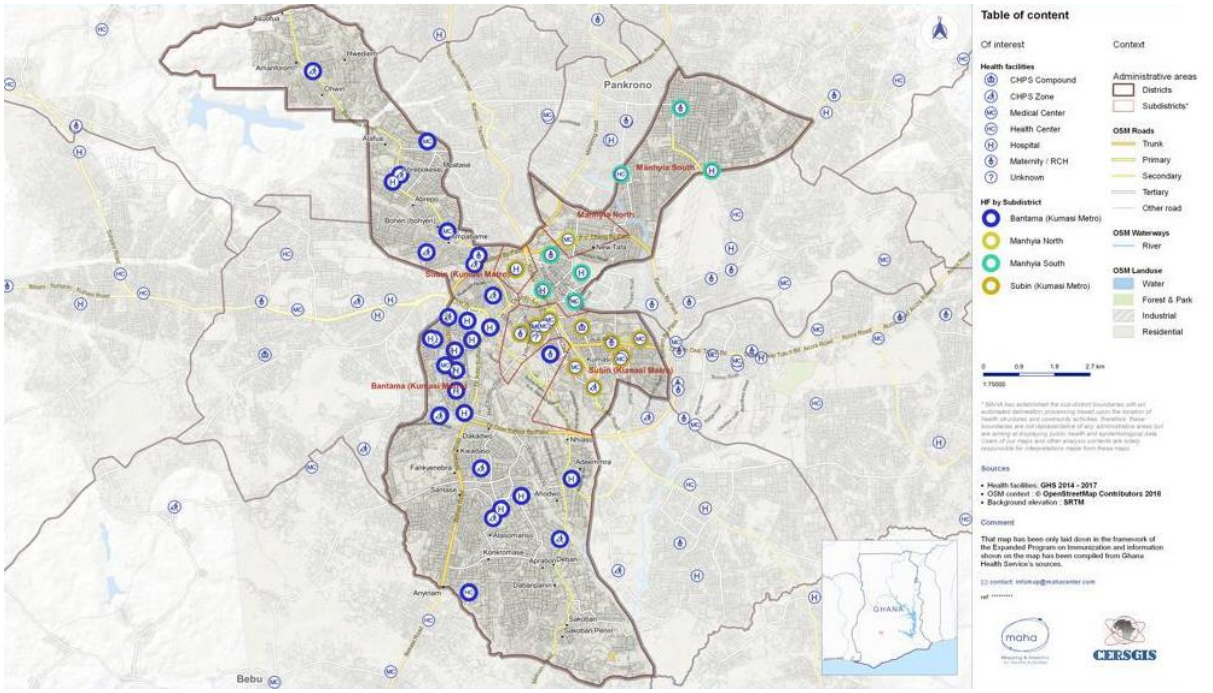

Figure 1: Map of Kumasi Metropolis

2.2 Study Design, Sampling and Data Collection Tool

Permission was sought from the Metropolitan Director of Health Services via the Ghana Field Epidemiology and Laboratory Training Programme (GFELTP) for this exercise. Verbal consent was sought from all participants prior to conducting an interview. Facility heads were also notified

A descriptive cross-sectional design was used for this evaluation in the Kumasi Metropolis. Records on AEFIs reported from the 2016-2020 (DHIMS and file copies) were also reviewed at the submetro and metropolitan levels.

Purposive sampling was used at the facility level to select health care workers, whiles simple random sampling was used at outreach sites to select caregivers. All three sub metros under the Kumasi Metropolis were selected. In all, 37 persons were interviewed, including 16 caregivers and 21 health care workers.

A semi-structured questionnaire was developed using the CDC updated guidelines for evaluating public health surveillance systems (Centers for Disease Control and Prevention, 2001) to collect qualitative and quantitative data from Ghana health service staff on AEFI Surveillance operations. Caregivers were also interviewed. These were used to assess the objectives, the attributes and systems usefulness. Records, including DHIMS data were reviewed to confirm previous reports of AEFIs as well as their timeliness.

2.3 Assessing the Attributes of the AEFI Surveillance System

The attributes assessed were based on the CDC updates guidelines on surveillance systems evaluation. These included timeliness, acceptability, usefulness, stability, data quality, flexibility, sensitivity and simplicity.

Simplicity: Staff were interviewed to see how easy or difficult it is in filling AEFI reporting and investigation forms and forwarding same to the next level. Also, the ability of staff to understand the case definition of AEFI was assessed.

Flexibility: To assess the AEFI surveillance system for flexibility, we evaluated how any changes such as changes in the reporting forms, channels of reporting and feedback path have affected the system in the past two years.

Acceptability: This was assessed based on the willingness of the staff and caregivers to participate, i.e. the likelihood of a caregiver reporting when an AEFI is detected and the willingness of staff to investigate and forward report to next level.

Sensitivity: The proportion of AEFIs experienced by caregivers or vaccinees that were reported or captured by the surveillance system.

Positive Predictive Value: This was to be assessed using the proportion of reported AEFIs that were attributable to vaccinations, after feedback from the Technical Advisory Committee.

Representativeness: This measured the extent to which the surveillance system covers the entire jurisdiction. It looks at the geographic coverage**.** This was determined by the proportion of reporting sites that reported during the period under review**.**

Stability: Availability of AEFI reporting forms, AEFI investigations forms and written guidelines was used to assess stability of the AEFI surveillance system of the Kumasi Metropolis.

Timeliness: The proportions of AEFI reports that are forwarded to the next level within the stipulated timelines was used to evaluate the timeliness of the system.

Data Quality: This was evaluated based on the completeness of filled forms, consistency and accuracy.

Usefulness: To evaluate for usefulness, the system was assessed based on how it was meeting its objective. Actions taken by the local authorities after an AEFI report, including staff retraining, changes in roles, upgrading of cold chain equipment was also used in assessing the usefulness of the system. The proportion of reports for which feedback had been received was assessed for usefulness.

2.4 Data Analysis

Data collected was entered into an excel spreadsheet. It was cleaned and validated. Analysis was conducted using Excel 2016 pivot tables, and results presented in frequencies, proportions, percentages and graphs**.** Qualitative data was analyzed based on the thematic areas through observations and descriptive content analysis.

3. RESULTS

3.1 Characteristics of respondents

A total of 37 stakeholders were selected based on convenience (availability and willingness to participate). These included 21 health workers and16 parents and/or guardians with children under 5 years. The median years of service among the healthcare workers was approximately 4 years, ranging from 1-30 (Table 1).

Table 1:Background characteristics of respondents, Kumasi Metro 2021

	Sex of Health Worker		
Category of Persons interviewed	**Female**	**Male**	**Total**
Community Health Nurse	4	0	4
Disease Control Officer	5	2	7
Nutrition Officer	2	0	2
Pharmacist	1	1	2

Public Health Nurse	3	0	3
Prescriber	3	0	3
Caregivers/Parents	15	1	16
Grand Total	**18**	**3**	**37**

3.2 Components of AEFI Surveillance

The AEFI surveillance system is passive. Caregivers and vaccine recipients are expected to report any AEFI to the nearest health facility. The case definition of AEFI at the time of the study was "*is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine"* (WHO, 2018) . The population under surveillance is children under 5, their caregivers and adults who receive vaccinations through EPI.

Health facilities are expected to do further investigations for serious AEFIs such as death, hospitalization or disability. Such reports together with non-serious AEFIs are then submitted from the municipality through the region to the national officers and FDA, as depicted in Figure 1. The two forms operational in the surveillance system includes AEFI case-based reporting forms and serious AEFI reporting form. Ideally, the submetros should analyse their reports to see how the AEFIs occurred. However, there was no evidence of AEFI data analysis in the metropolis during the period under review.

Any suspected AEFI is to be reported whenever they occur. AEFI focal persons fill forms on any suspected case and then forward copies of forms to the Metropolitan office for further action. On every Monday, the aggregated data from the previous records are reported through the weekly IDSR reports through the web based DHIMS. Computers and internet are used at the sub metro facility levels for the surveillance operations. A case is often given treatment while waiting for feedback from the Technical Advisory Committee.

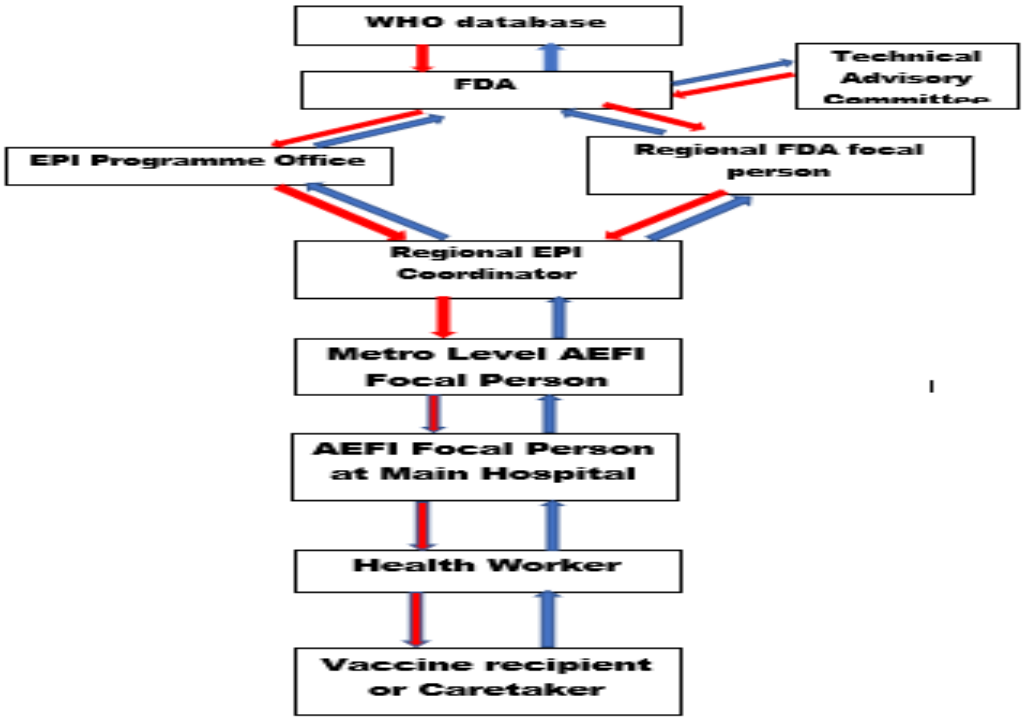

Figure 2: Route of reporting AEFIs in the Kumasi Metropolis

3.3 Knowledge

All 21-health staff interviewed were knowledgeable on AEFI case identification and detecting. All staff interviewed were able to describe what an AEFI was and were able to list at least two signs and symptoms of an AEFI. However, 28% (6/21) of them could not quote the standard case definition. They were aware that an AEFI reporting forms needed to be filled by an AEFI focal person, in order to complete the reporting. More than 57% (12/21) of them have been trained in AEFIs in the last 6 months prior to data collection.

3.4 AEFI Case Detection

The standard case definition for AEFI "*is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine"* (WHO, 2018). Based on this definition, cases were detected.

Illustrated in Figure 3, a noticeable decline in reported cases emerges between the years 2018 and 2020. Strikingly, throughout the entirety of 2020, not a single Adverse Events Following Immunization (AEFI) case found its way into the records from the Kumasi Metropolis. This encouraging trend suggests the effectiveness of public health initiatives and vaccination campaigns, underscoring the significance of safeguarding community well-being through preventive measures and awareness. It is a testament to the collective efforts of healthcare professionals and the community at large in maintaining a resilient defense against vaccine-related adverse events.

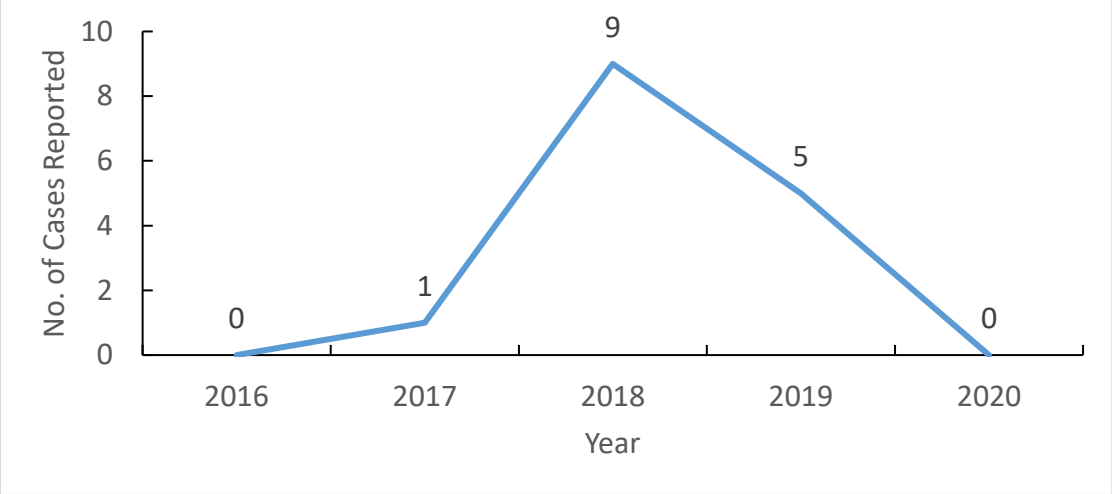

Figure 3: Reported AEFI cases in the Kumasi Metropolis, 2016-2020

1.4 System Attributes

Simplicity

The route of reporting starts from the caregiver or the vaccine recipients, through the various levels of the health systems and finally to the FDA, with copies to WHO as depicted in the Figure 1. However, in the Kumasi Metropolis, reports are only sent to the regional EPI coordinator who is expected to send copies to the FDA. Out of the 21 health care workers interviewed, 17 of them said they ever filled the AEFI form and they proved their ability to use the case definitions to detect cases. Of this number, only 1(5%) said it was difficult to fill the AEFI reporting form. The system therefore scored high in simplicity since about 95% of health workers interviewed said they were comfortable filling the form. Besides, the flow chart was simple and straight forward for reporting.

Flexibility

The AEFI surveillance was flexible. In recent times, there has been modifications of the reporting form to include pregnancy and lactation status for females. Also, the ages have been expanded to include people above 5 years. These changes over the period have not interrupted the operations of the system in meeting its objectives. All the Disease control officers and community health Nurses interviewed indicated filling the form was not difficult, even though you needed data from at least 2 sources before completing one form.

Acceptability

Among the caregivers, acceptability was low with majority 92% (15/16) of them never reporting non-serious AEFIs in their children such as fever, swelling and pain experienced. However, among the health workers, acceptability was high as all 71 facilities or reporting sites report AEFIs weekly through the IDSR weekly report and also through the immunization monthly reports, including zero reporting. All health staff identified the Disease Control Officer as the officer responsible for coordinating AEFI reports and were willing to refer reported cases to such officers whenever they encountered any.

Sensitivity

Out of the 93% (15/16) of the care givers who reported experiencing non-serious AEFIs, none of them reported same to the healthcare workers. This meant that the surveillance was unable to capture a lot of AEFI cases.

Positive Predictive Value: This could not be assessed since the metropolis did not receive any feedback during the period under review.

Representativeness

All reporting sites reported through the IDSR weekly reports and monthly immunization reports. The 71 reporting sites for monthly immunization reports and reporting rate ranged from 94.6% (67/71) in 2017 to 94.9% in 2020, according to data from DHIMS, the electronic report platform.

Stability

The EPI coordinators in the various sub metropolis serve as the focal persons for AEFI reporting. All facilities visited had AEFI reporting forms available during the visit. Computers and internet connectivity for DHIMS reporting were available during the period. According to the staff interviewed, there has not been a time where the AEFI surveillance system had ceased to operate as a result of lack of resources. It has successfully been integrated into IDSR weekly reporting, and also monthly EPI reporting. To that extent, the AEFI surveillance system was stable though there were no earmarked funds for it.

Timeliness

The timelines for reporting through the IDSR weekly are by 5.00 pm of every Monday. All reporting sites were expected to report first through the IDSR weekly reporting format and then monthly through the monthly immunization reports. As depicted in Table 2, apart from 2016, the system met the timeliness threshold of above 80%, using the weekly IDSR reporting.

Table 2: Timeliness of IDSR weekly reporting, including AEFIs in the Kumasi 2016-2020

Year	Timeliness Score (%)	No of Facilities Expected to report*
2016	70	53
2017	94.6	55
2018	92.3	62
2019	88.8	70
2020	94.9	71

** Each facility was expected to submit at least 52 reports per year.*

Data Quality

Data quality was high, with 80% (8/10) data completeness and accuracy. This was so because most of the vital information were picked from the maternal and child health record book (MCHRB). However, gaps identified included outcome, complete traceable address.

3. 6 Level of Usefulness

No feedback was received from the Technical Advisory Committee for the cases reported to them. There was no record observed of any decision taken or any changes made due to the reported cases of the AEFIs in the past 5 years within the metropolis. However, mere attention given by health staff when AEFIs were reported sought to assure the general public of vaccine safety. That is, health workers follow up on reported AEFIs and offer treatment for the AEFIs without upfront payment by caregivers, and this makes caregivers comfortable.

4. DISCUSSION

The flow of reporting for the AEFI surveillance system for Kumasi was similar to other systems (Ghana Health Service /Ministry Of Health, 2020) . All reportable cases were to be reported from the facility levels through the sub metropolis and to the metropolitan levels to the region. This does not present any ambiguity at all, and staff were conversant with the flow. All routine service reports are reported through similar routes. The high knowledge level of staff on AEFI case definitions could be attributable to recent trainings on immunizations for staff in the metropolis. This satisfactory knowledge conformed to what pertained in Zimbabwe (Zvanaka et al., 2017; Mutata et al., 2018).

The study's examination of the acceptability of the AEFI (Adverse Events Following Immunization) surveillance system within the Kumasi metropolis offered intriguing insights into the perspectives of healthcare professionals and caregivers. Among healthcare workers, there was a prevailing sense of duty and responsibility towards the AEFI surveillance system. They willingly and actively participated, considering it an integral part of their healthcare practice. For them, it wasn't merely an additional task but a vital element of ensuring public health and safety. Their commitment reflected a deep-seated dedication to their profession and the well-being of the community they served.

Conversely, the caregivers exhibited a different attitude, particularly concerning non-serious AEFIs. The majority of caregivers appeared to lack enthusiasm when it came to reporting such events. This reluctance seemed to stem from a variety of factors, including misconceptions, fear of causing undue alarm, or simply not perceiving non-serious AEFIs as significant. Their hesitance in reporting indirectly contributed to the underreporting of these events, despite the healthcare workers' best efforts.

This dynamic interaction between healthcare workers and caregivers in the AEFI surveillance system underscores the need for a comprehensive approach to bridge the gap in reporting adverse events. It may involve educational campaigns to clarify the importance of reporting all AEFIs, as well as strategies to foster a sense of shared responsibility between healthcare

professionals and caregivers. Strengthening the collaboration and communication between these two groups can ultimately enhance the overall effectiveness of the AEFI surveillance system and, in turn, promote the safety of immunization practices in the Kumasi metropolis.

It was not surprising that all caregivers reported that their children experienced non-serious AEFIs, given that it has been documented that minor AEFIs of fever, pain could occur among 95% of vaccinated individuals(FDA & Ghana Health Service / Expanded Programme on Immunisation, 2014). This was similar to what was reported in Zimbabwe where 39% of 33 caregivers interviewed confirmed that they encountered AEFIs but never reported (Mutata et al., 2018). In that study, caregivers thought that minor AEFIs were not a concern and probably treated same at home or resolved on their own. We did not, in this study, encounter a situation where staff shielded reports for fear of victimization as reported elsewhere in Ga East of the Greater Accra region (Laryea et al., 2022).

Some of the reasons why some caregivers decided not to report included the fact that Health Care workers educated them on minor side effects and what to do if they occurred. They therefore did not feel alarmed as they could manage them at home. In other words, they perceived the non-serious AEFI as normal.

Obviously, most caregivers actually expect minor AEFIs and go ahead to make available in their households, medications for home-based care before or just after the immunization. Mostly, these non-serious AEFIs resolve in 2-3 days and does not cause major concerns for the mothers. Time constraints, inconvenience and fear of incurring high cost could also be attributable to the non-reporting by caregivers. Even though there is a policy of free medical care for persons reporting AEFIs (Ghana Health Service /Ministry Of Health, 2020), most health workers do not inform caregivers about this.

It was obvious that minor side effects were not concerns for caregivers and one wonders why the case definition would not be realigned to cater for only serious AEFIs. If non-serious AEFIs such as fever, pain, localized swellings, resolve spontaneously, or are successfully treated at home by non-trained caregivers and or parents, available resources should then be channeled to only serious AEFIs.

AEFI surveillance in Kumasi is part of the broader IDSR system and as a result, the staffing and resources are readily available for the system. However, funds were not dedicated for IDSR routinely. This would be a major challenge. Funding was thus a challenge like the Nigeria example (Omoleke et al., 2023). Funding was also cited as a barrier to AEFI reporting and investigations in four regions of Ghana (Aborigo et al., 2022).

Absence of official feedbacks from the technical advisory committees for the reports submitted over the period was a major concern. This makes it difficult to lower-level staff to know whether causality was established or otherwise. To this extent, major decisions may not be taken since the results would be needed for such decisions such as trainings and orientations, staff redistribution, improvement of cold chain system. At the culmination of the surveillance system's implementation, a series of crucial public health measures were set into motion. Firstly, caregivers were thoughtfully sensitized to the significance of accurate data collection, emphasizing the pivotal role it plays in safeguarding community well-being. Secondly, major findings unearthed by the surveillance system were diligently disseminated to the Metropolitan Health Management Team, ensuring that key stakeholders were well-informed and equipped to make informed decisions. Lastly, the comprehensive AEFI (Adverse Events Following Immunization) guidelines were shared with the dedicated staff at the healthcare facilities that had been visited, enhancing their ability to respond effectively to any vaccine-related concerns. These coordinated efforts at the conclusion of the surveillance system's action were vital steps in promoting public health and enhancing the safety of the community.

5. CONCLUSION

Though knowledge of health workers of AEFI surveillance was high, the system in Kumasi was partially meeting its objectives. The system was acceptable among health workers but not acceptable among caregivers, and with low sensitivity. It was stable, flexible and representative but partially useful. Positive predictive value was not assessed since no feedback was received. Based on the findings of the study, several key recommendations have emerged to enhance the effectiveness of Adverse Event Following Immunization (AEFI) surveillance in Ghana. First and foremost, it is advised that the Disease Surveillance Unit of the Ghana Health Service should contemplate a revision of the case definition for AEFI surveillance. This revision would seek to establish a clear distinction between serious and non-serious AEFIs. In this framework, non-serious AEFIs could be streamlined for tallying and reporting, reducing the administrative burden associated with full case-based reporting.

Secondly, the Technical Advisory Committee is urged to ensure swift and thorough investigations for all AEFI reports received, with a parallel emphasis on providing prompt feedback to all stakeholders involved, fostering a culture of responsiveness and accountability. To further bolster AEFI reporting, it is essential to disseminate information about the policy of free treatment for reported AEFIs widely, targeting both caregivers and healthcare facilities. This outreach effort will contribute significantly to improving the overall reporting rates. Additionally, there is a pressing need for retraining and refresher courses for healthcare workers involved in AEFI detection and management. This training initiative should be spearheaded by the Metropolitan Health Directorate, ensuring that frontline workers possess the necessary skills and knowledge to effectively handle AEFIs. Lastly, for a more comprehensive understanding of the AEFI landscape, the Metropolitan Health Directorate should consider the implementation of a community-based cross-sectional study. Such an endeavor would aid in providing a more accurate estimate of the burden of AEFIs within the community, ultimately enhancing the utility of the AEFI surveillance system.

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In extending our deepest gratitude, we wish to express our heartfelt appreciation to the dedicated healthcare professionals within the Kumasi Metropolis, who have tirelessly worked to ensure the well-being of our community. Their unwavering commitment and selfless service have been instrumental in safeguarding the health of our residents. Additionally, we would like to convey our profound thanks to the esteemed faculty and diligent officers of the Ghana Field Epidemiology and Laboratory Training Programme (GFELTP), whose expertise and guidance have been invaluable in advancing public health initiatives within our region. Their contributions have not only enhanced the quality of healthcare but have also strengthened our capacity to respond to health challenges effectively. We recognize and commend their exceptional efforts in promoting a healthier and safer community.

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