



Pharmacovigilance newsletter

What is an Adverse Event Following Immunization?

An Adverse Event 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. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease. Reported adverse events can either be a result of the vaccine or immunization process, or coincidental events that are not due to the vaccine or immunization process but are temporally associated with immunization. Adverse events following immunization are one of the major concerns in immunization which inhibits public demand for immunization.

Vaccine pharmacovigilance is the process of ensuring and monitoring safety of all aspects of immunization, including vaccine quality, adverse events, vaccine storage and handling, vaccine administration, disposal of sharps and management of waste. This surveillance is therefore a major public health strategy in addressing public health concerns and build public confidence on immunization.

Vaccines unlike other medicines need strong post marketing surveillance for detecting AEFI's for the following reasons:-

Vaccines are biological products, therefore are more prone to lot/batch variation and instability.

Vaccines as opposed to medicines are given for prevention in healthy, larger population. Therefore, there is lower risk of tolerance .

Vaccines products unlike medicines, are

relatively limited in number .

In Vaccines, with single dose, there is a greater potential for temporal "coincidence" adverse events .

Vaccines are prone to "program error" (techniques, skills, appropriate logistics etc. often required).

In Vaccines, cold chain is often critical

Vaccines are mostly injectable and are more likely to have injection "reaction" .

Vaccines are commonly administered in mass campaigns: many doses in short time in defined population: therefore, more prone to many "reactions" in a short time.

Vaccines are associated with politics of access/safety.

The general objective of AEFI surveillance is early detection and appropriate and quick response to adverse events in order to lessen the negative impact on the health of the individuals and on the immunization program. It will also enhance program credibility and can provide country-specific data on vaccine risks.

As EFMHACA is given a mandate to lead and coordinate AEFI ,the focal point for AEFI surveillance will be EFMHACA. However, Vaccine pharmacovigilance requires a strong collaboration between all immunization stakeholders (i.e., National Immunization Programs, National Regulatory Authorities, Public Health Emergency Management, Suppliers and manufacturers), professional associations, academic institutions, Health institutions , Clients including guardians and developmental partners.

Volume 6 Issue 2

June 2016

This newsletter is prepared and shared quarterly by EFMHACA with the objective of providing Medicine safety information and sharing the activities of the pharmacovigilance center at EFMHACA to healthcare providers working at both the public and private sectors

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Activities at the pharmacovigilance center

Trainings on Pharmacovigilance were performed at regions

Trainings in the form of face to face discussions were given to health providers of Amhara, Tigray and Oromia, regions from March 8-May 31/2016. The objectives of the on site trainings were to introduce the national pharmacovigilance system and sensitize healthcare providers to report adverse events and to discuss challenges of reporting and design ways to overcome them. The programmes were organized by regional Senior technical advisors of USAID/SIAPS and branch EFMHACA experts. A total of 538 health care providers of 26 health facilities i.e; from Amhara 224 healthcare providers of Addis Alem, Dangila, Aykel, Mekaneyesus, Nifas mewcha, Merawi, Addis Zemen, Lumame, Yejube and Bichena hospitals; from Tigray 161 of Maereg, Maiani, Mehoni hospitals and Setit Humera and Sheraro healthcenters and from Oromia 153 of Kake hospital, Melkaoda, Metehara, Ogocha and Goro health centers) participated in the trainings. A Presentation that contains; the Definition of pharmacovigilance, basic

terminologies of ADE, limitations of premarketing evaluations, the importance of pharmacovigilance, the national pharmacovigilance system mandates responsibilities, and achievements, the three types of ADE reporting mechanisms, medication error and prevention mechanisms and the role of Drug and Therapeutic Committee in assessing and managing drug safety were discussed. The role of Manufacturers, importers, distributors and health professionals' responsibilities to insure medication safety were also raised and discussed with the participants and they responded with questions and comments. During the sessions the tools used in drug safety monitoring, i.e; ADE report form, allergy card, and the quarterly newsletters were distributed for the participants to be used. At the end of each session a focal person for the facility was chosen and was given the responsibilities of facilitating the ADE monitoring at the facility. During this sessions refreshments were provided by USAID/SIAPS.



Face to face discussions at Oromia region health facilities



Face to face discussions at Amhara region health facilities



Face to face discussion at Tigray

Activities at the pharmacovigilance center

Training of Trainers on Adverse Event following Immunization

Two rounds of Training of Trainers (TOT) was given on the monitoring of Adverse event Following Immunization (AEFI) from March 28 - April 01 and April 12-15 /2016 at Adama Comfort Hotel to regional AEFI task force members of all the 9 regions and 2 city administrations of the country and regional regulatory heads. The TOT was financially supported by GAVI and the trainers were WHO surveillance experts together with EFMHACA and USIAD/SIAPS pharmacovigilance experts. The objective of the TOT was to build the capacity of regional task force members on management and causality assessment of AEFI so that they could cascade down the training to their experts on immunization and medicine safety on proper detection ,reporting, investigation and analysis of the occurrence of adverse events following immunization and the national tools and guideline available in the Nation. A Total of 94 participants attended the TOTs. W/t Heran Gerba, Deputy Director General of Inspection and Licensing, EFMHACA, welcomed the participants to the AEFI monitoring and causality assessment training. She cited the Sustainable Development Goal (SDG) and

said that the country is working towards reducing child mortality and improving maternal health and the relevance of having a strong AEFI system to follow the safety profile of vaccines after they have been approved is undeniable. She emphasized that it is the responsibility of each healthcare provider to assure this and that this training provides the opportunity. During the training, Over view of National Pharmacovigilance system ,The vaccine regulatory system in Ethiopia, AEFI Concepts and Definitions, Methods for Monitoring and Management of AEFI, Investigation of AEFIs, Analysis of Vaccine Safety Data, Causality assessment, Global Initiatives to Support AEFI, The national AEFI surveillance system and its tools, Vaccine risk communication overview ,which are the standard WHO AEFI Curriculum on AEFI and other relevant topics (Adult teaching methodology) were discussed with the participants . Participants also actively discussed on group works of cases and presented their findings. Certificate of TOT was given to the participants and they were then advised and guided on how to cascade the AEFI trainings to their regional experts who will be involved in detecting, reporting and investigating AEFIs based on the allocated fund available.

Adverse Event Following Immunization training to regional healthcare providers

Training on AEFI monitoring was cascaded to regional healthcare providers based on the above TOT provided to the regional taskforce members. A total of 1286 participants attended the allocated number of training events of regions and the trainings were carried out at the nearest convenient city for the regions. Trainers were TOT trained regional taskforce members from the health bureaus and the regulatory offices, Central /branch EFMHACA ,WHO and USAID/ SIAPS. The trainings were aimed at enabling the participants to fully involve in AEFI monitoring.



Some pictures of the regional trainings on AEFI monitoring

Drug safety updates , International-

Fluoroquinolone antibacterial drugs Restricting use.

USA. The US FDA has issued advice based on the benefit/harm assessment for the use of fluoroquinolone antibacterials and in certain types of infections. A FDA safety review has shown that systemic use of fluoroquinolones is associated with serious adverse effects which involve tendons, muscles, joints, nerves and central nervous system. These adverse effects outweigh the benefits of fluoroquinolone when used for acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections. The FDA recommends that fluoroquinolones should be reserved for those with no alternative treatment options. The drug labels and medication guides for all fluoroquinolone antibacterial medication will be updated to reflect this new safety information. *Reference: WHO Pharmaceuticals Newsletter No.3 2016.7*



Drug safety updates, National - Investigation on adverse drug reaction of Gloves

All health facilities use gloves in their day to day healthcare delivery practice. Currently there has been international evidences and ADE complaints from healthcare providers which necessitated the Ethiopian Food Medicine and Healthcare Administration and Control Authority to do rapid post marketing safety assessment for powdered gloves in the country. Hence a team of experts were sent to conveniently selected health facilities with the objective of assessing the safety and encounter of ADRs of powdered gloves on healthcare providers and patients. The assessment was conducted in Addis Ababa city in eleven (11) health facilities both governmental and private. All the eleven health facilities are using powdered gloves. Some of the health professionals interviewed during the assessment had encountered **adverse drug events (ADEs)** related to powdered gloves usage (17 professionals out of 38). The most common types of ADEs reported by health professionals during the assessment was contact dermatitis, allergic rhinitis, respiratory allergic reactions, asthma and skin allergic reactions respectively. During the assessment the health providers were asked about the actions they have taken for these problems and they **made** the following interventions: requesting their facility to purchase non powdered gloves, under wearing thin protective gloves, using different types of ointments, after removing the gloves immediately washing their hands and applying different solutions and body lotions. Their final professional opinion and

recommendation was to use non powdered gloves for the future. Finally it was recommended to perform the assessment in a more standard form and specifically for each department of a healthcare delivery setting (Ex. Surgical ward, Gynecology ward, laboratory/diagnostics room, dental ward and emergency room). So that the mentioned adverse events could be detected and followed intensively both from patients and also healthcare providers side.

Further desktop review of other countries experience indicated that Powders in gloves create undesirable reactions and complications for both the patient and healthcare provider thereby contributing to increased healthcare costs. This is because; they can cause the development of adhesions and granulomas, increase the risk factor for post-operative wound infections, increase latex allergens sensitization and provoke hypersensitivity type I reactions, contaminate the hospital environment and increase occupational asthma and exposure to latex allergens through inhalation, increase the risk of cross contamination of microorganisms, can interfere with laboratory testing causing false results and has an abrasive action on the skin:

Hence Experts have recommended that-

Decisions should be made to switch from powdered to powder-free, low-protein latex gloves as an effective method of reducing the complication and exit strategy should be carefully designed to handle stock out and other procurement issues beforehand.



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